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Original Research Article

Efficacy of Calcipotriol and Betamethasone Combination with Betamethasone Alone in Plaque Psoriasis: A Comparative Study

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Conflict of interest: Nil

Abstract:

Background: The primary line of treatment for mild to moderate psoriasis is topical therapy. According to a literature search, there aren't many studies comparing the effectiveness of topical calcipotriol and betamethasone dipropionate in combination with betamethasone dipropionate alone for treating plaque psoriasis. In this study, the combination of betamethasone and calcipotriol for plaque psoriasis was assessed for safety and efficacy.

Methods: The study was conducted over the duration of a year, from January 2023 to December 2023, among inpatients and outpatients who presented to the dermatology department of the Jawaharlal Nehru Medical College and Hospital in Bhagalpur, Bihar. 66 individuals having a clinical diagnosis of plaque psoriasis were enlisted. A combination of topical calcipotriol 0.005% and betamethasone dipropionate 0.05% was administered once daily to 32 patients, while betamethasone dipropionate 0.05% was applied twice daily to 34 patients. Psoriasis area and severity index (PASI) was used for clinical follow-up of patients at baseline, week 2, 4, 6, 8, 10, and 12. Patients underwent clinical examinations at each follow-up visit, and the associated PASI values were recorded. They were evaluated for any negative effects as well.

Results: Thirty patients in each group completed the study by the conclusion of the twelve-week period. The PASI scores considerably dropped from the baseline in both groups. When compared to betamethasone dipropionate 0.05% monotherapy, the combination of calcipotriol 0.005% with betamethasone dipropionate 0.05% resulted in a statistically significant improvement in both clinical response and PASI score reduction.

Conclusion: In patients with mild to moderate plaque psoriasis, the combination of calcitriol and betamethasone proved to be more effective and well-tolerated than betamethasone dipropionate monotherapy.

Keywords: Psoriasis; Calcipotriol; Betamethasone.

Introduction

Psoriasis is a long-term autoimmune skin condition marked by inflammation, vascular abnormalities, inadequate epidermal differentiation, and excessive epidermal proliferation. The most prevalent kind of psoriasis is called vulgaris, and it is identified by well-defined red, raised, scaly plaques. Typically, lesions appear symmetrically on the scalp, buttocks, knees, elbows, and traumatized areas.[1] Psychological problems, such as high anxiety and depression levels, can arise in psoriasis patients.[2,3] Psoriasis is typically diagnosed clinically and is categorized as mild (affecting less than 3% of the body), moderate (3–10%), or severe (affecting more than 10%). The most commonly used measuring instrument is the Psoriasis Area and Severity Index, or PASI.[4,5] The cornerstone of care for mild to moderate psoriasis is topical therapy. When applied topically, calcipotriol—a synthetic version of 1,25-dihydroxy vitamin D3—acts via the vitamin D receptors on lymphocytes and keratinocytes, reducing angiogenesis, aberrant keratinization, and epidermal proliferation.[5] Psoriasin and koebnerisin's Th17-induced proinflammatory activities are inhibited by vitamin D analogs, which disrupts the inflammatory feedback loop in psoriatic skin.[6] Synthetic fluorinated topical steroid betamethasone reduces many inflammatory indicators in psoriasis without changing terminal differentiation. Moreover, it suppresses the synthesis of cytokines (interleukin-1 [IL-1], IL-2, IL-8, tumor necrosis factor-α, and interferon-γ), lowers inflammatory mediators (prostaglandins, leukotri-

enes, and nitric oxide), and reduces aberrant CD4:CD8 ratios as well as Langerhans cell counts and activity.[7,8] The aim of the current study was to compare the effectiveness of betamethasone monotherapy and the combination of calcipotriol and betamethasone.

Material and Methods

From January to December 2023, the Jawaharlal Nehru Medical College and Hospital in Bhagalpur, Bihar, collaborated with the Department of Dermatology to undertake this study. The patients gave their written informed consent, and the procedure was approved by the institutional ethics committee. The study was open-label. Two groups of sixty-six patients with a clinical diagnosis of plaque psoriasis were randomly assigned. Patients with mild to severe plaque psoriasis (less than 10% body involvement) of any gender between the ages of 18 and 70 were included.

Patients with pustular, scalp, or severe psoriasis as well as those on antipsoriatic medications (vitamin D3 analogs, corticosteroids, coal tar, anthralin, photochemotherapy, and immunosuppressants) were excluded. Patients having a history of allergy to calcium and vitamin D analogs, as well as those who had taken calcium/vitamin D3 analogs during the two months prior to trial enrollment. Ladies who are nursing or pregnant.

The initial visit included the recording of demographic information. Two groups of sixty-six patients with a clinical diagnosis of plaque psoriasis were randomly assigned. As topical therapy, 32 patients were assigned to Group A, which received calcipotriol (0.005%) and betamethasone ointment (0.05%) together once daily, and 34 patients were assigned to Group B, which received betamethasone ointment (0.05%) alone twice daily. For a period of 12 weeks, assessments were conducted at baseline and every two weeks. Patients' clinical responses were checked, their PASI score was recorded, and any negative reactions were evaluated during each visit.

The inability to provide an objective way to assess the severity of the disease affects the evaluation of new psoriasis treatments. The gold standard for determining the severity of psoriasis persists to be PASI, notwithstanding its shortcoming as a totally objective technique of assessment.

A sample size of 32 patients per group was recruited after accounting for a drop rate of 10%, a power of 85%, and an α error of 5% to detect a difference of 0.5 in the PASI score. The mean ± standard deviation is used to express data. After the distribution was found to be normal by applying the Kolmogorov-Smirnov test for normality, the PASI was examined both within and between groups using the paired and unpaired t-tests, respectively. For PASI, Mann-Whitney and Wilcoxon signed-rank tests were also utilized. The Chi-square test was used to assess categorical data. It was deemed statistically significant when $P < 0.05$.

Results

Sixty-six patients meeting the inclusion criteria were enrolled and randomly assigned to one of two groups: Group A (n = 32) received betamethasone ointment (0.05%) plus calcipotriol (0.005%) applied topically once daily, whereas Group B (n = 34) received betamethasone ointment (0.05%) applied topically twice daily.

There were more male patients overall. Among them, 30.3% of patients belonged to the 31–40-year age range, comprising 34.4% of Group A and 26.5% of Group B. In both groups, the majority of cases of psoriasis had duration of more than two years, with onset ages ranging from 30 to 50. According to Table 1, the most prevalent presenting complaints were itchy, scaly lesions, with plaques being the most common presentation. The extremities were covered in a variety of lesions. 53.3% of patients in Group B compared to 33.3% in Group A had lesions in either the upper or lower limb alone. Lesions were seen in various locations, such as the trunk, lower limb, and upper limb, in the remaining patients.

Table 1: Demographic and disease parameters in Group A and Group B

Variable	Group A(n=32)(%)	Group B(n=34)(%)
Female	9 (28.1)	11(32.4)
Male	23 (71.9)	23 (67.6)
Age years ± SD		
Males	39.7±13.0	40.0±10.0
Females	39.3±3.0	35.1±8.6
Duration of psoriasis		
<6 months	4 (12.5)	2 (5.9)
6 months-1 year	2 (6.2)	4(11.8)
1-2 years	7 (21.9)	6 (17.6)
>2 years	19 (59.4)	22 (64.7)
Educational status		
Nil	50	41.2

<10th	26.7	20.6
12th	6.7	17.6
Degree	16.7	20.6
History of smoking	9 (28.1)	13 (38.2)
History of alcohol	2 (6.2)	6 (17.6)
Presenting symptom		
Itchy scaly	28 (87.5)	31 (91.2)
Scaly	4 (12.5)	3 (8.8)
Type of lesion		
Macule+plaque	3 (9.4)	2 (5.9)
Plaque	29 (90.6)	32 (94.1)

The mean PASI score at baseline was similar for the two groups, as Table 2 illustrates. Mean PASI scores in Group A were significantly (P = 0.001) lower than baseline at various follow-up visits, and by week eight, the score was zero.

The mean PASI scores in Group B similarly showed a significant (P = 0.001) decline from the baseline; however, the score remained non-zero at the 12-week follow-up. From the baseline to each follow-up visit in both groups, PASI was also examined using the Wilcoxon signed-rank test, and the P value was statistically significant (P = 0.001). At 4, 6, 8, 10, and 12 weeks of follow-up, there was a significant (P = 0.0001) difference in PASI across the groups. The P value for the between-group comparison using the Mann-Whitney test was 0.0001 starting in week 4.

When the negative effects of the treatments were compared, they were found to be statistically insignificant.

Table 2: PASI score comparison within and between treatment group

Weeks	Mean±SD		P-value
	Group A	**Group B**	
Baseline (0)	4.63±1.75	3.85±1.62	0.079
2	2.46±1.20*	3.08±1.28@	0.064
4	0.95±0.61*	2.24±1.04@	0.0001
6	0.12±0.20*	1.37±0.75@	0.0001
8	0*	0.70±0.46@	0.0001
10	0*	0.24±0.24@	0.0001
12	0*	0.08±0.12@	0.0001

*@P=0.001 compared with baseline. SD: Standard deviation, PASI: psoriasis area and severity index

Discussion

The current study included more men than women. The male to female ratio, 2.3:1, is in line with findings from another study.[9] The patients ranged in age from 18 to 60, although the fourth decade of life was when psoriasis was most common.[10] Most of our patients had had psoriasis for longer than two years in both groups, but the length of the illness had no bearing on how well either group responded to treatment. Nine patients showed seasonal variation; six had a history of exacerbation of psoriatic lesions in the winter and three in the summer.

None of the patients enrolled had a family history of psoriasis. These results were consistent with a study that found that psoriasis was more common in colder climates than in warmer ones.[11] Itchy, scaly lesions were the most prevalent presenting complaint in both groups of individuals. Merely 10.6% of patients had a history of scaly lesions. Most of them (92.4%) had a clinical presentation resembling a plaque, which was consistent with what Naldi and Gambini found.[12] Elbows and knees are among the extremities that psoriasis primarily affects. The lumbosacral and intergluteal regions are the other, less frequent locations. 43.3% of patients in our study had extremity lesions, which was comparable to the previous study.[12] Every patient in our study was younger than 60 years old. The combination of calcipotriol (0.005%) and betamethasone ointment (0.05%) applied topically once daily, as well as betamethasone ointment (0.05%) applied topically twice daily, demonstrated improvement in clinical response based on PASI from week two itself, as Table 2 demonstrates a significant reduction in PASI score in both treatments compared to baseline. Table 2 presents a comparison of the various therapies; the combination of betamethasone and calcipotriol showed a considerable reduction by week 4, and by week 8, the PASI score was zero, indicating complete recovery. Individuals on betamethasone by itself began to show improvement, but full recovery was not seen until week 12. Therefore, it has been demonstrated that combination therapy results in both a full recovery and an improved clinical response. Since psoriasis is a

chronic condition that necessitates long-term care, tolerability and safety are crucial considerations in the therapy process. None of the patients receiving betamethasone and calcipotriol combination showed any side effects in this 12-week follow-up research; however, after two weeks of therapy, two patients receiving betamethasone monotherapy experienced minor itching around the lesions.

Conclusion

The PASI score significantly decreased in patients undergoing topical therapy with calcipotriol 0.005% and betamethasone dipropionate 0.05% combination once daily and betamethasone dipropionate 0.05% twice daily from baseline to subsequent follow-up. On the other hand, improvement was noticeable by week four and full recovery was observed by week eight in patients giving combination therapy. It was found that combination therapy was a successful and well-tolerated treatment for plaque psoriasis.

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