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Original Research Article

Comparative evaluation of therapeutic efficacy and safety of apremilast versus cyclosporine in psoriasis vulgaris

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Abstract

Background: Psoriasis is a chronic relapsing inflammatory skin condition with various treatment options, but achieving significant lesion clearance with minimal side effects remains challenging.
Aims: To compare efficacy and safety of Apremilast and Cyclosporine in the treatment of chronic plaque psoriasis.
Materials and Methods: This study was conducted with two groups of thirty participants each. Group A received Cyclosporine (2.5 to 5 mg/kg/day), while Group B received Apremilast (daily 60mg in two divded doses) for 16 weeks and evaluated at baseline and at 4, 8, 12, 16, and 24 weeks using the Psoriasis Area and Severity Index (PASI), Body Surface Area (BSA) and serial photographic assessments.
Results: The clinico-demographic parameters were comparable between the two groups. The mean PASI score in the Cyclosporine group decreased from 10.90±5.5 to 3.10±1.8 (*P* 0.001) at the end of 16 weeks, while in the Apremilast group, it decreased from 11.27±5.5 to 3.47±2. 1(*P* 0.04). The mean baseline BSA in Group A was 40.00±18.274, which decreased to 9.30±5.694 at 16 weeks (*P* 0.001) while in Group B, it decreased from 39.80±16.238 to 15.70±9.248 (*P* 0.001). Both treatments demonstrated similar efficacy in reducing the scores (*P* 0.669).
Conclusion: Apremilast demonstrated similar efficacy to Cyclosporine with the added benefits of lower cost and less need for laboratory monitoring. However, apremilast was linked to significant gastrointestinal side effects. Thus, this study shows that Apremilast is a valuable addition to the treatment armamentarium of psoriasis and may even be a suitable first-line treatment, particularly for patients with contraindications to other traditional systemic therapies or for use in combination or rotational therapy.

Keywords: Chronic plaque psoriasis, Apremilast, PDE-4 inhibitor, Cyclosporine

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1. Introduction

Psoriasis is a common chronic inflammatory and hyperproliferative condition of the skin, nails and joints.[1,2,3] The worldwide prevalence ranges from 0.09% to 11.4%.[4] Cyclosporine, an effective immunosuppressant and calcineurin inhibitor, shows both T-cell dependent and independent mechanisms. It prevents T-cell activation by decreasing IL-2 production and IL-2 receptor expression, which in turn hinders T-cell proliferation and the production of IFN gamma. Cyclosporine also inhibits transcription of proinflammatory cytokines as well as keratinocyte proliferation.[5] Apremilast is a phosphodiesterase-4 (PDE-4) inhibitor approved by FDA in 2014 for plaque psoriasis. It works by binding directly to the PDE-4 enzyme, which raises cAMP levels and lowers the levels of proinflammatory cytokines like TNF alpha, IL-23, IL-12, and LT-B4, while also increasing the levels of anti-inflammatory cytokines such as IL-10.It also binds to Toll like receptor in mononuclear cells and reduces proinflammatory cytokine production and reduces activity of nitric oxide synthase thereby decreasing the synthesis of nitric oxide which is an important proinflammatory mediator.[6] Nausea, diarrhea, headache and weight loss are the main side effects. Although

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various treatment options for psoriasis are available today, none have proven fully satisfactory in achieving significant lesion clearance with minimal side effects. Cyclosporine is a time tested drug being used in the treatment of psoriasis with proven efficacy with its own side effects and disadvantages like higher cost and requirement of continuous laboratory monitoring whereas Apremilast is a novel, easily available small molecular drug proposed to have efficacy in plaque psoriasis and psoriatic arthritis, without extensive laboratory monitoring in few studies. There is a paucity of literature for comparison between these two drugs in psoriasis. Therefore, we carried out this research to evaluate the effectiveness and safety of Cyclosporine versus Apremilast in the treatment of psoriasis vulgaris.

2. Aims

Our objective was to assess the effectiveness and safety of apremilast and cyclosporine in the treatment of psoriasis vulgaris and to compare their outcomes.

3. Materials and Methods

We carried out a hospital-based, prospective, comparative study at the dermatology department of a tertiary care center. The study was conducted between February 2018 and May 2019 following approval from the Institutional Ethics Committee. Adults aged 18 to 65 years with psoriasis vulgaris were enrolled after providing written informed consent. Exclusion criteria were pregnancy, lactation, abnormalities in complete hemogram, renal and liver function, uncontrolled hypertension and diabetes, active tuberculosis or risk of reactivation and hypersensitivity to the drugs. Sixty patients were randomly divided into two groups, each consisting of 30 individuals. Patients in Group A received oral Cyclosporine at a dosage of 2.5 mg to 5 mg/kg/day for a duration of 16 weeks.[7] while Group B patients received oral Apremilast daily 60mg in two divided dose from day 6 to 16 weeks adhering to the starter pack's specified initial dosage titration from day 1 to day 5.[8]

Psoriasis Area Severity Index (PASI) was calculated using the formula PASI=0.1(Eh+Ih+Dh) Ah + 0.2(Eu+Iu+Du) Au + 0.3(Et+It+Dt) At +0.4(El+Il+Dl) Al. PASI 75 is the standard used by FDA to assess the efficacy of any psoriasis agent. The Wallace rule of nines is used to estimate the total Body Surface Area (BSA) affected. All the patients were evaluated for therapeutic outcome both objectively (PASI Score and BSA score) and photographically at baseline, 4, 8, 12, 16 and 24 weeks. At each visit, the percentage change in BSA and PASI scores from baseline was computed as follows:

$$\frac{BL - F/U}{BL} \times 100 = \%$$ change from baseline

Where BL~ baseline, F/U~ follow up

The results were tabulated with respect to percentage of improvement in PASI and BSA scores and grading was done from 0 to 4 accordingly.

Grade 0	No response	No improvement
Grade 1	Mild response	<25% improvement
Grade 2	Moderate response	25% to <50% improvement
Grade 3	Good response	50% to <75% improvement
Grade 4	Very good response	≥75% improvement

Results obtained were analyzed statistically at the end of the study using SPSS version 20.0 with appropriate tests (Pearson's Chi-square test, Paired Samples T-test, Wilcoxon signed–rank test, Mann Whitney U test).

4. Results

All 60 patients completed the 24-week study period. The study cohort comprised 16 females (26.7%) and 44 males (73.3%) (*P* 1.000). In Group A, the mean age was 41.70 ± 10.551 years, while in Group B, it was 43.33 ± 12.704 years (P = 0.590). The duration of the disease ranged from 8 months to 40 years, with mean of 8 years (*P* 0.353). The most commonly affected sites were the scalp and lower limbs (91.7%), followed by the trunk (88.3%) and upper limbs (83.3%). The least affected areas were the palms and soles (8.3%) and genitals (5%). Itching was reported by 65% of patients (*P* 0.659). Around 45% of patients consumed alcohol (*P* 0.194). A positive family history of psoriasis was noted in 15% of the patients. The most common comorbidities included viral hepatitis, hypertension, diabetes and hypothyroidism. Disease exacerbation during winter was reported by 61.7% of the patients (*P* 0.680). Nail involvement was in 78.3% patients, with pitting being the most common finding (50%), followed by onycholysis (46.7%), prominent longitudinal striations (43.3%) and leukonychia (13.3%). Nail involvement was significantly higher in Group B (*P* 0.005). Clinicodemographic data of patients are summarized in **Table 1**.

4.1. Efficacy analysis

Both groups were statistically similar regarding age, sex, disease duration, personal and dietary habits, and baseline PASI and BSA scores. The mean baseline PASI score was 10.90 ± 5.505 in Group A and 11.29 ± 5.632 in Group B (*P* 0.750). Over the course of the study, the mean PASI scores in Group A at 4, 8, 12, 16, and 24 weeks were 7.63 ± 3.810, 5.57 ± 2.648, 4.10 ± 2.155, 3.10 ± 1.826, and 2.87 ± 1.943, respectively. In Group B, these values were 8.53 ± 4.509, 6.86 ± 3.883, 5.08 ± 2.733, 3.49 ± 2.155, and 3.24 ± 2.457, respectively. There was a statistically significant reduction in PASI scores from baseline at each visit in both groups (*P*< 0.005). At 12 weeks, in group A, 27(90%) patients achieved Grade 3 response and 1(3.3%) patient achieved Grade 4 response whereas in group B, only 15(50%) patients achieved

Grade 3 response and 3(10%) patients achieved Grade 4 response which was statistically significant (*P* 0.001). At 16 weeks, 12(40%) patients achieved Grade 4 response in both groups but Grade 3 response was higher in group A (56.7%) than group B (46.7%). At 24 weeks, all patients showed either Grade 3 (53.3%) or Grade 4 (46.7%) response in group A whereas in group B, 4(13.3%) patients showed Grade 2, 15(50%) patients showed Grade 3 and 11(36.7%) patients showed Grade 4 response.

The mean baseline BSA score was 40.00 ± 18.274 in Group A and 39.80 ± 16.238 in Group B. The mean BSA scores at 4, 8, 12, 16, and 24 weeks in Group A were 35.17 ± 15.866, 29.33 ± 13.319, 21.83 ± 10.681, 9.30 ± 5.694, and 8.83 ± 5.571, respectively. In Group B, these scores were 37.17 ± 15.295, 32.00 ± 13.846, 26.37 ± 11.657, 15.70 ± 9.248, and 13.60 ± 7.916, respectively. Both groups showed a statistically significant reduction in BSA scores from baseline at each visit. At 12 weeks, in group A, 16(53.3%) patients achieved Grade 3 response and 14(46.7%) patients achieved Grade 2 response whereas in group B, only 3(10%) patients achieved Grade 3 response and 25(83.3%) patients showed Grade 2 response only. At 16 weeks, in group A, 25(83.3%) and 5(16.7%) patients achieved Grade 4 and Grade 3 response respectively whereas in group B, 7(23.3%), 16(53.3%) and 7(23.3%) patients showed Grade 2, Grade 3 and Grade 4 response respectively. At 24 weeks, all patients showed either Grade 3 (20%) or Grade 4 (80%) response in group A whereas in group B, 2(6.7%) patients showed Grade 2, 19(63.3%) patients showed Grade 3 and 9(30%) patients showed Grade 4 response.

Group A showed recurrence in 4(13.3%) patients according to PASI and BSA, while in group B, 6(20%) patients according to PASI and 1(3.3%) patient according to BSA showed recurrence (*P* > 0.05).

Patient's clinical improvement in both groups is depicted in **Figure 1**, **Figure 2**, **Figure 3**.

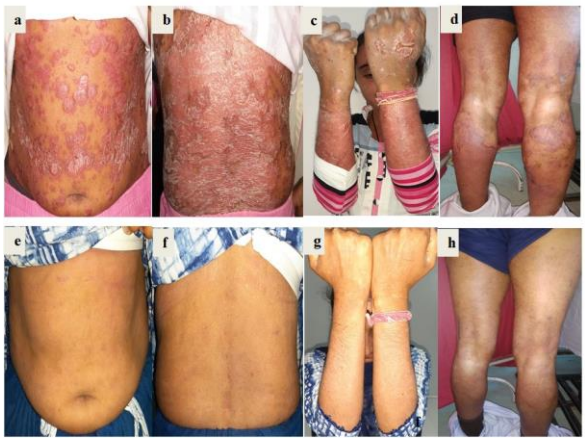

Figure 1: Clinical improvement in patients of group A from first visit (**a, b, c, d**) to 16th week (**e, f, g, h**)

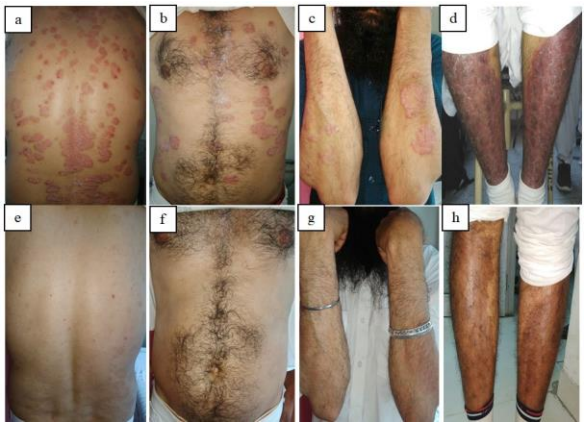

Figure 2: Clinical improvement in patients of group B from first visit (**a, b, c, d**) to 16th week (**e, f, g, h**)

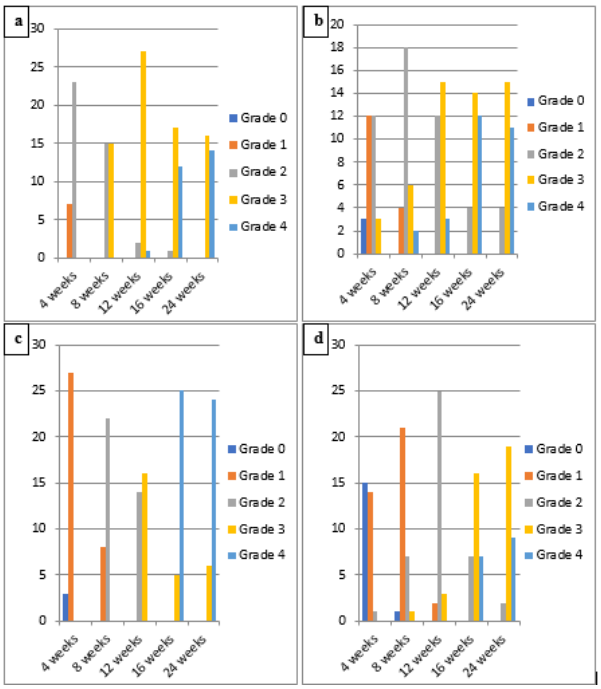

Figure 3: Showing the trends in grades of improvement by PASI score with treatment in Group A; (**a**): and Group B; (**b**): BSA score in Group A; (**c**): and Group B; (**d**): at each follow up visit.

4.2. Adverse effects

No adverse drug reactions noted in 53.3% (32) patients. Gastrointestinal side effects were the most common, occurring in 21.6% (3 in group A, 10 in group B) patients with a significantly higher incidence in group B (*P* 0.028) followed by headache in 6.7% (4) patients, more commonly in group B without statistical significance. Increase in blood sugar levels seen in 6.7% (4) patients, predominantly in group A (3 patients). Renal function test derangements and increased blood pressure were observed in 5% (3 patients in Group A but none in Group B). In Group B, 10% patients experienced initial aggravation of lesions, facial dryness and insomnia.

Table 1: Clinicodemographic data at baseline

	Group A (Cyclosporine) (n=30)	**Group B (Apremilast) (n=30)**
Age (in years) (Mean + SD)	41.70 + 10.551	43.33 + 12.704
Gender	Male 22, Female 8	Male 22, Female 8
Duration of disease	8 months to 23 years	9 months to 40 years
Sites involved		
Scalp	27(90%)	28(93.3%)
Trunk	26(86.7%)	27(90%)
Upper limb	22(73.3%)	28(93.3%)
Lower limb	27(90%)	28(93.3%)
Palms & soles	3(10%)	2(6.7%)
Genitals	1(3.3%)	2(6.7%)
Symptoms- Itching	18 (60%)	21(70%)
Joint pain	3(10%)	7(23.3%)
Alcoholics	11(36.7%)	16(53.3%)
Smokers	2(6.7%)	28(93.3%)
Family history of psoriasis	4(13.3%)	5(16.7%)
Seasonal exacerbation		
Winter	17(56.7%)	20(66.7%)
Summer	3(10%)	3(10%)
Nail involvement	19(63.3%)	28((93.3%))

5. Discussion

Psoriasis is now considered as the most prevalent T-cell mediated inflammatory disease of the skin. The concept regarding the etiopathogenesis and treatment is rapidly changing and these changes are immediately translated to the benefit of the patients. It has become a major psychosocial problem with cosmetic concern. Treatment aims at achieving maximum lesion clearance with minimum side effects and preventing recurrence.

This study aims to evaluate the therapeutic efficacy and safety of Apremilast, a novel drug believed to have minimal side effects and promising results in plaque psoriasis, in comparison to the established drug Cyclosporine.

In our study, which included a total of 60 patients aged 19 to 65 years, the majority of participants (36.7%) were in the 36-45 years age group. The mean age of the patients was 42.5 years, which is comparable to the mean age of 42.75 years reported in a study by Sandhu et al.[9] In a study by Sadollah Shamsadini et al, the mean age was found to be 36 years,[10] while Flytstrom et al reported a mean age of 46.5 years.[11]

In terms of gender distribution, males (73.3%) significantly outnumbered females (26.7%), with a male-to-female ratio of 2.75:1. This ratio is similar to the findings of Berbis et al, who reported a male prevalence of 73.1% and a female prevalence of 26.9%, resulting in a ratio of 2.71:1.[12] Additionally, a study by Rentenaar et al documented a male-to-female ratio of 2:1.[13]

Mean duration of the disease was 8 years (7.19 years in group A and 8.82 years in group B). The mean duration of disease was 9.2 + 8 years in a study by Gangaiah et al.[14] In our study, most common sites involved were scalp (91.7%) and lower limb (91.7%) followed by trunk (88.3%) and upper limb (83.3%). In a clinicopathological study by Raghuveer et al in 100 patients, extremities (86.5%) were the most common sites of involvement followed by trunk (85%) and scalp (75%).[15] Itching (*P* 0.659) was the most common symptom in 65% patients followed by joint pain (*P* 0.166) in few (10%) patients. Both symptoms were more in group B than group A without statistical significance. The incidence of joint symptoms has been about 9% in a study by Masood et al which is correlating with our study.[16] In our study, 45% of the patients consumed alcohol but whether it was associated with onset or severity of psoriasis per se was not assessed. A study conducted in Norway showed that alcohol consumption was linked to onset of psoriasis. A study done by Qassim et al on 98 individuals concluded that there was a correlation between alcohol use, smoking, and psoriasis. Alcohol consumption was reported among 31.9% of psoriatic cases.[17]

PASI score reduction at 16 weeks (P = 0.669) and 24 weeks (P = 0.776) showed no statistically significant difference between the groups. At 12 weeks, 90% of patients in Group A achieved Grade 3 response, compared to 50% in Group B, which was statistically significant. At 16 weeks, Grade 3 response was achieved by 96.7% in Group A and 86.7% in Group B while Grade 4 response was achieved equally in both groups (40% in each group). By 24 weeks,

Group A had more patients (46.7%) achieving Grade 4 response than group B (36.7%).

Group A showed a significantly greater reduction in BSA scores at 16 weeks (*P* 0.006) and 24 weeks (*P* 0.024) compared to Group B. At 12 weeks, more patients in Group A achieved higher response rates (G3 and G4) compared to Group B, with significant differences observed at 16 and 24 weeks.

Both Cyclosporine and Apremilast produced statistically significant improvements in PASI and BSA scores from baseline in all visits. However, Group A showed a greater mean reduction in PASI and BSA scores compared to Group B, particularly at weeks 16 and 24. Overall, Group A exhibited a higher mean difference in PASI and BSA from the baseline at every visit compared to Group B.

A meta-analysis study shows 579 patients with severe psoriasis found that after 3 months of cyclosporine treatment at doses of 1.25, 2.5, and 5 mg/kg/day, PASI reductions were 44.4%, 69.8%, and 71.5%, respectively. The average time to achieve a PASI 50 response was 4.3 weeks for the 5 mg/kg/day dose, 6.1 weeks for 2.5 mg/kg/day, and 14.1 weeks for the lowest dose. Twelve weeks of prospective, open-label research with sixty-one patients suffering from severe psoriasis was used to analyze the results of such various regimens. Participants were allocated to one of two groups: a starting dose of 2.5 mg/kg/day with a progressive "step-up" approach or a starting dose of 5.0 mg/kg/day with a reduced "step-down" method. At 12 weeks, PASI 50 response rates were 72.7% for the step-up regimen and 85.7% for the step-down regimen, though the difference was not statistically significant.[18]

Similarly, in our study, the mean time to achieve a PASI 50 response in the cyclosporine group was 12 weeks, with 90% of patients reaching this milestone. In ESTEEM 1 (N = 844) and ESTEEM 2 (N = 413) trials, Participants were assigned in a 2:1 ratio to receive either apremilast 30 mg twice daily or a placebo over a 16-week period. At the end of week 16, a greater percentage of patients in the apremilast group reached a PASI-75 response compared to those in the placebo group. (ESTEEM 1: 33% vs. 5%; ESTEEM 2:29% vs. 6%).[19]

Among the 250 patients included in the LIBERATE trial, 84 were assigned to placebo, 83 received apremilast 30 mg twice daily and etanercept 50 mg QW was given in 83 patients. At week 16, PASI-75 achievement in the apremilast group was 39.8% while 48.2% patients in the etanercept group.[20] During the apremilast-extension phase (Weeks 16-104), 226 patients were divided into the placebo/apremilast (n = 73), apremilast/apremilast (n = 74) and etanercept/apremilast (n = 79) groups. At Week 104, 50.7%, 45.9% and 51.9% of these patients, respectively, maintained ≥75% reduction from baseline in PASI score.[21] In our study, 40% of patients in the apremilast group achieved a PASI 75 response at 16 weeks.

Gastrointestinal adverse effects were notably greater in the Apremilast group (33.3%) while cyclosporine group showed hyperglycemia, renal function test abnormalities and elevated blood pressure in 10% patients.

The PISCES study found 45% of participants stayed relapse-free for 4 months post-treatment discontinuation, while 31% remained relapse-free after 6 months. The average time to relapse was 109 days for individuals who stopped cyclosporine suddenly and 113 days for those who tapered off.[22] In our research, 86.7% of patients had not experienced a relapse 2 months after ceasing cyclosporine. The difference in relapse rates between the two groups was not statistically significant.

6. Limitations

The limitations of our study included a small sample size and a short follow-up period of only 8 weeks. Blinding was not possible for either the treating physician or the patients.

7. Conclusion

Both Cyclosporine and Apremilast significantly reduced PASI and BSA scores, with Cyclosporine showing a faster and slightly greater overall reduction. Recurrence rates were slightly higher in the Apremilast group, but not significant. From our study, we conclude that, Apremilast has similar efficacy, cheaper than cyclosporine, without much alteration in the laboratory values. However, apremilast was linked to significant gastrointestinal side effects. Thus, this study shows that Apremilast is a valuable addition to the treatment armamentarium of psoriasis and may even be a suitable first-line treatment, particularly for patients with contraindications to other traditional systemic therapies or for use in combination or rotational therapy.

8. Source of Funding

None.

9. Conflict of Interest

None.

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