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Comparison Of Efficacy, Safety And Compliance Of Topical Clobetasol Propionate With Topical Calcipotriol In Chronic Psoriasis – A Prospective Double-Blind Study

Dr. C. Keerthi[1], Dr Sowmya Alahari[2], Dr. Syed Khaleel Basha[3], Dr. Suresha Kr[4], Dr. Sharon Sonia.S[5]

[1]Assistant Professor, Department of Pharmacology, Viswa Bharathi Medical College & Hospital, Andhra Pradesh,518467.

[2]Associate Professor, Department of Pharmacology, Viswa Bharathi Medical College & Hospital, Andhra Pradesh,518467.

[3]Assistant Professor, Department of Pharmacology, Viswa Bharathi Medical College & Hospital, Andhra Pradesh,518467.

[4]Professor and Head of Department, Department of Pharmacology, Viswa Bharathi Medical College & Hospital, Andhra Pradesh,518467.

[5]Professor and Head of Department, Department of Pharmacology, Government Medical College, Ananthapuramu,515002.

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*Corresponding Author:

Dr. C. Keerthi
Assistant Professor, Department of Pharmacology, Viswa Bharathi Medical College & Hospital, Andhra Pradesh,518467.

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A B S T R A C T

Introduction- Psoriasis is a chronic, immune-mediated skin disorder characterized by epidermal hyperproliferation and dermal inflammation. Topical corticosteroids, particularly Clobetasol propionate, have long served as the cornerstone of first-line therapy, either as monotherapy or in combination. But prolonged use is associated with several adverse effects. Vitamin D_3 analogues such as Calcipotriol (Calcipotriene), Tacalcitol, Maxacalcitol, and Calcitriol have emerged as effective alternatives. Among these, Calcipotriol remains one of the most frequently prescribed topical agents for plaque psoriasis due to its efficacy and safety profile. **Aim -** To evaluate the efficacy and safety of topical Clobetasol propionate with topical Calcipotriol in the patients with chronic psoriasis. **Methods:** A prospective, randomized, double-blind clinical trial was conducted on 100 patients aged 18–60 years with chronic plaque psoriasis. Participants were randomized to receive either clobetasol propionate 0.05% cream (Group B) or calcipotriol 50 µg/g ointment (Group A) once daily for 12 weeks. Efficacy was assessed using Psoriasis Area and Severity Index (PASI) and Physician Global Assessment (PGA) scores at baseline and follow-ups. Safety and compliance were evaluated through adverse event monitoring and tube weight measurements. **Results:** Both groups showed significant improvement in PASI and PGA scores over 12 weeks. Group B (clobetasol) demonstrated a more rapid decline in scores during initial follow-ups, while final mean PGA and PASI scores were comparable between the two groups ($P > 0.05$). Adverse events were minimal, with higher local irritation in the calcipotriol group but no serious adverse effects in either group. Compliance was good in both arms. **Conclusion**: Clobetasol propionate and calcipotriol are both effective and well-tolerated in the treatment of chronic plaque psoriasis with no relapse or reoccurrence at the end of the study. Subjects have shown equal compliance to both the drugs. Topical Clobetasol propionate 0.05% is more cost-effective option than topical Calcipotriol 50µg.

Keywords: Psoriasis, Clobetasol propionate, Calcipotriol, Psoriasis Area and Severity Index (PASI), Physician Global Assessment (PGA), Topical therapy.

INTRODUCTION

Psoriasis is chronic skin disorder characterized by epidermal hyperproliferation and dermal inflammation[1]. Psoriasis may begin at any age, but it is uncommon under the age of 10 years. Both men and women are affected equally[2] .Chronic

plaque psoriasis (Psoriasis vulgaris) is the most prevalent form of psoriasis. Red, scaly, and symmetrically distributed plaques are the characteristics[2]

Psoriasis treatment includes topical drugs, clinical drug therapy, and phototherapy as well. The topical medications are emollients, dithranol, coal tar, calcipotriol, retinoids, and glucocorticoids. Systemic care involves immunosuppressants, such as methotrexate and cyclosporine, retinoids, such as acitretin and etretinate, and regulators of biological responses such as etanercept, efalizumab, adalimumab, infliximab and alefacept. Phototherapy involves skin UVB irradiation and PUVA therapy as well. Laser therapy has also recently been approved for treating located psoriasis plaques.

Topical corticosteroids were the cornerstone of first-line psoriasis therapy either alone or in combination with other agents. Clobetasol propionate 0.05% has antiproliferative, anti-inflammatory, immunosuppressive action by stimulation of phospholipase A2 inhibitory proteins, which will be used in the treatment of limited plaque psoriasis[3] .But after a long-term application, they may give rise to various side effects.

The various non-steroidal topical treatments available are: Dithranol, salicylic acid, coal tar, topical retinoids, vitamin D3 derivatives[4] .The vitaminD3 derivatives Calcipotriol (Calcipotriene), Maxacalcitol, Tacalcitol, and more recently Calcitriol are administered topically [5,6] .Topical formulations of Calcipotriol and other vitamin-D3 analogues are probably the most widely prescribed active topical therapy for plaque psoriasis.

There is a clinical need to compare these two topical agents in terms of **efficacy**, **safety**, and **patient compliance** to guide evidence-based therapy, especially in resource-limited or primary care settings. Furthermore, few studies with a **prospective double-blind design** have evaluated this comparison in the Indian population.

Thus, this study aims to generate robust clinical data to evaluate which agent offers a better risk-benefit profile, with the goal of improving therapeutic outcomes and guiding clinical decision-making in the management of chronic plaque psoriasis.

AIM

To evaluate the efficacy and safety of topical Clobetasol propionate with topical Calcipotriol in the patients with chronic psoriasis

OBJECTIVES

Primary Objective:

To compare the efficacy of topical Clobetasol propionate with topical Calcipotriol in the patients with chronic psoriasis.

Secondary Objective:

To assess safety and compliance of topical Clobetasol propionate with topical Calcipotriol in the patients with chronic psoriasis

METHODS AND MATERIALS

Study design: A Prospective Randomized Double Blind Clinical Trial

Duration of study: The study is conducted for a period of one year (2021 – 2022)

Source of data: Patients attending department of Dermatology OPD, Government General Hospital, Anantapur (Dt).

Sample size:

The sample size for the randomized controlled trial was calculated using the sample size calculator (ClinCalc.com). Taking efficacy of drug 1 as 50% and efficacy of drug 2 as 50%, incidence is decreased by 25%, an allowable type-1 error of 0.05, type-2 error of 0.2 and a power of 0.8, a sample size of 116 is obtained. It is rounded off to 100 subjects, with 50 subjects in each group (Group A & Group B).

Inclusion criteria:

1. Both male and female individuals between the ages of 18 and 60.
2. Subjects with chronic psoriasis.
3. Body surface area (BSA) involvement <35%

Exclusion criteria:

1. Patients with erythrodermic, orthopathic, guttate, pustular, or unstable psoriasis.

2. Patients with the history of medical conditions like renal dysfunction, calcium-based calculi, hypercalcemia, conditions requiring the systemic supplements of calcium or vitamin D.
3. BSA involving >35%.
4. Patients with other extensive skin diseases and those with severe systemic illness.
5. Pregnant and lactating women.

Methods of collecting data

A total of 100 patients were enrolled in this study after meeting the inclusion and exclusion criteria after getting approval from the Institutional Ethical Committee. Subjects were informed about the trial and side effects of both the drugs. Written consent was taken from the subjects. The subjects were randomly allocated to Group A and Group B, fifty in each group. It is randomly allocated for subjects in Group A to receive topical CALCIPOTRIOL ointment 50µg (CALISOR™) & Group B (n = 50) to receive topical CLOBETASOL PROPIONATE cream 0.05% (LAMOVATE™) in identical tubes. Subjects were asked to apply the drug once daily at bedtime and advised to come for follow up at 4th, 8th and 12th week. In each visit —— history of any new side effects, any new lesions, and patient compliance were noted by weighing the ointment tubes.

The baseline demographic profile like age and gender, as well as the clinical profile, such as redness, thickening, and scaling on a 0–4-point scale, were collected using an appropriate prevalidated data collecting form.

The efficacy of both treatment approaches was evaluated by comparing the mean Physician Global Assessment (PGA) score, the difference in mean PGA score at each follow-up visit, the mean Psoriasis Area Severity Index (PASI) score. Measurements of the 2 groups' other treatment outcomes, such as total clearance, responders, poor responders, worsening, and relapses, were noted.

PGA has scoring scale - 0 to 4; 0 = Clear (No psoriasis signs, but post inflammatory discoloration), 1 = Almost clear (minimal plaque elevation, scaling, and erythema will present), 2 = Mild (slight plaque elevation, scaling, erythema), 3 = Moderate (significant plaque elevation, scaling, and erythema), and 4 = Severe (very marked plaque elevation, scaling and erythema). Based on the patient's current symptoms, they were assigned a score. During their follow-up visit, the Mean PGA and Mean difference of the PGA score are compared.

The level of psoriasis severity is measured using the PASI index. It includes the area affected (<35%) and the degree of erythema (redness), induration (thickness), and desquamation (scaling) severity (scaling). The PASI calculator will utilize a severity scale 0 to 4, with 0 denoting absence, 1 denoting mild severity, 2 denoting moderate severity, 3 denoting severe severity, and 4 denoting very severe severity. During follow-up visit, the Mean PASI and Mean difference of the PASI are compared and calculated.

The other outcomes of treatment includes “PASI 50” a 50% decrease in PASI, a “PASI 75” a 75% decrease in PASI, “Complete clearance” achieving a score of PASI 0 during any point of time of the treatment period, “Responders” is achieving the score of PASI<50, at end of the therapy, “Poor responders” is achieving a score of PASI >50 at the end of therapy, “Deterioration” is raise in PASI score from baseline at any time during the 12 weeks of treatment, “Relapse” is recurrence of disease in the therapy phase after obtaining PASI score 0 and treatment cessation, and “Loss to follow-up” of any patient, who didn’t return for follow-up consultations after the treatment commencement are assessed in the two groups. The two drugs safety was monitored by recording the Adverse drug reactions (ADR) in the subjects during the period of study.

Ethical Issues:

1. Written informed consent was taken before including subjects in the study
2. The individual subject data was kept strictly confidential.
3. The study subjects were identified by study ID only
4. Approval by the Institutional Ethics Committee was taken before beginning the study.

STATISTICAL ANALYSIS

The data was entered in Microsoft Excel & analysed using SPSS trial version 23. Results were expressed as means and proportions. The difference between various groups and various visits was measured using appropriate statistical analysis. P value < 0.05 was considered significant.

RESULTS

TABLE 1 - number of subjects in the starting and completion of study.

	GROUP A	GROUP B
No. of subjects in the study	50	50
No. of subjects completed the study	47	46

In table 1, out of 100 subjects **93 subjects completed** the study in both the groups.

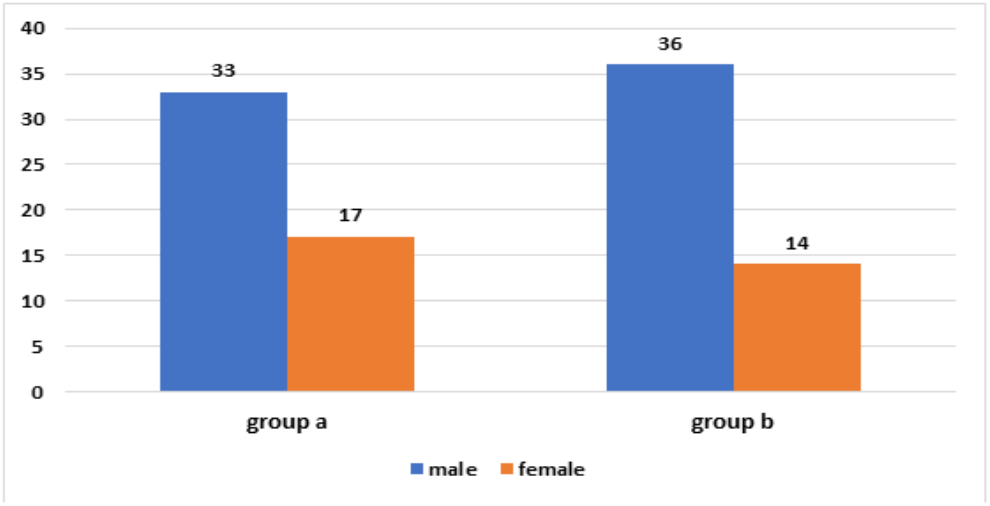

Figure 1 – Gender distribution in both the groups

Figure 1- there were **33 males and 17 females** in group A and **36 males and 14 females** in group B

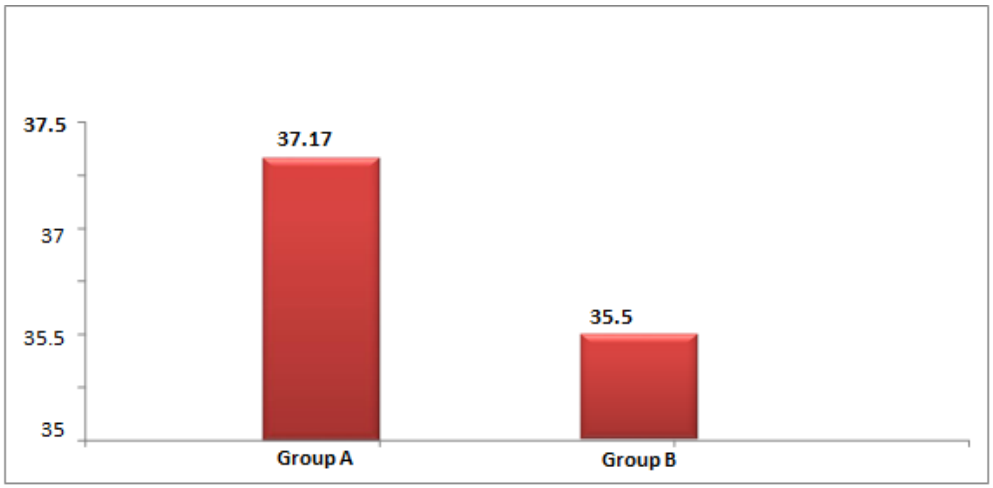

Figure 2 - Age distribution in the study subjects

Figure 2 – mean age in group **A was 37.17** and in group **B was 35**

Table 2: Clinical parameters of the subjects

CLINICAL PARAMETERS (MEAN + SD)	GROUP A	GROUP B
Redness	2.52 ± 0.89	1.69 ± 0.79
Thickening	2.44 ± 1.02	1.92 ± 0.92
Itching	3.47 ± 0.67	3.38 ± 0.72

In **table 2** clinical parameters taken were redness, thickness, itching which was 2.52 ± 0.89, 2.44 ± 1.02, 3.47 ± 0.67 in group A and 1.69 ± 0.79, 1.92 ± 0.92, 3.38 ± 0.72 in group B respectively.

Table 3: Distribution of Physician Global Assessment scores in the 2 groups during each follow-up

Physician Global Assessment scores during each visit				
	Week 0	**Week 4**	**Week 8**	**Week 12**
Group A	3.5 ± 1.7	2.3 ± 0.7	2.0 ± 1.2	1.5 ± 0.46
Group B	3.76 ± 0.89	2.12 ± 0.3	1.74 ± 0.5	1.43 ± 0.3

In **table 3**, On week 0 (Baseline), the mean PGA score of Group A (3.5) is almost equal to Group B (3.76). PGA score in Group B (2.12, 1.74) is decreased when compared to that of Group A (2.3, 2.) on week 4 and week 8 follow-up visits. On **week 12**, final follow-up, **group A & group B** attained almost an equal mean **PGA score of 1.5 & 1.43** respectively.

Table 4: Distribution of PASI in Group A & Group B

PASI during the visits				
	Week 0	**Week 4**	**Week 8**	**Week 12**
GROUP A	4.68 ± 2.7	3.44 ± 1.7	3.0 ± 1.24	1.85 ±0.46
GROUP B	4.87 ± 2.19	2.90 ± 0.23	2.24 ± 0.53	2.13 ± 0.4

On week 0, mean PASI score of Group A (4.68) is almost equal to that of Group B (4.87), it was declined almost equally in Group B (2.90, 2.24) when compared to that of mean PASI score of Group A (3.44, 3.0) on week 4 & week 8 follow-ups. On week 12 (final follow-up) group A and group B attained similar mean PASI score of 1.85 and 2.13 respectively.

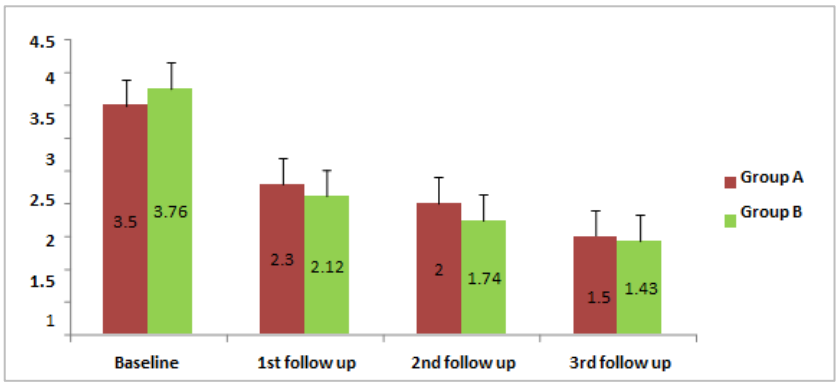

Figure 3: Distribution of Physician Global Assessment scores in the 2 groups during each follow-up

On week 0 (Baseline), the mean PGA score of Group A (3.5) is almost equal to Group B (3.76). PGA score in Group B (2.12, 1.74) is decreased when compared to that of Group A (2.3, 2.) on week 4 and week 8 follow-up visits. On week 12, final follow-up, group A & group B attained almost an equal mean PGA score of 1.5 & 1.43 respectively.

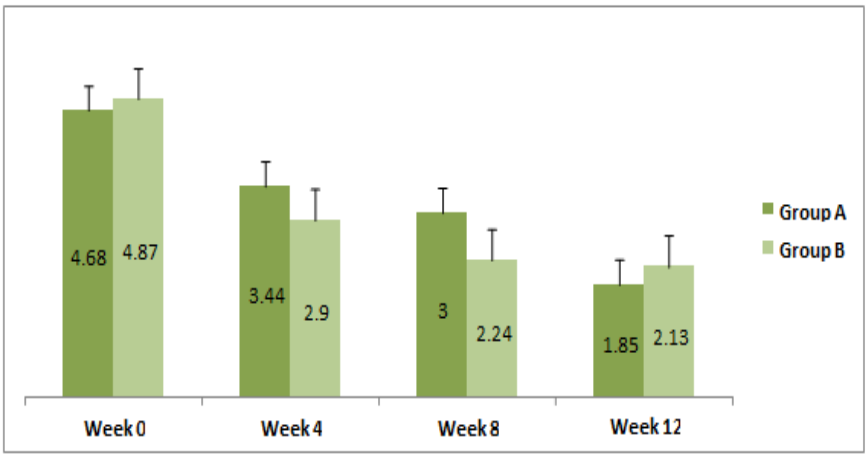

Figure 4 -Distribution of PASI scores in 2 groups during each follow-up

The difference in the mean PGA score is slightly higher in group B (0.51 ± 0.44, 1.35 ± 0.78, and 1.215 ± 0.64) during week 0 (baseline) visit to week 4 visit, from week 0 visit to week 8 visit, and from week 0 visit to week 12 (final follow-up) visit when compared to Group A (0.45 ± 0.38, 1.24 ± 0.5, and 1.05 ± 0.51) and P = 0.36, 0.51, and 0.62 .

Table 5: Comparison of difference in Psoriasis Area Severity Index and Physician Global Assessment scores in 2 groups during each follow-up

	GROUP A	GROUP B	P	Z
COMPARISION OF DIFFERENCE IN PGA SCORES BETWEEN TWO GROUPS				
Week 0 (Baseline) to week 4	0.45 ± 0.38	0.51 ± 0.44	< 0.36	0.88
week 0 to week 8	1.24 ± 0.5	1.35 ± 0.78	< 0.51	1.92
week 0 to week 12	1.05 ± 0.51	1.215 ± 0.64	< 0.62	1.22
COMPARISION OF DIFFERENCE IN PASI SCORES BETWEEN TWO GROUPS				
Week 0 (Baseline) to week 4	1.47 ± 0.16	1.72 ± 0.84	<0.00001	6.7
week 0 to week 8	2.1 ± 0.61	2.39 ± 1.379	<0.00001	4.43
	2.54 ± 1.3	2.86 ± 1.24	< 0.22	1.25

Table 5 - The difference in the mean PASI score is slightly higher in Group B (1.72 ± 0.84, 2.39 ± 1.379), during week 0 (baseline) visit to week 4 visit (1st follow up) and from week 0 (baseline) visit to week 8 (2nd follow up) visit when compared to the Group A (1.47 ± 0.16, 2.1 ± 0.61) and P < 0.00001. During the final follow up, there was no significant change in the difference in mean PASI scores of both the groups, Group A (2.54 ± 1.3) and Group B (2.79 ± 1.24) with a P = 0.22.

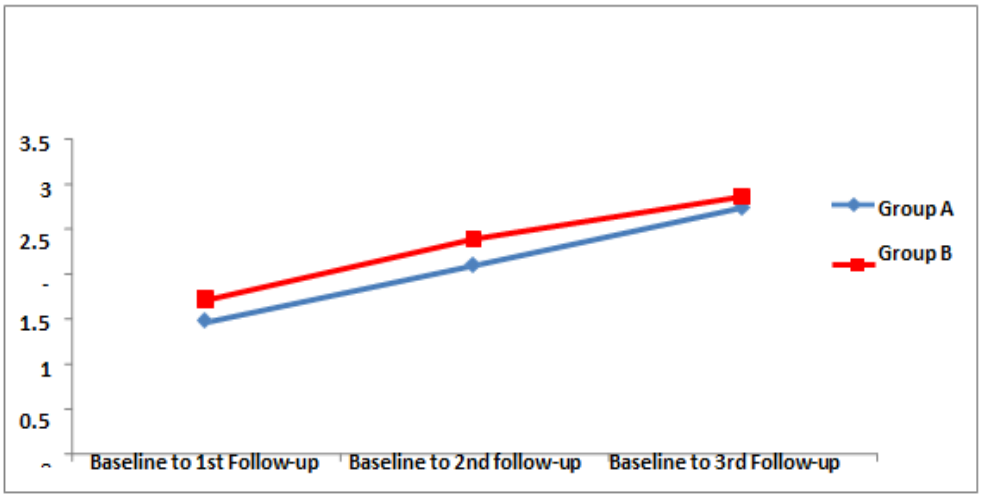

Figure 5: Trend of PGA score in the study subjects

The other outcomes of treatment included a slightly higher percentage of clearance in Group B (4%) when compared to Group A (3%) and nearly equal proportions of responders & poor responders in Groups A (21; 62.8%, 23; 57.5%) and B (23; 57.5%, 9; 22.5%), but neither group experienced a higher rate of worsening or recurrence.

Table 6: shows other treatment outcomes in the study subjects

Treatment outcome	Group A Frequency (%)	Group B Frequency (%)
Complete clearance (100%)	3%	4%
Responding (complete clearance cases + cases achieving 50<PASI<100)	21 (61)	24 (57.1)
Poor responders (PASI <50)	7 (22.1)	8 (22)

Deterioration	0	0
Relapse	0	0
Loss to follow up	3 (8.3)	4 (10.1)

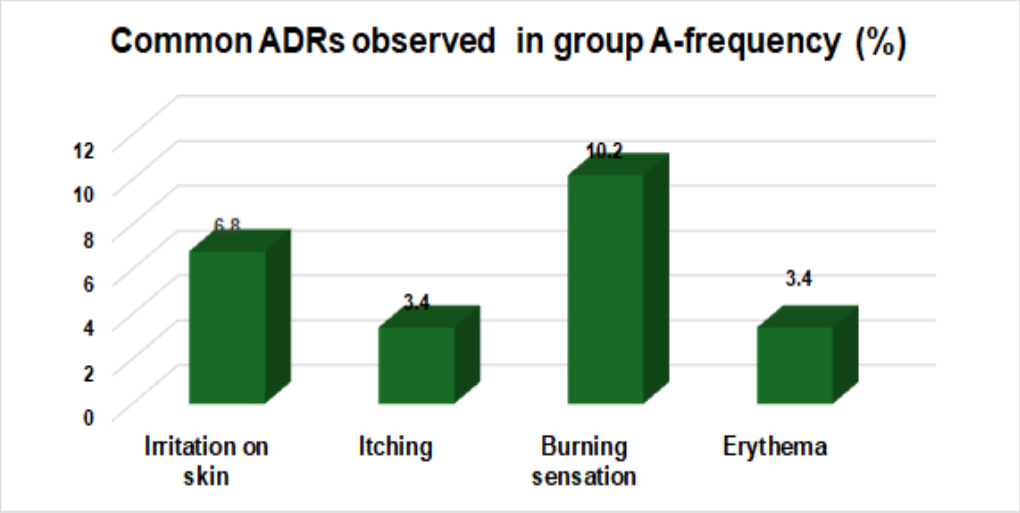

Figure 6 - Common ADRs observed in group A-frequency (%)

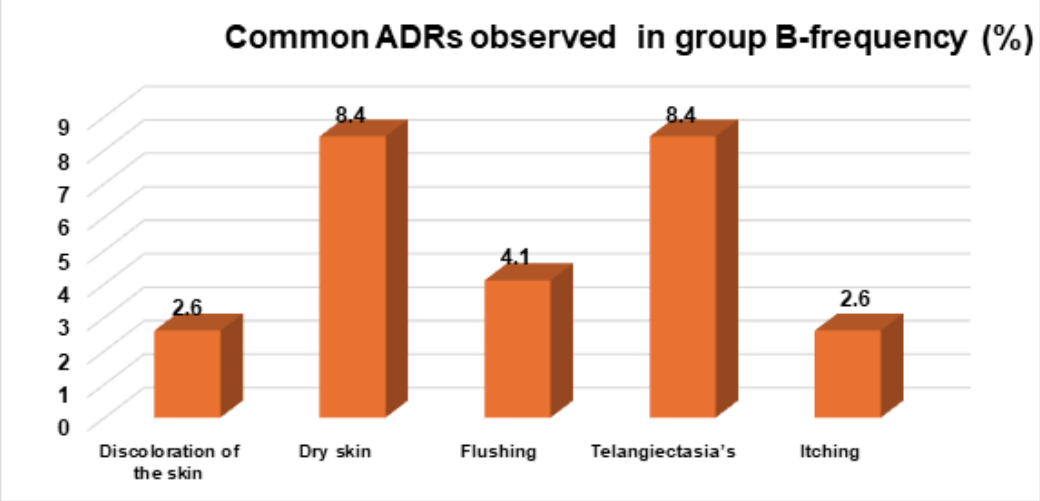

Figure 7- Common ADRs observed in group B-frequency (%)

Adverse effects: The most frequent side effects following the topical application of topical calcipotriol 50 µg were Irritation of skin, burning sensation, itching, and erythema. The most common side effects with application of topical Clobetasol propionate 0.05% were skin irritation and discoloration, flushing, itching, dry skin, and telangiectasias.

DISCUSSION

The anti-psoriatic effects of Clobetasol propionate 0.05% and topical Calcipotriol 50 µg have been individually established in various studies. However, direct comparative studies between the two are lacking. Some trials using combination regimens of corticosteroids and vitamin D analogues have shown similar improvements. Efficacy is typically assessed by percentage reduction in PASI, with PASI 50 and PASI 75 indicating clinically meaningful responses[7,8].

In present study majority of the subjects belonged to the age group 30 to 40 years. Almost 26.6% of patients belonged to this group, and the mean age of the subjects in Group A & Group B is 37.17 years and 35.5 years respectively. The Male to female ratio is 2:1 in both groups. 32% of patients had psoriasis family history. In the Noor SM et al study,[9] the patients age enrolled in the study ranged from 18-70years. The enrolled patients mean age is 40.99±14.99 yrs.89 In the current study most of the participants are men with 66% and 72% in Group A & Group B respectively. And women compromised of 34% in Group A & 28% in Group B.

According to the results of the current study, at the first and second follow-up visits, Group B's mean PASI score and the difference in mean PASI score were significantly lower than those of Group A (P 0.01), whereas at the final follow-up, there was no significant difference in mean PASI score between the two groups (P = 0.22).

Although both clobetasol propionate and calcipotriol led to similar clinical cure rates at 12 weeks, clobetasol showed more rapid symptom relief in the initial weeks. By the end of therapy, PGA and PASI reductions were comparable. However, our study noted early improvement with clobetasol, unlike previous studies which found no significant difference during early follow-ups.

In the study by Thakur A et al., both excimer laser and calcipotriol-clobetasol combination significantly reduced mean mPPPASI scores by weeks 12 and 20, with no statistically significant difference between them. At 12 weeks, 8 patients in each group achieved mPPPASI 75. Improvement levels across groups were comparable, though hyperpigmentation was more frequent with excimer therapy. Both treatments were effective and well tolerated in palmoplantar psoriasis[10]. By the end of the 12th week, both treatment groups showed many complete clearers and responders, but some patients remained poor responders, with PASI improvement below 50%. These findings align with those of Guenther et al.,[11] who reported similar variability in response while evaluating calcipotriol-betamethasone versus calcipotriol alone in psoriasis vulgaris.

By the end of the 12th week, both treatment groups showed many complete clearers and responders, but some patients remained poor responders, with PASI improvement below 50%. These findings align with those of Guenther et al., [11]who reported similar variability in response while evaluating calcipotriol-betamethasone versus calcipotriol alone in psoriasis vulgaris.

In the present study, most subjects in both groups showed complete clearance or were responders (PASI >50%), with few poor responders (PASI <50%). These findings align with Guenther et al.'s study. Both drugs were well tolerated with minimal side effects, similar to the Thailand study by Thawornchaisit and Harncharoen[12].

In the research article by Rudnicka L et al., [13] treatment with foam formulation is related with fewer medical appointments than treatment with an ointment, as well as a decreased likelihood of acquiring indications for systemic treatment. The safety profiles of foams, ointments, and gels are comparable, with itching at the site of application, being the most prevalent side event (in 5.8% of patients). Long-term proactive maintenance therapy significantly lowers the incidence of relapses and bridges the gap between topical & systemic psoriasis treatment.

Another study by Rosso JQ et al.,[14] reviews and discusses the literature on various aspects of clobetasol propionate for the management of plaque psoriasis, including patient product selection tendencies, conventional use and formulations of CP 0.05%, and utilization of special additives (e.g., penetration enhancers) to increase CP potency. The author discusses results from recent experiments that tested a novel CP cream formulation that has half the concentration of standard CP (0.025%) without losing super-potency (Class I) classification or using traditional potency augmentation with propylene glycol.

Topical Clobetasol propionate 0.05% may cause local adverse effects like skin discoloration, dryness, itching, and telangiectasia. Rare systemic effects include HPA axis suppression, growth retardation in children, and ocular complications such as raised intraocular pressure and cataracts. These risks increase with prolonged use, large area application, or occlusion. Caution is advised, especially for facial and periorbital use and in pediatric patients.

In a study by Ashcroft DM et al.[15] documented Calcipotriol irritated the skin substantially more than powerful topical corticosteroids (need to treat damage for irritation 10, 95% confidence interval 6 to 34). Calcipotriol alone produced higher irritation than calcipotriol coupled with a powerful topical corticosteroid. The number needed to treat dithranol to cause lesional or perilesional irritation, on the other hand, was 4.

In the present study, both clobetasol propionate and topical calcipotriol were well tolerated locally, with mild to moderate adverse reactions observed in 20% of patients in Group A and 15% in Group B (P > 0.05). These reactions resolved within 2–3 days without additional treatment and did not require discontinuation. In terms of cost-effectiveness, clobetasol propionate (Rs. 89 per tube) was more economical than calcipotriol (Rs. 359 per tube), making it a more viable option for long-term management of psoriasis.

Longer-term comparative studies of calcipotriol vs dithranol and topical corticosteroids are required to determine if the short-term advantages are reflected by long-term outcomes such as length of remission and improvement in quality of life[15].

CONCLUSION

Psoriasis is a common chronic inflammatory autoimmune skin disease. There is no definitive cure for psoriasis. The currently available treatment decreases disease activity & symptoms. Clobetasol propionate and Calcipotriol belong to classical topical treatment. From the result of the present study, it is concluded that both topical Clobetasol propionate 0.05% and topical Calcipotriol 50µg has shown similar effectiveness in chronic psoriasis. Subjects have shown equal compliance to both the drugs. Topical Clobetasol propionate 0.05% is more cost-effective option than topical Calcipotriol 50µg. Both the drugs were found to be equally safe and effective with no relapse or reoccurrence at the end of the study.

Limitations –

1. The study was limited by a small sample size and single-center design, necessitating larger multicentric trials for generalizability.
2. Calcipotriol's higher cost (Rs.461 vs. Rs.95 for Clobetasol) may impose financial burden due to the chronic nature of psoriasis treatment.

Conflicts of Interest - none declared

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Authors' contributions: All the authors equally contributed to the work.

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