UCB, Paid instructor for: Abbvie, Speakers bureau: AbbVie, BMS, Pfizer, Roche, Louis Coupal: None declared

DOI: 10.1136/annrheumdis-2020-eular.4339

FRI0332

EVALUATION OF THE INDIVIDUAL COMPONENTS OF ACR50+PASI100 AND MDA AT WEEK 24 FROM THE SPIRIT-H2H TRIAL COMPARING THE EFFICACY AND SAFETY OF IXE VERSUS ADA IN PATIENTS WITH PSA NAÏVE TO BDMARDS

L. C. Coates[1], M. Nissen[2], C. El Baou[3], J. Zochling[4], A. Marchesoni[5], S. Liu Leage[6], E. Soriano[7], V. F. Azevedo[8], K. Machold[9], C. Sapin[6]. [1]*Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford, United Kingdom*; [2]*University of Geneva, Rheumatology, Geneva, Switzerland*; [3]*Eli Lilly Research & Development, Windlesham, United Kingdom*; [4]*Rheumatology Tasmania, Hobart, Australia*; [5]*ASST Gaetano Pini-CTO Polo Isocrate, Milano, Italy*; [6]*Eli Lilly and Company Corporate Center, Indianapolis, United States of America*; [7]*Hospital Italiano de Buenos Aires, ABH, Argentina*; [8]*Federal University of Parana, Curitiba, Brazil*; [9]*Medical University of Vienna, Wien, Austria*

Background: Psoriatic arthritis (PsA) is a chronic systemic disease with manifestations affecting musculoskeletal and extra-articular domains. Treatment and assessment of response are therefore major challenges in routine clinical practice. Minimal disease activity (MDA) is a multidimensional endpoint that can define a treatment target[1]. In SPIRIT-H2H[2], a head-to-head clinical trial comparing the efficacy and safety of ixekizumab (IXE) versus) to adalimumab (ADA), the percentage of patients simultaneously achieving American College of Rheumatology 50 (ACR50) and Psoriasis Area and Severity Index 100 (PASI100), was the primary endpoint in order to reflect improvement in two domains of PsA.

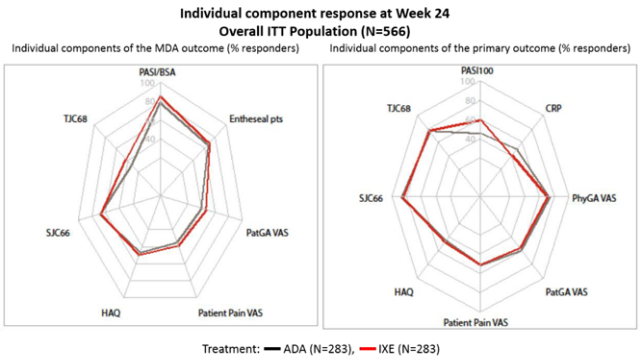
Objectives: To evaluate how individual components of the simultaneous achievement of ACR50 and PASI100 compare with those of MDA at week 24.

Methods: Patients with active PsA (defined as those with a tender joint count [TJC] ≥ 3/68, a swollen joint count [SJC] ≥ 3/66 and a body surface area [BSA] of active plaque psoriasis ≥ 3%) were randomised 1:1 to approved dosing (according to baseline psoriasis involvement) of IXE or ADA in SPIRIT-H2H, an open label, assessor-blinded study.

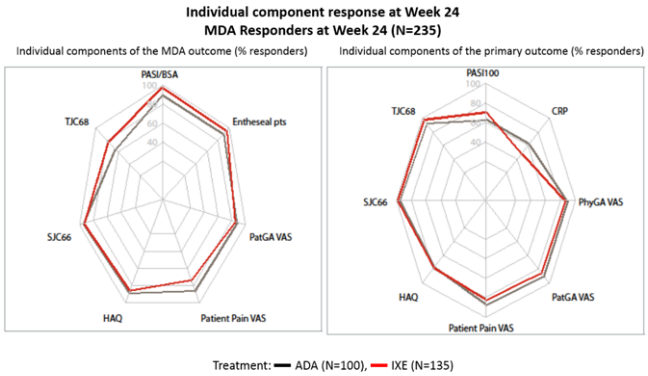
The proportion of patients meeting each criterion of the composite endpoints was calculated for the intent-to-treat ([ITT], N=566) population and the population of MDA responders at Week 24 (N=235). Missing individual responses were imputed with non-responder status. Spidergrams were generated using SAS 9.4.

Results:

For both the overall ITT population and the MDA responders population, the use of PASI≤1 or BSA≤3% in the skin-related component of the MDA contributed to the higher response rate relative to the PASI100 response. Thus, the PASI100 response is a more stringent endpoint. Proportions of responders are similar across MDA and ACR50+PASI100 individual components for HAQ and SJC. The high baseline TJC levels (mean TJC: IXE=19.1, ADA=21.3) as opposed to lower levels observed for baseline SJC (mean SJC: IXE=10.1, ADA=10.7) made MDA-TJC criterion (≤1) more difficult to achieve than the equivalent criterion of the ACR50+PASI100 endpoint.



MDA response:
Patients need to fulfil 5 of the 7 criteria: TJC≤1, SJC ≤1, PASI ≤1 or BSA ≤3, Patient pain visual analogue scale (VAS) score ≤ 15, Patient global VAS score ≤20, Health Assessment Questionnaire Disability Index (HAQ-DI) ≤ 0.5, tender entheseal points (18) ≤1.
ACR50 response
Patients need to report ≥ 50% improvement in TJC and SJC and a ≥ 50% improvement in at least 3 of the following: Patient pain VAS score, patient global VAS score, Physician global VAS score, HAQ-DI, high sensitivity CRP (hs-CRP).



N.B Nine pts with active PsO and BSA≥3% were assessed as PASI=0 at baseline, a medical inconsistency that was resolved using medical judgement. These patients were considered PASI100 responders if PASI=0 and BSA=0 at post baseline visits

Conclusion: Despite the differences in criteria definitions, there are consistent response patterns in the individual components of the simultaneous ACR50+PASI100 and MDA endpoints in particular for the peripheral arthritis domain.

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Disclosure of Interests: Laura C Coates: None declared, Michael Nissen Grant/research support from: Abbvie, Consultant of: Novartis, Lilly, Abbvie, Celgene and Pfizer, Speakers bureau: Novartis, Lilly, Abbvie, Celgene and Pfizer, Celine El Baou Consultant of: Eli Lilly and Company, Jane Zochling Employee of: Jannssen Cilag, Speakers bureau: Janssen Cilag, AbbVie, Novartis, UCB, BMS, Eli Lilly, Antonio Marchesoni Speakers bureau: Abbvie, Pfizer, UCB, Novartis, Celgene, Eli Lilly, Soyi Liu Leage Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Enrique Soriano Grant/research support from: AbbVie, Eli Lilly, GlaxoSmithKline, Novartis, Pfizer Inc, Sandoz, Consultant of: AbbVie, Eli Lilly, GlaxoSmithKline, Novartis, Pfizer Inc, Sandoz, Speakers bureau: AbbVie, Amber, Bristol-Myers Squibb, Eli Lilly, Novartis, Pfizer Inc, Roche, Valderilio F Azevedo Grant/research support from: Abbvie, Janssen, Bristol-Myers Squibb, Boehringer-Ingelheim, Lilly and Novartis, Consultant of: Lilly, Novartis, Janssen, Boehringer-Ingelheim, Amgen, Pfizer and Abbvie, Speakers bureau: Sandoz, Celltrion, Lilly, Novartis, Janssen, Boehringer-Ingelheim, Amgen, Pfizer and Abbvie, Klaus Machold Grant/research support from: AbbVie, MSD, UCB, Consultant of: Arsanis, Astro, Baxter, BMS, Celgene, Eli-Lilly, MSD, Pfizer, Roche, Novartis, Sandoz, Speakers bureau: MSD, Pfizer, BMS, Janssen-Cilag, Sandoz, Novartis, Eli-Lilly, Christophe Sapin Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company

DOI: 10.1136/annrheumdis-2020-eular.2830

FRI0333

ACHIEVEMENT OF VERY LOW DISEASE ACTIVITY AND REMISSION TREATMENT TARGETS IS ASSOCIATED WITH REDUCED RADIOGRAPHIC PROGRESSION IN PATIENTS WITH PSORIATIC ARTHRITIS TREATED WITH CERTOLIZUMAB PEGOL

L. C. Coates[1], J. F. Merola[2], A. Kavanaugh[3], P. J. Mease[4], O. Davies[5], O. Irvin-Sellers[5], T. Nurminen[6], D. Van der Heijde[7]. [1]*Nuffield Orthopaedic Centre, Oxford, United Kingdom*; [2]*Brigham and Women's Hospital, Harvard Medical School, Boston, United States of America*; [3]*Division of Rheumatology, Allergy and Immunology, UC San Diego School of Medicine, La Jolla, United States of America*; [4]*Swedish Medical Center and University of Washington, Seattle, United States of America*; [5]*UCB Pharma, Slough, United Kingdom*; [6]*UCB Pharma, Monheim am Rhein, Germany*; [7]*Leiden University Medical Centre, Leiden, Netherlands*

Background: Several disease activity measures and thresholds have been recommended as psoriatic arthritis (PsA) treatment targets, although consensus on the most appropriate assessment tool is lacking.[1] Reports suggest low disease activity (LDA) and remission may be associated with minimal structural progression in PsA.[2]

Objectives: To report the relationship between PsA disease activity and structural progression over 216 weeks' (wks) treatment with certolizumab pegol (CZP), an Fc-free, PEGylated, tumour necrosis factor inhibitor (TNFi) that has shown long-term efficacy and safety in PsA.[3]

Methods: Patients (pts) enrolled in RAPID-PsA (NCT01087788) with active PsA (≥3 tender joints; ≥3 swollen joints; ESR ≥28 mm/hour and/or CRP >upper limit of normal) who had failed treatment with ≥1 csDMARD were randomised 1:1:1 to CZP 200 mg every 2 wks (Q2W), CZP 400 mg every 4 wks (Q4W), or placebo (PBO). All CZP pts received CZP 400 mg at Wks 0/2/4. PBO pts were re-randomised to CZP 200 mg Q2W or 400 mg Q4W at Wk 16 or 24.[3]

Pts were heterogenous for structural damage and disease duration at baseline. Disease activity was assessed using minimal disease activity (MDA) criteria (MDA: 5–6/7 criteria; very LDA [VLDA]: 7/7 criteria), Psoriatic Arthritis Disease Activity Score (PASDAS) (LDA: >1.9–≤3.2; remission: ≤1.9), or Disease Activity Index for Psoriatic Arthritis (DAPSA) (LDA: >4–≤14; remission: ≤4). Radiographs were read in four reading campaigns using the van der Heijde modified Total Sharp Score (mTSS) for PsA. A risk of structural progression (RSP) subgroup (baseline mTSS >median for all pts) was also assessed. Mean change from baseline (CFB) in mTSS and associations with disease activity states were estimated using a hierarchical linear mixed effects model (fixed effects: reading campaign/interactions of concurrent disease activity levels with time; random effects: pt/reading campaign nested within pt) which allowed mean mTSS trajectory, and impact of disease activity levels on this, to differ over time.

Results: 407/409 randomised pts were assessed for mTSS at least once. At Wk 0, mean (standard deviation) DAPSA=44.5 (22.7), PASDAS=6.0 (1.1). 3/409 (0.7%) pts reported MDA. The proportion of pts achieving remission/VLDA states increased to Wk 216, as did estimated mean mTSS. Estimated mean mTSS CFB remained low overall (0.46 at Wk 216; standard error 0.16; **Figure**). Across disease activity measures, remission/VLDA states were associated with mTSS estimated mean CFB ≤0 in both the overall group and RSP subgroup (**Table**).

Conclusion: These data indicate that achievement of remission in PsA is important to prevent further structural damage, particularly in pts with pre-existing structural changes. This supports the rationale for strict disease activity targets.

References:

[1] Coates L. Arthritis Rheumatol 2018;70:345–55; **2.** Tucker LJ. Curr Rheumatol Rep 2018;20:71; **3.** van der Heijde D. RMD Open 2018;4:e000582.

Table. Estimated mTSS (mixed effects model)

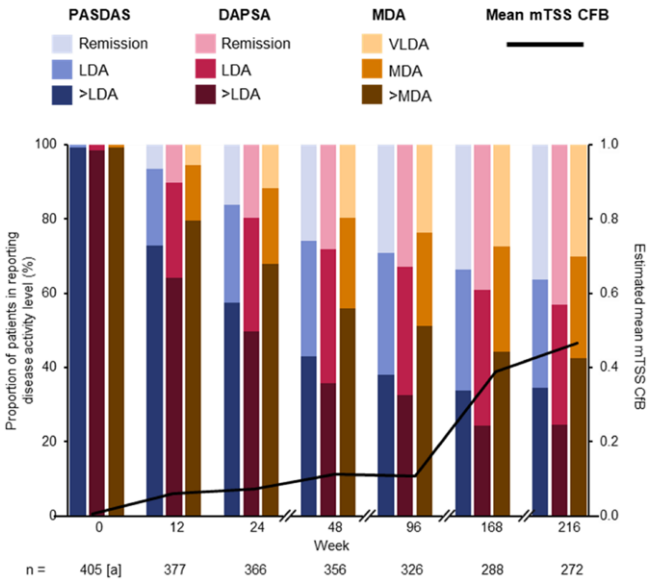
		mTSS estimated mean CFB (standard error)	
		All patients (N=407)	RSP (n=202)
PASDAS	Remission	-0.20 (0.25)	-0.55 (0.49)
	LDA	0.01 (0.23)	-0.07 (0.47)
	>LDA	1.31 (0.22)	2.54 (0.43)
DAPSA	Remission	-0.34 (0.23)	-0.67 (0.46)
	LDA	0.40 (0.22)	0.81 (0.44)
	>LDA	1.37 (0.24)	2.46 (0.48)
MDA	VLDA	-0.40 (0.28)	-0.84 (0.55)
	MDA	0.39 (0.24)	0.55 (0.48)
	>MDA	0.89 (0.20)	1.73 (0.39)

mTSS estimated mean CFB: ≤0; ≤0.5; >0.5. Data to Wk 216 pooled for all pts randomised.

Acknowledgments: This study was funded by UCB Pharma. Editorial services were provided by Costello Medical.

Disclosure of Interests: Laura C Coates: None declared, Joseph F. Merola Consultant of: Merck, AbbVie, Dermavant, Eli Lilly, Novartis, Janssen, UCB Pharma, Celgene, Sanofi, Regeneron, Arena, Sun Pharma, Biogen, Pfizer, EMD Sorono, Avotres and LEO Pharma, Arthur Kavanaugh Grant/research support from: Abbott, Amgen, AstraZeneca, BMS, Celgene Corporation, Centocor-Janssen, Pfizer, Roche, UCB – grant/research support, Philip J Mease Grant/research support from: Abbott, Amgen, Biogen Idec, BMS, Celgene Corporation, Eli Lilly, Novartis, Pfizer, Sun Pharmaceutical, UCB – grant/research support, Consultant of: Abbott, Amgen, Biogen Idec, BMS, Celgene Corporation, Eli Lilly, Novartis, Pfizer, Sun Pharmaceutical, UCB – consultant, Speakers bureau: Abbott, Amgen, Biogen Idec, BMS, Eli Lilly, Genentech, Janssen, Pfizer, UCB – speakers bureau, Owen Davies Employee of: UCB Pharma, Oscar Irvin-Sellers Employee of: UCB Pharma, Tommi Nurminen Employee of: UCB Pharma, Désirée van der Heijde Consultant of: AbbVie, Amgen, Astellas, AstraZeneca, BMS, Boehringer Ingelheim, Celgene, Cyxone, Daiichi, Eisai, Eli-Lilly, Galapagos, Gilead Sciences, Inc., Glaxo-Smith-Kline, Janssen, Merck, Novartis, Pfizer, Regeneron, Roche, Sanofi, Takeda, UCB Pharma; Director of Imaging Rheumatology BV

Figure: Observed disease activity levels and estimated mean CfB in mTSS (mixed effects model) through Wks 0–216 pooled for all randomised patients



[a] Baseline PASDAS data were only available for 398 patients. Data were pooled for all patients randomised to CZP and PBO. Radiographs were taken at Wks 0, 12, 24, 48, 96, 168 and 216. Mean CfB in mTSS was estimated using a hierarchical mixed effects model for repeated measures. The proportion of patients achieving each disease activity level is observed case. CfB: change from baseline; CZP: certolizumab pegol; DAPSA: Disease Activity Index of Psoriatic Arthritis; LDA: low disease activity; MDA: minimal disease activity; mTSS: modified Total Sharp Score; PASDAS: Psoriatic Arthritis Disease Activity Score; PBO: placebo; VLDA: very low disease activity.

DOI: 10.1136/annrheumdis-2020-eular.4269

FRI0334

COMPARATIVE ASSESSMENT OF COMORBIDITY IN ANKYLOSING SPONDYLITIS, PSORIATIC ARTHRITIS WITH AND WITHOUT SPINAL INVOLVEMENT

A. Dadalova[1], E. Vasilenko[1], R. Samigullina[1], V. Mazurov[1]. [1]*North-Western State Medical University named after I.I.Mechnikov, Department of Therapy, Rheumatology, Examination of Temporary Disability and Quality of Medical Care named after E.E.Eichwald, Saint Petersburg, Russian Federation*

Background: Axial spondyloarthritis (axSpA) is a chronic inflammatory disease is associated with a lot of comorbidities, especially the diseases of cardiovascular system. [1] These diseases not only lead to a decrease in the quality of life and disability of patients, but also to a decrease in life expectancy in comparison with the general population. [2]

Objectives: The goal of study is to identify the most significant and common comorbid conditions in patients with axial spondylitis and compare their prevalence in three groups: in patients with ankylosing spondylitis, patients with psoriatic arthritis with and without spinal involvement.

Methods: The study included 140 patients with a reliable diagnosis of axSpA (ASAS criteria, 2009), which were subsequently divided into three groups: patients with ankylosing spondylitis, patients with psoriatic arthritis with and without spinal involvement. In all patients comorbid conditions was evaluated.

Results: The most common comorbid conditions among patients with axSpA were overweight (65%), included obesity (44%), hypertension (45%), diabetes and prediabetes (31,4%), dyslipidemia (23,6%), coronary heart disease (9,3%), diseases of the gastrointestinal tract (38,6%). Then we analyzed the prevalence of these comorbid pathologies in three groups.

The characteristics of the groups are presented in Table 1.