

abbvie



NOVARTIS
PHARMACEUTICALS



Irish Society
for Rheumatology

Autumn Meeting 2017



21-22 September
Radisson Blu Hotel
Galway





Transforming lives¹

15 years of clinical trials and real world experience¹

1st approved anti-TNF in RA¹⁻⁷

More than 400 trials¹⁸

5 Over million patient-years of collective clinical experience¹¹

More than 6400 publications¹⁹

1 Over million patients treated¹⁰

of partnership and experience¹
over 15 years



ABBREVIATED PRESCRIBING INFORMATION

Enbrel®

etanercept

Before prescribing Enbrel® please refer to full Summary of Product Characteristics (SmPC).

Presentation: Enbrel Pre-filled Syringe: Enbrel 25 mg and 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYCLIC®): Enbrel 25mg and 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains either 25mg or 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for injection for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs DMARDs, including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. Non-radiographic axial spondyloarthritis (nr-axSpA). Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). **Children aged 2-17 years:** Juvenile idiopathic arthritis (JIA). Polyarthrits (rheumatoid factor positive or negative) and extended oligoarthritis from the age of 2 years when inadequate response to, or intolerant of methotrexate. Psoriatic arthritis from the age of 12 years when inadequate response to, or intolerant of methotrexate. Enthesitis-related arthritis from the age of 12 years when inadequate response to, or intolerant of, conventional therapy. **Children aged 6-17 years:** Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Dosage:** BRA – 25 mg twice weekly or 50 mg once weekly PP – 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. AS, nr-axSpA and PsA – 25 mg twice weekly or 50 mg once weekly. **Children aged 2-17 years:** JIA – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. **Children aged 6-17 years:** Plaque psoriasis in children aged 6-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. **Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. **Warnings and Precautions:** In order to improve the traceability of biological medicinal products, the trademark and the batch number of the administered product should be clearly recorded (or stated) in the patient file. Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure (CHF). There have been rare (< 0.1%) reports of new onset CHF, including CHF in patients without known pre-existing cardiovascular disease, including patients under 50 years of age. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients previously infected with hepatitis B and there have been reports of worsening hepatitis C in patients receiving Enbrel. Use with caution in patients with a history of hepatitis C. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Use caution when considering combination therapy with DMARDs other than methotrexate. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas, leukaemia or other haematopoietic or solid malignancies in patients treated with a TNF-antagonist cannot be excluded. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy ≤ 18 years of age) in the post-marketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF-antagonists, including Enbrel. Post-marketing cases of Merkel cell carcinoma have

been reported very infrequently in patients treated with Enbrel. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects:** Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and life threatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, elevated liver enzymes, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, heart failure, autoimmune hepatitis, Steven Johnson's syndrome, anaphylaxis, and very rare reports of: toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type 1 diabetes mellitus and soft tissue and post-operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. See section 4.8 of the SmPC for how to report adverse reactions. **Package Quantities:** Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYCLIC): Each carton contains 4 pre-filled pens containing either 25mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. **European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe, 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe, 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC), 25 mg: EU/1/99/126/023 Enbrel Pre-filled Pen (MYCLIC), 50 mg: EU/1/99/126/020 Enbrel Powder, 25 mg: EU/1/99/126/003 Enbrel Paediatric, 10 mg: EU/1/99/126/022. **Legal Category:** STA. **European Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NU, UK. **For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact:** Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. **API Reference Number:** EN 11_0 Pfilet number: 2017-0024332. **Date of Prescribing Information:** May 2017.

† Across all indications.

References: 1. Scott LJ. Drugs. 2014;74:1379-1410. 2. Enbrel Summary of Product Characteristics. 3. Humira Summary of Product Characteristics. 4. Remicade Summary of Product Characteristics. 5. Cimzia Summary of Product Characteristics. 6. Simponi Summary of Product Characteristics. 7. Enbrel EMA report 8. www.clinicaltrials.gov. Date accessed: May 2016. 9. http://www.ncbi.nlm.nih.gov/pubmed. Date accessed: May 2016. 10. Data on File. January 2015. 11. Data on File, February 2016.



Welcome

Dear Colleagues and Friends,

Welcome to Galway and first and foremost congratulations must go to the All Ireland winning Galway hurlers. I suspect that by the time our meeting convenes some three weeks after their victory over the Déise county celebrations will still be continuing around the county. And congratulations also to our colleagues in Galway who have I know you will agree put together a fascinating programme for us to enjoy. Topics range from the Mechanobiology of bone disease to Psychology, Surgical Management to Adolescent Rheumatology and patient fitness to "Making Smart Choices in Modern Medicine". Our speakers are also coming from far and wide including Prof. Saag from Alabama, USA, Prof Giangregorio from Ontario, Canada and Dr. Armon from Cambridge, UK as well as local experts from NUI Galway. I know we will all enjoy the programme and thanks again to Prof. John Carey and colleagues for all the hard work I know it takes to attract such world class speakers.



This year we will be taking the opportunity of having this meeting in Galway to thank Dr. Bobby Coughlan for all that he has done for Rheumatology not just in Galway but also for Rheumatology in Ireland as a whole and what he has achieved for the people of the West of Ireland over many years of dedicated hard work. Bobby was originally appointed to a post in the Mater Hospital Dublin but the call of the West dragged him to Galway and he must have faced a daunting task when he arrived in the beginning to set up and develop Rheumatology as a speciality along the Western sea border. That he did and it must be with great pride that he now looks at the Department of Rheumatology University Hospital Galway which he so lovingly nurtured over many years. Thanks again Bobby.

As I approach the end of my 2 year term as President of the ISR I would like to thank all those who actually do the work at the ISR and on the Board. I would like to thank Jenny Howard who has recently retired from her role as secretary to the ISR after many years of distinguished service. Jenny has kept the ship steady over the years and has overseen much progress and change at the ISR so once again, thanks Jenny, not just from me but from all your old friends at the ISR.

Further thanks to Michael Dineen and his team and my fellow Board members, particularly the Officers who put a lot of their own precious time into ISR matters for the good of all.

Prof. David Kane continues to finalise the National Rheumatology Clinical Programme and the CAG meeting on Thursday morning is a meeting I would urge you all to attend as this programme agreed between us and the HSE will provide the basis for the development of Rheumatology in Ireland for years to come. I would like to welcome Prof. Gerry Wilson who is launching the Arthritis Research Coalition (ARC). The ARC aims to be a national collaborative research programme helping researchers who wish to cooperate with colleagues on country wide basis facilitating academics to compete and publish on an international basis.

The pace of change within clinical Rheumatology continues to quicken and the recent Department of Health "National Biosimilar Medicines Policy – consultation document" is a reminder that the Biosimilar products are here and there are many more coming down the line in the next few years. It is essential that we as clinicians remain central to the decision making process around the use of biosimilar or biooriginator agents in order to ensure that our patients interests remain at the centre of any choices made. The next great change just upon us is the advent of the small molecules and where they may fit in terms of our management protocols.

All will be revealed, well if the world survives 4 years of Donald Trump.

I hope you all have a great time.

Dr Sandy Fraser
ISR President

Proud of our Heritage...



Remicade[®]

INFLIXIMAB



guaranteed irish[™]
promoting irish excellence

...Committed to our future

Remicade[®] 100mg Powder for Concentrate for Solution for Infusion (infliximab) Prescribing Information [Refer to full SPC text before prescribing Remicade (infliximab)] **Indications:** Rheumatoid Arthritis (RA): Remicade, in combination with methotrexate (MTX), is indicated for the reduction of signs and symptoms, as well as the improvement in physical function, in adult patients with active RA when the response to disease-modifying anti-rheumatic drugs (DMARDs), including MTX, has been inadequate; and in adult patients with severe, active and progressive disease not previously treated with MTX or other DMARDs. In these patient populations, a reduction in the rate of the progression of joint damage, as measured by X-ray, has been demonstrated. **Adult Crohn's Disease (CD):** Remicade is indicated for the treatment of moderately to severely active CD in adult patients who have not responded to, or are intolerant of, a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; and fistulising active CD in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). **Paediatric Crohn's Disease (CD):** Remicade is indicated for the treatment of severe, active CD in children and adolescents aged 6 to 17 years who have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy, or who are intolerant to or have contraindications for such therapies. **Ulcerative Colitis (UC):** Remicade is indicated for the treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Paediatric Ulcerative Colitis (UC):** Remicade is indicated for treatment of severely active UC, in children and adolescents aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies. **Ankylosing Spondylitis (AS):** Remicade is indicated for the treatment of severe, active AS, in adult patients who have responded inadequately to conventional therapy. **Psoriatic Arthritis (PsA):** Remicade is indicated for the treatment of active and progressive PsA, in adult patients when the response to previous DMARD drug therapy has been inadequate. Administration should be in combination with MTX or alone in patients who show intolerance to MTX or for whom MTX is contraindicated. A reduction in the rate of progression of peripheral joint damage in patients with polyarticular symmetrical subtypes of PsA has been measured by X-ray. **Psoriasis (PsO):** Remicade is indicated for the treatment of moderate to severe plaque PsO in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, MTX or PUVA. **Dosage and administration:** To improve the traceability of biological medicinal products, the trademark and the batch number of the administered product should be clearly recorded in the patient file. Remicade should be administered intravenously, initiated and supervised by physicians experienced in the diagnosis and treatment of RA, CD, UC, AS, PsA and PsO. Remicade should be administered intravenously over a 2 hour period. All patients administered Remicade should be observed for at least 1 to 2 hours post infusion for acute infusion-related reactions by appropriately trained healthcare professionals. **Shortened infusions across adult indications:** In carefully selected adult patients who have tolerated at least 3 initial 2-hour infusions of Remicade (induction phase) and are receiving maintenance therapy, consideration may be given to administering subsequent infusions over a period of not less than 1 hour. If an infusion reaction occurs in association with a shortened infusion, a slower infusion rate may be considered for future infusions if treatment is to be continued. Shortened infusions at doses ≥ 6 mg/kg have not been studied. **RA:** 3 mg/kg given as an intravenous infusion followed by additional 3 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. **Adult moderately to severely active CD:** 5mg/kg given as an intravenous infusion followed by an additional 5mg/kg infusion 2 weeks after the first infusion. If a patient does not respond after 2 doses, no additional treatment should be given. **Adult, fistulising, active CD:** 5mg/kg intravenous infusion followed by additional 5mg/kg infusions at 2 and 6 weeks after first infusion. If a patient does not respond after 3 doses, no additional treatment should be given. **UC:** 5mg/kg given as an intravenous infusion followed by additional 5mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks. Clinical response is usually achieved within 14 weeks of treatment (3 doses). **AS:** 5mg/kg given as an intravenous infusion followed by additional 5mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 6 to 8 weeks. If a patient does not respond after 2 doses, no additional treatment should be given. **PsA:** 5mg/kg given as an intravenous infusion period followed by additional 5mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. **PsO:** 5mg/kg given as an intravenous infusion followed by additional 5mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks. If a patient shows no response after 4 doses, no additional treatment should be given. **Readministration:** Remicade can be readministered within 16 weeks following the last infusion. The safety and efficacy of readministration after a Remicade-free interval of more than 16 weeks has not been established in either CD or RA. The safety and efficacy of readministration in AS, other than every 6 to 8 weeks and in PsA and UC, other than every 8 weeks, has not been established. Readministration with one single Remicade dose in PsO after an interval of 20 weeks suggests reduced efficacy and a higher incidence of mild to moderate infusion reactions when compared to the initial induction regimen. Limited experience from retreatment, using a reinduction regimen suggests a higher incidence of infusion reactions, some serious, when compared to 8 weekly maintenance treatment. In case maintenance therapy is interrupted in any indication, and there is a need to restart treatment, Remicade should be reinitiated as a single dose followed by the maintenance dose recommendations. **Paediatric population: CD (6 to 17 years):** 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. If a patient does not respond by 10 weeks, no additional treatment should be given. **UC (6 to 17 years):** 5 mg/kg given as an intravenous infusion over a 2-hour period followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Available data do not support further infliximab treatment in paediatric patients not responding within the first 8 weeks of treatment. **Contra-indications:** Tuberculosis; or other severe infections such as sepsis, abscesses and opportunistic infections; patients with a history of hypersensitivity to infliximab, other murine proteins or any of the excipients; patients with moderate or severe heart failure (NYHA class III/IV). **Precautions and Warnings:** **Infusion reactions:** Acute infusion reactions including anaphylactic reactions may develop during (within seconds) or within a few hours following infusion. If acute infusion reactions occur, the infusion must be interrupted immediately. Emergency equipment, such as adrenaline, antihistamines, corticosteroids and an artificial airway must be available. Antibodies to infliximab may develop and have been associated with increased frequency of infusion reactions. Symptomatic treatment should be given and further Remicade infusions must not be administered. In clinical studies, delayed hypersensitivity reactions have been reported. Available data suggest an increased risk for delayed hypersensitivity with increasing Remicade-free intervals. **Infections:** Patients must be monitored closely for infections, including tuberculosis, before, during and up to 6 months after treatment with Remicade. Exercise caution with use of Remicade in patients with chronic infection or a history of recurrent infection. Patients should be advised of potential risk factors for infections. Suppression of TNF α may mask symptoms of infection such as fever. Tuberculosis, bacterial infections including sepsis and pneumonia, invasive fungal, viral and other opportunistic infections, have been observed, some of which have been fatal. Infections were reported more

frequently in paediatric populations than in adult populations. There have been reports of active tuberculosis in patients receiving Remicade. Patients should be evaluated for active or latent tuberculosis before Remicade treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active tuberculosis is diagnosed, Remicade therapy must not be initiated. If latent tuberculosis is diagnosed, treatment with anti-tuberculosis therapy must be initiated before initiation of Remicade. Patients on Remicade treatment should be advised to seek medical advice if symptoms of tuberculosis appear. An invasive fungal infection such as aspergillosis, candidiasis, pneumocystosis, histoplasmosis, coccidioidomycosis or blastomycosis should be suspected in patients if a serious systemic illness is developed, a physician with expertise in the diagnosis and treatment of invasive fungal infections should be consulted at an early stage. Patients with fistulising CD and acute suppurative fistulas must not initiate Remicade therapy until possible source of infection is excluded. **Hepatitis B (HBV) reactivation:** Reactivation of HBV occurred in patients receiving Remicade who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Remicade. **Hepatobiliary events:** Very rare cases of jaundice and non-infectious hepatitis, some with features of autoimmune hepatitis have been observed. Isolated cases of liver failure resulting in liver transplantation or death have occurred. **Vaccinations:** It is recommended that live vaccines not be given concurrently. Prior to initiating Remicade therapy it is recommended that paediatric patients be brought up to date with all vaccinations. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Remicade and is positive for antibodies against double-stranded DNA, treatment must be discontinued. **Neurological events:** Anti-TNF α agents have been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of peripheral and CNS demyelinating disorders, including Guillain-Barré syndrome and multiple sclerosis. In patients with a history of demyelinating disorders, the benefits and risks of anti-TNF treatment should be carefully considered before initiation of Remicade therapy. Discontinuation of Remicade should be considered if these disorders develop. **Malignancies and lymphoproliferative disorders:** A risk of the development of lymphomas and other malignancies in patients (including children and adolescents) cannot be excluded. Caution is advised in patients with history of malignancy and in patients with increased risk for malignancy due to heavy smoking. Rare postmarketing cases of hepatosplenic T-cell lymphoma have been reported which were usually fatal. Most Remicade cases have occurred in patients with CD or UC treated concomitantly with AZA or 6-MP. Caution should be exercised in patients with PsO and a medical history of extensive immunosuppressant therapy or prolonged PUVA treatment. Patients with UC at increased risk for, or with a prior history of dysplasia or colon carcinoma should be screened for dysplasia before therapy and at regular intervals throughout their disease course. Melanoma and Merkel cell carcinoma have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart failure:** Remicade should be used with caution in patients with mild heart failure (NYHA class I/II) and discontinued in face of new or worsening symptoms of heart failure. **Others:** Patients requiring surgery whilst on Remicade therapy should be closely monitored for infections. **Haematologic reactions:** Discontinuation of Remicade therapy should be considered in patients with confirmed significant haematologic abnormalities, including pancytopenia, leucopenia, neutropenia and thrombocytopenia. **Special populations:** Particular attention should be paid when treating the elderly (≥ 65 years) due to a greater incidence of serious infections seen in Remicade treated patients. Some of these had a fatal outcome. **Interactions:** No interaction studies have been performed. Combination of Remicade with other biological therapeutics used to treat the same conditions as Remicade, including anakinra and abatacept is not recommended. It is recommended that live vaccines and therapeutic infectious agents should not be given concurrently with Remicade. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Remicade treatment. Administration of Remicade is not recommended during pregnancy or breastfeeding. Administration of live vaccines to infants exposed to infliximab in utero is not recommended for 6 months following the mother's last infliximab infusion during pregnancy. Effects of infliximab on fertility and general reproductive function are unknown. **Side-effects:** Very Common $\geq 1/10$: Viral infection, headache, upper respiratory tract infection, sinusitis, abdominal pain, nausea, infusion related reaction, pain. Common $\geq 1/100$ to $<1/10$: Bacterial infections, neutropenia, leucopenia, anaemia, lymphadenopathy, allergic respiratory symptom, depression, insomnia, vertigo, dizziness, hypoaesthesia, paraesthesia, conjunctivitis, tachycardia, palpitation, hypotension, hypertension, ecchymosis, hot flush, flushing, lower respiratory tract infection, dyspnoea, epistaxis, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation, hepatic function abnormal, transaminases increased, new onset or worsening psoriasis including pustular psoriasis (primarily palm & soles), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, arthralgia, myalgia, back pain, urinary tract infection, chest pain, fatigue, fever, injection site reaction, chills and oedema. In phase 3 clinical studies, 18% of infliximab-treated patients compared with 5% of placebo-treated patients experienced an infusion related reaction. In post-marketing spontaneous reporting, infections are the most common serious adverse event. The most frequently reported opportunistic infections with a mortality rate of $>5\%$ include pneumocystosis, candidiasis, listeriosis and aspergillosis. **Other less common and rarely reported side effects are listed in the SPC. Overdose:** No case of overdose has been reported. Single doses up to 20mg/kg have been administered without toxic effects. **Package Quantities:** Type I vials, with rubber stoppers and aluminium crimps protected by plastic caps, containing a lyophilised powder (infliximab 100mg). **Legal Category:** POM. **Marketing Authorisation Number:** EU/1/99/116/001. **Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands. **Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-2998700).** Date of Revision: June 2014. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie. © Merck Sharp & Dohme Ireland (Human Health) Limited, 2014. All rights reserved. Date of preparation: March 2015

References: 1. Data on file MSD PSUR 26. 2. Remicade SmPC, May 2014. 3. <http://www.ncbi.nlm.nih.gov/pubmed/?term=Remicade+infliximab>. Accessed 20 June 2013. 4. <http://www.clinicaltrials.gov/ct2/results?term=Remicade+Infliximab>. Accessed 20 June 2013. AS = ankylosing spondylitis; CD = Crohn's disease; PsA = psoriatic arthritis; RA = rheumatoid arthritis; UC = ulcerative colitis.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-299 8700)



Red Oak North, South County Business Park,
Leopardstown, Dublin 18, Ireland

RHEU-145303-0000



ISR Autumn Meeting
21-22 September 2017, Radisson Blu Hotel, Galway
Programme

Wednesday 20th September

20.00 **UCB Satellite Meeting**

Thursday 21st September

08.00 **Registration**

08.00 **CAG Meeting for Consultant Members**
Prof David Kane, Clinical Programme Lead

09.00 **Private Practice Meeting**
Drs John Mc Carthy/Susan Sant

09.30 **The National MSK Physio Programme Updates.**
Edel Callanan, Lead Physiotherapist Merlin Park Hospital, Galway

09.50 **Presidential Address Dr Alexander Fraser**
President ISR

10.00 **Oral Free Clinical Papers (1-4)**

10.40 **Launch of Arthritis Research Coalition (ARC)**
Chair: Dr Alexander Fraser
Presenter: Prof Gerry Wilson

11.00 **Making Smart Decisions in Modern Medicine**
Dr Louise Campbell, Senior Lecturer
Clinical Science Institute, NUI Galway

11.45 **Medical Management of Skeletal Complications of Rheumatic Disease**
Prof Kenneth Saag MD, MSc
University of Alabama (UAB)
at Birmingham, USA

12.45 **Lunch, Visit Industry & View Posters with Authors Standing by**

14.00 **Oral Free Basic Science papers (5 -8)**

14.40 **Mechanobiology of Bone Disease**
Prof Laoise McNamara,
Professor of Biomedical Engineering
College of Engineering & Informatics,
NUI Galway

15.10 **Coffee, Visit Industry & View Posters**

15.40 **Surgical Management**
Prof John McCabe,
Consultant Orthopaedic Surgeon
University College Hospital, Galway

16.15 **Psychological Management**
Prof Brian McGuire, Prof Clinical Psychology
School of Psychology & Centre for Pain Research,
NUI Galway

17.00 **Bernard Connor Award**

17.15 **ISR AGM**

18.15 **Satellite Meeting Eli Lilly**
'Redefining expectations for patients living with RA; The role of JAK inhibition and Baricitinib.
Dr David Walker, Consultant & Senior Lecturer
University of Newcastle & Freeman Hospital UK

20.00 **Conference Dinner**

Friday 22nd September

08.00 **Registration**

08.00 **Satellite Meeting Pfizer**
Clinical Experience with Tofacitinib – Patient Profiles from the CORRONA registry
Prof Orrin Troum, Clinical Professor of Medicine,
Keck School of Medicine/University of Southern California.

09.00 **Clinical Case Presentations**

10.00 **Fitness Matters for your patients**
Dr Lora Giangregorio,
Assoc. Professor - Dept of Kinesiology
University of Waterloo, Ontario Canada

11.00 **Coffee, Visit Industry & Poster Viewing**

11.30 **Adolescent Rheumatology – Longterm outcomes for JIA**
Chair: Dr Orla Killeen
Presenter: Dr Kate Armon,
Consultant Paediatric Rheumatologist at
Addenbrookes Hospital, Cambridge, UK

12.15 **Young Investigator Award**
Dr Richard Conway,
Dept of Rheumatology & Radiology
St Vincents University Hospital, Dublin 4.

12.45 **Prize Giving & Closing Remarks**

13.00 **Buffet Lunch Incorporating round table discussions on the following topics**

1. **Epidemiology:**
Prof Brian McGuire & Prof John Carey

2. **Cardiovascular Disease:**
Dr Miriam O'Sullivan and
Ms. Bridgette Connaughton

3. **Sports Medicine for Rheumatologists:**
Dr Conor McCarthy, Prof Mick Molloy,
& Dr Giangregorio

4. **STC Meeting**

FIGHT BACK AGAINST RAPIDLY PROGRESSING RA



ACPA positivity is a poor prognostic factor commonly linked to radiographic progression in early RA¹⁻³

Orencia is the only licensed biologic, in combination with MTX, that acts early in the inflammation cascade, specifically targeting T-cell activation. This deactivates B-cells and reduces ACPA levels⁴⁻⁶

In AMPLE, Orencia (with MTX) demonstrated similar efficacy to adalimumab in protection against joint erosion and reduction in disease activity⁷

In post hoc analyses, Orencia (with MTX) demonstrated results not seen in the adalimumab arm:

- Greater DAS reduction in high ACPA positive versus low ACPA positive patients⁸
- Continued decline in ACPA levels over 2 years in patients with major clinical response^{9*}

Orencia, in combination with MTX, is indicated for:

- The treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more DMARDs including MTX or a TNF-alpha inhibitor.
- The treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with MTX. See SmPC

Consider ORENCIA® as your first choice biologic for rapidly progressing RA

For more information, visit www.orencia.co.uk



ORENCIA® (abatacept) PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing.

PRESENTATION: 250 mg powder for concentrate for solution for IV infusion containing 250 mg abatacept per vial; each ml contains 25 mg of abatacept, after reconstitution. 125 mg pre-filled syringe and ClickJect pre-filled pen, for SC injection; each pre-filled syringe and pen contains 125 mg of abatacept in 1 ml.

INDICATION: Rheumatoid arthritis (RA) (IV infusion, SC pre-filled syringe and pen):

Orencia, in combination with methotrexate, is indicated for:

- The treatment of moderate to severe active rheumatoid arthritis in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate or a tumour necrosis factor (TNF)-alpha inhibitor.

- The treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate.

A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate, see SmPC.

Polyarticular Juvenile Idiopathic Arthritis (pJIA) (IV infusion only): Orencia in combination with methotrexate is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor.

DOSAGE and ADMINISTRATION: Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA or JIA. Orencia 250 mg powder for concentrate for solution for IV infusion. **Adults and elderly:** Patients weighing < 60 kg: 500 mg (2 vials). Patients weighing ≥ 60 kg to ≤ 100 kg: 750 mg (3 vials). Patients weighing > 100 kg: 1000 mg (4 vials). **Treatment of pJIA:** Paediatric patients, 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg. Paediatric patients weighing 75 kg or more: to be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, Orencia IV should be given at 2 and 4 weeks, then every 4 weeks thereafter. **Children:** Use in children below 6 years of age is not recommended.

Orencia 125 mg solution for injection (SC pre-filled syringe and pen) Adults and elderly: Orencia SC may be initiated with or without an IV loading dose. Orencia SC should be administered weekly at a dose of 125 mg by subcutaneous injection regardless of weight. If a single IV infusion is given to initiate treatment (IV loading dose before SC administration), the first 125 mg abatacept SC should be administered within a day of the IV infusion, followed by the weekly 125 mg abatacept SC injections. Patients transitioning from Orencia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. **Children:** The safety and efficacy of Orencia SC in children below 18 years of age have not been established. The continuation of treatment with abatacept should be re-assessed if patients do not respond within 6 months.

CONTRAINDICATIONS: Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections.

WARNINGS AND PRECAUTIONS: **Allergic Reactions:** Caution in patients with a history of allergic reactions. Anaphylaxis or anaphylactoid reactions

can occur after the first infusion and can be life threatening. Orencia IV or SC should be discontinued permanently if a patient develops serious allergic or anaphylactoid reaction. **Infections:** Caution should be exercised when considering use in patients with a history of frequent infections, or underlying conditions which may predispose to infection. Treatment with Orencia should not be initiated with patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and Orencia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to Orencia. Co-administration of Orencia with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). Orencia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. **Malignancies:** The potential role of Orencia in the development of malignancies is unknown. However periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. **Elderly:** Caution should be used when treating elderly patients due to a higher incidence of infections and malignancies in this patient group. **Autoimmune processes:** Theoretical risk of deterioration in autoimmune disease. **Immunisation:** Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orencia. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orencia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orencia in combination with sulfasalazine, hydroxychloroquine or leflunomide. **PREGNANCY AND LACTATION:** Abatacept may cross the placenta into the serum of infants born to women treated with abatacept during pregnancy. Consequently, these infants may be at increased risk of infection. Administration of live vaccines to infants exposed to abatacept in utero is not recommended for 14 weeks following the mother's last exposure to abatacept during pregnancy. Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment. **UNDESIRABLE EFFECTS:** In clinical trials and post-marketing experience, the following adverse drug reactions were reported. **Very Common (≥ 1/10):** upper respiratory tract infection including tracheitis, nasopharyngitis, sinusitis. **Common (≥ 1/100 to < 1/10):** Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes infections (including herpes simplex, oral herpes and herpes zoster), pneumonia, influenza, headache, dizziness, hypertension blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), fatigue, asthenia, local injection site reactions*, systemic injection reactions* (e.g. pruritus, throat tightness, dyspnea) **Uncommon (≥ 1/1,000 to < 1/100):** Tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, rhinitis, ear infection, basal cell carcinoma, skin papilloma, thrombocytopenia, leukopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, paraesthesia, conjunctivitis, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, blood pressure decreased, hot flush, flushing, vasculitis, chronic obstructive

pulmonary disease exacerbated, bronchospasm, wheezing, dyspnea, throat tightness, gastritis, increased tendency to bruise, dry skin, alopecia, pruritus, urticaria, psoriasis, acne, erythema, hyperhidrosis, arthralgia, pain in extremity, amenorrhoea, menorrhagia, influenza like illness, weight increased. **Rare (≥ 1/10,000 to < 1/1,000):** Tuberculosis, bacteraemia, gastrointestinal infection, pelvic inflammatory disease, lymphoma, lung neoplasm malignant, squamous cell carcinoma. *Orencia SC, see SmPC for information on other undesirable effects.

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER: Orencia 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack: £302.40

Orencia 125 mg solution for Injection (pre-filled syringe)-EU/1/07/389/008 and ClickJect pre-filled pen - EU/1/07/389/011, 4 pre-filled syringes with needle guard: £1209.60, 4 pre-filled pens: £1209.60

MARKETING AUTHORISATION HOLDER: Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH, UK.

Tel: 0800-731-1736

LOCAL REPRESENTATIVE IN IRELAND:

Bristol-Myers Squibb Pharmaceuticals, Watery Lane, Swords, Co. Dublin, Tel: +353 1 800 749 749

DATE OF PREPARATION: May 2017
Job No: 427UK1700544-01

Adverse events should be reported. Reporting forms and information can be found at:

UK - www.mhra.gov.uk/yellowcard;
Ireland - Freepost HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; Email: medsafety@hpra.ie

Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or 0800 731 1736 (UK); 1 800 749 749 (Ireland).

REFERENCES: 1. Krishnamurthy, et al. *Ann Rheum Dis* 2016; 75:721-729. 2. Sokolove J, et al. *Arthritis Rheum* 2011;63(1):53-62. 3. Kocjan J, et al. *Curr Rheumatol Rep* 2013;15:366 4. Orencia Summary of Product Characteristics. 5. Choy E, et al. *Clin Exp Rheumatol* 2009;27:510-18. 6. Scarci M, et al. *J Rheumatol* 2014;41:666-672. 7. Schiff M, et al. *Ann Rheum Dis* 2014;73:86-94. 8. Sokolove J, et al. *Ann Rheum Dis* 2016;75:709-714. 9. Connolly SE, et al. *Ann Rheum Dis* 2014;73:395. Abstract FR10039.

ABBREVIATIONS: RA, Rheumatoid Arthritis; DMARD, Disease Modifying Anti-Rheumatic Drugs; ACPA, anti-citrullinated protein antibodies.

*Major Clinical Response at Day 729 (MCR729) = defined as ACR70 response for a minimum of 6 consecutive months.

DATE OF APPROVAL: August 2017

427IE1703481-01



Programme for IRHPS Autumn Meeting & AGM
September 21st & 22nd 2017,
Radisson Blu Hotel, Galway

Thursday 21st September 2017

- 08.00 **Registration / Meet the industry**
- 09.30 **ISR Programme**
- 10.30 **IRHPS Programme**
Chairs: **Derek Deely & Rhona Galway**
- 10.30 Welcome by
IRHPS Chairperson; Trish Fitzgerald
- 10.35 **Oral Presentation 1:**
Greater Trochanteric Pain Syndrome: A retrospective study of thirty - eight patients treated with a structured physiotherapy program and extra corporeal shockwave therapy.
Paul Kirwan, Physiotherapy Department, Connolly Hospital, Blanchardstown, Dublin.
- 11.00 **Oral Presentations 2:**
A nurse led treat to target programme in early inflammatory arthritis showing trends that smoking and obesity may delay time to patients achieving disease remission.
Noreen Harrington, RANP, Our Lady's Hospital, Manorhamilton, Co. Leitrim.
- 11.30 ***"Overview of BSR/BHPR's work, sharing of results from national RA audit, workforce developments and outline of educational resources on offer"***
Dr Jill Firth – Consultant Nurse and Director for Service Improvement Pennine MSK Partnership, Oldham, UK, President of the British Health Professionals in Rheumatology .
- 12.00 **ISR Programme**
- 12.30 **Lunch / Poster viewing / Meet the industry**
- 13.30 **Keynote Speakers:**
- IRHPS Programme**
Chairs: **Una Martin, Catherine Cullinane**
- 13.30 ***"Health Promotion and Lifestyle Issues for men with Inflammatory Arthritis"***
Dr James Harrison GP, Lecturer, National University Of Galway.
- 14.15 ***"Men don't cry, you know this don't you?" Experiences, coping style and support preferences of men with rheumatoid arthritis.***
Dr Caroline Flurey – Clinical Psychologist, Senior Lecturer in Public Health President Elect of British Health Professionals in Rheumatology University of the West of England
- 15.00 ***"The impact of inflammatory arthritis on engagement and work in Men".***
Ms Yvonne Codd, Senior Occupational Therapist (Rheumatology) & PhD Researcher, Naas General Hospital, Naas, Co. Kildare and Discipline of Occupational Therapy, Trinity College Dublin.
- 15.45 **ISR Programme**
- 17.00 **IRHPS AGM**
- 20.00 **Gala Dinner**

abbvie

THEN, NOW,
— AND IN THE —
FUTURE





Biographical Sketches

Speakers

Dr Louise Campbell, Senior Lecturer
Clinical Science Institute, NUI Galway



The Centre of Bioethical Research & Analysis (COBRA) was established by Dr. Richard Hull in 2001 within the Department of Philosophy in the National University of Ireland, Galway (NUI Galway). Dr. Heike Schmidt-Felzmann joined the centre in 2003. We have a number of students doing postgraduate research in COBRA and have collaborative links with associates both within NUI Galway and abroad.

Dr. Louise Campbell is an established member of this group at NUI Galway.

Research Areas: Health Care Ethics, Clinical Ethics, Organisational Ethics, Kantian Philosophy, German Idealism

Prof Kenneth Saag MD, MSc
University of Alabama (UAB) at
Birmingham, USA



Kenneth G. Saag, MD, MSc earned his medical degree at Northwestern University in Chicago, Illinois and his Master of Science Degree with an emphasis in epidemiology, from the University of Iowa, Department of Preventive Medicine and Environmental Health (Iowa City, Iowa). Dr. Saag is a Professor of Medicine in the Division of Clinical Immunology and Rheumatology at the University of Alabama at Birmingham (UAB), as well as a rheumatologist and outcomes researcher at the same institution. His main areas of interest include rheumatoid arthritis, osteoporosis, and pharmacoepidemiology.

Dr. Saag is currently the Director for the Center for Education and Research on Therapeutics (CERTs) of Musculoskeletal Disorders at UAB. He is a Member of the Southern Society for Clinical Investigation, Chair of the Osteoporosis Abstract Selection Committee, American College of Rheumatology (ACR), and Associate Director of the UAB Center for Metabolic Bone Disease (CMBD) National Institutes of Health (NIH) T32 Institutional Training Grant entitled, "Comprehensive Training Grant in Bone Biology and Disease".

Prof. Laoise McNamara,
Professor of Biomedical Engineering
College of Engineering & Informatics, NUI
Galway



Professor Laoise McNamara is a Professor in Biomedical Engineering at the National University of Ireland Galway and the Program Director for the Masters in Biomedical Engineering (MSc). She holds a PhD in Biomedical Engineering from Trinity

College Dublin and a 1st class Honours degree in Mechanical Engineering from NUI Galway. She completed Postdoctoral training at Mount Sinai School of Medicine, New York, USA. From 2007-2009 she was a Lecturer in Mechanobiology and Musculoskeletal Biomechanics at the University of Southampton, United Kingdom. She was appointed to NUI Galway in 2009 as a Science Foundation Stokes Lecturer in Biomedical Engineering. She established the Mechanobiology and Medical Device Research group (MMDRG, www.mechanobiology.ie) at NUI Galway. Her research has been widely published and cited, and has attracted significant research funding.

Prof John McCabe,
Consultant Orthopaedic Surgeon
University College Hospital, Galway
Having commenced practice in Galway in 1996, Professor Mc Cabe is the longest serving Spine Surgeon in the Irish Public System. His expertise covers the full spectrum of traumatic, degenerative and tumour spine conditions as well as deformity surgery. He has pioneered technologies in this area including anterior and posterior cervical fixation and percutaneous spinal surgery. He has particular expertise in the management of complex spinal conditions in the presence of prior surgery.



Professor Mc Cabe also has an extensive practice in hip and knee surgery given his unique dual fellowship training in the world renowned Hospital For Special Surgery, New York. This experience has ensured that he is skilled and has a wealth of knowledge in dealing with all aspects of musculoskeletal conditions pertaining to the spine and hip/knee area, conditions which often times can be difficult to diagnose and treat.

Research and Publications:

Professor Mc Cabe is very involved in ongoing research and teaching particularly in the area of spinal surgery. He has over 80 publications in peer reviewed journals as well as a number of co-authored book chapters in both spinal surgery and arthroplasty. He presents regularly at national and international meetings.

Prof Brian McGuire,
Prof Clinical Psychology
School of Psychology & Centre for Pain
Research, NUI Galway



Brian McGuire is Professor of Clinical Psychology at NUI Galway (NUIG). A graduate of NUIG, he completed his professional training in clinical psychology and his PhD in Sydney. His clinical work in Australia focused on the rehabilitation of persons with chronic pain, acquired brain impairment, and those recovering from work and motor accidents. After leaving Australia, Brian was Consultant Clinical Psychologist in brain injury rehabilitation where he co-ordinated the clinical services of several in-patient rehabilitation units in the north of England. After returning to Ireland, Brian worked with Ability West learning disability



service. He joined NUIG in 2003 and was the Director of the Doctor of Psychological Science programme in Clinical Psychology until 2014 when he took up his role as HRB Research Leader in Population Health. In addition, he is Director of the Doctor of Psychological Science for Qualified Clinicians and Joint Director of the Centre for Pain Research. Research interests

Clinical health psychology and behavioural medicine, especially pain management and psychological treatment in chronic health problems. Brian's current projects focus on (1) evidence-based reviews of therapy (2) epidemiological research (3) development and evaluation of psychological interventions for pain management, especially internet-based therapy (4) chronic pain and cognitive impairment.

Dr Lora Giangregorio,

Assoc. Professor - Dept of Kinesiology
University of Waterloo, Ontario Canada



Dr. Giangregorio is an Associate Professor in the Department of Kinesiology at the University of Waterloo. Her research aims to increase physical activity and reduce osteoporotic fracture risk in older adults. She is a member of the Scientific Advisory Council for Osteoporosis Canada, with whom she partners on a number of initiatives to improve patient and health care provider education.

Her research team has worked with Osteoporosis Canada to develop BoneFit, a two-day workshop for physiotherapists and kinesiologists on appropriate assessment and exercise prescription for individuals with osteoporosis. She also led the development of the Too Fit To Fracture Exercise and Physical Activity Recommendations for Individuals with Osteoporosis.

Dr Kate Armon,

Consultant Paediatric Rheumatologist at
Addenbrookes Hospital, Cambridge, UK



Kate Armon is a Consultant Paediatric Rheumatologist who was appointed to Addenbrookes Hospital in June 2015 to develop the paediatric rheumatology specialist service within the East of England region. Over subsequent months the team has expanded to provide a fully comprehensive service to Cambridge, Norwich and the wider region.

Dr Armon trained at Nottingham medical school, graduating in 1989, and undertook paediatric speciality training mainly in the Trent region with additional training in South Africa (Johannesburg) and Norwich. Post consultant appointment specialist training continued at Birmingham Children's Hospital and Great Ormond Street Hospital. She obtained a Doctor of Medicine postgraduate degree at Nottingham University in 2001 following research into acute general paediatrics, determining the common presenting problems to the emergency department, and developing evidence based and formal consensus ratified guidelines for these (diarrhea and vomiting, seizures, breathing difficulty).

Dr Armon developed specialist expertise in paediatric rheumatology during the latter half of her paediatric training at Queen's Medical Centre, Nottingham, taking up her first Consultant post in Norwich in 2003. Current research grants and collaborations are focused on paediatric rheumatology problems. She developed a successful specialist paediatric rheumatology service in Norwich, serving Norfolk and Suffolk and as part of the regional network, she provides care in both Norwich and Cambridge.

Dr Armon provides expert advice on behalf of BSPAR to the National Institute for Clinical Excellence in the development of national paediatric rheumatology guidelines, as well as working with the Clinical Affairs committee, providing guidance for all members of BSPAR. She was appointed to the national Paediatric Rheumatology Clinical Studies Group, which has the remit of prioritizing and promoting paediatric rheumatology research in the UK (funded by Arthritis Research UK

Dr Richard Conway,

Dept of Rheumatology & Radiology
St Vincents University Hospital, Dublin 4.



Richard Conway graduated from the Royal College of Surgeons in Ireland in 2006, and completed rheumatology and general internal medicine training in Ireland in 2014.

He is currently working as a locum consultant rheumatologist at St. James's Hospital, and completing a PhD in giant cell arteritis at University College Dublin. He is the author of more than 70 peer-reviewed publications, with 50 as first author. His current research interests include epidemiology and vasculitis. He sits on the Leadership Committee of the EMerging EUlar NETwork (EMEUNET) and is the leader of the EMEUNET Newsletter Subgroup.

Dr Jill Firth

Consultant Nurse and Director for Service
Improvement Pennine MSK Partnership,
Oldham, UK, President of the British
Health Professionals in Rheumatology



Jill Firth was elected President of the British Health Professionals in Rheumatology in 2016. She is currently employed as Consultant Nurse and Director for Service Improvement at the Pennine MSK Partnership in Oldham. She has worked in rheumatology since 1997 including a period engaged in education and research at the University of Leeds (2004-2011) as Senior Research Fellow in Long Term Conditions and Lead Postgraduate Research Tutor for the School of Health care. Jill has promoted specialist nursing in rheumatology nationally and internationally through education, research and publications.



Dr Caroline Flurey

Clinical Psychologist, Senior Lecturer in Public Health President Elect of British Health Professionals in Rheumatology University of the West of England



Caroline Flurey is a senior lecturer in public health with a background in health psychology from the University of the West of England, Bristol, UK. Caroline's PhD focused on self-management and help-seeking behaviours for rheumatoid arthritis flares, in which she discovered that men appeared to be struggling to cope in comparison to women. Caroline will present the work from her Arthritis Research UK post-doctoral fellowship, which aimed to investigate the experiences, coping styles and support needs of men with rheumatoid arthritis.

Ms Yvonne Codd,

Senior Occupational Therapist (Rheumatology) & PhD Researcher, Naas General Hospital, Naas, Co. Kildare and Discipline of Occupational Therapy, Trinity College Dublin.



Yvonne Codd is a 3rd year PhD researcher with Trinity College Dublin and senior occupational therapist in rheumatology in Naas General Hospital. She is a graduate of Trinity College Dublin, holding a BSc. (1999) and an MSc. (2006) in Occupational Therapy. Yvonne has worked for many years in the clinical area of rheumatology. She has previously worked in Primary Care Paediatric OT and School Support Team roles as well as in Primary Care (adult services). Yvonne has worked as a visiting lecturer in Trinity College Dublin designing and delivering modules to Senior Freshman Occupational Therapy students (2016, 2011-2009). Her research areas interest include inflammatory arthritis, supporting engagement and participation in employment, social and community roles.

ISR Board members

Dr Sandy Fraser

President

Consultant Rheumatologist, General Physician and Honorary Senior Lecturer, University Hospitals Limerick. Dr. Alexander Fraser graduated in medicine from Trinity College Dublin in 1991. He began practicing Rheumatology in 1996 and the following year was appointed Specialist Registrar in Rheumatology at the Yorkshire Deanery. Training with Professor Emery's group in Leeds he developed a research interest in clinical, immunological and therapeutic aspects of Rheumatoid Arthritis, Psoriatic Arthritis and the Sero-negative Spondyloarthropathies. He was appointed Consultant



Rheumatologist and Honorary Senior Lecturer at the Leeds Teaching Hospitals NHS Trust, working at The Leeds General Infirmary and St. James' University Hospital in October 2001, and working closely with Professor Emery and Professor Doug Veale he published in the area of Angiogenesis, Vascularity and Inflammation in early and established arthritis and Biomarkers of cartilage turnover. Dr Fraser took up his current appointment as Consultant Rheumatologist, General Physician and Honorary Senior Lecturer at the University Hospitals Limerick in 2006. In conjunction with the University of Limerick Graduate Entry Medical School (GEMS) Dr. Fraser and his team have continued their strong academic interests while managing a busy clinical practice.

Professor David Kane

Prof David Kane attended medical school at Trinity College, Dublin, Ireland and was conferred MB BCH BAO BA in 1991, PhD in 2002 and FRCPI in 2006. He has trained in rheumatology with Prof. Barry Bresnihan and Prof. Oliver FitzGerald at St. Vincent's University Hospital, Dublin, Ireland and with Prof Roger Sturrock, Prof Iain McInnes and Dr Peter Balint at Glasgow Royal Infirmary, Glasgow, United Kingdom. He was appointed as Senior Lecturer in Rheumatology at the University of Newcastle (2003-2005) and is currently working as Consultant Rheumatologist at the Adelaide and Meath Hospital and Clinical Professor in Rheumatology at Trinity College Dublin. His special interests are musculoskeletal ultrasound, spondyloarthritis and synovial inflammation. He is a member of the European Working Party on Musculoskeletal Ultrasound and the OMERACT special interest group on musculoskeletal ultrasound, previous organiser of the BSR Musculoskeletal Ultrasound course and is Faculty member of the EULAR Musculoskeletal ultrasound course. He has served as a Board member of the Irish Osteoporosis Society, as President and Treasurer of the Irish Society for Rheumatology and is currently a Board member of Arthritis Ireland.



Dr Frances Stafford

Frances is a graduate of UCD, spent almost a decade in North America, training in Rheumatology first at University of Toronto, followed by a fellowship at Massachusetts General Hospital & Harvard Medical School. She was awarded a 4 year Arthritis Foundation Postdoctoral Fellowship, which she completed at the NIH, and then went on staff at the NIH. Frances is American Board Certified in Internal Medicine and in Rheumatology. She has been Consultant at Blackrock Clinic since 1995.





Dr Sinéad Harney

Dr Sinéad Harney graduated from UCG in 1994 and did her specialist training in Rheumatology and General Medicine in Dublin. She completed her training in Oxford in 2005 and was awarded a DPhil by thesis titled "Major Histocompatibility Genetics of Rheumatoid Arthritis". She was appointed to a Consultant Rheumatologist post in Cork University Hospital in 2005 and has worked there since. She completed a Masters in Sports and Exercise Medicine in UCC in 2007. Her research interests include – Genetics of inflammatory arthritis and occult cardiovascular disease in Rheumatoid Arthritis and she has over 90 publications. She is currently the treasurer of the Irish Society of Rheumatology and a board member of the TUE committee of the Irish Sports Council.



Prof Suzanne Donnelly

Associate Professor Suzanne Donnelly is a consultant rheumatologist at the Mater Misericordiae University Hospital Dublin & Associate Dean (Education) in UCD School of Medicine. She is a graduate of Trinity College Dublin and trained in Dublin and Oxford before being appointed consultant rheumatologist at St. George's Hospital and Medical School, London in 2002. Her clinical interests include systemic autoimmune disease, Systemic Lupus Erythematosus and pregnancy in the rheumatic diseases. Suzanne has held academic posts in medical education since 1996 including in Trinity College Dublin; the University of Oxford and in London. She joined UCD as Director of Clinical Education in 2008, and was appointed Associate Dean, UCD School of Medicine in 2017. In partnership with Arthritis Ireland, she initiated a patient educator programme to enhance medical students' education in rheumatological disease. The programme has enabled over 2000 medical students to meet patients with arthritis first hand. Suzanne is rheumatology author for the medical textbook Medicine at A Glance and a contributing author to The Rheumatology Handbook. She was ISR nominee to the board of Arthritis Ireland (2008-13), a board member of Raynauds and Scleroderma Ireland (2007-10) and medical patron of Lupus Group Ireland.



Dr Adrian Pendleton

Consultant Rheumatologist
Musgrave Park Hospital, Belfast

Dr Adrian Pendleton is a Consultant Rheumatologist and Clinical Lead for Rheumatology in the Belfast Health and Social Care Trust. Dr Adrian Pendleton trained in both Rheumatology and General Internal Medicine in Belfast and Nottingham. He was first appointed as a consultant Rheumatologist at the Queens Medical Centre, Nottingham University Hospitals before returning to the Belfast Trust



Health and Social care Trust. Dr Pendleton is a Fellow of the Royal College of Physicians of Edinburgh and a Fellow of the Royal College of Physicians of Ireland and a Fellow of the British Society for Sport and Exercise Medicine (BASM). He is currently the Regional Specialty Advisor for Rheumatology with the Joint Royal College Physicians Training Board. Dr Pendleton has many research interests which include Early diagnosis and management of inflammatory arthritis, use of musculoskeletal ultrasound in Inflammatory arthritis, vasculitis and soft tissue injury.

Dr John Ryan

Dr John Ryan is a graduate of the Royal College of Surgeons in Ireland, he completed his higher medical training in rheumatology and general internal medicine in Ireland. He undertook a fellowship at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) in Bethesda, Maryland. During this time he undertook translational research into disordered innate immunity manifesting as recurrent fever syndromes. He joined Dr Sinead Harney in the Rheumatology service at Cork University Hospital in 2010. The Rheumatology department has since expanded to include Dr Grainne Murphy. In July 2017 he took up the post of National Specialty Director for Rheumatology.



Dr Orla Killeen

Dr Orla Killeen qualified from UCG (NUI) Galway in 1996. She trained in General Paediatrics in Our Lady's Hospital for Sick Children, Crumlin and in Temple Street University Hospital, Dublin before subspecialising in Paediatric Rheumatology. She undertook her paediatric rheumatology training at Great Ormond Street Children's Hospital, London and went on to complete a Barbara Ansell Fellowship in Paediatric Rheumatology in the Royal Hospital for Sick Children, Glasgow. She was appointed as Ireland's first Paediatric Rheumatologist in 2004, and is based at Our Lady's Children's Hospital, Crumlin and St Vincent's University Hospital, Dublin since July 2006. She is the Clinical lead for the National Centre for Paediatric Rheumatology (NCPR), providing care for patients both on a local and national level up to 18 years of age. Her areas of interest include Adolescent Rheumatology Transition Care as well as JIA, Down's arthropathy and Auto-Inflammatory syndromes.



Dr Eamonn Molloy

Eamonn Molloy graduated from University College Dublin (1997) and completed rheumatology and internal medicine training in Ireland. He obtained an MD at RCSI (2006), which focused on calcium crystal induced inflammation. From 2005, he underwent subspecialty fellowship training in vasculitis at the Cleveland Clinic, completed a MS (Clinical Research)





at Case Western Reserve University and then joined the staff at the Vasculitis Center and RJ Fasnemeyer Center for Clinical Immunology at the Cleveland Clinic. In 2010, he was appointed as a consultant rheumatologist at St Vincent's University Hospital and is a UCD Senior Clinical Lecturer. He is the author of approximately 50 publications largely pertaining to vasculitis, complications of biologic therapy and crystal induced arthritis. Currently, his primary research focus is giant cell arteritis.

Dr Carl Orr

Carl Orr is a graduate of RCSI, completing his undergraduate studies in 2008 with Honours and later interning and undertaking basic specialist training at Beaumont Hospital. He entered Higher Specialist Training in Rheumatology in 2012. Currently working at the Mater Hospital, he has recently been the Clinical Newman Fellow in Rheumatoid Arthritis at UCD, and has successfully defended his PhD. Carl has presented at many International and National Rheumatology meetings, as well as publishing his work in leading peer-review journals. Following the completion of his Masters in Leadership and Management Development, he has recently been recognised for delivering innovation in rheumatology clinics by the Bernard Connor Award.



Dr Clare Matthews

Consultant Rheumatologist
Ulster Hospital, Belfast



**Dr Emily Pender
Bernard Connor
Medal Winner**



Emily Pender is a graduate of UCD Medicine 2017, and currently an intern in the Mater Hospital. Her interests in medicine include rheumatology, paediatrics and dermatology. Emily has also undertaken research in the area of empathy in medicine and medical education. In the future she hopes to combine her clinical and research interests aiming to improve student and patient experiences.

**Photos from
ISR Spring Meeting 2017**



Dr Joe Devlin & Dr Bryan Whelan



Prof Gerry Wilson & Mary O'Donnell



Delegates during coffee break

Cosentyx[®]

- The first and only fully human IL-17A inhibitor approved for the treatment of psoriatic arthritis, ankylosing spondylitis and psoriasis¹
- Rapid and sustained efficacy in PsA and AS patients, with benefits maintained through 2 years²⁻⁷
 - Up to 80% of patients had no radiographic progression on joints and spine^{3,8}
- Favourable safety profile across 3 indications^{9,10}



WATCH ME

SHOW MY FAMILY THAT I CAN STILL BE MYSELF.

 **Cosentyx[®]**
secukinumab

LIFE IN MOTION

ABBREVIATED PRESCRIBING INFORMATION. ▼ **COSENTYX 150 mg solution for injection in pre-filled pen.** This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** COSENTYX 150 mg solution for injection in pre-filled pen. **Therapeutic Indications:** The treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; the treatment, alone or in combination with methotrexate (MTX), of active psoriatic arthritis in adult patients when the response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate. **Dosage & Method of Administration:** **Plaque Psoriasis:** Recommended dose in adults is 300 mg given as two subcutaneous injections of 150 mg. Dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. **Ankylosing Spondylitis:** The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. **Psoriatic Arthritis:** For patients with concomitant moderate to severe plaque psoriasis or who are anti-TNF α inadequate responders, the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing starting. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For all other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. For all of the above indications, available data suggest that a clinical response is usually achieved within 16 weeks of treatment. Consideration should be given to discontinuing treatment in patients who have shown no response up to 16 weeks of treatment. Some patients with initially partial response may subsequently improve with continued treatment beyond 16 weeks. The safety and efficacy in children below the age of 18 years have not yet been established. **Contraindications:** Severe hypersensitivity reactions to the active substance or to any of the excipients. Clinically important, active infection (e.g. active tuberculosis). **Warnings/Precautions:** **Infections:** Cosentyx has the potential to increase the risk of infections. Infections observed in clinical studies are mainly mild or moderate upper respiratory tract infections such as nasopharyngitis not requiring treatment discontinuation. Non serious mucocutaneous candida infections more frequently reported for secukinumab than placebo in psoriasis clinical studies. Caution in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, close monitoring and discontinue treatment until the infection resolves. Should not be given to patients with active tuberculosis. Anti tuberculosis therapy should be considered prior to initiation in patients with latent tuberculosis. **Crohn's disease:** Caution should be exercised when prescribing to patients with Crohn's disease as exacerbations of Crohn's disease, in some cases serious, were observed in clinical studies. Close monitoring of patients with Crohn's disease treated with Cosentyx. **Hypersensitivity reactions:** In clinical studies, rare cases of anaphylactic reactions have been observed in patients receiving Cosentyx. If an anaphylactic or other serious allergic reactions occur, administration should be discontinued immediately and appropriate therapy initiated. **Latex-sensitive individuals:** The removable cap of the Cosentyx pre filled pen contains a derivative of natural rubber latex. **Vaccinations:** Live vaccines should not be given concurrently with Cosentyx. Patients may receive concurrent inactivated or non live vaccinations. **Concomitant immunosuppressive therapy:** Use in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. **Interactions:** Live vaccines should not be given concurrently with Cosentyx. No interaction studies have been performed in humans. A clinically relevant effect on CYP450 substrates with a narrow therapeutic index, where the dose is individually adjusted (e.g. warfarin) cannot be excluded. Therapeutic monitoring should be considered on initiation in patients treated with these types of medicinal products. No interaction seen when administered concomitantly with methotrexate (MTX) and/or corticosteroids. **Fertility, Pregnancy and Lactation:** Women of childbearing potential should use an effective method of contraception during treatment and for at least 20 weeks after treatment. It is preferable to avoid the use of Cosentyx in pregnancy as there are no adequate data from the use of secukinumab in pregnant women. It is not known whether secukinumab is excreted in human milk. A decision on whether to discontinue breast feeding during treatment and up to 20 weeks after treatment or to discontinue therapy with Cosentyx must be made taking into account the benefit of breast feeding to the child and the benefit of Cosentyx therapy to the woman. The effect of secukinumab on human fertility has not been evaluated. **Undesirable Effects:** **Very common** ($\geq 1/10$); **Common** ($\geq 1/100$ to $< 1/10$); **Uncommon** ($\geq 1/1,000$ to $< 1/100$); **Rare** ($\geq 1/10,000$ to $< 1/1,000$); **Anaphylactic reactions.** Please see Summary of Product Characteristics for further information on undesirable effects. **Legal Category:** POM. **Marketing Authorisation Holder:** Novartis Europharm Ltd, Frimley Business Park, Camberley, GU167SR, United Kingdom. **Marketing Authorisation Numbers:** EU/1/14/090/004-005. **Date of Revision of Abbreviated Prescribing Information:** June 2017. Full prescribing information is available upon request from: Novartis Ireland Limited, Vista Building, Elm Park Business Park, Elm Park, Dublin 4. Tel: 01-2204100 or at www.medicines.ie. Detailed information on this product is also available on the website of the European Medicines Agency <http://www.ema.europa.eu> *Patients received intravenous secukinumab (10 mg per kg of body weight) or matched placebo at weeks 0, 2, and 4, followed by subcutaneous secukinumab (150 mg or 75 mg) or matched placebo every 4 weeks starting at week 8. **References:** 1. Cosentyx Summary of Product Characteristics, June 2017. 2. Mease PJ *et al.* Presented at the American College of Rheumatology 2016. Presentation number 961. 3. Braun J *et al.* Ann Rheum Dis. 2016 Dec 13. pii: annrheumdis-2016-209730. doi: 10.1136/annrheumdis-2016-209730. 4. Strand V, *et al.* Ann Rheum Dis. 2016;doi:10.1136/annrheumdis-2015-2090553. 5. Novartis Data on File 2014. F2312_Patient assessment of pain through 24 weeks_Table 14.2-12.1. 6. Novartis Data on File 2014. F2305_Total spinal pain through 24 weeks_Table 14. 2-12.1. 7. Novartis Data on File 2014. F2310_Total spinal pain through 16 weeks_Table 14.2-12.1. 8. Mease P *et al.* Arthritis Rheum 2015; 67 (S10): 2576: Oral presentation 2148 at the American College of Rheumatology (ACR), 9 November 2015, San Francisco, USA. 9. van de Kerkhof P *et al.* J Am Acad Dermatol 2016; 75(1): 83-98. 10. European Medicines Agency Public Assessment Report. http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/003729/WC500183131.pdf. *Patients received intravenous secukinumab (10 mg per kg of body weight) or matched placebo at weeks 0, 2, and 4, followed by subcutaneous secukinumab (150 mg or 75 mg) or matched placebo every 4 weeks starting at week 8. **Date of Preparation:** August 2017. IE02/COS16-CNF010d(1)

 **NOVARTIS**



ISR Bernard Connor Medal

Dr Emily Pender

Award Winner 2017

RHEUM TO IMPROVE? A REFLECTION ON MEDICAL STUDENT ATTITUDES TO RHEUMATOLOGY AS A SPECIALTY

Introduction

When considering the brief of this essay – medical student observations in rheumatology - one particular topic stood out. While rheumatology is a dynamic and evolving specialty which has made huge strides in treatment and management of previously debilitating and chronic diseases in recent years, it suffers from an ‘image problem’. Medical students, on the whole, appear to regard the subject as, at best, mystifying – and at worst, an uninteresting or unfulfilling specialty. This essay will attempt to unpick the bad press rheumatology appears to receive, briefly explore potential reasons behind it, and conclude by proposing some possible solutions that may go some way towards rehabilitating rheumatology’s reputation among my own and future generations of medical students.

Multiple factors contribute to rheumatology’s bad name – or at least lack of a good name. . The first is that the day-to-day of rheumatology is seen as alternately ‘boring’ – primarily in relation to its image as a specialty dealing with osteoarthritis and osteoporosis in the elderly, and impenetrable – the whistle stop tour of ANAs, ENAs, ANCA and their interpretation leaves students more confused than they were when they started and with the overwhelming feeling that they will never understand the finer points. Finally, the increasing prevalence of somatisation disorders such as fibromyalgia, and their appearance in rheumatology clinics is poorly taught in medical school, or not taught at all, discussed with eye rolls and roundly dismissed, where better understanding of the disease could reduce the burden on both patients and rheumatologists and allow it to be treated in general practice or outside the rheumatology setting – or if better understood, be treated with less trepidation by students and removed as a potential reason to dislike or dismiss rheumatology.

The Problem

Starting at the very beginning – before medical students begin their training at all – it’s easy to see that rheumatology begins on the back foot. Ask a member of the public, without medical training, what a rheumatologist does. Unless they have come in contact with rheumatology services, directly or indirectly, they are unlikely to be familiar with the term. Contrast this with the role of the cardiologist or neurologist – well recognised, regularly featured in medical dramas and filling a generally less mysterious role in the eyes of the public. Move further into medical training, and the ‘systems-based’ approach to teaching – ensures that other specialties take precedence in the minds and workloads of medical students. Furthermore, rheumatology is relegated to the musculoskeletal system, along with orthopaedics. The musculoskeletal system is often taught once ‘the basics’, or more visible systems have been dealt with. This both essentially ensures that students will leave their study of rheumatology becomes almost an afterthought, pushed aside for more pressing matters, and completely ignores the fact that rheumatology is a speciality that has never been limited simply to disease of the bone and joint. It ignores the fact that rheumatological diseases are often multisystem processes. The opportunity to use rheumatology as a teaching tool in integrating the systems previously taught separately, alongside clinical data interpretation, is being missed. Meanwhile, this dynamic specialty is roundly regarded as alternately utterly mystifying, due to the confusion among students over the nuances of ANA, ENA or ANCA, and boring or frustrating - the image of the specialty as one in which ‘you can’t really ever cure patients’ remains, despite advances in treatments.

This idea that patients living with rheumatological diseases ‘can’t be cured’ seems to remain prevalent both among my fellow interns and current students. This is despite the advent of new biologic treatments which allow patients who may previously have suffered debilitating joint pain, and associated disability and loss of independence, to lead relatively ‘normal’ lives, with marked reductions in their pain and increased independence. It’s a phenomenon I was struck by on attending both paediatric and adult rheumatology clinic, and certainly framed the specialty as an exciting one. However, I believe the lack of exposure to rheumatology clinically denies most students the opportunity to realise this. The fact that, as a result of these treatments, rheumatology is primarily a specialty practised in the outpatient setting contributes to this – students are far less likely to meet patients on the wards with rheumatological diseases. [1] Furthermore, time constraints and increasing student numbers means that only a select few students are exposed to the specialty over the course of their clinical years. Taking into account the finding that clinical exposure to rheumatology was a factor in influencing the decision to pursue a career in the field [2], it is easy to see how, through underexposure, rheumatology falls down the list of preferred specialties. A 2012 study found that while students showed interest in rheumatology, it was close to the bottom of the list of specialties perceived as most useful in postgraduate training. [3] Conversely, research has found that self-rated confidence in MSK exams among clinicians

continues...

A case of ankylosing spondylitis from the 17th century.



M. T. Pugh Rheumatology 2002;41:942-943

© British Society for Rheumatology

RHEUMATOLOGY

NEW


CIMZIA®
(certolizumab pegol)

CIMZIA® AutoClicks®

Designed with patients for patients^{1*}



- **Injection confidence** - Double clicks and a large viewing window confirm when the injection starts and when it's complete¹
- **Comfort** - Wide non-slip grip¹
- **Ease of use** - Button-free delivery system¹

*** For patients with Rheumatoid Arthritis, Psoriatic Arthritis or Axial Spondyloarthritis²**

Cimzia® AutoClicks® has been designed for comfort and control in partnership with GOOD GRIPS®

Good Grips and the associated logos are registered trademarks of Helen of Troy Limited and are used under license.

PRESCRIBING INFORMATION

(Please consult the Summary of Product Characteristics (SPC) before prescribing.)

Cimzia® Certolizumab Pegol

Active Ingredient: Pre-filled syringe and pre-filled pen contain 200 mg certolizumab pegol in one ml.

Indication(s): *Rheumatoid arthritis (RA):* Cimzia, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active RA in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Cimzia in combination with methotrexate (MTX), is also indicated in the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. Cimzia has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX.

Axial spondyloarthritis: Cimzia is indicated for the treatment of adult patients with severe active axial spondyloarthritis, comprising:

Ankylosing spondylitis (AS): Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

Axial spondyloarthritis without radiographic evidence of AS: Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.

Psoriatic arthritis: Cimzia in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

Dosage and Administration: Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Cimzia is indicated in adult patients. Patients should be given the special alert card. For RA and psoriatic arthritis MTX should be continued during treatment with Cimzia where appropriate.

Loading dose: The recommended starting dose is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4.

Maintenance dose: RA and Psoriatic Arthritis: The recommended maintenance dose is 200 mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dose of 400 mg every 4 weeks can be considered. Axial spondyloarthritis: The recommended maintenance dose is 200 mg every 2 weeks or 400 mg every 4 weeks. For the above indications continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment.

Missed dose: Advise patients to inject the next dose as soon as they remember and inject

subsequent doses as originally instructed.

Paediatric population (<18 years old): Not recommended. Consult SPC for further information.

Contraindications: Hypersensitivity to the active substance or to any of the excipients; active tuberculosis or other severe infections such as sepsis or opportunistic infections; moderate to severe heart failure (NYHA classes III/IV).

Precautions: Prior to treatment with Cimzia all patients to be appropriately screened for tuberculosis, e.g. tuberculin skin test and chest X-ray (local recommendations may apply) and results recorded on the patient alert card. False negative tuberculin skin test results are possible in severely ill or immunocompromised patients. Do not initiate treatment in cases of latent tuberculosis, clinically important active infection, including chronic or localised infections until the infection is controlled. In patients with a past history of latent tuberculosis use of anti-tuberculosis therapy must be started before initiation of Cimzia. Evaluate and monitor patients closely for signs and symptoms of infections including chronic and local infections and active and latent tuberculosis. Treatment must not be initiated until infection is controlled. Some patients who have been successfully treated for active tuberculosis have redeveloped tuberculosis while being treated with Cimzia. Monitor patients closely for signs of infection during and up to 5 months after treatment in order to minimise delay in diagnosis and treatment. Serious infections (including sepsis, tuberculosis, miliary tuberculosis, disseminated and extrapulmonary disease) and opportunistic infections (including histoplasmosis, nocardia, candidiasis) have been reported with some fatal outcomes. Caution is advised in patients with a history of recurring or opportunistic infections including those on concomitant corticosteroid or immunosuppressive medications or elderly. Patients should be tested for HBV infection before initiating treatment with Cimzia and if treated should be continually monitored. In patients receiving TNF antagonists, HBV reactivation has occurred in chronic carriers with some fatal outcomes. Cimzia should be discontinued and effective antiviral therapy and appropriate supportive treatments initiated. There is an increase in background risk for lymphoma and leukaemia in patients with long-standing highly active RA. Periodic skin examination is recommended particularly for patients with risk factors for skin cancer. Exercise caution when initiating TNF antagonist therapy in patients with a history of malignancies and when considering continuing treatment if patients develop lymphoma, leukaemia, mild congestive heart failure and demyelinating disorders such as multiple sclerosis. Advise patients to seek immediate medical attention if they develop signs and symptoms suggestive of tuberculosis, blood dyscrasias or infection. Discontinue treatment if patients develop significant haematological abnormalities including aplastic anaemia, leucopenia, pancytopenia, thrombocytopenia; lupus-like syndrome; mild congestive heart failure and demyelinating disorders such as multiple sclerosis. There is a potential risk of worsening of congestive heart failure with TNF antagonists including Cimzia. As for all TNF antagonists COPD and heavy smoking may put patients at greater risk of

malignancies. Patients receiving Cimzia may receive vaccination except live vaccines. Live vaccines should not be administered concurrently with Cimzia. The 14 day half-life of certolizumab pegol should be taken into account prior to planned surgical procedures. Cimzia may cause erroneously elevated (aPTT) assay results in patients without coagulation abnormalities.

Interactions: The combination of Cimzia and anakinra or abatacept is not recommended.

Pregnancy and lactation: Cimzia is not recommended in pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception up to 5 months after the last administered dose.

Driving etc.: Cimzia may have a minor influence on the ability to drive and use machines. Dizziness may occur following administration. Caution is advised.

Adverse Effects: Common adverse-effects (+ 1/100 to <1/10): Bacterial infections (including abscess) and viral infections (including herpes zoster, papillomavirus and influenza), eosinophilic disorders, leucopenia (including neutropenia, lymphopenia), headaches (including migraine), sensory abnormalities, hypertension, nausea, hepatitis (including hepatic enzyme increased), rash, pruritus, pain (any site), asthma, pruritus (any site), injection site reactions. **Consult SPC in relation to other side effects.**

Pharmaceutical Precautions: Store in refrigerator (2°-8°C). Do not freeze. Keep the pre-filled syringe and pre-filled pen in the outer carton in order to protect from light.

Legal Category: POM

Marketing Authorisation Number(s): EU/1/09/544/001, EU/1/09/544/005
UK NHS Cost: £715 per pack of 2 pre-filled syringes or pens of 200 mg each

Marketing Authorisation Holder:

UCB Pharma S.A., Allée de la Recherche 60, 1070 Brussels, Belgium.

Further information is available from:

UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE.

Tel: +44 (0) 1753 777100. Fax: +44 (0)1753 536632.

Email: UCB.Cares.UK@ucb.com

UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive,

Magna Business Park, City West Road, Dublin 24, Ireland

Tel: +353 1 4632371 Fax: +353 14637396

Email: UCB.Cares.IE@ucb.com

Date of Revision: 09/2016 (UK/14C10101(2)).

Cimzia is a registered trademark.

UK Specific Information:

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to UCB Pharma Ltd.

References:

1. UCB data on file (Comparative Usability and Validation Study for CIMZIA® pre-filled pen - Study Report, Sections 11.1.1, 11.2.3, 11.2.4).
2. Cimzia® (certolizumab pegol) Summary of Product Characteristics, September 2016.



... conti'd

likely to come across patients with MSK diseases or issues was low [4]. This suggests to me that what needs to change is the perception of rheumatology as 'too specialised' or 'not useful'. The problem is not just lack of interest, but lack of exposure.

In my own medical school, every student was required to complete 3 weeks of musculoskeletal medicine through attachment to orthopaedic teams. As a result, students had no exposure to rheumatology, but it could be argued were over-exposed to the surgical side of musculoskeletal medicine, skewing the general perception of bone and joint disease towards the surgical aspects of its treatment and management. This heavy emphasis on orthopaedic attachment may be due in part to findings in previous research which suggested that while musculoskeletal issues comprised at least 15% of consultations in primary care, there was a lack of formal education in the topic across medical school curricula. (5, 6] Orthopaedics, however, is only one aspect of musculoskeletal medicine, and clinical instruction in rheumatology would be extremely helpful, particular for those who go on to train as general practitioners. This brings me on to potential solutions to the problem at hand.

The Solution?

As the 'problem' with rheumatology is multifactorial, it follows that the solution must be too. I don't believe there is a 'quick fix' that will both increase interest in rheumatology as a specialty and improve knowledge of rheumatology in general practice or internal medicine. However, modification of the current approach to teaching rheumatology at all stages, in a simple manner that does not require significantly increased resources, is possible and may go towards ensuring rheumatology joins the list of in-demand specialties, continuing to attract the brightest trainees.

In order to tackle the perception of rheumatology as a confusing topic in the preclinical years, often sandwiched into modules, it may be useful to provide small group teaching on the laboratory testing for rheumatological diseases. Interactive tutorials or a handbook, breaking down the specialty to basic explanation of the basic (CRP, ESR), and the more complex (recognition of ANCA patterns etc.) would have been infinitely more useful to me than the hurried lectures, delivered to some 200 students, that I remember from my preclinical years. While it is possible that these methods are already in place in many schools, focusing on their provision may ensure that students do not enter their clinical training with the preconceived idea of rheumatology as complex and mystifying.

As rheumatology is primarily an outpatient-based specialty, and student numbers rarely permit attachment of every student to a rheumatology team, it would be useful for students to be rostered to attend at least one rheumatology clinic as part of their MSK teaching. This ensures some level of exposure for all, and reduces the likelihood of interested students missing their opportunity to experience rheumatology. During my paediatrics rotation, every student attended a tutorial in the pGALS musculoskeletal exam, and rheumatology bedside tutorials were included in the clinical medicine teaching programme. The combination of these, along with outpatient clinics and data interpretation tutorials, would give a rounded exposure to rheumatology, and allow students form an opinion from experience rather than hearsay or outdated perceptions of the specialty.

Opportunities for clinical research, audits and electives in rheumatology must also be promoted to generate interest. Students are becoming ever more concerned with completing research projects prior to graduation, and the availability of projects in rheumatology could help attract those that may not previously have considered it.

Canadian rheumatologists have taken the bull by the horns, tackling the same problem with a hashtag - #makerheum – a concept that surely could be employed by rheumatologists, harnessing the power of social media as an emerging tool in medical education. This hashtag was paired with a superman-style poster campaign extolling the virtues of the specialty – 'Become a hero – become a rheumatologist'. [7] While the effort is admirable, it may prove difficult to persuade current Irish rheumatologists to partake – and the intended effect may not transfer across the Atlantic. In the context of Irish medical schools, more 'low-key' techniques may show more success, and be more economical. However, it shows that the problem is not limited to Irish schools, and should be closely followed to determine whether the intended increased number of rheumatology trainees materialises.

Finally, careers talks to medical students on rheumatology as a dynamic and exciting career are few and far between. Throughout my student training, the rheumatology consultants and NCHDs I have met have been interested, engaging and eager to teach. To share this enthusiasm with a wider range of student through lectures, talks and mentoring would go a long way to ensuring the future of rheumatology as a specialty that continues to attract the best and brightest of medical students, and reform its image as a new and exciting specialty.

Bibliography

- [1] Watson P, Gaffney K. Factors influencing recruitment to rheumatology. *Clinical Medicine*. 2011;11(5):509-510.
- [2] Kolasinski S, Bass A, Kane-Wanger G, Libman B, Sandorfi N, Utset T. Subspecialty choice: Why did you become a rheumatologist?. *Arthritis & Rheumatism*. 2007;57(8):1546-1551.
- [3] Thapper M, Roussou E. Medical students' attitude towards rheumatology training at foundation years' level in the UK and rationale behind the students' choice: results from a national survey. *Rheumatology International*. 2012;33(4):933-938.
- [4] Jandial S, Myers A, Wise E, Foster H. Doctors Likely to Encounter Children with Musculoskeletal Complaints Have Low Confidence in Their Clinical Skills. *The Journal of Pediatrics*. 2009;154(2):267-271.
- [5] 6. Monrad S, Zeller J, Craig C, DiPonio L. Musculoskeletal education in US medical schools: lessons from the past and suggestions for the future. *Current Reviews in Musculoskeletal Medicine*. 2011;4(3):91-98.
- [6] Hosie G. Series on education: Teaching rheumatology in primary care. *Annals of the Rheumatic Diseases*. 2000;59(7):500-503.
- [7] Crawshaw D. Training the Rheumatologists of Tomorrow (TROT). *CRAJ* 2017;27(1):6.

Adenuric[®]

(febuxostat)

Treat to target. Daily.^{1,2}



ADENURIC 80 mg and 120 mg film-coated tablets: Abbreviated Prescribing Information Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.

Presentation: Film-coated tablets containing 80 mg or 120 mg febuxostat. Also contains lactose monohydrate. **Use:** Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis) in adults. **Dosage and administration:** Oral use with or without food. Recommended dose is 80 mg once daily. If serum uric acid is > 6 mg/dL (357 µmol/L) after 2-4 weeks, 120 mg once daily may be considered. **Older people:** No dose adjustment required. **Renal impairment:** No dosage adjustment necessary in patients with mild or moderate renal impairment. Efficacy and safety not fully evaluated in patients with severe renal impairment. **Hepatic impairment:** Recommended dosage in patients with mild hepatic impairment is 80 mg. Limited information available in patients with moderate hepatic impairment. Efficacy and safety has not been studied in patients with severe hepatic impairment. **Children and adolescents:** Safety and efficacy in children under 18 has not been established. **Organ transplant recipients:** No experience therefore not recommended. **Contraindications:** Hypersensitivity to the active ingredient or to any of the excipients. **Warnings and precautions:** **Cardio-vascular disorders:** Not recommended in patients with ischaemic heart disease or congestive heart failure. **Product allergy/hypersensitivity:** Advise patients of signs/symptoms of allergic/hypersensitivity reactions and monitor closely for symptoms. Stop treatment immediately if serious reactions occur, including Stevens-Johnson syndrome, Toxic epidermal necrolysis and acute anaphylactic reaction/shock, do not re-start febuxostat at any time. Severe hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with fever, haematological, renal or hepatic involvement in some cases. **Acute gouty attacks (gout flare):** Do not start treatment until an acute attack of gout has completely subsided. As with other urate lowering medicinal products, gout flares may occur during initiation of treatment. At treatment initiation flare prophylaxis for at least 6 months with an NSAID or colchicine is recommended. If a gout flare occurs during treatment, do not discontinue. Manage the gout flare concurrently as appropriate. Continuous treatment decreases frequency and intensity of gout flares. **Xanthine deposition:** As with other urate lowering medicinal products, in patients in whom the rate of urate formation is greatly increased (e.g. malignant disease and its treatment, Lesch-Nyhan syndrome), the absolute concentration of xanthine in urine could, in rare cases, rise sufficiently to allow deposition in the urinary tract. As there has been no experience of treating gout in these patients with febuxostat such use is not recommended. **Mercaptopurine/azathioprine:** Not recommended in patients concomitantly treated with mercaptopurine/azathioprine. Where combination cannot be avoided, monitor patients closely. Dose reduction for mercaptopurine/azathioprine is recommended. **Theophylline:** No pharmacokinetic interaction shown with febuxostat 80 mg, no data for 120 mg. **Liver disorders:** Liver function test is recommended prior to the initiation of therapy and periodically thereafter based on clinical judgement. **Thyroid disorders:** Caution in patients with alteration of thyroid function. **Lactose:** Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions:** **Mercaptopurine/azathioprine:** On the basis of the mechanism of action of febuxostat on xanthine oxidase inhibition concomitant use is not recommended. No data is available regarding the safety of febuxostat during cytotoxic chemotherapy. **Rosiglitazone/CYP2C8 inhibitors:** No dosage adjustment required. **Theophylline:** No special caution advised for 80 mg febuxostat, no data available for 120 mg. **Naproxen and other inhibitors of glucuronidation:** Can be co-administered with naproxen with no dose adjustments necessary. **Inducers of glucuronidation:** Monitoring of serum uric acid is recommended 1-2 weeks after start of treatment with a potent inducer of glucuronidation. Cessation of treatment of an inducer might lead to increased plasma levels of febuxostat. **Colchicine/indometacin/hydrochlorothiazide/warfarin:** Can be co-administered with colchicine or indometacin with no dose adjustments

necessary. No dose adjustment necessary when administered with hydrochlorothiazide. No dose adjustment necessary for warfarin when administered with febuxostat. **Desipramine/CYP2D6 substrates:** Co-administration with other CYP2D6 substrates is not expected to require any dose adjustment for those compounds. **Antacids:** May be taken without regard to antacid use. **Pregnancy and lactation:** Do not use during pregnancy or breast-feeding. Effect on fertility unknown. **Side-Effects:** **Clinical Studies and post-marketing experience:** Common (1-10%): Gout flares, headache, diarrhoea*, nausea, liver function test abnormalities**, rash, oedema. **Uncommon (0.1-1%):** Blood thyroid stimulating hormone increased, diabetes mellitus, hyperlipidemia, decrease appetite, weight increase, decreased libido, insomnia, dizziness, paraesthesia, hemiparesis, somnolence, altered taste, hyposaesthesia, hyposmia, atrial fibrillation, palpitations, ECG abnormal, hypertension, flushing, hot flush, dyspnoea, bronchitis, upper respiratory tract infection, cough, abdominal pain, abdominal distension, gastro-oesophageal reflux disease, vomiting, dry mouth, dyspepsia, constipation, frequent stools, flatulence, gastrointestinal discomfort, cholelithiasis, dermatitis, urticaria, pruritus, skin discolouration, skin lesion, petechiae, rash macular, rash maculopapular, rash papular, arthralgia, arthritis, myalgia, musculoskeletal pain, muscle weakness, muscle spasm, muscle tightness, bursitis, renal failure, nephrolithiasis, haematuria, pollakiuria, proteinuria, erectile dysfunction, fatigue, chest pain, chest discomfort, blood amylase increase, platelet count decrease, WBC decrease, lymphocyte count decrease, blood creatine increase, blood creatinine increase, haemoglobin decrease, blood urea increase, blood triglycerides increase, blood cholesterol increase, haematocrit decrease, blood lactate dehydrogenase increased, blood potassium increase. **Rare (0.1-0.01%):** Pancytopenia, thrombocytopenia, anaphylactic reaction**, drug hypersensitivity**, blurred vision, weight decrease, increase appetite, anorexia, nervousness, tinnitus, pancreatitis, mouth ulceration, hepatitis, jaundice**, liver injury**, Toxic epidermal necrolysis**, Stevens-Johnson Syndrome**, DRESS**, angioedema**, generalized rash (serious)**, erythema, exfoliative rash, rash follicular, rash vesicular, rash pustular, rash pruritic**, rash erythematous, rash morbilliform, alopecia, hyperhidrosis, rhabdomyolysis**, joint stiffness, musculoskeletal stiffness, tubulointerstitial nephritis**, micturition urgency, thirst, blood glucose increase, activated partial thromboplastin time prolonged, red blood cell count decrease, blood alkaline phosphatase increase, blood creatine phosphokinase increase**. *Treatment-emergent non-infective diarrhoea and abnormal liver function tests in combined Phase III studies more frequent in patients concomitantly treated with colchicine. **Adverse reactions coming from post-marketing experience. Rare serious hypersensitivity reactions including Stevens-Johnson Syndrome and anaphylactic reaction/shock have occurred in post-marketing experience. Hypersensitivity reactions to febuxostat can be associated with the following symptoms: skin reactions characterised by infiltrated maculopapular eruption, generalised or exfoliative rashes, also skin lesions, facial oedema, fever, haematologic abnormalities such as thrombocytopenia, and single or multiple organ involvement (liver and kidney including tubulointerstitial nephritis). Gout flares commonly observed soon after treatment start and in first months. Frequency decreases after time. Gout flare prophylaxis is recommended. Please consult the SmPC for further information. **Pack sizes:** 80 mg and 120 mg tablets; 28 film-coated tablets. **Legal category:** POM **Marketing authorization number:** EU/1/08/447/001, 003, 014, 020. **Marketing authorization holder:** Menarini International Operations Luxembourg S.A., Avenue de la Gare, L-1611 Luxembourg, Luxembourg. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request to A. Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924 or may be found in the SmPC.

Last updated: January 2017.

References: 1. Adenuric 80 mg SmPC. January 2017. 2. Adenuric 120 mg SmPC. January 2017.

ADENURIC[®] is a trademark of Teijin Limited, Tokyo, Japan

Date of item: February 2017
IR-ADEN-03-2017

 **A.MENARINI**
PHARMACEUTICALS IRELAND LTD
Healthcare for Life



Young Investigator Award 2017

Dr Richard Conway



GIANT CELL ARTERITIS: DIAGNOSTIC TOOLS, TREATMENT TARGETS, AND PATHOGENIC PATHWAYS

Author(s) Richard Conway, Anna E. Smyth, Silvana Di Bello, Lorraine O'Neill, Karen Creevey, Phil Gallagher, Richard G. Kavanagh, Rory O'Donohue, Graeme McNeill, Eric J. Heffernan, Ronan P. Killeen, Geraldine M. McCarthy, Conor C. Murphy, Douglas J. Veale, Ursula Fearon, Eamonn S. Molloy

Department(s)/Institutions Centre for Arthritis and Rheumatic Diseases, St. Vincent's University Hospital
Department of Radiology, St. Vincent's University Hospital
Department of Rheumatology, Mater Misericordiae University Hospital
Department of Ophthalmology, Royal College of Surgeons of Ireland
Department of Molecular Rheumatology, Trinity College Dublin

Background Giant cell arteritis (GCA) is the most common form of systemic vasculitis. 25% of patients suffer cranial ischaemic complications (CIC). The diagnosis of GCA remains a clinical one. Temporal artery (TA) ultrasound (US) has been proposed as a new diagnostic tool, the real-world performance is uncertain, and complementary imaging modalities are needed. Current evidence suggests both TH1 and TH17 pathways are important in GCA pathogenesis but the proximal initiator and effector cytokines are unknown. IL-12 and IL-23 secreted by dendritic cells are hypothesised as stimulators. We have previously reported the efficacy of IL-12/23 blockade with ustekinumab in refractory GCA in a prospective clinical trial.

Aim To assess the performance of TA US and CTA in GCA diagnosis. To assess the role of IL-12 and IL-23 in GCA pathogenesis.

Methods All patients presenting with suspected GCA are recruited to a prospective registry, which has recruited 334 patients since 2011. Patients who had both a TA US and TAB at presentation were included in the US study. The performance characteristics were compared to physician diagnosis at six months. Predictive factors for positive US were explored in univariate and multivariable logistic regression analyses. The CTA study included patients ultimately diagnosed with GCA, and age- and sex-matched controls who had a CTA performed for the assessment of suspected stroke at presentation. CTAs were evaluated for the presence of abnormalities indicative of TA vasculitis – vessel wall blurring, narrowing, or occlusion, and perivascular enhancement. IL-12 and IL-23 were quantified by immunohistochemistry in TABs. TA explant, PBMC, and myofibroblast outgrowth culture models were established from patients with GCA and disease controls. PBMCs and TA explants were cultured for 24 hours in the presence or absence of IL-12 or IL-23. Gene expression was quantified by Real-time PCR and cytokine secretion by ELISA. Myofibroblast outgrowths were assessed following 28 days culture and quantified by counting the number of outgrowths/high-power field (hpf).

Results 162 patients were included in the US study, 76% with GCA. Mean duration of glucocorticoids was 6.6 days. US had a sensitivity of 52.8% and specificity of 71.8%. A hypothetical sequential strategy of US followed by TAB in the case of negative US had a sensitivity of 78.9% and specificity of 71.8%, equivalent to a simultaneous testing strategy. Time on glucocorticoids did not significantly impact the US. The only factor independently predictive of a positive US was male sex (OR 5.53, $p < 0.001$). Twenty-eight intracranial CTAs were evaluated; 14 GCA and 14 controls. TA CTA had a sensitivity of 100% and specificity of 71%. Positive predictive value was 78% and negative predictive value 100%. Immunohistochemistry demonstrated IL-12p35 and IL-23p19 in inflammatory cells in TABs ($n=33$). IL-12p35 was increased in those with CICs ($p=0.026$) and those with large vessel vasculitis ($p=0.006$). IL-23p19 was increased in those with two or more relapses ($p=0.007$). In cultured PBMCs, IL-12 stimulation increased IL-6 ($n=17$, $p=0.009$), IL-22 ($n=16$, $p=0.003$), and IFN- γ ($n=14$, $p=0.0001$) secretion and decreased IL-8 ($n=15$, $p=0.0006$) secretion, while IL-23 stimulation increased IL-6 ($n=40$, $p=0.029$), IL-22 ($n=16$, $p=0.001$), IL-17A ($n=16$, $p=0.0003$) and IL-17F ($n=9$, $p=0.012$) secretion. In the TA explant culture model, IL-23 stimulation increased gene expression of IL-8 ($n=13$, $p=0.0001$) and CCL-20 ($n=9$, $p=0.027$) and protein expression of IL-6 ($n=61$, $p=0.002$) and IL-8 ($n=60$, $p=0.004$), IL-12 stimulation ($n=14$) had no effect. IL-12 ($n=20$, $p=0.0005$) and IL-23 ($n=33$, $p < 0.0001$) stimulation increased the quantity of myofibroblast outgrowths from TABs.

Conclusion TA US and CTA are useful tools in the diagnosis of GCA. IL-12 and IL-23 play central and distinct roles in stimulating inflammatory and proliferative pathways in GCA.

I have arthritis, but arthritis doesn't have me

Arthritis affects almost one million people in Ireland, from newborn babies through to the elderly. It is the single biggest cause of disability in this country.

As a charity dedicated to working with people living with arthritis, we:

- Invest in research to find new treatments and a cure;
- Enable and empower people to become effective self-managers;
- Raise understanding of arthritis as a chronic disease and fight for better healthcare services.

National Arthritis Week
9-15 October 2017
#ConnectToday



To learn about the wide range of supports available:

Visit www.arthritisireland.ie

Helpline 1890 252 846



Arthritis Ireland

Little Things make a Big Difference



ISR Presidents

- Dr Sandy Fraser** 2016 - present
Limerick
- Prof D. Kane** 2014 - 2016
Dublin
- Dr G.Wright** 2012 - 2014
Belfast
- Prof Gaye Cunnane** 2010 - 2012
Dublin
- Dr R. Kavanagh** 2008 - 2010
Galway
- Dr J. Lee** 2006 - 2008
Craigavon
- Dr P. O'Connell** 2004 - 2006
Dublin
- Prof O. FitzGerald** 2002 - 2004
Dublin
- Dr A. Taggart** 2000 - 2002
Belfast
- Dr D. Raman** 1998 - 2000
Sligo
- Dr A. Bell** 1996 - 1998
Belfast
- Prof B. Bresnihan** 1994 - 1996
Dublin
- Prof M. Molloy** 1992 - 1994
Dublin
- Dr E. Casey** 1990 - 1992
Dublin
- Dr. S. Roberts** 1988 - 1990
Belfast
- Dr C. Barry** 1985 - 1987
Dublin
- Dr D. Roden** 1983 - 1985
Dublin
- Dr W. Boyd** 1981 - 1983
Belfast
- Dr T. Gregg** 1979 - 1981
Dublin
- Dr J. Molony** 1977 - 1979
Dublin
- Dr M .McMahon** 1975 - 1977
Cork
- Dr T.O'Reilly** 1973 - 1975
Dublin

Irish Society for Rheumatology Board Members

PRESIDENT

Dr Alexander Fraser
Consultant Rheumatologist
Mid-Western Regional Hospital
Dooradoyle, Limerick

HONORARY SECRETARY

Dr Frances Stafford
Consultant Rheumatologist
Blackrock Clinic, Co. Dublin

HONORARY TREASURER

Dr Sinéad Harney
Consultant Rheumatologist
Cork University Hospital, Cork

BOARD MEMBER

Professor Suzanne Donnelly
Consultant Rheumatologist
Mater University Hospital, Dublin 7

BOARD MEMBER

Professor David Kane
Consultant Rheumatologist
Adelaide and Meath Hospital
Tallaght, Dublin 24

BOARD MEMBER

Dr John Ryan
Consultant Rheumatologist,
Cork University Hospital, Cork

BOARD MEMBER

Dr Orla Killeen
Paediatric Consultant Rheumatologist
Crumlin Children's Hospital, Dublin 12

BOARD MEMBER

Dr Clare Matthews
Consultant Rheumatologist
Ulster Hospital, Belfast

BOARD MEMBER

Dr Eamonn Molloy
Consultant Rheumatologist
St. Vincent's University Hospital, Dublin 4

BOARD MEMBER

Dr Carl Orr
SpR Rep, Mater University Hospital, Dublin 7

BOARD MEMBER

Dr Adrian Pendleton
Consultant Rheumatologist
Musgrave Park Hospital, Belfast

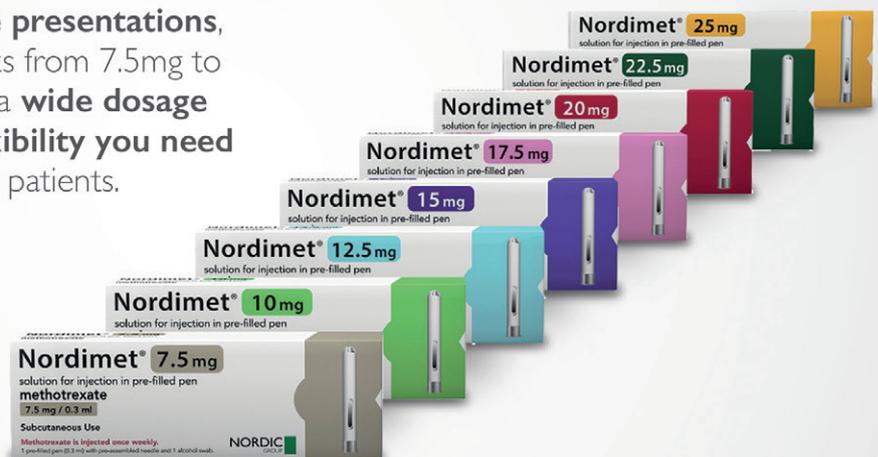


NEW NORDIMET[®] PEN

THE FIRST METHOTREXATE AUTO-INJECTOR FOR PATIENTS WITH RHEUMATOID ARTHRITIS

Featuring a unique **double click mechanism** at the start and end of each injection, a **compact design** and **no button to press** – designed to give confidence to you and your patients.

Available in **8 dose presentations**, in 2.5mg increments from 7.5mg to 25mg – giving you a **wide dosage range** and the **flexibility you need** when treating your patients.



NEW methotrexate auto-injector PEN

Nordimet (methotrexate) Solution for Injection in Pre-Filled Pen
Please refer to the **Summary of Product Characteristics** for full prescribing information. Further information is available on request
Presentation: *Nordimet*: Pre-filled pen containing 7.5 mg (in 0.3 ml), 10 mg (in 0.4 ml), 12.5 mg (in 0.5 ml), 15 mg (in 0.6 ml), 17.5 mg (in 0.7 ml), 20 mg (in 0.8 ml), 22.5 mg (in 0.9 ml) and 25 mg (1.0 ml) methotrexate in solution for injection. **Indications:** Active rheumatoid arthritis in adult patients. Polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drugs (NSAIDs) has been inadequate. Severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids, and severe psoriatic arthritis in adult patients. **Dosage and administration:** Nordimet should only be prescribed by physicians with experience in the various properties of the medicinal product and its mode of action. Nordimet is injected once weekly, administered subcutaneously. **Rheumatoid arthritis:** Recommended initial dose is 7.5 mg of methotrexate once weekly. Depending on the individual activity of the disease & patient tolerability, the initial dose may be increased. A weekly dose of 25 mg should in general not be exceeded. Once the desired therapeutic result has been achieved, the dose should be reduced gradually to the lowest possible effective maintenance dose. **Polyarthritic forms of severe, active juvenile idiopathic arthritis:** The recommended dose is 10-15 mg/m² BSA per week. In therapy-refractory cases the weekly dose may be increased up to 20mg/m² BSA per week. Use in children < 3 years of age is not recommended. **Psoriasis vulgaris and psoriatic arthritis:** A test dose of 5 - 10 mg subcutaneously administered one week prior to initiation of therapy is recommended. Recommended initial dose 7.5 mg

methotrexate once weekly. Dose increased gradually but should not, in general, exceed a weekly dose of 25 mg of methotrexate. Once the desired therapeutic result has been achieved, dose should be reduced gradually to the lowest possible effective maintenance dose. The dose should be increased as necessary but should in general not exceed the maximum recommended weekly dose of 25 mg. Renal impairment, hepatic impairment or elderly patients: Please refer to SmPC. Note: When switching from oral to parenteral use, a reduction in the dose may be required, due to the variable bioavailability of methotrexate after oral administration. **Contraindications:** Hypersensitivity to methotrexate or to any of the excipients. Severe hepatic impairment, if serum bilirubin is > 5 mg/dl (85.5 µmol/l). Alcohol abuse. Severe renal impairment (creatinine clearance < 30 ml/min). Pre-existing blood dyscrasias (e.g. bone marrow hypoplasia, leukopenia, thrombocytopenia or significant anaemia), Immunodeficiency. Serious, acute or chronic infections such as tuberculosis & HIV. Stomatitis. Ulcers of the oral cavity and known acute gastrointestinal ulcer disease. Pregnancy. Breast-feeding. Concurrent vaccination with live vaccines. **Special warnings and precautions:** Patients must be clearly advised that the therapy is to be administered once a week, and not every day. Patients receiving therapy should be appropriately monitored. Doses exceeding 20 mg/week can be associated with significant increase in toxicity, especially bone marrow suppression. The possible risks of effects on reproduction should be discussed with male and female patients of childbearing potential. **Interactions:** Consult SPC for detailed information on interactions. **Undesirable effects:** See SmPCs for full list of undesirable effects. **Nordimet:** **Very common:** Stomatitis, Dyspepsia, Appetite loss, Abdominal pain, Nausea, Raised liver enzymes. **Common:** Leukopenia, Anaemia,

Thrombopenia, Headache, Tiredness, Drowsiness, Pneumonia, Interstitial alveolitis/pneumonitis, Oral ulcers, Diarrhoea, Exanthema, Erythema, Pruritus. **Uncommon:** Pharyngitis, Pancytopenia, Precipitation of diabetes mellitus, Depression, Enteritis, Pancreatitis, Gastrointestinal ulceration and bleeding, Cirrhosis, Fibrosis and fatty degeneration of liver, Inflammation and ulceration of bladder, Renal impairment. **Rare:** Infection, Conjunctivitis, Sepsis, Allergic reactions, Anaphylactic shock, Hypogammaglobulinaemia, Visual disturbances, Pericarditis, Pericardial effusion, Pericardial tamponade, Thromboembolic events, Pulmonary fibrosis, Pneumocystis carinii pneumonia, Shortness of breath and bronchial asthma, Pleural effusion, Acute hepatitis, Renal failure, Anuria. **Very rare:** Lymphoma, Agranulocytosis, Severe courses of bone marrow depression, Acute aseptic meningitis, Convulsions, Paralysis, Impaired vision, Retinopathy, Haematemesis, Toxic megacolon, Hepatic failure, Stevens-Johnson syndrome, Toxic epidermal necrolysis. **Not known:** Eosinophilia, Encephalopathy/Leukoencephalopathy. **Legal classification:** POM. **MA numbers:** *Nordimet*: EU/1/16/1124/001 – 008. **Further information available from:** Nordic Pharma Ltd, Unit 3, Commerce Park, Brunel Road, Theale, Reading, United Kingdom. **Date of prescribing information:** January 2017. **Code for PI:** NOR/17/001i

Adverse events should be reported.
Adverse events should be reported. Reporting forms and information can be found at <http://www.hpra.ie>
Adverse events should also be reported to Nordic Pharma Ireland: info@nordicpharma.ie Phone no. +353 (0)1 4004141



Oral Presentations Thursday, 21 September 2017

Clinical Presentations

Abstract No.	Name	Title of Paper	Time
17A 171	Muhammad Haroon	Musculoskeletal manifestation of Diabetes Mellitus is highly prevalent and is associated with poor diabetic control	10.00
17A 112	Gillian Fitzgerald	Obesity predicts worse disease outcomes in axial spondyloarthritis patients	10.12
17A 129	Leah Rooney	The impact of radiology reporting of vertebral fractures on treatment of fracture risk	10.24
17A 109	Shama Khan	Formal Rheumatology teaching for General practitioners in training	10.36
17A 138	Dr Maria Usman Khan	Indications for Lowering LDL Cholesterol in Rheumatoid Arthritis: An Unrecognized Problem	10.48

Basic Science Presentations

Abstract No.	Name	Title of Paper	Time
17A 174	Mary Canavan	Joint Specific Transcriptional Programme Regulate Inflammation in CD141+DC in Inflammatory Arthritis	14.00
17A 187	Megan Hanlon	Distinct macrophage phenotype and bioenergetic profiles in Rheumatoid Arthritis	14.12
17A 182	Trudy McGarry	JAK-STAT blockade alters synovial bioenergetics, mitochondrial function and pro-inflammatory mediators in Rheumatoid arthritis	14.24
17A 188	Sarah Wade	Characterisation of PDE4 Inhibition in PsA Synovium	14.36
17A 115	Dr Wafa Abdulla Madan	The National Centre for Paediatric Rheumatology (NCPR) experience of the use of Tocilizumab (Ro-Actemra) in the treatment of JIA	14.48

Friday 22 September 2017

Oral Presentations - Case Reports

Abstract No.	Identify of Cases not to be disclosed prior to meeting. Audience Participation units available	Time
17A132	Case 1	9.00
17A144	Case 2	9.15
17A161	Case 3	9.30
17A177	Case 4	9.45



Stelara[®]
(ustekinumab)

...it's time for a different solution

Proven efficacy across multiple indications¹⁻⁵

- ☑ Inhibition of joint damage
- ☑ Lasting improvement in Enthesitis and Dactylitis
- ☑ Effective in axial involvement
- ☑ Lasting relief of skin symptoms
- ☑ Visible improvements in nail symptoms

...with just 4 maintenance doses per year^{6*}

* following a loading dose at week 0 and week 4

janssen  Immunology

PHARMACEUTICAL COMPANIES OF 

STELARA[®] 45 mg and 90 mg solution for injection and 130 mg concentrate for solution for infusion. **ACTIVE INGREDIENT(S):** Ustekinumab. Please refer to Summary of Product Characteristics (SmPC) before prescribing. **INDICATION(S):** **Plaque psoriasis adults:** Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA. **Plaque psoriasis paediatrics:** Moderate to severe plaque psoriasis in adolescent patients from 12 years of age, who are inadequately controlled by, or are intolerant to other systemic therapies or phototherapies. **Psoriatic arthritis:** Alone or in combination with methotrexate for treatment of active psoriatic arthritis in adult patients when response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **Crohn's Disease:** Treatment of adult patients with moderately to severely active Crohn's disease who had inadequate response with/lost response to/were intolerant to either conventional therapy or TNF α antagonist or have contraindications to such therapies. **DOSAGE & ADMINISTRATION: Adults:** Under guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis/psoriatic arthritis/Crohn's disease. **Psoriasis or psoriatic arthritis:** Subcutaneous (s.c.) injection. Avoid areas with psoriasis. Self-injecting patients or caregivers ensure appropriate training. Physicians are required to follow-up and monitor patients. **Plaque psoriasis, adults & elderly:** Patients <100kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients >100 kg, 90 mg at week 0 followed by a 90 mg dose at week 4, then every 12 weeks (45 mg was less effective in these patients). **Plaque psoriasis paediatrics (12 years and older):** Patients <60 kg, 0.75 mg/kg at week 0, followed by 0.75 mg/kg at week 4 then every 12 weeks thereafter. Patients \geq 60 - <100kg, 45 mg at week 0 followed by 45 mg at week 4, then every 12 weeks. Patients >100 kg, 90mg at week 0, followed by 90mg at week 4, then every 12 weeks. **Psoriatic arthritis, adults & elderly:** 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Alternatively, 90 mg may be used in patients with a body weight >100 kg. Consider discontinuation if no response after 28 weeks. **Crohn's Disease:** Initial single intravenous infusion dose based on body weight (260 mg or 390 mg or 520 mg) diluted in 0.9% w/v sodium chloride solution and given over at least one hour. At week 8 after intravenous dose, 90 mg s.c. dose is given; followed by every 12 weeks (or 8 weeks based on clinical judgement). Consider discontinuation if no response at 16 weeks. Immunomodulators and/or corticosteroids may be continued but consider reducing/discontinuing corticosteroids if responding to STELARA. If therapy interrupted, resume s.c. every 8 weeks if safe/effective. **Children: <12 years** - Not recommended for psoriasis. **<18 years** - Not recommended for psoriatic arthritis and Crohn's disease. **Renal & Hepatic impairment:** Not studied. **CONTRAINDICATIONS:** Hypersensitivity to product; clinically important, active infection. **SPECIAL WARNINGS & PRECAUTIONS:** Infections: Potential to increase risk of infections and reactivate latent infections. Caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis prior to initiation of STELARA. Consider anti-tuberculosis therapy prior to initiation of STELARA in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, closely monitor and STELARA should not be administered until infection resolves. **Malignancies:** Potential to increase risk of malignancy. No studies in patients with history of malignancy or in patients who develop malignancy while receiving STELARA. Monitor all patients, in particular those older than 60, patients with a medical history of prolonged immunosuppressant therapy or those with a

history of PUVA treatment for non-melanoma skin cancer. **Concomitant immunosuppressive therapy:** Caution, including when changing immunosuppressive biologic agents. **Hypersensitivity reactions:** Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur appropriate therapy should be instituted and STELARA discontinued. **Latex sensitivity:** Needle cover contains natural rubber (latex), may cause allergic reactions. **Immunotherapy:** Not known whether STELARA affects allergy immunotherapy. **Serious skin conditions:** Exfoliative dermatitis reported following treatment. Discontinue STELARA if drug reaction is suspected. **SIDE EFFECTS: Common:** upper respiratory tract infection, nasopharyngitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, vomiting, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain. **Other side effects:** cellulitis, serious hypersensitivity reactions (including anaphylaxis, angioedema), skin exfoliation, exfoliative dermatitis. Studies show adverse events reported in \geq 12 year olds with plaque psoriasis were similar to those seen in previous studies in adults with plaque psoriasis. **Refer to SmPC for other side effects.** **FERTILITY:** The effect of ustekinumab has not been evaluated. **PREGNANCY:** Should be avoided. **Women of childbearing potential:** Use effective contraception during treatment and for at least 15 weeks post-treatment. **LACTATION:** Limited data in humans. **INTERACTIONS:** In vitro, STELARA had no effect on CYP450 activities. **Vaccinations:** Live vaccines should not be given concurrently with STELARA, and should be withheld for at least 15 weeks after last dose of STELARA. STELARA can resume at least 2 weeks after such vaccinations. No data on secondary transmission of infection by live vaccines in patients receiving STELARA. **Concomitant immunosuppressive therapy: Psoriasis:** Safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. **Psoriatic arthritis:** concomitant MTX did not appear to affect STELARA. **Crohn's disease:** concomitant immunosuppressive or corticosteroid therapy did not appear to affect STELARA. **Refer to SmPC for full details of interactions.** **LEGAL CATEGORY:** Prescription Only Medicine. **PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S):** 45 mg, 1 x vial, EU/1/08/494/001. 45 mg, 1 x 0.5 ml pre-filled syringe, EU/1/08/494/003. 90 mg, 1 x 1.0 ml, pre-filled syringe, EU/1/08/494/004. 130 mg, 1 x vial, EU/1/08/494/005. **MARKETING AUTHORISATION HOLDER:** JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. **FURTHER INFORMATION IS AVAILABLE FROM:** Janssen-Cilag Limited, 50 - 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK. **Prescribing information last revised:** 11/2016

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via: HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie. Adverse events should also be reported to Janssen-Cilag Limited on +44 1494 567447 or dsafety@its.jnj.com.

1. Kavanaugh A et al. *Arthritis Care Res (Hoboken)* 2015;doi: 10.1002/acr.22645. 2. Kimball AB et al. *J Eur Acad Dermatol Venereol.* 2013;27:1535-1545. 3. Rich P et al. *Br J Dermatol.* 2014; 170:398-407. 4. McInnes I et al. *Lancet.* 2013;382:9894-780-789. 5. Ritchin C et al. *Ann Rheum Dis.* 2014;73:990-999. 6. Stelara Summary of Product Characteristics, available at www.medicines.ie

PHIR/STE/0317/0001 | Date of Preparation: March 2017



(17A171) ABSTRACT 1 ORAL PRESENTATION (CLINICAL)

Musculoskeletal manifestation of Diabetes Mellitus is highly prevalent and is associated with poor diabetic control

Author(s) Kamil Khan, Kabir Ali, Muhammad Haroon
Department(s)/Institutions Division of Rheumatology, Department of Medicine, University Hospital Kerry, Tralee
Introduction Rheumatic manifestations of diabetes mellitus (DM), are frequently associated with functional disabilities.
Aims/Background The aim of our study was to review the different musculoskeletal manifestations in diabetic patients and the associated factors of these rheumatic manifestations.
Method The study participants were all consecutive pts attending endocrinology clinics of University Hospital Kerry for the management of their DM. Patients with chronic inflammatory arthritis or chronic autoimmune diseases were excluded. Only the joint pains lasting more than 3 months were studied, and were labelled as DM-related musculoskeletal (DM-MSK) symptoms and included (Stiff hands, Bilateral Frozen Shoulders, Carpel Tunnel Syndrome, Charcot joint). Number of clinical variables and end organ complications of DM were included. Moreover, personal history of cardiovascular risk factors and diseases were also recorded.
Results A total of 278 patients were studied and 250 patients [mean age 66±16 years; 58% male; mean duration of DM 13±10 years; mean BMI of 27.5±6] fulfilling the inclusion criteria were evaluated. DM-MSK symptoms were present in 37.6% (n=94) of the cohort. On Univariate analysis, patients with older age, type-2 DM, using hypoglycaemic agents, hypertension, ischemic heart disease, peripheral vascular disease, cerebrovascular accident, congestive heart disease, and patients with renal involvement had significantly higher prevalence of joint pains lasting >3 months. On multivariate analysis, poor diabetic control, diabetic kidney disease and increasing age were independently associated with DM-MSK symptoms.
Conclusions DM-MSK symptoms are very common and are associated with poor diabetic control and its renal complications.

(17A112) ABSTRACT 2 ORAL PRESENTATION (CLINICAL)

Obesity predicts worse disease outcomes in axial spondyloarthritis patients

Author(s) Fitzgerald G¹, Gallagher P², O Sullivan C³, O Rourke K⁴, Sheehy C⁵, Stafford F⁶, Silke C⁷, Haroon M⁸, Mullan R⁹, Fraser A¹⁰, Murphy G¹¹, Chavrimootoo S¹², FitzGerald O², O Shea F¹
Department(s)/Institutions 1. St James's Hospital 2. St Vincent's Hospital 3. University Hospital Galway 4. Midlands Regional Hospital Tullamore 5. University Hospital Waterford 6. Blackrock Clinic 7. Sligo General Hospital 8. Kerry General Hospital 9. Tallaght Hospital 10. University Hospital Limerick 11. Cork University Hospital 12. Our Lady's Hospital, Navan.
Introduction Obesity is a worldwide public health concern, due to its association with morbidity and mortality. Existing literature looking at obesity in axial spondyloarthritis (axSpA) is sparse, but indicates increased BMI is prevalent. The impact of obesity on disease outcome is less well known.
Aims/Background We aimed to determine the prevalence of obesity in a large axSpA cohort and describe its association with disease outcomes.
Method Ankylosing Spondylitis Registry of Ireland (ASRI) provided the cohort for this study. A standardised clinical assessment is performed on each patient. Structured interviews provide patient-

reported data. Weight is recorded in kilograms (kg) and height in centimetres (cm). BMI is categorised per the World Health Organisation criteria: normal weight <25 kg/m², overweight 25-29.9 kg/m² and obese ≥ 30 kg/m². Disease activity is assessed by Bath AS Disease Activity Index (BASDAI), spinal mobility by Bath AS Metrology Index (BASMI), function by the Bath AS Functional Index (BASFI) and Health Assessment Questionnaire (HAQ) and quality of life by AS Quality of Life (ASQoL). SPSS is used for statistical analysis.

Results As of June 2017, 683 patients have been enrolled: 77% (n=526) male, mean age 45.9 ± 12.4 years, mean disease duration 19±12.2 years, mean delay to diagnosis 8.6±8.1 years, 78.8% fulfil modified New York criteria. Mean BASDAI is 3.9±2.5, BASMI is 3.6 ± 2.5, BASFI is 3.6± 2.7 and HAQ is 0.52 ±0.52. Mean BMI in the cohort is 27.8±5.3 kg/m²: 1.1% (n=7) underweight, 31.6% (n=205) normal BMI, 38.9% (n=252) overweight, 28.4% (n=184) obese. Overall, 67.3% are overweight or obese: these patients are significantly older, have longer disease duration and more comorbidity than normal weight patients (table 1). Obese patients have significantly higher disease activity and worse physical function, spinal mobility and quality of life than both normal weight and overweight patients. The prevalence of smoking is lower in obese patients than normal weight patients. In univariable linear regression, BMI and obesity are associated with higher BASDAI, ASQoL, BASMI, BASFI and HAQ scores (table 2). In multivariable regression analysis, obesity remains an independent predictor of higher disease activity and worse function.
Conclusions Over two thirds of this axSpA cohort is overweight or obese. Higher BMI and obesity independently predicts worse disease outcomes. Strategies should be put in place to actively reduce axSpA patient's BMI.

Table 1: Patient characteristics stratified according to BMI categories. Values are mean (±SD) or n (%).

Characteristic	Normal weight n=212	Overweight n=252	Obese n=184
Age, years	41.6 (±12.3)	47.4 (±11.8)*	48.7 (±11.8)*
Male	156 (73.6%)	202 (80.2%)	143 (77.3%)
Disease duration, years	16.5 (±11.2)	20.1 (±11.9)*	20.6 (±12.9)*
BMI, kg/m ²	22.6 (±1.7)	27.3 (±1.4)	34.4 (±4.5)
ASQoL (0-18)	6 (±5.5)	6 (±5.5)	8 (±5.4)* †
HAQ (0-3)	0.47 (±0.5)	0.57 (±0.5)	0.68 (±0.57)* †
BASDAI (0-10)	3.7 (±2.5)	3.8 (±2.4)	4.5 (±2.3)* †
BASH (0-10)	2.9 (±2.5)	3.6 (±2.6)*	4.6 (±2.6)* †
BASMI (0-10)	3 (±2.3)	3.5 (±2.5)	4.6 (±2.5)* †
Iritis	76 (35.8%)	88 (34.9%)	67 (36.4%)
Psoriasis	33 (15.6%)	49 (19.4%)	39 (21.2%)
Inflammatory bowel disease	17 (8%)	30 (11.9%)	14 (7.6%)
Hypertension	19 (9%)	53 (21%)* †	71 (38.6%)* †
Hyperlipidaemia	15 (7.1%)	40 (15.9%)* †	56 (30.4%)* †
Diabetes	3 (1.4%)	11 (4.4%)	15 (8.2%)*
Current smoker	81 (38.2%)	78 (31%)	33 (17.9%)* †
Current alcohol intake	160 (75.5%)	189 (75%)	116 (63%)* †
Biologic use	155 (73.1%)	182 (72.2%)	129 (70.1%)
NSAID use	113 (53.3%)	109 (43.3%)	106 (57.6%) †

*p value <0.05 compared to BMI <25 kg/m²; † p value <0.05 compared to BMI 25-30 kg/m².



Table 2. Linear regression analysis of association between BMI and obesity with clinical outcome.

Dependent variable	Predicting variable	Univariable analysis, B (95% CI)	P	Multivariable analysis, B (95% CI)	P
BASDAI	BMI	0.089 (0.01-0.08)	0.02	0.07 (0-0.07)	0.1
	Obesity	0.13 (0.29-1.1)	<0.01	0.13 (0.25-1.1)	<0.01
ASQoL	BMI	0.14 (0.07-0.23)	<0.01	0.14 (0.06-0.23)	<0.01
	Obesity	0.16 (1.1-2.9)	<0.01	0.17 (1.14-3.08)	<0.01
BASMI	BMI	0.26 (0.09-0.16)	<0.01	0.17 (0.05-0.11)	<0.01
	Obesity	0.22 (0.8-1.63)	<0.01	0.18 (0.62-1.38)	<0.01
BASFI	BMI	0.24 (0.08-.16)	<0.01	0.17 (0.05-0.12)	<0.01
	Obesity	0.21 (0.78-1.66)	<0.01	0.17 (0.58-1.45)	<0.01
HAQ	BMI	0.14 (0.01-0.02)	<0.01	0.1 (0-0.02)	0.02
	Obesity	0.16 (0.1-0.28)	<0.01	-0.15 (0.09-0.27)	<0.01

(17A129) ABSTRACT 3 ORAL PRESENTATION (CLINICAL)

The impact of radiology reporting of vertebral fractures on treatment of fracture risk.

Author(s) Leah Rooney, Donncha O’Gradaigh.

Department(s)/Institutions University Hospital Waterford

Introduction Vertebral fractures, the most common sites of fracture secondary to osteoporosis, are often incidentally identified on radiographs or CT scans. This represents an opportunity to investigate and treat individuals for osteoporosis, reducing the incidence of future fractures.

Radiologists use a variety of terms to describe vertebral fractures, and do not always use the term ‘fracture’. Terminology such as wedge deformity, vertebral loss of height, collapse, compression, concavity, and vertebra plana are commonly used. Our study investigates the variation in terminology used to report a vertebral fracture and its impact on clinicians’ decision to investigate and treat for osteoporosis.

Aims/Background To review the variation in reporting of vertebral fractures in thoracic spine radiographs and study the impact of such variation on the decision to commence treatment for osteoporosis and/or on referral to the Fracture Liaison Service (FLS).

Method We reviewed the reports of all thoracic spine X-rays performed in a tertiary hospital over a 1-year period. We identified those with fractures and the noted the wording used, such as: fracture, wedge, loss of height, collapse or concavity. We determined if each fracture case over age 50 had been referred to the FLS and, via electronic records, if treatment for osteoporosis had been started / continued or not. Of those with vertebral fractures not referred to the FLS, hospital records were reviewed and GPs contracted to determine if treatment for osteoporosis had been commenced.

Results Over 1-year, 586 thoracic spine radiographs were performed of which 234 had positive findings consistent with vertebral fractures. Of the 234, 74% used the term ‘fracture’ in the report and the other 26% described the vertebral fracture using different terminology, excluding the word fracture (19% wedge deformities; 2% vertebral loss of height and 5% other, such as: compression, collapse, concavity and vertebra plana).

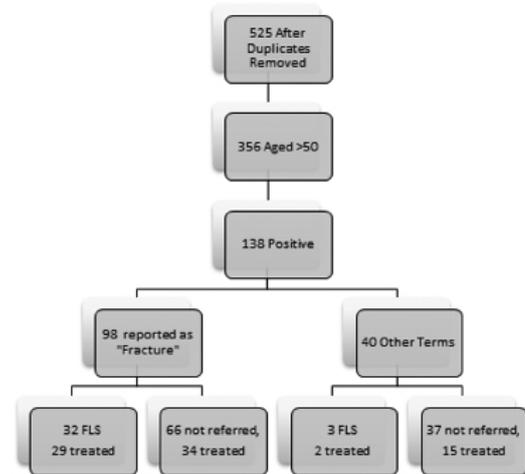
There were 138 fracture cases over the age of 50, of whom only 35 (25%) were referred to the FLS.

Within the over-50 cohort, patients whose thoracic spine X-ray reports used the word ‘fracture’ are more likely to be treated for osteoporosis than patients whose reports used other terminology, 64% vs 42%.

In addition to the impact of report terminology, treatment rates among the individuals reviewed in the FLS were higher than among those treated as inpatients or by GPs, 90% vs 48%.

Conclusions In this study, two important observations were made. A significant proportion of radiology reports, while recognising vertebral fractures, do not refer to them as such. Secondly, fewer cases are referred for further assessment by a FLS when the term fracture is not used. In both instances, fewer patients are recommended treatment demonstrating that the terminology used to describe vertebral fractures impacts the clinician’s decision to treat for osteoporosis.

Image 1



(17A109) ABSTRACT 4 ORAL PRESENTATION (CLINICAL)

Formal Rheumatology teaching for General practitioners in training

Author(s) Shama Khan, Aine Gorman, Angela Camon,,Killian O’Rourke, Ausaf Mohammad

Department(s)/Institutions Rheumatology Department, Midlands Regional Hospital, Tullamore

Introduction Formal post graduate training in rheumatology is limited for primary care physicians or general practitioners . General practitioners (GPs) have extraordinary wide knowledge base ,and deal with all age groups, from minor ailments to serious illnesses , thus it’s not possible to expect them to have a strong hold of specialised conditions like inflammatory arthritis(IA). General practitioners can be trained to manage these conditions in order to break the disconnect between the flow of knowledge and the burden of care in rheumatic conditions.

Aims/Background The Rheumatology department in Midlands Regional Hospital and University Hospital Waterford facilitates GPs teaching in rheumatology outpatients clinics. Every year six GP trainees are trained by consultant rheumatologist. Each trainee receives one on one education in managing rheumatologic conditions including joints and soft tissue injections. This survey was done to evaluate whether GP trainees benefited from it in diagnosing and treating rheumatologic diseases when compared to non rheumatology trainees.

Method This is a cross sectional study of a convenience cohort. GP trainees who received rheumatology training as part of their hospital



rotation were included as “cases”, and compared to those who didn’t have any formal rheumatology exposure during their training as a “control”. The cases attended supervised rheumatology outpatients for one year, and a questionnaire was emailed as well as distributed to the GP trainees, it included questions on trainees’ ability and comfort level in diagnosing, assessing and managing inflammatory and non-inflammatory conditions, along with joint and soft tissue injections.

Results There were 60 participants in the study, 30 cases and controls each. Majority (94%) didn’t have formal rheumatology teaching in the medical school, but had rheumatology experience post graduation, 30 being GP trainee in rheumatology and 7 as senior house officers attached to rheumatology team. The GP trainees had an average of 7 months exposure to rheumatology. The GP trainees who attended the rheumatology clinics were confident in: examining joints, differentiating musculoskeletal/mechanical from inflammatory conditions, educating patients and commencing them on DMARDs, interpreting serological tests (RF, CCP, ANA etc), managing osteoarthritis, tennis elbow, and soft tissue and intra-articular Knee and shoulder injections, as compared to the trainees who didn’t have any formal rheumatology training (P <0.001).

Conclusions Rheumatology teaching for the GP trainees is certainly beneficial, and helps them in managing rheumatologic conditions in primary care settings.

(17A138) ABSTRACT 5 ORAL PRESENTATION (CLINICAL)

Indications for Lowering LDL Cholesterol in Rheumatoid Arthritis: An Unrecognized Problem

Author(s) Maria Usman Khan^{1,3,4}, Usman Azhar Khan^{2,3}, Alwin Sebastian¹, Fahd Adeeb^{1,3}, Eoghan Maher³, Hafiz Hamid Bajwa⁴, Muddassar Ahmad⁴, Mary Brady¹, Siobhan Morrisey¹, John Paul Doran¹, Joseph Devlin¹, Alexander Fraser^{1,3} preprocessed

Department(s)/Institutions 1. Department of Rheumatology, University Hospital Limerick, Limerick, Ireland. 2. Department of Cardiology, University Hospital Limerick, Limerick, Ireland. 3. Graduate Entry Medical School, University of Limerick, Limerick, Ireland. 4. Department of Rheumatology, Beaumont Hospital, Dublin, Ireland

Introduction Rheumatoid arthritis (RA) is a recognized independent risk factor of accelerated atherosclerosis. The 2016 Joint European Society of Cardiology (ESC) guidelines on cardiovascular disease (CVD) prevention in clinical practice recommended a systematic CVD assessment as a screening tool in individuals at increased cardiovascular risk including targeted high-risk subpopulation such as RA, using the Systematic Coronary Risk Evaluation (SCORE) tool that gives an estimate of the 10-year risk of a first fatal atherosclerotic event.

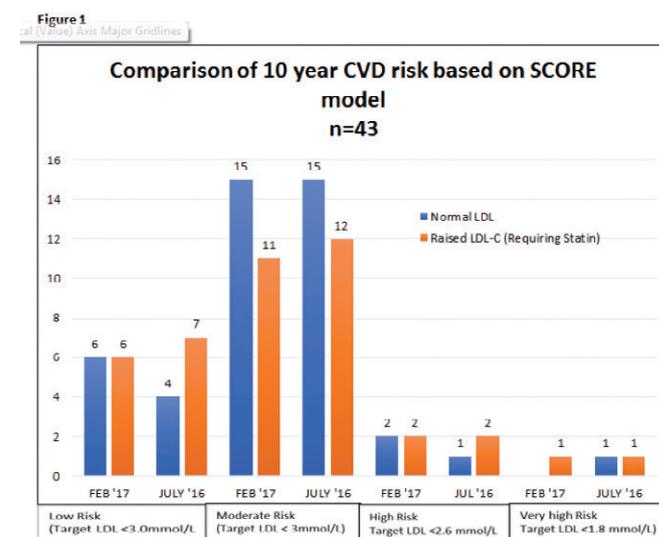
Aims/Background The aim of the study is twofold: To determine the efficiency of screening for hyperlipidemia in our RA cohort and secondly, to evaluate the initiation and optimization of lipid lowering therapy among the indicated RA patients after devising departmental guidelines and continuous education based on the initial results of first audit in June 2016.

Method This multicenter re-audit involved 2 teaching hospitals (Croom hospital & University Hospital Limerick). 100 consecutive patients with definite RA were recruited in January-February 2017. A proforma was completed for each patient based on medical notes and electronic record. In those patients where data on age, gender, smoking, blood pressure and lipid profile were complete, the 10-year risk of fatal CVD was calculated by using the SCORE chart. The patients were stratified into 4 risk categories, and together with measurement of target LDL-cholesterol (LDL-c) levels,

recommendations for lipid lowering measures were adapted: Ideal LDL-c for low (SCORE <1%) and moderate risk patients (SCORE ≥1- <5%) should be <3.0 mmol/L, <2.6mmol/L for high risk (SCORE ≥5- <10%) and <1.8mmol/L for very high risk patients (SCORE ≥10%). Statins were the recommended treatment.

Results Among the 100 patients, full lipid profile was performed in 80% patients within the last 4-years as compared to 87% patients in first audit. In both studies 43% patients had adequate data to calculate the 10-year risk of fatal CVD. Figure-1 illustrates 10-year CVD risk based on SCORE model stratifying patients in 4 risk categories on the basis of target LDL-c and also compares patients in these categories in both audits. We found that overall there was 5% improvement in lipidaemic control indicating optimized statin dose and 14% patients achieved their target LDL-c while on treatment. Overall 41% patients (18/43) had an indication for de novo statin therapy in both audits as they were not on treatment despite fulfilling the above-mentioned criteria.

Conclusions Despite sufficiently having adequate indication to be on lipid lowering therapy, majority of the patients remained untreated. To address this issue, we recommend further education both at departmental and community level and annual screening using the latest Joint ESC guidelines of the 10-year risk of fatal CVD in combination with target LDL-c measurement, with re-audit to see if this is achieved.



(17A174) ABSTRACT 6 ORAL PRESENTATION (BASIC SCIENCE)

Joint Specific Transcriptional Programmes Regulate Inflammation in CD141+DC in Inflammatory Arthritis.

Author(s) Canavan M¹, Walsh, AM², McGarry T¹, Wade SM¹, Moran B³, Biniecka M⁴, Convery H⁴, Wade S¹, Orr C⁴, Mullan R⁵, Fletcher JM⁶, Nagpal S², Veale DJ⁴, Fearon U¹

Department(s)/Institutions 1 Molecular Rheumatology, School of Medicine, Trinity College Dublin, Ireland. 2 Immunology, Janssen Research & Development, 1400 McKean Road, Spring House, PA 19477, USA 3 School of Biochemistry and Immunology, Trinity College Dublin, Ireland. 4 Centre for Arthritis & Rheumatic Diseases, Dublin Academic Medical Centre, University College Dublin, Ireland. 5 Department of Rheumatology, Adelaide and Meath Hospital, Dublin, Ireland. 6 Schools of Biochemistry and Immunology and Medicine, Trinity College Dublin, Ireland.

Introduction CD141+Dendritic Cells (DC) are implicated in anti-viral & anti-tumour immunity. However, due to their rarity in human



blood and tissues, limited data exists on their role in autoimmune disease or rheumatic diseases.

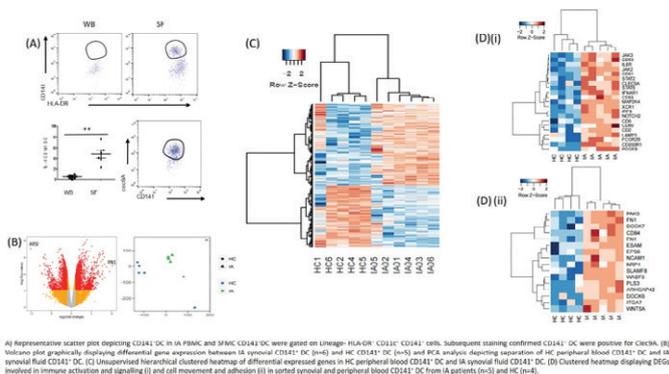
Aims/Background Our aims were to identify CD141+DC within the inflamed synovium of Inflammatory Arthritis (IA) patients, determine if synovial CD141+DC are distinct from peripheral blood (PB) CD141+DC and subsequently if this diversity translates into a joint specific phenotype.

Method Synovial fluid/Peripheral mononuclear cells (SFMC/PBMC) were isolated from IA patients and CD141+DC were magnetically purified. Sorted cells were stimulated & stained with a panel of fluorochrome conjugated antibodies for multicolour flow cytometry. RNA sequencing was performed on CD141+DC from SFMC & PBMC and differentially expressed genes (DEG), Principal Component Analysis (PCA), Enriched pathway analysis, heatmaps and hierarchical clustering were identified using the DeSeq2 R package and Ingenuity® Pathway Analysis (IPA). For functional experiments, SF CD141+DC were cocultured with allogeneic CD3+T cells and intracellular cytokine quantified. Finally the effect of SF CD141+ DC-T cell cocultures on synovial fibroblast function was assessed.

Results CD141+DC are significantly enriched in IA (SF) compared to blood and express XCR1, Clec9A and are negative for CD1c. RNASeq revealed 1417 upregulated genes in IA SF CD141+DC compared to PB CD141+DC & 1088 downregulated genes (FDR < 0.05; magnitude of fold-change > 2). Using hierarchical clustering and PCA analysis, SF CD141+DC clustered separately from PB CD141+DC, indicating the presence of distinct transcriptional variation between SF & PB CD141+DC. Specifically, we identified differential expression of genes involved in cell signalling (JAK2, JAK3, STAT2, STAT6), immune activation (CD53, CLEC9A, CD80) and cell adhesion (PLS3, ROBO, CD84) indicating the presence of unique gene signatures in synovial CD141+DC. To explore the functional consequence of this, DC-T cell coculture experiments were performed. SF CD141+DC induced proliferation of allogeneic CD4+ and CD8+T cells, with increased expression of IFN γ , TNF α , GM-CSF, IL-17A & Granzyme B. Furthermore SF CD141+DC-T cell interactions had the ability to further activate synovial fibroblasts, inducing IL-8, ICAM-1 and invasive mechanisms. Finally IPA identified joint-specific gene encoding pathways, including CD40, MAPK, and Jak-STAT, distinct to the synovial CD141+DC phenotype.

Conclusions Synovial CD141+DC display unique mechanistic and transcriptomic signatures, contribute to synovial inflammation and are distinguishable from blood CD141+DC.

Image 1



(17A187) ABSTRACT 7

ORAL PRESENTATION (BASIC SCIENCE)

Distinct macrophage phenotype and bioenergetic profiles in Rheumatoid Arthritis

Author(s) Megan Hanlon¹, Trudy McGarry², Mary Canavan¹, Candice Lowe², Siobhan Wade¹, Douglas J. Veale², Ursula Fearon¹.

Department(s)/Institutions 1Molecular Rheumatology, Trinity Biomedical Sciences Institute, Trinity College Dublin. 2Centre for Arthritis and Rheumatic Diseases, St. Vincent's University Hospital, Dublin.

Introduction Diversity and plasticity of macrophage subsets within the joint has yet to be explored. The concept of macrophage polarization into M1 inflammatory macrophages (or classically activated) and M2 tissue resolving macrophages (or alternatively activated) paralleled by changes in the bioenergetic cell profile has received much attention in recent years.

Aims/Background We therefore aimed to examine the phenotype and metabolic profile of M1 and M2 macrophages in the inflamed RA joint.

Method Blood was obtained from healthy and RA donors, PBMC isolated CD14+ cells sorted and differentiated into macrophages in the presence of M-CSF for 8 days. Macrophages were polarised to either M1 (LPS and IFN γ) or M2 (IL-4). Markers of in vitro polarisation KLF6, PPARG, TGM2 and STAB1 and of metabolism HIF1 α , HK2, LDHA, PFKFB3, G6PD, PDK1 and PDK2 were quantified by Real Time-PCR. Seahorse XFE technology was utilised to measure the two major energy-using pathways, glycolysis (ECAR) and oxidative phosphorylation (OCR). Finally, to phenotype macrophages in the RA joint, synovial tissue was digested to yield a single cell suspension which was subsequently stained with a panel of fluorochrome antibodies (CD68, CD45, CD40, CD253, CD163, CD206), acquired by multicolour flow cytometry and analysed using FlowJo software.

Results M1 macrophages were confirmed by increased expression of KLF6 and PPARG while M2 macrophages expressed high TGM2, PPARG and STAB1. M1 cells had significantly higher expression of pro-glycolytic genes HIF1 α , HK2, LDHA and PFKFB3, all of which were deficient in M2 macrophages (All p<0.05) and significantly higher than their healthy counterpart, suggesting a greater glycolytic profile in RA-derived cells G6PD was significantly decreased in M1 and increased in M2 macrophages, with PDK enzymes 1/2 decreased in M1 (both p<0.05). Seahorse technology demonstrated that M1 macrophages have higher baseline ECAR and lower OCR, whereas M2 macrophages tend to utilise oxidative phosphorylation more readily. This was paralleled by higher pro-inflammatory cytokines levels (IL-6, IL-8, OSM) in M1 vs M2 macrophages. Finally, RA ST analysis determined that approximately 40% of infiltrating CD45+ immune cells are positive for the pan-macrophage marker CD68. Interestingly, the classical paradigm of M1 and M2 macrophages is not found in the RA synovium. Instead, a spectrum of macrophages which express both M1 and M2 markers were identified. Specifically, 35-55% of ST macrophages express M2 markers CD206 and CD163. However these cells also have high expression of M1 markers CD40 and 253, indicating that the unique inflammatory environment of the RA synovium maintains M1 like macrophages with M2 like properties.

Conclusions This study demonstrated distinct metabolic profiles in M1 and M2 RA macrophages, demonstrating their opposing roles in perpetuating and resolving inflammation, respectively. Furthermore, we have identified for the first time, a spectrum of tissue-specific macrophages which have both an M1-like and M2-like phenotype, suggesting that RA joint macrophages remain plastic and function according to their surrounding microenvironment.



(17A182) ABSTRACT 8

ORAL PRESENTATION
(BASIC SCIENCE)

JAK-STAT blockade alters synovial bioenergetics, mitochondrial function and pro-inflammatory mediators in Rheumatoid arthritis.

Author(s) Trudy McGarry¹, Carl Orr¹, Sarah Wade², Monika Biniecka¹, Siobhan Wade², Douglas Veale¹, Ursula Fearon²

Department(s)/Institutions 1Centre for Arthritis and Rheumatic Diseases, St Vincents University Hospital, University College Dublin, Dublin.

2Molecular Rheumatology, Trinity Biomedical Sciences Institute, Trinity College Dublin, Dublin.

Introduction Rheumatoid arthritis (RA) is a chronic joint disease, characterised by synovial inflammation and a shift in the metabolic profile of cells to a more destructive phenotype. The JAK-STAT signalling pathway is implicated in the pathogenesis of RA.

Aims/Background This study examines the effect of JAK inhibitor tofacitinib on synovial cellular bioenergetics, mitochondrial function and subsequent pro-inflammatory mechanisms in RA.

Method Ex-vivo RA synovial explants and primary RA synovial fibroblasts (RASFC) were cultured with tofacitinib (1 μ M)/DMSO control for 24-72hrs. RASFC were also cultured with Oncostatin M (OSM)(10ng/ml) in the presence and absence of tofacitinib (1 μ M) or DMSO control for 24 hrs. Mitochondrial function was assessed for reactive oxygen species (ROS), mitochondrial membrane potential (MMP) and mitochondrial mass (MM) using the specific cell fluorescent probes and differential gene expression by mitochondrial gene arrays or RT-PCR. RASFC mitochondrial mutagenesis was quantified using a mitochondrial random mutation capture assay (RMCA) and Lipid peroxidation (4HNE) by ELISA. Immunofluorescence was performed to demonstrate co-expression of pSTAT3 and mitochondrial markers. RASFC glycolysis and oxidative phosphorylation were assessed by the XF24-Flux-analyser, and key metabolic genes by real-time PCR. Western blotting was used to examine pSTAT3, PIAS3 and SOCS3 and ELISA used to quantify Using RA whole tissue synovial organotypic explant cultures, the effect of tofacitinib (1 μ M) on spontaneous release of pro-inflammatory mediators were quantified by ELISA/MSD multiplex assays and metabolic markers by real-time PCR. Finally, RASFC invasion and matrix degradation were assessed by Transwell invasion and ELISA.

Results Tofacitinib differentially regulated key mitochondrial genes in RA synovial tissue, and pSTAT3 was co-localised with mitochondrial protein COX-IV. In parallel, tofacitinib significantly decreased MMP and MM and the production of ROS in RASFC. Tofacitinib significantly increased baseline oxidative phosphorylation, ATP production, maximal respiratory capacity and the respiratory reserve in RASFC, an effect paralleled by an and inhibition of key glycolytic genes, HK2, LDHA and HIF1 α . OSM induced pSTAT3 and could also significantly decrease the OCR and increase ECAR, an effect which could be reversed in the presence of tofacitinib. In support of this data, tofacitinib inhibited the effect of OSM on IL-6, MCP-1 and RANTES promoting resolution of inflammation. Using RA whole tissue synovial organotypic explants, tofacitinib inhibited key metabolic genes Glut-1, PFK3B, PDK1, HK2, GSK3A, spontaneous secretion of pro-inflammatory mediators IL-6, IL-8, IL-1b, ICAM-1, VEGF, Tie2 and matrix degrading MMP-1 and RASFC invasion.

Conclusions In this study, we describe a potential mechanism of action for tofacitinib, through reversing mitochondrial dysfunction and subsequent switch in cellular bioenergetics, in favour of a less glycolytic microenvironment leading to the reduction of inflammatory mediators. Thus, we have demonstrated that pathological cellular

metabolism may be reversed by therapeutic treatment with tofacitinib.

(17A188) ABSTRACT 9

ORAL PRESENTATION
(BASIC SCIENCE)

Characterisation of PDE4 Inhibition in PsA Synovium

Author(s) Wade SM¹, Canavan M¹, Trenkman M¹, McGarry T¹, Viviana Marzaioli¹, Wade SC¹, Mullan R³, Veale DJ², Fearon U¹.

Department(s)/Institutions 1 Molecular Rheumatology, School of Medicine, Trinity College Dublin, Ireland.

2 St Vincent's University Hospital, Centre for Arthritis and Rheumatic Diseases, Dublin Academic Medical Centre, Dublin 4, Ireland.

3 Rheumatology Department, Tallaght Hospital, Tallaght, Dublin 24, preprosess

Introduction Phosphodiesterase 4 (PDE4) plays an important role inflammatory responses through the regulation of cellular cAMP. Apremilast, a PDE4 inhibitor approved for the treatment of Psoriatic Arthritis (PsA), has demonstrated potent anti-inflammatory activity in the peripheral blood yet has not been examined in the synovial tissue (ST). In this work we demonstrate the expression and anti-inflammatory effects of PDE4 inhibition on whole PsA explant and more specifically on activated polyfunctional T cell subsets enriched in the PsA ST.

Aims/Background To examine the expression, regulation and the disease modifying effects of PDE4 in PsA synovial tissue.

Method Whole synovial tissue explants were cultured in the presence of PDE4 inhibitor, Rolipram (10 μ M) for 24hrs and spontaneous release of IL-6, IL-8, MCP-1, IL-1b and IL-10 production was analysed by ELISA. Western blotting was used to examine protein expression of PDE4B. In addition, an ex vivo explant matrigel model was utilised to assess synovial fibroblast outgrowth over a time course of 8 – 21 days in the presence or absence of Rolipram. T cells liberated from PsA ST and PsA PBMC were cultured in the presence of Rolipram or DMSO for 4hr. To enable cytokine analysis samples were stimulated with PMA (Sigma, 50ng/ml) and Ionomycin (Sigma, 500ng/ml) in the presence of Brefeldin A (Sigma, 5 μ g/ml) for a subsequent 4 hours. Cells stained with a fixable viability dye were subsequently stained for the surface markers, CD45, CD3, CD8 and CD161, and intracellular cytokines TNF α , GM-CSF, IFN- γ and IL-17 α .

Results PDE4 inhibition significantly inhibits explant outgrowths from PsA explant tissue over a timcourse of 8-21 days (p<0.05). In parallel, PDE4 inhibition significantly decreased ex vivo spontaneous release of IL-6, IL-8, MCP-1 and MMP1 (p<0.05), with observed decreases in IL-1 β production but did not reach significance. To elucidate the anti-inflammatory effects of PDE4 inhibition on different cell types within the synovium we assessed it's effect on synovial T cell populations and their pro-inflammatory cytokine profiles. Highly pathogenic T cell subsets Th1, exTh17 and Th17, recently implicated in the pathogenesis of RA and JIA, were found to be enriched in the PsA ST as compared to the peripheral blood. Furthermore, these synovial enriched T cells were more polyfunctional in nature as indicated by their co-expression of TNF/GMCSF, IL-17 and/or IFN γ and were associated with greater disease severity. Ex vivo PDE4 inhibition limits the pro-inflammatory capacity of Th1, exTh17 and Th17 synovial T cell subsets as exhibited by the reduced frequencies of TNF+GMSCF+ polyfunctional populations.

Conclusions In this study, we show ex vivo PDE4 inhibition in PsA synovial tissue significantly decreases pathogenic explant outgrowth, MMP expression and pro-inflammatory cytokine secretion. Furthermore, we describe the enrichment of activated polyfunctional T cells in the PsA ST which were specifically target



by Rolipram. Taken together, our data shows for the first time the anti-inflammatory action of PDE4 inhibition in the PsA synovial tissue.

(17A115) ABSTRACT 10

ORAL PRESENTATION
(BASIC SCIENCE)

The National Centre For Paediatric Rheumatology (NCPR) Experience of the Use of Tocilizumab (Ro-Actemra) in the treatment of Juvenile Idiopathic Arthritis (JIA): A 7-Year Story

Author(s) Madan WA, Foley C, Lang C, Killeen OG, MacDermott E.

Department(s)/Institutions National Centre For Paediatric Rheumatology (NCPR), Our Lady's Children's Hospital (OLCHC), Dublin, Republic of Ireland.

Introduction Tocilizumab (TCZ) is a recombinant-humanised-monoclonal-antibody that acts as interleukin-6-receptor antagonist. Approved for treatment of children over 2 years with Systemic-onset JIA (SJIA) and Poly-articular JIA (PJIA). Since 2010, TCZ has been used in the NCPR for these indications.

Aims/Background The aim is to describe to-date NCPR experience of the use of TCZ, and reports on outcomes, efficacy and tolerability.

Method A retrospective chart review of all children with JIA who received TCZ since its NCPR introduction in 2010. Baseline demographics recorded. Subtype of JIA documented. Prior and adjunctive treatments particularly oral steroids recorded. Completion of Pre-TCZ biologic workup reviewed.

TCZ dose and infusion frequency documented. Active disease was defined by active joint count (AJC), and/or presence of raised Acute Phase Reactants (APR). At TCZ commencement Initial AJC and raised APR documented.

Clinical remission defined by achievement of 0 AJC and Laboratory Remission defined by normalisation of APR. Outcome measures included clinical remission rate, laboratory remission rate, time to clinical remission and successful steroid wean.

Results A total of 32 JIA patients (81% Females) have been treated with TCZ over the past 7 years. The majority (41%) were SoJIA, 34% PJIA (3/11 RF-positive), 12.5% Extended OligoJIA (EoJIA), 6.25% Enthesitis-Related Arthritis (ERA) and 6.25% were Psoriatic JIA (PsJIA). Median age at diagnosis 5.7yr (1.8-12.5yrs), median age at TCZ commencement 10 yrs and Median time to commencing TCZ 4.3 yrs (0.9-10.4yrs).

Prior to TCZ, 97% of children received Methotrexate (MTX) monotherapy. Following MTX, Majority (91%) received at least two Biologics, 6% received four. Overall, Etanercept was most commonly used followed by Adalimumab.

All children had a full biologic prescreening prior to TCZ. All had negative TB screen and 97% were varicella immune. All received TCZ fortnightly at the outset with a dose of 12mg/kg if weight <30kg and 8mg/kg if weight >30kg.

Escalation to weekly infusions was required in 28% (9/32), 56% SoJIA. Adjuvant steroids were required in 56% at commencement of TCZ. Complete steroid wean was achieved in 83%. Average Initial AJC was 9 (3-23joints) and APR were raised in 56%. Clinical Remission achieved in 83% (25/30) and average time to remission was 5 months (0.5-16 mo). APR normalised in 78% after one infusion, 100% after three.

As a long term outcome, TCZ was continued in 78% (25/32), 36% (9/25) achieved and maintained reduced infusion frequency (3-8weekly). TCZ was discontinued in 22% (7/32), 3 of these children had primary loss of response and underwent stem cell transplant (HSCT), the remaining 4 had secondary loss of response

and were switched to another biologic (Rituximab, Ustekinumab, Adalimumab & Golimumab).

The outcome of TCZ is variable in different JIA subtypes with best results observed in PJIA and EoJIA with 100% remission rate and 100% continuation rate.

Conclusions NCPR experience with TCZ has been positive, with high rates of remission (83%) and tolerability, 78% remaining on the drug. TCZ Improved Outcomes and Steroid Sparing in Refractory Cases. Rather than using multiple biologics, this encourages consideration of the drug earlier.

(17A101) ABSTRACT 11

POSTER 1

Monitoring of lipids in patients on tocilizumab

Author(s) Dr Katarzyna Nowak, Dr James Burns, Debbie Collins, Dr Claire Masih, Dr Gary Meenagh, Dr Esme Whitehead

Department(s)/Institutions Department of Rheumatology, Antrim Area Hospital, Northern Ireland

Introduction Tocilizumab is a humanised monoclonal antibody that inhibits cytokine interleukin-6. It is licensed in treatment of rheumatoid arthritis. The British Society for Rheumatology recommends lipid monitoring in patients receiving tocilizumab—fasting lipids should be done at baseline and at 3 months into treatment. Cholesterol lowering treatment should be instituted based on the results.

Aims/Background Tocilizumab can potentially cause significant hypercholesterolaemia. Our aim is to look at lipid monitoring in patients on tocilizumab and the institution of treatment where necessary.

Method We obtained a list of patients who were currently on tocilizumab from rheumatology nurse specialist in Antrim. Thirty-five patients were identified with one excluded from analysis due to missing data. A retrospective data collection from medical charts was performed. Data were analysed using Microsoft Excel.

Results The patient cohort included 24 females and 10 males with an average age of 57 years.

Fasting lipids were checked at baseline in 85% of patients and 59% of those patients had high cholesterol levels. Lipids were then re-checked at 2-3 months into therapy in 91% of patients and 74% had high cholesterol identified.

In summary, a total of 21 patients had high cholesterol levels (either on initial or repeat check or both) and were not on cholesterol-lowering therapy prior to tocilizumab treatment. Only 10 of those patients were commenced on statin.

Poor compliance with guidelines on lipid management was revealed and as a result the biologic review document has been modified in order to highlight the importance of lipid check. (Image 1)

During a re-audit we looked at 6 patients newly commenced on tocilizumab over 5-month period. 100% had baseline lipids checked; however only 50% had them repeated at 2-3 months. 3 patients were identified to have high cholesterol but only 1 had been commenced on statin.

Conclusions The number of patients having their baseline cholesterol checked increased from 85% to 100%. However, still not all patients are having their lipids checked at 2-3 months and even if they are checked not all results are acted upon. Furthermore, in many charts there was still the 'old' biologic pathway used which lacks the reminder to check lipids in patients on tocilizumab. Potential reasons for the lack of improvement include shortage of staff amongst nurse specialist team and inadequate dissemination of results amongst the consultant medical team due to junior staff changeover. Therefore further recommendations are to replace the 'old' biologic pathway with the 'new' version and formally present these results at a fully



Pioneer in Rare Diseases

Sobi is an international specialty healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients.



We also market a portfolio of specialty and rare disease products across Europe, the Middle East, North Africa and Russia for partner companies.



Sobi is a pioneer in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing



We care about patients with rare diseases

www.sobi-uk.co.uk

Swedish Orphan Biovitrum Ltd, Suite 2, Riverside 3, Granta Park, Great Abington, Cambridgeshire, CB21 6AD, UK
NP-2714 Date of preparation: August 2017



with 7 possibly inflammatory diagnoses in progress. Inflammatory diagnoses included seropositive RA (9), seronegative arthritis (7), spondyloarthropathy (5), gout (4), palindromic rheumatism (3), psoriatic arthritis (3) and one each of GPA, Sjogrens syndrome, CPPD and erosive osteoarthritis.

Interventions included 13 DMARD commencements and 18 other prescriptions including prednisolone (6) and NSAIDs (8).

Eight patients received IM steroid and eight had joint injections, of which 2 had 2 joints injected.

Imaging requests included 3 MRIs, 2 CTs and 1 US. Xray requests were not recorded.

Twelve referrals to different specialties were made, excluding MDT referrals.

Conclusions The clinic ran smoothly with all required resources present. Grading of patients for synovitis clinic was excellent with 79% of patients having inflammatory conditions. Of the patients with inflammatory arthritis 59% commenced DMARD at the first attendance. This is lower than recommendations suggest. Reasons for not commencing DMARDs were not formally recorded but included deranged LFTs, requirement to liaise with other specialties and time needed for patient consideration.

The clinic also proved to be an excellent resource for teaching and training with a high concentration of musculoskeletal pathology.

(17A105) ABSTRACT 14

POSTER 4

Analysis of new referrals to the Rheumatology Department Connolly Hospital

Author(s) Ali Al Shamsi, Maurice Barry

Department(s)/Institutions Rheumatology Department, Connolly Hospital

Introduction In order to improve the departmental service, the issue of a reduction in the new referral to the Rheumatology unit is analysed. We assessed 100 new referral to the Rheumatology department at Connolly Hospital during the three months. They were classified into 6 categories: 1. Polyarthropathy, 2. Intra-articular / soft tissue injection, 3. Fibromyalgia, 4. Osteoporosis, 5. Vasculitis & connective tissue disease, 6. Miscellaneous.

Aims/Background Assess frequency of new referrals in various diagnostic categories to Rheumatology department.

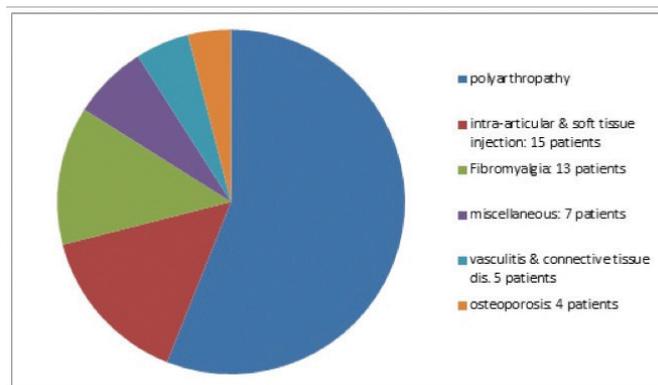
Method 100 consecutive new referrals to the Rheumatology department at Connolly Hospital were collected during the 3 months from September to November 2015. The referrals were classified into one of 6 diagnostic categories. These are: a) Polyarthropathy, b) Intra-articular/ soft tissue steroid injection, c) Fibromyalgia, d) Osteoporosis, e) Vasculitis and connective tissue disease, and f) Miscellaneous

Results There were 56 patients in the polyarthropathy group. Of these 48 had inflammatory arthritis and 8 were degenerative. Patients were referred for intra-articular and soft tissue steroid injection. Thirteen patients had Fibromyalgia. Of these 4 patients were referred by other specialties and the remainder from General Practice. Five patients were diagnosed with Vasculitis & connective tissue disease. Four patients were referred with Osteoporosis, 2 from General Practice and one each from Orthopaedics and Gastroenterology. Finally 7 patients had miscellaneous conditions. This clinical audit showed that 15% of patients are referred from Primary care for intra-articular / soft tissue steroid injection only. This suggests that teaching General Practitioners to perform commonly performed intra-articular / soft tissue steroid injections could significantly reduce referrals. We have begun teaching GP Registrars how to perform joint and soft tissue injections. Thirteen percent were referred with Fibromyalgia which is a physical manifestation of stress. Improved public awareness

about musculo-skeletal pain and stress may reduce referrals. Also improved management pathway e.g. referral straight to physiotherapy or psychologist would also likely reduce referrals. A pilot scheme referring patients with Fibromyalgia directly to a Psychologist based in the Rheumatology Department (and not to the Rheumatologist) has been commenced, in part as a consequence of this audit.

Conclusions Almost 30% of new referrals to Connolly Rheumatology service could be appropriately managed without requiring the opinion or intervention of a Rheumatologist

Image 1



(17A107) ABSTRACT 15

POSTER 5

Development of a Holistic, Multidisciplinary Program for Patients with Fibromyalgia- a report on the pilot phase

Author(s) McCarron, M; Gibson, L; Henry, E; Taggart, P.

Department(s)/Institutions Musgrave Park Hospital, Belfast Health and Social Care Trust

Introduction Fibromyalgia Syndrome (FMS) is a chronic disorder characterised by widespread pain, fatigue and multiple somatic symptoms. It has a major impact on quality of life. It is associated with significant societal cost particularly with regard to healthcare use and reduced economic productivity. Management can be challenging with patients frequently frustrated by lack of a co-ordinated approach. Exercise is known to be effective but patients are notoriously reticent. Psychological therapies are important but access can be limited. Specialist services for fibromyalgia are not available in Northern Ireland. ('A Hidden Condition'- Patient and Client Council report 2016).

Aims/Background We report on a pilot program which was developed and delivered by a rheumatologist, physiotherapist and two occupational therapists, with a nutritionist as guest speaker. The aim was to provide a holistic, multidisciplinary approach with the emphasis on empowering the individual and facilitating self-management.

Method The program consisted of a two hour session per week for six weeks with an additional session with ArtsCare and was delivered September/October 2016. The program included education, introduction to yoga, exercise program, self management skills, relaxation and breathing practices, peer discussion. All sessions were interactive and tailored to the individuals present. Supporting written materials were provided. Homework activities were encouraged.

Results 7 patients enrolled- 6 female, 1 male; mean age 48years. Attendance ranged from 50-83%.

Patients (5/7) completed Fibromyalgia Index Questionnaires at baseline and end of program, all had reduction in scores.

Patient reported outcomes- 100% scored each week's content



10/10; 100% would recommend program to others with FMS; 80% instigated lifestyle change(s).

Conclusions This was a novel intervention for patients in our trust with FMS. Feedback was positive. An example of successful multiprofessional team working and opportunity for interprofessional education.

(17A110) ABSTRACT 16

POSTER 6

Impact of smoking cessation advice on Rheumatoid arthritis

Author(s) Shama Khan, Ahmad Butt, Emmet Brennan, Roisin Mcmanus, Aine Gorman, Angela Camon, Ausaf Mohammad, Killian O'Rourke

Department(s)/Institutions Rheumatology Department, Midlands Regional Hospital, Tullamore.

Introduction Smoking is associated with an increased risk of comorbidities in rheumatoid arthritis (RA) and may reduce the efficacy of anti-rheumatic therapies. Smoking cessation is therefore critically important in RA management and may lead to a reduced comorbid burden

Aims/Background The aim of this pilot study was to investigate whether smoking cessation rates are increased following a smoking cessation advice for people with RA.

Method We conducted a prospective study of 800 RA patients fulfilling the 1987 American College of Rheumatology classification criteria, from October 2016 to March 2017, attending our rheumatology services. Ethics approval was obtained. Information on demographics and cigarette smoking status was collected through patients' interviews and medical notes review. Current smokers were given advice on quitting smoking through face-to-face advice, handout, and nicotine replacement. Subjects were re-interviewed at 6-months to ascertain smoking status. The primary outcome was smoking cessation at 6 months.

Results 180 current smokers among the 800 patients with RA were included: mean age 56± 11.9 years and 76% were females. Overall, 64% of subjects stopped smoking at 6 months, and remainder RA smokers were thinking about quitting. More female subjects quit smoking as compared to males (74% vs. 26%). Those who quit smoking were younger (49 years vs. 57 years), had higher BMI (28.7 ± 3.6 vs. 26.7 ± 3.6), and had aggressive disease, DAS28-CRP (4.9 ± 0.9 vs. 2.9 ± 0.9) (P < .05). Subjects who stopped smoking stated "healthy life style" as motivation to quit.

Conclusions In our study significant proportion of RA patients stopped smoking when given advice on quitting. Smoking cessation advice was very beneficial in motivating them to quit smoking. There should be a structured plan in place to educate RA patients on smoking cessation, both in verbal and written form.

(17A111) ABSTRACT 17

POSTER 7

"Fast-tracking" a diagnosis of GCA

Author(s) J Geraghty, S Maguire, M Medani, D Moneley, P O'Connell

Department(s)/Institutions Department of Rheumatology, Beaumont Hospital

Introduction Giant cell arteritis (GCA) is an immune-mediated vasculitis of large- and medium-sized vessels occurring in older patients (Usually > 60 Years (1). Symptoms include headaches, malaise, jaw pain raised ESR, and if untreated sudden vision loss occurs in up to 20% of patients (2), making early diagnosis with

temporal artery biopsy (TAB) critical (3). Treatment is with high dose corticosteroids which is started immediately diagnosis is suspected. TAB could be a day case surgical procedure but at present the majority of patients are kept as inpatients as the procedure should be done within a week of starting treatment. This results in added strain to an already crowded tertiary care center in addition to exposing patient to hospital borne pathogens.

Aims/Background To document the current route by which patient with a suspected diagnosis of GCA are investigated and determine areas in our current practice that could be changed to improve patient experience, time to diagnosis and decrease the financial burden on the hospital.

Method A chart review was carried out for all patients who underwent a temporal artery biopsy in the past 3 years in Beaumont Hospital. Data collected included: patient demographics, length of inpatient stay awaiting biopsy and biopsy outcome. From this the mean inpatient wait time to TAB was calculated.

Results Of the 29 patients reviewed 26 required an inpatient admission. The average inpatient stay awaiting a biopsy was 5.23 days, with the longest wait of 14 days. Only 3 patients had biopsies done as day case procedures over the 3 years analysed.

Conclusions At present, otherwise well GCA patients are spending on average, 5 unnecessary days in hospital awaiting TAB. A proposed outpatient TAB pathway has significant quality implications for patients by avoiding hospital admissions and improving time to diagnosis, and has financial benefits for the hospital also.

An outpatient pathway proposed by the Rheumatology & Vascular Surgery Department will allow rapid outpatient TAB. Following Rheumatology review, a patient is booked into a reserved weekly day surgery slot. Treatment is started immediately and an ophthalmology review is also arranged if visual symptoms are present. A week post biopsy, the patient is reviewed in the Rheumatology clinic to discuss the results and treatment options going forward. A further audit will be required in time to demonstrate benefits of this new pathway.

References: 1. American College of Rheumatology Guidelines for Giant Cell Arteritis. www.rheumatology.org
2. Mukhtyar C, Guillevin L, Cid MC, et al. . EULAR Recommendations for the management of large vessel vasculitis, Ann Rheum Dis , 2009, vol. 68 (pg. 318-23)
3. Dasgupta B, Borg FA, Hassan N, Alexander L, Barraclough K, Bourke B, Fulcher J, Hollywood J, Hutchings A, James P, Kyle V, Nott J, Power M, Samanta A.; BSR and BHRP guidelines for the management of giant cell arteritis. Rheumatology 2010; 49 (8): 1594-1597.

(17A113) ABSTRACT 18

POSTER 8

High prevalence of sarcopenia in men with axial spondyloarthritis

Author(s) Gillian Fitzgerald, Finbar O' Shea

Department(s)/Institutions Department of Rheumatology, St James's Hospital, Dublin 8.

Introduction Sarcopenia, or age-related loss of muscle mass, is well documented in the general population and is associated with functional limitation and increased mortality. Although sarcopenia is now a recognised feature of rheumatoid arthritis, literature on sarcopenia in axial spondyloarthritis (axSpA) is sparse and so the extent of the problem is virtually unknown.

Aims/Background The aim of this study is to determine the prevalence of sarcopenia in patients with axSpA and determine associations with severity of disease.

Method Forty-three consecutive patients (79.1% male, 97.7% Caucasian) with axSpA were included. Demographic data, spinal



metrology, anthropometric measures, serum markers and patient-reported outcome measures were collected. Body composition analysis was performed using bioelectrical impedance analysis (BIA): fat mass, fat-free mass and predicted skeletal muscle mass were collected. Skeletal muscle mass index (SMI) was calculated by appendicular skeletal muscle mass (sum of predicted muscle mass in all 4 limbs) divided by height squared. Sarcopenia was defined as per the European Working Group on Sarcopenia in Older People definition as SMI \leq 8.87 kg/m² in men and \leq 6.42 kg/m² in women. BMI was categorised as normal if <25 kg/m², overweight if >25 kg/m² and obese if >30 kg/m². SPSS was used for statistical analysis.

Results Baseline characteristics are outlined in table 1, along with significant differences between genders. Mean BMI is 28.8 kg/m² (SD 6.3). A high BMI is present in 72.1% of the cohort: 27.9% have normal weight, 37.2% are overweight and 34.9% are obese. Sarcopenia is present in 41.9% (n=18) of the cohort. It is frequently seen in males (17/34, 50%) but is less common in females (1/9, 11%). The following measurements are lower in axSpA males with sarcopenia compared to those without: BMI (24 v 34.1 kg/m², p<0.01), waist circumference (88.9 v 105.1 cm, p=0.01), hip circumference (95.6 v 109.9 cm, p<0.01), fat percentage (20% v 30%, p<0.01). There is no significant difference in disease activity parameters, although there is a trend towards lower BASMI in patients with sarcopenia (3.7 v 4.8, p=0.09). There is no significant difference in number of co-morbidities between patients with and without sarcopenia.

Of all axSpA men with sarcopenia, 58.8% have a BMI <25 kg/m² (normal weight). The remaining 41.2% are overweight. There are no cases of co-existent sarcopenia and obesity in this cohort. All men with normal weight were sarcopenic.

Conclusions Almost 42% of this axSpA cohort has sarcopenia. Of the sarcopenic patients, almost half are overweight, which is at odds with our usual perception of sarcopenia. Physicians need to consider sarcopenia in axSpA, even in patients with high BMI.

Table 1: Baseline and anthropometric characteristics of cohort, along with significant differences between genders.

	Total (n=43)	Male (n=34)	Female (n=9)	p
Age, years (mean \pm SD)	50.8 \pm 11.1	51.1 \pm 10.5	50.4 \pm 13.7	0.9
Disease duration, years (mean \pm SD)	24.5 \pm 11.7	24.5 \pm 11.6	22.2 \pm 12.7	0.6
Delay to diagnosis, years (mean \pm SD)	8 \pm 7.3	7.8 \pm 7.3	9.7 \pm 7.7	0.6
BASDAI (mean \pm SD)	4.2 \pm 2.1	4.1 \pm 2.2	5 \pm 1.6	0.2
BASMI (mean \pm SD)	4.2 \pm 1.9	4.3 \pm 1.9	4.3 \pm 1.9	0.9
BASFI (mean \pm SD)	4.1 \pm 2.6	4.1 \pm 2.6	4 \pm 2.8	0.9
ASQoL (mean \pm SD)	7.1 \pm 5	6.7 \pm 4.9	8.8 \pm 5.1	0.3
BMI, kg/m ² (mean \pm SD)	28.8 \pm 6.3	29 \pm 6.9	27.8 \pm 3.4	0.6
Fat percentage, % (mean \pm SD)	27.6 \pm 8.9	25 \pm 7.8	37.5 \pm 4.9	<0.01
Waist circumference, cm (mean \pm SD)	95.1 \pm 0.17	97 \pm 18	87.9 \pm 12.6	0.2
Hip circumference, cm (mean \pm SD)	103.7 \pm 11.4	102.8 \pm 12.5	104.9 \pm 6	0.6
Waist:hip ratio (mean \pm SD)	0.93 \pm 0.18	0.95 \pm 0.18	0.84 \pm 0.1	0.07
Smooth muscle index (SMI), kg/m ² (mean \pm SD)	8.7 \pm 1.7	9.18 \pm 1.6	6.98 \pm 0.55	<0.01

(17A114) ABSTRACT 19

POSTER 9

The Rheumatoid Arthritis Susceptibility Gene C5orf30 is an Immunomodulator in Macrophages

Author(s) Emma R Dorris¹, Karen Creevey¹, John Moylett¹, Simon Tazzyman², Munitta Muthana² and Anthony G Wilson¹

Department(s)/Institutions 1EULAR Centre of Excellence/UCD Centre for Arthritis Research, Conway Institute of Biomolecular & Biomedical Research, University College Dublin. 2University of Sheffield, Sheffield, United Kingdom

Introduction Macrophages are central in the pathogenesis of rheumatoid arthritis (RA). An early hallmark of active rheumatic disease is an increased number of sublining macrophages in the synovium. The degree of joint erosion correlates with synovial macrophage infiltration.

Aims/Background rs26232 in the first intron of C5orf30 has been associated with risk of developing RA and severity of tissue damage. C5orf30 is highly expressed by RA synovial fibroblasts (RASf) and macrophages. Inhibition of C5orf30 in RASf increases cellular invasion and migration in vitro and inhibition in the collagen-induced arthritis model accentuated joint inflammation and damage. There is no published data on the biological activities of C5orf30 in macrophages.

Method Monocyte cell line (THP1) and primary monocyte-derived macrophages (MDM) were used. C5orf30 mRNA was assessed by qPCR and protein via Western blot. Transcript and protein half-lives were assessed using actinomycin D and cyclohexamide. Polarization to M1 and M2a phenotypes and stimulation with TNF and LPS on C5orf30 expression were compared. C5orf30 levels were manipulated using siRNA and functional effects on macrophage biology was assessed using ELISAs, invasion assays, pathogen phagocytosis assays, reactive oxygen species assays, gene expression and intracellular signalling assays. In vivo, antisense morpholino oligonucleotides were used to knockdown C5orf30 in zebrafish. Confocal imaging was used to assess the number of invading macrophages.

Results C5orf30 has a half-life of 3.13 hours, which does not significantly change with the addition of inflammatory (LPS +IFN γ) or anti-inflammatory (IL-4) stimuli. Protein half-life is 20.13 hours, rising to 22.26 hours when pretreated with LPS+ IFN γ (M1-like) and decreasing to 12.21 hours when pretreated with IL-4 (M2a-like). Polarization to M2a increased C5orf30 protein expression whereas polarization to M1 resulted in phosphorylation of C5orf30 protein and decreased expression of C5orf30 (p=0.01). Treatment with TNF or LPS reduced C5orf30 expression (TNF p=0.001, LPS p=0.02). LPS phosphorylates C5orf30. Pretreatment of cells with the JNK inhibitor SP600125 retarded the phosphorylation of C5orf30 in response to LPS in a dose-dependent manner and prevented downregulation of C5orf30 gene expression. Knockdown of C5orf30 reduced the invasive capacity of macrophages (p=0.003) with an associated decrease in MMP1 (p=0.01), MMP3 (p=0.01) and MMP9 (p=0.03). Decrease in invasion was intensified upon incubation with either TNF (p=0.02) or LPS (p=0.01). C5orf30 knockdown increased phagocytosis when co-stimulated with LPS (p=0.01). C5orf30 knockdown also increased activation of the JNK pathway. In vivo, tail amputations in zebrafish with C5orf30 deficient embryos showed an increased macrophage infiltration at the wound site (p=0.01).

Conclusions C5orf30 knockdown enhanced the proinflammatory macrophage phenotypes of phagocytosis and JNK activation whilst diminishing the tissue-clearing (M2-like) phenotype of macrophage invasion. This data indicates an important role for C5orf30 in the immunomodulatory regulation of macrophages and is consistent with our previous findings in RASf.



(17A117) ABSTRACT 20

POSTER 10

Baricitinib Inhibits Radiographic Progression of Structural Joint Damage at 1 Year in Patients with Rheumatoid Arthritis (RA) and an Inadequate Response to csDMARDs

Author(s) Erica Tierney (non-author presenter)¹, Désirée van der Heijde², Maxime Dougados³, Ying-Chou Chen⁴, Maria Greenwald⁵, Edit Drescher⁶, Rena Klar⁷, Li Xie⁸, Inmaculada de la Torre⁸, Terence Rooney⁸, Sarah Witt⁸, Douglas Schlichting⁸, Stephanie de Bono⁸, Paul Emery⁹

Department(s)/Institutions 1Eli Lilly and Company Limited, Lilly Ireland, Dublin, Ireland; 2Leiden University Medical Center, Leiden, The Netherlands; 3Department of Rheumatology, Cochin Hospital, Paris, France; 4Chang Gung Memorial Hospital, Kaohsiung, Taiwan; 5Desert Medical Advances, Palm Desert, USA; 6Veszprém Csolnok Ferenc County Hospital, Veszprém, Hungary; 7Quintiles Transnational INC, Durham, USA; 8Eli Lilly & Company, Indianapolis, USA; 9Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK

Introduction Baricitinib (bari), a JAK1/2 inhibitor, was efficacious in a 24-week (wk) Ph 3 study in patients (pts) with active RA and an inadequate response (IR) to conventional synthetic DMARDs (csDMARDs) (RA-BUILD).

Aims/Background To evaluate radiographic progression of structural joint damage in RA-BUILD pts with IR or intolerance to ≥ 1 csDMARD over 48 wks of bari treatment in the long-term extension study, RA-BEYOND.

Method In the 24-wk RA-BUILD study, pts were randomized to placebo (PBO) (N=228), bari 2mg (N=229) or bari 4mg (N=227) once daily (QD), with rescue possible from Wk16. Pts completing RA-BUILD and entering RA-BEYOND continued to receive the bari dose received at the end of RA-BUILD. Pts receiving PBO at the end of RA-BUILD were switched to bari 4mg in RA-BEYOND. Pt and investigator blinding was maintained in RA-BEYOND. Joint damage was measured using the van der Heijde modified total Sharp score (mTSS). To account for missing scores and scores obtained after rescue or discontinuation of study drug, data were analyzed using 1) linear extrapolation (LE), and 2) last observation carried forward (LOCF). The observed/LOCF method used all available observed data, including after rescue or switch, with pts analyzed according to original treatment assignment.

Results Using LE, progression of mTSS, bone erosion, and joint space narrowing (JSN) at 24 and 48 wks was statistically significantly lower for both bari 2 or 4mg compared to PBO ($p \leq 0.05$). Only bari 4mg demonstrated statistically significant inhibition of progressive radiographic joint damage compared to PBO using observed/LOCF at Wk 48 or based on categorical measures ($p \leq 0.05$).

Conclusions Once daily oral bari inhibited radiographic progression of structural joint damage in pts with an IR or intolerance to csDMARDs over 48 wks of treatment. The most robust benefit across measures of radiographic progression was seen for the 4mg dose.

This abstract was previously presented at EULAR 2016 London, UK 8-11 June and published in the Annals of the Rheumatic Diseases, June 2016, Volume 75 (Supplement 2), pages 244-245.

(17A118) ABSTRACT 21

POSTER 11

Safety Profile of Baricitinib in Patients with Active Rheumatoid Arthritis: An Integrated Analysis

Author(s) Erica Tierney (non-author presenter)¹, Josef S. Smolen², Mark C. Genovese³, Tsutomu Takeuchi⁴, David Hyslop⁵, William L.

Macias⁵, Terence P. Rooney⁵, Lei Chen⁵, Christina Dickson⁵, Jennifer Riddle⁵, Tracy E. Cardillo⁵, Kevin Winthrop⁶

Department(s)/Institutions 1Eli Lilly and Company Limited, Lilly Ireland, Dublin, Ireland; 2Medical University of Vienna, Vienna, Austria; 3Stanford University Medical Center, Palo Alto, CA, USA; 4Keio University, Tokyo, Japan; 5Eli Lilly and Company, Indianapolis, IN, USA; 6Oregon Health Sciences University, Portland, OR, USA

Introduction Baricitinib (bari) (an oral janus kinase [JAK]1/JAK2 inhibitor) is in development for patients (pts) with active rheumatoid arthritis (RA).

Aims/Background To assess the safety of bari in pts with active RA across 8 completed studies (4 phase 3, 3 phase 2, 1 phase 1b) and 1 ongoing long-term extension study).

Method Primary safety analysis was based on 6 studies (all with bari 4-mg once daily [QD] and placebo [PBO] arms) and dose response assessments on 4 studies (all with bari 2- and 4-mg QD and PBO arms). In addition, the "all-bari" RA set included all pts exposed to any bari dose. Two studies contained active comparators.

Results In total, 3464 pts were exposed to bari (4214 patient-years [PY]; 2166 pts [62.5%] >1 year; 467 [13.5%] >2 years). In controlled periods of the program, no increases in deaths, adverse events leading to study drug discontinuation, malignancies, major adverse cardiac events, or serious infections were seen for bari versus PBO/active treatment. Herpes zoster was reported more frequently for bari vs PBO. In randomized, controlled periods of the program, tuberculosis (TB) was reported in 2 pts: 1 bari 4 mg, 1 adalimumab; in uncontrolled periods, 6 TB events were reported (bari 4 mg: 2 with incomplete TB screening, 3 without organism confirmed). All TB occurred in endemic areas. Two gastrointestinal perforations were reported (0.05/100 PY). Bari treatment has been associated with changes in selected hematology/clinical chemistry analytes; few pts (<1%) discontinued due to abnormal laboratory results. There was no observed increased risk over time for the above outcome measures with longer exposure.

Conclusions In the context of reported efficacy, bari had an acceptable safety profile in pts with moderately to severely active RA.

This abstract was previously presented at EULAR 2016 London, UK 8-11 June and published in the Annals of the Rheumatic Diseases, June 2016, Volume 75 (Supplement 2), pages 243-244.

(17A119) ABSTRACT 22

POSTER 12

Speed of Onset of Effect on Patient- Reported Outcomes Assessed through Daily Electronic Patient Diaries in the Baricitinib Phase 3 RA Clinical Program

Author(s) Erica Tierney (non-author presenter)¹, Peter C. Taylor², Grace C. Wright³, Carol L. Gaich⁴, Amy M. DeLozier⁴, Stephanie de Bono⁴, Douglas E. Schlichting⁴, Terence P. Rooney⁴, Jiajun Liu⁴, Scott D. Beattie⁴, and Maxime Dougados⁵

Department(s)/Institutions 1Eli Lilly and Company Limited, Lilly Ireland, Dublin, Ireland; 2NDORMs, University of Oxford, Oxford, United Kingdom, 3New York University Langone Medical Center, New York, United States, 4Eli Lilly and Company, Indianapolis, United States, 5Department of Rheumatology, Cochin Hospital, Paris, France

Introduction Baricitinib (bari), an oral Janus kinase (JAK) 1/ JAK2 selective inhibitor, has demonstrated clinical efficacy with a satisfactory safety profile when administered once daily in 4 completed Phase 3 studies in patients with RA.

Aims/Background In 2 studies, RA-BEAM (52-week study in patients with inadequate response [IR] to MTX) and RA-BUILD



(24-week study in patients with IR to conventional synthetic [cs] DMARDs), patients recorded their worst joint pain, duration and severity of morning joint stiffness (MJS), and worst tiredness each day for 12 weeks using electronic diaries. In previous analyses based on weekly averages of daily scores, bari produced significant improvements in patient-reported outcomes (PROs) compared to placebo (pbo) as early as Week 1 and compared to adalimumab (ada) as early as Weeks 2-4. The aim of these analyses was to explore the kinetics of response using daily diary scores without weekly averaging.

Method PRO data were analyzed by study day after randomization (Day 1) - Day 28 for all treated patients. Mixed models for repeated measures analysis were applied (with MJS duration by nonparametric methods).

Results Consistent with the original weekly-averaged data, daily diary scores showed significant improvement in patients receiving bari compared to pbo and ada. Improvements relative to pbo were apparent as early as the 3rd day of treatment for MJS severity, worst tiredness, and worst joint pain, and by Day 5 for MJS duration. Improvements relative to ada were apparent as early as Day 19 for MJS severity, Day 21 for worst tiredness, and Day 17 for worst joint pain. The greatest rapidity and magnitude of benefit was seen with the bari 4-mg daily dose.

Conclusions In this post hoc analysis from Phase 3 studies of patients with RA with inadequate response to MTX or other csDMARDs, treatment with bari produced rapid improvements in PROs compared to pbo and ada, with significant differences appearing within the initial days of treatment.

(17A120) ABSTRACT 23

POSTER 13

Ixekizumab Provides Improvements Through 52 Weeks in Physical Function, Quality of Life, and Work Productivity in Biologic Disease-Modifying Antirheumatic Drug-Naive Patients with Active Psoriatic Arthritis

Author(s) Erica Tierney (non-author presenter)¹, Alice B. Gottlieb², M. Elaine Husni³, Catherine L. Shuler⁴, Russel Burge⁴, Chen-Yen Lin⁴, Chin H. Lee⁴, Dafna D. Gladman⁵

Department(s)/Institutions 1Eli Lilly and Company Limited, Lilly Ireland, Dublin, Ireland; 2Department of Dermatology, New York Medical College, Metropolitan Hospital New York, New York, USA; 3Cleveland Clinic, Cleveland, United States; 4Eli Lilly and Company, Indianapolis, United States; 5University of Toronto, Toronto, Canada

Introduction In the phase 3 trial, SPIRIT P1, previously reported results showed that IXE treatment significantly improved (versus placebo), at Week 24, PRO measures of the Health Assessment Questionnaire-Disability Index (HAQ-DI), Short Form-36 Health Survey Physical Component Summary (SF-36 PCS), European Quality of Life 5 Dimensions Visual Analog Scale (EQ-5D VAS), and Work Productivity and Activity Impairment-Specific Health Problem (WPAI-SHP; presenteeism, work productivity, and activity impairment).

Aims/Background To evaluate whether the monoclonal antibody ixekizumab (IXE), a high-affinity interleukin-17A antagonist, improves patient-reported outcomes (PROs) over 52 weeks in biologic disease-modifying antirheumatic drug (bDMARD)-naive patients with active psoriatic arthritis (PsA) in a phase 3 study (SPIRIT-P1).

Method 417 bDMARD-naive patients with active PsA were randomly assigned 1:1:1:1 to subcutaneous IXE 80mg every 4 weeks (Q4W) or 2 weeks (Q2W), each with a 160mg starting dose; adalimumab 40mg Q2W (active reference); or placebo in the

double-blind treatment period (Weeks 0 to 24). Of these patients, 381 continued into the extension period (EP; Weeks 24 to 52). Placebo- and adalimumab-treated patients were randomly re-assigned (1:1) to 80mg IXEQ4W or IXEQ2W at Week 16 (inadequate responders) or Week 24. Analyses for the EP were conducted on the EP population (patients who received at least 1 dose of study drug during the EP). Missing values were imputed by nonresponder imputation for categorical data and modified baseline observation carried forward for continuous data.

Results Baseline demographics and clinical characteristics were generally similar between treatment groups; population mean baseline (Week 0) scores for HAQ-DI, SF-36 PCS, and EQ-5D VAS indicated impaired physical function and quality of life. Physician-assessed American College of Rheumatology (ACR) 20 response was achieved by 69% of patients treated with IXE for 52 weeks. Patients receiving IXEQ4W or IXEQ2W for 52 weeks reported similar improvements from baseline in HAQ-DI (IXEQ4W: -0.53, IXEQ2W: -0.55), SF-36 PCS (9.5, 9.2) EQ-5D VAS (14.7, 14.4), and WPAI-SHP (presenteeism [-23.6, -25.4], work productivity [-25.3, -24.9], and activity impairment [-26.2, -29.1]) as reported at Week 24. The percentage of patients receiving IXE for 52 weeks with improvement from baseline HAQ-DI score ≥ 0.35 who achieved a minimally clinically important difference for HAQ-DI was sustained at Week 52 (57.1%) compared with Week 24. At Week 52, patients receiving adalimumab/IXE showed similar improvements in ACR20 response and most PRO measures to those observed at Week 24.

Conclusions IXE provided sustained improvement over 52 weeks in physical function, quality of life, and work productivity in bDMARD-naive patients with active PsA.

(17A121) ABSTRACT 24

POSTER 14

Moving towards a National Behçet's disease Registry: Results From a Single Registry in the Midwest of Ireland

Author(s) Fahd Adeb^{1,2}, Alwin Sebastian¹, Maria Usman Khan^{1,2}, Wan Lin Ng¹, Mary Brady¹, Siobhan Morrissey¹, John Paul Doran¹, Austin Stack^{2,3}, Joseph Devlin¹, Alexander D. Fraser^{1,2}

Department(s)/Institutions 1. Department of Rheumatology, University Hospital Limerick, Limerick, Ireland

2. Graduate Entry Medical School, University of Limerick, Limerick, Ireland

3. Department of Nephrology, University Hospital Limerick, Limerick, Ireland

Introduction The epidemiology of Behçet's disease (BD) has been poorly studied in many parts of the world, especially among the non-endemic countries. One of the main challenges faced by the scientific community today relates to the magnitude of racial, regional and geographical phenotypic and genotypic differences among BD patients. An established national registry will enable physicians to improve disease awareness, assist in making informed decisions and enhance patients' overall outcome.

Aims/Background 1) To conduct a pilot project to establish a local BD registry and provide a framework for a national registry 2) to clarify the true prevalence, incidence and treatment strategies among BD patients in Ireland and to compare with other international studies.

Method BD patients attending our rheumatology service were identified and specific clinical data were collected: 1) Basic demographics including ethnicity 2) time and age of diagnosis 3) evolution of clinical characteristics 4) HLA-B*51 status 5) pathergy phenomenon 6) details of treatment strategy, safety and efficacy

Results 24 Caucasian Irish patients (16 female, 8 male) and 1 male patient from the Middle Eastern ancestry were identified satisfying the diagnostic criteria for BD. The most common clinical manifestation



was recurrent oral aphthosis (100%) followed by genital ulcerations (92%) and skin lesions (92%), arthralgia/arthritis (40%), ocular involvement (32%), vascular thrombosis (12%) and pathergy phenomenon (8%). The most frequently encountered skin lesion was pseudofolliculitis and/or papulopustular eruptions (18 patients, 72%) followed by erythema nodosum-like lesions, (2 patients; 8%). The most common ocular manifestation was unilateral uveitis (5 patients; 20%), while two patients had bilateral involvement. Two male patients (8%) lost their vision totally in one eye. Only 1 patient was positive for HLA-B*51. 18 patients (72%) were on anti-TNF (5 of which had potentially life-threatening structural laryngeal destruction). The point prevalence of BD on the 30th of June 2017 was 6.5 per 100,000 population.

Conclusions The prevalence of BD in the Midwest of Ireland is higher than previously reported in the Northern European region. The establishment of this first BD registry in Ireland would hopefully drive further new research and collaborations to improve patients' overall outcome. We advocate for future collaborations among all rheumatology centres throughout Ireland to gain more insights into the epidemiology and determine the extent of geographical influences on this rather complex disease.

(17A122) ABSTRACT 25

POSTER 15

Prevalence of and temporal trends in hyperuricaemia among adult patients with chronic kidney disease in Ireland

Author(s)

Arunkumar A. Udayakumar^{1,2}, Fahd Adeeb^{2,3}, David Ryan², Xia Li², Alexander D. Fraser^{2,3}, Austin G. Stack^{1,2}

Department(s)/Institutions 1. Department of Nephrology, University Hospital Limerick, Limerick, Ireland. 2. Graduate Entry Medical School, University of Limerick, Limerick, Ireland. 3. Department of Rheumatology, University Hospital Limerick, Limerick, Ireland

Introduction An increasing body of evidence links hyperuricaemia with the development of several metabolic disorders and major cardiovascular outcomes. A better understanding of the burden and variation of hyperuricemia within the health system is important in order to identify high-risk groups and facilitate early intervention with effective management strategies.

Aims/Background The aim of this study was to describe the prevalence of hyperuricaemia, and period trends within the Irish Health System among patients with chronic kidney disease (CKD).

Method 136,325 adult CKD patients aged 18 and above with valid measurements of serum uric acid and creatinine levels were identified between 2006 and 2014 from the laboratory systems within the Irish health system. Hyperuricaemia was defined as serum uric acid $\geq 420\mu\text{mol/L}$ in men and $\geq 360\mu\text{mol/L}$ in women. Estimated glomerular filtration rates were determined using the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) equation and patients were classified by CKD stage according to the Kidney Disease Improving Global Outcomes (KDIGO) staging system. Age- and sex-specific prevalence of hyperuricemia estimates with 95% confidence intervals were determined for each group and across calendar years. Comparisons among groups and across years were conducted using chi-square and multivariate logistic regression was used to explore associations using adjusted odds ratios (AOR) and 95% Confidence Intervals (CI).

Results Patients with hyperuricaemia were noted to be older [58.2 (18.5) vs. 51.2 (17.4) years]. The prevalence of hyperuricaemia increased progressively between 2006 and 2014 from 20.3% (19.5,

21.0) to 26.5% (25.8, 27.2%) in men and from 17.9% (17.2, 18.6) to 20.4% (19.8, 21.0) in women, $p < 0.001$. Age-specific prevalence increased significantly over time for all age groups (18–39, 40–59, 60–79, and ≥ 80 years) for men and women, $p < 0.001$. Prevalence was significantly higher with more advanced CKD stage: 15.1% (14.5, 15.6) in Stage 1 CKD compared to 43.0% (34.8, 51.1) in Stage 5 CKD, $p < 0.001$. However, rates fell significantly for those Stage 4 and 5 CKD respectively. In multi-variable models, the adjusted likelihood of hyperuricaemia increased with each successive year.

Conclusions Burden of hyperuricaemia is substantial in the Irish health system and has increased in frequency over the past decade. Burden was highest in young and middle-aged men and older age women. Although the burden was highest among patients with advanced CKD, an encouraging decline was evident in recent years, which may reflect increasing utilization of urate lowering therapies.

(17A123) ABSTRACT 26

POSTER 16

A comparative study of lean muscle mass in patients with newly diagnosed Inflammatory Arthritis and established Inflammatory Arthritis

Author(s) Bernie McGowan^{1,3}, Mary Jane Reodica¹, Sarah McDonald¹, Keunjae Ahn², Noreen Harrington¹, Miriam O Sullivan^{1,2}, Bryan Whelan^{1,2}, Carmel Silke^{1,2}

Department(s)/Institutions 1. The North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim, Ireland
2. Dept of Medicine, National University of Ireland Galway
3. The Department of Pharmacology and Therapeutics, Trinity College Dublin

Introduction Low lean muscle mass has been commonly identified in patients with chronic inflammatory diseases. Studies however, evaluating changes in lean muscle mass at different stages of disease progression are limited.

Aims/Background 1) To identify differences in lean mass in two separate patient groups attending the NWRU, one group newly diagnosed with Inflammatory Arthritis (IA) and a second group of patients with established Inflammatory Arthritis.

Method In total N=196 patients attending the NWRU were included in the study. The mean age of the patients was 59.2 yrs (+14.8), males n=73(37%) and females n=123 (63%). In total 86 (44%) of patients had established Inflammatory Arthritis and 108 (56%) were newly diagnosed patients with Inflammatory Arthritis (rheumatoid arthritis and psoriatic arthritis). Anthropometric measurements were recorded including weight, height and BMI. Body Composition analyses including Appendicular Lean Mass was measured using Dual-Energy-X-ray-Absorptiometry (DXA) scan. We used the Sarcopenia definition in order to quantify low lean muscle mass. Sarcopenia is quantified as appendicular skeletal mass divided by height squared (ASM/H^2) and considered present if the calculated skeletal muscle mass index (SMI) is two standard deviations (SD) below the mean for a population of young adults as based on the Rosetta study. The cut-off points for sarcopenic muscle mass are gender-specific: SMI of $< 7.26 \text{ kg}/\text{m}^2$ for males and $< 5.5 \text{ kg}/\text{m}^2$ for females. All data was recorded and analysed on SPSS version 23.0. Factors associated with low SMI in the two patient groups were assessed using Independent T tests.

Results A total of 56 patients (29%) had low lean muscle mass and 138 (71%) of patients had normal muscle mass. The SMI in females was significantly lower in the established IA group compared to females newly diagnosed with IA ($P = .038$). The mean SMI of male patients was also lower in the established IA group than the newly diagnosed IA group however the difference was not statistically



significant. In the established Inflammatory Arthritis patients (N=86) further analyses did not identify any statistical significant differences in the SMI of patients treated with biologic therapy compared to patients not on biologic therapy.

Conclusions A total of 56 (29%) of patients with inflammatory arthritis attending the NWRU were identified as having low lean muscle mass. SMI of females in the established IA group was significantly lower than the SMI of females in the newly diagnosed IA group. This would suggest that efforts should be made to address loss of lean muscle mass in established IA and it may explain why outcomes are still poor in patients with established IA despite the availability of some excellent treatments.

(17A124) ABSTRACT 27

POSTER 17

Employment, work disability and quality of life associated with Ankylosing Spondylitis. Results from the Ankylosing Spondylitis Registry of Ireland (ASRI)

Author(s) Bernie McGowan^{1,2}, Orla Reynolds¹, Maria Lynch¹, Miriam O Sullivan^{1,3}, Bryan Whelan^{1,3}, Carmel Silke^{1,3}.

Department(s)/Institutions 1. The North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim. 2. The Dept of Pharmacology and Therapeutics, Trinity College Dublin. 3. The Dept of Medicine, NUIG

Introduction The results of international studies have identified that unemployment has a negative impact on physical and mental health. In Ireland it is estimated that approximately 10% (458,825) of the Irish population are unemployed due to work disability. Unemployment rates in people with Ankylosing Spondylitis (AS) can be up to three times higher than in the general population.

Aims/Background To identify the prevalence of work disability (WD) in a cross-sectional study of patients with ankylosing spondylitis (AS) attending the NWRU and the associated clinical characteristics associated with their work disability (WD).

Method In collaboration with the Ankylosing Spondylitis Registry of Ireland (ASRI) data on patients attending the NWRU with a diagnosis of AS was routinely recorded on the ASRI database and included in the study analyses. The main outcome variable (WD) referred to all patients who were unemployed or working part-time directly as a result of their AS. Independent T-tests were carried out to identify differences between the two groups. Functional status and disease activity were measured using the BASDAI, BASFI, ASQoL and HAQ scores. Spinal and hip mobility were assessed using the Tragus to wall, cervical rotation, chest expansion, schobers test and lumbar flexion measures. The relationship between WD and extra-articular manifestations (EAMs) such as enthesitis, uveitis, dactylitis psoriasis, and other co-morbidities were also assessed.

Results In total 128 patients 113 males (88.3%) and 15 females (11.7%), mean age 47.0 (\pm 13.3) were included in the study. The average disease duration since diagnoses was 9.7yrs (\pm 9.4) and a total of 38 patients (29.7%) were either unemployed or working part-time as a direct result of their AS. Several variables had statistically significantly different values in patients with WD compared to those without WD. The result of the independent T-test identified that disease duration ($p=0.041$), Bath AS Functional Index (BASFI; $p=0.010$), tragus to wall ($p=0.016$), cervical rotation ($p=0.03$) and ASQoL ($p=0.010$), retained an independent association with work disability. WD did not correlate significantly with age, gender, marital status or number of co-morbidities.

Conclusions The prevalence of WD in a cohort of Irish patients with AS attending the NWRU was 30% similar to the findings of other studies. The main factors associated with WD in this group were longer disease duration, structural damage and poorer quality of life.

(17A125) ABSTRACT 28

POSTER 18

The Prevalence of Sarcopenia in Patients with newly diagnosed Rheumatoid Arthritis and associated factors

Author(s) Bernie McGowan^{1,2}, Noreen Harrington¹, Mary Jane Reodica¹, Sarah McDonald¹, Keunjae Ahn³, Miriam O Sullivan^{1,3}, Bryan Whelan^{1,3}, Carmel Silke^{1,3}.

Department(s)/Institutions 1. The North Western Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim, 2. The Department of Pharmacology and Therapeutics, Trinity College Dublin 3. The Dept of Medicine, NUIG

Introduction The European Working Group on Sarcopenia in Older People (EWGSOP) defines sarcopenia as a progressive and generalised loss of skeletal muscle mass and strength either age or disease activity related or both. Furthermore, sarcopenia has been commonly identified in patients with chronic inflammatory diseases, such as rheumatoid arthritis (RA).

Aims/Background To identify: 1) the prevalence of sarcopenia in newly diagnosed Rheumatoid Arthritis (RA) patients attending the NWRU 2) factors associated with sarcopenia. 3) changes in body composition 12 months post initiation of therapy in these patients

Method A total of 108 patients (females 57 (53%), males 51 (47%)), newly diagnosed with RA were included in the study. Body Composition including Appendicular Lean Mass and Tissue % Fat were measured using Dual-Energy-X-ray-Absorptiometry (DXA) scan. Disease activity was measured using the CDAI, quality of life using the HAQ scores and muscle strength using the Handgrip Strength. Additional information recorded included numbers of co-morbidities, duration of symptoms and level of exercise. Sarcopenia is quantified as appendicular skeletal mass divided by height squared (ASM/H^2) and considered present if the calculated skeletal muscle mass index (SMI) is two standard deviations (SD) below the mean for a population of young adults as based on the Rosetta study². In total 30 of the patients had a repeat DXA scan carried out approximately 12 months post initial visit. All data was recorded and analysed on SPSS version 23.0. Factors associated and related to sarcopenia were assessed using Independent T tests.

Results The prevalence of sarcopenic muscle mass was 22.2% (25% in men, 19% in females). The prevalence of sarcopenic muscle mass and sarcopenic muscle strength was 12% (11% in females and 14% in males). While not statistically significant patients with sarcopenic muscle mass tended to be older and had reduced dominant hand grip strength. There was no statistically significant association identified in the HAQ or CDAI scores between the groups or in duration of symptoms. There was an overall 3.5% ($+5.87$) increase in the SMI/kg² between the first and second DXA scan with no significant difference between the sarcopenic and non sarcopenic patients ($P=0.498$).

Conclusions The prevalence of sarcopenia in patients newly diagnosed with RA attending the NWRU was 22.2%. Results of previously published studies suggest that sarcopenia is a reversible cause of disability and may benefit from intervention, especially at the early stage.

(17A126) ABSTRACT 29

POSTER 19

Trends in hospitalisations for musculoskeletal diseases in Ireland 2005-2015

Author(s) Bernie McGowan^{1,6}, John J. Carey^{2,5}, Siobhán O Higgins³, Edel Doherty⁴, Carmel Silke^{1,5}, Bryan Whelan^{1,5}, Miriam O Sullivan^{1,3}, Brian McGuire³

Department(s)/Institutions 1. The North Western Rheumatology

TAPENTADOL PALEXIA® SR

...A KEY FOR CHRONIC PAIN



FOR SEVERE CHRONIC PAIN

PALEXIA® SR Tablets are indicated for the relief of **severe chronic pain** in adults, which can be adequately managed only with opioid analgesics.¹



PALEXIA SR® PROLONGED RELEASE TABLETS PRESCRIBING INFORMATION

Refer to the Summary of Product Characteristics (SmPC) before prescribing. **PRESENTATION:** 50 mg (white), 100 mg (pale yellow), 150 mg (pale pink), 200 mg (pale orange) and 250 mg (brownish red) prolonged-release tablets contain 50 mg, 100 mg, 150 mg, 200 mg and 250 mg of tapentadol (as hydrochloride) respectively. **INDICATION:** Palexia SR is indicated for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics. **DOSEAGE AND METHOD OF ADMINISTRATION:** Individualise according to severity of pain, the previous treatment experience and the ability to monitor the patient. Swallowed whole with sufficient liquid, not divided or chewed, with or without food. Initial dose 50 mg twice a day. Switching from other opioids may require higher initial doses. Titrate in increments of 50 mg twice a day every 3 days for adequate pain control. Total daily doses greater than 500 mg not recommended. **Discontinuation of treatment:** Taper dose gradually to prevent withdrawal symptoms. **Renal/hepatic impairment:** Not recommended in patients with severe cases. Caution and dose adjustments with moderate hepatic impairment. **Elderly:** May need dose adjustments. Children below 18 years: Not recommended. **CONTRAINDICATIONS:** Hypersensitivity to ingredients, suspected or having paralytic ileus, acute intoxication with alcohol, hypnotics, centrally acting analgesics or psychotropics. Not for use when mu-opioid receptor agonists are contraindicated (e.g. significant respiratory depression, acute or severe bronchial asthma or hypercapnia). **SPECIAL WARNINGS AND PRECAUTIONS:** At risk patients may require monitoring due to misuse, abuse, addiction or diversion. At high doses or in mu-opioid receptor agonist sensitive patients, dose-related respiratory depression may occur. Caution and monitoring required with impaired respiratory function. Should not use in patients susceptible to intracranial effects of carbon dioxide retention (e.g. increased intracranial pressure, impaired consciousness or coma). Use with caution with head injury, brain tumours, moderate hepatic impairment, biliary tract disease including acute pancreatitis. Not recommended if history of or at risk of seizures or with severe renal or hepatic impairment. Care should be taken when combining with mixed mu-opioid agonists/antagonists (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine). Should not use with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **INTERACTIONS:** Use with benzodiazepines, barbiturates and opioid analgesics, antitussive drugs and substitutive treatments may enhance the risk of respiratory depression. Central nervous system (CNS) depressants (e.g. benzodiazepines, antipsychotics, H1-antihistamines, opioids, alcohol) can enhance the sedative effect and impair vigilance. Consider dose reduction with respiratory or CNS depressant agents. In isolated cases, serotonin syndrome has been reported with Palexia SR in combination with serotonergic medicinal products (e.g. serotonin re-uptake inhibitors). Use with strong inhibitors of uridine diphosphate transferase isoenzymes (involved in glucuronidation) may increase systemic exposure of Palexia SR. Risk of decreased efficacy or adverse events if used with strong enzyme inducing drugs (e.g. rifampicin, phenobarbital, St John's Wort). Avoid use in patients who have taken monoamine oxidase inhibitors (MAOIs) within the last 14 days, due to cardiovascular events. **PREGNANCY AND LACTATION:** Use in pregnancy only if the potential benefit justifies the potential risk to the foetus. Not recommended during and immediately before labour and delivery. Do not use during breast feeding. Driving and using machines: May have major effect on ability to drive and use machines, especially at the beginning or change in treatment, in connection with alcohol or tranquilisers. **UNDESIRABLE EFFECTS:** **Very common (≥1/10):** dizziness, somnolence, headache, nausea, constipation. **Common (≥1/100, <1/10):** decreased appetite, anxiety, depressed mood, sleep disorder, nervousness, restlessness, disturbance in attention, tremor, involuntary muscle contractions, flushing, dyspnoea, vomiting, diarrhoea, dyspepsia, pruritus, hyperhidrosis, rash, asthenia, fatigue, feeling of body temperature change, mucosal dryness, oedema. Other important undesirable effects: palpitations, heart rate increased/decreased (**uncommon ≥1/1000, <1/100**), drug hypersensitivity including angioedema, anaphylaxis and anaphylactic shock (**uncommon ≥1/1000, <1/100**), respiratory depression (**rare ≥1/10,000, <1/1000**), convulsion (**rare ≥1/10,000, <1/1000**). No evidence of increased risk of suicidal ideation or suicide with Palexia SR. Additional information is available on request. **OVERDOSE:** Seek specialist treatment (see SmPC). **LEGAL CLASSIFICATION:** POM, CD (Schedule II). **MARKETING AUTHORISATION NUMBERS AND PACK SIZES:** 50 mg: PA 1189/7/4, 28 and 56 packs; 100 mg: PA 1189/7/5, 56 pack; 150 mg: PA 1189/7/6, 56 pack; 200 mg: PA 1189/7/7, 56 pack and 250 mg: PA 1189/7/8, 56 pack. **MARKETING AUTHORISATION HOLDER:** Grünenthal Ltd, Regus Lakeside House, 1 Furzeground Way, Stockley Park East, Uxbridge, Middlesex, UB11 1BD, UK. **DATE OF PREPARATION:** November 2013. IRE/P13.0025b. **REFERENCE:** 1. Palexia SR Summary of Product Characteristics



Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim, Ireland. 2. The Dept of Rheumatology, Merlin Park Hospital, Galway 3. The Dept of Psychology, NUIG 4. Discipline of Economics, NUIG 5. Dept of Medicine, NUIG 6. Dept of Pharmacology and Therapeutics, TCD

Introduction The incidence and prevalence of several musculoskeletal (MSK) diseases are rising rapidly, including osteoarthritis (OA), rheumatoid arthritis (RA) and gout. Hospitalisations are an important metric of health care utilization for any diagnosis, reflecting disease severity, availability of resources, and the infrastructure and policies of the healthcare system.

Aims/Background This study aimed to analyse hospitalisation trends for MSKs in Ireland over a 11 year period between 2005 and 2015.

Method Absolute numbers and direct age-standardised rates of hospitalisations for OA, RA and gout in men and women were analysed using the National Hospital In-Patient Enquiry System (HIPE) database between 2005 and 2015. Age bands were further grouped into 3 age categories: 'young adults' (Age 19-44 years), 'middle-aged adults' (Age 45-69 years) and 'older adults' (Age 70 years and older). Future projections of absolute numbers of hospitalisations to 2045 were computed based on the 2015 incidence rates applied to the projected populations.

Results The age-standardised rates of hospitalisation for OA, RA and Gout increased by 79% with a yearly % increase of 9% (p<.001). Increases in age standardised rates were evident across the three age bands all 3 disease groups. The highest rate of hospitalisations was evident in the over 70 year age group which increased by 38% from 12.2/1000 population to 16.9/1000 population and a significant yearly % increase of 4% (p=0.0004). The number of patient-days per year spent in hospital with a principal diagnoses of OA, RA and Gout decreased from 72,063 days to 53,372 with the largest decrease of 31% in the number of bed days for OA from 62,452 to 43,035. The mean LOS for hospitalisations for the 3 MSDs decreased overall by 43% over the 11-year study period. Assuming stable age-standardised incidence rates from 2014 over the next 30 years, the number of hospitalisations with a principal diagnoses of OA, RA and Gout would be expected to increase by 66 % from 19,924 to 32,999.

Conclusions The age-standardised rates of hospitalisation for OA, RA and Gout increased by 79% with the highest rate of increase identified in the over 70 year age group which increased from 12.2/1000 population to 16.9/1000 population. The number of hospitalisations with a principal diagnoses of OA, RA and Gout are projected to increase by 66 % from 19,924 to 32,999 by 2045.

(17A127) ABSTRACT 30

POSTER 20

Audit of in-patient referrals to Rheumatology department at University Hospital Waterford

Author(s) Sanjeev Verma, Claire Sheehy, Donnacha O'Gradiagh, Darragh Foley Nolan.

Department(s)/Institutions Department of Rheumatology/ University Hospital Waterford

Introduction Early assessment of patients with rheumatological problem is critical in the establishment of a diagnosis and institution of appropriate therapy. A Rheumatology consult form was introduced, in September 2015, to aid prioritization.

Aims/Background To assess the number and most common inpatients referrals made to rheumatology.

Method Consults received using the new referral form over 18 months were audited. The referring team's assessment and diagnosis were recorded.

Results 163 patients were referred using the form; 85 patients were female and 78 male. 15% patients were known patients of the rheumatology service and were referred for review following

admission with an unrelated illness. 85% were new referrals. N= 115 from medical team and N= 27 and 12 from ortho. and surgery teams respectively.

The majority of the patients referred were for management of gout and osteoarthritis (n=91), which were managed with intra articular steroid injections and/or NSAIDs and Colchicine. Patients with joint swelling or effusion underwent aspiration +/- intra articular injection. 8 patients were diagnosed with SLE post renal biopsy. There were 12 newly diagnosed patients with inflammatory arthritis. Most (n=109) of the patients were seen and managed within 2-4 hrs of the referral period. Patients were followed as out-patients as required.

Conclusions 163 patients were referred using the template over 18 months. The majority of referrals were crystal arthritis and osteoarthritis. Further work needed to educate regarding management of crystal arthritis among hospital teams.

Image 1

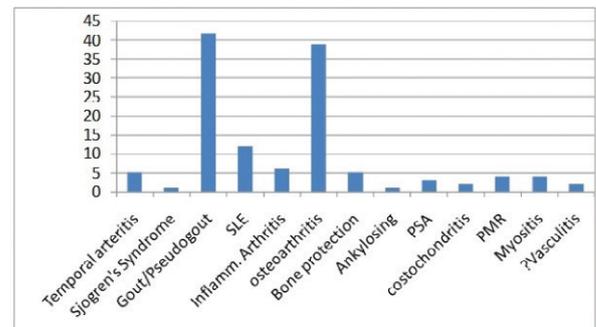


Image 2

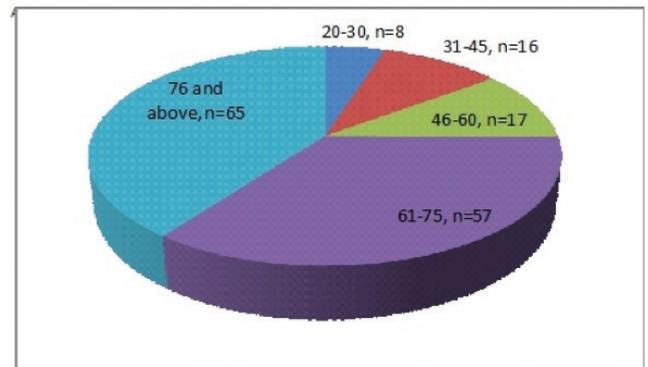
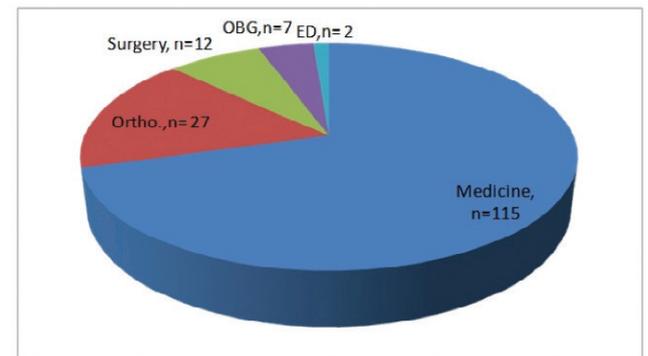


Image 3





“ Remsima is a New Generation Treatment for Rheumatology ”

Remsima is

- ✓ Remsima is a *TNF- α* inhibitor to help rapid reduction in inflammation^{1,2}
- ✓ Remsima helps to reduce the risk of radiographic progression in RA³
- ✓ Remsima is right for your patients through faster and earlier access

[QUALITATIVE AND QUANTITATIVE COMPOSITION] One vial contains 100 mg of infliximab. Infliximab is a chimeric human-murine IgG1 monoclonal antibody produced in murine hybridoma cells by recombinant DNA technology.

[CLINICAL PARTICULARS] 1) Rheumatoid arthritis Remsima, in combination with methotrexate, is indicated for the reduction of signs and symptoms as well as the improvement in physical function in adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate. Adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs. In these patient populations, a reduction in the rate of the progression of joint damage, as measured by X ray, has been demonstrated. 2) Ankylosing spondylitis Remsima is indicated for treatment of severe, active ankylosing spondylitis, in adult patients who have responded inadequately to conventional therapy. 3) Adult Crohn's disease Remsima is indicated for treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

Treatment of fistulating, active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy). 4) Ulcerative colitis Remsima is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. 5) Psoriatic arthritis Remsima is indicated for treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. Remsima should be administered in combination with methotrexate or alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated. Infliximab has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X ray in patients with polyarticular symmetrical subtypes of the disease. 6) Psoriasis Remsima is indicated for treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

[Posology and method of administration] During Remsima treatment, other concomitant therapies, e.g. corticosteroids and immunosuppressants should be optimised.

Rheumatoid arthritis 3 mg/kg given as an intravenous infusion followed by additional 3 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Remsima must be given concomitantly with methotrexate. Available data suggest that the clinical response is usually achieved within 12 weeks of treatment. If a patient has an inadequate response or loses response after this period, consideration may be given to increase the dose step-wise by approximately 1.5 mg/kg up to a maximum of 7.5 mg/kg every 8 weeks. Alternatively, administration of 3 mg/kg as often as every 4 weeks may be considered. If adequate response is achieved, patients should be continued on the selected dose or dose frequency. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment or after dose adjustment. 2) Ankylosing spondylitis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 6 to 8 weeks. If a patient does not respond by 6 weeks (i.e. after 2 doses), no additional treatment with infliximab should be given. 3) Crohn's Disease ① Moderately to severely active Crohn's disease 5 mg/kg given as an intravenous infusion followed by an additional 5 mg/kg infusion 2 weeks after the first infusion. If a patient does not respond after 2 doses, no additional treatment with infliximab should be given. Available data do not support further infliximab treatment, in patients not responding within 6 weeks of the initial infusion. In responding patients, the alternative strategies for continued treatment are: Maintenance: Additional infusion of 5 mg/kg at 6 weeks after the initial dose, followed by infusions every 8 weeks or re-administration: Infusion of 5 mg/kg if signs and symptoms of the disease recur. Although comparative data are lacking, limited data in patients who initially responded to 5 mg/kg but who lost response indicate that some patients may regain response with dose escalation. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit after dose adjustment. ② Fistulising, active Crohn's disease 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusions at 2 and 6 weeks after the first infusion. If a patient does not respond after 3 doses, no additional treatment with infliximab should be given. In responding patients, the alternative strategies for continued treatment are: Maintenance: Additional infusions of 5 mg/kg every 8 weeks or re-administration: Infusion of 5 mg/kg if signs and symptoms of the disease recur followed by infusions of 5 mg/kg every 8 weeks. Although comparative data are lacking, limited data in patients who initially responded to 5 mg/kg but who lost response indicate that some patients may regain response with dose escalation. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit after dose adjustment. In Crohn's disease, experience with re-administration if signs and symptoms of disease recur is limited and comparative data on the benefit/risk of the alternative strategies for continued treatment are lacking. 4) Ulcerative colitis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. Available data suggest that the clinical response is usually achieved within 14 weeks of treatment, i.e. three doses. Continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within this time period. 5) Psoriatic arthritis 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg infusion doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter. If a patient shows no response after 14 weeks (i.e. after 4 doses), no additional treatment with infliximab should be given. Re-administration for Crohn's disease and rheumatoid arthritis if the signs and symptoms of disease recur, infliximab can be re-administered within 16 weeks following the last infusion. In clinical studies, delayed hypersensitivity reactions have been uncommon and have occurred after infliximab-free intervals of less than 1 year (see sections 4.4 and 4.8). The safety and efficacy of re-administration after an infliximab-free interval of more than 16 weeks has not been established. This applies to both Crohn's disease patients and rheumatoid arthritis patients.

Re-administration for ulcerative colitis the safety and efficacy of re-administration, other than every 8 weeks, has not been established. Re-administration for ankylosing spondylitis the safety and efficacy of re-administration, other than every 6 to 8 weeks, has not been established. Re-administration for psoriatic arthritis the safety and efficacy of re-administration, other than every 8 weeks, has not been established. Re-administration for psoriasis limited experience from re-treatment with one single infliximab dose in psoriasis after an interval of 20 weeks suggests reduced efficacy and a higher incidence of mild to moderate infusion reactions when compared to the initial induction regimen. Limited experience from re-treatment following disease flare by a re-induction regimen suggests a higher incidence of infusion reactions, including serious ones, when compared to 8-weekly maintenance treatment. **[Contraindications]** Patients with ① history of hypersensitivity to infliximab, to other murine proteins, or to any of the excipients ② tuberculosis or other severe infections such as sepsis, abscesses, and opportunistic infections ③ moderate or severe heart failure (NYHA class III/IV)



(17A128) ABSTRACT 31

POSTER 21

Novel potentially pathogenic stop codon mutation in the nuclear factor NF- κ B p65 subunit (RELA): Discovery of a new player driving inflammation in monogenic Behçet-like disease in the Midwest of Ireland

Author(s) Fahd Adeb^{1,2}, Emma R. Dorris³, Austin G. Stack^{2,4}, Anthony G. Wilson³, Alexander D. Fraser^{1,2}

Department(s)/Institutions 1. Department of Rheumatology, University Hospital Limerick, Limerick, Ireland. 2. Graduate Entry Medical School, University of Limerick, Limerick, Ireland. 3. EULAR Centre of Excellence/UCD Centre for Arthritis Research, Conway Institute of Biomolecular & Biomedical Research, University College Dublin, Dublin, Ireland. 4. Department of Nephrology, University Hospital Limerick, Limerick, Ireland

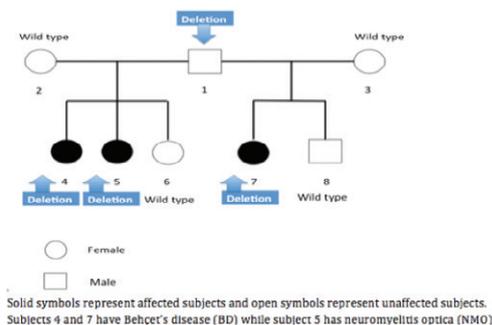
Introduction Behçet's Disease (BD) has a multifactorial etiology and susceptibility is influenced by a complex interplay between genetic and environmental components. Familial aggregation in BD has been described among different ethnic populations and there have been reported cases of monogenic conditions with similarity to BD. Better insights and understanding of orphan monogenic defects in inflammatory syndromes carries high clinical impact on the affected patients and "at risk" family members and will hopefully reshape the landscape in managing this subset of BD patients through early recognition, identification of characteristics pattern, risk prediction, choice of treatment and discovery of different novel therapies.

Aims/Background The primary goal of this study was to identify novel genetic mutation(s) in a BD family using whole exome sequencing (WES).

Method WES were performed on a complex Caucasian Irish pedigree composed of eight family members that include 2 half sisters with BD, both presented with similar phenotypic picture of orogenital ulcerations and skin pustulosis without evidence of uveitis. One of the two proband also had a sister who was subsequently diagnosed with neuromyelitis optica (NMO) while the remaining family members remained healthy and were asymptomatic.

Results A novel potentially pathogenic stop codon mutation in the nuclear factor NF- κ B p65 subunit (RELA) was present in all 3 affected subjects as well as their father. The WES data suggests p65 haploinsufficiency and a dominant mode of inheritance with incomplete penetrance (Figure 1). Activation of the transcriptional regulator NF- κ B is a critical step in inflammation and is widely implicated in inflammatory syndromes including in BD. Cytokines that are stimulated by NF- κ B, such as IL-1 β , TNF- α and IL-6, can also directly activate the NF- κ B pathway, thus establishing a positive autoregulatory loop that can amplify the inflammatory response and increase the duration of chronic inflammation. The mutation at the stop codon may potentially have caused uncontrolled inflammation resulting phenotypic characteristics similar to BD.

Figure 1 Pedigree of the family affected with BD and NMO



Conclusions This study provides novel evidence for the pathogenic stop codon mutation in the nuclear factor NF- κ B p65 subunit (RELA) as a potential driver of inflammation in monogenic Behçet-like disease.

(17A130) ABSTRACT 32

POSTER 22

Knowledge, Attitude and Satisfaction of Patients Undergoing Intra-articular Injection with Steroid in CUH Rheumatology Service

Author(s) Safi Ghazi Alqatari, Kaumal Baig, Dr Grainne Murphy, Dr Joe McKenna, Dr. Eanna Falvey

Department(s)/Institutions Rheumatology Department/Cork University Hospital

Introduction Proper education of patients undergoing invasive but non-lifesaving procedures is very important. It is crucial to properly educate patients regarding the procedure they will undergo to maintain their autonomy.

Proper consenting for these procedures requires patient education about their indications, contraindications, benefits and side effects. One of these procedures is intra-articular steroid injection.

With the ever progressive media, people's attention are changing. One of the things that we should explore is the attention and response to different educational materials.

Aims/Background To compare knowledge, attitude and satisfaction of patients when exposed to a leaflet or a video for education in advance of therapeutic joint injection. Secondly to correlate the time spent with each educational modality and rates of treatment refusal following education.

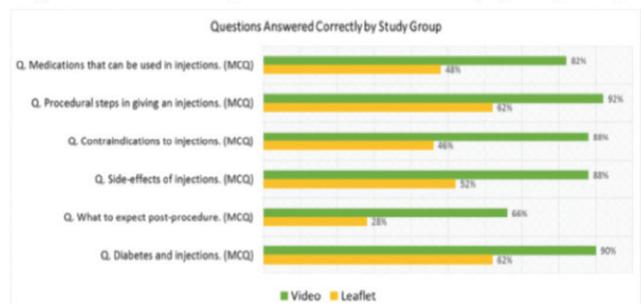
Method This study was conducted in a large tertiary referral rheumatology centre. 100 patients considered for therapeutic injection were included (50 leaflet, 50 video). A specifically designed animated educational video was developed which included the same information regarding intra-articular steroid injection as those receiving paper-based education. Information retention post-procedure was assessed after 30 minutes.

Results 92% in the video group were very satisfied compared with 72% of the leaflet group (P=0.03). The video group displayed higher rates of data retention (84% versus 50%) (P<0.001). For each question, the video group outperformed (P<0.001). Older people were less likely to know their diagnosis (P=0.001) and people who attained a higher education were aware more of their diagnosis (P=0.02). 18% of the video group withdrew from receiving the injection compared with 12 % of those receiving the leaflet (P=0.401). The length of time spent reading the leaflet increased the patients' ability to answer correctly (P<0.001).

Conclusions Supporting other studies, video education is superior to an information leaflet in educating patients with no impact of age, sex or education. Although most of the our patients were satisfied with either method, rates were higher in those educated by video. Patients who withdrew from the injection, regardless of method, had a better understanding of the procedure.

Image 1

Figure 7. Breakdown of Questions Answered Correctly by Study Group

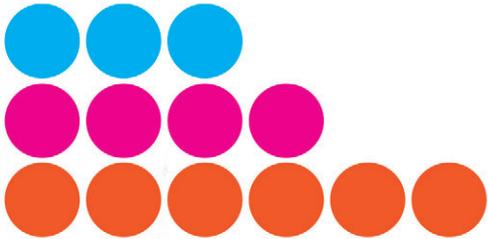


Take a **closer** look at **why** you can

TRUST HUMIRA®

(adalimumab)

13



INDICATIONS

The most of any self-administered biologic^{1**}

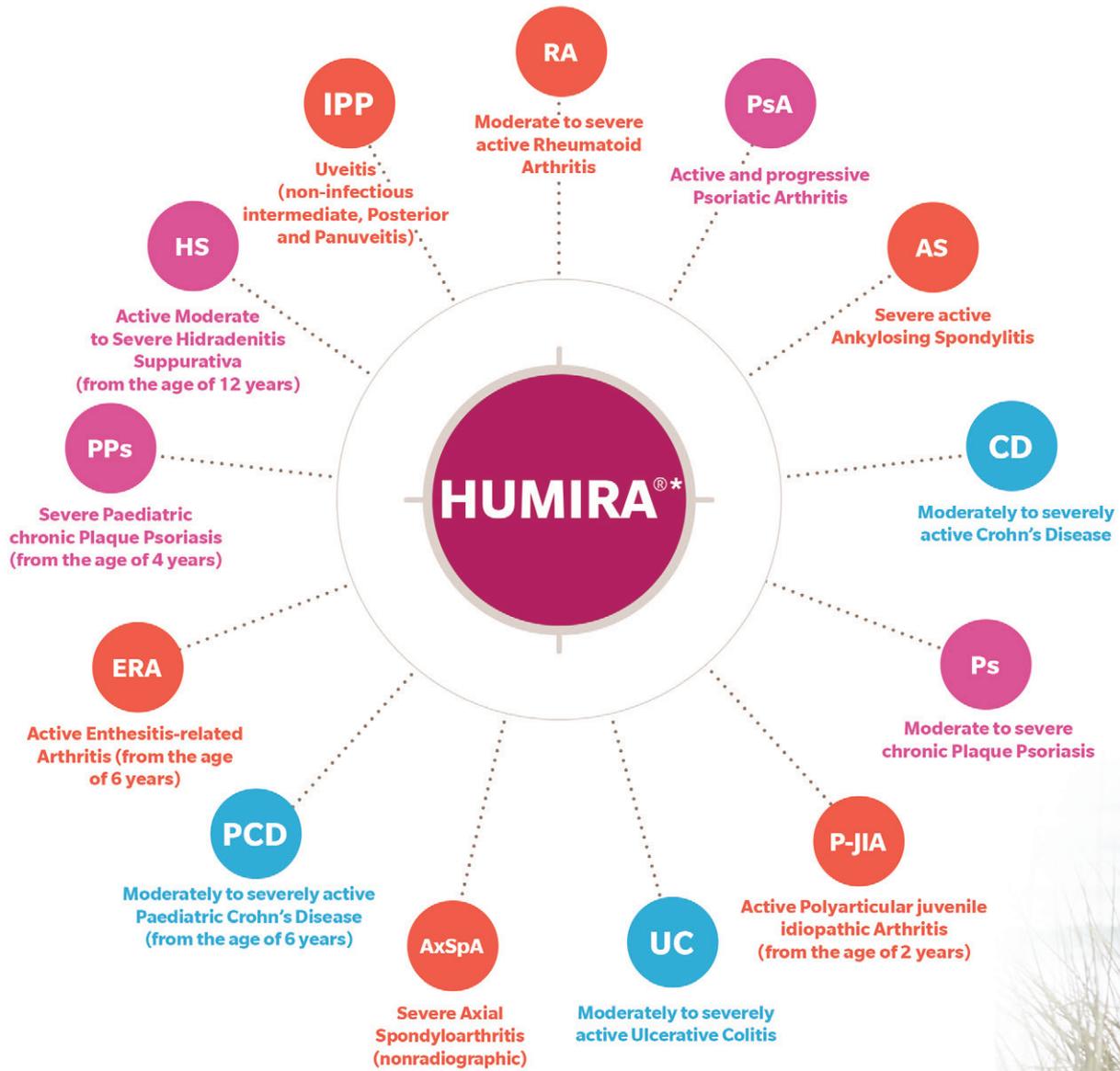
More than
one million patients
currently treated worldwide²



Prescribing Information Humira (adalimumab) 40mg solution for injection in pre-filled pen or pre-filled syringe or Humira 40mg/0.8ml solution for injection for paediatric use. Refer to Summary of Product Characteristics (SmPC) for full information.

Presentation: Each 0.4 ml single dose pre-filled pen or pre-filled syringe contains 40mg of adalimumab. Each 0.8 ml single dose vial contains 40mg of adalimumab. **Indications:** **Rheumatoid arthritis (RA), adults:** In combination with methotrexate (MTX) for moderate to severe, active RA with inadequate response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX. In combination with MTX for severe, active and progressive RA when not previously treated with MTX. Can be given as monotherapy if intolerance to or when continued treatment with MTX is inappropriate. Reduces rate of progression of joint damage on X-ray and improves physical function, in combination with MTX. **Polyarticular juvenile idiopathic arthritis (pJIA), paediatrics 2 years and above:** In combination with MTX, for active pJIA, with inadequate response to one or more DMARDs; or monotherapy if intolerance to or when continued treatment with MTX is inappropriate. **Enthesitis-related arthritis (ERA), paediatrics 6 years and above:** For active ERA with inadequate response or intolerance to, conventional therapy. **Psoriatic arthritis (PsA), adults:** For active and progressive PsA with inadequate response to DMARDs. Reduces rate of progression of peripheral joint damage on X-ray in polyarticular symmetrical subtypes of the disease and improves physical function. **Ankylosing spondylitis (AS), adults:** For severe active AS with inadequate response to conventional therapy. **Axial spondyloarthritis without radiographic evidence of AS (nr-axSpA), adults:** For severe nr-axSpA with objective signs of inflammation (elevated CRP and / or MRI), and an inadequate response to, or intolerance to nonsteroidal anti-inflammatory drugs (NSAIDs). **Crohn's disease (CD), adults:** For moderately to severely, active CD with inadequate response, contraindication or intolerance to corticosteroid and/or an immunosuppressant therapy. **Crohn's disease (CD), Paediatrics 6 years and above:** For moderately to severely active CD with inadequate response, contraindication or intolerance to conventional therapy including primary nutrition therapy and a corticosteroid, and/or an immunomodulator. **Psoriasis (Ps), adults:** For moderate to severe chronic plaque psoriasis who are candidates for systemic therapy. **Psoriasis, paediatrics 4 years and above:** For severe chronic plaque psoriasis with inadequate response, or if topical therapy and phototherapies are inappropriate. **Hidradenitis suppurativa (HS), adults and adolescents from 12 years of age:** For active moderate to severe hidradenitis suppurativa (acne inversa) in patients with an inadequate response to conventional systemic HS therapy. **Ulcerative colitis (UC), adults:** For moderately to severely active UC with inadequate response, contraindication or intolerance to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA). **Uveitis, adults:** For non-infectious intermediate, posterior and panuveitis with inadequate response to corticosteroids, in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate. **Dosage and administration:** Specialist physicians experienced in the diagnosis and treatment of the condition, to initiate and supervise treatment. Ophthalmologists to consult with an appropriate specialist before initiation of treatment. Provide patients with special alert card. Patients may self-inject after proper injection training, with physician approval and appropriate medical follow-up. Optimise other concomitant therapies. **RA, adults:** 40mg dose every other week. Concomitant MTX should be continued. During monotherapy patients may require 40 mg each week if they experience a decrease in clinical response. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Consider need for dose interruption, e.g. before surgery or if serious infection occurs. Re-introduction after 70 days dose interruption gave same magnitudes of clinical response and similar safety profile as before dose interruption. **pJIA, paediatrics 2 years and above:** Treatment beyond 12 weeks reconsidered if no clinical response in that time. **pJIA, paediatrics 2-4 years:** 24mg/m² body surface area up to 20mg maximum single dose every other week (see vial SmPC for height/weight dosing chart). **pJIA, paediatrics 4-12 years:** 24mg/m² body surface area up to 40 mg maximum single dose every other week (see vial SmPC for height/weight dosing chart). **pJIA, paediatrics 13 years and above:** 40mg every other week regardless of body surface area. **ERA, paediatrics 6 years and above:** 24mg/m² body surface area up to a maximum single dose of

40mg every other week. (see vial SmPC for height/weight dosing chart). **PsA, AS and nr-axSpA, adults:** 40 mg every other week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **CD, Adults:** Induction: 80mg at Week 0 followed by 40mg at Week 2. For a more rapid response, 160mg at Week 0 (either as 4 injections in 1 day or 2 injections/ day for 2 consecutive days), 80mg at Week 2; risk of adverse events higher during induction. Maintenance: 40mg every other week. If decrease in clinical response, can increase dose to 40 mg weekly. Corticosteroids may be tapered in maintenance phase in accordance with clinical guidelines. Patients with no response by Week 4 may benefit from continued therapy to Week 12. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **CD, paediatrics 6 years and above <40Kg:** Induction: 40mg at Week 0, 20mg at Week 2. For a more rapid response: 80mg at Week 0 (2 injections in 1 day), 40mg at Week 2; risk of adverse events higher during induction. Maintenance: 20mg every other week. If insufficient response, consider 20mg every week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **CD, paediatrics 6 years and above >40Kg:** Induction: 80 mg Week 0, 40 mg at Week 2. For a more rapid response: 160 mg at Week 0 (4 injections in 1 day or 2 injections/day for 2 consecutive days), 80 mg at Week 2; risk of adverse events higher during induction. Maintenance: 40 mg every other week. If insufficient response, consider 40 mg every week. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **Psoriasis, adults:** 80mg induction dose at week 0, 40mg every other week from week 1. Treatment beyond 16 weeks should be reconsidered if no clinical response in that time. Beyond 16 weeks, patients with inadequate response can increase dosing frequency to 40 mg every week. If adequate response is achieved with an increased dosing frequency, dose may subsequently be reduced to 40 mg every other week. If there is inadequate response to the increased frequency, carefully reconsider treatment. **Psoriasis, Paediatrics 4 years and above:** 0.8 mg per kg body weight (maximum of 40 mg/dose) weekly for the first 2 doses and then every other week (see vial SmPC for weight dosing chart). Treatment beyond 16 weeks should be reconsidered if no response in that time. **HS, Adults:** 160mg initially at Day 1 (four 40mg injections in one day or two 40mg injections per day for two consecutive days), followed by 80 mg two weeks later at Day 15 (two 40mg injections in one day). Two weeks later (Day 29) continue with a dose of 40 mg every week. Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions should be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. Reintroduction after interruption: 40 mg every week. Evaluate periodically the benefit and risk of continued long-term treatment. **HS, adolescents from 12 years of age weighing at least 30 kg:** 80 mg initially at week 0 (given as two 40 mg injections on day one), 40 mg injection in week 1 followed by 40mg every other week. In adolescent patients with inadequate response to Humira 40 mg every other week an increase in dosing frequency to 40 mg every week may be considered. Antibiotics may be continued if necessary. Concomitant topical antiseptic wash on HS lesions should be used on a daily basis. Treatment beyond 12 weeks should be reconsidered if no clinical response in that time. **UC, Adults:** Induction: 160mg at week 0 (4 injections in 1 day or 2 injections / day for 2 consecutive days) and 80mg at week 2. Maintenance: 40mg every other week. During maintenance, corticosteroids may be tapered in accordance with clinical practice guidelines. If insufficient response, consider 40mg every week. Treatment beyond 8 weeks should be reconsidered if no clinical response in that time. **Uveitis: Adults:** 80 mg induction dose at week 0, 40 mg every other week from week 1. Experience of initiating treatment with Humira alone is limited. Treatment can be initiated in combination with corticosteroids and/or other non-biologic immunomodulatory agents. Two weeks after initiating treatment, concomitant corticosteroids may be tapered in accordance with clinical guidelines. Evaluate on a yearly basis, the benefit and risk of continued long term treatment. **Contraindications:** Active tuberculosis (TB), severe infections (e.g. sepsis), and opportunistic infections; moderate to severe heart failure (NYHA class III/IV); hypersensitivity to adalimumab or any of the excipients. **Precautions and Warnings:** Clearly record trade name and batch number of administered product to improve traceability of biological medicinal product. **Infections:** Patients are more susceptible to serious infections especially if impaired lung function. Monitor for infections, including TB, before,



during and for 4 months after treatment. Do not initiate treatment with an active infection, until it is controlled. Consider risk/benefit prior to treatment in patients exposed to high risk of TB or endemic mycoses. Evaluate new infections during treatment and monitor closely. Stop treatment if new serious infection or sepsis, and treat appropriately. Exercise caution in patients with a history of recurring infections or who are predisposed to infections. **Serious infections:** Serious infections, including those with hospitalisation or death reported in patients receiving treatment. **TB:** Consult SmPC for details. Reactivation and new onset TB, both pulmonary and extra-pulmonary (disseminated) reported. Screen all patients before therapy initiation for active or latent TB. If active TB is diagnosed Humira therapy must not be initiated. If latent TB is suspected, consult a physician with appropriate expertise and follow local treatment recommendations for prophylaxis prior to initiation of Humira. Despite prophylaxis TB reactivation has occurred on Humira. **Other opportunistic infections:** Opportunistic infections observed in patients receiving Humira. Stop treatment in patients with signs and symptoms of such infections. Consult with physician with appropriate expertise for diagnosis and administration of empiric antifungal therapy in these patients. **Hepatitis B Reactivation:** Reactivation has occurred in chronic carriers (i.e. surface antigen positive) tested for HBV infection before initiating treatment. HBV carriers should consult with a specialist physician and be closely monitored for reactivation of HBV infection throughout therapy and for several months following termination of Humira. If reactivation occurs stop treatment and initiate appropriate anti-viral and supportive treatment. **Neurological events:** Caution in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders and consider stopping treatment if these disorders develop. Rare association with new onset or exacerbation of symptoms and/or radiographic evidence of central and peripheral demyelinating disease. Known association between intermediate uveitis and central demyelinating disorders. Evaluate patients with non-infectious intermediate uveitis before therapy initiation and regularly during treatment to assess for pre-existing or developing central demyelinating disorders. **Allergic reactions:** Reports of serious allergic reactions including anaphylaxis received. For serious allergic or anaphylactic reaction stop Humira immediately and initiate appropriate therapy. **Malignancies and lymphoproliferative disorders:** A possible risk of malignancy, including lymphoma and leukaemia, in all patients including paediatric patients, treated with TNF antagonists. Monitor all patients, especially those with a medical history of extensive immunosuppressant or PUVA treatment for non-melanoma skin cancer prior to and during Humira therapy, caution in COPD patients, and in patients with increased risk of malignancy due to heavy smoking. Consider the potential risk with the combination of AZA or 6-MP and Humira (hepatosplenic T-cell lymphoma has occurred). Risk of hepatosplenic T-cell lymphoma cannot be excluded. Caution in patients with a history of malignancy. Risk for developing dysplasia or colon cancer is unknown. Patients with UC, prior history of dysplasia or colon carcinoma to be screened for dysplasia before therapy and during treatment. **Haematologic reactions:** Adverse events of the haematologic system reported with Humira. Patients should seek immediate medical attention if signs and symptoms of blood dyscrasias. **Vaccinations:** Patients may receive concurrent vaccinations, except for live vaccines. Bring paediatric patients up to date with all immunisations prior to Humira treatment. **Congestive heart failure:** See contraindications. Caution is advised in mild heart failure (NYHA class I/II). Discontinue treatment for new or worsening symptoms of congestive heart failure. **Autoimmune processes:** Autoimmune antibodies may form. Stop treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA. **Surgery:** Consider the long half-life of Humira for planned surgical procedures. Closely monitor for infections. **Small bowel obstruction:** Failure to respond to treatment for CD may indicate the presence of fixed fibrotic stricture requiring surgical treatment. **Elderly:** Serious infections were higher in patients over 65 years of age, some of whom had fatal outcomes. Consider risk of infection. **Interactions:** Combination of adalimumab with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. **Fertility, pregnancy and lactation:** Not recommended during pregnancy. Women of childbearing potential should use adequate contraception and continue its use for at least five months after the last Humira treatment. Women must not breast-feed for at least five months after the last treatment. **Side Effects:** Very common $\geq 1/10$: Infections, leukopenia, anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction. **Serious, including fatal, side effects have been reported** including infections/sepsis, intestinal perforation, opportunistic infections, TB, endemic mycoses, demyelinating disease, malignancies including lymphoma (including hepatosplenic T-cell lymphoma), leukaemia and skin cancer (including melanoma and merkel cell carcinoma), cytopenias, worsening heart failure, myocardial infarction, pulmonary embolism, pleural effusion, pulmonary fibrosis, cerebrovascular accident, interstitial lung disease, lupus, Stevens-Johnson syndrome, angioedema, anaphylaxis, sarcoidosis, hepatitis, liver failure and worsening of symptoms of dermatomyositis. **Prescribers should consult the SmPC for the complete list of reported side effects.** **Legal Category:** POM. **Marketing Authorisation Numbers/Presentations:** Vial: EU/1/03/256/001; Pre-filled Syringe: EU/1/03/256/013; Pre-filled Pen: EU/1/03/256/017. Further information is available from AbbVie Limited, 14 Riverwalk, Citywest Business Campus, Dublin 24. **HCPs are asked to report any suspected adverse reactions via HPRRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Date of revision of PI: January 2017, PI/256/018**

* Please refer to the HUMIRA SmPC on www.medicines.ie for full indications.
** In use in any of the diseases/indications mentioned above.

References: 1. HUMIRA [summary of product characteristics]. AbbVie Ltd.
2. Data on File, AbbVie.

Date of Preparation: June 2017
IREHUR160874(1)

HUMIRA[®]
adalimumab
destination you[™]



Image 2

Figure 9. Satisfaction levels with Information Material by Study Group

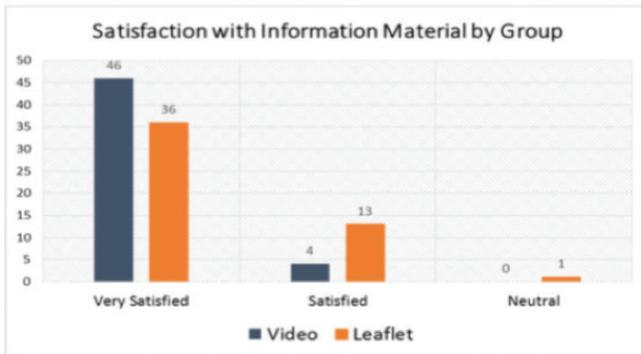
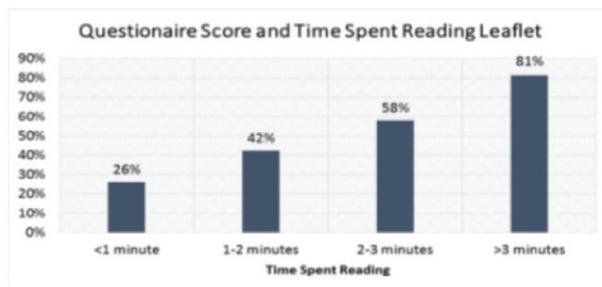


Image 3

Figure 10. Questionnaire Score and Time Spent Reading Leaflet



(17A131) ABSTRACT 33

POSTER 23

Are We Bang On Target? An investigation on the Efficacy & Efficiency of the Treat To Target Clinic Model, Rheumatology Department, Tallaght Hospital.

Author(s) Ronan Mullan

Department(s)/Institutions Department of Rheumatology, Adelaide and Meath Hospital, Tallaght Dublin 24

Introduction Suboptimal treatment of Inflammatory Arthritis (IA), which includes Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA) and Ankylosing Spondylitis (AS), is associated with increased joint destruction, increased functional disability, and higher rates of mortality. The European League Against Rheumatism (EULAR) best practice guidelines for RA advocate aggressive early treatment using a sequential or step up approach using synthetic Disease Modifying Anti Rheumatic Drugs (sDMARD) or biological DMARD (bDMARD) therapies until low disease activity or remission levels of arthritis have been attained, as measured by a composite disease activity scoring method. In 2015, a Treat To Target (TTT) Clinic was initiated in the Department of Rheumatology, to maximise remission induction for patients with poorly controlled RA, PsA and AS.

Aims/Background To compare the Rheumatology Treat To Target (TTT) Approach at Tallaght Hospital to International Best Practice guidelines for the management of Inflammatory Arthritis.

Method Frequency of Composite Disease Activity Scoring Methods and Treatment Interventions at the TTT clinic appointments in Tallaght Hospital were compared to the European League Against Rheumatism (EULAR) recommendations for treatment escalation

and disease monitoring for patients with Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA) and Ankylosing Spondylitis (AS).

Results Only 34% of RA patients had a DAS28 composite disease activity score taken at clinic to guide treatment decisions. 9% of PsA patients had a composite disease activity score and 0% of AS patients had a composite disease activity score. Appropriate management decisions were taken according to global physician disease assessment, however a discrepancy between physician assessment and DAS28 scores indicates non-adherence to EULAR treatment recommendations for these patients.

Conclusions An education campaign among physician attendees leading to composite disease activity measures being performed to guide standard practice is required to attain best international standards. An education campaign, to implement changes followed by re-audit is recommended.

(17A134) ABSTRACT 34

POSTER 24

An Audit of the Diagnosis and Management of Giant Cell Arteritis: Evolving Pathways of Care

Author(s) Stephen McDonald, Khemerin Eng, Philip Gardiner

Department(s)/Institutions Altnagelvin hospital, Londonderry (Western Health and Social Care Trust)

Introduction Giant Cell Arteritis (GCA) can present in many different ways and can lead to permanent blindness in up to 20% of cases. Fast track clinics are being introduced to reduce the risk of complications.

Aims/Background To examine existing pathways of care in the presentation and management of GCA in a busy general hospital and to audit our adherence to the 2010 BSR/BHPR guidelines for management of GCA.

Method Retrospective review of the records of 31 patients with a provisional diagnosis of GCA selected consecutively. Information on diagnosis and management was retrieved.

Results There was no delay in diagnosis in 27 of 31 patients, four of whom had a final diagnosis that was not GCA. In 4 cases diagnosis was delayed for more than 48h (3days, 18d, 17d, and one atypical case took 90d to come to rheumatology attention). For the 27 who had a final diagnosis of GCA, 25 had fulfilled at least 3 of the 5 ACR diagnostic criteria.

The initial clinical and ESR response to steroid was documented in all cases except one in whom the therapy had been initiated in primary care. A Temporal artery biopsy (TAB) was performed in 19 cases, ultrasound in 7. One patient with a visibly thickened temporal artery (and a normal ESR) had a negative initial biopsy but a repeat biopsy on the other side was positive. 8/19 biopsies were under 1cm in length.

The initial referral pathways were quite varied, with some patients being admitted or referred directly through the emergency department. A high proportion were seen and managed on the day ward over the first few months before transferring to the outpatient clinics. The starting dose of steroid was in keeping with BSR guidelines in all patients. After 6 months, 22 out of 28 had reduced the steroid dose below 10mg/day. Of the three recommended adjunct therapies, 19 were prescribed all three drugs, 10 were not on Aspirin and one was only on a PPI.

Three patients suffered loss of vision before presentation to hospital. In one elderly patient the visual loss resolved but unfortunately that patient later died from TB. In two cases of visual loss the diagnosis was delayed. Four other cases had symptoms of transient visual disturbance. In spite of bisphosphonate prophylaxis, two patients had a vertebral fracture, and one had a fractured neck of femur.



Conclusions The pathway of care for GCA patients has improved but not everyone was aware of it and delays in diagnosis still occurred. The major challenges are to increase awareness of the fast track referral system among GPs and Opticians and to reduce the delay in performing TAB. A fast track pathway of care for GCA is being widely circulated.

(17A135) ABSTRACT 35

POSTER 25

Abatacept (Orencia), a Promising Treatment for Early- and Late-stage Morphea Subtypes: A Follow-up Study from the Midwest of Ireland

Author(s) Maria Usman Khan^{1,2}, Fahd Adeeb^{1,2}, Mary brady¹, Siobhan Morrissey¹, Joseph Devlin¹, Alexander Fraser^{1,2}

Department(s)/Institutions

1. Department of Rheumatology, University Hospital Limerick, Limerick, Ireland. 2. Graduate Entry Medical School, University of Limerick, Limerick, Ireland

Introduction Morphea is a rare autoimmune inflammatory fibrosing skin disease of unknown aetiology characterized by excessive collagen deposition resulting in significant cosmetic, functional, and psychological sequelae. The treatment is individualized despite various suggested treatment algorithms for morphea subtypes and limited data is available showing some benefit of methotrexate combined with systemic corticosteroids [1]. Abatacept (Orencia) is a recombinant fusion protein that competitively binds to CD80 or CD86 receptors, hence selectively inhibits T-cell activation [2].

Aims/Background With reference to the work of Stausbøl-Grøn et al. [3] and our previous pilot work [4], we conducted a follow-up study to assess the efficacy of abatacept (Orencia), a selective T cell costimulation modulator, in patients with morphea subtypes, where Th-17 subtypes of effector CD4 +T cell has been proposed in the pathogenesis [5].

Method Six Caucasian patients with established morphea subtypes according to the Mayo Clinic Classification [6] and with no contraindication to abatacept were included in this prospective open-label study. Descriptive statistics were reported as median, SD and IQR for non-parametric calculations or number and percentages as appropriate.

Results This was an open-label, prospective study highlighting the excellent response and good safety profile of abatacept in all patients. Methotrexate in combination with systemic steroid was the only therapy used prior to abatacept in 3 patients at median dose of 17.5 mg/week (median duration of 3 months). 4 of the 6 patients received subcutaneous form of abatacept at dose 125mg/week with the exception of 2 of the 6 patients with severe disease who also received abatacept infusions at standard dose of 10mg/kg body weight as the induction therapy prior to the subcutaneous form. All patients on abatacept received concomitant treatment with methotrexate and low dose glucocorticoid that was discontinued in 3 patients after a mean duration of 12.9 months at median dose of 15mg/week (median duration of 10 month) due to gastrointestinal upset, recurrent urinary tract infection and deranged liver function tests respectively and this cohort showed excellent response using abatacept as monotherapy. Patient demographics and details of outcomes are shown in Table 1. No adverse event was reported with abatacept treatment at a median duration of 29 months.

Conclusions Abatacept was well tolerated in all 6 patients with excellent clinical outcome. These case series highlights abatacept (Orencia) as a promising therapeutic option for severe or resistant morphea subtypes.

Table 1: Demographic and Other Treatment Modalities of Patients with Morphea Subtypes Treated with Abatacept (Orencia) in the Midwest, Ireland

Age, years, Median (SD)	59.5 (16.272)
Female, n (%)	6 (100)
Biopsy proven morphea, n (%)	6 (100)
Disease duration, months, median (IQR)	52.5 (25.5)
Morphea Subtypes:	
• Generalised, n (%)	2 (33.33)
• Linear Morphea, n (%)	1 (16.66)
• Plaque Morphea with deep tissue involvement, n (%)	1 (16.66)
• Mixed subtype, n (%)	2 (33.33)
Relapses, median (IQR)	3, 0 (1.25)
Clinical presentation at last relapse	
• Progression, n (%)	1 (16)
• New lesions, n (%)	2 (33)
Prior treatment with Abatacept	
• Glucocorticoids, n (%)	2 (33.33)
• Methylprednisolone pulses as part of initial treatment regime, n (%)	3, 1 (16)
• Methotrexate, n (%)	3(50)
• Duration of methotrexate, months, median (IQR)	3 (3)
• Dose of methotrexate, mg/week, median (IQR)	17.5 (5)
Current concomitant treatment with Abatacept	
• Glucocorticoids, n (%)	5 (83.33)
• Av. Glucocorticoid dose, Median (IQR)	5 (5)
• Methotrexate, n (%)	6 (100)
• Duration of methotrexate, months, median (IQR)	15 (3.75)
• Dose of methotrexate, mg/week, median (IQR)	24 (24)
• Duration of abatacept, months, median (IQR)	29 (28.5)
Currently on Abatacept only, n (%)	6 (100)
Currently on combination Abatacept and methotrexate, n (%)	3 (50)

SD: standard deviation; n: number of patients; %: percentage; IQR: interquartile range; Av: average

(17A136) ABSTRACT 36

POSTER 26

A Quality Improvement Project to Facilitate Annual Cardiovascular Disease Risk Assessment in Rheumatoid Arthritis Patients: A Mid-Western Experience

Author(s) Maria Usman Khan^{1,3,4}, Usman Azhar Khan^{2,3}, Fahd Adeeb^{1,3}, Alwin Sebastian¹, Eoghan Maher³, Muddassar Ahmad⁴, Azhar Abbas⁴, Mary Brady¹, Mary Gillespie¹, Siobhan Morrissey¹, John Paul Doran¹, Joseph Devlin¹, Alexander Fraser^{1,3}

Department(s)/Institutions 1. Department of Rheumatology, University Hospital Limerick, Limerick, Ireland. 2. Department of Cardiology, University Hospital Limerick, Limerick, Ireland. 3. Graduate Entry Medical School, University of Limerick, Limerick, Ireland. 4. Department of Rheumatology, Beaumont Hospital, Dublin, Ireland

Introduction Rheumatoid arthritis (RA) is associated with accelerated atherosclerosis and increased risk of morbidity and mortality from cardiovascular disease (CVD) due to the high prevalence of traditional CVD risk factors (tCVD-RF) and systemic inflammation. EULAR recommends annual cardiovascular risk assessment (CRA) for patients with RA.

Aims/Background To assess the compliance with EULAR recommendations and improvement in CRA we re-audited RA patients at our rheumatology clinics after devising departmental guidelines and continuous education on CRA based on the results from the first audit. The re-audit had same three-fold aims: To determine the prevalence of the tCVD-RF (diabetes, hypertension, hyperlipidemia, long term steroid use and smoking), to assess CVD risk management in RA patients in comparison to the EULAR recommendations, and to identify whether RA disease activity is adequately controlled.

Method This multicenter study involved 2 teaching hospitals in Mid-West region of Ireland. 100 consecutive patients with definite RA were recruited between May-June 2016 and January-February 2017 in each audit and re-audit phases respectively. A proforma was completed for each patient based on medical notes and electronic record following information at any time since diagnosis of RA: demographic data, disease duration and activity, RF/ACPA status, concomitant ESR



& CRP, DAS28, tCVD-RFs, past history of ischemic heart disease (IHD), related co-morbidities (TIA, CVA, PVD, aortic aneurysm) and drug history (current RA, anti-hypertensive and lipid lowering medications). Data on blood pressure (BP), lipid profile and blood glucose (random, fasting or HbA1c) were sought in the preceding 4-years, and if treatment were commenced as per the guidelines. The 10-year risk of fatal CVD was calculated using the Systematic COronary Risk Evaluation (SCORE) chart: total cholesterol/HDL ratio was used & risk was multiplied by 1.5 if patient had 2 of these 3 criteria: disease duration of >10 years, positive RF/ACPA, presence of severe extra-articular manifestations.

Results Overall results are summarized in Figure 1. There was improvement in the efficiency of recording tCVD-RFs i.e. BMI, smoking, hypertension by 66%, 7% and 4% respectively and better management of hypertension by 9%. 8% patients received smoking cessation advice versus none before. Blood glucose and lipid profiles were well monitored but reduced by 8% and 7% respectively. RA disease activity was adequately controlled with 60% patients in remission in both audits. Due to the lack of required data, only 43 patients had their 10-year CVD risk SCORE model calculated. There was 12% reduction in the moderate risk group to develop fatal CVD within 10-years.

Conclusions CVD risk management although improved, still remains suboptimal and requires ongoing surveillance. Rheumatologists should actively participate in annual CRA in RA patients to reduce the incidence of IHD.

departmental guidelines and continuous education based on the results of first audit cycle (May-June 2016).

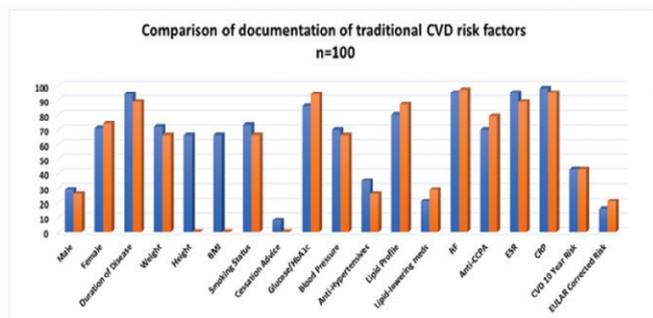
Method 100 consecutive patients with definite RA were recruited in this multicenter quality improvement project involving 2 teaching hospitals (Croom hospital & University Hospital Limerick) between January-February 2017. A proforma was completed for each patient based on medical notes & electronic data including BP record within the last 4 years and recent antihypertensive medications. HTN was defined as BP of $\geq 140/90$ mmHg. Based on the EULAR guidelines, ACE inhibitors (ACE-I) & angiotensin II (AT-II) blockers are preferred agents when indicated due to favorable effect on inflammatory markers and the endothelial function in RA. Based upon the results of our first audit cycle, we encouraged the use of ACE-I and AT-II blockers in our RA cohort as the preferred antihypertensive agents when indicated at both departmental and community level.

Results 1) There was an overall improvement in BP monitoring by 4%, and 70% of the patients had up-to-date BP recordings. 2) There was 5% increment in hypertensive patient cohort (element of white coat HTN not excluded) and at least 45% of patients were sub-optimally managed with mono or combination antihypertensive therapy in both cycles. Encouragingly ACE-I and AT-II blockers remained the main stay of treatment and constituted 50% of total drugs in the second audit compared to 54% in the first audit. 3) There were 6% reduction in the numbers of normotensive patients; 36% patients were adequately controlled with antihypertensive therapy in both audits. Interestingly the overall use of both ACE-I and AT-II blockers as primary antihypertensive was increased by 7% as compared to the first audit.

Conclusions Management of HTN in our RA cohort remained low and will require a re-audit. Several major barriers exist, including lack of time and staff. Rheumatologists need to be more actively involved in managing HTN in RA patients with possible referral to the relevant specialty if in doubt regarding the diagnosis and/or management.

References available on demand.

Figure 1:



(17A137) ABSTRACT 37

POSTER 27

Marked Underdiagnosis and Undertreatment of Hypertension in Rheumatoid Arthritis: A large Gap to Close

Author(s) Maria Usman Khan^{1,3,4}, Fahd Adeeb^{1,3}, Usman Azhar Khan^{2,3}, Alwin Sebastian¹, Azhar Abbas⁴, Hafiz Hamid Bajwa⁴, Mary Brady¹, Siobhan Morrissey¹, Mary Gillespie¹, John Paul Doran¹, Joseph Devlin¹, Alexander Fraser^{1,3}

Department(s)/Institutions 1. Department of Rheumatology, University Hospital Limerick, Limerick, Ireland. 2. Department of Cardiology, University Hospital Limerick, Limerick, Ireland. 3. Graduate Entry Medical School, University of Limerick, Limerick, Ireland. 4. Department of Rheumatology, Beaumont Hospital, Dublin, Ireland

Introduction In rheumatoid arthritis (RA), hypertension (HTN) doubles the risk of the composite cardiovascular outcome. Current guidelines [1] provide evidence-based indications for time to initiate therapeutic interventions & specific target blood pressure (BP) goals.

Aims/Background To determine the prevalence of HTN and to evaluate BP management in comparison to the EULAR recommendations [2] in our Midwest RA cohort after devising

Figure 1

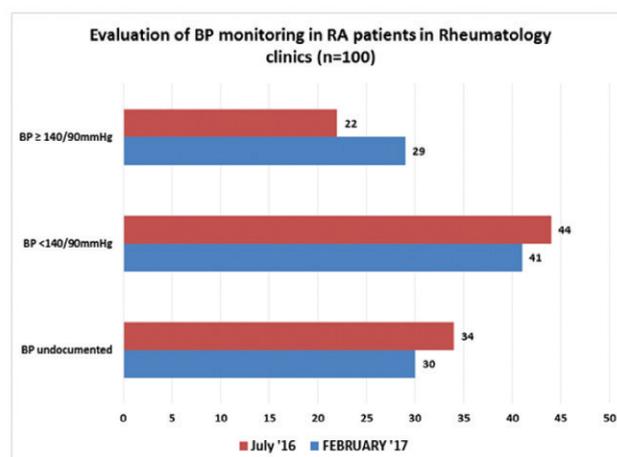
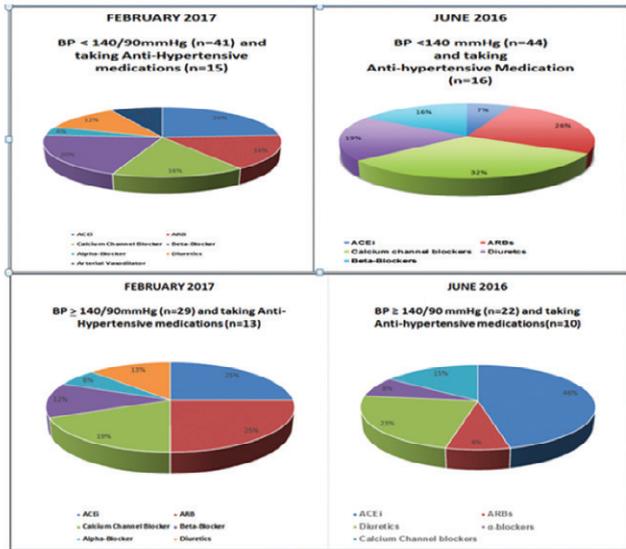




Figure 2: Comparison of normotensive and hypertensive patient-cohorts in two audit cycles in Mid-West region of Ireland



- DLQI>10
- Body Surface Area >10.

Method Patients with PsA attending our center completed PROMs and had clinician assessment. The following data was recorded: age, diagnosis, MDA components, DAS28 components, PASI, DLQI, EQ-5D-3L and Health Assessment Questionnaire (HAQ-DI). An ethics approved cross-sectional analysis was used. Statistics were performed using SPSS Version 23.

Results 129 sequential patients attending the department between February and November 2016 were included in this analysis. Population characteristics are outlined in Table 1. 82% (N=106) of patients had psoriasis, with a DLQI score available for 88% (N=93). In the patients who met MDA criteria, 20% had an EQ5D of 1 indicating perfect health, and 39% had a HAQ score of 0. In contrast in those who met DAS28 remission, 16% had an EQ5D of 1 and 32% had a HAQ score of 0. The EQ-5D and HAQ-DI results for the group assessed by MDA are shown in Table 1, and by DAS28 states are shown in Table 2, data are shown as mean (SD).DLQI scores were higher in active PsA. The DAS28 remission group had 11% of patients with a DLQI >10. In contrast the MDA group had only 3% of patients with DLQI >10

Conclusions Our study found that MDA and DAS28 measures identify patients with similar arthritis outcomes. Patients in MDA and low DAS28 states have lower DLQI values and better EQ5D and HAQ scores .

These results suggest that MDA identifies patients who have a better overall PsA disease outcome.

(17A139) ABSTRACT 38

POSTER 28

Comparison of Quality-of-Life, Function and Psoriasis measures in Minimal Disease Activity and DAS28 states in routine care of patients with Psoriatic Arthritis

Author(s) Catherine Hughes, Nora Ng, Toby Garrood, Bruce Kirkham

Department(s)/Institutions Rheumatology Department, Guy's and St Thomas' NHS Foundation Trust, London, UK

Introduction Psoriatic arthritis (PsA) is a chronic inflammatory arthritis with a varied clinical phenotype characterized by multiple disease components

- Axial arthritis
- Peripheral arthritis
- Enthesitis
- Dactylitis,
- Psoriasis including nail changes.

Improving Quality-of-Life is increasingly accepted as an important goal of treatment.

PsA disease activity can be measured using several tools including Minimal Disease Activity (MDA) or the 28 joint count disease activity score (DAS28) borrowed from Rheumatoid Arthritis. The Psoriasis Area and Severity Index (PASI) is used to assess the severity of Psoriasis. Patient Reported Outcome Measures (PROMs) allow a unique insight into the patient's perception of disease activity and remission. The importance of these measures has recently been highlighted, resulting in their inclusion in the PsA Core Domain Set. PROMs include:

- Dermatology Quality of Life Index (DLQI)
- EuroQol 5 dimensions questionnaire (EQ-5D).

Aims/Background The objective of this study was to compare PROMs in MDA and DAS28 disease states, including severe psoriasis, defined as

- PASI >10

Table 1: Patient characteristics MDA and Very Low (VL)- MDA

Characteristics	VL-MDA N=19	MDA N=46	Not - MDA N=83	P Value
Age years	51 (19.4)	47 (13.44)	52 (14.15)	0.92 *
Gender (%F)	32% (6/19)	33% (15/46)	36% (30/83)	0.686**
Mean DAS28	1.6(0.46)	1.86 (0.54)	3.88 (1.25)	
DAS28 remission	100% (19/19)	91% (42/46)	12% (10/83)	<0.0001 **
DAS28 2.6-3.2	0	4% (2/46)	17% (14/83)	0.388**
DAS28 3.2-5.1	0	0	53% (44/83)	
DAS28 >5.1	0	0	18% (15/83)	
EQ5D Utility Index	0.86	0.78	0.45	<0.0005 *
EQ5D VAS	84	79	50	<0.0005 *
PASI>10	0	0	5	0.222**
DLQI >10	0	3% (1/36)	34% (20/59)	0.001**
HAQ-DI	0.0789	0.22	1.32	<0.0005 *
VAS Pain (0-100)	15	25	63	<0.0005 *

P Value calculated comparing MDA and not-MDA groups using: *Mann Whitney U test; ** Chi Squared test

Table 2: MDA and QOL measures compared to DAS28 scores

Total number	DAS remission N= 50	DAS 2.6-3.2 N=17	DAS 3.2-5.1 N= 45	DAS>5.1 N= 15	P Value
PSO	40/50 (80%)	15/17 (88%)	37/45(82%)	12/15(80%)	1.00**
MDA	80% (40/50)	18% (3/17)	2% (1/45)	0	0.000**
HAQ-DI	0.432	0.583	1.49	1.86	0.000**
EQ5D Utility Index	0.77	0.687	0.53	0.138	0.000*
EQ5D VAS	70	71	53.4	36	0.000*
VAS Pain 0-100	29	55	60	81	0.000*
PASI >10	1/50 (2%)	0	3/45 (7%)	1/15 (7%)	0.662**
DLQI >10	4/38 (11%)	3/13(23%)	8/32 (25%)	5/10 (50%)	0.033**
DLQI 5-10	8/38 (21%)	1/13 (8%)	8/32 (25%)	3/10 (30%)	
DLQI <5	26/38(68%)	9/13(69%)	16/32(50%)	2/10 (20%)	

P Value calculated comparing DAS28 remission and non DAS28 remission groups using: *Mann Whitney U; **chi squared test



(17A140) ABSTRACT 39

POSTER 29

Implementation and comparison of the first evidence-based detection algorithm for pulmonary arterial hypertension in systemic sclerosis vs current practice.

Author(s) K.Robinson, G.Wright, A.Elliott, A.Flynn

Department(s)/Institutions Rheumatology Department, Musgrave Park Hospital, Belfast Trust, Northern Ireland.

Introduction Pulmonary arterial hypertension (PAH) is a leading cause of death in systemic sclerosis (SSc). Earlier detection of PAH facilitates earlier treatment. The DETECT study has developed the first evidence-based detection algorithm for PAH in SSc. Current practice is annual pulmonary function tests and echocardiograms. The issue with this method is that echo is not the most sensitive test for PAH. Pulmonary arterial pressure (PAP) cannot be calculated when there is no tricuspid regurgitation (TR) however; patients can have raised PAP despite having no TR. In the DETECT study they found that 7% of patients with RHC diagnosed PAH had no TR on echo. Note this was a high-risk population group and not comparable with the general population of SSc patients.

Aims/Background The aim of the study was to ensure implementation of the DETECT algorithm was practically feasible and that the algorithm was more sensitive than current practice in the general population of systemic sclerosis patients in Northern Ireland.

Method Randomly selected SSc patients were entered into the study. They had the appropriate investigations performed in order to complete the DETECT algorithm and had annual PFTs and echo requested (if not performed in the last year). The results from both

methods were compared to ensure patients who scored <300 in step 1 of the algorithm and therefore would not be referred for an echo did not have raised PAP.

Results 41 patients were recruited. 9 patients had incomplete investigations leaving 32 patients with completed algorithms and annual PFTs/echocardiograms. 27 patients scored <300 in step 1 and therefore would not be referred for echo or considered for right heart catheterisation. 5 patients scored >300 in step 1 indicating they should have updated echo requested.

Of these 27 patients, all but 3 had normal estimated PAP on annual echo. 2 of the 3 patients had known pulmonary fibrosis and therefore their pulmonary hypertension was secondary to lung disease. The other patient with raised PAP was seen by a cardiologist who repeated the echo and found normal estimated PAP.

Of the 5 patients who scored >300 in step 1 of the algorithm, 3 patients scored >35 in step 2 and therefore should be referred for RHC. All of these patients had raised PAP on echo and so would have been referred for RHC based on the echo result alone.

Conclusions Of the 32 patients included in our regional study using the DETECT algorithm did not detect PAH any earlier than current practice although the algorithm also did not miss any PAH diagnoses so we can conclude we found it equally as sensitive. However, our numbers are small and from the results in the DETECT study; the algorithm is a superior mode of earlier detection of PAH in SSc so we plan to change current practice and implement it long term. We also note it is not developed to identify any other causes of pulmonary hypertension, so patients with ILD should be excluded.

Learn from yesterday,
live for today,
hope for tomorrow.
The important thing is
not to stop questioning.

A l b e r t E i n s t e i n

Unmet needs require new solutions to old problems, which is why we push ourselves to see challenges from different perspectives, constantly questioning and forging new paths toward solutions, both in the lab and in our communities.

Committed to improving the lives of patients worldwide®

UK-CELG160205
Date of Preparation: November 2016





(17A141) ABSTRACT 40

POSTER 30

Identifying Patients with Poor Treatment Compliance

Author(s) Sinead Maguire, Una Martin, Paula Dreehan, Claire Sheehy

Department(s)/Institutions Department of Rheumatology, University Hospital Waterford

Introduction Poor compliance with treatment is a well-recognized issue in patients with chronic diseases (1). In patients with inflammatory arthritis, this can result in disease progression, irreversible deformity, and increased disability (2). Suboptimal disease control may be compounded or may even be due to poor compliance.

Aims/Background The Health Beacon Reporting System monitors patients' compliance with medication via the frequency of subcutaneous pen disposals into a sharps container. The system is programmed to record the time and date of the s/c pen disposal and compare to the expected date of disposal. This was an opt-in monitored sharps disposal system on the patient's part. This allows for accurate assessment of patient compliance with minimal effort and cost on the part of the clinician. Review of this data is a simple way to identify patients with possible compliance issues, which, may otherwise be mistaken for lack of efficacy of the drug.

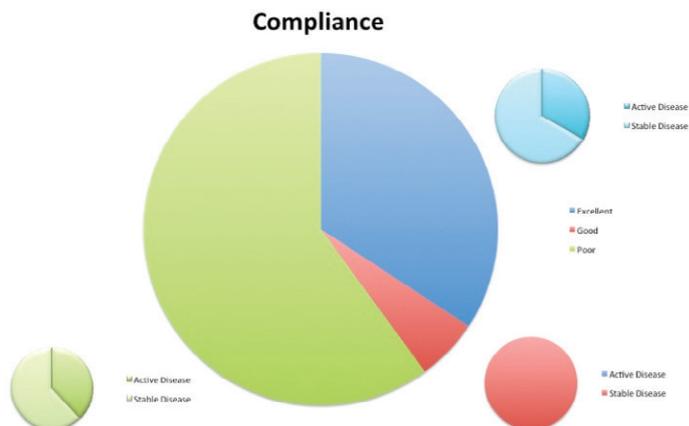
Method A retrospective review was carried out on data from all patients on Humira (Adalimumab) being monitored via the AbbVie Care Health Beacon Reporting System since its implementation in March 2016. There were 35 patients identified and information on background demographics, diagnosis, compliance, duration of treatment and current disease status were recorded. Patients were compared on the basis of their disease activity and compliance. Compliance was divided into excellent (81-100% adherence), good (66-80%) and poor (<65%). Disease activity was determined by review of recent clinical notes to be active or stable.

Results The 35 patients studied had either a diagnosis of rheumatoid arthritis or psoriatic arthritis. The mean duration of treatment was 7.15 months. For most patients (80%), Humira was their first biological agent. This review included patients on combined (57%) and monotherapy (43%) with DMARDs. Of the patients studied 34.3% were classified as having active disease. Of those patients 66.7% had poor compliance with treatment. Interestingly it was also noted that only 43.5% of the patients with stable disease were reported to have good to excellent compliance. Larger patient numbers would provide greater insights into issues affecting compliance.

Conclusions Compliance should always be considered in patients with active disease. The Health Care Beacon Reporting System can be a helpful tool to the clinician in monitoring compliance. In patients with poor compliance, patient education and identification of issues affecting compliance could significantly affect patient outcomes.

References 1. Joplin S et al. Medication adherence in patients with rheumatoid arthritis: the effect of patient education, health literacy, and musculoskeletal ultrasound. *BioMed Res Int*.

2. Pasma A, Schenk CV et al. Non-adherence to DMARDs is associated with higher disease activity in early arthritis patients in the first year of the disease. *Arthritis Res Ther*.



(17A146) ABSTRACT 41

POSTER 31

Treating SpA to target

Author(s) Dr. Adriana Ramona Valea, Dr. Shawn Chavrimootoo, Dr. SA Ramakrishnan

Department(s)/Institutions Rheumatology Department, Our Lady's Hospital, Navan, Co Meath

Introduction Spondyloarthritis (SpA) is a chronic inflammatory disease involving the spine and peripheral joints, with possible extra-articular manifestations such as uveitis, psoriasis and bowel inflammation. The treatment goals are maintenance of physical function, control of disease activity and prevention of radiographic progression.

The "treat to target" concept is based on having clearly identified goals for guiding therapy. It is implemented in many areas of medicine and specifically in rheumatology it has proven to be successful for Rheumatoid arthritis and Gout.

Aims/Background The aim of the audit was to compare our clinical practice in Rheumatology Department in Our Lady's Hospital Navan to the international ASAS recommendations for the use of anti-TNF agents in patients with SpA.

In our Department we enroll all patients with established SpA diagnosis in a Treat to Target Programme where they are followed-up 6 weekly and therapy is conducted as per ASAS guidelines until achieving remission.

Method We performed a retrospective analysis of 29 charts of patients diagnosed with SpA between January and December 2016 that have attended Physiotherapy Programme and registered data on duration of symptoms before presentation, diagnosis and type of joint involvement and extraarticular manifestations, initial NSAID therapy and subsequent DMARD or TNF therapy when appropriate.

Results In this group, 38% were male patients and 62% were female, with a mean age of 35 yrs and mean duration of low back pain 5 yrs. 82.7% had been diagnosed with axial SpA out of which one had psoriatic arthritis for the last 5yrs, and 17.3% were diagnosed with axial and peripheral SpA out of which one had IBD. In the group with peripheral involvement there were 4 cases of uveitis, 2 of enthesitis and 1 dactylitis.

Sacroiliitis was confirmed on MRI in 68.9%, on x-ray in 17.2% and 13.7% were diagnosed on HLA pathway. HLA B27 was found positive in 62% of all patients.

All patient with the exception of IBD case were started on NSAIDs after diagnosis and re-assessed by the rheumatology nurse 6 weekly for escalation of therapy to second NSAID and TNF inhibitor as needed. Out of 5 patients with peripheral involvement 3 were started



on Salazopyrine after diagnosis and are still on it along with TNF therapy after failure to control symptoms, 1 refused DMARDs or TNF and 1 BD pt started on TNF therapy from diagnosis. Once achieving remission patients were offered outpatient appointment.

At present in this patient group 14 pt (48.2%) are still controlled with NSAIDs (7 on first NSAID and 7 on second, 13 pt (44.8%) are on TNF inhibitor (6 on the first one and 7 on the second one) with 2 patients offered TNF and refused.

Conclusions In all 29 patients diagnosed with SpA the ASAS guidelines for management were correctly implemented ASAS guidelines recommend using the BASDAI score for assessing disease activity. In our clinical practice ASDAS-CRP score is used for this purpose. The ASAS guidelines were initially developed before the development of ASDAS-CRP score and it is not yet included in the guidelines though it had proven a longitudinal relationship with subsequent syndesmophyte formation that BASDAI score is lacking

(17A147) ABSTRACT 42

POSTER 32

**NSAIDS REMAIN WIDELY USED IN AS AND PSA
DESPITE THE INCREASING USE OF BIOLOGIC
THERAPIES**

Author(s) Safi Alqatari, Roberta Visevic, Grainne Murphy, John Ryan

Department(s)/Institutions Rheumatology Department, Cork University Hospital

Introduction Ankylosing spondylitis (AS) and psoriatic arthritis (PsA) are chronic inflammatory diseases for which NSAIDs are recommended. Widespread publicity regarding the adverse cardiovascular risk with NSAIDs has resulted in a dramatic decrease in its use in patients with rheumatoid arthritis, however there are limited data regarding NSAID use in patients with AS or PsA. We sought to determine the prevalence of NSAID use in our hospital practice, and the prevalence of prescription of synthetic DMARDs and biologic therapies in the same cohort. Access to biologics is perceived to be generous in Ireland compared to other countries which may influence prescribing patterns.

Aims/Background To identify patients attending the rheumatology clinic in Cork University Hospital, Ireland with a clinical diagnosis of AS or PsA. To determine the prevalence of NSAID use in this cohort.

Method All patients attending the rheumatology clinics over a 1 month period in 2016 were evaluated. A review of all AS and PsA patients identified was undertaken to record the medications prescribed at the time of review with particular attention to NSAID use.

Results Over the month in question, 39 patients were identified with AS and 52 with PsA. had PsA.

Of the 39 AS, 16/39 (43.59%) were taking NSAIDs, 11 (28.2%) as monotherapy. 60% were treated with a biologic agent. TNF inhibitors, namely Golimumab and Etanercept (7 patients equally) were the most common, followed by Adalimumab (6). 3/39 received secukinumab. 8/39 (20.5%) received sDMARDs, with 3 (7.6%) as monotherapy.

Regarding PsA, 37% used NSAIDs, 21% used it as monotherapy. 21 patients (40.4%) were receiving TNF inhibitors, 8 as a monotherapy. The most commonly used bDMARD was adalimumab (13). 30/52 (58%) were treated with a sDMARD, and used as monotherapy in 20%. Methotrexate was the most commonly used (50%).

Conclusions Despite the publicised concerns regarding the CVD risk associated with NSAIDs they remain commonly used in patients with PsA and AS. This is despite the relatively high use of biologics in this population. While NSAID use was higher than we expected it

was not as high as that previously reported in a German population (67%) with AS. Publicity in relation to the adverse cardiovascular outcomes associated with NSAIDs does not appear to have reduced their use in populations with spondyloarthritis.

(17A148) ABSTRACT 43

POSTER 33

**Rheumatoid Arthritis Biologics Registry of Ireland
(RABRI) - the first year**

Author(s) Dr. Michele Doran (1), Prof. David Kane (2), Prof. Douglas Veale (3), Ms. Phil Gallagher (3)
Prof. Gerry Wilson (4)

Department(s)/Institutions 1. St. James's Hospital, 2. AMNCH Tallaght, 3. St. Vincent's University Hospital. 4. University College Dublin

Introduction Biologics registries have been in existence in many other European countries for more than 10 years. These large epidemiological cohort studies evaluate unselected patients treated in routine care, and have yielded valuable information regarding biologic therapies in RA.

Aims/Background RABRI was established in Ireland in 2015 to document information regarding patients with Rheumatoid Arthritis (RA) commencing a new biologic (including biosimilar) therapy in participating centres in Ireland. The aims of RABRI are to monitor response to therapy, safety, and to record adverse events and events of special interest.

Method A RABRI Steering Committee was established within the Irish Society for Rheumatology, consisting of 5 ISR Members. Data collection tools were drawn up and an electronic database was established, in which anonymised data is stored electronically. Ethical approval was obtained in each participating centre. All patients entering RABRI are reviewed at baseline (starting 1st biologic or changing biologic), at 6-monthly intervals for the 1st 2 years and yearly thereafter for 5 years.

Data collected includes demographics, factors relating to RA, use of other DMARDs and steroids, and comorbidities. Disease activity is assessed at each visit using validated tools including CDAI, SDAI, PROMIS-HAQ and DAS.

Results Enrolment started in early 2016. To date 6 centres have commenced enrolling patients and further 4 have approval. A total of 107 patients have been enrolled and a total of 120 visits have been recorded (42 2nd visits and 8 3rd visits)

Of the patients enrolled to date, a total of 70 (65%) were starting their first biologic. Of these, 38 were prescribed etanercept, 18 adalimumab, 15 abatacept, 14 tocilizumab, 11 rituximab, 7 golimumab, 2 certolizumab, and 1 each infliximab and baricitinib.

A total of 9 biologic therapies have been included to date and 7 switches have taken place.

In the patients with recorded follow-up visits, disease activity, measured by all indices dropped between first and subsequent visits. CDAI (Table 1) and SDAI (Table 2) dropped between first and subsequent visits. Average DAS score on the 1st visit was 5.27 and on 2nd visit it was 3.52.

Four patients have had events of special interest to date. Two patients experienced malignancy, one patient experienced aplastic anaemia with pancytopenia, and one experienced a serious skin reaction.

Conclusions This is the first study examining biologics use in Ireland, and early results show a similar pattern of biologic use to that reported by other European registries. The number of events of special interest is small and is within the expected range based on similar registries.



Fig 1

CDAI activity	Visit #1 (% of total patients)	Visit #2 (% of total patients)
Low Activity	32%	60%
Moderate Activity	58%	29%
High Activity	10%	11%

Fig 2

SDAI activity	Visit #1 (% of total patients)	Visit #2 (% of total patients)
Low Activity	17%	61%
Moderate Activity	71%	26%
High Activity	12%	13%

(17A150) ABSTRACT 44

POSTER 34

Experience of Tight Control in Psoriatic Arthritis Management within the Belfast Trust

Author(s) A.Elliott, A.Quinn, D.Torrens, M.McHenry, A.Pendelton and G.Wright.

Department(s)/Institutions RVH Rheumatology Department, Belfast.

Introduction The development of scores in Rheumatoid Arthritis including ACR and DAS-28 led to an ability to monitor disease activity.

This led to treat to target studies and clinical guidelines including disease activity scores. TICORA was the first study to demonstrate tight control in RA leading to better clinical and radiographic outcomes compared to route care.

The lack of treatment targets and disease heterogeneity has made strategy trials in PSA more difficult.

In 2015 the first evaluation of tight control concepts in PSA was performed in the TICOPA paper assessing 206 DMARD naive PSA patients. Using the minimal disease Activity (MDA) criteria for PSA, patients were either assigned to a tight control (TC) strategy as per Figure 1 or standard care with percentage of patients achieving ACR 20 being the primary outcome. The paper was the first to demonstrate that a TC strategy achieved better outcomes for patients.

Aims/Background The concept of tight control has been evident from 2013 within the Belfast Trust.

After the TICOPA paper patients were referred for 'tight control' of their PSA.

The aim was to commence patients on DMARDs with a new diagnosis of PSA with review every 4 weeks with either the Nurse Specialist or Medical team.

The nurse specialist would perform baseline joint and skin scores along with other aspects of disease activity and treatment is then escalated as per the TICOPA paper. (See figure 1)

I sought to review those enrolled in the tight control strategy from 2014 and assess how treatment was escalated and what the outcomes at one year were.

Method I reviewed the notes of those PSA patients enrolled in the tight control strategy who had one year of data available within the Belfast Trust.

Results 20 patients aged between 21 and 70yrs who were all diagnosed by a consultant rheumatologist with PSA and referred for tight control within the Belfast trust were included in the review as they had one year data.

All patients were DMARD naive. All patients in the first 3 months were seen every 4 weeks and all patients at 6 months were seen at least every 6 weeks for review.

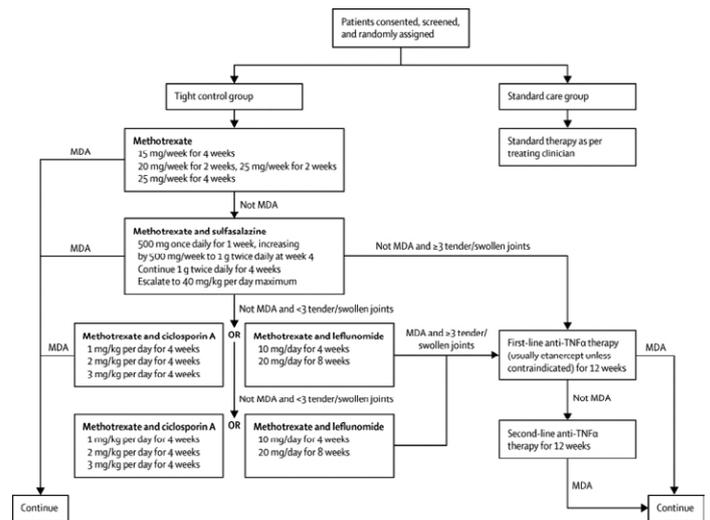
5 patients were commenced on Sulfasalazine (SLP) initially and 15 patients on methotrexate (MTX). No patients at any point in the review reached MDA if on SLP therapy. Three patients were escalated to biologics at 6 months and there was 10 out of 20 patients on biologic therapy by one year. Also overall at one year ACR 20

was achieved in 70% of cases and MDA in 50% matching up with results seen in the TICOPA paper.

Conclusions Tight Control in Clinical Practice will yield results but is time consuming.

The main benefits are regular review to get on top of disease and patients feeling like they are not lost to system. The focus should be on achieving MDA on 2 occasions by escalating treatment to control disease and thinking about Biologic therapy early. If MDA is achieved then review can be stretched out after 24 weeks. Treatment strategies must obviously relate to patient's goals.

Image 1



(17A152) ABSTRACT 45

POSTER 35

Does comorbidity adversely impact upon treatment response in patients with rheumatoid arthritis? A retrospective analysis of routine care data

Author(s) Catherine Hughes, Nicola Gullick

Department(s)/Institutions King's College Hospital, London, UK

Introduction Patients with Rheumatoid Arthritis (RA) have on average 1.6 comorbidities, and the number of comorbidities increases with age.

The 2016 the European League Against Rheumatism (EULAR) published a list of six comorbidities of particular importance as they occur more frequently, affect clinical outcomes and often they are poorly managed.

These are: cardiovascular disease, malignancy, infections, gastrointestinal disease, osteoporosis and depression.

Aims/Background The aim of this project was to examine the link between comorbidity and treatment response in RA patients treated with biologic agents.

Method A systematic literature review of EMBASE and Ovid Medline was carried out up until 7th January 2017.

Retrospective data was gathered from the King's College London Virtual Biologics Clinic on patients who attended this clinic from 2013-2016.

Statistical analysis was completed using STATA to assess the impact of comorbidity on treatment response.

Results The literature review identified 5 articles and 2 abstracts, all of which showed that comorbidity impacts negatively on treatment response in patients who are treated with biologic agents.

Baseline characteristics are in Table 2. Age and BMI were significantly increased in patients with comorbidity compared to

When life is *too busy* for RA

Given a choice, 53% of RA patients
would chose a monthly regime^{1*}



SIMPONI 50 MG, 100 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN **SIMPONI 50 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE (GOLIMUMAB)** **ABRIDGED PRODUCT INFORMATION** Refer to Summary of Product Characteristics before prescribing **PRESENTATION** Simponi 50 mg solution for injection in pre filled pen Simponi 50 mg solution for injection in pre filled syringe Simponi 100 mg solution for injection in pre filled pen **INDICATIONS** *Rheumatoid Arthritis (RA):* Simponi, in combination with methotrexate (MTX), is indicated for: the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; *Psoriatic Arthritis (PsA):* Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. *Ankylosing Spondylitis (AS):* Simponi is indicated for the treatment of severe, active AS in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-Axial SpA):* Simponi is indicated for the treatment of severe, active nr-Axial SpA who have had an inadequate response to or are intolerant to NSAIDs. *Ulcerative colitis (UC):* Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. *Polyarticular juvenile idiopathic arthritis (pJIA):* Simponi 50mg in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX. **DOSE AND ADMINISTRATION** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS, nr-Axial SpA, UC or pJIA. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. *RA:* Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. *PsA:* Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. *AS and nr-Axial SpA:* Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses).

Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. *UC: Patients weighing < 80 kg:* Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks. *Patients weighing > 80 kg:* Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). *pJIA:* Simponi 50 mg administered once a month, on the same date each month, for children with a body weight of at least 40 kg. Clinical response is usually achieved within 12 to 14 weeks of treatment (after 3-4 doses). *Missed dose:* If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. *Older patients (≥ 65 years):* no dose adjustment required. *Paediatric patients (<18 years):* For indications other than pJIA, Simponi is not recommended. *Patients with renal and hepatic impairment:* Simponi is not recommended. **CONTRAINDICATIONS** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic infections; patients with moderate or severe heart failure (NYHA class III/IV). **PRECAUTIONS AND WARNINGS** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. The invasive fungal infection should be suspected if they develop a serious systemic illness. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should

be recorded on the Patient Alert Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. *Hepatitis B (HBV) reactivation:* Reactivation of HBV occurred in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi. *Malignancies and lymphoproliferative disorders:* Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine (AZA) or 6-mercaptopurine (6-MP). The potential risk with the combination of AZA or 6-MP and Simponi should be carefully considered. A risk for the development of HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma and Merkel cell carcinoma (all TNF-blocking agents including Simponi) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. *Heart Failure:* Simponi should be used with caution in patients with mild heart failure (NYHA class I/II). Patients should be closely monitored and Simponi must be discontinued in patients who develop new or worsening symptoms of heart failure. Some cases had a fatal outcome. *Neurological events:* Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demyelinating disorders. *Surgery:* Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. *Autoimmune processes:* If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. *Haematological reactions:* There



GO further with Simponi

With Simponi, approximately 70% of patients remained on treatment after 5 years.² *Make your 1st choice count.*



have been post-marketing reports of pancytopenia, leukopenia, neutropenia, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers. Cytopenias including pancytopenia have been reported infrequently in clinical trials. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. **Vaccinations/therapeutic infectious agents:** It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. **Allergic reactions:** If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. **Special populations: Older patients (≥ 65 years):** Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. There were no patients age 45 and over in the nr-Axial SpA study. **Paediatric patients (<18 years):** **Vaccinations:** it is recommended that prior to initiating Simponi therapy, paediatric patients be brought up to date with all immunisations in agreement with current immunisation guidelines. **Excipients:** Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **INTERACTIONS:** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **PREGNANCY AND LACTATION:** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **SIDE EFFECTS Refer to SmPC for complete information on side effects Very Common (≥ 1/10):** upper respiratory tract infection; **Common (≥ 1/100):** bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, anaemia, allergic reactions, autoantibody positive, depression, insomnia, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia, injection site reaction, chest discomfort, bone fractures were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma, hepatosplenic T-cell lymphoma*, leukopenia, thrombocytopenia, pancytopenia, aplastic anaemia, serious systemic

hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, interstitial lung disease and lupus-like syndrome. * Observed with other TNF-blocking agents. **Paediatric population: pJIA:** The safety of golimumab has been studied in a phase III study of 173 pJIA patients from 2 to 17 years of age. The average follow-up was approximately two years. In this study, the type and frequency of adverse events reported were generally similar to those seen in adult RA studies. **PACKAGE QUANTITIES** 1 x 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection 1 x 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection **Legal Category:** Prescription Only Medicine. **Marketing Authorisation Number** 50 mg Pre-filled Pen EU/1/09/546/001 50 mg Pre-filled Syringe EU/1/09/546/003 100 mg Pre-filled Pen EU/1/09/546/005 **Marketing Authorisation Holder** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands **Date of Revision of Text:** February 2017. **Simponi/PI-IRE/02-17** © Merck Sharp & Dohme Ireland (Human Health) Limited 2017. All rights reserved. Further information is available on request from: MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-2998700)

References: 1. Huynh, T.K. et al. Preferences of patients and health professionals for route and frequency of administration of biologic agents in the treatment of rheumatoid arthritis. *Patient Preference and Adherence*, 2014;8: 93-99. 2. Keystone EC, Genovese MC, Hall S et al. Safety and efficacy of subcutaneous golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: final 5-year results of the GO-FORWARD trial. *J Rheumatol*. 2016;43:298-306.

*Rheumatoid arthritis patients preferring subcutaneous therapies
Date of preparation: May 2017.



Red Oak North, South County Business Park,
Leopardstown, Dublin D18 X5K7 Ireland

monthly 
Simponi[®]
golimumab



those with no comorbidity. Patients with multi-morbidity were more likely to receive a DMARD as well as their biologic treatment compared to those without multi-morbidity.

There were no statistical significant findings in terms of DAS change, EULAR good response and DAS28 remission in those with or without comorbidity and with or without multi-morbidity.

Further analysis using logistic regression examining those with comorbidity and a combination of predictor factors (age, gender, BMI, DMARD use, smoking status) showed a trend towards statistical significance ($p=0.057$).

Conclusions Despite limited available research, the literature review supported the hypothesis that greater comorbidity burden and older age at disease onset could reduce chances of achieving a good treatment response. Retrospective data analysis of the King's dataset did not support this hypothesis, however there were limitations in the routine data collected. Certain trends in the data suggest that age, gender, BMI, DMARD use, smoking status may impact on ability to achieve a good EULAR response.

Image 1

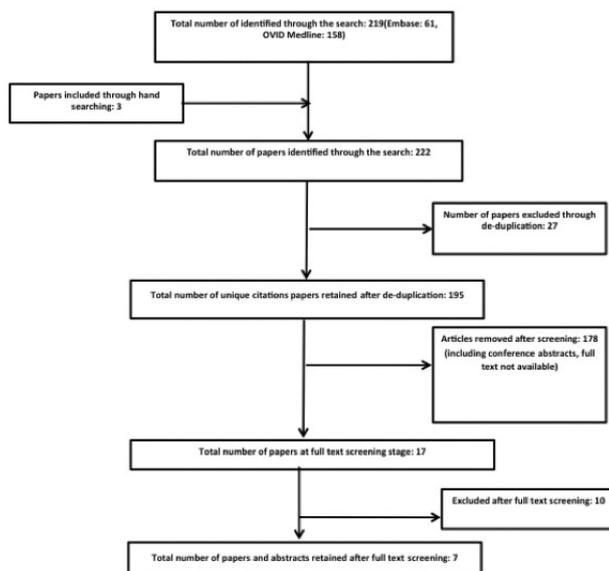


Image 2

Results- Data Analysis

Characteristics	All (n=132)	No comorbidity (n=23)	Comorbidity (n=109)	P Value	No multimorbidity (n=59)	Multimorbidity (n=73)	P Value
Age in years (SD) *	58 (12.9)	59.5 (12.2)	59.5 (12.6)	0.0033	52.4 (11.6)	62.4 (12.4)	<0.0001
Gender (%)**	104 (79)	16 (70)	88 (81)	0.234	42 (71)	46 (63)	0.055
Mean baseline DAS28 (SD) *	6.28 (0.9)	6.3 (1.1)	6.3 (0.9)	0.7591	6.3 (1.0)	6.3 (0.9)	0.8601
Seropositive (%)***	101 (77)	17 (74)	84 (78)	0.689	45 (76)	56 (78)	0.834
Disease Duration (years) (median IQR)****	7 (3-13)	4.5 (3-12.5)	7 (2-13)	0.6448	7 (3-12)	7 (2-15)	0.8623
Patients on DMARDS (%)**	108 (82)	21 (91)	87 (80)	0.194	51 (90)	35 (48)	0.032
BMI (SD) *	29.3 (7.2)	24.2 (5.1)	30.4 (7.2)	0.0002	27.1 (6.9)	31.0 (7.1)	0.0019
Smoking status**							
-Current	41 (31)	7 (30)	34 (31)	0.464	15 (25)	26 (36)	0.117
-Ex	23 (17)	4 (17)	19 (17)		14 (24)	9 (12)	
-Never	25 (19)	2 (9)	23 (21)		8 (14)	17 (23)	
-Not known	43 (33)	10 (43)	33 (30)		22 (37)	21 (29)	
Baseline HAQ***	1.9 (1.375-2.375)	1.625 (0.75-2)	2 (1.5-2.375)	0.1446	1.875 (1.25-2.25)	2 (1.5-2.375)	0.2769

Image 3

Response Table

	All	No comorbidity	Comorbidity	P Value	No Multimorbidity	Multimorbidity	P Value
DAS Change*	1.98 (1.57)	2.09 (1.59)	1.95 (1.58)	0.7047	2.11 (1.68)	1.87 (1.48)	0.3726
EULAR Good Response (%)**	34 (26)	9 (39)	25 (23)	0.107	18 (31)	16 (22)	0.262
DAS Remission (%)**	21 (16)	5 (22)	16 (15)	0.4	11 (19)	10 (14)	0.44

(17A153) ABSTRACT 46

POSTER 36

A comparison of BASDAI, BASFI and ASQoL in smoker versus non smokers and in male versus female in a West of Ireland cohort

Author(s) Larkin MA, Curran AM, Sullivan C, Lynch, B
Department(s)/Institutions Rheumatology Department, Galway University Hospital

Introduction Ankylosing spondylitis (AS) is a chronic inflammatory disorder with an estimated prevalence of 0.2–0.8% in the adult Caucasian population of Western Europe. Numerous studies have shown that there is a long delay in diagnosing AS, with a mean delay of approximately 7 years.

Subjective measures of symptom severity, functional ability and quality of life are determined using various tools; Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI) and Ankylosing Spondylitis Quality of Life (ASQoL) respectively.

Lifestyle factors have been shown to influence BASDAI, BASFI and ASQoL scores. Cigarette smoking has been linked to worse functional, clinical and radiological outcome in AS.

A previous study examined the difference in severity of AS between genders; radiographic spinal changes are more severe in men. The same study showed self-reported functional limitations were worse in women than men.

Aims/Background To analyse the AS cohort attending Galway University Hospital (GUH). To compare the BASDAI, BASFI and ASQoL in smokers vs non smokers and in males vs females.

Method Data was initially gathered prospectively using a web based data system; Ankylosing Spondylitis Registry of Ireland. Patients who attended GUH submitted their data over 3 years. Their data was then collated retrospectively.

Results There were 43 patients; 5 female (11.6%), 38 males (88.4%). The median age was 42 years (21-82) with the median age at diagnosis, 35 years (17-72). 17 years (2-56) was the median duration of symptoms. In keeping with previous studies the average delay in diagnosis was 6.7 years. 55.8% have extra spinal manifestations; 60% of the female cohort and 55% of the male.

At diagnosis, 25.6% of the cohort were current smokers, 74.4% non smokers. ASQoL, BASDAI and BASFI scores for current smokers were higher than the same median values in non smokers. However, when compared using the Mann-Whitney U test this difference was not statistically significant; as demonstrated in table 1.

ASQoL, BASDAI and BASFI were also compared in males vs females using Mann-Whitney U test. Despite a higher median value of ASQoL in females it did not reach statistical significance.

Conclusions Although this is a small cohort of patients from the West of Ireland it could be deemed to be representative of a larger



population with a mean delay in diagnosis of 6.7 years in keeping with international trends. Although the median scores were not statistically significant in terms of smokers vs non-smokers, a significant difference in ASQoL scores were noted. Similarly BASDAI and BASFI scores were higher in smokers vs non-smokers and would suggest the trend is in keeping with international norms. Although the study does not definitively prove adverse effects of smoking in AS we should continue to recommend smoking cessation in every AS patient as part of their treatment plan.

Image 1

	Smokers	Non-smokers	P Value
ASQoL	5.00	4.00	0.41
BASDAI	3.5	3.00	0.62
BASFI	3.7	3.25	0.55
	Female	Male	P Value
ASQoL	10	4.00	0.15
BASDAI	4.3	3.1	0.78
BASFI	3.5	3.25	0.99

(17A154) ABSTRACT 47

POSTER 37

Depression assessment in Rheumatoid Arthritis patients in Rheumatology clinic in Connolly Hospital

Author(s) Al Ghafri Aadil¹, Hussain Omar¹, Duffy Trevor¹, Murphy Ethene¹, Barry Maurice¹

Department(s)/Institutions 1Department of Rheumatology, Connolly Hospital, Dublin, Ireland

Introduction Rheumatoid arthritis (RA) is a systemic, chronic, and inflammatory disease causes many harmful psychosocial consequences for patients. Continuous pain, functional disability, tiredness, incapacity to work, economic limitations, and side effects of therapeutic drugs, which RA may bring about, can end up reducing these patients' quality of life. Commonly associated with these biopsychosocial problems, psychiatric symptoms -especially depressive and anxiety ones- are relatively frequent in RA patients. Several studies have identified depressive symptoms as an important aspect in RA. The prevalence of depressive symptoms in RA has been reported to vary between 6% and 65%, according to the screening methods used and to the samples studied.

Aims/Background To determine the frequency of depressive and anxiety symptoms in patients with rheumatoid arthritis (RA) (a chronic inflammatory disease) and to evaluate rheumatologist adherence to depression and anxiety assessment and management in comparison to a control group with Diabetes Mellitus (DM) (a chronic non-inflammatory disease).

Method 60 RA patients and another 60 DM patients participated in the study. The Hospital Anxiety and Depression Scale (HADS) was applied.

Results Among 60 RA patients, 51(85.0%) had a normal depression score. 4(6.7%) were borderline and 5(8.3%) had an abnormal score. Regarding anxiety, 37(61.7%) had a normal score, 16(26.7%) were borderline and 7(11.7%) had an abnormal score. When depression and anxiety scores were combined, 35(58%) patients were normal, 3(5%) patients had abnormal score with 22(37%) of 60 patients either borderline or abnormal for anxiety/ depression. Of 60 RA patients, only 7(11.7%) patients had had formal assessment for depression and anxiety at the rheumatology clinic. 53(88.3%) did not receive any assessment. Of the 7 patients who received depression and anxiety assessment, only 1(13%) received it in rheumatology clinic, while

the remainder were assessed by their GP. Of the patients treated, 9 received medication, while only 1(1.7%) received a combination of medications and cognitive behavioural therapy (CBT).

Of the 60 DM patients, 47(78.4%) had a normal depression score, 5(8.3%) were borderline and 8(13.1%) were normal. 49(81.6%) had a normal anxiety score, 8(13.4%) were borderline and 3(5%) abnormal. Combining depression and anxiety scores, results were both normal in 28(46.6%) patients, both abnormal in 27 (45%) patients and borderline in 5(8.3%) patients. Out of 60 DM patients, only 18(30%) patients were formally assessed for depressive and anxiety symptoms, whilst 42(70%) didn't receive any assessment.

Of the 18 patients who received depression and anxiety assessment, only 2(3.3%) received it in the endocrine clinic, while the remainder 16(26.6%) were carried out by their GPs. Of patients treated, 9(15%) received medications, while only 6(10%) received combination of medications and CBT.

Conclusions This audit provides similar data for high frequency of depression and anxiety among RA patients. In addition, it shows under-assessment and under-treated depressive and anxiety symptoms in RA patients. Patient at risk should be screened and managed by medication, CBT, or both.

(17A159) ABSTRACT 48

POSTER 38

A Physiotherapy-led In-patient Intensive Rehabilitation Programme for Ankylosing Spondylitis: Follow-up Outcomes

Author(s) Caroline Clarke¹, Pauline Taggart¹, Julie Monaghan¹, Jonathan McKnight², Andrew Cairns²

Department(s)/Institutions 1. Physiotherapy Department, Mitre Rehabilitation Unit, Musgrave Park Hospital, Stockman's Lane, Belfast BT9 7JB. 2 Department of Rheumatology, Musgrave Park Hospital, Stockman's Lane, Belfast BT9 7B

Introduction Ankylosing Spondylitis (AS) is a chronic inflammatory rheumatological disease which primarily affects the axial spine. AS is associated with reductions in physical activity, work productivity and quality of life (O'Dwyer et al 2017).

Aims/Background To assess the short-term effectiveness of an intensive rehabilitation programme using BASMI and EASI-QOL outcomes, and long-term patient satisfaction and physical activity behaviour and adherence to exercise plan.

Method Thirty-two AS patients (25 males and 7 females) admitted to an in-patient rheumatology ward underwent a 1 to 2-week physiotherapy-led intensive rehabilitation programme and were discharged with a home exercise programme. Pre/post rehabilitation BASMI scores were available for 26 patients. The primary outcome measure was the proportion of patients achieving an improvement on BASMI scores at discharge. Secondary outcome measures included improvements in physical activity levels and adherence to home exercise plan for longer than 3 months which was obtained via a postal patient satisfaction and physical activity questionnaire which achieved a response rate of 50% (n=16).

Results Improvements in BASMI scores was achieved in 69% of patients (n=18) at the end of the in-patient rehabilitation period. Improvements in EASI-QOL were achieved in 83% of patients (n=15) at the end of the in-patient rehabilitation period. Ninety-four percent of patients (n=15) reported increased levels of physical activity after discharge, with 81% (n=13) of patients maintaining their home exercise programme for 3 months or more. Thirty-one percent (n=5) of patients carry out at least 150 minutes of physical activity per week (National Recommended Physical Activity Guidelines is 150 minutes/week of moderate intensity).

Restoring the Quality of Life.

Metoject® 50 mg/ml Solution for Injection, pre-filled syringe, in Everyday Life

Metoject® –
The 50 mg/ml methotrexate injection available in:

- 7.5mg / 0.15ml single syringe
- 10mg / 0.20ml single syringe
- 15mg / 0.30ml single syringe
- 20mg / 0.40ml single syringe
- 25mg / 0.50ml single syringe

Distributed in Ireland by:
Fannin Ltd
Fannin House
South County Business Park
Dublin 18
Ph: +353 1 290 7000
Fax: +353 1 290 7111

FN/2016/108/00
Date of Preparation: March 2017

Metoject 50 mg/ml solution for injection, pre-filled syringe (refer to full Summary of Product Characteristics before prescribing).
Qualitative and quantitative composition: 1 ml of solution contains 50 mg methotrexate (as methotrexate disodium). 1 pre-filled syringe of 0.15ml (0.20ml; 0.40 ml; 0.50ml) contains 7.5 mg (10 mg; 15 mg; 20 mg; 25 mg) methotrexate. Excipients: sodium chloride, sodium hydroxide, water for injections. **Therapeutic Indications:** Active rheumatoid arthritis in adult patients; severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids; severe psoriatic arthritis in adult patients. **Posology and method of administration:** Should only be prescribed by physicians who are familiar with the various characteristics of the medicinal product and its mode of action. **Adults: rheumatoid arthritis:** The recommended initial dose is 7.5 mg of Metoject once weekly, administered either subcutaneously, intramuscularly or intravenously. Depending on the individual activity of the disease and tolerability, the dose may be increased gradually by 2.5 mg per week. A weekly dose of 25 mg should not be exceeded. **Psoriasis vulgaris, psoriatic arthritis:** Test dose of 5–10 mg should be administered parenterally, one week prior to therapy to detect idiosyncratic adverse reactions. The recommended initial dose is 7.5 mg of methotrexate once weekly, administered either subcutaneously, intramuscularly or intravenously. The doses to be increased gradually but should not, in general, exceed a weekly dose of 25 mg of methotrexate. **Elderly:** Dose reduction should be considered due to reduced liver and kidney function as well as lower folate reserves. If changing from oral methotrexate a reduction in dose may be required due to the variable bioavailability of methotrexate by the oral route. **Contraindications:** Hypersensitivity to methotrexate or any of the excipients; liver insufficiency, alcohol abuse; severe renal insufficiency (creatinine clearance <20ml/min), pre-existing blood dyscrasias; (bone marrow hyperplasia; leukopenia; thrombocytopenia; Signiant anaemia); serious, acute or chronic infections such as tuberculosis, HIV, other immunodeficiency syndromes; ulcers of the oral cavity and known active gastrointestinal ulcer disease; pregnancy, breastfeeding; concurrent vaccination with live vaccines. **Special warnings and precautions for use:** Patients must be clearly informed that Metoject has to be administered once a week. Patients undergoing therapy should be subject to appropriate supervision. Because of the risk of the possibility of severe or even fatal toxic reactions, the patient should be fully informed by the physician of the risks involved and the recommended safety measures. **Interactions with other medicines:** Special care should be taken with Methotrexate and Alcohol, other haematotoxic medicinal products, antibiotics, other medicinal products with high plasma protein binding, probenecid, weak organic acids, pyrazoles, non-steroidal anti-inflammatory agents, medicinal products with adverse reactions on the bone marrow, medicinal products which cause folate deficiency, folic acid, other antineoplastic medicinal products, sulphasalazine, Mercaptopurine, proton-pump inhibitors, theophylline, caffeine or theophylline-containing beverages. **Fertility, pregnancy and lactation:** methotrexate is contraindicated during pregnancy and is excreted in breast milk and there is a risk for the infant. Methotrexate can be genotoxic, all women are advised to consult a genetic counselling centre, if possible, already prior to therapy. Men should seek advice about the possibility of sperm preservation before starting therapy. **Effects on ability to drive and use machines:** Metoject has minor or moderate influence on the ability to drive and use machines. **Undesirable effects:** The following headings are used to organise the undesirable effects in order of frequency: Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data). The most relevant undesirable effects are suppression of the haematopoietic system and gastrointestinal disorders. **Very common:** Stomatitis, dyspepsia, nausea, loss of appetite, common: oral ulcers, diarrhoea. **Uncommon:** pharyngitis, enteritis, vomiting, rare: gastrointestinal ulcers, very rare: haematemesis, haematochezia, toxic megacolon. **Skin and subcutaneous tissue disorders:** common: Exanthema, erythema, pruritus, uncommon: photosensitisation, loss of hair, increase in nevi, herpes zoster, vasculitis, herpesiform eruptions of the skin, urticaria. **Rare:** increased pigmentation; acne, actinomyces. **Very Rare:** Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyle's syndrome), increased pigmentation of the nails, acute paronychia, funiculosis, telangiectasia. **General disorders and administration site conditions:** Rare: Allergic reactions, anaphylactic shock, allergic vasculitis, fever, conjunctivitis, infection, sepsis, wound-healing impairment, hypogammaglobulinaemia. **Very Rare:** local damage of injection site following intramuscular or subcutaneous administration. **Metabolism and nutrition disorders:** uncommon: Precipitation of diabetes mellitus. **Nervous system disorders:** Common: headache, tiredness, drowsiness, uncommon: dizziness, confusion, depression. **Very rare:** impaired vision, pain, muscular asthenia and paraesthesia in the extremities, changes in sense of taste, convulsions, meningism, paralysis, unknown: **Leukoencephalopathy**. **Eye disorders:** Rare: Visual disturbances. **Very rare:** retinopathy. **Hepatobiliary disorders:** Very common: Elevated transaminases. **Uncommon:** cirrhosis, fibrosis and fatty degeneration of the liver, decrease of serum albumin. **Rare:** acute hepatitis, **Very Rare:** hepatic failure. **Cardiac disorders:** Rare: Pericarditis, pericardial effusion, pericardial tamponade. **Vascular disorders:** Rare: Hypotension, thromboembolic events. **Respiratory, thoracic and mediastinal disorders:** Common: Pneumonia, interstitial alveolitis/pneumonitis often associated with eosinophilia. **Rare:** pulmonary fibrosis, pneumocystis carinii pneumonia, shortness of breath and bronchial asthma, pleural effusion. **Blood and lymphatic system disorders:** Common: Leukopenia, anaemia, thrombopenia. **Uncommon:** pancytopenia. **Very rare:** agranulocytosis, severe courses of bone marrow depression. **Renal and urinary disorders:** uncommon: Inflammation and ulceration of the urinary bladder renal impairment, disturbed micturition. **Rare:** renal failure, oliguria, anuria, electrolyte disturbances. **Reproductive system and breast disorders:** **Uncommon:** Inflammation and ulceration of the vagina. **Very rare:** Loss of libido, impotence, gynaecomastia, oligospermia, impaired menstruation, vaginal discharge. **Musculoskeletal and connective tissue disorders:** uncommon: Arthralgia, myalgia, osteoporosis. **Neoplasms benign malignant and unspecified (incl. cysts and polyps):** Very rare: Reports of individual cases of lymphoma which subsided in a number of cases once treatment with methotrexate had been discontinued. **Overdose:** Calcium folinate is the specific antidote for neutralising the toxic undesirable effects of methotrexate. **Legal classification:** POM. **Marketing Authorisation Holder:** Medac Gesellschaft für Klinische Spezialpräparate MbH, Theaterstr.6,22880 Wedel, Germany. **Marketing authorisation number:** PA 623/14/1. **Date of Revision of PI:** February 2017. **MARKETED IN IRELAND BY:** FANNIN LTD, FANNIN HOUSE, LEOPARDSTOWN, DUBLIN 18.

For a copy of the SmPC or further medical information, please contact medical@DCCVital.com. Adverse events should be reported to Fannin Ltd, Pharmacovigilance at +353 868394447 or medical@DCCVital.com

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions via HPR Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. REF: IE17/05/SmPC - APR2015



Conclusions This recent audit shows the effectiveness of an intensive physiotherapy-led in-patient rehabilitation programme for Ankylosing Spondylitis improving BASMI scores in the short-term and increasing physical activity behaviour over the long-term. Future work will aim to compare demographics and medical treatment differences between improvers and non-improvers.

Reference O'Dwyer T., Monaghan A., Moran J., O'Shea, Wilson F (2017) Behaviour change intervention increases physical activity, spinal mobility and quality of life in adults with ankylosing spondylitis: a randomised trial. *Journal of Physiotherapy* 63: 30-39

Image 1

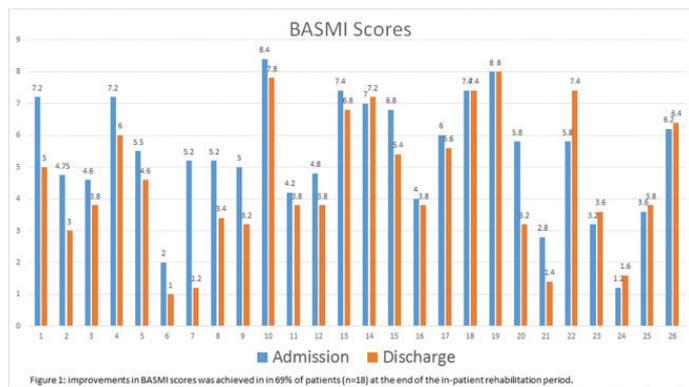
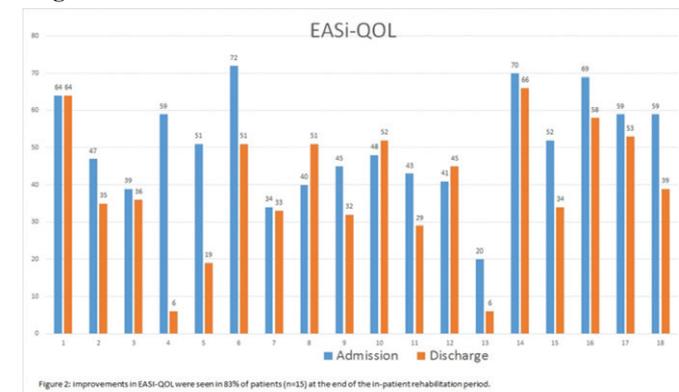


Image 2



(17A163) ABSTRACT 49

POSTER 39

The Threshold of Vitamin D Deficiency should not be related to PTH

Author(s) Maria Walsh, Donncha O'Gradaigh, Melanie Fox

Department(s)/Institutions Department of Rheumatology, UHW

Introduction The interaction between parathyroid hormone (PTH) levels, calcium levels and vitamin D is not fully explained. Threshold levels of vitamin D deficiency have been determined based on changes in PTH, and adverse effects on bone are thought to be mediated by PTH. However, both serum vitamin D levels and serum PTH measurements are usually taken during assessment of bone health.

Aims/Background To measure the correlation between PTH and vitamin D and to determine if a cut-off point of PTH measurement could be identified that would signify vitamin D deficiency / sufficiency without the need to run both tests.

Method A pragmatic sample group from the DXA and FLS Report database (2014-17) at Department of Rheumatology, UHW, which is filed by patient MRN. A sample of 230 reports were screened. Of these, 105 had measurements of both serum 25-hydroxy-vitamin D

[vitamin D] and serum intact PTH [PTH] available (15 males (mean age=67) and 90 females (mean age=68)).

Results In total, 105 contemporaneous samples of vitamin D and PTH levels were analysed. A correlation of -0.3 between serum 25hydroxy vitamin D level and serum intact PTH was found. Mean vitamin D in those with normal PTH level (<65pg/ml) was 61 nmol/L. Mean vitamin D when PTH was raised (>65pg/ml) was 41nmol/L. As 36% of patients with normal PTH had vitamin D <50nmol/L (false negative) while 40% of those with raised PTH had vitamin D >50nmol/L (false positive), a cut-off value was not realistic and ROC analysis was not carried out. One case of hypercalcaemia was noted, and follow-up revealed a parathyroid adenoma. (This patient has declined surgery and remains medically well). Potential variation in PTH assay secondary to delay in transportation of samples from a wide geographical area was excluded in a sub-study with the UHW laboratory. A sample of those patients with discordant results were requested to present for repeat blood tests to exclude the possibility of a blunted parathyroid response to vitamin D supplementation, but too few complied to allow analysis.

Conclusions The relationship between vitamin D, parathyroid hormone and calcium is complex, and the literature on effects on bone turnover suggests that the requirement for vitamin D intervention should be based on a threshold of 50nmol/L irrespective of parathyroid levels. Our finding of a poor correlation is consistent with the literature in other, non-Irish settings.

(17A167) ABSTRACT 50

POSTER 40

The Effect of Certolizumab Pegol on Extra-Articular Manifestations of Psoriatic Arthritis Over 4 Years of Treatment in Patients With and Without Prior Anti-TNF Exposure

Author(s) O. FitzGerald¹, R. Fleischmann², A. Kavanaugh³, B. Hoepken⁴, L. Peterson⁵, D. Gladman⁶

Department(s)/Institutions 1St. Vincent's University Hospital and Conway Institute for Biomolecular Research, University College Dublin, Dublin, Ireland, 2UT Southwestern Medical Center and Dallas Metroplex Clinical Research Center, Dallas, 3UC San Diego School of Medicine, La Jolla, United States, 4UCB Pharma, Monheim, Germany, 5UCB Pharma, Raleigh, United States, 6Krembil Research Institute, Toronto Western Hospital, Toronto, Canada preprocessed

Introduction Extra-articular manifestations (EAMs) of psoriatic arthritis (PsA) include nail psoriasis, dactylitis, and enthesitis, which can significantly impact patients' (pts') quality of life. In the RAPID-PsA trial (NCT01087788), certolizumab pegol (CZP) improved the signs and symptoms of EAMs in pts with PsA over 96 weeks (wks).

Aims/Background

To report improvements in EAMs of PsA in pts treated with CZP over 4 years, both with and without prior anti-TNF exposure.

Method The RAPID-PsA trial was double-blind and placebo-controlled to Wk24, dose-blind to Wk48, and open-label (OL) to Wk216. Pts had active PsA and had failed ≥1 DMARD. Pts originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose at Wks0, 2, 4) continued their assigned dose in the OL period. We present EAM data for those pts originally randomized to CZP, with involvement of the particular EAM at baseline (BL), and both with and without prior anti-TNF exposure. EAMs assessed include nail psoriasis (modified Nail Psoriasis Severity Index [mNAPSI], BL involvement = BL mNAPSI >0), enthesitis (Leeds Enthesitis Index [LEI], BL involvement = BL LEI >0), and dactylitis (Leeds Dactylitis Index [LDI], BL involvement = ≥1 digit affected with a difference in circumference ≥10% compared to the opposite digit). Also presented are the proportions of pts with BL involvement of each EAM who achieved total resolution of the respective EAM on follow-up (a score of 0 for mNAPSI, LEI, or LDI). Observed



values are reported, combined for pts receiving either CZP dose regimen.

Results A total of 409 PsA pts were randomized; 273 received CZP from Wk0. Among CZP-randomized pts, 197 had nail psoriasis at BL (159 without, and 38 with, prior anti-TNF exposure), 172 had enthesitis (133 without, and 39 with, prior anti-TNF exposure), and 73 had dactylitis (56 without, and 17 with, prior anti-TNF exposure). Although relatively few pts were anti-TNF experienced, a large proportion of pts both with and without prior anti-TNF exposure with BL involvement went on to achieve total resolution of the respective EAM following 48 wks of CZP treatment (Table). Among pts completing the study, the proportions achieving total resolution were maintained or further increased from Wk48 to Wk216 (Table). Mean scores of all EAMs assessed showed improvements by Wk48 of CZP treatment in pts both with and without prior anti-TNF exposure, which were maintained to Wk216 in pts completing the study (Table).

Conclusions PsA patients treated with CZP for up to 4 years, both with and without prior anti-TNF exposure, exhibited sustained improvements in the extra-articular manifestations of PsA.

Image 1

Table: Improvements in extra-articular manifestations of PsA over 216 weeks of CZP treatment in patients with and without prior anti-TNF exposure (observed values)

	Week 0 CZP dose combined (N=273)			
	Baseline	Week 48	Week 96	Week 216
Number of patients observed				
Mean score (standard deviation)				
Patients with total resolution, n (%)				
Nail psoriasis (mNAPSI) [a]				
Anti-TNF naive (n=159)	159 (3.4 (2.1))	139 (1.1 (1.5))	129 (0.7 (1.3))	109 (0.4 (0.8))
Anti-TNF experienced (n=38)	38 (2.9 (1.8))	33 (0.9 (2.1))	29 (0.6 (1.1))	23 (0.5 (0.7))
Enthesitis (LEI) [b]				
Anti-TNF naive (n=133)	133 (3.0 (1.7))	116 (0.8 (1.5))	104 (0.7 (1.3))	85 (0.5 (1.0))
Anti-TNF experienced (n=39)	39 (2.9 (1.6))	33 (1.2 (2.1))	27 (0.8 (1.4))	25 (0.5 (1.2))
Dactylitis (LDI) [c]				
Anti-TNF naive (n=56)	56 (50.9 (64.7))	48 (0.0 (0.0))	46 (0.0 (0.0))	41 (0.3 (2.1))
Anti-TNF experienced (n=17)	17 (52.5 (42.7))	14 (12.6 (25.3))	11 (0.0 (0.0))	9 (11 (78.6))

EAMs were assessed in patients with involvement of the respective EAM at baseline. [a] Patients with mNAPSI >0 at baseline; [b] Patients with LEI >0 at baseline; [c] Patients with LDI >0 at baseline, defined as having at least 1 digit affected and with a difference in circumference $\geq 10\%$ compared to the opposite digit.

(17A169) ABSTRACT 51

POSTER 41

The Efficacy of Certolizumab Pegol over 4 Years in Psoriatic Arthritis Patients With and Without Concomitant Use of DMARDs

Author(s) O. FitzGerald¹, J. Walsh², A. B. Gottlieb³, B. Hoepken⁴, T. Nurminen⁴, P. J. Mease⁵

Department(s)/Institutions 1St. Vincent's University Hospital and Conway Institute for Biomolecular Research, University College Dublin, Dublin, Ireland; 2Division of Rheumatology, University of Utah, UT, USA; 3Department of Dermatology, New York Medical College, NY, USA; 4UCB Pharma, Monheim, Germany; 5Swedish Medical Center and University of Washington, WA, USA.

Introduction In RAPID-PsA (NCT01087788) certolizumab pegol (CZP) improved signs and symptoms of psoriatic arthritis (PsA) over 4-years' treatment.

Aims/Background Here we report short- and long-term efficacy of CZP with and without concomitant DMARD use, including effects on extra-articular manifestations of the disease (EAMs).

Method RAPID-PsA was double-blind and placebo-controlled to Week (Wk)24, dose-blind to Wk48 and open-label (OL) to Wk216. Patients (pts) had active PsA with ≥ 1 failed DMARD. Wk0 CZP-randomized pts (200mg Q2W or 400mg Q4W, following 400mg loading dose at Wks 0, 2, 4) continued their assigned dose in OL. We report efficacy to Wk216 for pts receiving CZP from Wk0 (dose

combined) with and without DMARD use at baseline (BL; DMARD+ and DMARD-). Outcomes included ACR20, Psoriasis Area Severity Index (PASI), Leeds Enthesitis Index (LEI), and Leeds Dactylitis Index (LDI) in pts with involvement of the respective EAM at BL (psoriasis: BSA $\geq 3\%$; enthesitis: LEI >0; dactylitis: ≥ 1 digit affected and LDI ≥ 0). Data are observed case (OC) and imputed: NRI for dichotomous outcomes and LOCF for quantitative data.

Results 273 pts received CZP from Wk0. 74 (27.1%) CZP pts were DMARD-, 6 (8.1%) of whom initiated a new DMARD during the study. 8 DMARD+ pts (4.0%) increased, 29 (14.6%) reduced/discontinued and 13 (6.5%) increased and reduced/discontinued DMARD use. 141 (70.9%) DMARD+ and 42 (56.8%) DMARD- pts completed Wk216. Efficacy of CZP in both DMARD+ and DMARD- pts was maintained over 4 years (NRI [OC]: DMARD+: ACR20 at Wk24=62.8%, at Wk216=57.3% [79.7%]; DMARD-: ACR20 at Wk24=52.7%, at Wk216=47.3% [83.3%]). Among DMARD+ and DMARD- pts, at BL, 113 and 53 (56.8%; 71.6%) had psoriasis (mean PASI=11.4; 13.3), 125 and 47 (62.8%; 63.5%) enthesitis (mean LEI=3.1; 2.7), and 47 and 20 (23.6%; 27.0%) dactylitis (mean LDI=54.3; 59.7). Improvements in EAMs at Wk24 were maintained to Wk216 in both DMARD+ and DMARD- pts (imputed [OC]: DMARD+ pts: mean PASI at Wk24=2.6, at Wk216=2.3 [1.7]; PASI75 at Wk24=57.5%, at Wk216=54.0% [79.2%]; mean LEI at Wk24=1.0, at Wk216=0.8 [0.6]; mean LDI at Wk24=3.7, at Wk216=4.3 [0.4]; DMARD- pts: mean PASI at Wk24=2.9, at Wk216=3.2 [2.2]; PASI75 at Wk24=69.8%, at Wk216=47.2% [78.1%]; mean LEI at Wk24=1.0, at Wk216=0.9 [0.2]; mean LDI at Wk24=5.7, at Wk216=3.7 [2.5]).

Conclusions Pts completing RAPID-PsA, treated with CZP both with and without concomitant DMARD use, showed sustained improvements in their disease, maintained over 4 years.

(17A170) ABSTRACT 52

POSTER 42

Tofacitinib alters monocyte-derived dendritic cell differentiation in rheumatoid arthritis and psoriatic arthritis.

Author(s) Marzaioli Viviana, Canavan Mary, Wade Siobhán, Low Candice, Douglas J. Veale, Fearon Ursula

Department(s)/Institutions The Department of Molecular Rheumatology, Trinity College Dublin

Introduction Tofacitinib (Pfizer) is an oral Janus kinase inhibitor, recently approved for the treatment of rheumatoid arthritis (RA). An emerging body of literature has investigated the mechanism of action of Tofacitinib in circulating cells, in particular neutrophils and lymphocyte. However, its effect on dendritic cell development has not been yet explored.

Aims/Background The aim of this project is to evaluate the effect of Tofacitinib on inflammatory monocyte-derived dendritic cells (Mo-DC), and in particular on the ability of monocyte to differentiate into dendritic cells, an important step in innate immunity.

Method Mo-DC were isolated from blood of healthy donor and RA and psoriatic arthritis (PsA) patients by magnetic separation. Monocyte were plated in presence/absence of GM-CSF/IL-4 cocktail for 7 days, to acquire immature dendritic cell phenotype. To evaluate the function of Tofacitinib on Mo-DC differentiation, monocyte were treated with Tofacitinib for 15 minute prior to cytokine stimulation. CD209 (immature DC marker) and CD14 (monocyte marker) were evaluated by flow cytometry in the CD11c positive population.

Results Tofacitinib inhibited Mo-DC differentiation in both healthy and RA, as shown by reduced CD209 surface marker expression. Interestingly, a decrease in CD209 marker was mirrored by an increase in the monocyte surface marker CD14. In addition, we analysed monocyte from PsA patients and we observed a similar



decrease in Mo-DC differentiation, after Tofacitinib treatment. Preliminary data suggest that Tofacitinib also inhibited LPS-induced Mo-DC maturation, reducing CD86, CD80 and CD40 maturation markers.

Conclusions Together, these observations suggest a novel mechanism of action of Tofacitinib in RA and PsA, by inhibiting Mo-DC development, which may alter migration of DC to the joint and subsequent activation of the immune response. Further studies will evaluate the functional implication of these observations.

(17A172) ABSTRACT 53

POSTER 43

Revision of an Occupational Therapy (OT) and Physiotherapy (PT) combined care pathway for the conservative management of OA of the first CMC joint; A quality improvement project

Author(s) Paula Minchin, Senior Occupational Therapist
Carol Rafferty, Senior Occupational Therapist
Sarah O’Driscoll, Senior Physiotherapist
Maria Mc Grath, Senior Physiotherapist
Department(s)/Institutions Occupational Therapy & Physiotherapy Department, Tallaght Hospital.

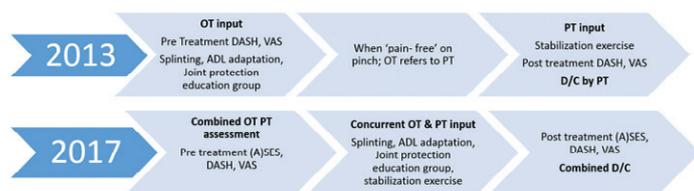
Introduction A combined OT/PT evidence-based OA CMCJ pathway, established in 2013, ceased functioning due to OT staff shortages in 2016. This created a 12 month wait for OT input, which increased the chronicity of the caseload, and failed to maximise outcomes post-injection. Where OT was not involved, patients missed the vital components of joint protection group education, functional adaptation and pain management through splinting (1-3). When OT input was delayed, increased numbers of patients were referred back to the medical team for injection/surgical review. Also, Physiotherapy input for stability and strengthening was delayed as a result.

Aims/Background To update the original pathway, ensuring it is in line with current evidence based practice (EBP) (4) and providing maximum efficiency and minimal waiting times for OA CMCJ patients.

To set up a database of outcome measures to facilitate a study of pathway outcomes in 2018.

Method When staff allocation was restored, the pathway was revised as follows, to include Joint OT/PT assessment, joint documentation, inclusion of the Arthritis Self-Efficacy Scale (A)SES as an outcome measure to reflect the importance of self-management (2), and earlier inclusion of stabilisation exercise for suitable patients. We set an aim to see ‘post-injection’ patients within 1 month, and conservatively managed patients within 3 months.

Image 1



Results

20 patients have commenced the new pathway via 10 joint OT/PT appointments. 50% (n=10) have been seen within the target timeframe of 3 months (a reduction of 9 months). All post-injection patients (n=5) have been seen within the target of 1 month (a reduction of 11 months). Pre-treatment outcome measures have been recorded for these patients, in preparation for an upcoming review of

the service in 2018.
(17A173) ABSTRACT 54

POSTER 44

Review of low-dose rituximab for retreatment of rheumatoid arthritis.

Author(s) Omer Hussein, Trevor Duffy, Maurice Barry
Department(s)/Institutions Rheumatology Department, Connolly Hospital Blanchardstown

Introduction Rituximab is a monoclonal antibody against CD20 which selectively depletes B-cells. It is effective in treatment of rheumatoid arthritis (RA) which is refractory to methotrexate and other biologics. There is a need to achieve sustained efficacy by repeated courses of rituximab. The licensed initial dose is course of two 1000 mg, however different retreatment doses have been studied. The low-dose of rituximab for retreatment showed no clear difference in outcomes from the higher dose. In our department in Connolly Hospital Blanchardstown we use the first course of rituximab as the licensed dose of two 1000 mg infusions, followed by low maintenance dose of single 500 mg infusion every six months.

Aims/Background We aim to evaluate the response of low maintenance dose of rituximab for treatment of rheumatoid arthritis in our department.

Method We reviewed charts of 24 patients of rheumatoid arthritis who are on rituximab maintenance therapy. We assessed the current dose and duration. Erythrocyte sedimentation rate (ESR) and C-Reactive protein (CRP) were recorded from last six months. Three patients had DAS28 reported.

Results Out of 24 patients, 22 patients are on 500 mg maintenance dose, one patient is on 750 mg and one patient is on 1000 mg dose. The average duration of the current dose is 37 months. The average for recent CRP is 5.45 (range 0.45 – 32.12) and for ESR is 20.16 (range 2 - 70). Two patients showed evidence of disease activity and their rituximab dose was increased. Three patients had their DAS28 recorded with low disease activity.

Conclusions Maintenance low-dose rituximab treatment of our rheumatoid arthritis patients seems to be effective and maintains low disease activity. This is supported by the prolonged period of same dose (average duration of 37 months) and low inflammatory markers. Those patients will have to be followed to have their DAS28 reported. Using low dose could be cost-saving as well as using single dose which means a day less of hospitalization per patient.

(17A175) ABSTRACT 55

POSTER 45

Undetected High Fracture Risk in an Acute Medical Inpatient Cohort

Author(s) Deniz Demirdal¹, Gillian Fitzgerald¹, Eimear Keane¹, Caleb Powell¹, Declan Byrne², Finbar O’ Shea¹

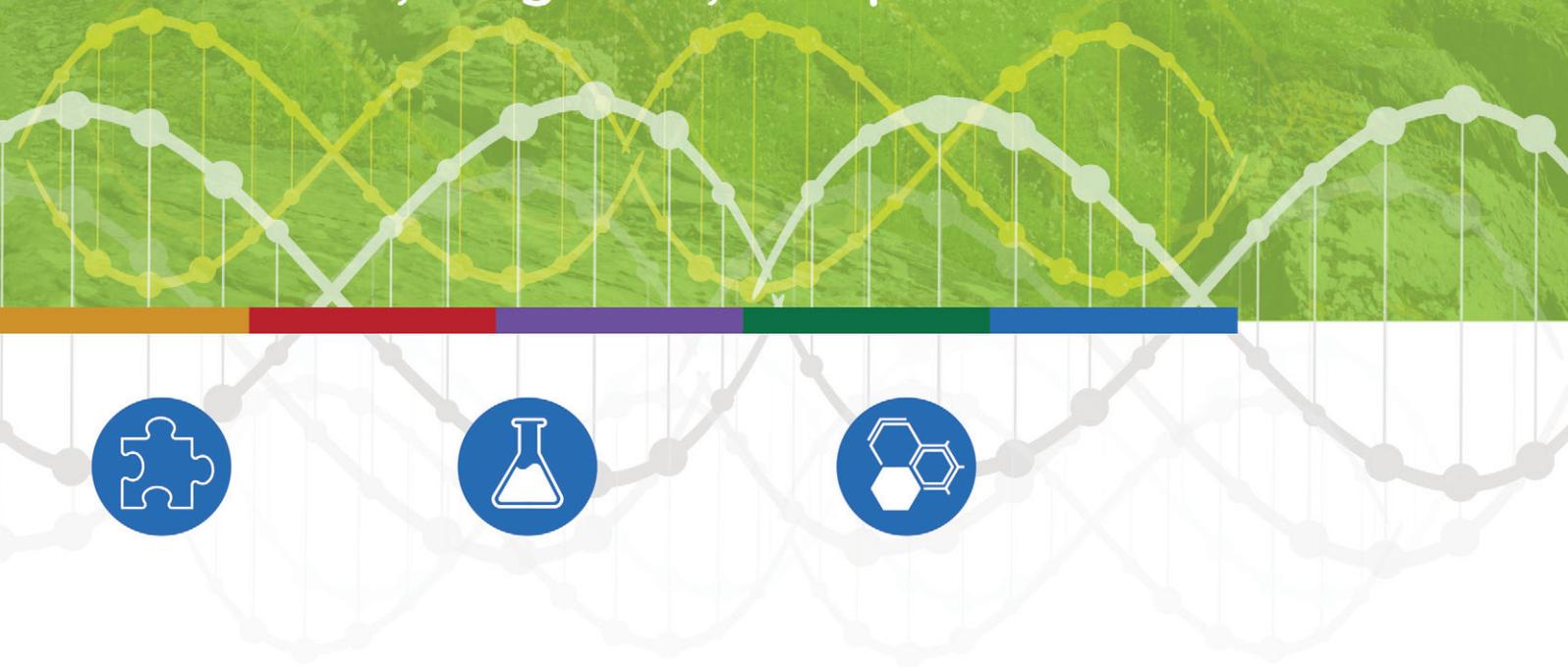
Department(s)/Institutions 1. Department of Rheumatology, St James’s Hospital, Dublin 8. 2. Department of Medicine, St James’s Hospital, Dublin 8

Introduction Osteoporosis is a growing public health problem, with significant morbidity and mortality. It is poorly managed, with most individuals at high risk neither identified nor treated, including those who have already fractured. The majority of fractures occur in patients at moderate risk. The World Health Organisation (WHO) Fracture Risk Assessment tool (FRAX) is a validated computer based algorithm that provides models for the assessment of fracture probability in men and women. It uses easily obtained clinical risk factors to estimate the 10-year probability of a major osteoporotic fracture and hip fracture.



Join Our Journey

We aim to significantly advance genomic research in Ireland to help improve patients' lives through disease treatment, diagnosis, and prevention.



**Now seeking clinical collaborations
for GMI-sponsored studies on
Spondyloarthropathies (AS and nr-AxSpA)**

For more information,
visit us at our exhibition stand at ISR 2017 or
contact Karl Quinn, Clinical Partnerships Leader,
karl.quinn@genomicsmed.ie





Aims/Background The aim of this study is to determine the fracture risk of a patient cohort admitted under an acute medical team of an inner city tertiary teaching hospital.

Method Consecutive patients between the age of 40 and 90 years admitted under an acute medical speciality in St James's Hospital over a 3-month period were screened. Patients were excluded if they lacked capacity to answer questions or had exposure to osteoporosis treatments. We evaluated previous fractures, family history of fractures, smoking, alcohol consumption, use of glucocorticoids and secondary causes of osteoporosis. Weight and height of the participants was measured. The FRAX tool was used to calculate the 10-year probability of a major osteoporotic and hip fracture. The National Osteoporosis Guideline Group (NOGG) intervention thresholds were used to categorise patients into low, medium or high fracture risk.

Results In total, 54 patients (51.9% (n=28) females, mean age 68.8 ± 14.5 years) were screened. The mean BMI is 26.6 kg/m^2 (SD 8.1) and 48.2% of the cohort is overweight or obese. With regards to clinical risk factors, 25.9% are smokers, 16.7% have had clinically significant exposure to steroids, 16.7% have risk factors for secondary osteoporosis, 18.5% of patients consume more than 3 units of alcohol per day and 20.4% have had a fragility fracture. The mean 10-year risk of a major osteoporotic fracture is 12.3% (SD 8.8) and of a hip fracture is 5.7% (SD 6.2). Applying the NOGG thresholds, 48.1% of the cohort is in the low risk category for fracture, 37% are in the intermediate category and 14.8% are in the high-risk category. No-one in the low-risk category has ever had a fracture. However, 30% of patients in the intermediate and 62.5% of patients in the high-risk categories have had fragility fractures.

A dual-energy x-ray absorptiometry (DXA) scan has been previously performed in 36.8% of patients with intermediate fracture risk and 75% of patients with high fracture risk.

Conclusions Over 50% of acute medical inpatients have an intermediate or high 10-year risk of fracture. One-third of the intermediate and almost 2/3 of the high-risk groups have already sustained a fragility fracture, yet are not on treatment. This suggests that the FRAX tool is not being used effectively to capture patients at risk of fracture.

(17A176) ABSTRACT 56

POSTER 46

One-year impact of osteoporotic hip fracture and practices of post-fracture osteoporosis management: a snapshot from a single Irish centre

Author(s) Shehla Farrukh, Mohsin Ashraf, Muhammad Haroon

Department(s)/Institutions Division of Rheumatology, Department of medicine, University Hospital Kerry, Tralee

Introduction Hip fractures, which are potentially avoidable are one of the most devastating complications of osteoporosis.

Aims/Background To assess one-year mortality and morbidity of hip fractures. To observe the practices of osteoporosis management post-hip fracture

Method Patients presented in University Hospital Kerry with hip fractures from January 2014 through to December 2014 (one year) were identified, and contacted by telephone. A short interview was carried out to assess the mortality and morbidity impact of osteoporotic hip fractures, especially on their level of functionality.

Results During the study period, 127 individuals were admitted with hip fractures, with a mean age 78.6 ± 11 years, and females predominance (67%). At the time of assessment, 35.4% (n=45) of patients had died, and the rest of patients (n=82) underwent interview assessments. Prior to hip fracture, only 18% of these patients were known to have osteoporosis; 23.6% of patients had previous fragility fractures; and only 3% (n=4) of patients were using pharmacologic

treatment for osteoporosis. Post hip fracture, only 27% (n=22) of patients were using pharmacologic osteoporotic treatment. Since hip fracture, only 24% of patients returned to their baseline functional level, and 28% ended up in long-term residential care. Patients with prior fragility fracture were significantly more likely to die within one year ($p=0.008$)

Conclusions Osteoporosis-related hip fractures are associated with significant mortality and functional decline but remain poorly managed. Prior fracture in such patients was found to have significant association with mortality.

(17A178) ABSTRACT 57

POSTER 47

Prevalence of Abdominal Aortic Calcification in Ankylosing Spondylitis Cohort

Author(s) Salim Sebaoui¹, Gillian Fitzgerald², Finbar O' Shea²

Department(s)/Institutions 1. School of Medicine, Trinity College Dublin. 2. Department of Rheumatology, St James's Hospital, Dublin 8

Introduction Ankylosing spondylitis (AS) is a chronic inflammatory condition predominantly affecting the axial skeleton. Recent literature has demonstrated an increased cardiovascular (CV) risk in AS patients. Abdominal aortic calcification (AAC) on plain radiographs is a marker of CV risk, both in the general population and in rheumatoid arthritis (RA), with an estimated prevalence of 25 to 50% in people over 50 years. To our knowledge, no studies have reported on AAC in AS.

Aims/Background The aim of this study is to determine the prevalence of AAC in AS and explore relationships.

Method AS patients were recruited from the St. James's Hospital Spondylitis Clinic. Demographic data, comorbidities, patient-reported outcome measures and spinal metrology were collected. Lateral lumbar spinal radiographs were evaluated by consensus using a previously validated 24-point AAC severity scale (AAC24), where 0 represents no AAC and 24 represents maximum AAC. AAC24 scores were subdivided into four categories (0: no calcification, 1-4: mild, 5-12: moderate, and >12 severe). Radiographic severity was quantified using the modified Stoke AS spinal score (mSASSS). Statistical analysis was performed using SPSS software.

Results Between May and July 2017, 57 patients with radiographic AS (mean age: $50.89 (\pm 11.36)$ years; 73.7% (n=42) male) were consecutively recruited. Baseline demographic and disease-related variables are outlined in Table 1. Aortic calcification is present in 36.8% (n=21) of the cohort; 22.8% (n=13) are mild and 14% (n=8) are moderate. AAC24 correlates positively with age ($r=0.415$, $p<0.01$; mean age difference 6.6 years, $p=0.03$), disease duration ($r=0.412$, $p<0.01$) and delay to diagnosis ($r=0.3$, $p=0.02$). The prevalence of hypertension is significantly higher in patients with calcification than those without (52.4% (n=11) vs. 22.2% (n=8), $p=0.04$). In smokers, AAC24 correlates positively with increasing number of cigarettes per day ($r=0.334$, $p=0.04$). There is no difference in the prevalence of AAC in patients with hypercholesterolaemia or diabetes. There is no association between AAC24 and mSASSS, BASDAI, ASDAS or BASMI. However, there is a positive correlation with both AS quality of life (ASQoL) ($r=0.33$, $p=0.01$) and fatigue severity scale scores ($r=0.272$, $p=0.04$).

Conclusions The prevalence of AAC in this AS cohort is 36.8%, which is comparable to that of the general population and RA. Age and hypertension are associated with AAC. Of specific interest, there is no relationship with disease activity or radiographic damage, but patients with AAC have worse quality of life scores. Further studies are required to explore the association of AAC with CV disease in AS patients.



Table 1. Baseline demographic and disease characteristics of the study population.

Characteristics	All patients (n=57)
Age, years	50.89 (± 11.36)
Male	42 (73.7%)
Caucasian	56 (98.2%)
BMI, kg/m ²	28.7 (± 6.31)
• Normal	16 (28.1%)
• Overweight	23 (40.4%)
• Obese	18 (31.4%)
Smoking Status	
• Current	14 (24.6%)
• Past	24 (42.1%)
• Never	19 (33.3%)
Disease duration, years	23.5 (± 11.69)
Delay to diagnosis, years	8.7 (± 8.87)
Co-morbidities:	
• Ischaemic Heart Disease	1 (1.8%)
• Hypertension	19 (33.3%)
• Hyperlipidaemia	21 (36.8%)
BASDAI	3.9 (± 2.3)
BASMI	4.2 (± 1.9)
ASDAS-ESR	2.2 (± 1)
ASDAS-CRP	2.1 (± 1.2)
Currently on NSAIDs	25 (41.0%)
Currently on biologic agent	33 (57.9%)
mSASSS, median (interquartile range)	12 (23.3)
Abnormal mSASSS (Score > 0)	53 (93%)

Variables are n (%), mean (± standard deviation). ASDAS: ankylosing spondylitis disease activity score, BASDAI: Bath ankylosing spondylitis disease activity index, BASMI, Bath ankylosing spondylitis metrology index, BMI: body mass index, CRP: C-reactive protein, ESR: erythrocyte sedimentation rate, mSASSS: modified Stoke ankylosing spondylitis spinal score, NSAIDs: non-steroidal anti-inflammatory drugs.

Table 1:

Duration of treatment (wk)	Number discontinued (%) n=29
≤ 1	1 (3.44%)
1- 4	9 (31.03%)
4-24	16 (55.71%)
24-52	2 (6.7%)
>52	1 (3.44%)

Table 2:

Side Effects leading to discontinuation	Frequency (%) N=21
GI upset	95% (20)
• Nausea and vomiting	38.1% (8)
• Diarrhoea	57.1% (12)
Headache	28.57% (6)
Mood disturbance	19% (4)
Other	19% (4)

(17A180) ABSTRACT 58

POSTER 48

Audit: Discontinuation of Apremilast in a Cohort of Rheumatology Patients

Author(s) Úna Lannin, Safi Alqatari, Usman Amin, Aoife Driscoll, Gráinne Murphy, John Ryan
Department(s)/Institutions Rheumatology Department, Cork University Hospital.

Introduction Apremilast is an orally-active agent. It works by inhibiting phosphodiesterase-4 (PDE4) and modulates the production of interferon (IFN)-gamma, TNFalpha, IL-12 and IL-23 – the pro-inflammatory cytokines that play a major role in the pathogenesis of psoriatic arthritis (1). Clinical trials have demonstrated its efficacy and safety in the management of psoriatic arthritis. The most commonly reported side effect was gastrointestinal upset with studies demonstrating discontinuation rates of 2-3% (2).

Aims/Background To estimate the discontinuation rate of apremilast in a single centre cohort of rheumatology outpatients

To investigate the reasons for discontinuation of apremilast

Method We used a local patient database to identify all patients commenced on apremilast within our unit. A chart review and telephone interview was conducted to obtain the following variables: patient demographics, indication for drug initiation, disease duration, date commenced on apremilast, date apremilast discontinued, dosing regimen and reason for discontinuation of apremilast.

Results Thirty nine patients were included in the study. 66.6% of patients were female. The majority of patients (56.4%) were aged between 46-65years. 36 (92.3%) patients had psoriatic arthritis, 2 had Behcet's disease and 1 had enteropathic arthritis. The majority of patients (51.3%) had a disease duration of 1-5 years (see table 1). Most patients (87.2%) were taking the full dose regimen (30mg PO BD) at the time of discontinuation.

30 patients (76.9%) discontinued apremilast. 11 (28.2%) patients stopped due to inefficacy. The remainder of patients (53.6%, n=21) stopped due to side effects after an average of 11.6 weeks (see Table 2). Some patients reported more than one side effect.

9 patients (23.1%) continued to take apremilast. Of these, 6 reported side effects but continued the apremilast because of efficacy.

Conclusions In our cohort, there was a high discontinuation rate of apremilast. The most common reason for discontinuation was gastrointestinal upset, mainly diarrhoea.

(17A181) ABSTRACT 59

POSTER 49

Human synovial fibroblasts and CD4 T cells cooperate to promote inflammation in the RA synovial joint

Author(s) Andreea Petrasca¹, Grainne Jameson¹, Trudy McGarry², Douglas J Veale³, Ursula Fearon^{2,3} and Jean M Fletcher^{1,2}

Department(s)/Institutions 1 School of Biochemistry & Immunology, Trinity Biomedical Sciences Institute, Trinity College Dublin, Ireland. 2 School of Medicine, Trinity Biomedical Sciences Institute, Trinity College Dublin, Ireland

Introduction Rheumatoid arthritis (RA) is a chronic autoimmune disease characterised by synovial tissue proliferation and degradation of articular cartilage. Activated synovial fibroblasts proliferate and express matrix-degrading proteases, adhesion molecules and proinflammatory cytokines, which contribute to cartilage and joint destruction. Moreover, synovial cell activation correlates with infiltration of inflammatory lymphocytes and monocytes which in turn contribute to synoviocyte activation, thus further exacerbating inflammation.

Aims/Background The functional relationship linking fibroblasts and T lymphocytes in this complex microenvironment has yet to be characterised. Therefore, we established an in vitro model to examine the outcomes of co-culturing activated human CD4 T cells with RA synovial fibroblasts.

Method Co-culture assays were carried out using synovial fibroblast cells derived from arthroscopy biopsies of RA patients or immortalised K4 synovial fibroblasts. Human CD4 T cells were stained with a proliferation-tracking dye, stimulated and co-cultured with synovial fibroblasts for 5 days. The resulting cell cultures and supernatants were examined for proliferation, cytokine production, secretion of matrix metalloproteinases and expression of adhesion molecules. Furthermore, we investigated the invasive and migrative potential of synovial fibroblasts cultured with CD4 T cell conditioned medium.

Results We found that CD4 T cells and synovial fibroblasts reciprocally induced an increased expression of adhesion molecules ICAM and VCAM. In addition, we saw that factors secreted by activated CD4 T cells increased the migrative and invasive capability of synoviocytes. Furthermore, co-culture of CD4 T cells and synovial fibroblasts resulted in proliferation of CD4 T cells expressing increased levels of the proinflammatory cytokines IFN-γ and IL-17a and RANKL, and an increase in secretion of IL-6, IL-8, IFN-γ and IL-17a and matrix metalloproteinases MMP-1 and MMP-



3 from the co-cultures. Lastly, we demonstrate that these changes in pro-inflammatory profiles are linked with alterations in metabolism. **Conclusions** These results indicate that CD4 T cells work mutually with synoviocytes to create an inflammatory microenvironment likely to promote joint destruction through a milieu of proinflammatory cytokines and increased adhesiveness and invasiveness of synovial cells.

(17A183) ABSTRACT 60

POSTER 50

Down's Arthritis - Clinical and Radiological Features of arthritis in children with Trisomy 21

Author(s) Dr Orla Killeen¹, Dr Emma MacDermott¹, Professor Ursula Fearon², Professor Gerry Wilson³, Professor Douglas Veale⁴

Department(s)/Institutions 1. The National Centre for Paediatric Rheumatology (NCPR), Our Lady's Children's Hospital, Crumlin (OLCHC) 2. Trinity Biomedical Sciences Institute (TBSI), Trinity College, Dublin. 3. Conway Institute, University College Dublin (UCD). 4. St. Vincent's University Hospital, Dublin

Introduction DA was first reported in the literature in 1984. Crude estimates suggest higher incidence and prevalence rates of DA compared with JIA, (JIA prevalence 1/1000, estimated DA prevalence 8.7/1000). Despite this fact, there remains a paucity of data on this condition. DA is rarely recognised at onset & remains under-diagnosed. As a direct consequence, children with DA are presenting with significant joint damage and disability at diagnosis. We set up a National Musculoskeletal Screening Programme (NMSP) for children with Down syndrome (DS), age 0-21yrs, living in the Republic of Ireland.

Aims/Background 1. Identify whether DA is missed, leading to a delay in diagnosis. 2. Describe the clinical and radiological features of DA

Method Children with DS were invited to attend a screening clinic. During the screening appointment, completion of a health questionnaire and a comprehensive musculoskeletal examination were performed. DA cases detected were investigated and managed as per normal clinical practice. Data on a convenience sample of 33 newly diagnosed children with JIA was collected to create a comparison group.

Results Over an 18-month period, 550 children with DS were screened for DA (56% Male; age 0.6-19.2yrs;). The NCPR cares for 40 children with DA, 75% of these children were detected through the NMSP. Only 11% of these parents suspected that their child may have arthritis, and this was only after reading our recruitment literature. Our results suggest an Irish DA point prevalence of 18-21/1000. There was a significant delay ($p<0.05$) in diagnosis of DA, 1.7 years (0.2-4.9yrs) versus 0.7 years (0.2-2.4yrs) in the JIA cohort. Children with DA were noted to have a significantly higher restricted joint count (RJC) than observed in the JIA comparison group (DA-RJC = 5 (0-12) versus JIA-RJC = 2 (0-10), $p<0.05$). Small joint involvement of the hands was noted in 88% of the DA cohort, significantly higher ($p<0.01$) than that observed in the JIA comparison group (43%). Erosive joint damage was higher in DA (29%) compared with JIA (10%). These data suggest that DA is associated with greater joint damage and functional disability. On average, in a given JIA cohort, 19% of patients would be expected to have the ILAR subtype polyarticular (pJIA) RF negative arthritis. Based on clinical features, this is the subtype most frequently diagnosed in our DA cohort (85%), a significantly greater proportion than expected (chi square=106, df=7, $p<0.0001$). Methotrexate-associated nausea was a significant barrier to treatment with this DMARD in DA.

Conclusions Our data suggests that DS is associated with a very high risk of developing polyarticular inflammatory arthritis, greater

than previously reported. There is a lack of awareness of this risk among health care professionals and the general public at large. This almost certainly contributes to poor recognition of the disease and a delay in diagnosis. Treatment with standard protocols used in JIA is complicated by drug-associated side effects in children with DS. However, a good response to treatment with steroid joint injections and anti-TNF therapy has been observed. We advocate that all children with DS have an annual musculoskeletal examination as part of their health surveillance programme.

(17A184) ABSTRACT 61

POSTER 51

Audit: Osteoporosis Screening In a Cohort of COPD Outpatients

Author(s) Una Lannin, James Hayes

Department(s)/Institutions General Medicine Department, Respiratory Department

Introduction Osteoporosis is a significant cause of morbidity and mortality in the Irish population (1). COPD is a risk factor for the development of osteoporosis both due to the underlying disease pathogenesis and the use of steroids. It is recommended that all patients with a chronic illness, such as COPD, should undergo screening for osteoporosis (2).

Aims/Background The aim of this audit is to investigate the frequency of screening for osteoporosis in a group of Irish outpatients with COPD.

Method The COPD Outreach Programme in Cavan General Hospital enrolls patients with COPD who have had at least one prior hospital admission. The patients are reviewed shortly after discharge and then on an as required basis. Data for each patient relating to disease severity, smoking status and previous DEXA scanning is collected and entered onto a database. Data was extracted from this database and analysed using SPSS for the purposes of this audit. A chart review was then performed to obtain results of DEXA scan.

Results 89 subjects were included, 40 male and 49 female. The average age was 71. 50 identified as ex smokers, 20 as current smokers and 3 as lifelong non-smokers. 30 patients underwent screening for osteoporosis. 21 were found to have osteoporosis. FRAX score was not used to calculate fracture risk for any patient.

Conclusions This audit found that there is an inadequate level of screening for osteoporosis in patients with COPD. Greater awareness is required among health care professionals regarding the association between COPD and the development of osteoporosis and its related comorbidities. We recommend the implementation of a validated screening tool such as FRAX. The FRAX tool is used to estimate a patient's fracture risk. Patients found to be at significant risk should undergo a DEXA scan. This tool should be applied on the initial visit and subsequent assessments determined by the results.

Table 1:

VARIABLE	
Number	89
Gender (n=89)	
Male:	40 (44.9%)
Female:	49 (55.1%)
Age (average, yr)	71.9
FEV1 (n=57)	
>80%	3 (5.2%)
50-79%	20 (35.1%)
30-49%	20 (35.1%)
<30%	12 (21.1%)
Smoking Status (n=73)	
Lifelong non smoker	3 (4.1%)
Current smoker	20 (27)
Ex-smoker	50 (68)
DEXA Scan	30 (33.7%)
18 in CGH	
12 outside CGH	
Presence of osteoporosis	21 (70% of DEXA group; 23% of entire group)
11 with T score	
10 w/o T score	
Average T-score	
Spine AP	-2.9
Femoral	-2.7

Truxima[®]

is rituximab

WHY PAY MORE FOR RITUXIMAB THERAPY?

Truxima[®] (rituximab) 500mg concentrate for solution for infusion. Prescribing Information Republic of Ireland. Please read the Summary of Product Characteristics (SPC) before prescribing. Presentation: Type I glass vials, with butyl rubber stopper. Each vial contains 500mg of rituximab in 50 mL. Indications and dosage: **Adult patients: Follicular non-Hodgkin's lymphoma (FL):** (i) as induction treatment in combination with chemotherapy for previously untreated or relapsed/refractory patients with stage III-IV FL: 375 mg/m² body surface area (BSA) on day 1 of each chemotherapy cycle for up to 8 cycles. (ii) as maintenance therapy in previously untreated patients responding to induction therapy: 375 mg/m² BSA once every 2 months (starting 2 months after the last dose of induction therapy) until disease progression or for a maximum of 2 years. In relapsed/refractory patients responding to induction therapy: 375 mg/m², once every 3 months (starting 3 months after the last dose of induction therapy) until disease progression or for a maximum of 2 years. (iii) as monotherapy in patients with stage III-IV FL who are chemo-resistant or are in the second or subsequent relapse after chemotherapy and for retreatment in patients responding to monotherapy: 375 mg/m² BSA, administered once weekly for 4 weeks. **Diffuse large B-cell non-Hodgkin's lymphoma (DLBCL):** for treatment of CD20 positive DLBCL in combination with CHOP: 375 mg/m² BSA on day 1 of each chemotherapy cycle for 8 cycles. Administer after i.v. infusion of the glucocorticoid component. **Chronic lymphocytic leukaemia (CLL):** in combination with chemotherapy, for previously untreated and relapsed/refractory CLL: 375 mg/m² BSA, on day 0 of the first treatment cycle, followed by 500 mg/m² BSA on day 1 of subsequent cycles for 6 cycles in total. Prophylactic hydration and urocostatics recommended 48 hours prior to **Truxima**. Where lymphocyte counts >25x10⁹/L, administration of prednisone/prednisolone 100mg i.v. shortly before **Truxima** is recommended. **Rheumatoid arthritis (RA):** in combination with methotrexate (MTX), for adults with severe active RA who have had an inadequate response or intolerance to other DMARDs including one or more TNF inhibitor therapies. 1000mg i.v. infusion followed by a second 1000 mg i.v. infusion two weeks later. Evaluate need for further courses after 24 weeks (see SPC). Premedication with i.v. 100 mg methylprednisolone should be given 30 minutes prior to each infusion. **Gonulomatosis with polyarthritis (GPA) and microscopic polyangiitis (MPA):** in combination with glucocorticoids, for the induction of remission in adult patients with severe, active GPA (Wegener's) and MPA: 375 mg/m² BSA once weekly for 4 weeks. **All indications:** No dose reductions of **Truxima** are recommended. Standard dose reductions for any concomitant chemotherapeutic medicinal product should be applied. **Administration:** Give RA, GPA and MPA patients the patient alert card with each infusion. Administer prepared **Truxima** as an i.v. infusion, through a dedicated line, with full resuscitation facilities immediately available, under the supervision of an experienced healthcare professional. Do not administer as an i.v. push or bolus. Administer anti-pyretic and an antihistaminic before each infusion. Consider glucocorticoid (GCC) premedication if **Truxima** is not given with GCC-containing chemotherapy. Monitor closely for onset or evidence of cytokine release syndrome (CRS). Interrupt infusion immediately if evidence of a severe reaction (e.g. severe dyspnoea, bronchospasm or hypoxia). Evaluate NHL patients for tumour lysis syndrome (TLS). **First infusion:** Recommended initial rate of 50 mg/h for the first 30 minutes, which can then be escalated in increments of 50 mg/h every 30 minutes up to 400 mg/h. **Subsequent infusions:** Recommended initial rate of 100 mg/h and increased by 100 mg/h increments every 30 minutes, up to 400 mg/h. **Alternative faster infusion schedule in RA only (4mg/mL in 250mL infusion volume):** if no serious infusion related reaction (IRR) during first or subsequent infusions at standard rates (above), initiate at 250 mg/h for the first 30 minutes and escalate to 600 mg/h over 90 minutes. Faster infusion not suitable for patients who have clinically significant cardiovascular disease, arrhythmias or previous serious IRR to biologic therapy or rituximab. **Contraindications:** Hypersensitivity to the active substance, murine proteins, or any of the other excipients; active, severe infections; severely immunocompromised patients. Severe heart failure (NYHA class III/IV) or severe, uncontrolled cardiac disease in patients with RA, GPA or MPA. **Precautions and warnings:** To improve the traceability of biological medicinal products, the trade mark and the batch number of the administered product should be recorded in the patient file. **Progressive multifocal leukoencephalopathy (PML):** Very rare cases of fatal PML have been reported. Monitor patients for new or worsening neurological symptoms suggestive of PML and suspend until PML excluded. Permanently discontinue if confirmed. See SPC for further information. **Infusion related reactions (IRRs):** Rituximab is associated with IRRs, including CRS, TLS, anaphylactic and hypersensitivity reactions, including severe reactions with fatal outcome. Severe IRRs are characterised by pulmonary events and may include features of tumour lysis or rapid TLS in addition to reactions such as fever, chills, rigors, hypotension, urticaria and angioedema. Use extreme caution and closely

monitor first infusion when treating patients with >25x10⁹/L circulating malignant cells or high tumour burden (higher risk of severe CRS). Consider reduced infusion rate or split dosing where lymphocyte counts >25x10⁹/L. See SPC for further details on severe IRRs. IRRs of all kinds have been observed in 77% of patients treated with rituximab. Common IRRs are generally reversible with a reduction in rate, or interruption, of rituximab infusion and administration of an antipyretic, an antihistaminic and occasionally, oxygen, i.v. saline or bronchodilators. Temporary or permanent discontinuation may be necessary if severe or if the same adverse events recur a second time. In most cases the infusion can be resumed at a 50% reduction in rate when symptoms have completely resolved. Anaphylaxis and other hypersensitivity reactions have been reported following i.v. administration of proteins to patients. IRRs may also be associated with myocardial infarction, atrial fibrillation, pulmonary oedema and acute reversible thrombocytopenia. Consider withholding antihypertensives for 12 hours prior to infusion due to risk of hypotension. Treat with caution and closely monitor patients with a history of pulmonary insufficiency or pulmonary tumour infiltration. **Cardiac disorders:** Closely monitor patients with a history of cardiac disease and/or cardiac chemotherapy. **Infections:** Patients are at an increased risk of developing infections, including serious infections with fatal outcome. Do not administer if active and/or severe infection present or if severely immunocompromised. Caution in patients with a history of, or susceptibility to recurring/chronic infections. Determining immunoglobulin levels in RA, GPA and MPA before treatment is recommended. Hepatitis B (HBV) reactivation has been reported, including cases with a fatal outcome. HBV screening should be performed before initiation of **Truxima**. Patients with active hepatitis B disease should not be treated. Patients with positive serology for HBV should consult liver specialists and be monitored and managed to prevent reactivation. **Haematological toxicities:** Caution in patients with neutrophil counts <1.5 x 10⁹/L and/or platelet counts <75 x 10⁹/L as clinical experience in this population is limited. Perform regular blood counts during **Truxima** therapy in all indications, and prior to each course and regularly up to 6-months after cessation of treatment in RA and GPA/MPA. **Immunisations:** Live viral vaccines are not recommended. Response to non-live vaccinations may be reduced. See SPC for further information. **Skin reactions:** Severe skin reactions such as Toxic Epidermal Necrolysis (TEM) and Stevens-Johnson Syndrome (SJS), including fatal outcomes, have been reported - permanently discontinue treatment. **Malignancy:** The possible risk for the development of solid tumours with the use of immunomodulatory drugs cannot be excluded. **Concomitant/sequential use of other DMARDs in RA:** The concomitant use of **Truxima** and anti-rheumatic therapies other than those specified for RA is not recommended. Monitor patients for signs of infection if biologic agents and/or DMARDs are used following **Truxima** therapy. **Interactions:** Limited data are available (see SPC). Patients with human anti-mouse antibody or human anti-chimeric antibody titres may have allergic or hypersensitivity reactions when treated with other diagnostic or therapeutic monoclonal antibodies. **Fertility, pregnancy and lactation:** Women of childbearing potential should use adequate contraception and continue its use for at least 12 months after **Truxima** treatment. **Truxima** should not be administered during pregnancy. Do not breast-feed in the 12 months following treatment. **Side effects:** **Very common (>1/10) and common (>1/100 to <1/10):** side effects: Viral infection, bacterial infection, bronchitis, acute bronchitis, sepsis, pneumonia, febrile infection, herpes zoster, respiratory tract infections, fungal infection, sinusitis, hepatitis B, infections of unknown aetiology, neutropenia/febrile neutropenia, leucopenia, thrombocytopenia, anaemia, pancytopenia, granulocytopenia, infusion related reaction (hypertension, nausea, rash, pyrexia, pruritus, urticaria, throat infection, hot flush, hypotension, rhinitis, rigors, tachycardia, fatigue, oropharyngeal pain, peripheral oedema, erythema), angioedema, hypersensitivity, hyperglycaemia, weight decrease, face oedema, increased LDH, hypercalcaemia, paraesthesia, hypoaesthesia, insomnia, vasodilatation, dizziness, anxiety, agitation, lacrimation disorder, conjunctivitis,

tinnitus, ear pain, myocardial infarction/myocardial arrhythmia, atrial fibrillation, cardiac disorder, orthostatic hypotension, bronchospasm, respiratory disease, chest pain, dyspnoea, cough/increased cough, vomiting, diarrhoea, abdominal pain, dysphagia, stomatitis, constipation, dyspepsia, anorexia, throat irritation, alopecia, sweating/night sweats, skin disorder, hypertonia, myalgia, back pain, neck pain, pain, fever, chills, asthenia, headache, tumour pain, flushing, malaise, cold syndrome, shivering, multi-organ failure, decreased IgG levels, urinary tract infection, gastroenteritis, linea pedis, hypercholesterolemia, migraine, sciatica, depression, oesophageal reflux, mouth ulceration, arthralgia/musculoskeletal pain, muscle spasms, muscle weakness, osteoarthritis, bursitis, decreased IgM levels. **Additional side effects in ≥ 5% GPA/MPA patients in clinical trials:** Nasopharyngitis, cytokine release syndrome, hyperkalaemia, tremor, acne, epistaxis, nasal congestion, pain in extremities, decreased haemoglobin. **Uncommon (<1/100) but potentially serious, including fatal side effects:** Serious viral infection, Pneumocystis jirovecii, progressive multifocal leukoencephalopathy, reactivation of hepatitis B, infusion related reactions (generalised oedema, bronchospasm, wheezing, laryngeal oedema, angioneurotic oedema, generalised pruritus, anaphylaxis, anaphylactoid reaction), tumour lysis syndrome, cytokine release syndrome, serum sickness, coagulation disorders, aplastic anaemia, haemolytic anaemia, late neutropenia, depression, peripheral neuropathy, cranial neuropathy, severe vision loss, facial nerve palsy, loss of other senses, left ventricular failure, supra-ventricular tachycardia, ventricular tachycardia, angina/angina pectoris, heart failure, atrial flutter, atrial fibrillation, myocardial ischaemia, bradycardia, severe cardiac disorders, vasculitis, leukocytoclastic vasculitis, asthma, bronchiolitis obliterans, hypoxia, respiratory failure, pulmonary infiltrates, interstitial lung disease, gastrointestinal perforation, Steven's-Johnson syndrome, toxic epidermal necrolysis, renal failure. Cases of posterior reversible encephalopathy syndrome (PRES) / reversible posterior leukoencephalopathy syndrome (RPLS) have been reported. Please refer to the SPC for further information and a full list of side effects. **Overdose:** Intravenous doses of up to 5000 mg have been administered in a dose escalation study in CLL patients, which did not identify any safety signals. The infusion should be interrupted immediately and patient monitored closely, if overdose is experienced. **Legal category:** POM. **Presentation:** 1 vial of 500 mg. **Marketing Authorisation holder:** Celltrion Healthcare Hungary Kft, 1051 Budapest, Bajcsy-Zsilinszky út 12., 4. em. 410.Hungary. For medical information enquiries, please contact info@mundipharma.ee. **Truxima** is a registered trade mark of Celltrion, Inc. and is used under licence. **Mundipharma** device (logo) is a Registered Trade Mark. © 2017 Mundipharma Pharmaceuticals Limited. PI Code UK/TRU-17025. Date of Preparation March 2017.

Truxima[®]

Rituximab



▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See www.hpra.ie for how to report side effects. Distributed in Ireland by: Mundipharma Pharmaceuticals Limited, Millbank House, Arke Road, Sandyford, Dublin 18, Ireland. Phone +353-1-2063800 www.mundipharma.ie Date of Item: June 2017. IRE/TRX-17024.

© TRUXIMA is a registered trade mark of Celltrion, Inc. and is used under licence.
© MUNDIPHARMA and the 'mundipharma' logo are registered trade marks of Mundipharma AG.



(17A185) ABSTRACT 62

POSTER 52

C.I.M.P.A.C.O.: An audit of the accuracy of patient self-reported diagnoses amongst a cohort of Rheumatology patients in Ireland.

Author(s) Wan Lin Ng¹, Brian McGuire^{2,3,4*}, Siobhan O'Higgins^{2*}, Edel Doherty^{2,5*}, Bernadette McGowan^{2,6*}, Bryan Whelan^{4,6*}, Carmel Silke^{4,6*}, Miriam O'Sullivan^{4,6*}, Amina Gsell^{1,4*}, Bernadette Lynch^{1,4*}, Gwen Marie Brown⁴, Michelle Hanlon⁴, Sarah Quinn⁴, Arron Claffey-Conneely⁴, Ann Colleran⁴, John J. Carey^{1,2,4*}

Department(s)/Institutions 1 Department of Rheumatology, University Hospital Galway, Ireland. 2 Centre for Pain Research, National University of Ireland Galway. 3 Department of Psychology, National University of Ireland Galway. 4 Department of Medicine, National University of Ireland Galway. 5 Department of Health Economics, National University of Ireland Galway. 6 Department of Rheumatology, Sligo/Manorhamilton, Ireland

* C.I.M.P.A.C.O. Research Team

Introduction Musculoskeletal diseases account for the bulk of disability and are the commonest diagnoses globally today. Validated data on the Irish population are scarce, and there is a lack of validated national epidemiological and economical information. European studies show reported diseases in Ireland to be similar to some other countries but the rates of self-reported and validated data are limited and differ dramatically between studies. A pan-EU study shows Irish people report having rheumatoid arthritis more frequently than osteoporosis and/or osteoarthritis, in younger and older adults.

Aims/Background As part of a larger research programme to understand the epidemiology, costs and impact of arthritis and osteoporosis in Ireland, we have completed questionnaires on >100 patients with several forms of arthritis, fibromyalgia and osteoporosis. Patients attending an outpatient speciality clinic need to understand and know their diagnosis and treatment to effectively manage their care. We performed an audit of data validity evaluating the accuracy of patient self-reported diagnoses with those recorded in the medical record.

Method This study has been approved by the I.R.B. for National University of Ireland, Galway and the Saolta University Hospitals I.R.B. boards. Patients attending rheumatology outpatients in Merlin Park or Sligo-Manorhamilton were offered the opportunity to fill out an 18-page questionnaire on the impact, cost and economic burden of arthritis and/or osteoporosis using established published international metrics. Patients who agreed to participate filled out written informed consent and filled out paper questionnaires in clinic or at home. All results have been entered into a database. Patients with 5 forms of arthritis, fibromyalgia and osteoporosis were questioned. In order to validate the accuracy of self-reporting, patients self-reported diagnoses and medications were compared to those recorded in their medical record by members of the rheumatology team. In this audit, we present the results of the accuracy of self-reported diagnoses for the first 274 patients.

Results 274 participant questionnaires were reviewed.

Diagnostic agreement was generally good: 2/3 or higher except for the lowest ankylosing spondylitis at 24% and gout at 44%. The highest recorded was the fibromyalgia cohort at 88%.

Conclusions The accuracy of patients' self-reported diagnoses attending a rheumatology outpatient clinic was generally good with the exception of gout and ankylosing spondylitis. These data should help projections for self-reported diagnoses at a national level.

(17A189) ABSTRACT 63

POSTER 53

Implementation of MSK Injection therapy administered by Physiotherapy staff in Rheumatology

Author(s) Connolly E, Lynch B, O Colmain A, Callanan E.

Department(s)/Institutions Rheumatology and physiotherapy departments, Galway University Hospitals

Introduction Injection therapy can be offered as part of an integrated approach to treatment of musculoskeletal conditions seen in Rheumatology. The provision of MSK Injection therapy by physiotherapists in Ireland is relatively new (ISCP Guidelines 2014). Following the initiation of a Rheumatology Physiotherapy Triage service in Galway University Hospitals (GUH) in April 2016 a service need for the provision of injection therapy was identified.

Aims/Background A prospective study was established to assess the utility of a Physiotherapy led Musculoskeletal Injection Therapy Service and to assess patient outcomes.

Method Mentoring, funding and study leave was approved by GUH for a Clinical Specialist Physiotherapist (CSP) to undertake an Injection therapy module consisting of 5 teaching days. To complete the course 10 supervised injections, a clinical practice portfolio, a critical evaluation essay and a presentation analysing the evidence base for injection therapy were required. Policies, Procedures, Protocols and Guidelines for injection therapy were written.

GP referrals requesting joint injections were paper triaged to the Rheumatology Physiotherapy triage clinic. In April 2017 the CSP began contributing to the GP led Rheumatology shoulder clinic shadowing and administering injections under supervision.

Patient telephone reviews were conducted 2-3 weeks post injection for the initial 20 patients who received injections. Patients who reported pain relief were asked to rate their relief as 20%, 50%, 80% or 100%.

Results A total of 51 injections were administered by the CSP from July 2016 to July 2017 in Rheumatology Physiotherapy triage, Shoulder and Rheumatology clinics. Injection sites included; 22 subacromial shoulder joint, 13 1st carpal metacarpal (CMC) joint, 7 knee joint, 5 hip trochanter bursa and 4 acromio-clavicular joint (Fig 1).

20 patients had telephone reviews 2-3 weeks post injection; 16 patients reported 80% pain relief. 2 patients reported 1-2 days relief and no further relief. 2 patients reported increased pain for 2-3 days followed by no relief, both of whom had received 1st CMC injections (Fig 2). No other adverse effects were observed.

Conclusions Injection therapy can be implemented by physiotherapy staff in rheumatology departments with appropriate training, clinical governance and mentorship.

Image 1

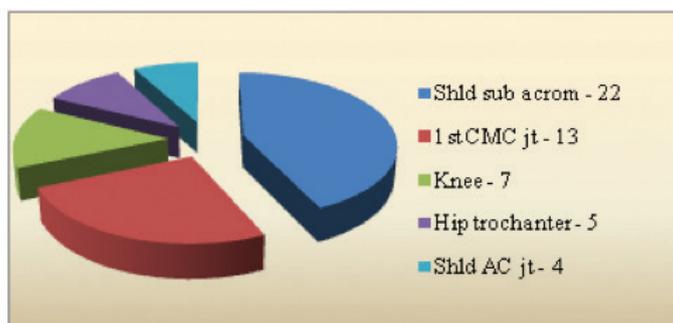
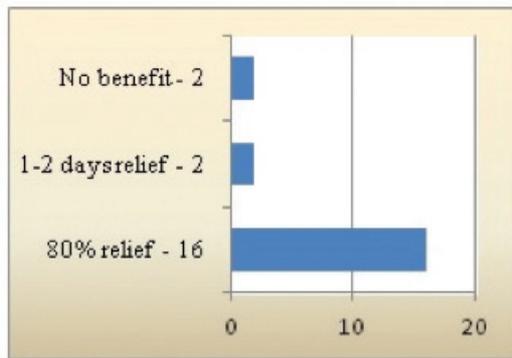




Image 2



(17A190) ABSTRACT 64

POSTER 54

Retrospective review of initial biological agent prescribing practice in a single centre in patients with inflammatory arthritis.

Author(s) A. Gorman, S. Cowley, A. Camon, I. Osman, S. Khan, A. Mohammad, K P. O'Rourke.

Department(s)/Institutions Department of Rheumatology, Midlands Regional Hospital, at Tullamore, Tullamore, Co. Offaly.

Introduction Biologics have revolutionised the treatment of inflammatory arthritis.¹ However there is no clear consensus as to which biologic to prescribe first line. This has led to a large inter-individual variation among prescribers when choosing the first biologic to prescribe.²

Aims/Background To identify the first biologic prescribed to patient with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis in a clinical setting.

To assess the length of time patients remained on their first biological treatment

To explore reasons why patients were switch from their first biologic to an alternative treatment.

Method A database of patients who attend the Rheumatology department of the Midlands Regional Hospital, Tullamore up until the 1st of July 2017 and who are receiving a biologic agent was reviewed. Those who had a diagnosis of inflammatory arthritis were identified. Outpatient summaries were reviewed. Data collection included diagnosis, concomitant DMARD therapy, month of commencement of their first biologic therapy, month of stoppage were identified and reason for stoppage were documented.

Results As of July 1st 2017, 706 patients were receiving biological therapy. 505 patients had a diagnosis of RA, PsA or AS where the date of commencement and duration of use of the first biologic was identifiable. Overall 59.6% of patients are still on their first biologic treatment.

In the RA group (329), the first biological agents prescribed were Adalimumab (82), Etanercept (87), Golimumab (64), Tocilizumab (13), Abatacept (13), Certolizumab (67), Rituximab (2) and Infliximab (2). 259 (78.72%) patients were also receiving DMARD therapy. 182 patients (55.32%) are still on their first biological therapy with a mean treatment duration of 50 months. 147 (44.68%) patients required a switch to an alternative agent. The mean length of time that patients were on their first biological therapy before switching was 24 months. The two main reasons for switching treatment were: loss of efficiency (36) and lack of benefit (73).

Among the PsA group of patients (132), the first biological agent prescribed consisted of Adalimumab (42), Etanercept (26), Golimumab (16), Ustekinumab (15), Certolizumab (12) and Secukinumab (1). 61.8% of patients are still receiving their first

biologic treatment. 103 (78.03%) of patients were receiving DMARD therapy also. 89 (67.42%) patients are still receiving their first biological agent. The mean length of time that patients were on their first biologic before switching is 18.7 months. Lack of benefit was the main reason for a change in therapy (17).

Biological therapy prescribed for AS comprised of Adalimumab (14), Etanercept (13), Golimumab (15), Certolizumab (1) and Secukinumab (1). 30 (68.18%) patients are still receiving the first biological agent prescribed with the mean duration of therapy being 73.73 months. Reason for switching included lack of benefit (6), loss of efficiency (3).

Conclusions There was a wide variety of biological agents chosen as the first biologic. The retention rate of patients on their first biologic is higher in patients in AS and PsA than RA. Lack of benefit and failing efficiency were the main reasons for switch to an alternative agent in all the groups studied.

(17A191) ABSTRACT 65

POSTER 55

Can a pharmacist-led gout clinic help patients achieve target serum uric acid levels?

Author(s) Jane Whiteman, Adrian Pendleton, Gary Wright

Department(s)/Institutions Department of Rheumatology, Musgrave Park Hospital, Belfast, United Kingdom

Introduction Gout is the most common form of inflammatory arthritis, affecting 2.5% of the UK population. It is associated with chronic disability, multiple co-morbidities and an increase in all-cause mortality. Treatment of gout is often suboptimal with many patients not achieving reductions of serum uric acid (sUA) levels to target levels as recommended in the British Society for Rheumatology/British Health Professionals in Rheumatology (BSR/BHPR) (<300µmol/l) or the EULAR guidelines (360µmol/l). The 2017 BSR/BHPR guideline for the management of gout strongly emphasises the importance of patient education and an individualised package of care with monitoring of treatment through ongoing clinical review to improve outcomes for gout patients.

Aims/Background To investigate whether a pharmacist-led gout clinic, providing individualised patient education and monitoring of treatment, helps patients achieve target sUA levels.

Method A monthly pharmacist-led gout clinic was established in June 2015 and patients were referred to the clinic by the rheumatology consultants. A proforma was developed to record information such as family history, medication, co-morbidities, alcohol intake, smoking status, cardiovascular risk, weight, height, body mass index, frequency of gout flares/month, duration of flares, blood pressure and blood investigations. Patients were given information about gout and its treatment, the need for dietary and lifestyle modification and the importance of compliance with urate lowering therapy (ULT) so that a target sUA level of <300µmol/l was achieved (BSR/BHPR guidelines). Patients were offered ongoing clinical review and adjustment of treatment until their sUA was within target range. They were then discharged back to primary care.

Results 52 patients were seen at the monthly gout clinic between June 2015 and May 2017. Within this time period, 38 patients were discharged from the clinic (Figure 1). The average sUA of discharged patients decreased from 460 µmol/l at baseline to 290 µmol/l at discharge. 96.5% of discharged patients achieved a sUA of <360 µmol/l. 58.6% of discharged patients achieved a sUA of <300 µmol/l. The mean percentage change in sUA from baseline was 33% (Table 1).



Conclusions Monitoring of gout treatment at a pharmacist-led gout clinic in conjunction with the provision of patient education and information about gout and its treatment helps patients achieve target sUA levels

Figure 1: Patients discharged from Gout Clinic

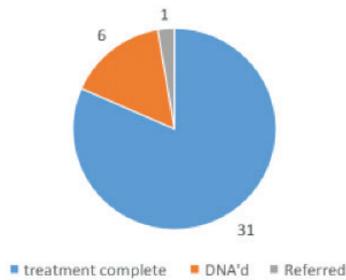


Table 1 Results

% subjects achieving SUA<0.36 mmol/l at final visit	96.5%
% subjects achieving SUA<0.3 mmol/L at final visit	58.6%
Mean % change from baseline SUA at final visit	33%

(17A193) ABSTRACT 66

POSTER 56

Perioperative Management of Rheumatology Patients on Immunosuppressive Therapy

Author(s) Aine Stakelum, Azhar Abbas, Bernie McGowan, Miriam O’Sullivan, Bryan Whelan, Carmel Silke

Department(s)/Institutions Northwestern Rheumatology Unit, Our Lady’s Hospital, Manorhamilton, Co Leitrim

Introduction Disease Modifying Anti-Rheumatic Drugs (DMARDs) and Biologics are an important part of treatment for many rheumatology patients. They have been shown to slow disease progression in patients with inflammatory arthritis and allow patients to maintain high levels of independence. The decision on when to continue, withhold and restart these medications in the perioperative period has varied between both rheumatologists and surgeons over the past number of years. Randomised control trials have demonstrated increased risk of infection in patients on biologics undergoing surgery [1]. It is important to balance this risk of infection with the risk of disease flare if therapy is stopped. Until recently there were no definitive guidelines on the subject and practices varied between institutions and between specialists. In June 2017 the American College of Rheumatology and the American Association of Hip and Knee Surgeons published guidelines [1] on the optimal perioperative management of anti rheumatic medications. These recommend that methotrexate, hydroxychloroquine, leflunomide and sulfasalazine may be continued, while biologic agents should be held prior to surgery and where possible surgery should be planned at the end of the dosing cycle.

Reference 1. Goodman et. al, Arthritis Care and Research (2017)

Aims/Background Our aim was to survey a selection of patients and assess their knowledge regarding medication changes in the perioperative period. We also aimed to examine the literature regarding the optimal management of patients on DMARDs and ensure our unit was compliant with current guidelines.

Method We surveyed a random selection (n=42) of our outpatients on DMARD therapy over a two-week period. We included patients on methotrexate, hydroxychloroquine, leflunomide and/or biologic therapy.

Results Of the patients surveyed, 19% (8) had a surgical procedure since commencing their anti-rheumatic therapy. 36%(15) of the patients surveyed were on Methotrexate. Of these, 13% said they would continue their medication if they had to undergo elective surgery, 33% said they would discontinue their Methotrexate and 53% were unsure what they would do.

45% (19) of our patients were on biologic therapy. Of these, 26% said they would stop their biologic prior to a surgical procedure, 5% would continue biologic therapy and the remaining 68% were unsure.

Conclusions Our study showed that the majority of our patients were unsure whether they should stop or continue their anti-rheumatic medication if they were to have elective surgery. One third would unnecessarily discontinue their Methotrexate. In our unit, it is policy that all patients attend an education session prior to starting treatment where they are educated on the risks and side effects of their new medication. This study highlights the need for more patient education on medication changes in the perioperative period. Although the ACR and AAHKS guidelines include a number of recommendations for perioperative dosing of anti-rheumatic medications, these recommendations are based on low quality scientific evidence and there is a need for more high quality RCTs to assess the safety and efficacy of stopping and resuming biologic therapy in the perioperative period.

(17A194) ABSTRACT 67

POSTER 57

Changing Prescribing Practices in Osteoporosis Result in Cost Saving in the Infusion Suite.

Author(s) Azhar Abbas, Hafiz Bajwa, Maria Khan, Grainne Kearns, Dr Donough Howard, Paul O’Connell, Laura Durkin

Department(s)/Institutions Rheumatology Department, Beaumont Hospital, Dublin

Introduction Osteoporosis is a chronic disease with associates with accelerated mortality, disability and fragility. The treatment of osteoporosis is hindered by adherence, intolerance and inefficacy. We have previously used infusional bisphosphonates to overcome some of these issues.

Aims/Background Comparison of change of practice and evaluation of cost saving.

Method We performed a retrospective review of infusion service use for the management of osteoporosis in Beaumont hospital and compared practices in 2014 to 2017 to ascertain whether therapeutic advances have impacted upon service provision. A secondary aim was to evaluate any cost saving which could be attributed to these changes in practice. Data collected, from 2014 and 2017 included age, gender, T score where available, number of infusions and reason for bisphosphonate.

Results There were 19 individuals receiving yearly bisphosphonate infusions in 2014 compared with 3 in 2017. See Table 1. for a comparison of 2014 to 2017 in terms of age, gender, number of infusions and indications for treatment. The cost of yearly infused bisphosphonate is more than € 500 (not including the infusion costs which are considerable) , which is shouldered by the institution,



compared to denosumab, or oral bisphosphonates with are administered and acquired in the community.

Conclusions Therapeutic advances now mean that we are utilising the infusion room less and less with resultant cost saving to the hospital and department. In osteoporosis, prescribing practices have changed considerably in the last 3 years and the resultant cost saving should be highlighted.

(17A196) ABSTRACT 68

POSTER 58

Predicting the future development of spondyloarthritis among patients with idiopathic acute anterior uveitis using real-world data

Author(s) Muhammad Haroon¹, Keith A. Betts², Fan Mu², Martha Skup³, Jaclyn K. Anderson³, Avani D. Joshi³

Department(s)/Institutions 1. Division of Rheumatology, University Hospital Kerry, Tralee, Ireland. 2. Analysis Group, Boston, MA, USA. 3. AbbVie Inc., North Chicago, IL, USA

Introduction At least 40% of idiopathic AAU patients have undiagnosed SpA. However, the clinical factors to predict the incident diagnosis or future development of SpA remain poorly understood.

Aims/Background The objectives of this study were: 1) To describe the patient characteristics of AAU patients with and without SpA diagnosis, and 2) To identify the predictive factors of SpA diagnosis among AAU patients using real-world data.

Method Data were extracted from the Truven Health MarketScan Commercial Claims Encounters database and the Medicare Supplemental database from USA. Data period Q1 2008 to Q2 2015 was used for analysis. Index date was the date of first AAU diagnosis. Patients included in the analysis were grouped into two cohorts: 1) Patients with SpA: AAU patients with at least one SpA diagnosis post index date, 2) Patients without SpA: AAU patients without any SpA diagnosis post index date. Figure-1 describes the study design. Number of clinical characteristics were measured during the 6-month baseline period. SpA diagnosis was assessed after the index date. Baseline factors predictive of SpA diagnosis were selected into a multivariable Cox proportional hazards model based on statistical significance, magnitude of hazard ratios (HR), and clinical relevance.

Results A total of 48,822 patients with AAU were included (Figure-2). Among them, 1,032 patients were newly diagnosed with SpA and 47,790 patients did not have any SpA diagnosis during the follow-up period. Using Cox Proportional Hazards Models of SpA diagnosis among adult AAU patients, the most predictive factors of SpA diagnosis were male, age<45 years, recurrent AAU, back pain, inflammatory bowel disease and psoriasis. To the best of our knowledge, this is the first study to identify the risk factors of future SpA diagnosis among AAU patients.

Conclusions There are significant differences among isolated AAU patients and AAU patients that developed SpA later. Since delayed diagnosis is common among SpA patients, identifying such predictive factors can help inform risk stratification.

Image 1

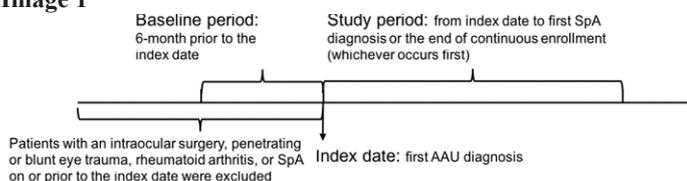


Image 2

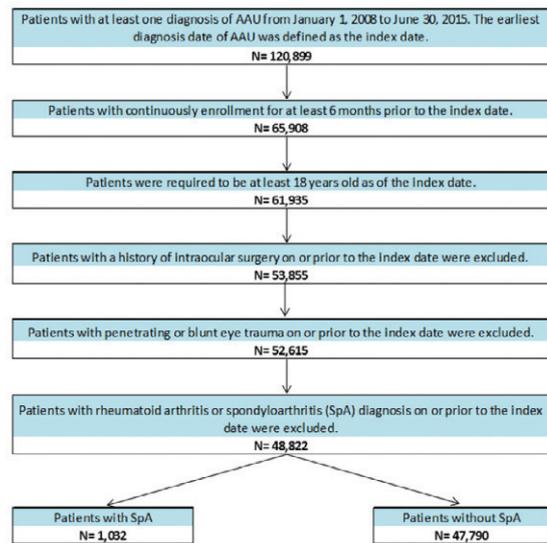
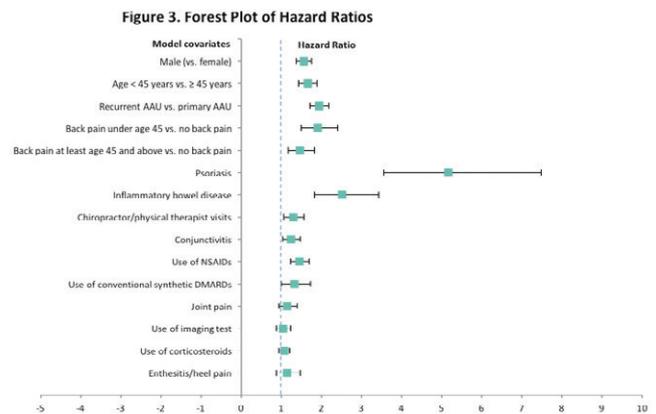


Image 3



(17A199) ABSTRACT 69

POSTER 59

Inflammatory Back Pain in Psoriatic arthritis is significantly more responsive to Corticosteroids compared to back pain in Ankylosing Spondylitis: A Prospective, Open-labelled, Controlled Pilot study

Author(s) Muhammad Haroon¹, Muddassar Ahmad¹, Numan Baig², Olivia Mason³, John Rice², Oliver FitzGerald⁴

Department(s)/Institutions 1Division of Rheumatology, Department of Medicine, University Hospital Kerry, Tralee; 2Department of Orthopaedics, University Hospital Kerry, Tralee, Ireland; 3CSTAR, University College Dublin, Ireland; 4Department of Rheumatology, St Vincent's University Hospital, Dublin, Ireland

Introduction The efficacy of corticosteroids in psoriatic arthritis (PsA) patients with inflammatory back pain has not been studied to date. Most of the treatment response data about axial involvement in PsA come from ankylosing spondylitis (AS) studies

Aims/Background In this controlled trial, we aimed to investigate the comparative performance of corticosteroids for active axial-PsA (AxPsA) versus those with active ankylosing spondylitis (AS).

Method AxPsA and AS patients (naïve to biologic therapies), who not only had clinically active disease, but also had bone marrow oedema on MRI of sacroiliac joints were recruited. Clinically active disease was defined as patients with inflammatory back pain (fulfilling ASAS Expert Criteria)¹³, with spinal pain score (numerical rating



scale 0-10) of ≥ 4 and BASDAI score ≥ 4 despite taking NSAIDs. Moreover, we recruited a control group of non-inflammatory lower back pain (table-1). All patients received a single, intra-muscular dose of depot corticosteroid injection (Triamcinolone Acetonide 80mg) at baseline. The intra-muscular corticosteroid option was used to overcome any drug compliance issues. Clinical outcome assessments were made at following time points: baseline, week-2, and week-4. The primary efficacy end point was the mean change in Ankylosing Spondylitis Disease Activity Score (ASDAS) at week-2. **Results** In total, 40 patients were recruited – AxPsA=15, AS=15, control=10. At week-2 following corticosteroid treatment, patients with AxPsA had significantly higher improvements in the mean ASDAS compared to patients with AS (1.43 ± 0.39 vs. 1.03 ± 0.30 , $p=0.004$), and also when compared to controls ($p<0.001$). At week-4, similar significant trend of ASDAS improvement was seen among AxPsA patients compared to AS patients (1.09 ± 0.32 vs. 0.77 ± 0.27 , $p=0.007$) and controls ($p<0.001$). Similarly, the mean BASDAI, VAS spinal pain score, ASQoL and BASFI improved significantly among AxPsA patients compared to AS patients and controls at week-2, with this trend also largely maintained at week-4 (Figure-1,2).

Conclusions Axial inflammation in PsA patients responds significantly better to corticosteroids than in patients with AS. This furthers the argument and adds to the growing evidence that AxPsA and AS are distinct entities.

Image 1

Parameter	Axial Psoriatic Arthritis	Ankylosing Spondylitis	Control
Number of patients, n	15	15	10
Age in years (mean \pm SD)	38.6 \pm 7.93	33.9 \pm 8.28	40.0 \pm 11.6
Gender (female %)	60	46.7	60
CRP (mean \pm SD)	9.00 \pm 4.74	7.27 \pm 3.61	4.00 \pm 1.56
VAS (mean \pm SD)	6.60 \pm 1.12	6.47 \pm 1.13	6.60 \pm 1.51
ASQoL (mean \pm SD)	11.8 \pm 4.19	11.9 \pm 3.74	10.0 \pm 1.49
BASFI (mean \pm SD)	6.40 \pm 1.52	6.06 \pm 1.49	4.14 \pm 1.53
BASDAI (mean \pm SD)	5.95 \pm 1.24	5.86 \pm 1.32	5.18 \pm 1.07
ASDAS (mean \pm SD)	3.81 \pm 0.61	3.75 \pm 0.55	2.82 \pm 0.67

Image 2

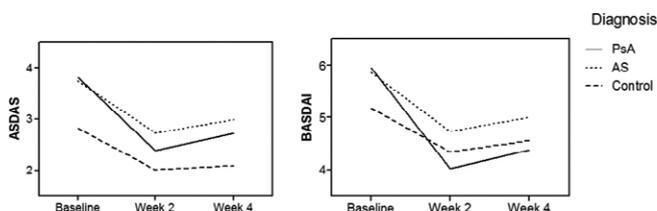
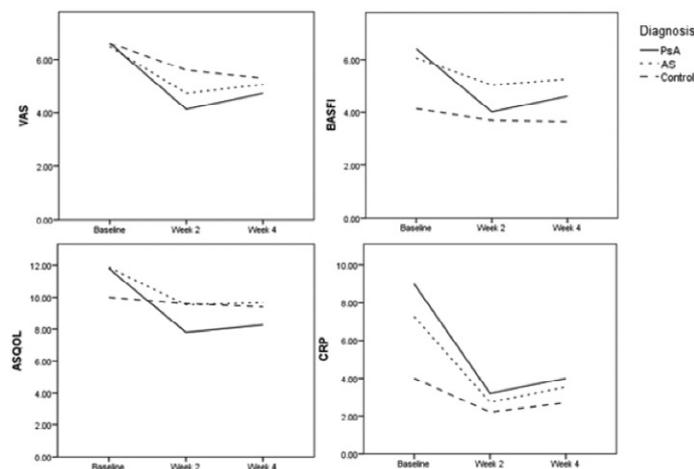


Image 3



(17A200) ABSTRACT 70

POSTER 60

Four Year Imaging Outcomes in Axial Spondyloarthritis Patients Treated with Certolizumab Pegol, Including Patients with Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

Author(s) E. McGarry,¹ D. van der Heijde,² X. Baraliakos,³ K. G. Hermann,⁴ R. Landewé,⁵ P. M. Machado,⁶ W. P. Maksymowych,⁷ O. Davies,⁸ N. de Peyrecave,⁸ B. Hoepken,⁹ L. Bauer,⁹ T. Nurminen,⁹ J. Braun¹⁰

Department(s)/Institutions 1UCB Pharma, Dublin, Ireland; 2Department of Rheumatology, Leiden University Medical Center, Leiden, Netherlands; 3Ruhr-University Bochum, Herne, Germany; 4Charité Medical School, Berlin, Germany; 5Academic Medical Center, Amsterdam & Atrium Medical Center Heerlen, Netherlands; 6Centre for Rheumatology Research & MRC Centre for Neuromuscular Diseases, University College London, London, UK; 7Department of Medicine, University of Alberta, Edmonton, Alberta, Canada; 8UCB Pharma, Slough, UK; 9UCB Pharma, Monheim, Germany; 10Rheumazentrum Ruhrgebiet, Herne, Germany.

Introduction RAPID-axSpA (NCT01087762) was a long-term study in patients (pts) with axial spondyloarthritis (axSpA) treated with certolizumab pegol (CZP).

Aims/Background his is the first report of 4-year imaging results in CZP-treated axSpA pts, including ankylosing spondylitis (AS) and non-radiographic (nr-)axSpA.

Method RAPID-axSpA was double-blind, placebo (PBO)-controlled to Wk24, dose-blind to Wk48 and open-label to Wk204. Pts fulfilling ASAS axSpA criteria were stratified according to presence/absence of radiographic sacroiliitis (AS/nr-axSpA) at randomization, and had active disease. Wk0 CZP-randomized pts (200 mg Q2W/400 mg Q4W) continued assigned dose; PBO pts received CZP after Wk 16 or 24. Lateral X-rays of cervical/lumbar spine at BL, Wk 96 and 204 were assessed using mSASSS (average of 2 independent central readers blind to timepoint). SI joint X-rays were scored for sacroiliitis by 2 independent central readers (3rd reader adjudicated grade scoring differences) at BL and Wk 204. MRI scans using STIR sequences were performed at BL, Wk 12, 48, 96 and 204, and were assessed using SPARCC for SI joints and Berlin score for spine. Data are shown for CZP-treated pts (including those starting on PBO). mSASSS data were estimated for all pts by MMRM analysis covering all available observations. MRI data at each timepoint are



shown as observed for pts with a valid assessment at that timepoint. SI joint X-ray data were assessed in pts with valid assessments at both BL and Wk 204.

Results Of 315 CZP-treated pts, 196 had available spinal X-rays and were included in MMRM analysis (BL mean mSASSS: 9.47). 158 pts had MRI assessments and were included in this reading campaign (BL mean SPARCC: 8.17 [n=151]; Berlin: 6.10 [n=153]) and 137 pts had SI Joint X-rays at BL and Wk 204 (BL: 67.9% radiographic sacroiliitis). In AS pts, mean mSASSS change between BL and Wk 204 was 0.98 (95% CI: 0.34–1.63); 0.67 (0.21–1.13) from BL to Wk 96 and 0.31 (0.02–0.60) from Wk 96 to Wk 204. These numbers were 0.06 (-0.17–0.28), -0.01 (-0.19–0.17), and 0.07 (-0.07–0.20) respectively for nr-axSpA. MMRM estimates were similar to observed values (axSpA Wk 204 mean change: 0.62 and 0.70 respectively). Limited changes in SI joint X-ray grading were observed to Wk 204: only 2/44 pts (4.5%) progressed to AS, while 4/93 (4.3%) shifted from an AS classification to nr-axSpA. MRI assessments showed maintained improvements in SPARCC and Berlin scores from Wk 12 to Wk 204 (Table).

Conclusions This is the first report of imaging data from a clinical trial including both AS and nr-axSpA pts over 4 years. Limited spinal radiographic progression was observed in CZP-treated pts with lower progression between Wk 96 and Wk 204, compared to the first 96 wks. Limited change in radiographic sacroiliitis was observed and scores were even similar in both directions. Early reductions in MRI inflammation were maintained to Wk 204.

Photos from ISR Spring Meeting 2017



Table A: Mixed-effects model repeated measures (MMRM) estimates of mSASSS to Week 204 of the RAPID-axSpA study for all patients treated with CZP

	Baseline		Week 96		Week 204	
	LS mean score (95% CI)	LS mean score (95% CI)	LS mean change from BL (95% CI)	LS mean score (95% CI)	LS mean change from BL (95% CI)	LS mean score (95% CI)
axSpA (n=196)	9.47 (7.20 – 11.73)	9.86 (7.52 – 12.21)	0.40 (0.11 – 0.69)	10.08 (7.71 – 12.46)	0.62 (0.22 – 1.01)	
AS (n=113)	13.17 (9.79 – 16.56)	13.84 (10.35 – 17.34)	0.67 (0.21 – 1.13)	14.16 (10.61 – 17.71)	0.98 (0.34 – 1.63)	
nr-axSpA (n=83)	4.42 (2.02 – 6.82)	4.41 (1.97 – 6.84)	-0.01 (-0.19 – 0.17)	4.47 (2.06 – 6.88)	0.06 (-0.17 – 0.28)	

Table B: MRI outcomes to Week 204 of the RAPID-axSpA study for all patients treated with CZP (observed values)

	Baseline		Week 204			
	N	Mean score (SD)	N	Mean score (SD)	N	Mean change from BL (SD)
SI Joint Inflammation – SPARCC						
axSpA	151	8.17 (13.08)	72	1.90 (5.00)	72	-4.70 (9.40)
AS	91	8.50 (13.83)	41	1.84 (5.60)	41	-4.35 (8.49)
nr-axSpA	60	7.66 (11.93)	31	1.97 (4.18)	31	-5.16 (10.60)
Spinal Inflammation – Berlin						
axSpA	153	6.10 (8.68)	82	2.13 (4.46)	82	-4.84 (8.33)
AS	92	7.38 (8.80)	50	2.62 (5.23)	50	-5.51 (7.61)
nr-axSpA	61	4.17 (8.21)	32	1.36 (2.75)	32	-3.78 (9.38)

Data shown for all CZP-treated patients with valid assessments (including patients re-randomized from PBO at Week 16 or 24)



Case Submissions – Autumn Meeting

Ref No.	Author	Title
17A102	G Fitzgerald	Giant Cell Arteritis Presenting as an Ischaemic Upper Limb
17A106	Sharon Cowley	A long history of shortness of breath
17A142	Rosemary Friel	Case of Multiple Insufficiency Fractures in a Patient with Rheumatoid
17A143	Maria Usman Khan	Cortical Blindness in Systemic Lupus erythematosus: A Blind Wolf
17A145	Ramona Valea	Is this a case of PMR?
17A149	Alwin Sebastian	An unusual presentation of primary myositis with lung involvement mimics compartment syndrome: Is it a medical emergency?
17A151	Stephen McDonald	Eosinophilic Granulomatosis with Polyangiitis versus Hypereosinophilic syndrome - a diagnostic dilemma
17A160	Cathy Donaghy	A Crystal Clear Case of Seropositive Rheumatoid Arthritis
17A164	Julie-Ann Henderson	Large vessel vasculitis in a patient with a background of atypical PMR and normal inflammatory markers
17A165	Lorraine Murray	Seizures and rapidly progressing dementia as an initial presentation of cerebral lupus in a 58-year old male - a diagnostic challenge
17A166	Laoise Griffin	Giant Cell Arteritis (GCA) presenting as scalp necrosis
17A168	Natalie McKee	A complex case of massive ascites, pleural effusions, and pancytopenia, with low complement levels in a patient with bowel malignancy
17A192	Aine Gorman	Case Report: IgG4 related disease masquerading as Tuberculosis
17A195	Sonia Sundanum	Pyoderma Gangrenosum - uncommon extra-articular manifestation of inflammatory arthritis
17A198	James Fay	A Case of Dermatomyositis with Co-existent SAE-1 and RO-52 Antibodies



IRHPS Autumn 2017 Update

Welcome to the Annual Scientific Meeting of the Irish Society for Rheumatology and the Irish Rheumatology Health Professional Society.

A very warm welcome to our keynote speakers this year. Dr. James Harrison, GP Lecturer from National University of Galway who will be presenting on health promotion and lifestyle issues for men with inflammatory arthritis. Dr. Caroline Flurey, Clinical Psychologist, Senior Lecturer in Public Health from the University of the West of England and President Elect of British Health Professionals in Rheumatology who will discuss experiences, coping styles and support preferences of men with rheumatoid arthritis.

We also welcome Ms. Yvonne Codd, Senior Occupational Therapist and PhD Researcher from Naas General Hospital and Discipline of Occupational Therapy, Trinity College Dublin who will present on the impact of inflammatory arthritis on engagement and work in men. Dr. Jill Firth, Consultant Nurse and Director for Service Improvement Pennine MSK Partnership and President of the British Health Professionals in Rheumatology who will present an overview of BSR/BHPR's work, sharing of results from national RA audit, workforce developments and outline of educational resources on offer.

Well done to all those who submitted abstracts demonstrating the high quality and varied research that is currently taking place in rheumatology centres and universities throughout Ireland. Please take the opportunity to look at the large number of posters we received this year and remember to vote for the "People's Choice" poster.

I would like to extend my gratitude to the ISR and Michael Dineen. Without their support our annual meeting would not be possible.

Thanks again to the Pharma companies for their continued support, without which valuable educational opportunities would be lost. Thanks must go to Abbvie, MSD, Roche, Janssen, UCB and Pfizer. Full details on this and all our bursaries are available on our website www.irhps.ie.

The IRHPS committee's support and dedication over the past year has been invaluable. My sincere thanks to you all.

I do hope you enjoy this year's conference and that you will find the discussions educational and beneficial to your everyday practice.

Trish Fitzgerald
IRHPS Chair



ABSTRACT 1

ORAL PRESENTATION

Greater Trochanteric Pain Syndrome: A retrospective study of thirty-eight patients treated with a structured physiotherapy program and Extra Corporeal Shockwave Therapy

Author(s): Paul Kirwan^{1,2}, Mary McCallan¹, Trevor Duffy³
Department(s)/Institution(s): 1. Physiotherapy Department, Connolly Hospital, Dublin 15; 2. School of Physiotherapy, Royal College of Surgeons in Ireland, Dublin 2. 3. Rheumatology Department, Connolly Hospital, Dublin 15

Aim/Introduction: Lateral hip pain is a common musculoskeletal complaint, and has been traditionally diagnosed as Trochanteric Bursitis. Recent evidence suggests that lateral hip pain is more commonly associated with gluteal tendon or muscle damage, and that the bursa was only involved in a small number of cases¹. The term Greater Trochanteric Pain Syndrome (GTPS) is more appropriate for this diagnosis. The purpose of this study was to review the outcomes of patients with GTPS to a standardized treatment program that targets the gluteal tendon and muscle unit.

Method: Thirty-eight patients diagnosed with GTPS were included in the review. Baseline assessment involved a routine examination and completion of the Victorian Institute of Sport Assessment – Gluteal (VISA-G) questionnaire. Patients were instructed to complete a standardised home exercise program of two exercises, twice per day. Patients were reviewed at six and twelve weeks. Extra Corporeal Shockwave Therapy (ESWT) was used as an adjunct for patients with a response of less than fifteen points on the VISA-G at each review.

Results: The treatment program was completed by thirty-eight patients. Thirty (79%) of the patients received ESWT as part of their treatment. The mean change in VISA G was 13 points at six weeks and 23 points at 12 weeks (see Table 1).

Conclusion: A structured program of exercise, advice and ESWT has been shown to bring about improvements in the management of GTPS. The results of this review suggest a structured physiotherapy approach should be considered as a treatment option for those suffering from GTPS. For those who do not respond to exercise alone, ESWT should be considered as an adjunct to a loading program.

Table 1. VISA G scores (mean results and SD) at baseline, 6 and 12 weeks

No. of participants	Mean Age	Mean BMI	Male:Female	VISA G Baseline	VISA G Week 6	VISA G Week 12
38	56	28.7	04:34	53 (+/-17)	66 (+/-17)	76 (+/-14)

References 1. Connell DA, Bass C, Sykes CA, Young D, Edwards E. Sonographic evaluation of gluteus medius and minimus tendinopathy. *Eur Radiol.* 2003;13:1339-1347. <http://dx.doi.org/10.1007/s00330-002-1740-4>

ABSTRACT 2

ORAL PRESENTATION

A Nurse led Treat to target programme in early inflammatory arthritis showing trends that smoking and obesity may delay time to patients achieving disease remission.

Author(s): Noreen Harrington, Bernie McGowan, C. Silke, Miriam O Sullivan, Bryan Whelan
Department(s)/Institution(s): Northwestern Rheumatology Unit, Our Lady's Hospital, Manorhamilton, Co Leitrim.

Introduction/ Aim Systematic screening of patients for co morbidities and co morbid risk factors is an important part of management of inflammatory arthritis (I.A).

To evaluate prevalence of co-morbid risk factors and co-morbidities among newly diagnosed I.A patients and determine if they had any impact on time to achieving disease target.

Newly diagnosed patients were referred to the RANP for 12 month follow up in a treat to target (T2T) programme.

Disease activity was assessed using clinical disease activity index (CDAI) at each visit and recorded with all other data pertaining to patients on SPSS for analysis. Data included :duration of symptoms before referral to rheumatology, waiting time from referral to first appointment, age, gender, body mass index (BMI), smoking status, lipademia (HDL, LDL), glucose and blood pressure. Pre-existing and newly detected co morbidities and co morbid risk factors was recorded. All patients had a DEXA scan and were screened for vitamin D deficiency.

Data was analysed on 158 patients.

Results: Correlation statistics were analysed to identify if any factors were significantly associated with time to reaching disease target.

Duration of symptoms before referral was significantly associated with time to reaching target in the log –rank test (p=0.034)

In a secondary analysis using chi-square tests there was a significant association identified between T2T and BMI status, smoking status and CDAI group at initiation with p-values of 0.031, 0.031 and 0.026 identified respectively. BMI identified 60(40%) of patients as overweight and 41(27%) obese, 47 (30%) were current smokers.

Conclusion: These findings highlight the benefits of implementing nurse led T2T programmes to target modifiable risk factors as part of the T2T strategy in inflammatory arthritis.

ABSTRACT 3

POSTER PRESENTATION

Advanced Physiotherapy Practice in Musculoskeletal Services in Ireland: A National Survey

Author(s): Orna Fennelly¹, Catherine Blake¹, Oliver Fitzgerald², Roisin Breen³, Caitriona Cunningham¹.

Department(s)/Institution(s): 1School of Public Health, Physiotherapy and Sports Science, UCD.

2Department of Rheumatology, St. Vincent's University Hospital.

3Health Service Executive, HSE.

Aim/Introduction: In 2011, Advanced Practice Physiotherapist (APP) posts were established across rheumatology and orthopaedic services at 16 hospitals in Ireland. For the first time, this study profiles APP musculoskeletal (MSK) services in Ireland.

Method: Ethical approval was granted by UCD HREC. A national online survey of APPs (n=25) was conducted using a specifically-designed questionnaire with open and closed questions. Data were analysed using descriptive statistics and qualitative content analysis.



Results: Profile of physiotherapists

68% (n=17) of APPs, working at 13 different hospitals responded. The majority (n=14) have MSc degrees, and all have more than five years MSK clinical experience. Seven respondents have qualifications to administer injections and role-specific training was provided via consultant shadowing and mentoring (n=14) and a HSE course (n=7).

APP services

- More than half the APPs work in both orthopaedic and rheumatology services alongside 25 Consultant Rheumatologists and 67 Orthopaedic Consultants at 13 sites.
- GP referral letters are screened by Consultants only (n=7) and/or APPs (n=10). GPs can refer directly to APP services at 3 sites.
- APP clinics are usually co-located with Consultant clinics (n=15).
- One APP has delegated authority to order clinical imaging.

APP experience of the role

Themes identified:

- Need for service development
- Opportunity for interdisciplinary communication and support
- Learning opportunities
- Formal training required
- Service dependent on Consultant Doctor

Conclusion: The APPs are experienced and most have specialist qualifications. Discrepancies exist between sites and these relate to initial referral screening procedures, role-specific training provided and individual Consultant practice. Additional formal staff training across sites is recommended.

ABSTRACT 4

POSTER PRESENTATION

Cross incidence of smoking in patients on Rheumatology and Musculoskeletal Unit (RMDU) and interest in smoking cessation support services.

Author(s): Amy Byrne

Department(s)/Institution(s): Pharmacy department. Our Lady's Hospice & Care Services Harold's Cross, Dublin 6W.

Aim/Introduction: Cardiovascular disease and respiratory disease are the major causes of death in patients with RA. 1 Furthermore smoking is associated with a reduced response to anti-TNF drug therapy in this patient group. 2 The aim of the audit was:

- To determine the number of patients who smoke at RMDU and assess the level of dependence in these patients.
- To determine the number of patients who have made previous quit attempts and how these quit attempts were carried out.
- To determine the willingness to quit and patient interest in smoking cessation support.

Method: Permission was sought from the Research and Ethics committee, consultants and ward managers. The audit was conducted over a four week period. The approved smoking cessation tool was used to interview all patients (see attached). Patients were approached specifically to conduct the questionnaire or were given the questionnaire at medicines reconciliation.

Results: 63 patients were assessed (17% smokers), 7 were willing to quit (63%), 5 were interested in a smoking cessation support service. The average dependence on cigarettes was low-moderate (mean score of 3) determined by the Fagerstrom test.

Conclusion: The mean dependence score of 3 indicates low-moderate dependence, an ideal group for healthcare professionals to support with quit attempts. Brief smoking interventions by healthcare professionals has been consistently shown to increase post-hospitalisation quit rates. 3 The high level of interest in a smoking

cessation support service in those willing to quit (71%) provides evidence that a support service would be valuable to patients.

- References:**
1. Peters MJL, et al., EULAR evidence-based recommendations for cardiovascular risk management in patients with rheumatoid arthritis and other forms of inflammatory arthritis *Ann Rheum Dis* 2010;69:325-331 doi:10.1136/ard.2009.113696
 2. Chang K et al. Smoking and Rheumatoid Arthritis. *Int. J. Mol. Sci.* 2014, 15, 22279-22295; doi:10.3390/ijms15122279
 3. Ohakim A, Mellon L, Jafar B, O'Byrne, C, McElvaney NG, Cormican L, McDonnell R, Doyle F. Smoking, attitudes to smoking and provision of smoking cessation advice in two teaching hospitals in Ireland: do smoke-free policies matter? *Health Psychology and Behavioral Medicine.* 2015;3(1)142-153.

ABSTRACT 5

POSTER PRESENTATION

Programme for Education and Exercise (PEdEx) for Inflammatory Arthritis Patients: A Service Development Report.

Author(s): Martina Fitzpatrick, Ruth Staunton, Trish Fitzgerald

Department(s)/Institution(s): Physiotherapy, Occupational Therapy

Aim/Introduction: To provide group therapy consisting of Physiotherapy, Occupational Therapy and Nurse Education for Inflammatory Arthritis Patients. To expand this service by developing videolinks (Healthsnaps) to reinforce the programme.

Method: All rheumatology clinic patients with a new diagnosis of inflammatory arthritis will be invited to attend group therapy consisting of three Physiotherapy and Occupational Therapy sessions and two Nurse Education sessions. Sessions will consist of presentations, discussions, exercise and joint protection sessions. The programme is based on the Lifestyle Management for Arthritis Programme (Hammond, 2008).

Patients will also receive links to recorded video messages from their therapists and nurse in the form of Healthsnaps. Healthsnap allows clinicians to record and send short video messages.

The Arthritis Self Efficacy Scale - Short form 2 (ASES -SF2) and a programme evaluation form is completed before and after programme attendance.

Results: In a six month period, 26 patients were offered a place on two programmes; 15 patients attended the programmes, and 11 completed pre and post ASES-SF2 and patient feedback forms. Mean scores of the 11 participants were collated. Results identified positive changes in mean scores for self-efficacy in pain management, function and symptom management for all participants.

Conclusion: Clinical standards supporting early therapy intervention for newly diagnosed inflammatory arthritis patients led to the development of a group therapy inter-disciplinary approach to managing this patient cohort.

Videolinks were developed to further support the programme.

References: Hammond, A. (2008). Lifestyle Management Arthritis Programme. Available at: www.rheumatology.oxfordjournals.org (Accessed 06 January 2016).

Ethical Approval: Clinical Audit Department at St. Vincent's University Hospital.



ABSTRACT 6

POSTER PRESENTATION

Evaluation of Advanced Practice Physiotherapy in rheumatology and orthopaedic services in Ireland.

Author(s): Orna Fennelly¹, Catherine Blake¹, Oliver Fitzgerald², Róisín Breen³, Caitriona Cunningham¹.

Department(s)/Institution(s): ¹School of Public Health, Physiotherapy and Sports Science, UCD.

²Department of Rheumatology, St. Vincent's University Hospital.

³Health Service Executive

Aim/Introduction: Demands on musculoskeletal (MSK) services led to the establishment of Advanced Practice Physiotherapy posts (APPs) across orthopaedic and rheumatology services in Ireland (16 hospital sites) in 2011. This study evaluated the Irish APP service.

Method: Ethical approval was granted by UCD HREC. In 2014, 22 APPs submitted deidentified clinical data to the National APP Database and all valid data were analysed using descriptive statistics and chi-square tests.

Results: 2014

- APPs assessed 13,981 new patients including 2,222 rheumatology patients.
- Rheumatology patients presented most commonly with: multiple joint (34%), shoulder (15%) and lower back (13%) MSK disorders.
- Median wait time from GP referral to APP appointment was 110 days for rheumatology and 177 days for orthopaedics.
- Compared to orthopaedics (15%), rheumatology patients required more follow-up appointments (20%) and Consultant input at the APP assessment (Table 1).

Table 1. Clinical Outcomes of APP Assessments

Table 1. Clinical Outcomes of APP Assessments			
	Rheumatology (n=2,586) n (%)	Orthopaedics (n=13,579) n (%)	p-value
Consultant input required	739 (26.8)	2,719 (20.1)	p<.05
Physiotherapy	1,022 (38.0)	5,492 (41.5)	p<.05
Investigations	827 (30.0)	4,023 (29.7)	p>.05
Orthopaedic referral	73 (2.7)	2,339 (17.2)	p<.05
Rheumatology referral	270 (9.8)	98 (0.7)	p<.05
Injection	179 (6.5)	506 (3.7)	p<.05
Other hospital speciality	114 (4.9)	539 (5.1)	p>.05
Surgical Listing	43 (1.6)	361 (2.7)	p<.05

Conclusion: The APPs managed a busy caseload of 13,981 patients in 2014 and only 23% required Consultant input and 18% onward medical referral, thus reducing medical services burden. While rheumatology patients required more Consultant input and follow-up, fewer patients were referred onwards to medical services compared to orthopaedics.

ABSTRACT 7

POSTER PRESENTATION

What's the deal with Hypermobility and Fibromyalgia? Maybe not the weakest link!

Author(s): Petrina Donohue, Dr. Chavrimootoo, & Dr. Ramakrishnan.

Department(s)/Institution(s): Rheumatology, OLH, Navan, Co. Meath

Aim/Introduction: The 2010 classification of fibromyalgia has many overlapping features with hypermobility-EDS. Hypermobility-EDS may be misdiagnosed as fibromyalgia because of diffuse pain with a strong myofascial component (1). Fatigue and anxiety disorders are also associated with both fibromyalgia and hypermobility

syndromes (2).

The 5PQ is a simple questionnaire to detect hypermobility and is claimed to have good reproducibility in addition to satisfactory sensitivity and specificity (3).

This audit examined the numbers of fibromyalgia clients that also fulfil the hypermobility criteria according to the 5PQ.

Method: 66 clients with a diagnosis of fibromyalgia who attended the Multidisciplinary Fibromyalgia Education Session were invited to fill in the 5PQ along with their FIQ. 57 of the 66 clients completed both questionnaires, over a 13-month period.

The recommended cut off points of 2 out of 5 for the 5PQ and 50 on the FIQ were used.

The individual scores for the FIQ questions on anxiety and depression were also examined.

Results:

5PQ:	Score	FIQ >50	FIQ Q19 Anxiety (8+/10):
15/57	2+/5		
3/15	4/5	2	2
3/15	3/5	3	2
9/15	2/5	5	3

Conclusion: From this audit 26% of fibromyalgia clients also score positively for joint hypermobility as per 5PQ. This may account for or contribute to some or all of their symptoms.

The 5PQ is a quick and easy tool to use. It may improve hypermobility detection rates and could be used in a busy rheumatology clinic.

Further research is required to ascertain whether those with positive scores meet the physical criteria for hypermobility.

References: 1. Chopra P, Tinkle B, Hammonet C, Brock I, Gompel A, Bulbena A, Francomano C. 2017. Pain management in the Ehlers-Danlos syndromes. *Am J Med Genet Part C Semin Med Genet* 175C:212-219.

2. Hakim AJ, Keer R, Grahame R, 2010. Hypermobility, Fibromyalgia and Chronic Pain. Churchill Livingstone Elsevier.

3. Hakim AJ, Grahame R, 2003. A simple questionnaire to detect hypermobility: an adjunct to the assessment of patients with diffuse musculoskeletal pain. *Int. J. Clin Pract* 57:163-166, 2003b

ABSTRACT 8

POSTER PRESENTATION

Development and Outcomes of Rheumatology Clinical Nurse Specialist (CNS) Telephone Clinic, Tallaght Hospital.

Author(s): Shona Lee

Department(s)/Institution(s): Department of Rheumatology Tallaght Hospital, Dublin

Aim/Introduction: To demonstrate development of a safe, efficient and effective telephone clinic review service managing a cohort of inflammatory arthritis patients at a Dublin teaching hospital.

Method: Pilot study over 6 months with one structured clinic per week. Telephone clinic set up on hospital administration system (Pims) coded TELRHU. Telephone booking option added to medical OPD outcome booking form for telephone review appointments. Development of telephone assessment in the rheumatology electronic patient record EPR (Cellma). Patients were booked into telephone clinic follow up if deemed suitable by rheumatology doctor/team.

Results: To date 419 patients have had either a 1/12, 3/12 or 6/12 month telephone review in the rheumatology telephone clinic. Telephone assessment is completed on electronic record with assessment, investigation results, blood results actions taken and plan of care documented. Letter created electronically when call



complete. Letter sent to patient letters portal. Fast track back to treat to target clinic (TTT) if medical review required. Service report with further results on time spent per review and other outcomes from electronic record has been requested (not yet available).

This process frees up medical review patient appointments for patients with more unstable disease and urgent review visits. It also produces a significant financial cost saving to the service.

Conclusion: Fully integrated electronic telephone clinical assessment, documentation, actions and recommendations through use of electronic patient record (EPR) Cellma. Efficient effective care and patient satisfaction has been demonstrated. Effort will now be invested seeking payment for telephone reviews as currently none available in ROI. UK telephone reviews attract a £24 /31 euro payment per call.

ABSTRACT 9

POSTER PRESENTATION

Delivery of Continuing Education Programme on Managing Rheumatic Diseases to Primary Care Nurses in the Midlands Region

Author(s): Angela Camon¹, Eileen Shinnors¹, Shona Lee²

Department(s)/Institution(s): ¹Department of Rheumatology, Midland Regional Hospital Tullamore Campus, Tullamore, Co Offaly, R35 NY51; ² Department of Rheumatology, AMNCH, Tallaght, Dublin 24, D24 NR0A.

Aim/Introduction: Despite the continued commitment by the HSE to provide chronic disease management services largely within primary care (HSE, 2017), levels of knowledge of arthritis remain poor among primary care professionals (Bartels et al 2016). And with almost a million people in Ireland living with some form of arthritis (Arthritis Ireland, 2017), primary care professionals have limited training on how to manage these complex diseases and the complications that can arise.

Method: A one day programme of education was devised by clinical specialist and education nurses in rheumatology practice, based on identified need, to improve knowledge and skills among nurses working across primary care settings, who provide care to patients with arthritis. Post education evaluations were examined to ascertain if learning needs were met.

Results: >90% of attendees reported improvements in:

- Clinical assessment of patients
- Levels of knowledge in the relevance of using biologics in this cohort
- Understanding blood monitoring and relevance of results in this patient cohort
- Confidence in using pen devices for s/c injections of biologics
- Importance of treatment compliance and health promotion opportunities and when secondary referral is required

Conclusion: While more regular, formal education is required to ensure primary care nurses have the skills and knowledge to support patients living with arthritis to stay out of hospital services and manage their disease effectively, this one programme served to increase awareness among this nursing group regarding key information relevant to support people living with arthritis.

References: Bartels, C.M., Roberts, T.J., Hansen, K.E, Jacobs, E.A, Gilmore, A., Maxcy, C. Bowers, B.J. (2016) Rheumatologist and Primary Care Management of Cardiovascular Disease Risk in Rheumatoid Arthritis: Patient and Provider Perspectives, *Arthritis Care and Research* 68(4), 415-423.

Health Service Executive (2017) Service Plan 2017- Building a better health service, accessed 04/08/2017 at <http://www.hse.ie/eng/services/publications/serviceplans/Service-Plan-2017/2017-National-Service-Plan.pdf>

Arthritis Ireland (2017) Information About Arthritis, accessed 04/08/2017 at http://www.arthritisireland.ie/go/information/about_arthritis

ABSTRACT 10

POSTER PRESENTATION

Piloting an Evidence-Based Group Programme for Occupational Therapy Management of Hand Osteoarthritis.

Author(s): Katie McCausland

Department(s)/Institution(s): Rheumatology Team, Our Lady's Hospital, Navan

Aim/Introduction: Occupational Therapy interventions for patients with Hand OA can reduce hand pain, and improve hand function and grip strength. Long waiting times for this cohort of patients for OT highlighted a need for a new approach – the group format is a viable alternative to 1:1 sessions.

Method: A review was done of group OT interventions for Rheumatology patients locally and internationally. Based on current evidence, a programme with three, half-day sessions was developed and piloted in late 2016 and 2017. It was delivered in Our Lady's Hospital, Navan, by two OTs and an OTA, and included self management education, hand exercise programmes and splinting. All patients with Hand OA on the OT waiting list were invited to attend the group, with the option of remaining on the waiting list to see a therapist 1:1.

Results: Initial results are very positive, with the majority of patients who attended the group sessions having improved grip strength, reduced hand pain, better hand function and they also reported increased confidence of how to manage their arthritis.

Conclusion: The development and commencement of a pilot group programme for OT management of Hand OA in Our Lady's Hospital, Navan, has provided effective intervention, and also provides patient access to therapy in a more timely manner.



ISR Meeting Autumn, 2017 Exhibitors

AbbVie Ltd
MSD Ireland Ltd
Novartis Ireland Ltd
Pfizer Healthcare Ireland
Roche Products (Ireland) Ltd

A Menarini Pharmaceuticals Ltd
Actelion Pharmaceuticals UK Ltd
Amgen
Arthritis Ireland
Biogen Ltd
Bristol-Myers Squibb Pharmaceuticals
Celgene Ireland Ltd
Eli-Lilly & Co (Ireland) Ltd
Fannin Ltd
Genomics Medicine Ireland
Grunenthal Pharma Ltd
Janssen-Cilag Ltd
Nordic Pharma Ireland
Mundipharma Pharmaceuticals Ltd
Pinewood Healthcare Ltd
Sanofi-Genzyme
Swedish Orphan Biovitrum Ltd
UCB (Pharma) Ireland Ltd

The above Sponsors have supported this meeting through a payment to exhibit a stand and have no involvement in any other aspect of this meeting.



ISR Spring Meeting 2017



Alwin Sebastian, Mary Gillespie, John Paul Doran, Mary McCarthy, Sandy Fraser, Maria Usman Khan, Joe Devlin & Mary Brady.



Breeda McCarthy, Geraldine Whelan, Mary Brady, Olive Kelly, Shona Lee, Angela Camon, Thersa Higgins & Mary O'Donnell



ISR Spring Meeting 2017



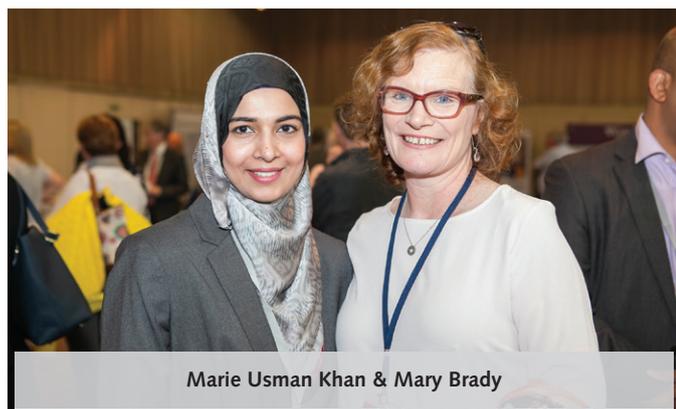
Aadil Al Ghafri, Nihal Ali, Wafa Madan & Fatemah Baron



Graham Cooke & Patrick Tehan.



Tommy O'Donoghue & Ann Walsh (MSD)



Marie Usman Khan & Mary Brady



Michael Comerford, Sandy Fraser & Orla Ni Muircheartaigh



ISR Spring Meeting 2017



Prof John Carey, Dr Orla Killeen,
Dr Carmel Silke & Dr Bryan Whelan



Dr Sandy Fraser



Dr Sandy Fraser & Prof Douglas Veale



Prof John Carey



Dr Sinead Harney (Incoming President)



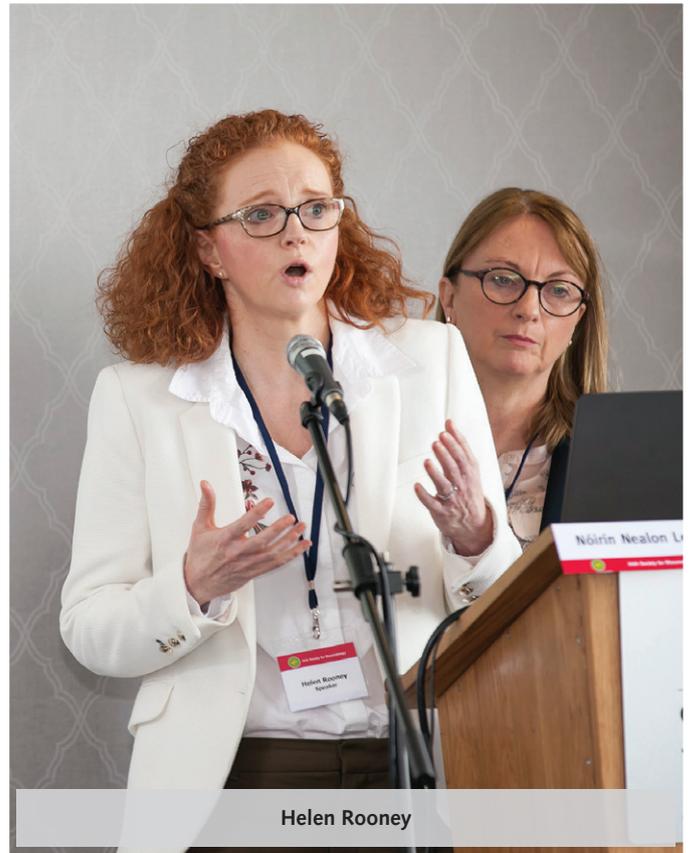
Prof Gerry Wilson



ISR Spring Meeting 2017



Gillian Broderick, Amia Gsel & Bridgette Connaughton.



Helen Rooney



Trish Cregan & Troina Buckley.



Heyley Collins, Declan Connolly & Catherine Vesey (Pfizer)



Prof Austin Stack (Speaker)



Anne Lynch, John O'Sullivan & Kathy Shannon (A. Menarini)



ISR Spring Meeting 2017



Maureen MacAlister, Sandy Fraser & Marie McAuliffe



Shehla Farrukh & Ann O'Riordan



Dr Donncha O'Gradaigh in deep conversation



ISR Spring Meeting 2017



Sinead Harney, John Carey, Sandy Fraser & Orla Ni Muircheartaigh



Full House



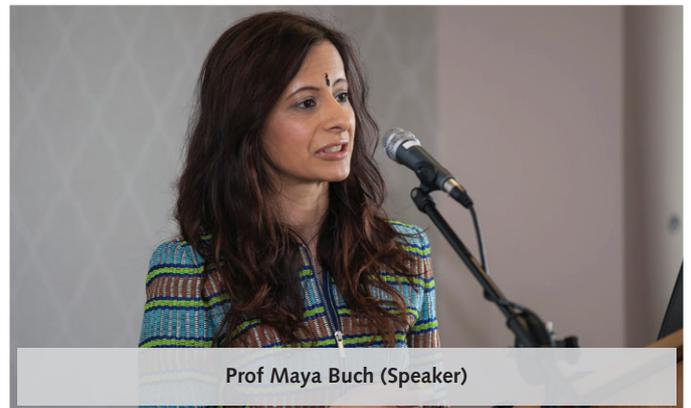
ISR Spring Meeting 2017



Trevor Freeman & Marie Kennedy (AbbVie)



Nóirín Nealon Lennon (Speaker)



Prof Maya Buch (Speaker)



Dr Philip Hodnett (Speaker)



Prof Howard Amital (Speaker)



Enbrel[®] etanercept

Transforming lives¹

15 years
of clinical
trials
and real world
experience¹

1st approved
anti-TNF
in RA¹⁻⁷

More than
400
trials¹⁸

5 Over
million
patient-years
of collective
clinical experience¹¹

More than
6400
publications¹⁹

1 Over
million
patients
treated¹⁰

of partnership and experience¹
over
15
years



ABBREVIATED PRESCRIBING INFORMATION

Enbrel[®]

etanercept

Before prescribing Enbrel[®] please refer to full Summary of Product Characteristics (SmPC).

Presentation: Enbrel Pre-filled Syringe: Enbrel 25 mg and 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYCLIC[®]): Enbrel 25 mg and 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains either 25 mg or 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for injection for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. Non-radiographic axial spondyloarthritis (nr-axSpA). Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). *Children aged 2-17 years:* Juvenile idiopathic arthritis (JIA). Polyarthritides (rheumatoid factor positive or negative) and extended oligoarthritis from the age of 2 years when inadequate response to, or intolerant of methotrexate. Psoriatic arthritis from the age of 12 years when inadequate response to, or intolerant of methotrexate. Enthesis-related arthritis from the age of 12 years when inadequate response to, or intolerant of, conventional therapy. *Children aged 6-17 years:* Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Dosage:** BRA – 25 mg twice weekly or 50 mg once weekly PP – 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. AS, nr-axSpA and PsA – 25 mg twice weekly or 50 mg once weekly. *Children aged 2-17 years:* JIA – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. *Children aged 6-17 years:* Plaque psoriasis in children aged 6-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. **Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. **Warnings and Precautions:** In order to improve the traceability of biological medicinal products, the trademark and the batch number of the administered product should be clearly recorded (or stated) in the patient file. Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure (CHF). There have been rare (< 0.1%) reports of new onset CHF, including CHF in patients without known pre-existing cardiovascular disease, including patients under 50 years of age. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients previously infected with hepatitis B and there have been reports of worsening hepatitis C in patients receiving Enbrel. Use with caution in patients with a history of hepatitis C. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Use caution when considering combination therapy with DMARDs other than methotrexate. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas, leukaemia or other haematopoietic or solid malignancies in patients treated with a TNF-antagonist cannot be excluded. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy ≤ 18 years of age) in the post-marketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF-antagonists, including Enbrel. Post-marketing cases of Merkel cell carcinoma have

been reported very infrequently in patients treated with Enbrel. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects:** Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and life-threatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, elevated liver enzymes, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, heart failure, autoimmune hepatitis, Steven Johnson's syndrome, anaphylaxis, and very rare reports of: toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type I diabetes mellitus and soft tissue and post-operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. See section 4.8 of the SmPC for how to report adverse reactions. **Package Quantities:** Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYCLIC): Each carton contains 4 pre-filled pens containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. **European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC) 25 mg: EU/1/99/126/023 Enbrel Pre-filled Pen (MYCLIC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **Legal Category:** S1A. **European Marketing Authorisation Holder:** Pfizer Limited, Hammersmith Road, Sandwich, Kent, CT13 9NJ, UK. **For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact:** Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. **API Reference Number:** EN 11_0 Pfilet number: 2017-0024332. **Date of Prescribing Information:** May 2017.

† Across all indications.

References: 1. Scott LJ. Drugs. 2014;74:1379-1410. 2. Enbrel Summary of Product Characteristics. 3. Humira Summary of Product Characteristics. 4. Remicade Summary of Product Characteristics. 5. Cimzia Summary of Product Characteristics. 6. Simponi Summary of Product Characteristics. 7. Remicade EMA report 8. www.clinicaltrials.gov. Date accessed: May 2016. 9. <http://www.ncbi.nlm.nih.gov/pubmed>. Date accessed: May 2016. 10. Data on File. January 2015. 11. Data on File, February 2016.

Date of preparation: August 2017. PP-ENB-IRL-0163

NOW AVAILABLE IN
SUBCUTANEOUS
(SC)

THINK RoACTEMRA¹

IN DMARD-IR AND TNF-IR RA PATIENTS,
WHEN COMBINATION WITH MTX IS NOT AN OPTION

ABRIDGED PRESCRIBING INFORMATION. For full prescribing information, refer to the Summary of Product Characteristics [SmPC]. **RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and RoActemra® 162mg solution for injection in pre-filled syringe (RoActemra SC).** **Indications:** **RoActemra SC:** In combination with methotrexate (MTX) for (i) the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX (ii) the treatment of adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. **RoActemra IV:** In combination with MTX for the treatment of (i) severe, active and progressive RA in adults not previously treated with MTX, (ii) adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists, (iii) active systemic juvenile idiopathic arthritis (sJIA) in patients ≥ 2 years of age, who responded inadequately to previous therapy with NSAIDs and systemic corticosteroids, (iv) juvenile idiopathic polyarthritis (pJIA) (rheumatoid factor positive or negative and extended oligoarthritis) in patients ≥ 2 years of age, who responded inadequately to previous therapy with MTX. RoActemra IV/SC can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate for all indications. RoActemra IV/SC has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX for the treatment of adult RA patients. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. Assess suitability of patient for subcutaneous home use and instruct patient to inform HCP if they experience symptoms of an allergic reaction before administering the next dose. Limited data available regarding switching patients from RoActemra IV to RoActemra SC. **RA: RoActemra IV:** 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients >100 kg, doses >800 mg per infusion are not recommended. No data on doses above 1.2g. **RoActemra SC:** 162mg once every week, irrespective of weight. Patients may self-inject after training. Alternate injection site frequently. **sJIA (RoActemra IV only):** Patients <2 years of age – no data. Patients ≥ 2 years, 8mg/kg diluted to final volume of 100ml for patients ≥ 30 kg or 12mg/kg diluted to final volume of 50ml for patients <30 kg once every 2 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement. **pJIA (RoActemra IV only):** Patients <2 years of age – no data. Patients >2 years of age, 8mg/kg diluted to final volume of 100ml for patients ≥ 30 kg or 10 mg/kg diluted to final volume of 50ml for patients <30 kg once every 4 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement. For pJIA/sJIA: check patient's weight at each visit. **Dose adjustments:** For raised liver enzymes, modify concomitant DMARDs if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count reduce or interrupt RoActemra. In some instances discontinue RoActemra (see SmPC). In patients not previously treated with RoActemra, initiation is not recommended in patients with an absolute neutrophil count (ANC) below $2 \times 10^9/l$. **Special Populations:** No data available for RoActemra SC in patients <18 years of age. Closely monitor renal function in patients with moderate to severe renal impairment. No data in patients with hepatic impairment. No dose adjustments in patients >65 years. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Special Warnings & Precautions:** Cases of serious infections (sometimes fatal) have been reported; interrupt therapy until controlled. Do not initiate treatment in patients with active infections. Caution in patients with recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which predisposes to infection. Vigilance for the timely detection of serious infection is recommended – signs and symptoms of acute inflammation may be lessened, associated with suppression of the acute phase reaction. Consider effects of RoActemra on C-reactive protein (CRP), neutrophils and signs and symptoms of infection when evaluating a patient for a potential infection. Patients and parents/guardians of sJIA and pJIA patients should contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Patients to seek medical attention if sign/symptoms suggestive of TB occur during or after treatment. Viral reactivation (e.g. hepatitis B) reported with biologic therapies. Caution in patients with a history of intestinal ulceration or diverticulitis. Serious hypersensitivity reactions, including anaphylaxis, reported and may be more severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous treatment even if they have received premedication with steroids and anti-histamines. Appropriate treatment should be available for immediate use in the event of an anaphylactic reaction during treatment with RoActemra. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, immediately stop administration and permanently discontinue RoActemra. Use with caution in patients with active hepatic disease/impairment. In clinical trials, transient or intermittent mild-moderate elevations of hepatic transaminases reported commonly with RoActemra treatment, without progression to hepatic injury. An increased frequency of these elevations was observed when potentially hepatotoxic drugs (e.g. MTX) were used in combination with RoActemra. When clinically indicated, consider other liver function tests including bilirubin. Not recommended in patients with baseline ALT or AST $> 5 \times$ ULN; caution in patients with ALT or AST $> 1.5 \times$ ULN (see SmPC for frequency of monitoring and dose modifications/interruptions). Decreases in neutrophil and platelet counts have occurred following treatment with RoActemra 8mg/kg in combination with MTX. Risk of neutropenia may increase in patients previously treated with TNF antagonist. Continued therapy not recommended in patients with ANC $< 0.5 \times 10^9/l$ or platelet count $< 50 \times 10^9/l$. Do not initiate RoActemra treatment where ANC is below $2 \times 10^9/l$. Caution in patients with low platelet count; monitor neutrophils and platelets in RA, sJIA and pJIA patients according to SmPC. Elevations in lipid parameters seen; assess every 4 to 8 weeks; if elevated, follow local guidelines. Be vigilant for symptoms of new-onset central demyelinating disorders. Immunomodulatory medicines may increase malignancy risk in RA patients. Live and live attenuated vaccines should not be given concurrently (see SmPC). RA patients have an increased risk for cardiovascular disorders – manage risk factors (e.g. hypertension, hyperlipidaemia) as part of usual standard of care. Not recommended for use with other biological agents. RoActemra (for IV use) contains 1.17 mmol (or 26.55 mg) sodium per maximum dose of 1200 mg – to be considered by patients on a controlled sodium diet. Macrophage activation syndrome (MAS), a serious life-threatening disorder, may develop in sJIA patients – RoActemra not studied in patients during an active MAS episode. Trade name and batch number should be clearly recorded in patient file to improve traceability of biological medicines. **Drug Interactions:** Studies only performed in adults. Monitor patients taking medicines individually adjusted and metabolised via CYP450 3A4, 1A2 or 2C9 when starting/stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. Effects of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy (refer to SmPC for further details on cytochrome CYP450 and other drug interactions). **Fertility, Pregnancy & Lactation:** Women must use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed increased risk of spontaneous abortion/embryo-fetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. No lactation data in humans. A decision on whether to continue/discontinue breastfeeding or RoActemra therapy should be made taking into account the relative benefits to the child and mother. Refer to SmPC. **Effects on ability to drive and use machines:** RoActemra has minor influence on the ability to drive and use machines (dizziness). **Undesirable Effects:** Prescribers should consult SmPC for full details of ADRs. **RoActemra IV: RA:** The most commonly reported ADRs (occurring in $\geq 5\%$ of patients treated with tocilizumab monotherapy or in combination with DMARDs) were upper respiratory tract infections, nasopharyngitis, headache, hypertension and increased ALT. The most serious ADRs were serious infections, complications of diverticulitis, and hypersensitivity reactions. ADRs occurring in RoActemra trials: **Very Common ($\geq 1/10$):** upper respiratory tract infections, hypercholesterolaemia. **Common ($\geq 1/100 - <1/10$):** cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. **Uncommon ($\geq 1/1000 - <1/100$):** diverticulitis, stomatitis, gastric ulcer, hypertriglyceridaemia, nephrolithiasis, hypothyroidism. **sJIA:** ADRs were similar to those seen in RA patients. sJIA patients experienced a higher frequency of nasopharyngitis, decrease in neutrophil counts, hepatic transaminases increased, and diarrhoea. **Very Common ($\geq 1/10$):** upper respiratory tract infections, nasopharyngitis, decrease in neutrophil count. **Common ($\geq 1/100 - <1/10$):** diarrhoea, infusion related reactions, headache, platelet count decreased, cholesterol increased. **pJIA:** ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count more frequently reported in the pJIA population. **Very Common ($\geq 1/10$):** upper respiratory tract infections, nasopharyngitis, headache. **Common ($\geq 1/100 - <1/10$):** nausea, diarrhoea, infusion related reactions, hepatic transaminases increased, decrease in neutrophil count. **Uncommon ($\geq 1/1000 - <1/100$):** platelet count decreased, cholesterol increased. **RoActemra SC:** The safety and immunogenicity was consistent with the known safety profile of IV. Injection site reactions (including erythema, pruritus, pain and haematoma) were mild to moderate in severity. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), GI perforations (as complications of diverticulitis), serious hypersensitivity reactions, Stevens-Johnson syndrome. See SmPC section 4.8 for instructions on the reporting of suspected adverse reactions. **Legal Category:** Subject to medical prescription (which may not be renewed (A)). **Presentations & Marketing Authorisation Numbers:** 80mg of tocilizumab in 4ml (20mg/ml) pack of 1 (EU/1/08/492/005); 162mg of tocilizumab in 10ml (20mg/ml) pack of 1 (EU/1/08/492/003); 400mg of tocilizumab in 20ml (20mg/ml) pack of 1 (EU/1/08/492/005); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled syringe (EU/1/08/492/007). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690790. Fax: (01) 4690791. **Date of Preparation:** June 2017. **Reference:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. *Int. J. Clin. Rheumatol.* (2012) 7(1): 9-19. **Date of item:** August 2017. IE/RACE/0517/0035(1)



RoACTEMRA[®]
tocilizumab