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A Descriptive Study of Apremilast in Psoriasis in Govt General Hospital, Kurnool

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Abstract
Introduction: *Apremilast is a novel oral phosphodiesterase-4 inhibitor approved for psoriasis treatment. Randomized trials have documented its efficacy and safety, but data on real world patients are scarce.*
Objectives: *Our objective is to characterize psoriasis patients treated with apremilast in a real world setting and calculate drug survival as an important measure of efficacy and compliance.*
Materials and Methods: *This is a descriptive study of 30 patients with psoriasis at the time of presentation, Conducted from January 2019 to August 2019 (8 months) in the Department of DVL, Kurnool Medical College & GGH, Kurnool. Patients under 12 year's age were excluded in this study. Relevant history was taken, clinical examination was done and data was analyzed.*
Results:*Thirty patients were included. Thirty patients with psoriasis who received at least one month dose of apremilast and had at least two follow-up visits were included in the study. The median age at the time of the first apremilast dose was 50 years (range 21–77), and 18 patients (60%) were males. The mean body mass index (BMI) was 27.4 (range 17.1-40.6). 13 patients (43.33%) actively smoking during theobservation period. Seven patients (56%) had a positivefamily history of psoriasis. The majority (n = 24, 85.4%) received at least one systemic psoriasis treatment prior to Apremilast. At the beginning of Apremilast treatment, the mean PASI in our study cohort was 10.7.*
Conclusion: *This study was done to know whether, despite differences between real world and trial patients, apremilast is safe and effective for the treatment of skin psoriasis in the daily practice*
Key Words: *Apremilast, Psoriasis, PASI Score, BMI.*

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I. Introduction

Psoriasis is a chronic inflammatory dermatosis with a waxing and waning course.[1] The management of psoriasis has witnessed a tremendous change over the last 1 decade paving ways to the newer biological agents. While the common systemic agents, such as methotrexate, acitretin, and cyclosporine are associated with end-organ toxicities and treatment-related side effects, the biological agents have the limitations of added costs to the care and inconvenient mode of administration apart from the possibility of iatrogenic immunosuppression. In this background, an agent that is less toxic, cost-effective, convenient to prescribe, and having optimal efficacy is always welcomed by the patients and dermatologists.[2]Apremilastwas approved by the US Food and Drug Administration (FDA) on March 21, 2014, for the management of active psoriatic arthritis (PsA) in adults. Soon, on September 23, 2014, FDA approved apremilast for treating patients of moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.[3] It has got marketing approval from Drug Controller General of India in 2017. However, there is a paucity of information on apremilast in the Indian literature. In this review, we would like to comprehensively yet concisely discuss the various clinical aspects of apremilast use in psoriasis

II. Materials And Methods

The study was conducted at Department of DVL, Kurnool Medical College & GGH, Kurnool. We included all patients affected by plaquepsoriasis that received at least one month of apremilast and had at least two follow-up visits between January 2019 to August 2019. Apremilast was used following its prescriptionrecommendations (start 10 mg/day, stepwise increase to 30 mg twice/day). All patients were recommended to use additionaltopical treatments. None of the patients received additional systemic antipsoriatic therapy.

All patients were evaluated by at least one expert dermatologist at predefined time points (week 0, 1, 4, 8, 12, 16, 20, 32 and 40). At each visit, the following data werenoted and later extracted from our electronic psoriasis database: age, weight, height, smoking status, family history of psoriasis, joint involvement, previous psoriasis treatments, psoriasis areaseverity index (PASI) scores, and the onset and duration of adverse events (AE).

III. Data Analysis

Treatment efficacy was evaluated by PASI50, PASI75 andPASI90, reflecting the improvement of skin lesions compared toPASI-baseline (PASI calculated at the beginning of treatment).Psoriasis severity was classified based onPASI as mild (PASI <10) and moderate–severe (PASI ≥ 10).

Cohort PASI scores were calculated for weeks 1, 4, 8, 12, 16, 20, 32and 40. Data were analysed with Stata software. Descriptive statistics were used to express patient demographicsand AE distribution. Kaplan–Meier statistics were usedfor drug survival estimates; censored patients are patients whowere still on treatment on January 19th, 2017 (lock date), orpatients who were lost to follow-up; the time to event was calculatedas the time from the beginning of treatment until the lastvisit;. Pearson-chi2-test was used to compare percentages ofpatients reaching PASI50, PASI75 and PASI90 in differentgroups. The variable selection was based on published literature.

IV. Results

Thirty patients with psoriasis who received at least one month of apremilast and had at least two follow-up visits were includedin the study (Table 1). The median age at the time of the first apremilast dose was 50 years (range 21–77), and 18 patients (60%) were males.

The mean body mass index (BMI) was 27.4 (range 17.1-40.6). 13 patients (43.33%) actively smoking during theobservation period. Seventeen patients (56%) had a positivefamily history of psoriasis. The majority (n = 24, 85.4%) received at least one systemic psoriasis treatment prior to apremilast.

S.No	Characteristics	Apremilast (n=30)
1	Age years, median (Range)	50 (21-27)
2	Males/females n (% males)	18/12 (60)
3	Body Mass index, median (range)	27.4 (17.1-40.6)
4	Current Smoker, n (%)	13 (43.33)
5	Psoriasis family history, n (%)	7 (23.33)
6	Previous systemic treatments (%)	
	3 Lines	3 (10)
	2 Lines	7 (23.33)
	1 Line	16 (46.66)
	None	4 (13.33)
	PASI-baseline, mean (SD)	10.4 (4.8)
	PASI < 10	16
	PASI 10–20	11
	PASI > 20	3
8	Treatment status at lock date*, n (%)	
	Unknown (lost to follow-up)	2 (6.66)
	Treatment ongoing	23 (43.33)
	Adverse events	5(10.33)

Table 1: Baseline demographics and clinical characteristics of 30 psoriasis patients treated with apremilast

S.No	Type of adverse event	Number of patients	(Grade 3 or 4)
1	Gastrointestinal (diarrhoea/nausea	3	
2	Joint pain	1	
3	Headache	1	
4	Fatigue	0	
5	Ureteric pain	0	
6	Sleep disturbance	0	
7	Tachycardia	0	
8	Depression	0	
9	Allergic reaction type I	0	

Table 2: Adverse events (AE) attributed to the drug in 30 psoriasis patients treated with apremilast. Severe AE leading to therapy discontinuation are indicated separately

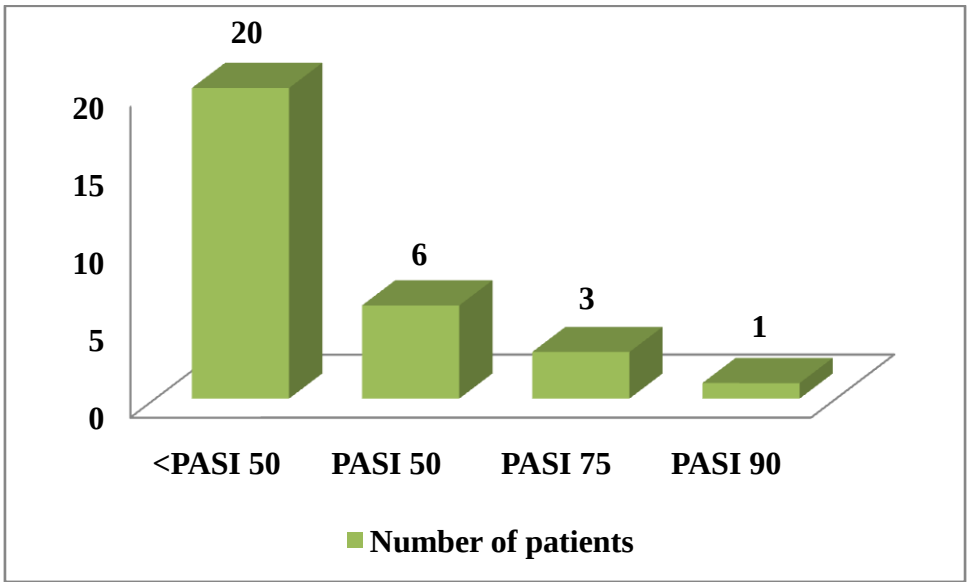

Figure 1: Bar graph depicting the best PASI response

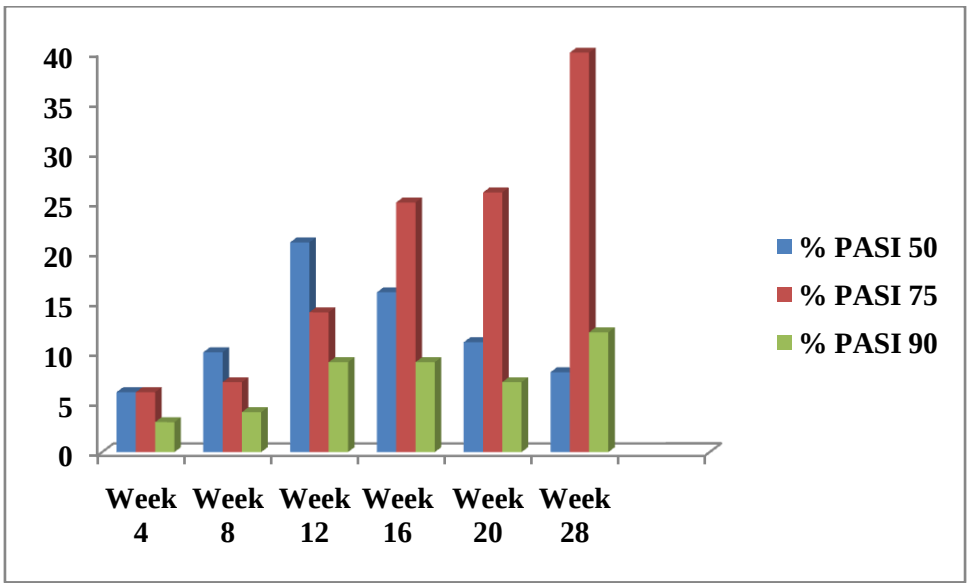

Figure 2: Percentage of evaluable patients at indicated time points reaching PASI50, PASI75 and PASI90

Figure 3: Psoriasis patient after 1st week treatment with Apremilast

Figure 4: Psoriasis patient after 12weeks treatment with Apremilast

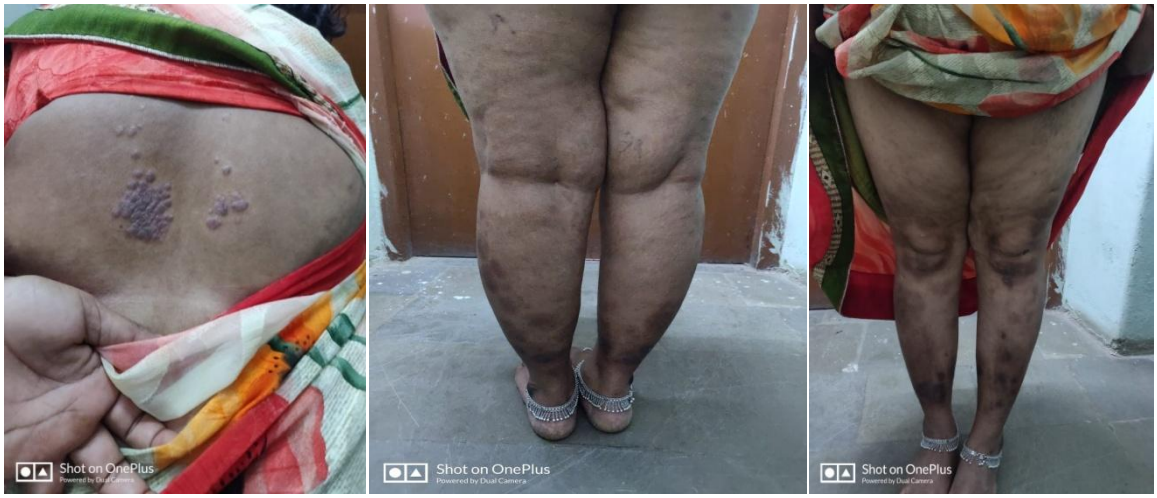

Figure 5: Psoriasis patient after 16weeks treatment with Apremilast

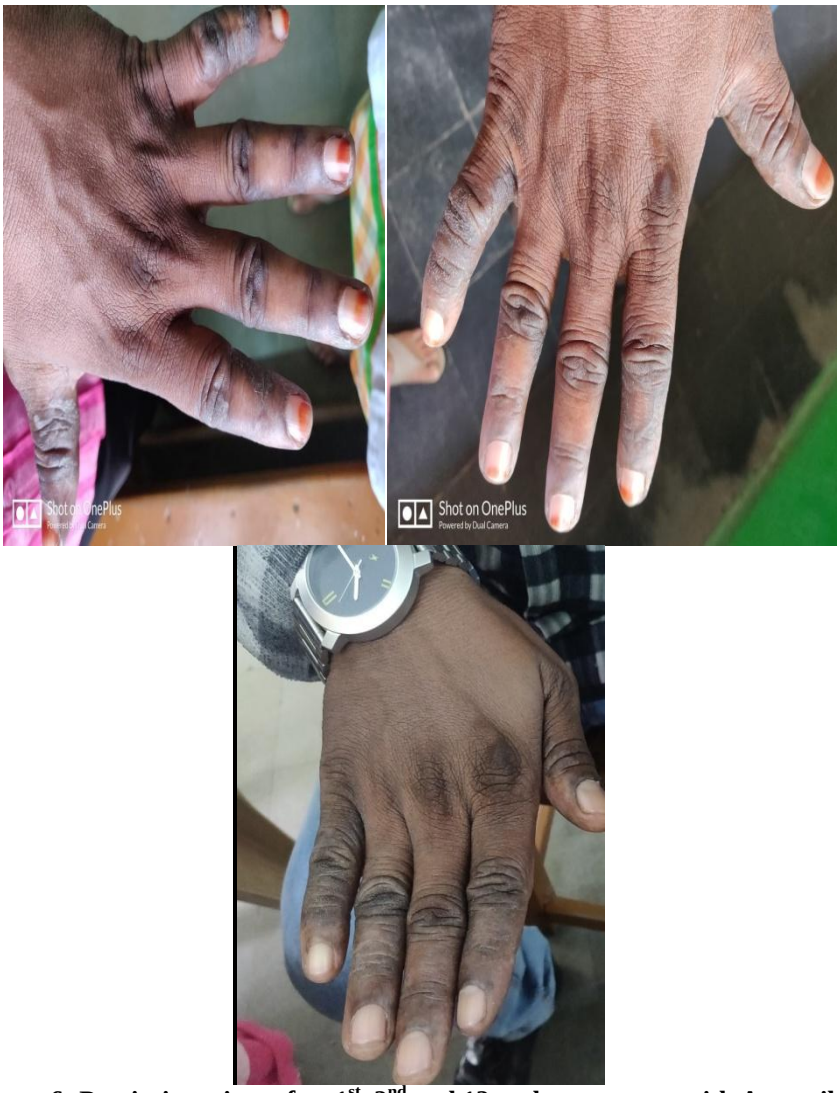

Figure 6: Psoriasis patient after 1st, 2nd and 12weeks treatment with Apremilast

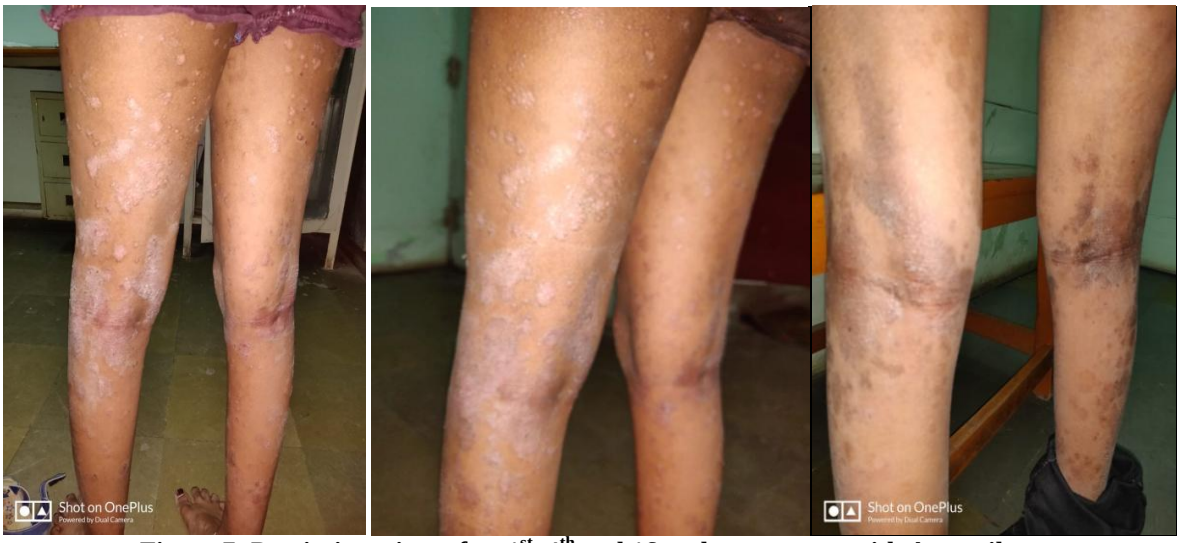

Figure 7: Psoriasis patient after 1st, 4th and 16weeks treatment with Apremilast

The median apremilast drug survival was 12.5 weeks (range 1-87), with 23 patients (41.7%) still on treatment at lock date. Two patients were lost to follow-up. and five stopped because of treatment-related adverse events. Gender, age, smoking, psoriatic arthritis and PASI score at the beginningof treatment did not affect drug survival (log-rank test, P> 0.05).

To analyse treatment efficacy in our cohort, we were able toinclude 30 patients. Using the measure 'best PASI reached', eight patients (16.7%) had at least a PASI50, nine (18.8%) a PASI75and three (6.3%) a PASI90. The best treatment response wasachieved between weeks 12 and 16. BMI was calculated for 30 patients. Even though not statistically significant, none of the obesepatients (BMI > 30.0, n = 6) reached PASI75, compared to 32%ofthe non-obese patients (BMI < 30.0, n = 31; chi2-test, P = 0.1).

Patient weight negatively correlated with treatment efficacy whenmeasured as PASI50 or better (P < 0.05, n = 30), whilst bodyweightdid not correlate with PASI75 and PASI90 achievement.

The severity of psoriasis at the beginning of treatment did not influence apremilast efficacy (chi2 test, P > 0.05). Moreover, wedid not find any significant difference in treatment responsescomparing treatment naive patients to patients who previouslyreceived systemic psoriasis therapy (chi2 test, P > 0.05).

V. Discussion

Real-life treatment outcomes may differ from clinical trial results due to preselected patient cohorts in clinical trials. Thus, it iscritical to also evaluate efficacy and safety in everyday practice.[6] Such data give us valuable information and can impact our therapeutic regimen. In this study, we report our experiences on drug survival, efficacy and AEs in psoriasis patients treated with apremilast. Clear limitations of the study are the non-comparative study design, the modest patient numbers and the fact that 23 patients (41.7%) were still on treatment at lock date, which may alter drug survival numbers.

Drug survival time (time until drug discontinuation) has beenreported to be a valuable tool measuring therapeutic efficacy inchronic diseases such as psoriasis. It reflects treatment adherenceand is thus a function of long-term efficacy of therapeutics in areal-life setting. Thus, it might be more useful for the clinicianthan the mere comparison of PASI score changes during treatment.[9]

VI. Conclusion

Apremilast is a safe and valuable therapeuticmodality for patients with psoriasis. Its benefits are easy patientmanagement, and the factthat no pre-treatment laboratory tests are required. In our experience, up to 40% of the patients will reach PASI50 or better, butonly few will reach PASI90. Further studies, including pharmacogenomics and transcriptomic analyses from psoriatic skin, areneeded to identify patients who are most likely to benefit from apremilast treatment.

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