imputation. Safety was assessed from exposure adjusted incidence rates of serious adverse events (SAEs) and treatment-emergent AEs of special interest.

Results: Analyses included 70/265 patients with/without MetS receiving tildrakizumab 100 mg and 64/241 patients with/without MetS receiving tildrakizumab 200 mg. Median percentage change from baseline PASI score is shown in Figure 1. Among patients with/without MetS receiving tildrakizumab 100 mg, 78.6%/87.9% achieved PASI 75, 57.1%/63.8% achieved PASI 90, and 25.7%/32.5% achieved PASI 100 response at week 244; the PASI 75, PASI 90, and PASI 100 response rates at week 244 in patients with/without MetS receiving tildrakizumab 200 mg were 76.6%/85.1%, 46.9%/61.4%, and 26.6%/36.5%, respectively. Safety outcomes over the 5-year extension period were consistent with the known safety profile of tildrakizumab. Rates of SAEs were <8.5 per 100 patient-years among all patients, and there were no new safety signals in patients with vs without MetS (Table 1).

Table 1. SAEs and TEAEs of special interest by MetS status through up to 5 years of tildrakizumab exposure

	TIL 100 mg		TIL 200 mg	
	Without MetS	With MetS	Without MetS	With MetS
	n = 265	n = 70	n = 241	n = 64
n (EAIR per 100 PY)	1149.1 PY	304.1 PY	1057.1 PY	287.6 PY
SAEs	53 (4.61)	22 (7.23)	52 (4.92)	24 (8.35)
TEAEs of special interest	24 (2.09)	6 (1.97)	27 (2.55)	15 (5.22)
Infections and infestations	10 (0.87)	2 (0.66)	13 (1.23)	6 (2.09)
Malignancies ^a	5 (0.44)	1 (0.33)	4 (0.38)	3 (1.04)
Nonmelanoma skin cancer	3 (0.26)	1 (0.33)	6 (0.57)	1 (0.35)
Confirmed extended MACE	3 (0.26)	1 (0.33)	3 (0.28)	3 (1.04)
Drug hypersensitivity	2 (0.17)	1 (0.33)	1 (0.09)	2 (0.70)
Melanoma skin cancer	2 (0.17)	0	0	0
Injection site reactions ^b	1 (0.09)	0	0	0

Incidence rates reported as events per 100 PY.^aExcluding nonmelanoma and melanoma skin cancer.^bNot considered of special interest in the extension study. AE, adverse event; EAIR, exposure adjusted incidence rate; MACE, major adverse cardiovascular events; MetS, metabolic syndrome; PY, patient-years; SAE, serious AE; TEAE, treatment-emergent AE; TIL, tildrakizumab.

Figure 1. Median percent change from baseline PASI score through week 244 in patients with and without MetS

Missing data were handled using multiple imputation.
MetS, metabolic syndrome; PASI, Psoriasis Area and Severity Index; PASI 75/90, 75%/90% improvement from baseline PASI score; TIL, tildrakizumab.

Conclusion: The efficacy and safety of tildrakizumab were maintained in patients with and without MetS following 5 years of treatment.

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AB0545

COMPARISON BETWEEN METHOTREXATE AND APREMILAST IN PSORIATIC ARTHRITIS-A SINGLE BLINDED RANDOMIZED CONTROLLED TRIAL (APREMEPsa STUDY)

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Background: Both methotrexate and apremilast were found to be effective in controlling joint disease in psoriatic arthritis (PsA) patients [1-4]. However, there are no head-to-head trials comparing the efficacy of these two drugs in PsA.

Objectives: Primary outcome measure was rate of major cDAPSA response (>85% change in cDAPSA score from baseline) at week 24 and secondary outcome measures were ACR 20 response, change in Psoriasis Area and Severity Index (PASI), Maastricht enthesitis score, Leeds dactylitis index, and health assessment questionnaire-disability index (HAQ-DI) and number of adverse events at week 24 between methotrexate and apremilast groups.

Methods: Single blinded (physician), parallel group, randomized controlled trial was conducted at a single centre in India between October 2019 and December 2020. Adult PsA patients (age>18 years), fulfilling CASPAR criteria, not receiving methotrexate/apremilast in last 3 months and never receiving bDMARDs or, JAK inhibitors, having active articular disease (one or more swollen joint or, having one or more tender enthesal point) were recruited in this study.

Results: A total of 31 patients were recruited (15 in apremilast arm and 16 in methotrexate arm) amongst whom 26 patients completed 24 weeks follow up (13 patients in apremilast arm and 13 patients in methotrexate arm). At baseline, median (IQR) swollen joints were 2 (1) in apremilast group and 2.5 (4) in methotrexate group. Median cDAPSA score at baseline was 23 (9) in apremilast group and 20 (21) in methotrexate group. Major cDAPSA response at week 24 was achieved in three (20%) subjects in apremilast arm and six (37.5%) subjects in methotrexate arm (p=0.433). Seven (46.67%) subjects in apremilast group and nine (56.25%) subjects in methotrexate group achieved ACR 20 response at 24-weeks (p=0.724). The change of PASI score from baseline was significant in apremilast group (2.0, p=0.003) and methotrexate group (0.35, p=0.003), but when compared between the two groups, there was no significant difference (p=0.378). Change in enthesitis score was not significant in both the groups (0.0 in apremilast group, p=0.285; 0.0 in methotrexate group, p=1.0). The median change in dactylitis score [0.0 (9.1), p=0.028] and HAQ-DI score (0.33, p=0.01) were significant in methotrexate group only. However, when compared to the change in apremilast group, the difference was not significant for both the parameters. A total of 9 minor adverse events, 3 with apremilast and 6 with methotrexate, were observed with transaminitis (number of events) being the commonest event noted with methotrexate. There were no serious adverse events noted in either of the groups.

Conclusion: There was no significant difference between methotrexate and apremilast in terms of efficacy as measured by cDAPSA and ACR20 responses. Both the drugs were well tolerated by the study population. A larger study with head-to-head comparison between methotrexate and apremilast is needed to conform these findings.

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AB0546

5 YEARS FOLLOW-UP OF PSORIATIC ARTHRITIS PATIENTS TREATED ACCORDING TREAT-TO-TARGET STRATEGY. PRELIMINARY RESULTS

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Background: The concept of treat to target (T2T) in psoriatic arthritis (PsA) has been established recently and already shown its benefits [1]. But the long-term outcomes of the T2T have not been studied yet.

Objectives: To study 5 years (yrs) follow-up of PsA patients (pts) treated according to T2T strategy at the early stage.

Methods: 35 (M/F=17/18) PsA pts fulfilling CASPAR criteria, who were treated according to T2T strategy at the early stage (PsA duration≤2 yrs) within 24 months (mos) were analyzed. At the time of evaluation mean age is 42.7±11.2 yrs, median (Me) PsA duration 72 [60;95] mos, psoriasis duration 120 [88;180] mos. All pts underwent standard clinical examinations of PsA before started T2T therapy and at follow-up. Within 24 mos of T2T strategy all pts were taking Methotrexate (MTX) monotherapy in increasing dose up to 25mg/wk and 18 out of 35 (51%) pts received MTX in combination with iTNF. When T2T study was stopped all pts were treated according to standard care with NSAIDs, bDMARDs, MTX, tsDMARDs based on PsA activity and physician decision. The number of pts achieved minimal disease activity (MDA, 5 of 7) and remission by DAPSA (≤4)/low disease activity (LDA)≤14) at the 24 mos of T2T strategy and at 5 yrs follow-up were calculated. The results are presented in the form of mean values, median, upper and lower quartiles.

Results: Me duration of follow-up is 68 [53.5;81.5] mos. At 24 mos Me DAPSA 3.48 [0.45;21.76], remission by DAPSA (REM-DAPSA) were seen in 20 out of 35 (57%) pts, LDA-DAPSA in 4 (12%) pts, moderate activity (MoA) by DAPSA in 6 (17%) pts and high disease activity by DAPSA (HDA-DAPSA) in 5 (14%) pts. MDA was noted in 21 out of 35 (60%) pts. At 5 yrs Me DAPSA 7.4 [2.22;13.87], REM-DAPSA was noted in 12 (34%) pts, LDA-DAPSA in 14 (40%), MoA-DAPSA in 5 (14%), HDA-DAPSA in 4 (12%) pts. MDA was observed in 17 of 35 pts (49%). Among 20 pts who had REM-DAPSA at 24 mos only 6 pts (30%) remained in remission at 5 yrs follow-up and 12 out of 21 pts (57.14%) remained in MDA status.

Conclusion: In early PsA pts remission and MDA are achievable goal of T2T strategy. But most pts lost remission/MDA after this strategy was changed to a standard care, despite being in remission/MDA status before change of therapy. Further investigations of the long-term outcomes of T2T strategy in PsA, including radiographic outcomes are needed.

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AB0547

ASSOCIATION BETWEEN ACHIEVEMENT OF LOW DISEASE ACTIVITY OR REMISSION WITH IMPROVEMENT IN QUALITY OF LIFE IN UPADACITINIB-TREATED PATIENTS IN THE PHASE 3 SELECT-PsA 1 AND 2 STUDIES

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Background: The efficacy and safety of upadacitinib (UPA) in patients (pts) with active psoriatic arthritis (PsA) was demonstrated in the phase 3 SELECT-PsA 1 and SELECT-PsA 2 clinical trials.^{1,2}

Objectives: To explore the relationship between achievement of low disease activity (LDA) or remission (REM) and pt-reported outcomes (PROs) in SELECT-PsA 1 and 2.

Methods: The SELECT-PsA program enrolled pts with prior inadequate response or intolerance to ≥1 non-biologic disease-modifying antirheumatic drug (DMARD; SELECT-PsA 1) or ≥1 biologic DMARD (SELECT-PsA 2). Pts were randomized to 56 weeks (wks) of blinded treatment with UPA 15 or 30 mg once daily (QD), placebo switched to UPA 15 or 30 mg QD at Wk 24, or adalimumab (SELECT-PsA 1 only) 40 mg every other wk. LDA and REM were evaluated using the minimal disease activity (MDA; fulfillment of 5 out of 7) criteria and the Disease Activity index for Psoriatic Arthritis (DAPSA; cutoff ≤4), respectively. PROs assessed included Health Assessment Questionnaire-Disability Index (HAQ-DI), 36-Item Short-Form Survey physical component summary (SF-36 PCS), 5-Level EuroQol 5-Dimension (EQ-5D-5L) Index, and EQ-5D-5L Visual Analog Scale (VAS). Integrated data through Wk 56 from SELECT-PsA 1 and 2 from the full analysis set with both continuous UPA 15mg and 30mg groups were analyzed by responder status at Wks 24 and 56. Changes from baseline (BL) in PROs were analyzed using mixed effects repeated measures models (fixed effects for study, current use of non-biologic DMARDs, treatment group, visit, responder status, and continuous BL PROs). As-observed data were used in the models.

Results: A total of 1281 pts were included in the analysis (UPA 15mg, n=640; UPA 30mg, n=641). MDA was achieved by 33% (UPA 15mg) and 40% (UPA 30mg) of patients at Wk 24, and 40% (UPA 15mg) and 43% (UPA 30mg) at Wk 56; and DAPSA-REM by 10% (UPA 15mg) and 17% (UPA 30mg) at Wk 24, and 16% (UPA 15mg) and 18% (UPA 30mg) at Wk 56. Pts who achieved MDA or DAPSA-REM (responders) at Wk 56 achieved larger reductions in HAQ-DI and larger increases in SF-36 PCS, EQ-5D-5L Index and EQ-5D-5L VAS compared with non-responders (Table 1) (all p<0.0001; statistical significance was exploratory in nature). MDA or DAPSA-REM response at Wk 24 was also associated with greater PRO improvements at Wk 56 (Figure 1). Consistent with the results presented for MDA and DAPSA-REM, patients who achieved Very Low Disease Activity or DAPSA-LDA also experienced greater improvements in PROs than those who did not.

Table 1. Change from BL in PROs at Wk 56 by MDA and DAPSA-REM responder status at Wk 56

	UPA 15mg QD (n=640)		UPA 30mg QD (n=641)	
Least squares mean change from BL (95% CI), unless stated otherwise	Non-responder	Responder	Non-responder	Responder
MDA, n ^a	386	254	368	273
HAQ-DI	-0.26 (-0.30, -0.61* (-0.66, -0.22)	-0.56 (-0.56)	-0.27 (-0.31, -0.69* (-0.74, -0.23)	-0.64 (-0.64)
SF-36 PCS	5.25 (4.60, 5.90)	12.63* (11.84, 13.41)	5.09 (4.42, 5.75)	13.84* (13.08, 14.59)
EQ-5D-5L Index	0.11 (0.09, 0.12)	0.25* (0.23, 0.26)	0.10 (0.09, 0.12)	0.27* (0.25, 0.28)
EQ-5D-5L VAS	9.3 (7.8, 10.9)	23.3* (21.4, 25.1)	9.0 (7.4, 10.5)	26.1* (24.4, 27.9)
DAPSA-REM, n ^a	539	101	526	115
HAQ-DI	-0.36 (-0.39, -0.63* (-0.71, -0.32)	-0.55 (-0.55)	-0.39 (-0.43, -0.71* (-0.78, -0.35)	-0.63 (-0.63)
SF-36 PCS	6.99 (6.39, 7.59)	14.54* (13.22, 15.86)	7.43 (6.82, 8.03)	15.16* (13.91, 16.40)
EQ-5D-5L Index	0.14 (0.13, 0.15)	0.27* (0.24, 0.30)	0.15 (0.14, 0.16)	0.29* (0.26, 0.31)
EQ-5D-5L VAS	12.7 (11.3, 14.0)	26.7* (23.7, 29.8)	13.3 (11.9, 14.7)	30.0* (27.1, 32.8)

*p<0.0001 vs non-responder (statistical significance was exploratory in nature)^an may vary by PRO assessed

Conclusion: Among UPA-treated pts with PsA, improvements in quality of life and physical function were greater in pts who achieved MDA or DAPSA-REM than in those who did not. Despite DAPSA-REM being a more stringent measure (achieved by a smaller proportion of patients), these improvements were similar between MDA and DAPSA-REM responders.

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