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

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## ABSTRACT

**Objective:** To compare the effectiveness of calcipotriol versus betamethasone dipropionate in the treatment of mild to moderate chronic plaque psoriasis.

**Methodology:** A total of 112 patients with mild to moderate psoriasis were enrolled in this randomized controlled trial. 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 50% reduction in psoriasis area and severity index (PASI) score after 4 weeks of topical treatment. SPSS version 21 for Windows was used for data entry and analysis.

**Results:** In group A, Betamethasosne was effective in 44 patients (78.57%), while it was not effective in 12 patients (21.43%). In group B, calcipotriol was effective in 41 patients (73.21%). while it was not effective in 15 (26.79%). The P value was 0.659 which was statistically not significant.

**Conclusion:** Both betamethasone dipropionate and calcipotriol were found effective in mild to moderate forms of chronic plaque psoriasis. Calcipotriol has comparable effectiveness to betamethasone dipropionate.

**Key Words:** Betametasone dipropionate, Calcipotriol, Chronic plaque psoriasis

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## INTRODUCTION

Psoriasis is a chronic inflammatory disease. Patients suffering from psoriasis experience skin tissue damage and can also simultaneously develop other systemic complications[1]. Both genetic and environmental factors interplay leading to increased turnover of epithelial cells and formation of scales. The hallmark of psoriasis is red, scaly, well demarcated plaques, involving the extensor surfaces and scalp[2].It has several types like chronic plaque psoriasis (comprises almost 90% of psoriasis patients), guttate psoriasis, pustular psoriasis and erythrodermic psoriasis[3].

Psoriasis is a common dermatosis affecting, approximately 125 million people world over. The prevalence of psoriasis varies from 0 to 12 % in different populations[4]. Topical modalities are the cornerstone of treatment for mild to moderate psoriasis[5]. Topical therapies for psoriasis include emollients, calcipotriol[6], topical corticosteroids (including combination preparations), tar preparations[7] and dithranol[8]. Potent corticosteroids and calcipotriol are the most common topical modalities used for psoriasis. Calcipotriol can be used solely or in combination with steroids[9]. Topical potent corticosteroids are widely used for treatment of mild to moderate chronic plaque psoriasis in our part of world. There mechanism of action is based on anti-inflamatory, vasoconstrictive, immunosuppressive and anti-proliferative effects on epithelial cells. Long term application of topical steroids leads to skin atrophy, telengectasias, localized skin infections and rarely suppression of hypothalamic-pitutary–adrenal axis. There is a need for topical drug which should be comparable in efficacy to topical steroids and devoid of adverse effects resulting from long term use of topical steroids. Therefore, the present study was carried out to compare the effectiveness of calcipotriol versus betamethasone dipropionate in the treatment of mild to moderate chronic plaque psoriasis.

## METHODOLOGY

This randomized controlled trial was conducted in the Department of Dermatology, Lady Reading Hospital, Peshawar from1st April, 2013 to 30th September, 2013. A total of 112 patients were enrolled. Sample size was 56 in each group, using 36.8%[10] PASI reduction in

calcipotriol group and 64% PASI reduction in betamethasone dipropionate group[11], at 95% confidence level and 90% power of test, with the help of WHO software for sample size determination. Psoriasis area and severity index (PASI) scoring was established by Fredricksson and Pettersson in 1978, and is used to quantify the severity of the disease and extent of skin involvement. In this scoring system, four regions of the body head, trunk, upper and lower limbs are assessed. These four areas are assessed on the basis of extent of erythema, induration, desquamation of plaques and total surface area of the body involved. A score of 0 to 4 is given for the intensity of erythema, scaling and induration to rate the extent of severity of the disease[5].

Patients suffering from mild to moderate chronic plaque psoriasis 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 betamethasone dipropionate, whereas patients in group B received topical calcipotriol. Response to treatment was considered excellent on the basis of reduction of greater than 50% PASI score from baseline after four weeks of application of medication in each group, whereas response was judged as poor if the reduction in PASI was less than 50% from the baseline.

SPSS version 21 for Windows was used for data entry and analysis. Age and PASI scores were calculated and presented as Mean ±SD. Frequencies and percentages were calculated for gender and effectiveness. significance level was set at <0.05. Chi square and t test were used for qualitative and quantitative variables respectively.

## RESULTS

Out of 112 patients, 62 (55.36%) were males and 50 (44.64%) were females. In group A, 29 (56.86%) were males while in group B, 33 (58.92%%) were males. PASI score and other characteristics of both groups are shown in Table 1.

In group A, effectiveness was achieved in 44 patients (78.57%) and In group B, the treatment was effective in 41 patients (73.21%). The P value was .659 (two sided) which was statistically not significant (Table 2).

## DISCUSSION

Treatment of psoriasis has remained a therapeutic challenge for treating physicians. Topical steroids and vitamin D analogues are routinely used for treatment of mild to moderate chronic plaque psoriasis. In our study, both groups were well-matched in terms of pre-treatment characteristics. It was consistent with a study done by Ahmad et al[10] in which mean age was 34.7 ±12 years in Group A (calcipotriol group) and 34.5 ±15.8 years in Group B (topical betamethasone dipropionate group).

In our study, effectiveness in Group A was 78.57% while it was 73.12% in Group B, (p value 0.659). Both drugs were equally efficacious and the observed difference was statistically not significant between the two groups. These findings are consistent with study carried out by Ahmad et al[10], who reported a reduction of 39.4% in group A (topical calcipotriol) and and 35.4% in group

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

| Characteristics | GROUP A | GROUP B |
|---|---|---|
| Males | 29 (51.78%) | 33 (58.92%) |
| Females | 27 (48.22%) | 23 (41.08%) |
| Mean Age | 37.77±13.9 | 39.88 ± 14.34 |
| Baseline PASI | 12.70 ± 2.97 | 12.45 ± 2.22 |
| Follow-up PASI | 5.32 ± 2.4 | 5.32 ± 2.31 |

**Table 2: Effectiveness of Groups A and B Drugs**

| Effectiveness | Group A | Group B | Total | P value |
|---|---|---|---|---|
| Yes | 44 (78.57%) | 41 (73.21%) | 85 (75.89%) | 0.659 |
| No | 12 (21.43%) | 15 (26.79%) | 27 (24.11%) | |
| Total | 56 (50%) | 56 (50%) | 112 (100%) | |

B (topical betamethasone) respectively (P>0.05) at 4th week of treatment. The study conducted by Dahri et al[11] showed that in group A (topical calcipotriol), the mean PASI score at the start of treatment was 14.08 ±0.03, while it was 4.52 ±0.81 (i.e. 67.89% decrease in PASI) at the end of study; on the other hand, in Group B (topical calcipotriol plus betamethasone), mean PASI score at the start of treatment was 12.81 ±0.35 and at the end of study it was 2.27 ±0.25 with 81.49% reduction in PASI score. The results are comparable with our study, however, little bit greater decrease in Group B might be due to the use of two compound formulations. They concluded that betamethasone plus calcipotriol therapy is safer as it produces less adverse effects than calcipotriol alone.

Kamal et al[12] showed mean PASI reduction in calcipotriol group from 6.33 at week 0 to 1.9 at week 6 (i.e. 69.6%), whereas betamethasone valerate ointment group showed a decrease in mean PASI score from 6.22 at week 0 to 2.26 (i.e. 63.8%) at the end of treatment. Our results are in accordance with the above mentioned study. Decrease in efficacy of calcipotriol compared to betamethasone group was observed, which may be because of the use of betamethasone valerate in the study by Kamal et al[12] which is less potent than betamethasone dipropionate used in our study.

Molin et al[13] conducted a trial on 421 patients suffering from mild to moderate chronic plague psoriasis. There was no statistically significiant difference between the two treatment groups. They reported more treatment related adverse effects with calcipotriol in comparison to betamethasone. The difference from our study could be because, their study was on different population and they used cream formulation which is less absorbable than ointment form used in our study.

## CONCLUSION

Betamethasone dipropionate and calcipotriol were effective in the treatment of mild to moderate forms of chronic plaque Psoriasis. Calcipotriol has comparable effectiveness to betamethasone dipropionate.

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### CONTRIBUTORS

SA conceived the idea, planned the study and drafted the manuscript. SMN, HZ and MMP helped acquisition of data, did statistical analysis and critically revised the manuscript. All authors contributed significantly to the submitted manuscript.