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AB0770 SYMPTOMS AND IMPACTS IN PSORIATIC ARTHRITIS: FINDINGS FROM QUALITATIVE PATIENT INTERVIEWS

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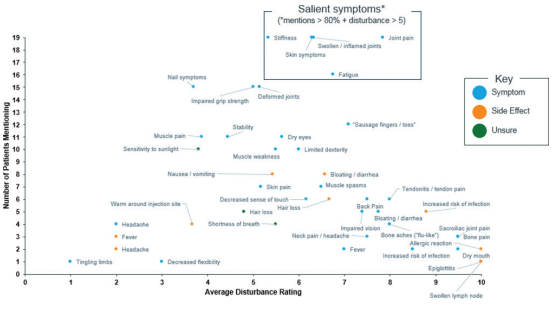
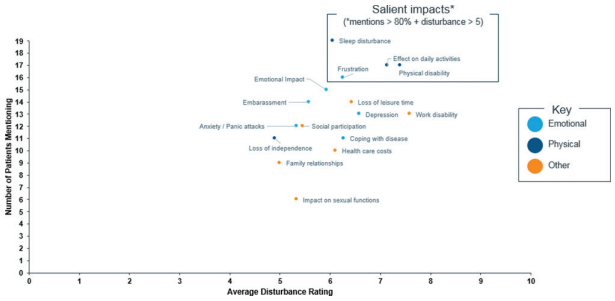
Background: Psoriatic arthritis (PsA) is a chronic inflammatory disease resulting in significant symptom burden.[1] Over time and without adequate treatment, PsA can lead to disability and reduced patient quality of life.[2] Fatigue is among the most common symptoms,[1] but is complex and difficult to measure. The most burdensome symptoms that impact PsA patients need to be better understood in order to select patient reported outcomes (PRO) tools that adequately capture these concepts.
Objectives: 1.) Identify the signs and symptoms of PsA experienced by patients, with a focus on fatigue, and how the disease and its treatment (s) impact patients' lives. 2.) Assess the content validity of select PRO instruments and items to measure fatigue.
Methods: Qualitative interviews were conducted among patients with PsA recruited through the FORWARD databank. The most frequently experienced symptoms and impacts of PsA and the degree to which they disturbed patients' lives, were tabulated. Disturbance was evaluated on a scale from 0 (not at all) to 10 (greatly disturbs). Patients reporting fatigue were probed to describe the experience in their own words, and descriptors were recorded. Interviews were conducted and assessed on a rolling basis and recruitment continued until concept saturation was achieved.
Results: Nineteen PsA patients were interviewed for this study. A core set of PsA symptoms were identified by nearly all patients and with moderate to high average disturbance ratings (Figure 1): joint pain, skin symptoms, stiffness, swollen/inflamed joints, and fatigue. The most salient impacts (Figure 2) were sleep disturbance, physical disability, effects on daily activities, and feelings of frustration. Most common descriptors of fatigue included "fatigue," "tiredness," "lack of energy," "mental fatigue," and "exhaustion."
Conclusion: Salient symptoms were consistent with those previously reported, along with a broader range of symptoms and impacts, which included fatigue. In addition to physical disability, others such as sleep disturbance, frustration, and effect of daily activities were common high impact themes that emerged.



***Abstract AB0770 Figure 1.**. Salient Symptoms Reported by Patients in Qualitative Interviews (n=19)*



Abstract AB0770 Figure 2.. Salient Impacts Reported by Patients in Qualitative Interviews (n=19)

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AB0771 IMPROVEMENT IN MORNING STIFFNESS IN SUBJECTS WITH PSORIATIC ARTHRITIS IS ASSOCIATED WITH IMPROVEMENTS IN PAIN, PHYSICAL FUNCTION AND PATIENT GLOBAL RESPONSE TO TREATMENT

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Background: Stiffness is an important component of inflammatory arthritis and plays a role in psoriatic arthritis (PsA) flare. Patients with inflammatory arthritis report difficulty with activities, "slowing down" due to stiffness and reduced quality of life. Stiffness is hard to quantify because it cannot be measured directly.
Objectives: We examined morning stiffness in PsA patients treated with apremilast (APR) for 16 weeks in the ACTIVE study and explored the relationship between improvements in morning stiffness and pain, physical function and Patient's Global Assessment of Disease Activity (PtGA).
Methods: Subjects who met CASPAR criteria for PsA, were biologic-naïve and had prior exposure to ≤1 conventional disease-modifying anti-rheumatic drug (DMARD) were randomized (1:1) to APR 30 mg twice daily or placebo (PBO) for 24 weeks. Subjects initially randomized to PBO

were switched to APR at Week 16 (early escape) or Week 24. Duration of morning stiffness and severity, assessed by subjects' reported categories of stiffness (none, mild, moderate, moderately severe, severe), was reported. In the post hoc analysis, changes in morning stiffness severity and effect on pain, physical function and PtGA from baseline to Week 16 were compared between treatment arms. An analysis of covariance model adjusting the baseline value was used in the analysis, where missing values were imputed using the last-observation-carried-forward approach.

Results: A total of 219 subjects were randomized (APR: n=110; PBO: n=109), and 192 remained in the study through Week 16. APR and PBO groups were balanced with respect to baseline tender joint count (mean [SD]: 17 [13] vs. 18 [14]), swollen joint count (mean [SD]: 9 [5] vs. 10 [6]), and severity of morning stiffness (moderate to very severe: 87% vs. 80%), as well as previous use of DMARD (67% vs. 72%), baseline use of non-steroidal anti-inflammatory drug (69% vs. 68%) and oral corticosteroid use (12% vs. 13%). Mean [SD] duration of morning stiffness at baseline was shorter with APR vs. PBO (48 [49] vs. 72 [127] minutes). Baseline PtGA (mean [SD]: 5.9 [2.1] vs. 6.1 [2.0]), Patient's Pain Numeric Rating Scale (NRS; mean [SD]: 6.1 [1.9] vs. 5.8 [2.2]), Health Assessment Questionnaire-Disability Index (HAQ-DI; mean [SD]: 1.3 (0.6) vs. 1.2 [0.6]), Short-Form Health Survey version 2 (SF-36v2) Physical Component Summary (mean [SD]: 32.4 [9.2] vs. 33.9 [8.3]), SF-36v2 Physical Functioning subscale (mean [SD]: 33.2 [11.2] vs. 34.2 [10.1]) and SF-36v2 Bodily Pain domain (mean [SD]: 35.4 [7.6] vs. 37.4 [7.8]) scores were similar in the APR and PBO groups, respectively. As early as Week 2, a significantly greater proportion of APR vs. PBO subjects experienced morning stiffness severity improvements (≥1 category improvement) (43% vs. 21%; *P*=0.0007). Significant improvements in morning stiffness severity were sustained through Week 16 in APR vs. PBO subjects (46% vs. 26%; *P*=0.0015). Subjects with improvements in morning stiffness severity in the APR and PBO groups showed consistent improvements in pain, physical function and PtGA at Week 16 (Table). In patients with unchanged stiffness severity, greater improvements were observed across outcome measures in the APR vs. PBO group, although the change from baseline was less than the improved stiffness group. Worsened morning stiffness was associated with lack of improvement in other patient-reported outcome measures.

Conclusion: In biologic-naïve PsA subjects treated with APR for 16 weeks, improvement in morning stiffness severity was evident as early as Week 2 and associated with improvements in pain, physical function and PtGA response.

Stiffness Dynamics With APR Treatment and PBO and Improvement in Pain, Physical Function and PtGA Response From Baseline to Week 16

Change in Stiffness Severity*	Improved			No Change			Worsened		
Outcomes, Least-Squares Mean Change (SD)	APR n=58	PBO n=30	*P* Value	APR n=37	PBO n=57	*P* Value	APR n=14	PBO n=22	*P* Value
HAQ-DI score§	−0.37 (0.06)	−0.35 (0.09)	0.876	−0.14 (0.05)	0.01 (0.04)	0.018	0.40 (0.12)	0.16 (0.1)	0.126
PtGA score‡	−1.99 (0.27)	−1.61 (0.38)	0.414	−0.69 (0.29)	−0.12 (0.24)	0.132	1.06 (0.61)	1.15 (0.48)	0.911
Patient's Pain NRS score¶	−2.11 (0.25)	−1.76 (0.35)	0.425	−0.93 (0.30)	0.01 (0.24)	0.016	1.30 (0.47)	1.40 (0.37)	0.875
SF-36v2 Physical Component Summary score	6.14 (1.00)	4.55 (1.39)	0.356	3.11 (1.07)	−0.79 (0.85)	0.005	−3.86 (1.82)	−5.38 (1.45)	0.516
SF-36v2 Physical Functioning subscale score	4.71 (1.10)	3.73 (1.52)	0.605	2.95 (1.08)	−0.58 (0.87)	0.013	−6.13 (2.18)	−5.57 (1.74)	0.841
SF-36v2 Bodily Pain subscale score	8.29 (0.93)	7.01 (1.30)	0.428	3.27 (1.01)	0.25 (0.82)	0.022	−2.86 (1.72)	−5.79 (1.37)	0.193

The n reflects the number of subjects randomized to the group; actual number of subjects having data available for each parameter may vary. *Improved and worsened are defined as a shift by at least 1 stiffness severity category (none, mild, moderate, moderately severe, very severe); subjects with baseline value and at least 1 post-baseline value are included. §Range of 0 to 3. ‡0 indicates not active, 10 indicates very active. ¶0 indicates no pain, 10 indicates most severe pain. The lower the scores, the better for HAQ-DI, PtGA, Patient's Pain scores. The higher the scores the better for SF-36v2 scores.

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AB0772

EFFICACY OF GUSELKUMAB IN PSORIASIS PATIENTS WITH SELF-REPORTED PSORIATIC ARTHRITIS WITH INVOLVEMENT OF THE SCALP, NAILS, HANDS, AND FEET: A POOLED ANALYSIS FROM 2 PIVOTAL PHASE 3 PSORIASIS STUDIES

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Background: VOYAGE 1 & 2 were the pivotal Ph3 GUS trials for plaque psoriasis (PsO).[1,2]

Objectives: Here we compare efficacy of GUS vs PBO & vs adalimumab (ADA) on PsO involving scalp, nail & palmoplantar (palmoplantar pustular PsO excluded per protocol) in a a subgroup of pts with self-reported psoriatic arthritis (PsA), given the association between these distinct PsO phenotypes & PsA.

Methods: VOYAGE 1(n=837) & VOYAGE 2(n=992) enrolled adult pts who had plaque PsO for ≥6 months, an Investigator Global Assessment (IGA) score ≥3, PASI score ≥12, ≥10% BSA involvement at baseline (BL), & were candidates for phototherapy or systemic treatment for PsO. Pts were randomized to GUS, PBO or ADA at BL, w/PBO crossover to GUS at wk16. This post-hoc analysis used observed pooled efficacy data for scalp-specific Investigator Global Assessment (ss-IGA), Physician's Global Assessment (PGA) of Hands &/or Feet (hf-PGA), fingernail PGA (f-PGA), & Nail Psoriasis Area & Severity Index (NAPSI) in subset of pts self-reporting PsA.

Results: In VOYAGE 1 & 2 combined, 335 (18.3%) PsO pts self-reported PsA (PBO 76, GUS 153, ADA 106). Baseline demographics were generally comparable across all 3 treatment grps, with history of methotrexate use: PBO 64.5%, GUS 70.6%, ADA 61.3%. A significantly greater proportion of GUS-treated pts achieved a ss-IGA score of 0/1 (absent/very mild) at wk16 vs PBO, & at wk24 vs ADA (Figure A). Significantly higher proportions of GUS-treated pts achieved a hf-PGA score of 0/1 (clear/almost clear) vs PBO at wk16 with numerically greater differences at wk24 vs ADA (Figure B). At wk16, proportions of pts achieving a f-PGA score of 0/1 (clear/minimal) were 47.6% for GUS vs 17.0% for PBO (p<0.001). The proportions of pts achieving an f-PGA score of 0/1 for GUS vs ADA were comparable at wk16 (47.6% vs 46.4%) & wk24 (67.0% vs 60.9%), but were higher for GUS by wk48 (82.5% vs 57.5%, Table). Mean (SD)% improvement from BL in NAPSI score was significantly higher for GUS vs PBO [39.5 (48.9) vs 6.5(47.5), p<0.001] at wk16 & was comparable for GUS vs ADA at wk24 [58.0 (51.3) vs 59.9 (40.4)]. By wk48, mean% improvement from BL in NAPSI score was higher for GUS vs ADA (70.8% vs 61.3%, Table).

Conclusion: GUS-treated PsO pts with self-reported PsA showed clinically meaningful improvements vs ADA in ss-IGA & hf-PGA scores at wks16 & 24. Although improvements in f-PGA & NAPSI were similar in pts treated with GUS vs. ADA at earlier timepoints, numerically greater differences were observed with GUS by wk48, likely requiring the additional duration to discriminate between treatments in this slow-growing cutaneous appendage.