Figure 1. Classification of disease activity according to DAPSA at the indicated timepoints. Percentages in each category were calculated based on the number of patients with available data at each timepoint. DAPSA, Disease Activity in Psoriatic Arthritis.

Conclusion: Forty-one (75.9%) patients with PsA naïve to biological therapies were treated with apremilast during ≥ 6 months. After treatment, the number of swelling joints, and dactylitis and enthesitis decreased and changes in disease activity according to DAPSA and PGA pointed to a favorable disease evolution. Apremilast treatment provides a clinical benefit to patients with PsA treated in clinical practice.

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AB0543

CHARACTERISTICS AND TREATMENT CHANGES IN PATIENTS WITH PSORIATIC ARTHRITIS SEEN IN A COMBINED DERMATOLOGY-RHEUMATOLOGY CLINIC

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Background: Data on patients with Psoriasis (PSO) referred to a combined Dermatology-Rheumatology outpatient Clinic (Derm-Rheum) with suspected psoriatic arthritis (PsA) are limited.

Objectives: To assess patient characteristics and treatment changes in PsA patients referred to a Derm-Rheum Clinic.

Methods: Prospective study of PSO patients referred to a combined Derm - Rheum Clinic from February 2018 to June 2020 in a Tertiary University Hospital.

Results: Among 151 patients with PSO referred to the Clinic, 129 (85%) with a final diagnosis of PsA were included. In 73% of patients (n=94) PsA was diagnosed there for the 1st time. 56% were females with a mean age of 55 years and a median disease duration of 14.2 years. At initial evaluation, 95% had peripheral arthritis, 45% nail involvement, 23% axial involvement, 12% enthesitis and 6% dactylitis with a median DAPSA score of 20.5 and PASI score of 1.6, respectively. 31% of the patients were not receiving any systemic treatment, 45% were on biologics (30% as monotherapy, 15% in combination with non-biologics), 29% were on non-biologics (14% as monotherapy, 15% in combination with biologics or targeted synthetic agents) and 10% were on targeted synthetic (ts) agents. At last visit (median follow-up: 15 months) only 8% did not receive any systemic therapy (p<0.001 compared to 1st visit), 62% were on biologics (39% monotherapy – 23% in combination with non-biologics, p=0.009), 46% were on non-biologics (20% as monotherapy – 26% in combination with biologics or ts agents, p=0.01) and 10% of the patients were on apremilast. The median DAPSA and PASI scores at last visit were 5.3 and 0, respectively.

Conclusion: About 2/3 of patients with PSO referred to a combined Derm - Rheum Clinic with suspicious musculoskeletal complaints were diagnosed for the 1st time as PsA. During follow-up the percentage of PsA patients who started or continued systemic therapy significantly increased with significant improvement of disease activity indices. These data emphasize the value of combined Derm - Rheum Clinics for earlier diagnosis and more efficacious treatment of PsA patients.

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AB0544

EFFICACY AND SAFETY OF TILDRAKIZUMAB IN PATIENTS WITH AND WITHOUT METABOLIC SYNDROME: 5-YEAR POOLED DATA FROM reSURFACE 1 AND reSURFACE 2

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Background: Patients with psoriasis and metabolic syndrome (MetS) may have reduced absolute Psoriasis Area and Severity Index (PASI) response and long-term drug survival. Tildrakizumab is approved for the treatment of moderate to severe plaque psoriasis in the US, EU, Australia, and Japan. Efficacy and safety of tildrakizumab were previously shown to be comparable in patients with vs without MetS after 1 and 3 years of treatment.¹

Objectives: This post hoc analysis of pooled data from reSURFACE 1 and reSURFACE 2 (NCT01722331/NCT01729754) assessed tildrakizumab efficacy and safety through up to 5 years of treatment in patients with psoriasis with and without MetS.

Methods: reSURFACE 1 and 2 were 3-part, double-blind, randomized controlled phase 3 trials with long-term extensions evaluating tildrakizumab 100 or 200 mg monotherapy at Weeks 0, 4, and every 12 weeks thereafter in adults with moderate to severe plaque psoriasis.² Patients who achieved $\geq 50\%$ improvement from baseline PASI score (PASI 50 response) at both week 28 and at the end of the phase 3 studies could enter the long-term extension studies continuing the same dose of tildrakizumab.¹ This post hoc analysis reports results from a pooled data analysis through up to 5 years of tildrakizumab exposure from patients with and without MetS by National Cholesterol Education Program-Adult Treatment Panel III criteria who continuously received the same dose of tildrakizumab throughout the base studies and entered the long-term extensions. Efficacy was assessed as change from baseline PASI score; missing data were handled using multiple

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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