

AB0739 MHAQ RESPONSE AMONG PATIENTS WITH PSORIATIC ARTHRITIS INITIATING A TNFI

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Background: Improved functional ability is among the most relevant outcomes for patients with psoriatic arthritis (PsA).¹ The modified health assessment questionnaire (mHAQ) is one of the most commonly used patient reported outcome measures used in PsA and addresses the domains of disability and physical function.

Objectives: We examined the change in mHAQ over one year among patients with PsA initiating a TNFi and examined predictors of a clinically meaningful improvement in disability and physical function, as measured by the mHAQ.

Methods: Patients with PsA enrolled in the Corrona Registry between 2005–2013 were followed from initiation of a TNFi (etanercept, adalimumab, infliximab, certolizumab, or golimumab) to the visit closest to 12 months. Patients were required to have at least three tender or swollen joints for inclusion for this study (this is not an inclusion criteria for Corrona), mHAQ within six months prior to TNFi initiation date, and at least one follow up visit 5–13 months after TNFi initiation with mHAQ. The primary outcome was the proportion of patients with a decrease of 0.35 or more in the mHAQ score, the minimal clinically important improvement in PsA.² Predictors of mHAQ response were measured in the six months before TNFi initiation. Covariates with p-value ≤ 0.10 in univariable logistic regression models and $\leq 5\%$ missing values were included in a multivariable model and removed individually until all remaining variables were significant ($p < 0.05$).

Results: Among 1742 TNFi initiations, 721 initiations (623 patients) met inclusion criteria. Mean age at initiation was 51.5 years (SD 12.3), 56% were female, median PsA duration was 5 years (IQR 2–11), and median baseline mHAQ was 0.375 (IQR 0.125–0.875). The mean change in mHAQ was -0.098 (SD 0.38) and median change in mHAQ was 0 (IQR: -0.25 to 0.125); 23% had a mHAQ decrease of 0.35 or more. In univariable models, college education and being married or partnered were inversely associated with mHAQ response (baseline scores were lower in patients with these characteristics) while patient global, patient pain, baseline clinical disease activity index (CDAI) and swollen joint count were positively associated with the outcome. However, in a multivariable model, only age (0.96 per year, 0.94–0.98) and baseline mHAQ score (17.7 per one point, 10.6–29.4) were associated with a decrease of 0.35 or more in the mHAQ.

Table: Predictors of modified Health Assessment Questionnaire (mHAQ) decrease of 0.35 or greater at follow up visit closest to one year*

| Predictor | Univariable | | | Multivariable | | |
|-----------------------------|-------------|------------|---------|---------------|------------|---------|
| | OR | 95% CI | p | OR | 95% CI | p |
| Female Gender | 0.90 | 0.63-1.28 | 0.64 | | | |
| Age at initiation | 0.97 | 0.96-0.98 | <0.0001 | 0.96 | 0.94, 0.98 | <0.0001 |
| BMI >30 (versus ≤ 30) | 0.88 | 0.58-1.17 | 0.35 | | | |
| Baseline mHAQ | 16.24 | 9.91-26.61 | <0.0001 | 17.7 | 10.6, 29.4 | <0.0001 |
| Hypertension | 0.71 | 0.48-1.04 | 0.09 | | | |
| Cardiovascular disease | 0.72 | 0.34-1.51 | 0.36 | | | |
| Work Full Time | 0.91 | 0.64-1.29 | 0.50 | | | |
| Smoker (Prev/Current) | 1.10 | 0.77-1.56 | 0.60 | | | |
| Alcohol | 0.86 | 0.61-1.23 | 0.45 | | | |
| Previous biologic use | 1.06 | 0.75-1.51 | 0.65 | | | |
| College Education | 0.68 | 0.47-0.97 | 0.03 | | | |
| Married/Partnered | 0.58 | 0.40-0.84 | 0.005 | | | |
| Prednisone | 1.59 | 0.998-2.52 | 0.06 | | | |
| Patient Global | 1.02 | 1.01-1.05 | <0.0001 | | | |
| Patient Pain | 1.02 | 1.01-1.03 | <0.0001 | | | |
| Baseline CDAI | 1.05 | 1.01-1.05 | 0.0002 | | | |
| Tender joint count | 1.02 | 0.995-1.05 | 0.13 | | | |
| Swollen joint count | 1.04 | 1.004-1.07 | 0.03 | | | |

Conclusions: A clinically meaningful change in mHAQ occurred in 23% of patients and was strongly associated with age and baseline mHAQ score. In this real world population, there was little change in mHAQ scores over one year, despite treatment. These analyses are limited by the floor effect of the mHAQ among patients with established PsA. Despite having at least 3 tender and 3 swollen joints, many patients in this cohort had a low mHAQ at baseline which did not allow for sufficient change to meet the MCII.

References:

[1] Mease PJ et al. *J Rheumatol* 2011; 38:2461–5.

[2] Orbai AM et al. *Ann Rheum Dis* 2016; Epub.

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AB0740 SECUKINUMAB IN PSORIATIC ARTHRITIS: HIGH DISEASE BURDEN OBSERVED IN THE CORRONA PSORIASIS REGISTRY

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Background: Secukinumab (SEC), a fully human anti-IL-17A monoclonal antibody, has significant efficacy in the treatment of moderate-to-severe psoriasis (Ps) and psoriatic arthritis (PsA), with a favourable safety profile. The Corrona Psoriasis Registry is an independent observational registry of Ps patients (pts) receiving FDA-approved systemic treatments (TNFis, anti-IL-17s and IL-12/23 and non-biologics) in the United States.

Objectives: To assess demographics, clinical features and pt reported outcomes (PROs) of Ps pts with concomitant PsA receiving systemic treatments at registry enrolment.

Methods: Adult Ps pts who initiated a systemic therapy at enrolment or in the previous 12 months, and concomitant PsA reported by a dermatologist, were included. Demographics (e.g. age, gender, BMI), disease activity (body surface area, investigator global assessment, psoriasis area severity index) and PROs (pain, fatigue, itch, EQ-VAS 0–100, work productivity and activity impairment and dermatology life quality index) were evaluated at enrolment and stratified by therapy: SEC, etanercept (ETN), adalimumab (ADA), ustekinumab (UST), and non-biologics (Non-B).

Results: As of October-2016, 2073 Ps pts were enrolled in the registry; 823 (39.7%) had a PsA diagnosis (mean disease duration 7.6 years) of which 37% were biologic naïve. Of the 823 pts with PsA, 25.4% received SEC, 6.2% ETN, 21.5% ADA, 17.6% UST, and 24.8% Non-B. Pts on SEC had a mean age 53.2 years, mean BMI 32.4; 45% were female; all comparable across the treatment groups. PsA pts treated with SEC had higher Ps disease activity than other treated groups (Table). A higher proportion of SEC treated PsA pts had diabetes and cardiovascular disease (25% and 19% respectively). Mean pain scores were higher in the SEC group; however other PROs assessed at enrolment were similar across treatment groups (Table).

Table 1. Pt characteristics at enrolment¹

| Mean \pm SD | SEC N=209 | ETN N=51 | ADA N=177 | UST N=145 | Non-B* N=204 | Overall N=823 |
|---|-----------------|-----------------|-----------------|-----------------|-----------------|------------------|
| PASI, (0–72) [#] | 7.7 \pm 9.4 | 4.0 \pm 4.0 | 4.6 \pm 6.6 | 5.0 \pm 5.9 | 4.6 \pm 6.6 | 5.5 \pm 7.4 |
| IGA, (0–4) [#] | 2.5 \pm 1.2 | 2.4 \pm 0.9 | 2.0 \pm 1.2 | 2.1 \pm 1.2 | 2.3 \pm 1.1 | 2.2 \pm 1.2 |
| BSA, (0–100%) [#] | 14.4 \pm 20.9 | 6.8 \pm 9.9 | 8.0 \pm 13.3 | 8.8 \pm 15.0 | 7.8 \pm 12.0 | 9.9 \pm 15.8 |
| Pain, (VAS 0–100) | 33.2 \pm 33.2 | 20.3 \pm 24.8 | 22.9 \pm 30.6 | 21.9 \pm 28.0 | 23.7 \pm 30.4 | 25.6 \pm 30.8 |
| Fatigue, (VAS 0–100) | 39.4 \pm 29.7 | 36.3 \pm 33.1 | 34.6 \pm 29.9 | 33.4 \pm 27.5 | 39.1 \pm 30.6 | 37.0 \pm 29.9 |
| Itch, (VAS 0–100) | 41.6 \pm 34.7 | 34.6 \pm 31.4 | 32.9 \pm 34.5 | 33.5 \pm 32.8 | 37.7 \pm 33.7 | 36.7 \pm 33.9 |
| EQ-VAS, (VAS 0–100) | 69.0 \pm 22.8 | 68.5 \pm 23.4 | 71.1 \pm 22.2 | 71.0 \pm 20.3 | 66.3 \pm 24.1 | 69.0 \pm 22.7 |
| DLQI (0–30) | 7.6 \pm 6.2 | 5.6 \pm 5.5 | 6.6 \pm 6.1 | 7.4 \pm 7.1 | 6.2 \pm 5.4 | 6.8 \pm 6.1 |
| WPAI - % overall work affected by Ps ^a | 16.8 \pm 22.8 | 19.8 \pm 23.8 | 15.3 \pm 25.9 | 12.8 \pm 21.5 | 14.8 \pm 23.5 | 15.5 \pm 23.8 |

¹Data on infliximab and ixekizumab not presented due to small sample sizes; [#]Mean scores were higher in incident users compared to prevalent users; *Non-biologics include: apremilast, cyclosporine, MTX; ^aAssessed only in employed: n=124 (SEC); 37 (ETN); 121 (ADA); 98 (UST); 105 (Non-B); 510 (Overall).

Conclusions: These data show that Ps pts with concomitant PsA who initiated SEC in the Corrona Psoriasis Registry had higher disease activity, more comorbidities and suffered from more severe pain at enrolment. These differences need to be factored in for future analyses between treatment groups as data mature in this registry.

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