

# EFFICACY OF BETAMETHASONE DIPROPIONATE VERSUS CALCIPOTRIOL IN TREATMENT OF MILD TO MODERATE CHRONIC PLAQUE PSORIASIS

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## ABSTRACT

**Objectives of study:** To compare the efficacy of betamethasone dipropionate with calcipotriol in treatment of mild to moderate chronic plaque psoriasis.

**Methodology:** A total of 112 patients were enrolled in our study. These patients were randomly allocated into two groups A and B by lottery method. Betamethasone dipropionate was given to group A, while Calcipotriol was given to group B. Response to treatment was assessed on the basis of 50percent reduction in PASI score after 4 weeks of topical treatment.

**Results:** In group A the Betamethasone was efficient in 44 patients (78.57%), while it was not efficient in 12 patients (21.43%). In group B the Calcipotriol was efficient in 41 patients (73.21%). while it was not efficient in 15(26.79%). The P value was 0.659 ( $P > 0.05$ ) which is statistically not significant.

**Conclusion:** Both betamethasone dipropionate and calcipotriol are effective in mild to moderate chronic plaque Psoriasis.

**Key Words:** Efficacy, Betamethasone dipropionate, calcipotriol, chronic plaque psoriasis.

## INTRODUCTION

Psoriasis is a common chronic, disfiguring, inflammatory and proliferative condition of the skin, in which both genetic and environmental influences have a critical role. The most characteristic lesions consist of red, scaly, sharply demarcated, indurated plaques, present particularly over extensor surfaces and scalp<sup>1</sup>. It has several types like chronic plaque psoriasis (comprises almost 90% of psoriasis patient) Guttate psoriasis, Pustular psoriasis and Erythrodermic psoriasis<sup>2</sup>.

Psoriasis is a common disease affecting, approximately 125 million people worldwide. The prevalence of psoriasis in different populations vary between 0 and 12%, with estimates as high as 2.8% in western populations<sup>3</sup>. Topical therapies remain the mainstay of treatment for mild psoriasis<sup>4</sup>. The main groups of topical therapies for psoriasis are emollients, calcipotriol<sup>5</sup>, topical corticosteroids (including combination preparations), coal tar preparations<sup>6</sup>, dithranol<sup>7</sup>. Potent corticosteroids and calcipotriol are most common topical treatment used for Psoriasis.

Corticosteroids are the cornerstone of Psoriasis treatment because they exert anti-inflammatory, vaso-

constrictive, immunosuppressive and anti-proliferative effects. Calcipotriol can be used as monotherapy or as steroid sparing adjunctive therapy in patient with Psoriasis<sup>8</sup>. It is used in combination with steroids. As topical potent corticosteroids are widely used for treatment of mild to moderate chronic plaque psoriasis in our part of world. But the problem with topical potent steroids are that, they cause skin atrophy, telengectasias, localized skin infections and sometime suppression of hypothalamic-pituitary – adrenal axis. That's why they can't be used for prolong time. So another topical drug which should be comparable in efficacy to topical steroids, but having no such type of adverse effects, is desired by dermatologists.

## METHODOLOGY

This randomized controlled trial was conducted in the department of Dermatology, Lady Reading Hospital Peshawar from 1st April, 2013 to 30th September, 2013. Sample size was 56 in each group, using 36.8% PASI reduction in calcipotriol group and 64% PASI reduction in betamethasone dipropionate, at 95% confidence level and 90% power of test, with the help of WHO software for sample size determination. Patients suffering from mild to moderate of either gender and age greater than 18 years were included in the study. Patients suffering from other forms of psoriasis, with severe disease and those taking Vitamin D and Calcium supplements were excluded from the study. The participants included in the study were randomized into two groups A and B by lottery method. Group A patients were given Topical steroids whereas patients in Group B received Topical steroids plus calcipotriol. Response to treatment was considered excellent on the basis of reduction of greater than 50 percent PASI score from baseline after

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four weeks of application of medication in each group, whereas response was judged as poor if the reduction in PASI was less than 50 percent from the baseline.

## RESULTS

A total of 112 patients were enrolled for the study after fulfilling the inclusion/exclusion criteria to compare the efficacy of betamethasone dipropionate versus calcipotriol in treatment of mild to moderate chronic plaque Psoriasis. All these patients were divided into two groups A and B, by lottery method. Betamethasone dipropionate was given to group A, while Calcipotriol was given to group B.

In group A, who received betamethasone dipropionate, 56 patients were included. In these 29(56.86%) were Males and 27(43.14%) were females. In Group A, Baseline PASI was  $12.70 \pm 2.97$ , and follow up PASI was  $5.32 \pm 2.4$ . In group A, efficacy was achieved in 44 patients (78.57%). The mean age of group A patients was  $37.77 \pm 13.9$  years. Similarly in group B, who received Calcipotriol, 56 patients were included. In these 33(58.92%) were Males and 23(41.08%) were females. In Group B, Baseline PASI was  $12.45 \pm 2.73$ , and follow up PASI was  $5.32 \pm 2.22$ . In group B the treatment was efficient in 41 patients (73.21%). The mean age of group B patients was  $39.88 \pm 14.34$  years. (Table 1)

In group A the drugs were efficient in 44 patients (78.57%), while it was not efficient in 12 patients (21.43%). And in group B the drugs were efficient in 41 patients (73.21%) while it were not efficient in 15(26.79%). The P value was .659 (two sided) ( $P > 0.05$ ) which is statistically not significant (Table 2). Out of total 112 patients 62 were male and 50 were female. In group A 56 patients were enrolled, out of which 29(51.78%) were male and 27(48.22%) were female. In group B, also, 56 patients were included, out of which 33 patients

**Table 1: Characteristics of Group A and Group B**

Characteristics	Group A	Group B
Mean age	$37.77 \pm 13.9$	$39.88 \pm 14.34$
Males	29(51.78%)	33(58.92%)
Females	27(48.22%)	23(41.08%)
Baseline PASI	$12.70 \pm 2.97$	$12.45 \pm 2.22$
Follow Up PASI	$5.32 \pm 2.4$	$5.32 \pm 2.31$

**Table 2: Efficacy of Drugs Groups**

Efficiency	Group A	Group B	Total
Efficient (percentage)	44 (78.57%)	41 (73.21%)	85 (75.89%)
Not efficient (percentage)	12 (21.43%)	15 (26.79%)	27 (24.11%)
Total count (percentage)	56 (50%)	56 (50%)	112 (100%)

(58.92%) were male and 23 patients (41.08%) were females.

## DISCUSSION

Psoriasis has always posed a therapeutic challenge and various modalities have proved beneficial in this regard. Topical corticosteroids and Vitamin D analogues are usually recommended for mild to moderate Chronic Plaque Psoriasis. In our study both groups were well-matched in terms of pretreatment characteristics. The mean age in our study was  $37.77 \pm 13.9$  years and  $39.88 \pm 14.34$  years in group A and group B, respectively. There were 29(51.78%) males in group A and 33 (58.92%) in group B. Similarly baseline PASI on start of treatment was not statistically significant between two groups. Two groups were equally matched approximately in age, sex, race and there were no confounding variables found between these two groups. It was consistent with study done by Ahmad et al<sup>9</sup> in which mean age  $34.7 \pm 12$  years of Group A ie Calcipotriol group and  $34.5 \pm 15.8$  years in Group B ie topical Betamethasone dipropionate group and 7 patients (46.7%) were males in Group A while 8 patients (53.3%) were males in Group B.

In our study efficacy in Group A was 78.57(44), while it was 73.12(41) in Group B, with p value of 0.659 which shows no statistical significance in efficacy between two groups. Mean PASI at baseline and after 4 weeks of treatment between two groups was also not significant ( $p > 0.05$ ), showing that both drugs were equally efficacious. These findings were consistent with study carried out by Ahmad et al<sup>9</sup>. They found that mean percentage of PASI reduction after 4th week of treatment was 39.4 and 35.4 in group A and group B ( $p > 0.05$ ) respectively. After 8th week of therapy the mean percentage of PASI reduction was respectively 59.6 in group A and 60.7 in group B. This study showed statistically significant reduction in PASI score from baseline after 8 weeks of treatment in both treatment groups ( $p < 0.001$ ). This is in accord with our results which may be due to the people in Dhaka Bangladesh share the demographic features with our part of world. However they selected patient on the basis of PASI score (ie those psoriasis patients whose PASI are  $< 7$ ), while we selected patients on the basis of involved body area (measuring body surface area by rule of 9) by the disease i.e. mild to moderate types.

The study conducted by Dahri et al<sup>10</sup> spanned over a period of three months (90 days). 30 patients, designated as group A, were treated with calcipotriol ointment and in the group B, calcipotriol plus betamethasone combined therapy was used. In group A the mean PASI at the start of treatment was  $14.08 \pm 0.03$ , while it was  $4.52 \pm 0.81$  at the end of 90 days ie 67.89% decrease in PASI, on other hand in Group B PASI at the start of treatment was  $12.81 \pm 0.35$  and  $2.27 \pm 0.25$  at the end of 90 days with 81.49% reduction in PASI score. The results were almost in match with our study, with little bit greater decrease in Group B was seem to because of two compound formulation. Among the patients in

group A, five patients reported itching and 3 of them discontinued the treatment. While in the group B, no patient complained about the itching. They concluded that betamethasone plus calcipotriol therapy is safer as it produces less adverse effects than calcipotriol alone. In our study we did not look for adverse effect of drugs but measured only the efficacy of drugs. Moreover we compared both the drugs alone not in combination.

Tahir Kamal et al<sup>11</sup> showed the mean PASI reduction in Calcipotriol group was from 6.33 at week 0 to 1.9 at week 6 ie 69.6%, where Betamethasone Valerate ointment group showed a decrease in mean PASI from 6.22 at week 0 to 2.26 ie 63.8% at the end of treatment. My study result are in matching with above mentioned study. The one thing which is in contrast with my study is the slight great decrease in Calcipotriol then Betamethasone group, this may be because of Betamethasone valerate used in Tahir Kamal study is less potent then betamethasone dipropionate used in our study. Moreover there were slight rapid response in betamethasone group in their study, but I did not follow the patients in between the study.

Molin et al<sup>12</sup> showed that Calcipotriol in a cream formulation was effective, safe and well tolerated and equal in effect to betamethasone valerate cream. Patients with stable mild-to-moderate chronic disease were randomized to treatment with either calcipotriol, 50 micrograms/g, in a cream formulation (210 patients) or betamethasone 17-valerate cream, 1 mg/g (211 patients). After a wash-out period of 2 weeks, the treatment was applied twice daily, without occlusion, for 8 weeks or to complete clearing. The severity of psoriasis was assessed using the PASI at baseline and after 4 and 8 weeks treatment. The mean percentage reduction of PASI from baseline to end of treatment was 47.8% in the calcipotriol group and 45.4% in the betamethasone group. The reduction from baseline was highly significant in both groups, but the difference between the groups was not significant. There was a difference in the reduction in thickness of the lesions in favour of calcipotriol. The investigator's as well as the patient's overall assessment of treatment response at end of treatment showed no difference between the two treatment groups. Treatment-related adverse events were more frequent with calcipotriol than betamethasone. Lesional/perilesional irritation was reported in 16% and 9% ( $P = 0.03$ ), and facial irritation in 10% and 0.5% ( $P < 0.001$ ), respectively. The difference from our study would be because, their study was on different population, their study population number was more than our study and they used cream form which is less absorbable than ointment form used in our study.

## CONCLUSION

It is obvious from our study that both betamethasone dipropionate and calcipotriol are effective and 1st line treatment in mild to moderate chronic plaque Psoriasis.

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