

## Comparative Role of Topical Betamethasone Valerate with Topical Calcipotriol in Mild and Moderate Plaque Type Psoriasis

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### ABSTRACT

**Objective:** Comparative role of topical Betamethasone valerate (0.1%) and topical Calcipotriol (0.005%) in the treatment of plaque psoriasis.

**Materials and Methods:** This 12 weeks research project was conducted in the Department of Pharmacology and Therapeutics, BMSI, JPMC, Karachi. Total 80 psoriatic (mild and moderate) patients were included in the study and they were divided into two groups, A and B; 40 patients in each group. The patients of group A were treated by Betamethasone valerate (0.1%) and the patients of group B were treated by Calcipotriol (0.005%). To observe any significant changes, the PASI parameter was applied at the end of study period.

**Results:** Psoriasis severity improvement was monitored by Psoriasis Area Severity Index (PASI). As compared to day 0, the mean PASI score changes in both treated groups i.e group A (Betamethasone valerate) and group B (Calcipotriol) was highly significant at day 90 but the changes in mean PASI score was more marked in group B. In mild psoriasis, Calcipotriol causes 71.61% improvement in PASI score whereas Betamethasone valerate causes 63.2% improvement. In moderate psoriasis, Calcipotriol causes 69.21% improvement in PASI score whereas Betamethasone valerate causes 60.44% improvement.

**Conclusion:** Topical Calcipotriol was more effective in improvement of mild and moderate plaque psoriasis as compared to Betamethasone valerate in local population.

**Key words:** Calcipotriol, betamethasone valerate, plaque psoriasis, psoriasis area severity index (PASI) parameter.

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### INTRODUCTION

Psoriasis is characterized by common raised thickened patches of red skin. It is a T-cell-mediated immune disorder and the cause of psoriasis is not known.<sup>1</sup>

There is no gender limitation as women and men both are equally affected by psoriasis at any age. Psoriasis has a bimodal age of disease onset. The first peak occurs at the age of 15 to 20 years and the second peak occurs at the age of 55 to 60 years. The onset of psoriasis around 20 years old patients have stronger genetic predisposition.<sup>2</sup>

Psoriasis affects up to 2.5% of people worldwide and more than 250,000 new cases are diagnosed each year. The prevalence of psoriasis varies markedly depending on geographical locations and ethnicity. It occurs most commonly in Northern Europe and Scandinavian countries.<sup>3</sup> It is much less common in China.<sup>4</sup> The incidence of psoriasis in the population of Pakistan has been reported as similar to those of Europeans in some studies, whilst in others, it is lower and similar to Chinese.

Depending on geographic location, psoriasis is generally more common in the cold northern countries than in the tropical countries.<sup>5</sup>

Psoriasis is classified into several subtypes. Among all subtypes, plaque psoriasis accounts for about 90 percent of cases. It is usually characterized by well-circumscribed, red, raised, silvery white scaly plaques. In majority cases it occurs symmetrically, effecting the knees, elbows, back, buttocks, scalp, extremities and areas subjected to trauma.<sup>6</sup>

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## MATERIALS & METHODS

This research project was completed in the Department of Pharmacology and Therapeutics, BMSI, JPMC, Karachi in collaboration with Department of Dermatology, JPMC, Karachi. The research project was started from April 2013 to September 2013. The effects of drugs were observed for 90 days in each psoriatic patient. JPMC Ethical Committee approved this study.

### Inclusion Criteria:

- Diagnosed mild and moderate plaque psoriatic patients of both sexes.
- Age 20 years to 60 years.

### Exclusion Criteria:

- Diagnosed patients of severe plaque psoriasis.
- Diagnosed patients of plaque psoriasis of scalp region.
- Pregnant or lactating women.
- History of allergy to study drugs.
- Patients of renal or hepatic disease.
- Patients with other skin disease.
- Patients taking Betamethasone valerate and Calcipotriol within 4 week period prior to study.

### Materials:

#### Drugs:

- Betamethasone valerate ointment (0.1%).
- Calcipotriol ointment (0.005%).

#### Tools:

- Psoriasis Area and Severity Index (PASI)

#### Psoriasis Area and Severity Index (PASI)

To monitor psoriasis severity, PASI is the most commonly used tool. PASI is used for the lesion severity as well as psoriasis affected area. The PASI score starts from 0, no disease to 72, maximal disease<sup>7</sup> where as three clinical signs such as redness (erythema), thickness (induration) and scaling (desquamation) are estimated for disease severity.

### Study design:

Total 80 psoriatic patients were enrolled in the study. They were divided into two groups, A and B; 40 patients in each group.

The group A patients were treated by Betamethasone valerate and group B patients were treated by Calcipotriol. On the basis of disease severity, each group was subdivided into two sub-groups, mild and moderate and each sub- group consists of 20 patients. All the values were taken as mean and  $\pm$ SEM. The primary efficacy measurement was the mean percentage change in PASI, from the base line to the end of study.

## RESULTS

80 psoriatic patients completed the 90days study period. The baseline characteristics of psoriatic patients were also observed as shown in Table 1.

Table 1: The baseline characteristics of mild and moderate psoriatic patients

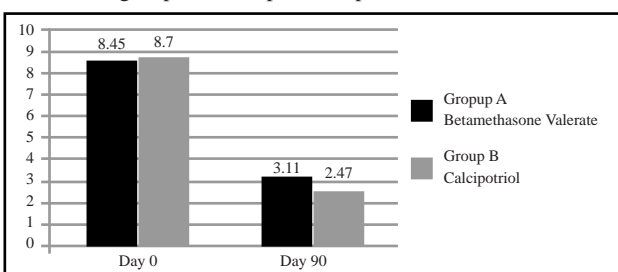
Variable	Betamethasone valerate ointment n=40		Calcipotriol ointment n=40	
	Mild n=20	Moderate n=20	Mild n=20	Moderate n=20
Age in years (Mean $\pm$ SEM)	39.35 $\pm$ 2.77	36.63 $\pm$ 2.58	38.35 $\pm$ 2.33	38.32 $\pm$ 2.29
Gender				
Male (%)	9 (45%)	10 (50%)	10 (50%)	11 (55%)
Female (%)	11 (55%)	10 (50%)	10 (50%)	9 (45%)
History of previous psoriasis therapy (%)				
Positive	5 (25%)	4 (20%)	5 (25%)	7 (35%)
Negative	15 (75%)	16 (80%)	15 (75%)	13 (65%)
Family history of psoriasis (%)				
Positive	2 (10%)	3 (15%)	3 (15%)	5 (25%)
Negative	18 (90%)	17 (85%)	17 (85%)	15 (75%)

Topical Betamethasone valerate ointment and Calcipotriol ointment given for 90 days to mild psoriatic patients revealed overall decrease in mean PASI score. An overall reduction of 71.61% was found in Calcipotriol treated group B psoriatic patients with the decrease in mean PASI score level from 8.70  $\pm$ 0.11 at day 0 to 2.47 $\pm$ 0.12 at day 90. Whereas an overall reduction of 63.2% was found in Betamethasone valerate treated group A psoriatic patients with the decrease in mean PASI score level from 8.45 $\pm$ 0.17 at day 0 to 3.11 $\pm$ 0.26 at day 90, indicating the improvement was more profound in group B on the basis of PASI score as shown in Table 2 and Figure 1.

Table 2: Changes in mean PASI score from day 0 to day 90 in different groups of mild psoriatic patients

Group	Drugs	Mean PASI score at day 0	Mean PASI score at day 90	Percentage change	P-value
A	Betamethasone valerate	8.45 $\pm$ 0.17	3.11 $\pm$ 0.26	63.2%	<0.0001
B	Calcipotriol	8.70 $\pm$ 0.11	2.47 $\pm$ 0.12	71.61%	<0.0001

Figure 1: Changes in mean PASI score from day 0 to day 90 in different groups of mild psoriatic patients

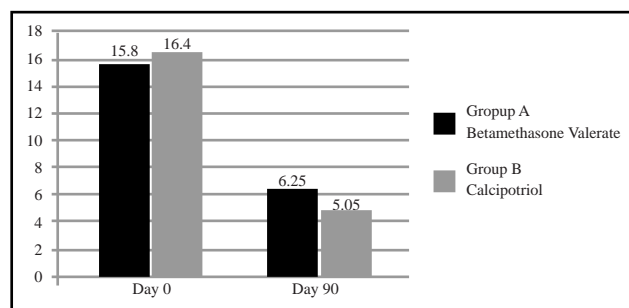


Topical Betamethasone valerate ointment and Calcipotriol ointment given for 90 days to moderate instead mild psoriatic patients revealed overall decrease in mean PASI score. An overall reduction of 69.21% was found in Calcipotriol treated group B psoriatic patients with the decrease in mean PASI score level from  $16.40 \pm 0.45$  at day 0 to  $5.05 \pm 0.14$  at day 90. Whereas an overall reduction of 60.44% was found in Betamethasone valerate treated group A psoriatic patients with the decrease in mean PASI score level from  $15.80 \pm 0.54$  at day 0 to  $6.25 \pm 0.40$  at day 90, indicating the improvement was more marked in group B on the basis of PASI score as shown in Table 3 and Figure 2.

Table 3: Changes in mean PASI score from day 0 to day 90 in different groups of moderate psoriatic patients

Group	Drugs	Mean PASI score at day 0	Mean PASI score at day 90	Percentage change	P-value
A	Betamethasone valerate	$15.80 \pm 0.54$	$6.25 \pm 0.40$	60.44%	<0.0001
B	Calcipotriol	$16.40 \pm 0.45$	$5.05 \pm 0.14$	69.21%	<0.0001

Figure 2: Changes in mean PASI score from day 0 to day 90 in different groups of moderate psoriatic patients



## DISCUSSION

In this research project both drugs were effective in improvement of plaque psoriasis but Calcipotriol in mild (71.61%) and moderate (69.21%) was more effective as compared to Betamethasone valerate in mild (63.2%) and moderate (60.44%) psoriasis. In the study Dahri et al.<sup>8</sup> (2010) the improvement in psoriasis in Calcipotriol group on the basis of PASI was 67%. Ahmad et al.<sup>9</sup> (2013) carried out a comparative study in psoriatic patients and showed an improvement in PASI score of 59.6% in Betamethasone valerate group. Kragballe and Austad<sup>10</sup> (2006) carried out a comparative

study and reported that the mean reduction in the PASI score in Calcipotriol treated patients was 68.8% while in Betamethasone valerate treated patients was 61.4%. These results were highly significant ( $p < 0.0001$ ) and are comparable to our study.

## CONCLUSION

Topical Calcipotriol 0.005% ointment was more effective in improvement of mild and moderate plaque psoriasis as compared to Betamethasone valerate 0.1% ointment. Therefore it is recommended that topical Betamethasone valerate 0.1% ointment can be replaced with topical Calcipotriol 0.005% ointment.

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