## FRI0493   DISEASE ACTIVITY TOGETHER WITH DEPRESSION CONTRIBUTES TO WORK DISABILITY IN PSORIATIC ARTHRITIS

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**Background:** Work disability (WD) is an important functional outcome measure in inflammatory arthritis, which has been studied comprehensively in rheumatoid arthritis and ankylosing spondylitis, however limited data are available in psoriatic arthritis (PsA)[1]. Depression and anxiety are well known comorbidities in psoriasis and PsA with higher prevalence in PsA[2].

**Objectives:** The aim of this study was to compare 1) patient-reported outcomes (PROs), including depression/anxiety scores; 2) physician-assessed measures and 3) disease activity using minimal disease activity (MDA) and Composite Psoriatic Disease Activity Index (CPDAI) in PsA patients with and without WD.

**Methods:** Consecutive patients with PsA fulfilling the CASPAR criteria were enrolled. Patients on disability pension, those with early retirement due to arthritis, those unemployed, away from work due to sick leave were considered as having WD. Patients have completed questionnaires on physical function and health-related quality of life and they were assessed for depression/anxiety using the Hospital Anxiety and Depression Scale (HADS-A and HADS-D) and Penn State Worry Questionnaire (PSWQ). Patients underwent musculoskeletal and skin assessments. Disease activity was compared between work-disabled and employed patients using MDA and CPDAI. Mann-Whitney, Chi-square tests and linear regression model were used to perform statistical analysis.

**Results:** 100 PsA patients were recruited, 18 were natural retirees, leaving 82 patients available for analysis. Thirty-one (17 male, age 50.9±9.97 years) participants of working age had work disability versus fifty-one (29 male, age 49.1±8.65 years) employed patients. Work-disabled patients had significantly higher HADS-D score (5.07±3.01 vs. 2.57±2.64; p<0.001) and significantly worse PROMs, including HAQ, PsAQoL, EQ-5D, BASDAI, BASFI, ASQoL, BRAF-NRS, pain and general health VAS. HADS-A and PSWQ scores were similar in both groups. Leeds enthesitis index and ESR were significantly higher (p=0.008; p=0.04, respectively) in patients with WD compared to those employed; furthermore the % of patients with CPDAI>4, suggesting moderate to severe disease activity were significantly higher (51.6% vs. 28%; p=0.032) in the WD group. There was no significant difference in MDA status between the two groups. Multiple regression analysis revealed significant relationship between HADS-D scores and CPDAI (B=0.566; p=0.03).

**Conclusions:** Consistent with previous studies we have observed that the WD rate is high (37.8%) among patients with PsA. This is the first study assessing the relationship between depression and disease activity using CPDAI in PsA patients with work disability. We have found significantly higher HADS-D score and higher % of patients with CPDAI>4 in the WD group compared to those employed. Significant relationship was revealed between depression and CPDAI, which suggests that disease activity together with depression contributes to work disability in PsA.

**References:**
[1] Tillett W. Rheumatology (Oxford) 2012.
[2] McDonough E. JRheumatol 2014.

## FRI0494   SECUKINUMAB PROVIDES RAPID AND SUSTAINED PAIN RELIEF IN PSORIATIC ARTHRITIS: 2-YEAR RESULTS FROM THE FUTURE 2 STUDY

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**Background:** Pain remains a major clinical challenge in the treatment of psoriatic arthritis (PsA). Secukinumab (SEC) has demonstrated significant efficacy in PsA patients (pts), across a range of quality of life related outcome measures.[1,2]

**Objectives:** This *post-hoc* analysis evaluated change in pain scores from baseline (BL) to Week (Wk) 104 in PsA pts receiving SEC in the FUTURE 2 study.

**Methods:** FUTURE 2 study design has been reported.[2] Mean change from BL in pain VAS and SF-36 bodily pain domain scores were evaluated using mixed-effect model for repeated measures (MMRM) through Wk 16 and as observed through Wk 104. Proportion of pts reporting improvements ≥clinically meaningful differences in pain VAS (mean change from BL ≥20%) was assessed. Results are reported for SEC 300 and 150mg in overall population and stratified by prior use of TNF inhibitor (TNFi; TNFi-naïve vs. inadequate responder/intolerant [TNFi-IR]).

EQ–5D-3L pain item scores (no-, moderate- or extreme-pain/discomfort) were assessed as proportions.

**Results:** Mean changes from BL in pain VAS were greater with SEC vs. placebo (PBO) by Wk 3 (least squares mean [LSM]: -16.9, -12.6 with SEC 300 and 150mg, respectively vs. -5.75 with PBO; *P*<0.05), and Wk 16 (LSM: -24.0 and -23.0 for SEC 300 and 150mg, respectively vs. -8.41 with PBO; *P*<0.05). Mean changes were sustained through Wk 104 (-26.1 and -25.9 with SEC 300 and 150mg, respectively). In both SEC groups, >50% pts reported improvements of ≥20% by Wk 3 and this increased through Wk 104. Similarly, SF-36 bodily pain domain scores improved from BL by Wk 4 and 16 with SEC vs. PBO, exceeding minimum clinically important differences of 5.0 (Wk 4: LSM: 16.2 and 16.3 for SEC 300 and 150mg, respectively vs. 5.9 with PBO; *P*<0.05 and Wk 16: LSM: 21.1 and 22.0 for SEC 300 and 150mg, respectively vs. 6.9 with PBO; *P*<0.05). Improvements in pain were consistent in TNFi-naïve and TNFi-IR pts; and of greater magnitude in the naïve subgroup (table). Based on the EQ–5D-3L pain/discomfort item, 99% pts reported moderate to extreme pain or discomfort at BL. At Wk 4, the proportion of pts with no pain or discomfort was greater for the SEC 300mg (15%) and 150mg (10%) vs. PBO (5%) and increased through Wk 104 to 28% and 16% with SEC 300 and 150mg, respectively.

Table 1. Summary of results by TNFi status at baseline

| | TNFi-naïve | | | TNFi-IR | | |
|---|---|---|---|---|---|---|
| | SEC 300mg | SEC 150mg | PBO | SEC 300mg | SEC 150mg | PBO |
| N | 67 | 63 | 63 | 33 | 37 | 35 |
| Pain VAS | | | | | | |
| Wk 16 | -27.8* | -25.1† | -11.3 | -18.2‡ | -21.1§ | -4.4 |
| Wk 104 | -29.6 | -28.3 | – | -19.3 | -20.4 | – |
| SF-36 bodily pain | | | | | | |
| Wk 16 | 23.8* | 25.4* | 8.6 | 18.3§ | 17.9§ | 5.2 |
| Wk 104 | 24.2 | 22.2 | – | 24.5 | 14.0¶ | – |

*P*<0.0001; †*P*<0.001; §*P*<0.01; ‡*P*<0.05 vs. PBO. *P*-values and LS mean change at Wk 16 from MMRM analysis. Mean change at Wk 104 from observed data in n=57 (300mg) and 53 (150mg) for TNFi-naïve and n=29 (300mg) and 24 (150mg) for TNFi-IR; ¶n=26.

**Conclusions:** SEC provides rapid and sustained pain relief through 104 wks in pts with PsA as assessed by multiple clinically relevant patient-reported measures of pain. Improvements were reported by pts regardless of their prior TNFi therapy status.

**References:**
[1] Strand V, et al. Ann Rheum Dis 2017;76:203–7.
[2] McInnes IB, et al. Lancet 2015;386:1137–46.

## FRI0495   USE OF MELATONIN IN PATIENTS WITH PSORIATIC ARTHRITIS VIOLATIONS OF EMOTIONAL STATUS

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**Background:** The ability of melatonin to reduce the activity of the sympathetic nervous system tone and of pituitary-adrenal system ensures its anti-stress properties. It can be used to reduce psycho-emotional manifestations of chronic pain in patients with psoriatic arthritis (PsA).

**Objectives:** To evaluate the effect of combined therapy with the use of melatonin on the expression of psycho-emotional disorders, and pain in patients with PsA.

**Methods:** High levels of anxiety and depressive disorders were established in the survey on Spielberger Anxiety Scale and on Hamilton Rating Scale for Depression (HRDS) in 43 patients with PsA (≥5 SJC and ≥5 TJC; CRP ≥0.3 mg/dL). The quality of life was studied by questionnaire Medical Outcomes Study Short Form (SF-36); the severity of morning stiffness, pain, patient's health status (EWS) - using the 100-mm visual analog scale (VAS). All patients were receiving a stable dose of MTX for at least 6 months. They were divided into two groups; 1 group (n=22) additionally received 3 mg of melatonin at bedtime for 2 months of observation

**Results:** At the end of the observation period the frequency and the level of

severity of depression by HRDS (p=0.0098), and the index of personal anxiety (P=0.009) in group 1 decreased. In the 2nd group above mentioned parameters have not changed. On the 1 group data of SF-36 evaluation: the physical health component has improved - the increase of RP and BP 57.4% and 37.8% from the baseline; vital activity and role functioning due to emotional state, have also increased by 35.6% and 43.5%, respectively. In the 2nd group (n=22) investigated parameters have not undergone significant changes in dynamics. In the 1 receiving melatonin group TJC and SJC have decreased by 15% and 22% (p=0.0079, p=0.0022, respectively) and their dynamics in the 2nd group was less significant (p=0.013 and p=0.017, respectively). Also, patients in group 1 have highly significant (p<0.001) reduction in the severity of morning stiffness and joint pain, and in the 2nd group the changes were less significant (respectively, p=0.043, p=0.016). Positive dynamics of CRP in group 1 was more significant (p=0.003), than it was in 2 patients' group (p=0.033).

**Conclusions:** In the group of patients treated with melatonin was noted improvement in general condition (a significant improvement in the parameters of the physical components of health, reduction of depressive and psycho-vegetative disorders) and also more significant decrease of the intensity of pain and of morning stiffness duration, of TJC and SJC, than in not treated with melatonin patients. Inclusion of Melatonin in the comprehensive PsA therapy promotes not only reduction of depression symptoms and sleep disorders, but also reduces the severity of the chronic pain manifestations and, consequently, improves the quality of life of patients with this disease

**Disclosure of Interest:** None declared

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FRI0496    **COMPARING TOFACITINIB SAFETY PROFILE IN PATIENTS WITH PSORIATIC ARTHRITIS IN CLINICAL STUDIES WITH REAL-WORLD DATA**

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**Background:** Tofacitinib is an oral Janus kinase inhibitor under investigation for the treatment of psoriatic arthritis (PsA). Two Phase 3 studies have been completed (NCT01877668; NCT01882439) and a long-term extension (LTE) study is ongoing (database not locked; NCT01976364).

**Objectives:** To compare incidence rates (IR) for adverse events (AEs) of special interest in a tofacitinib cohort from the Phase 3 PsA trials with real-world experience in a comparison cohort from the US Truven MarketScan database.

**Methods:** The tofacitinib cohort included adult patients (pts) from 2 Phase 3 studies with ≥6 months PsA diagnosis who met ClASsification of Psoriatic ARthritis (CASPAR) criteria, had active plaque psoriasis, and active arthritis (≥3 swollen and ≥3 tender/painful joints) and who were treated with tofacitinib. Pts were grouped by those who received tofacitinib 5 (N=238) or 10 mg (N=236) twice daily (BID) in the 2 Phase 3 studies, and all pts who received ≥1 dose of tofacitinib in the 2 Phase 3 studies or the LTE (tofacitinib all doses, N=783). The comparison cohort (N=5799) comprised pts with moderate to severe PsA, defined by ≥1 inpatient or ≥2 outpatient 696.0 diagnosis codes on 2 unique calendar days (≥1 by a rheumatologist) between Oct 2010 and Sep 2015, initiating therapy with a systemic agent for PsA. Key Phase 3 study exclusion criteria were applied to the comparison cohort. IRs for serious infection events (SIEs), herpes zoster (HZ), malignancies (excluding non-melanoma skin cancer [NMSC]), NMSC and major adverse cardiovascular events (MACE) were compared.

**Results:** Mean age, gender and diabetes history were generally similar between the tofacitinib and comparison cohorts (48.7–49.5 years, 42.4–49.2% male, 12.2–15.7% with diabetes history). Overall more pts treated with tofacitinib had prior experience with corticosteroids (15.7–28.2%), conventional synthetic disease-modifying antirheumatic drugs (100%) and tumour necrosis factor inhibitors (48.1–55.9%) vs the comparison cohort (11.9%, 46.6% and 36.6%, respectively). IRs for SIEs were lower for the tofacitinib vs the comparison cohort (Table 1). The tofacitinib cohort had a higher rate of HZ vs the comparison cohort (Table 1). IRs for malignancies and MACE were similar between cohorts (Table 1).

**Conclusions:** IRs of AEs of special interest reported in tofacitinib PsA Phase 3 studies were generally comparable to those in a general PsA population comprising pts receiving a range of biologic agents, except HZ, which was higher for pts treated with tofacitinib but similar to the incidence observed with tofacitinib treatment in other indications.

**Disclosure of Interest:** J. Curtis Grant/research support from: Amgen, Bristol-Myers Squibb, Eli Lilly, Janssen, Pfizer Inc, Consultant for: AbbVie, Amgen, Bristol-Myers Squibb, Eli Lilly, Janssen, Pfizer Inc, H. Yun Grant/research support from: Pfizer Inc, O. FitzGerald Grant/research support from: AbbVie, Bristol-Myers Squibb, Consultant for: Bristol-Myers Squibb, Eli Lilly, Janssen, Pfizer Inc, Speakers bureau: Celgene, Janssen, Novartis, K. Winthrop Grant/research support

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**Table 1. Incidence rates (95% CI)[a] [PY exposure] for adverse events of special interest**

|  |  | SIEs[b] | HZ | Malignancies[c] | NMSC | MACE |
|---|---|---|---|---|---|---|
| Tofacitinib cohort[d] | Tofacitinib 5 mg BID (N=238) | 1.30 (0.16, 4.69) [154] | 1.96 (0.41, 5.74) [153] | NR | NR | NR |
|  | Tofacitinib 10 mg BID (N=236) | 2.00 (0.41, 5.83) [150] | 2.66 (0.73, 6.81) [150] | NR | NR | NR |
|  | Tofacitinib all doses (N=783) | NR | NR | 0.63 (0.21, 1.48) [791] | 0.51 (0.14, 1.30) [789] | 0.38 (0.08, 1.11) [791] |
| Comparison cohort | Any bDMARD (N=8075) | 5.02 (4.19, 5.97) [2569] | 1.26 (0.91, 1.70) [3343] | 0.51 (0.34, 0.74) [5499] | 1.40 (1.10, 1.75) [5488] | 0.38 (0.22, 0.61) [4468] |
|  | Any bDMARD + csDMARD (N=2542) | 5.10 (3.83, 6.66) [1058] | 1.53 (0.94, 2.37) [1303] | 0.40 (0.16, 0.82) [1751] | 1.79 (1.21, 2.53) [1736] | 0.25 (0.07, 0.64) [1593] |
|  | Any TNFi (N=4617) | 5.13 (4.26, 6.11) [2419] | 1.26 (0.90, 1.71) [3181] | 0.51 (0.33, 0.74) [5144] | 1.39 (1.09, 1.76) [5098] | 0.41 (0.24, 0.65) [4183] |
|  | Any TNFi + csDMARD (N=2383) | 5.12 (3.83, 6.72) [1015] | 1.51 (0.91, 2.36) [1257] | 0.42 (0.17, 0.86) [1670] | 1.75 (1.17, 2.52) [1656] | 0.26 (0.07, 0.67) [1520] |
|  | Adalimumab (N=1934) | 4.16 (3.00, 5.63) [1009] | 1.16 (0.65, 1.91) [1297] | 0.48 (0.23, 0.88) [2095] | 1.40 (0.94, 2.01) [2070] | 0.41 (0.16, 0.84) [1724] |
|  | Etanercept (N=1412) | 4.82 (3.37, 6.67) [747] | 1.10 (0.55, 1.97) [1000] | 0.41 (0.16, 0.84) [1720] | 1.46 (0.95, 2.16) [1709] | 0.30 (0.08, 0.76) [1343] |
|  | Infliximab (N=618) | 8.91 (6.09, 12.57) [359] | 1.94 (0.93, 3.57) [516] | 1.21 (0.55, 2.30) [743] | 1.35 (0.65, 2.48) [741] | 0.47 (0.10, 1.37) [638] |
|  | Golimumab (N=389) | 3.49 (1.40, 7.19) [201] | 1.16 (0.24, 3.39) [258] | 0.00 (0.00, 0.90) [410] | 0.99 (0.27, 2.53) [404] | 0.91 (0.19, 2.67) [328] |
|  | Certolizumab (N=267) | 6.80 (2.74, 14.02) [110] | 0.91 (0.02, 5.06) [110] | 0.00 (0.00, 2.09) [176] | 1.72 (0.35, 5.02) [174] | 0.00 (0.00, 2.44) [151] |
|  | Apremilast (N=617) | 5.34 (2.56, 9.82) [187] | 2.62 (0.85, 6.13) [191] | 1.14 (0.24, 3.35) [262] | 3.45 (1.58, 6.56) [261] | 0.00 (0.00, 1.60) [231] |

[a]Patients with event per 100 PY; [b]SIEs: any infection requiring parenteral antimicrobial therapy or hospitalisation or if the infection met criteria for a serious adverse event in the tofacitinib cohort; infections requiring parenteral antimicrobial treatment and hospitalisation in the comparison cohort; [c]All malignancies excluding non-melanoma skin cancer; [d]Tofacitinib 5 and 10 mg BID rows include patients randomised to these doses, respectively, in the two Phase 3 studies (12 or 6 months' duration), tofacitinib all doses row includes patients who received ≥1 dose of tofacitinib in the two Phase 3 studies or the LTE. IR estimates include events occurring ≤28 days after last dose of study drug (or to data cut-off in the LTE). Exposure (PY) is the total follow-up time to the day of the first event within the event-counting period for patients with events, or the last dose day plus a risk period of 28 days after the last dose (or to data cut-off for LTE) for patients without events. bDMARD, biologic disease-modifying antirheumatic drug; BID, twice daily; CI, confidence interval; csDMARD, conventional synthetic disease-modifying antirheumatic drug; HZ, herpes zoster; LTE, long-term extension study; MACE, major adverse cardiovascular event; NMSC, non-melanoma skin cancer; NR, not reported; PY, patient-years; SIE, serious infection event; TNFi, tumour necrosis factor inhibitor.

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FRI0497    **WHAT CHOICES DO RHEUMATOLOGIST MAKE IN ESCALATING DMARD THERAPY IN EARLY PSA?**

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**Background:** Psoriatic arthritis (PsA) is a multifaceted disease.

**Objectives:** We aimed to evaluate change in medication over time guided by joints, skin, enthesis, low back pain and dactylitis in newly diagnosed PsA patients

**Methods:** Newly diagnosed PsA patients were included in the Dutch Early south-west Psoriatic Arthritis cohoRt (DEPAR) study between August 2013 and March 2016. Initial drug treatment and escalation of therapy were described for all patients. Drivers of treatment changes in the first year were evaluated by mixed

**Table 1** Multivariable mixed effects ordered ordinal logistic regression of treatment change over time in early PsA

| Covariates | Odds Ratio | 95% CI | |
|---|---|---|---|
| Swollen joint count (per joint) | **1.14** | **1.06** | **1.24** |
| Tender joint count(per joint) | 0.98 | 0.94 | 1.02 |
| Tender entheses (per enthesis) | 1.06 | 0.94 | 1.19 |
| BASDAI (per point) | 1.05 | 0.97 | 1.15 |
| Dactylitis Index (per point) | **1.05** | **1.00** | **1.09** |
| timepoints (baseline reference) | | | |
| 3 months | **1.55** | **1.01** | **2.37** |
| 6 months | 1.25 | 0.78 | 2.02 |
| 9 months | **0.45** | **0.25** | **0.81** |
| 12 months | 1.52 | 0.79 | 2.91 |
| initial starting values ( no dmard reference) | | | |
| other sdmards | 0.05 | -0.52 | 0.62 |
| methotrexate oral | 0.49 | -0.08 | 1.07 |
| methotrexate subcutaneous | 4.67 | 3.95 | 5.38 |
| leflunomide | 5.32 | 4.57 | 6.08 |
| biological dmards* | 6.23 | 5.42 | 7.05 |
| mixed effects parameters | | | |
| random slope | 0.02 | 0.01 | 0.06 |
| random intercept | 8.30 | 6.12 | 11.25 |

in bold **p<0.05**; *biological dmards were TNF inhibitors