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 CIASification 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.

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

	SIE ^a	HZ	Malignancies ^c	NMSC	MACE
Tofacitinib cohort ^b					
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) [548]	0.38 (0.08, 1.11) [791]
Comparison cohort					
Any bDMARD (N=6075)	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 + cDMARD (N=2542)	5.10 (3.83, 6.66) [1058]	1.53 (0.84, 2.37) [1303]	0.40 (0.16, 0.82) [1736]	1.79 (1.21, 2.53) [1736]	0.25 (0.07, 0.64) [1591]
Any TNFi (N=4617)	5.13 (4.26, 6.11) [2149]	1.26 (0.90, 1.71) [3181]	0.51 (0.33, 0.74) [5098]	1.39 (1.09, 1.76) [5098]	0.41 (0.24, 0.65) [4183]
Any TNFi + cDMARD (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]
Abatacept (N=1934)	4.16 (0.90, 5.63) [1009]	1.16 (0.65, 1.91) [1277]	0.48 (0.23, 0.88) [2095]	1.40 (0.94, 2.01) [2070]	0.41 (0.16, 0.84) [1724]
Enbrel (N=1412)	4.82 (3.37, 6.67) [747]	1.10 (0.55, 1.97) [1000]	0.41 (0.16, 0.84) [1729]	1.46 (0.95, 2.16) [1729]	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) [338]
Certolizumab (N=618)	6.80 (2.74, 14.02) [103]	0.91 (0.02, 5.06) [110]	0.00 (0.00, 2.09) [176]	1.72 (0.35, 5.02) [175]	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 (1.38, 6.56) [261]	0.00 (0.00, 1.60) [231]

*Patients with event per 100 PY. ^aSIEs: any infection requiring parenteral antimicrobial therapy on hospitalization or if the infection met criteria for a serious adverse event in the tofacitinib cohort; infections requiring parenteral antimicrobial treatment and hospitalization in the comparison cohort. ^bAll malignancies excluding non-melanoma skin cancer. ^cTofacitinib 5 and 10 mg BID rows include patients randomized 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 38 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; cDMARD, 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, enthesitis, 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

	Odds Ratio	95% CI	
Covariates			
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 enthesitis)	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 sdmarks	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

ordered ordinal regression with outcome treatment change and variables joints (66/68 count), skin (PASI), entheses (LEI and MASES), dactylitis (LDI) and axial disease (BASDAI)

Results: 323 patients had had baseline assessment in March 2016. Their average age was 50.0 years (SD 13.8) and 49% were male. 80% patients had arthritis (19% monoarthritis, 39% oligoarthritis and 23% polyarthritis), 9% had an enthesitis subtype, 2% axial disease and 9% dactylitis. Initial treatment consisted of methotrexate (MTX) (52%), in 7% of other synthetic disease modifying antirheumatic drugs (sDMARDs) and due to treatment of psoriasis 3% biologicals. Within the different phenotypes MTX was most frequently started in polyarthritis (84%) followed by oligoarthritis (63%), monoarthritis (33%) and other phenotypes (5%). At 12 months 70% (n=148) stayed on the initial drug. Of those switched, 9 started MTX, within the initial MTX users (n=74) almost equal percentages stopped, switched to metoject or biological (4%). A smaller percentage (2%) switch to leflunomide. Changes in medication were driven by swollen joint count and the presence of dactylitis (Table 1)

Conclusions: MTX was initiated in about half of the early PsA patients. The majority of patients were kept on the initial treatment strategy in first year. Failure on initial drug led to variation in subsequent drugs with additional start of other sDMARDs, switch subcutaneous MTX, to other sDMARDs or to biological DMARDs. Treatment change was driven by Swollen Joint Count and presence of Dactylitis. Skin, Enthesis and Axial disease did not play a role in escalating treatment.

Disclosure of Interest: None declared

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FRI0498 OUTCOMES ASSOCIATED WITH ACHIEVEMENT OF VARIOUS TREATMENT TARGETS IN PATIENTS WITH PSORIATIC ARTHRITIS RECEIVING ADALIMUMAB

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Background: Various instruments are currently used for disease activity and outcome assessment in psoriatic arthritis (PsA). Some measures attempt to incorporate the total spectrum of psoriatic disease manifestations [eg, minimal disease activity (MDA)] while others focus on arthritis assessments [eg, disease activity index for PsA (DAPSA)]. Whether in patients (pts) with PsA it is sufficient to primarily consider joint disease aspects remains unclear.

Objectives: To compare DAPSA remission and low disease activity (LDA) with MDA and very low disease activity (VLDA) for the presence of residual abnormalities of the respective composing variables.

Methods: This post hoc analysis included pts with PsA receiving adalimumab (ADA) in one of two multicenter studies: ADEPT was a 24-week (wk), randomized, double-blind, placebo-controlled trial; ACCLAIM was a 12-wk, open-label study conducted in Canada in care settings that reflected usual practice. Frequencies of DAPSA remission/LDA and MDA/VLDA were summarized, and the individual PsA manifestations within these states were assessed. DAPSA was summed from the following continuous variables: swollen (66) and tender (68) joints, pt global assessment (PtGA, cm), pt pain (PP, cm), and C-reactive protein (CRP, mg/dL). DAPSA remission was defined as ≤ 4 and DAPSA LDA as ≤ 4 and ≤ 14 . MDA criteria were as follows: ≤ 1 tender, ≤ 1 swollen joint, ≤ 1 entheses point, PP ≤ 15 mm, PtGA ≤ 20 mm, HAQ ≤ 0.5 , and PASI ≤ 3 . MDA was calculated as fulfilling 5 of the 7 criteria, and VLDA calculated as fulfilling all 7 criteria. Data were as observed.

Results: Among 151 pts receiving ADA in ADEPT, 33 (22%) each achieved DAPSA remission and LDA at wk 24, and 20 (14%) and 11 (7%) achieved MDA and VLDA, respectively. Pts achieving DAPSA LDA appeared to mirror those in MDA, with the exception of experiencing numerically higher PP, PtGA, and PASI scores at wk 24 (Table). Pts in DAPSA LDA did experience numerically lower SJC when compared with the MDA achievers, and, like MDA achievers, displayed little residual enthesitis. Only VLDA, but not MDA, could match the stringency of DAPSA remission, a finding that was confirmed through analysis of the ACCLAIM cohort.

Table. Mean Values of DAPSA and MDA Components Following 12 or 24 Weeks of Adalimumab in ACCLAIM or ADEPT, Respectively

Variable	DAPSA LDA ($\geq 4 - \leq 14$)		DAPSA Remission (≤ 4)		MDA (5 of 7 criteria)		VLDA (all 7 criteria)	
	ADEPT n=33	ACCLAIM n=37	ADEPT n=33	ACCLAIM n=37	ADEPT n=20	ACCLAIM n=32	ADEPT n=11	ACCLAIM n=9
TJC, 0-78	3.1 ± 2.96	2.0 ± 1.80	0.3 ± 0.73	0.1 ± 0.38	3.4 ± 5.85	5.1 ± 5.49	0.1 ± 0.30	0.2 ± 0.44
SJC, 0-76	1.7 ± 2.00	2.4 ± 2.53	0.7 ± 1.36	0.3 ± 0.49	4.0 ± 7.97	4.8 ± 4.31	0.1 ± 0.30	0.2 ± 0.44
Pain, 100 mm VAS	17.8 ± 13.28	18.9 ± 16.66	4.1 ± 4.38	3.1 ± 3.89	8.9 ± 7.03	14.3 ± 14.55	4.8 ± 3.92	4.9 ± 4.59
PtGA, 100 mm VAS	17.2 ± 11.92	18.9 ± 18.02	3.7 ± 4.09	1.9 ± 2.67	8.9 ± 7.07	15.6 ± 20.35	4.3 ± 3.64	4.4 ± 4.88
CRP, mg/dL	0.4 ± 0.77	1.0 ± 0.99	0.2 ± 0.18	1.1 ± 0.79	0.3 ± 0.30	1.0 ± 1.27	0.2 ± 0.16	1.6 ± 0.97
PASI	2.5 ± 5.24	1.7 ± 1.47	0.6 ± 1.40	1.3 ± 0.58	0.7 ± 0.59	2.0 ± 3.02	0.3 ± 0.34	1.2 ± 0.55
HAQ-DI	0.4 ± 0.46	0.3 ± 0.47	0.1 ± 0.39	0.2 ± 0.34	0.2 ± 0.40	0.2 ± 0.35	0.0 ± 0.12	0.0 ± 0.09
Enthesitis	0.1 ± 0.40	0.1 ± 0.28	0.1 ± 0.24	0.1 ± 0.38	0.2 ± 0.37	0.2 ± 0.37	0.0 ± 0.00	0.1 ± 0.33
ΔmTSS, 0- 570	-0.1 ± 1.30	N/A	-0.2 ± 0.70	N/A	-0.5 ± 2.20	N/A	-0.1 ± 0.51	N/A

All values are mean ± SD, unless otherwise indicated.

ADAPSA, disease activity index of psoriatic arthritis; MDA, minimal disease activity; VLDA, very low disease activity; TJC, tender joint count based on 78 joints; SJC, swollen joint count based on 76 joints; mm, millimeter; VAS, visual analog scale; PtGA, patient global assessment of disease activity; CRP, C-reactive protein; mg, milligram; dL, deciliter; PASI, psoriasis activity score index; HAQ-DI, health assessment questionnaire disability index; mTSS, modified total Sharp score.

However, VLDA allowed for numerically higher residual PP and PtGA levels when compared with DAPSA remission. Importantly, residual enthesitis did not differ among pts achieving DAPSA remission or VLDA. Irrespective of disease activity assessment, pts receiving ADA displayed little to no radiographic progression.

Conclusions: In the ADEPT and ACCLAIM cohorts, pts who achieved DAPSA remission or VLDA demonstrated similar outcomes with respect to the individual components of both scores, despite the omission of several of these within the DAPSA. Given the DAPSA's continuous nature, its use may offer a good alternative to fulfillment of the VLDA criteria, but these results require confirmation in different pt populations.

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FRI0499 REAL-WORLD STUDY ON THE PATTERNS AND COST OF TREATMENT FAILURE IN PATIENTS WITH PSORIATIC ARTHRITIS USING US CLAIMS DATA

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Background: Current treatments for psoriatic arthritis (PsA) are associated with a range of limitations, e.g. side effects, safety concerns and inadequate efficacy. The economic burden of biologic (b)DMARD failure among patients (pts) with PsA is thought to be substantial,¹ but there is a need to quantify this formally.

Objectives: To evaluate PsA treatment failure (i.e. discontinuation and switching rates) in a US managed care setting and its economic consequences.

Methods: Pts aged ≥ 18 years with 2 diagnosis codes for PsA and 1 claim for a bDMARD from 1 Jan 2007 to 31 Mar 2015 in the Truven Health MarketScan[®] Database (Commercial and Supplemental Medicare) were eligible for the study. Pts were considered incident if they did not have a PsA diagnosis or a bDMARD prescription during 1 year prior to first PsA diagnosis in the study period, and as prevalent otherwise. Pts had a 1-year follow-up from first PsA diagnosis in the study period. The percentages of pts discontinuing a drug, switching to another drug or continuing on the same drug for 1 year from first date of treatment were reported. Healthcare costs for 1 year from initiation of the first bDMARD, (medical and drug costs associated with treatment failures) were reported as cost per-pt-per-month (PPPM), and a generalized linear model was used to analyse the cost after controlling for various demographic variables.

Results: Of the 18,632 pts treated with a bDMARD, 1298 (6.97%) were incident and 17,334 (93.03%) prevalent. Almost half (n=8994; 48.27%) of the pts continued on the index bDMARD for 1 year. Treatment failed for the remaining pts, with 7852 (42.14%) discontinuing, and 1630 (8.75%; overlap ≤ 30 days between drugs) and 156 (0.84%; overlap > 30 days) switching. In the prevalent group, 8754 (50.50%) pts continued on the index drug, 7043 (40.63%) discontinued, and 1399 (8.07%; overlap ≤ 30 days) and 138 (0.79%; overlap > 30 days) switched to another drug. Among incident pts, only 240 (18.49%) continued, 809 (62.33%) discontinued, and 231 (17.80%; overlap ≤ 30 days) and 18 (1.38%; overlap > 30 days) switched to another drug. Pts with an overlap > 30 days were excluded from the analysis. Overall, pts who switched had a higher PPPM total cost (\$3317) than those who discontinued (\$2650; p<0.0001) or continued (\$2708; p<0.0001). Similar results were observed in the prevalent and incident groups, respectively, with pts who switched incurring a higher PPPM total cost (\$3241 and \$3779) compared with those who discontinued (\$2583 and \$3237; both p<0.0001) or continued (\$2700 and \$3080; both p<0.0001). Increasing age (per year) was associated with a 0.57% higher total cost in the incident group (p=0.002) and with a 0.49% higher cost in the prevalent group (p<0.0001). Among prevalent pts, females had a 3.08% higher cost than males (p=0.0069). The Charlson Co-morbidity Index score predicted a higher cost (p<0.0001) among prevalent but not incident pts.

Conclusions: In a US claims study population of pts with PsA, rates of treatment failure as defined by switching or discontinuation were high. Follow-up costs for pts who switched were higher than for pts who continued or discontinued their medication. Baseline age, female sex and co-morbidities were associated with higher treatment costs.

References:

[1] Taylor PC, et al. Rheumatol Int 2016;36:685-95.

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