*Research Article*

# A comparative study on efficacy of treatment regimens with Calcipotriol/ Betamethasone Dipropionate Vs Calcipotriol ointments in Plaque type Psoriasis patients at Tertiary Care Hospital, Telangana

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**Abstract**

**Objective:** This study was aimed to compare clinical efficacy and safety in two groups of plaque psoriasis patients at baseline and after 12 weeks of treatment using two drug combination of topical calcipotriol/betamethasone with topical calcipotriol. **Methods:** A prospective, comparative study was conducted at Department of Dermatology, OGH on patients (n=70) diagnosed with plaque type psoriasis. Patients were randomised in two groups, Group A receiving combination of calcipotriol and betamethasone ointment while group B receiving single drug calcipotriol, daily once application for 12 weeks. The efficacy of two groups was evaluated using PASI (psoriasis area and severity scale) at baseline and end of 12 weeks. **Results**: At the end of the study we observed intra group data comparison showed PASI score decreased significantly ($p < 0.001$) at 15th, 30th, 45th, 60th, 75th and 90th day of treatment in comparison with baseline in both groups Inter group comparison shows PASI score decreased more in Group A than Group B and the difference became strongly significant at 30th day of treatment (12.36±2.91 vs. 10.49±2.89; $p=0.009$). The difference between the two groups increased further at 45th, 60th, 75th and 90th day of treatment with $p<0.001$ for all visits. **Conclusion:** The study emphasised that using a combination of Vitamin D3 analogue with topical steroid combination provided better efficacy, quick response in alleviating the symptoms, patient compliance and safety as opposed to monotherapy.

***Keywords:*** Calcipotriol, betamethasone, ointment, psoriasis, plaque

## Introduction

Psoriasis is a chronic, hyperproliferative autoimmune cutaneous disease typified by atypical patches on the skin, nails, and joints (Kragballe et al., 2004). Psoriasis is common disease with the prevalence ranging from 2-3% affecting approximately 120 to 180 million people worldwide according to the International Federation of Psoriasis Associations. Plaque or discoid type psoriasis is the most common disease variant seen to be affecting approximately 90% of all psoriasis cases. It commonly manifests as erythematous plaques with thick scale on the extensor surfaces, trunk, and scalp (Lebwohl et al., 2021). These skin patches might be red, itchy, scaly, or dry, and the severity of the condition can range from small isolated areas to the entire body (Lebwohl et al., 2021). Approximately 48% of people said that psoriasis affected their daily lives. Prevalence of plaque type psoriasis is 0.44-2.8 percent in India, it is frequently misunderstood as a communicable disease, and those infected are ostracised by the society. Psoriasis is reported in about 1.5 million new cases every year. Psoriasis is a non-contagious skin condition that affects both men and women equally and has no age preference (Velasco et al., 2014; Gerdes et al., 2020). The skin is infiltrated with immunologically active cells, and dilatation of the dermal blood vessels (Bos, 1988), exact etiology is yet unknown, although it comprises a complex interplay of hereditary and environmental variables. Recent research suggests that diverse components of the innate and acquired immune systems (T cells, dendritic cells, and inflammatory cytokines) are crucial in developing and perpetuating the immune response (Tagami and Alba, 1997; Jullien, 2006). Psoriasis could be caused by genetically determined factors, environmental factors, recurrent or chronic bacterial and viral infections, immunological factors, stress, seasonal

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weather changes, and certain types of drugs like non-steroidal anti-inflammatory drugs (NSAIDs), beta blockers, calcium channel blockers, and among others (Veverka et al., 2020). Patients suffering with psoriasis report higher rates of many comorbidities, like that of cardiovascular disease, heart attack (Gerdes et al., 2017), stroke (Khandpur and Sahni, 2014), metabolic syndrome (Kuehl and Shear, 2018) and depression (Rogalski, 2015) etc.

It has been a chronic ailment with eruptions and remissions which can be erratic. The severity of psoriasis is usually graded from mild to severe using indices such as Psoriasis Area Severity Index (PASI), Physician's Global Assessment of Disease Severity (PGA), and Dermatology Life Quality Index (DLQI), while the extent of disease is commonly measured by the percentage of body surface area (BSA) affected.

Psoriasis treatment aims to alleviate the symptoms of skin manifestations and symptoms. Topical vitamin D analogues and corticosteroids may be recommended as first-line therapy for patients with plaque psoriasis (Velasco et al., 2014). Many existing topical medications, on other hand, have inadequate adherence due to limited efficacy, possible complications, undesirable cosmetic attributes, and the inconvenient licencing of multiple medications for lesions on different skin area on different parts of body. Poor adherence translates to treatment failure, which results in a cycle where the patient pursues systemic, biologic, or phototherapies, which are accompanied with higher healthcare expenditures and potentially more substantial adverse effects.

The objective of this study is to evaluate clinical efficacy and the safety of two different treatment regimens involving the two compound combination product i.e. Calcipotriol 50microgm/gm and betamethasone dipropionate 0.5mg/gm in comparisons with calcipotriol 50 microgm/gm monotherapy for 12 weeks on patients diagnosed with plaque type psoriasis at Department of Dermatology ,Osmania General Hospital, Hyderabad, Telangana.

**Materials and methods**

This is a prospective, comparative study which was conducted at Department of Dermatology at Osmania General Hospital, Hyderabad.70 patients who were diagnosed with plaque type psoriasis clinically by dermatologists and their diagnosis confirmed by skin biopsy were the study subjects. We used PASI score at baseline and after completion of study (12 weeks) as the study tool.

**Inclusion and exclusion criteria**

***Inclusion criteria***

Age group: 18 TO 65 years of either gender

Patients diagnosed to have plaque psoriasis affecting at least 10% of body surface area.

Patients who could understand and able to adhere to dosing and follow up visits schedule.

Subjects willing to give informed content for the study.

***Exclusion criteria***

- Patients with unstable form of psoriasis in the area intended to be treated.
- Patients having more than 30% of body surface area affected by psoriasis.
- Patients with psoriatic arthritis or erythroderma.
- Patients having other inflammatory skin diseases which will confound with the findings (atopic dermatitis, contact dermatitis, tinea)
- Patients on treatment with systemic anti psoriatic treatment within 4-8weeks,psoralen+ UVA within 4 weeks or UVB within 2 weeks or any corticosteroids within 4 weeks.
- Concomitant medication that may affect psoriasis, such as beta-blockers, antimalarial drugs, lithium and angiotensin-converting enzyme (ACE) inhibitors, within 2 weeks.
- Patients having other systemic diseases (liver and renal failure etc)
- Patients with known history of allergy to study medications and severely immunocompromised
- Pregnant women, Lactating mothers
- Children below 18years and Adults above 65years.
- Females in reproductive age group were advised to use an alternative method of contraception apart from OCPs.

**Duration of study**- 12 weeks for each group and was carried on during October 2021 to February 2022.

**Ethical approval** – Approval was taken from Institutional Ethical Committee at Osmania Medical College to conduct the study

Ethical Approval Number- IEC/OMC/2021/M.No (13) Acad-141

**Methodology**

A detailed history including present, past, family and diet, drug history was taken and a thorough general physical examination and systemic examination done. Informed consent was obtained from all the 70 participants.

PASI scoring and investigations done at baseline (at start of study)

All the participants were than randomised by simple randomisation in 1:1 ratio in two groups of 35 each:

**Group A**: Calcipotriol 50 m g /g plus betamethasone dipropionate 0.5 mg/g (Daivobet ointment- Win – Medicare pvt limited) FIXED DOSE COMBINATION ONCE DAILY

**Group B**: Calcipotriol ointment 50 microg/ g (Calpsor ointment- Biocon) ONCE DAILY.

The same dosage of drugs was to be maintained throughout the study, and the patients were advised to apply the drugs at the same time everyday preferably at the night time as a thin layer over the lesions.

Follow Up- It was done at end of 2 weeks, 4 weeks, 8 weeks and 12 weeks.

**Evaluations**

Severity and extent of psoriasis were evaluated at pre-treatment baseline (day 0) and then at follow ups for 12 weeks (days 14, 28, 56 and 74) by means of the Psoriasis Area and Severity Index(PASI). Severity of erythema (E), scaling (S), and induration (I) was recorded on a 5-point scale (0 to4) and area of involvement (A) on a 7-point scale (0 to 6) for upper limbs (U), trunk (T), and lower limbs (L) separately, as previously described ( Koo et al., 2019). Severity and extent of psoriasis on head region were not evaluated. PASI was calculated as 0.2(EU + SU + IU) AU +0.3(ET + ST + IT) AT + 0.4(EL + SL + IL) AL and ranged from 0 to 64.8.

At each follow up visit, both an investigator (S. S.) and the patient separately made assessment of overall response to treatment compared with baseline condition on a 6-point scale (–1 = worse, 0 = no change, 1 = slight improvement, 2 = moderate improvement, 3 = marked improvement, 4 =almost or completely cleared). This assessment took into account both the extent and severity of psoriasis. At each visit, the patients were first asked a nonleading question about adverse events and then specifically about itching or burning sensation in lesional or perilesional skin. Patients were also examined for perilesional erythema.

**Outcome measures**

Primary efficacy criterion was the proportion of patients who had at least a 90% reduction in baseline PASI score at the end of 12 weeks of treatment. To further characterize the treatment response, the following secondary efficacy criteria were also compared between the two groups: PASI scores on each visit assessments, percentage reduction in PASI scores after 2 and 4 weeks of treatment, and the proportion of patients who had marked improvement or were almost or completely cleared at the end of treatment.

**Statistical analysis**

The data entry was done in MS Excel 2019. DATA analysis was by SPSS Version 23 and Epi info 7.2.0 Microsoft word and Excel was used to generate figures, tables etc.

Descriptive and inferential statistical analysis was carried out in the present study. Results on continuous measurements were presented on Mean +- SD (Min-Max) and results on categorical measurements were presented in Number (%). Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Significance was assessed at a 5% level of significance.

**Results and Discussion**

In this prospective, open labelled, comparative study which was undertaken at Dermatology department at Osmania General Hospital we tried to evaluate the efficacy and safety of treatment regimens with calcipotriol/betamethasone dipropionate ointment vs calcipotriol ointment in patients with plaque type psoriasis. In this present study the mean age of the subjects was 41.38±11.41 years and maximum number of patients were found in 31-40 years of age group (Table 1 and Figure 1), which resembles the findings and

**Table 1. Distribution of patients according to Age (n=70)**

| Age | No. of Patients | | Total No. of patients |
|---|---|---|---|
| | Group A | Group B | |
| 20-30 | 9(25.7%) | 6(17.1%) | 15(21.4%) |
| 31-40 | 11(31.4%) | 10(28.6%) | 21(30%) |
| 41-50 | 9(25.7%) | 9(25.7%) | 18(25.7%) |
| 51-60 | 4(11.4%) | 8(22.9%) | 12(17.1%) |
| >60 | 2(5.7%) | 2(5.7%) | 4(5.7%) |
| Total | 35(100%) | 35(100%) | 70(100%) |
| Mean ± SD | 38.77±11.54 | 44.00±10.99 | 41.38±11.41 |

p= 0.0564, Insignificant, Student t test

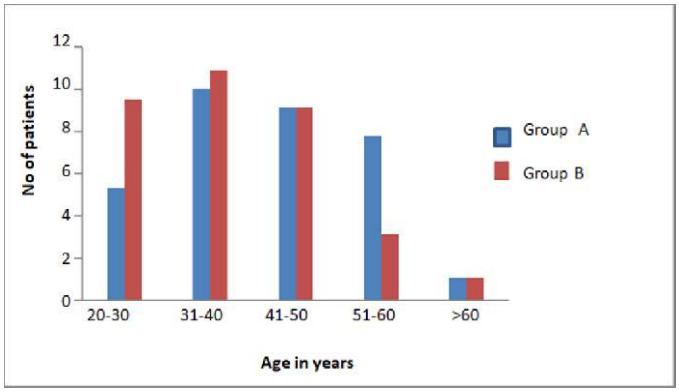



**Figure 1. Distribution of patients according to Age (n=70)**

**Table 2. Distribution of patients according to Gender (n=70)**

| Gender | Group A | Group B | Total |
|---|---|---|---|
| **Female** | 16(45.7%) | 8(22.9%) | 24(34.3%) |
| **Male** | 19(54.3%) | 27(77.1%) | 46(65.7%) |
| **Total** | 35(100%) | 35(100%) | 70(100%) |

**p=0.8079, Insignificant, Chi-Square test**

observations made by (Ogra et al., 2010) who reported that the most of the patients were in their third or fourth decade of life at the time of presentation. (Kumar et al., 2014) shows highest prevalence was noted in the age group of 21-30 and 41-50 years. It was observed that males 46 (65.7%) outnumbered the females 24 (34.3%) (Table 2 and Figure 2). The data correlates with (Dogra et al., 2016) and (Nevitt et al., 1996) that psoriasis occurs mostly in males as compared to females (Lebwohl et al., 2021).

Table 1 & Figure 1 shows that out of 70 patients, 15 (21.4%) patients were in the age group of 20-30 years, followed by 21 (30%) between age 31-40 years, 18 (25.7%) were between 41-50 years, 12 (17.1%) were between 51-60 years and 4 (5.7%) patients were above 60 years. In this study the mean age of subject was 41.38 ± 11.41.

Table 2 & Figure 2 shows out of 70 subjects taken for clinical trial, males 46 (65.7%) outnumbered females 24(34.3%).

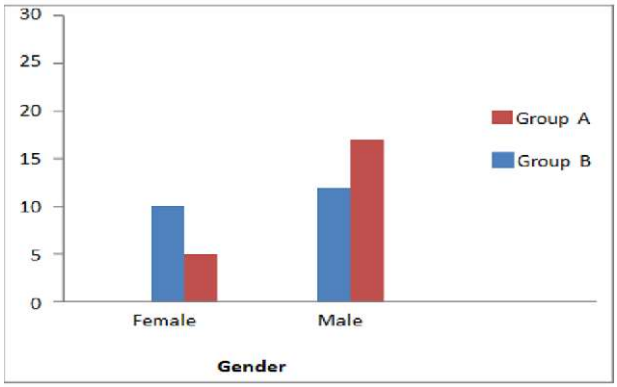



**Figure 2.** Distribution of patients according to Gender (n=70)

**Effect of intervention on Psoriasis Area and Severity Index score (PASI)**

Clinical data on the extent of the disease was obtained by using the Psoriasis Area and Severity Index (PASI). Intra group data comparison showed PASI score decreased significantly ($p < 0.001$) at 15th, 30th, 45th, 60th, 75th and 90th day of treatment in comparison with baseline in both groups with difference of 1.514, 3.040, 4.689, 5.94, 7.574 and 8.546 in Group A and 0.446, 1.034, 1.697, 2.66,3.063 and 3.560 in Group B respectively. Inter group comparison shows PASI score decreased more in Group A than Group B and the difference became strongly significant at 30th day of treatment (12.36±2.91 vs. 10.49±2.89; p=0.009). The difference between the two groups increased further at 45th, 60th, 75th and 90th day of treatment with $p<0.001$ for all visits (Table 3 and Figure 3).

Table 3 & Figure 3 shows mean duration of disease was 5.35±5.21. Out of 70 patients 47 (67.1%) patients had psoriasis from <6 years, 16 (22.9%) patients had psoriasis from 6-12years, 4 (5.7%) patients had psoriasis from 12-18 years and 3 (4.3%) patients had psoriasis from above 18yrs.

**Effect of intervention on Physician's Global Assessment (PGA)**

Clinical data on the extent of the disease were obtained by

**Table 3. Distribution of patients according to Duration of Illness (in years)**

| Duration of Illness (yrs) | Group A | Group B | Total |
|---|---|---|---|
| **<6** | 23 (65.7%) | 24 (68.6%) | 47 (67.1%) |
| **6-12** | 9 (25.7%) | 7 (20%) | 16 (22.9%) |
| **12-18** | 2 (5.7%) | 2 (5.7%) | 4 (5.7%) |
| **>18** | 1 (2.9%) | 2 (5.7%) | 3 (4.3%) |
| **Total** | 35(100%) | 35(100%) | 70(100%) |
| **Mean ± SD** | 4.75±4.67 | 5.96±5.71 | 5.35±5.21 |

**p=0.3347, Insignificant, Student t test**

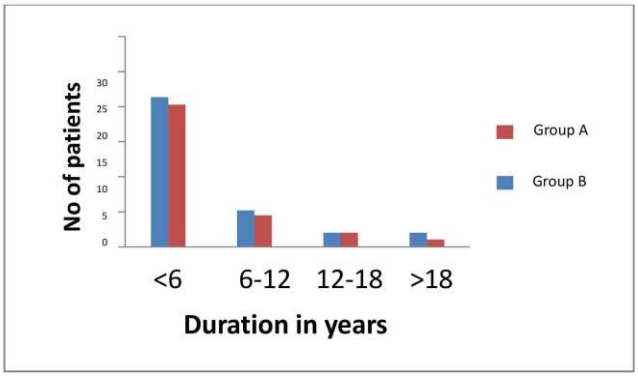



**Figure 3.** Distribution of patients according to Duration of Illness

Physician's Global Assessment (PGA) with great reliability. Intra group data comparison showed PGA score decreased significantly (p <0.001) at 15th, 30th, 45th, 60th, 75th and 90th day of treatment in comparison with baseline in both groups with difference of 0.200, 0.514, 1.000, 1.257, 1.829, 2.029 in Group A and 0.086,0.143,0.314, 0.629, 0.686, 0.743 in Group B respectively. Inter group data comparison showed PGA score decreased more in Group A than Group B and the difference became strongly significant at 45th day of treatment (3.51±0.56 vs. 2.97±0.66 with p<0.001). The difference between the two groups increased further at 60th, 75th and 90th day of treatment with p= 0.005 at 60th day and p<0.001 for last two visits (Table 4,5 & Figure 4,5).

**Table 4. Distribution of patients according to Family history (n=70)**

| Family History | Group A | Group B | Total |
|---|---|---|---|
| **NO** | 32(91.4%) | 35(100%) | 67(95.7%) |
| **YES** | 3(8.6%) | 0(0%) | 3(4.2%) |
| **Total** | 35(100%) | 35(100%) | 70(100%) |

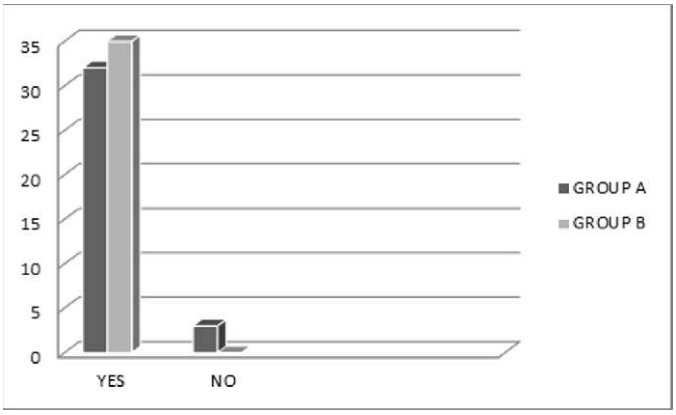


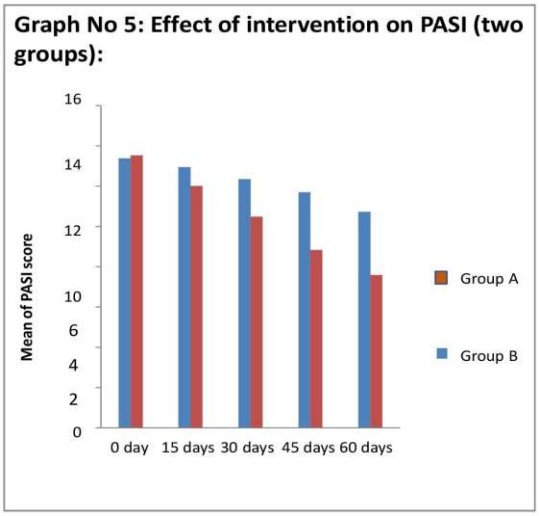

**Figure 4.** Distribution of patients according to Family history (n=70)

**Table 5. Effect of intervention on PASI (two groups)**

| PASI Results | Group A | Group B | p value |
|---|---|---|---|
| $0^{th}$ day | 13.53±2.71 | 13.39±3.12 | 0.851 |
| $15^{th}$ days | 12.01±2.71 | 12.95±2.97 | 0.173 |
| $30^{th}$ days | 10.49±2.89 | 12.36±2.91 | 0.009** |
| $45^{th}$ days | 8.84±2.71 | 11.70±2.85 | <0.001** |
| $60^{th}$ days | 7.59±2.86 | 10.73±3.33 | <0.001** |
| $75^{th}$ days | 5.95±2.75 | 10.33±2.81 | <0.001** |
| $90^{th}$ days | 4.98±2.74 | 9.83±2.85 | <0.001** |
| difference from $0^{th}$ day | | | |
| $15^{th}$ days | 1.514 | 0.446 | - |
| $30^{th}$ days | 3.040 | 1.034 | - |
| $45^{th}$ days | 4.689 | 1.697 | - |
| $60^{th}$ days | 5.940 | 2.660 | - |
| $75^{th}$ days | 7.574 | 3.063 | - |
| $90^{th}$ days | 8.546 | 3.560 | - |
| p value from $0^{th}$ day | | | |
| $15^{th}$ days | <0.001** | <0.001** | - |
| $30^{th}$ days | <0.001** | <0.001** | - |
| $45^{th}$ days | <0.001** | <0.001** | - |
| $60^{th}$ days | <0.001** | <0.001** | - |
| $75^{th}$ days | <0.001** | <0.001** | - |
| $90^{th}$ days | <0.001** | <0.001** | - |

Table 4 & Figure 4 shows out of 70 patients only 3(4.2%) patients had positive family history of psoriasis

Table 5 & Figure 5 showing Intra group data comparison shows PASI score decreased significantly (p= <0.001) at $15^{th}$,$30^{th}$,$45^{th}$,$60^{th}$,$75^{th}$ and $90^{th}$ day of treatment in comparison with baseline in both groups with difference of 0.446, 1.034, 1.697, 2.66, 3.063 and 3.560 in group B and with difference



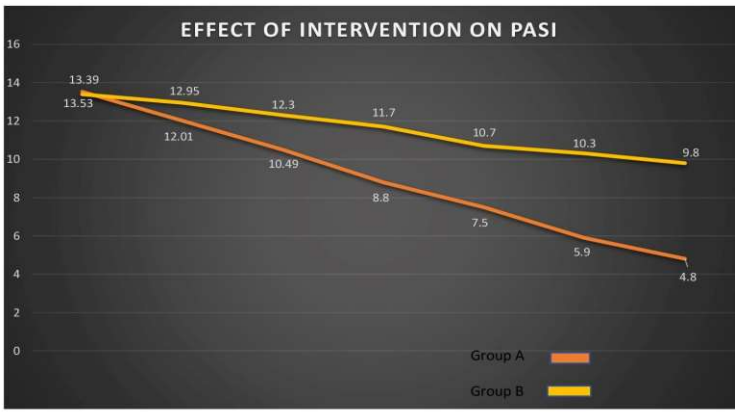




**Figure 5.** Effect of intervention on PASI (two groups):

Table 6. Distribution of patients according to PGA grades

| PGA grades | No of Patients | | | |
|---|---|---|---|---|
| | Group A | | Group B | |
| | 0th day | 90th day | 0th day | 90th day |
| Moderate | 34 | 0 | 29 | 10 |
| Mild- Moderate | 1 | 8 | 6 | 17 |
| Mild | 0 | 18 | 0 | 7 |
| Almost clear | 0 | 8 | 0 | 1 |
| Clear | 0 | 1 | 0 | 0 |
| Total | 35 | 35 | 35 | 35 |

of 1.514, 3.040, 4.689, 5.94, 7.574 and 8.546 in group A respectively. Inter group comparison shows PASI score decreased more in Group A than Group B and the difference became strongly significant at 30th day of treatment (12.36±2.91 vs 10.49±2.89; p=0.009). The difference between the two groups increased further at 45th, 60th, 75th and 90th day of treatment with p<0.001 for all visits. Table 6 shows at base line out of 70 subjects 63 (29 in Group B and 34 in control group) were in moderate grade and 7 (6 in test and 1 in control group) were in mild - moderate grade of PGA scale of psoriasis. At 90th day distribution of patients shows out of 70 subjects 10 (all from test group) were in moderate grade, 25 (18 in test and 7 in control group) in mild- moderate grade and 26 (7 in test and 19 in control group) in mild grade and 9 (all from control group) in almost clear grade of PGA scale of psoriasis.

Table 7. Effect of intervention on PGA (two groups)

| PGA Results | Group A | Group B | p value |
|---|---|---|---|
| • 0th day | 3.97±0.17 | 3.83±0.38 | 0.047 |
| • 15th days | 3.77±0.43 | 3.74±0.44 | 0.784 |
| • 30th days | 3.46±0.56 | 3.69±0.53 | 0.084+ |
| • 45th days | 2.97±0.66 | 3.51±0.56 | <0.001** |
| • 60 days | 2.71±0.75 | 3.20±0.63 | 0.005** |
| • 75th days | 2.14±0.85 | 3.14±0.65 | <0.001** |
| • 90th days | 1.94±0.68 | 3.09±0.70 | <0.001** |
| **Difference from 0th day** | | | |
| • 15th days | 0.200 | 0.086 | - |
| • 30th days | 0.514 | 0.143 | - |
| • 45th days | 1.000 | 0.314 | - |
| • 60th days | 1.257 | 0.629 | - |
| • 75th days | 1.829 | 0.686 | - |
| • 90th days | 2.029 | 0.743 | - |
| **p value from 0th day** | | | |
| • 15th days | 0.006 | 0.083 | - |
| • 30th days | <0.001** | 0.023 | - |
| • 45th days | <0.001** | <0.001** | - |
| • 60th days | <0.001** | <0.001** | - |
| • 75th days | <0.001** | <0.001** | - |
| • 90th days | <0.001** | <0.001** | - |

Table 7 shows Intra group data comparison shows PGA score (p<0.001) decreased significantly at 15th, 30th, 45th, 60th, 75th and 90th day of treatment in comparison with baseline in both groups with difference of 0.086, 0.143, 0.314, 0.629, 0.686, 0.743 in Group B and with difference of 0.200, 0.514, 1.000, 1.257, 1.829, 2.029 in groupA respectively. Inter group data comparison shows PGA score decreased more in group A than group B and the difference became strongly significant at 45th day of treatment (3.51±0.56 vs. 2.97±0.66) with p=0.0010. The difference between the two groups increased further at 60th, 75th and 90th day of treatment with p=0.005 at 60th day and p<0.001 for last two visits.

This study has shown that the use of topical betamethasone dipropionate 0.05% cream and calcipotriol 0.005% ointment daily is superior to calcipotriol ointment alone for the treatment of plaque psoriasis over a period of 12 weeks. The study had a power of 95.7% with respect to the primary efficacy variable. In the present study, once-daily dosing frequency was chosen for augmented betamethasone cream because several studies (Rogalski, 2015) have shown it to be effective. A calcipotriol and betamethasone dipropionate combination ointment (Dovobet , Daivobet, LEO pharma A/S Ballup, Denmark) in strength of Calcipotriol 50 microgm/gm and betamethasone dipropionate 0.5mg/gm

was developed with careful selection of vehicular components to decrease their incompatibility. This has lead achieve optimal delivery of both drugs at the affected site without interference of absorption from either compounds with other.

Three major clinical studies have shown that once- or twice-daily usage of the two-compound solution for up to four weeks has greater efficacy and better tolerability than once- or twice-daily application of its separate active components in the treatment of plaque type psoriasis (Menter et al., 2009; Menter et al., 2008; Chandrasekar and Sivagami, 2016). Also one more study have shown that once daily application of the combination ointment is equally efficacious and safe than twice daily use.

Superior efficacy of the treatment regimen of corticosteroid and calcipotriol may be attributable to prevention or minimization of tachyphylaxis to the corticosteroid and the use of a potent ant psoriatic agent (calcipotriol). Cutaneous atrophy, the most common local adverse effect of topical corticosteroids, occurred less severely in this a regimen.

An additional interesting finding of the present study was absence of lesional or perilesional irritation in the corticosteroid-calcipotriol group which is the most common adverse event associated with regular calcipotriol use.

With combining different drugs with different mode of action and safety profiles efficacy is seen to be better and improve the outcome.

This study has shown that the use of topical betamethasone dipropionate 0.05% cream and calcipotriol 0.005% ointment daily is superior to calcipotriol ointment alone for the treatment of plaque psoriasis over a period of 12 weeks.

The former regimen was significantly more effective than the latter from the proportion of patients who had at least a 90% reduction in baseline PASI scores at the end of treatment (primary efficacy variable) and percentage reduction in PASI scores after 2 and 4 weeks.

The study had a power of 93.7% with respect to the primary efficacy variable. In the present study, once-daily dosing frequency was chosen for augmented betamethasone cream because several studies (10) have shown it to be very effective.

Calcipotriol ointment was applied once daily, which is its conventional dosing frequency.

Superior efficacy of the treatment regimen of corticosteroid and calcipotriol may be attributable to prevention or minimization of tachyphylaxis to the corticosteroid and the use of a potent antipsoriatic agent.

Cutaneous atrophy, the most common local adverse effect of topical corticosteroids, will occur less severely in such a regimen compared with regular use.

An additional interesting finding of the present study was absence of lesional or perilesional irritation in the corticosteroid-calcipotriol group. This is the most common adverse event associated with regular calcipotriol use. With combining different drugs with different mode of action and safety profiles efficacy is seen.

**Conclusion**

Psoriasis is a lifelong, troublesome disease having a complex and substantial impact on physical, psychological, social and economic domains of patients.

Topical corticosteroids which have been mainstay of treatment for mild to moderate plaque type psoriasis from several years though very effective have shown to be associated with several local and systemic adverse effects as seen with previous studies (Kragballe et al., 2004; Lebwohl et al., 2021), complain of loss of efficacy of the medication on prolong use (Velasco et al., 2019) (phenomenon of tachyphylaxis).

The last decade having seen the emergence of Vitamin D3 analogue calcipotriol as a very effective agent for treatment of plaque type psoriasis. Calcipotriol and topical corticosteroid combination therapy have shown promising results as compared against monotherapy .The different mechanisms of action and safety profiles of these two compounds have shown enhanced efficacy, quick response in patients and better compliance.

Hence from this study we can conclude that usage of two drug therapy with Calcipotriol and Betamethasone combination has better advantages clinically, with regard to compliance, adverse effects and therefore be considered as first line therapy in mild to moderate plaque type psoriasis.

**Limitations of the study**

It is an open labelled, prospective study hence results cannot be generalised. Also randomised control trial with larger sample size and time period will provide better outcome and prove the efficacy of one drug over other.

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