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IS TOPICAL CALCIPOTRIOL A BETTER OPTION IN MILD TO MODERATE PLAQUE PSORIASIS? AN OPEN LABEL, RANDOMIZED, COMPARATIVE STUDY

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ABSTRACT

Aim: To evaluate whether topical Calcipotriol (0.005%) is a better option in the treatment of mild to moderate plaque psoriasis in an open label, randomized, comparative study. **Study population:** All outpatients visiting Department of Dermatology, JPMC, Karachi from April 2013 to September 2013. **Materials and Methods:** This open labeled, comparative 12 weeks research work was done in Basic Medical Science Institute (BMSI), Postgraduate Medical Centre (JPMC), Karachi in the Department of Pharmacology and Therapeutics. In the study, mild to moderate 80 enrolled plaque psoriasis patients were divided into topical Betamethasone valerate (0.1%) ointment treated group A patients and topical Calcipotriol (0.005%) ointment treated group B patients i.e 40 patients in each group. Psoriasis Area and Severity Index (PASI) parameter and adverse effects were analyzed in the study period. **Results:** Psoriasis Area and Severity Index (PASI) in group B patients, topical Calcipotriol ointment showed marked progress of 71.61% and 69.21% in Psoriasis Area and Severity Index (PASI) score in mild to moderate plaque psoriasis respectively as compared to group A patients, topical Betamethasone valerate ointment showed progress of 63.2% and 60.44% in Psoriasis Area and Severity Index (PASI) score in mild to moderate plaque psoriasis respectively. **Conclusion:** Topical Calcipotriol ointment was a better option regarding progress in Psoriasis Area and Severity Index (PASI) score and minimum adverse effects in mild to moderate plaque psoriatic patients.

Keywords: Calcipotriol ointment, Betamethasone valerate ointment, Plaque psoriasis, Psoriasis Area Severity Index (PASI) parameter, skin irritation, rashes, burning sensation, striae, telangiectasia.

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INTRODUCTION

Psoriasis is an immune-mediated, chronic inflammatory dermal disease

characterized by recurrent itchy, scaly, erythematous marks.[1]

No age and gender discrimination have been found in psoriasis onset as men and women of any age group have even chance of psoriasis.[2]Psoriasis has a bimodal age of disease onset therefore the first peak of disease occurs around 20 years and the second peak of disease occurs around 60 years. Strong genetic predisposition is seen in psoriatic patients of age around 20 years.[3]

Depending on geological locations, the occurrence of psoriasis varies noticeably. Psoriasis occurs most commonly in northern cold countries located nearer to Arctic ocean mainly Scandinavian countries[4] as compared to topically located countries like China.[5, 6]

Among various types of psoriasis, plaque psoriasis is the commonest type accounting about 90 percent of cases. In majority cases, plaque psoriasis appears as symmetrical, well-confined, red and scaly silvery white lesion. It usually covers extensor surfaces of the body and affects scalp, chest, back, elbows, legs, and trauma exposed areas.[7]

Topical therapies are main stay remedy in mild-to-moderate plaque psoriasis. Corticosteroids (Betamethasone valerate), Vitamin D analogues (Calcipotriol), emollients, keratinolytics, anthralin, coal tar and topical retinoids are commonly applied topical medications.[8]

A medium-potent synthetic glucocorticoid, Betamethasone valerate decreases dermal cells growth and slows down inflammation of lesions in psoriatic patients.[9]Calcipotriol - a synthetic 1, 25-dihydroxy vitamin D_3, binds to vitamin D receptors on epidermal cells and causes inhibition of cell proliferation and induction of cell differentiation in psoriatic skin.[10]

The efficacy and safety profile of topical Betamethasone valerate and topical Calcipotriol are compared by using these drugs separately. Thus, the purpose of this study was to assess if topical Calcipotriol ointment is a superior choice in mild and moderate plaque psoriasis therapy when compared to topical Betamethasone valerate ointment.

MATERIALS AND METHODS

At Jinnah Postgraduate Medical Centre, Karachi, this open labeled comparative study was conducted in the Department of Pharmacology and Therapeutics, Basic Medical Science Institute (BMSI). The patients of mild to moderate plaque psoriasis were randomly selected from dermatology out-patient department from April 2013 till September 2013. These psoriatic patients got treatment for 90 days. Ethical Committee of JPMC certified this research study.

Diagnosed patients of mild and moderate plaque psoriasis, aged between 20 years and 60 years of either sex were part of this research study. Pregnant/ lactating mother, diagnosed cases of scalp region plaque psoriasis, patients of severe plaque psoriasis, patients of liver/ kidney disorder, patients allergic to study drugs, patients of additional skin disorder and patients who took ointments of either Betamethasone valerate or Calcipotriol within 30 days prior research were not part of this research study.

Psoriasis Area and Severity Index (PASI) is a routinely done parameter. The severity of psoriatic lesion can be assessed by three clinical signs i.e erythema (redness), induration (thickness) and desquamation (scaling). The extent of involvement of psoriasis affected area can be checked by Psoriasis Area and Severity Index (PASI) score that starts from 0, no disease to 72, maximal disease.[11]

Common adverse effects observed in psoriasis treated patients are skin irritation, rashes, burning sensation, striae and telangiectasia (angioectasia).[12] The safety of a drug is assessed by lesser adverse effects observed in plaque psoriatic patients.

By using Open Epi version 16, the sample size of patients was calculated. In the research 80 enlisted patients of plaque psoriasis were placed into group A and group B; each group had 40 patients. Betamethasone valerate ointment was used to treat group A plaque psoriatic patients while Calcipotriol ointment was used to treat group B plaque psoriatic patients. On the basis of disease intensity, each group consisting of 40 patients was subdivided into mild and moderate sub-groups; 20 patients in each sub-group as shown in table 1.

The mean percentage change in Psoriasis Area and Severity Index (PASI) was the primary criterion study tool. All the values were analyzed as mean and ±SEM by using SPSS 16. The adverse effects of given drugs were also observed.

RESULT

For the study period of 90 days, 80 enlisted psoriatic patients (both mild and moderate) used Betamethasone valerate and Calcipotriol ointments topically.

In group A Betamethasone valerate treated mild plaque psoriatic patients an overall 63.2% reduction

TABLE-1
GROUPING OF PATIENTS

Drugs	Groups	Psoriasis grading	Number of patients
B Betamethasone valerate ointment	A	Mild	20
		Moderate	20
C Calcipotriol ointment	B	Mild	20
		Moderate	20

FIGURE-1
Changes in mean PASI score from day 0 to day 90 in two groups of mild psoriatic patients

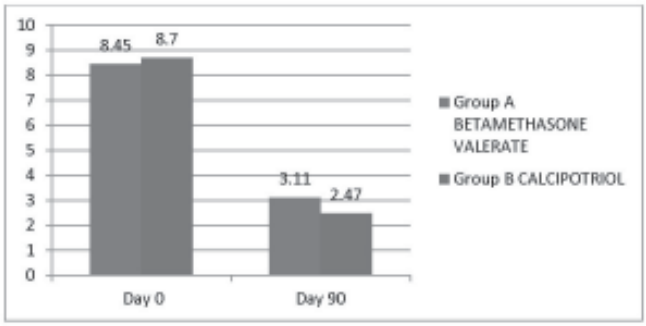


FIGURE-2
Changes in mean PASI score from day 0 to day 90 in two groups of moderate psoriatic patients

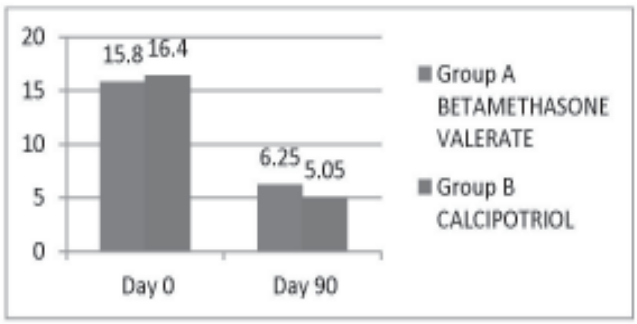


FIGURE-3
Adverseeffects in mild plaque psoriatic patients after treatment with Betamethasone valerate ointment (Group A) and Calcipotriol ointment (Group B)

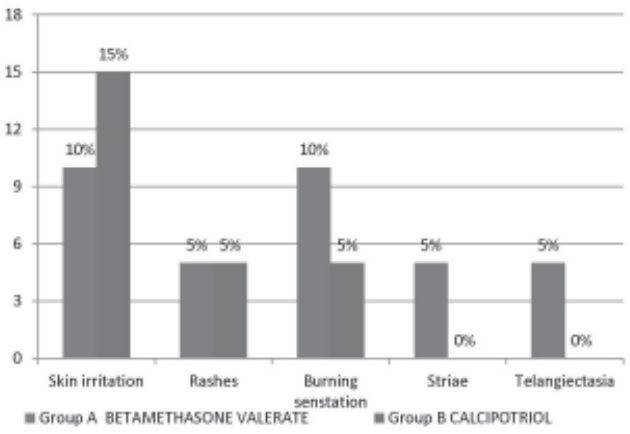
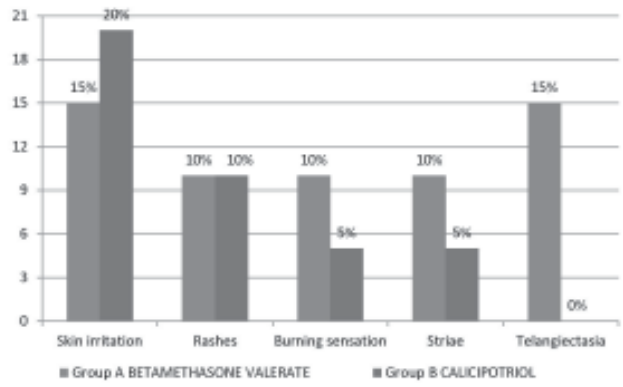


FIGURE-4
Adverse effects in moderate plaque psoriatic patients after treatment with Betamethasone valerate ointment (Group A) and Calcipotriol ointment (Group B)



was noticed with a decrease in mean Psoriasis Area and Severity Index (PASI) score level from 8.45±0.17 at day 0 to 3.11±0.26 at day 90. At the same time in group B Calcipotriol treated mild plaque psoriatic patients an overall 71.61% reduction was seen with a decrease in mean Psoriasis Area and Severity Index (PASI) score level from 8.70 ±0.11 at day 0 to 2.47±0.12 at day 90. Hence as compared to mild plaquepsoriatic patients of group A, a distinct recovery in mild plaquepsoriatic patients of group B was observed as shown in Figure-1.

In group A Betamethasone valerate treated moderate plaque psoriatic patients an overall 60.44% reduction was noticed with a decrease in mean Psoriasis Area and Severity Index (PASI) score level from15.80±0.54 at day 0 to 6.25±0.40 at day 90. Although in group B Calcipotriol treated moderate plaque psoriatic patients an overall 69.21% reduction was seen with a decrease in mean Psoriasis Area and Severity Index (PASI) score level from 16.40 ±0.45 at day 0 to 5.05 ±0.14 at day 90. Hence as compared to moderate plaque psoriatic patients of group A, a profound recovery in moderate plaquepsoriatic patients of group B was observed as shown in Figure-2.

Therefore, from day 0 to day 90 the average percentage change in Psoriasis Area and Severity Index (PASI) score was more pronounced in group B (71.61% and 69.21%) as compared to group A (63.2% and 60.44%) in both mild and moderate plaque psoriasis as depicted in above figures.

In group A Betamethasone valerate treated mild plaque psoriatic patients, skin irritation was observed in 10% patients, rashes in 5% patients and burning sensation was seen 10% patients. While 5% patients each were affected by striae and telangiectasia. However, in group B Calcipotriol treated mild plaque psoriatic patients, skin irritation was found in 15% patients while rashes and burning sensation were found in each 5% patients. No patient was either affected by striae or telangiectasia as depicted in figure 3.

In group A Betamethasone valerate treated moderate plaque psoriatic patients, skin irritation was observed in 15% patients, where as 10% patients each were affected by rashes, burning sensation and striae. While telangiectasia was seen in 15% patients. However, in group B Calcipotriol treated moderate plaque psoriatic patients, skin irritation was found in 20% patients while rashes was observed in 10% patients. Burning sensation and striae were found in each 5% patients. No patient was affected by telangiectasia as depicted in figure 4.

DISCUSSION

In this study, both drugs were effectual in the treatment of plaque psoriasis but Calcipotriol ointment proved to be more effectual with lesser adverse effects i.e 71.61% in mild and 69.21% moderate plaque psoriasis when compared to topical Betamethasone valeratei.e 63.2% in mild and 60.44% moderate plaque psoriasis. Dahri et al. (2010) reported 67% betterment in Psoriasis Area and Severity Index (PASI) score in topical Calcipotriol treated patients.[13]In the study conducted by Lovato et al. (2016), better Psoriasis Area and Severity Index (PASI) scores were found in patients treated with topical Calcipotriol ointment as compared to topical Betamethasone ointment.[14]In the comparative study of Ahmad et al. (2013), 59.6% betterment in Psoriasis Area and Severity Index (PASI) score was seen in psoriatic patients who applied topical Betamethasone valerate ointment.[15]Menter et al. (2007) in his comparative study observed skin irritation slightly more common adverse effect in Calcipotriol treated patients. He also noticed that rashes were equally found in psoriatic patients of both study groups but burning sensation, striae and telangiectasia were more common in patients treated by Betamethasone valerate in mild and moderate plaque psoriasis.[16]Saoji et al. (2015) came to the point that Calcipotriol ointment was as effective as corticosteroid ointment in the treatment of psoriasis and could replace corticosteroid which are correlated with tolerance and various adverse effects.[17] These results are in agreement to our study.

CONCLUSION

Calcipotriol ointment was more effectual regarding progress in Psoriasis Area and Severity Index (PASI) score with lesser adverse effects when compared to Betamethasone valerate ointment and can be a better option in the treatment of mild to moderate plaque psoriasis.

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* Main author, researcher ** Helped in searching references
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