Figure. Efficacy responses from Week 48 to Week 156 (NRI and OC)

Full analysis set (N=254). Patients received BKZ 160 mg or 320 mg during the BE AGILE dose-ranging study. Missing data were imputed using NRI. ASAS: Assessment of SpondyloArthritis International Society, ASAS20/40: ASAS 20%/40% response; ASAS PR: ASAS partial remission; ASDAS: Ankylosing Spondylitis Disease Activity Score; ASDAS-CII: ASDAS clinically important improvement (≥ 1.1 decrease from baseline ASDAS score); ASDAS-ID: ASDAS inactive disease (ASDAS <1.3); ASDAS-MI: ASDAS major improvement (≥ 2.0 decrease from baseline ASDAS score or achievement of lowest possible ASDAS score [0.6]); BKZ: bimekizumab; NRI: non-responder imputation; OC: observed case; OLE: open-label extension.

Disclosure of Interests: Désirée van der Heijde Consultant of: AbbVie, Amgen, Astellas, AstraZeneca, Bayer, BMS, Boehringer Ingelheim, Celgene, Cyxone, Daiichi, Eisai, Eli Lilly, Galapagos, Gilead, GSK, Janssen, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi, Takeda, UCB Pharma, Employee of: Director of Imaging Rheumatology, Atul Deodhar Speakers bureau: Janssen, Novartis, Pfizer, Consultant of: AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Eli Lilly, Gilead, GSK, Janssen, Novartis, Pfizer, UCB Pharma, Grant/research support from: AbbVie, Eli Lilly, GSK, Novartis, Pfizer, UCB Pharma, Lianne S. Gensler Consultant of: AbbVie, Eli Lilly, Gilead, GSK, Novartis, Pfizer, UCB Pharma, Grant/research support from: Pfizer, Denis Poddubnyy Speakers bureau: AbbVie, BMS, Eli Lilly, MSD, Novartis, Pfizer, UCB Pharma, Consultant of: AbbVie, Biocad, Eli Lilly, Gilead, GSK, MSD, Novartis, Pfizer, Samsung Bioepis, UCB Pharma, Grant/research support from: AbbVie, MSD, Novartis, Pfizer, Alan Kivitz Shareholder of: Pfizer, Novartis, Speakers bureau: Amgen, Eli Lilly, Pfizer, Novartis, Consultant of: Novartis, UCB Pharma, Maxime Dougados Consultant of: AbbVie, Eli Lilly, Novartis, Pfizer, UCB Pharma, Grant/research support from: AbbVie, Eli Lilly, Novartis, Pfizer, UCB Pharma, Natasha de Peyrecave Employee of: UCB Pharma, Marga Oortgiesen Employee of: UCB Pharma, Thomas Vaux Employee of: UCB Pharma, Carmen Fleurinck Employee of: UCB Pharma, Xenofon Baraliakos Speakers bureau: AbbVie, BMS, Chugai, Eli Lilly, Galapagos, Gilead, MSD, Novartis, Pfizer, UCB Pharma, Paid instructor for: AbbVie, BMS, Chugai, Eli Lilly, Galapagos, Gilead, MSD, Novartis, Pfizer, UCB Pharma, Consultant of: AbbVie, BMS, Chugai, Eli Lilly, Galapagos, Gilead, MSD, Novartis, Pfizer, UCB Pharma

DOI: 10.1136/annrheumdis-2021-eular.156

POS0227 SHOULD ALL PATIENTS TRIAL SUBCUTANEOUS METHOTREXATE PRIOR TO COMMENCING BIOLOGIC THERAPY – A REAL WORLD STUDY

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Background: Methotrexate (MTX) is the bed rock of inflammatory arthritis management. However intolerance is a major limiting factor for drug optimisation and retention. There is data to suggest that subcutaneous (SC) MTX is tolerated better and is now being recommended in several guidelines including ACR's. It is less clear though whether this strategy is effective in those where oral preparation is inefficacious and its potential to avoid escalation to biologic therapy.

Objectives: Our aim was to analyse the reasons for switching to SC formulation in a real world setting, clinical outcomes achieved and proportion requiring biologic prescription.

Methods: We undertook a retrospective survey of all patients prescribed SC MTX in a large university teaching hospital between 1983 and Apr 2019. We had access to full patient records including details on co-morbidities, drugs and disease management. We analysed demographics, reasons for SC MTX initiation, clinical outcomes and impact on biologic prescription.

Results: 352 patients were identified during the study period. The mean age of the cohort was 54 yrs (3-87). 192 (70%) were women. 260 (74%) were Caucasian, 64 (18%) Asian, 21 (6%) Afro-Caribbean and remaining of other ethnicity. Two most common diagnoses were RA [n=243 (69%)] and pSpA [n=66 (18%)]. Average disease duration was 74 months (11-324) with mean of three comorbidities (0-11).

284 (80%) had switched from oral to SC MTX. 137 (49%) stopped oral MTX due to side effects. Mean duration of oral MTX prior to switching was 26 months (0.25-167). Follow up period for SC MTX ranged from two to 132 months (mean 29) until the data cut-off date of Apr 2019. 103 (29%) patients progressed to biologic therapy.

Amongst RA patients, DAS28 improved from mean 4.16 (0.63-8.06) to 2.83 (0.14-7.32) following the switch. pSpA cohort's mean TJC and SJC improved from mean seven (0-42) and two (0-26) to two (0-25) and one (0-6) respectively.

Conclusion: Our study confirms that SC MTX is an effective solution irrespective of whether oral MTX is inefficacious or intolerable. This applies to people with both RA and pSpA. In accordance with prior published data, our findings support the utility of SC MTX for those intolerant of enteral option. Additionally, it shows that even in instances where oral MTX was ineffective, a switch to SC formulation achieved low disease activity despite multi-morbidity, long disease course and protracted oral MTX exposure. This intervention also prevented over two-thirds of patients progressing to biologic therapy with significant financial savings. SC MTX therefore remains a durable strategy with excellent disease outcomes and confers substantial economic benefits to healthcare.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2021-eular.1116

POS0228 BASELINE CHARACTERISTICS AND TREATMENT RESPONSE TO IXEKIZUMAB CATEGORISED BY SEX IN RADIOGRAPHIC AND NON-RADIOGRAPHIC AXIAL SPONDYLARTHRTIS PATIENTS THROUGH 52 WEEKS: DATA FROM 3 PHASE III, RANDOMIZED, CONTROLLED TRIALS

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Background: Axial spondyloarthritis (axSpA) is a chronic inflammatory disease of the axial skeleton comprising two subtypes within the same spectrum: radiographic (r-axSpA) and non-radiographic (nr-axSpA). Previous studies have shown that clinical presentation and treatment response of males and females may differ¹ despite similar disease burden.² Ixekizumab (IXE), a high-affinity monoclonal antibody that selectively targets interleukin-17A, has demonstrated superior efficacy to placebo in the treatment of patients with r-axSpA (COAST-V/W [bDMARD-naïve/TNFi-experienced]) and nr-axSpA (COAST-X [bDMARD-naïve]).³

Objectives: Assess baseline characteristics and treatment response to IXE categorised by sex in patients with r-axSpA and nr-axSpA for up to 52 weeks.

Methods: Patients fulfilled the ASAS classification criteria for r-axSpA or nr-axSpA. Patients were randomized to receive 80mg subcutaneous IXE every 2 weeks (Q2W) or 4 weeks (Q4W), or to placebo (PBO) [16 weeks COAST-V/W; 52 weeks COAST-X]. Baseline characteristics and treatment outcomes were assessed. Patients were categorised by sex, missing data was controlled for using non-responder imputation (NRI) and modified baseline observation carried forward (mBOCF) analysis was conducted on continuous efficacy variables.

Results: At baseline, females were older, with significantly higher pain and fatigue scores and peripheral joint symptoms (table 1). ASAS40 response rate with IXEQ4W was achieved in 39% of males with r-axSpA by week 16, and 44% by week 52. Females achieved 16.7% at week 16, and 33.3% at week 52. In nr-axSpA, 46% of IXEQ4W males achieved ASAS40 at week 16 and 30% at week 52. 23.9% of females achieved ASAS40 at week 16, increasing to 30.4% at week 52.

Conclusion: This analysis demonstrates that for the axSpA disease spectrum, females present with higher disease burden as reflected by higher scores in fatigue/tiredness, and spinal pain at night. Our findings indicate that males and females respond to IXE; however, females experience this benefit later in their treatment course, with a more prolonged attainment of peak response.