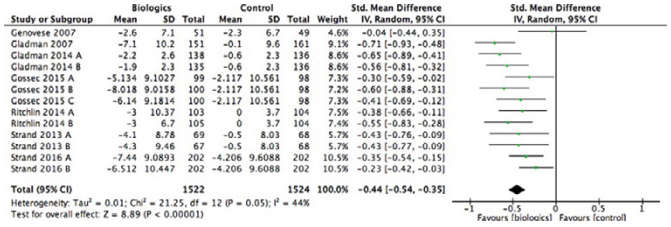
score used), with data available for fatigue were included. Data were collected by 2 regarding levels of fatigue (6 trials used FACIT, 1 VAS) and pain (if available) at baseline and at the timepoint closest to 24 weeks after the biologic introduction. A MA was performed using RevMan and SMDs were calculated for each trial and each study dose, for fatigue and for pain. A SMD <0.5 is usually considered small, between 0.5 and 0.8 moderate and >0.8 as important.

Results: After screening 295 publications, 7 RCTs were included in the meta-analysis and assessed TNF blockers (N=3: adalimumab N=2, certolizumab pegol, N=1), secukinumab (N=2), apremilast (N=1) and ustekinumab (N=1) with or without methotrexate, compared to placebo. The studies included 2340 PsA patients: weighted mean age ± standard deviation (SD), 48.7±1.3 years, disease duration 7.7±1.3 years, 53.3% were females. At baseline, joint disease activity was high (weighted mean swollen joint count: 13.0±3.1, HAQ-DI: 1.2±0.1, PASI: 10.4±3.3). Fatigue levels were high at baseline (weighted mean FACIT score: 29.2±1.5). The pooled SMD for fatigue was 0.44 (95% CI -0.35, 0.54) and it ranged 0.04 to 0.71 across drugs and trials with a small to moderate effect (Graph). In 6 of the same studies, the pooled SMD for pain was 0.62 (95% CI 0.52, 0.73) and ranged 0.46 to 0.84.



Conclusions: Biologics had a mild to moderate effect on fatigue at 24 weeks in PsA RCTs. No notable differences across drugs were apparent. Effect sizes were higher on pain with a moderate effect. This effect seems similar to effects noted in RA in the Cochrane meta-analysis (1).These results confirm fatigue may be multifactorial in PsA; biologics bring some improvement at the group level but other treatment modalities should be further explored also.

References:

[1] Almeida C, Choy EHS, He wlett S, Kirwan JR, Cramp F, Chalder T, Pollock J, Christensen R. Biologic interventions for fatigue in rheumatoid arthritis. Cochrane Database of Systematic Reviews 2016, Issue 6. Art. No. CD008334. DOI:10.1002/14651858.CD008334.pub2.

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FRI0520 IMPROVED PATIENT-REPORTED OUTCOMES IN PSORIATIC ARTHRITIS PATIENTS TREATED WITH ABATACEPT: RESULTS FROM A PHASE III TRIAL

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Background: In the Phase III ASTRAEA study (NCT01860976), abatacept (ABA) significantly increased ACR20 responses, with benefits on other musculoskeletal symptoms in patients (pts) with active psoriatic arthritis (PsA).[1] As PsA impacts HRQoL, assessing treatment (tmt) effect using patient-reported outcomes (PROs) is important.

Objectives: To explore the effect of ABA tmt using PROs in intent-to-treat and *post hoc* analyses of ASTRAEA.

Methods: Pts were randomized (1:1) to SC ABA 125 mg weekly or placebo (PBO) for 24 weeks (W). At W16, pts without ≥20% improvement in joint counts started open-label ABA. Adjusted mean changes from baseline (BL) to W16 (all pts) and W24 (responder analysis) in Short Form-36 (SF-36; physical and mental component summary [PCS, MCS] and individual domains using spydergrams), pain VAS and HAQ-DI scores, Dermatology QoL Index (DLQI) and FACIT-Fatigue scale (FACIT-F) were evaluated in the total population and subgroups stratified by BL CRP level and prior TNFi use. Proportions of pts reporting improvements ≥minimal clinically important difference (MCID) in SF-36 summary (≥2.5) and domain (≥5.0), FACIT-F (≥40) and HAQ-DI (<–0.22) scores and ≥normative values in SF-36 summary (≥50) and domains, FACIT-F (<40) and HAQ-DI (<0.5) at W16 were analysed in the total population.

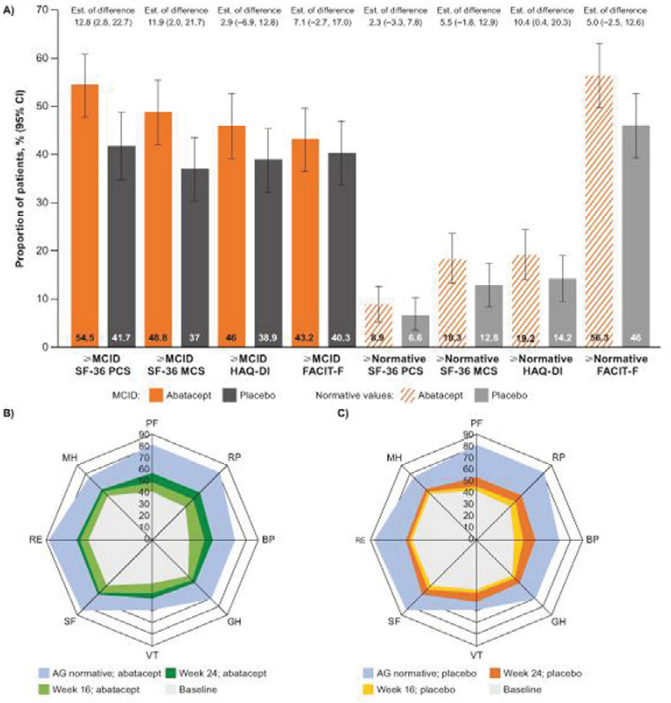
Results: In the total population, improvements in all PROs were numerically greater for ABA (n=213) vs PBO (n=211) at W16 and W24 and significant for SF-36 PCS at W16 and HAQ-DI at W24 (Table). At W16, improvements in all SF-36 domains were numerically greater with ABA, and significant for physical function, bodily pain and vitality. A higher proportion of pts receiving ABA vs PBO reported improvements ≥MCID in SF-36 PCS, MCS, SF-36 domains, FACIT-F, HAQ-DI (Fig) and DLQI (not shown) at W16. The proportion of pts whose scores were ≥normative values at W16 was higher with ABA vs PBO in SF-36 PCS, MCS, FACIT-F and HAQ-DI scores. At W24, improvements in SF-36 domain scores accrued in both groups, with numerical differences in favour of ABA except in social function. Improvements in PROs were greater with ABA tmt in BL CRP>upper limit of normal (ULN) vs CRP≤ULN and in TNFi-naïve vs -exposed subpopulations.

Table 1. Change from Baseline in PROs at 16 and 24 Weeks

PRO	Week 16 (total population)		Week 24 (responder analysis)	
	Abatacept	Placebo	Abatacept	Placebo
SF-36	*n=202*	*n=186*	*n=124*	*n=97*
PCS	3.76 (0.55)*	2.02 (0.57)	5.11 (0.64)	3.69 (0.71)
MCS	2.42 (0.70)	1.15 (0.73)	2.56 (0.83)	2.62 (0.92)
HAQ-DI	*n=202*	*n=187*	*n=124*	*n=98*
	–0.25 (0.04)	–0.15 (0.04)	–0.33 (0.04)*	–0.20 (0.05)
DLQI	*n=212*	*n=189*	*n=126*	*n=98*
	–2.28 (0.34)*	–1.24 (0.35)	–2.49 (0.42)*	–0.71 (0.48)
FACIT-F	*n=202*	*n=189*	*n=126*	*n=99*
	–3.67 (0.65)	–2.61 (0.67)	–4.58 (0.80)	–4.49 (0.89)

Data are adjusted mean change (SE). *95% CI of difference vs placebo did not cross 0.

Figure. Percentage of Patients Reporting Improvements ≥MCID or ≥Normative Values on PROs at Week 16 (A) and SF-36 Domain Scores at Baseline, Week 16 and Week 24 for Abatacept (B) and Placebo (C) Groups Versus Age/Gender Matched Normative Population



AG=age/gender; BP=bodily pain; FACIT-F=Functional Assessment of Chronic Illness Therapy-Fatigue scale; GH=general health; MCID=minimal clinically important difference; MCS=mental component summary; MH=mental health; PCS=physical component summary; PF=physical function; RE=role emotional; RP=role physical; SF=social function; SF-36=Short-Form 36; VT=vitality

Conclusions: Abatacept treatment improved many PROs in pts with active PsA, with larger benefits in the CRP>ULN and TNF-naïve subpopulations.

References:

[1] Mease P, et al. Arthritis Rheumatol 2016;68(suppl 10): [Abstract 1041].

Disclosure of Interest: V. Strand Consultant for: AbbVie, Amgen Corporation, AstraZeneca, Biogen Idec, Bristol-Myers Squibb, Boehringer Ingelheim, Celgene, Celltrion, Corrona, Crescendo/Myriad Genetics, EMD Serono, Genentech/Roche, GlaxoSmithKline, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Samsung, Sandoz, Sanofi, UCB, E. Alemao Shareholder of: Bristol-Myers Squibb, Employee of: Bristol-Myers Squibb, T. Lehman Shareholder of: Bristol-Myers Squibb, Employee of: Bristol-Myers Squibb, A. Johnsen Employee of: Bristol-Myers Squibb, S. Banerjee Shareholder of: Bristol-Myers Squibb, Employee of: Bristol-Myers Squibb, H. Ahmad Shareholder of: Bristol-Myers Squibb, Employee of: Bristol-Myers Squibb, P. Mease Grant/research support from: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Janssen, Lilly, Novartis, Pfizer, Sun, UCB, Speakers bureau: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Crescendo Bioscience, Genentech, Janssen, Novartis, Pfizer, UCB

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