Research Article

Topical Betamethasone Valerate and Calcipotriol Ointments for the Therapyof Mild and Moderate Psoriasisvulgaris: A Randomized, Comparative Study

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Abstract | To determine the effectiveness of both topically applied Betamethasone valerate and Calcipotriol ointments for the therapy of mild and moderate types of psoriasis. This comparative study was conducted in Jinnah Postgraduate Medical Centre, Karachi in the Pharmacology and Therapeutics department of Basic Medical Science Institute (BMSI). In 90 days study, 80 patients of mild and moderate psoriasis vulgaris were placed into A and B groups. The Betamethasone valerate treated patients were placed in group A while Calcipotriol treated patients were placed in group B; 40 patients in each group. The Psoriasis Area Severity Index (PASI criterion) was used to observe improvement in psoriatic patients taking these drugs. In this randomized and comparative study, psoriasis severity was checked by Psoriasis Area Severity Index (PASI). At day 90 Calcipotriol treated group B patients showed more improvement in mean PASI score as compared to Betamethasone valerate treated group A patients. In PASI score, Calcipotriol shows 71.61% betterment whereas Betamethasone vale rate shows 63.2% betterment in mild psoriatic patients. In PASI score, Calcipotriol shows 69.21% betterment whereas Betamethasone valerate shows 60.44% betterment in moderate psoriatic patients. In Pakistani population topically applied Calcipotriol ointment was more efficacious in the treatment of mild and moderate types of psoriasisvulgaris when compared to topically applied Betamethasone valerate ointment.

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Introduction

Psoriasis is a widespread disfiguring inflammatory skin disease. It is an immunological skin disorder in which affected area appears as red, thickened and raised lesions affecting upto 2%-4% of people every year worldwide.[(1)]Psoriasis cases are found more in northern cold countries as compared to topically located countries. The Northern Europe and Scandinavian population is most commonly affected[(2)] while Eastern Asia particularly Chinese population is least commonly affected. [(3)]The incidence of psoriasis vulgaris differs in population of Pakistan as in some studies it is found alike to that of people of North Europe while in some researches it is found alike to people of China.[(4)]

There is no age and gender limitation of psoriasis onset as both men and women of any age are equally affected. The disease has bimodal age of onset. The first and second peaks of disease onset occur around 20 years and around 60 years respectively.[5]

There are several types of psoriasis, in which psoriasis vulgarisis the commonest type. Psoriasis vulgaris appears asred and raised silvery white well-circumscribed encrustedlesions.Itusuallyoccurssymmetrically,mainly over extensor surfaces but also often involving other areas of the body. The scalp, arms, elbows, nails, chest, back, legs, knees and fold between the buttocks are commonly affected body parts.[6]

Patients of mild-to-moderate psoriasis are generally managed disease effectively with topical therapies, including emollients, anthralin, coal tar, corticosteroids (Betamethasone valerate), Vitamin D analogues (Calcipotriol) and topical retinoids. [7], [8]Betamethasone vale rate is a medium-potent synthetic glucocorticoid. It acts by slowing down the growth of skin cells and decreases the inflammation of lesions in patients with psoriasis.[9] Continuous use often leads to tachyphylaxis, skin irritation, rashes and burning sensation.[10]Calcipotriol is a synthetic 1, 25-dihydroxyvitamin D_3. It acts by binding to vitamin D receptors on epidermal cells and tissue cells. Activation of this ligand-receptor complex results in inhibition of cell proliferation and induction of cell differentiation in psoriatic skin. Skin rashes, burning sensation and tachyphylaxis are uncommon but skin irritation is common which subsides subsequently.[11]The adverse effects are less in topical Calcipotriol as compared to topical Betamethasone vale rate.

By applying topical Betamethasone vale rate and topical Calcipotriol separately, the efficacy and safety profile of both drugs are compared. Therefore, the rationale of this study was to evaluate whether topically applied Calcipotriol ointment is a better option in the treatment of mild and moderate psoriasis vulgaris as compared to topically applied Betamethasone vale rate ointment.

Materials and Methods

This 90 days comparative study was done in Jinnah Postgraduate Medical Centre, Karachi in the Pharmacology and Therapeutics department of Basic Medical Science Institute (BMSI). These psoriatic patients were selected in dermatology OPD from April 2013 till September 2013. Randomization of patients was done by lottery method. After selection & randomization these psoriatic patients got drug treatment for 90 days. JPMC Ethical Committee endorsed this research.

Sufferers of both genders aged 20 to 60 years with recognized case of mild and moderate psoriasis vulgaris were included in the study. The patients who were excluded from the study were pregnant/ lactating mother, sufferers of severe psoriasis vulgaris (as these patients also usually need systemic treatment besides topical treatment), sufferers of scalp region psoriasis vulgaris, sufferers allergic to these drugs, sufferers of liver/ kidney disorder, sufferers of additional dermal ailment and sufferers using topically applied any anti-psoriatic drug especially Betamethasone valerate ointment and Calcipotriol ointment within a month before research.

PASI is the generally prescribed criterion to access psoriasis lesion intensity and psoriasis involved area. The score of PASI criterion commences from no disease (score 0) to maximal disease (score 72). Psoriasis intensity is judged by three clinical signs i.e erythema, induration and desquamation. [12]Psoriasis can be categorized according to the total body surface area involved. Mild psoriasis involves <5% of the body surface area, moderate psoriasis involves 5% to 10% of the body surface area and severe psoriasis involves >10% of the body surface area.[13]

The sample size was calculated by using Open Epi version 16. 80 enlisted patients of psoriasis vulgaris in the research were placed into group A and group B and in every group there were 40 patients. The patients of psoriasis vulgaris of group A and group B were dealt with Betamethasone vale rate ointment and Calcipotriol ointment respectively. Every group of 40 patients was subdivided into mild and moderate sub-groups on the justification of disease intensity; 20 patients in every sub-group.

In the research, the mean percentage change in PASI was the primary criterion study tool. All the values were analyzed as mean and ±SEM by using SPSS 16.

Results and Discussion

80 enrolled mild and moderate psoriatic patients took topical Betamethasone valerate ointment and topical Calcipotriol ointment for 90 days study period.

Table 1: *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±0.17	3.11 ±0.26	63.2%	<0.0001
B	Calcipotriol	8.70 ±0.11	2.47±0.12	71.61%	<0.0001

Table 2: *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 ±0.54	6.25 ±0.40	60.44%	<0.0001
B	Calcipotriol	16.40 ±0.45	5.05 ±0.14	69.21%	<0.0001

It was found an overall reduction of 63.2% in group A Betamethasone valerate treated mild psoriatic patients with a decrease in mean PASI score level from 8.45±0.17 at day 0 to 3.11±0.26 at day 90. While an overall reduction of 71.61% was found in group B Calcipotriol treated mild psoriatic patients with a decrease in mean PASI score level from 8.70 ±0.11 at day 0 to 2.47±0.12 at day 90. Therefore on the basis of PASI score, it showed marked betterment in group B patients of mild psoriasis vulgaris when compared to group A patients of mild psoriasis vulgaris as shown in Table 1.

It was seen an overall reduction of 60.44% in group A Betamethasone valerate treated moderate psoriatic patients with a decrease in mean PASI score level from 15.80±0.54 at day 0 to 6.25±0.40 at day 90. While an overall reduction of 69.21% was seen in group B Calcipotriol treated moderate psoriatic patients with a decrease in mean PASI score level from 16.40 ±0.45 at day 0 to 5.05 ±0.14 at day 90. Therefore on the basis of PASI score, it showed profound betterment in group B patients of moderate psoriasis vulgaris when compared to group A patients of moderate psoriasis vulgaris as shown in Table 2.

The mean value on day 90, when compared statistically it showed significant differences (p<0.0001) in mild and moderate psoriasis vulgaris between group A Betamethasone valerate treated patients and group B Calcipotriol treated patients with higher mean PASI score in Group B. The average percentage change in PASI score from day 0 to day 90 was more decreasing in group B (71.61% and 69.21%) as compared to group A (63.2% and 60.44%) in both mild and moderate psoriasis vulgaris as depicted in above tables and figures.

In the research work, though these two topical ointments were efficacious in psoriasis vulgaris therapy however topical Calcipotriol was more efficacious with less adverse effects i.e 71.61% in mild and 69.21% moderate psoriasis vulgaris when compared to topical Betamethasone valerate i.e 63.2% in mild and 60.44% moderate psoriasis vulgaris. Ahmad et al.(2013) in his comparative study, showed 59.6% betterment in PASI score on psoriatic patients who applied topical Betamethasone valerate ointment.[14] P. Lovato et al. (2016) also showed better results in psoriasis treatment with topical Calcipotriol ointment as compared to topical Betamethasone ointment. [15]In the comparative study of Admed GKA et al. (2014), the mean percentage of PASI reduction after 4th week of treatment was 39.4% and 35.4% in Calcipotriol treated patients and in Betamethasone valerate treated patients respectively. However, the mean percentage of PASI reduction after 8th week of treatment was 59.6% in Calcipotriol treated patients and 60.7 in Betamethasone valerate treated patients. [16] On the other hand, Khan MSI et al. (2014) in his comparative study reported betterment in PASI score of 39.4% and 35.4% in twice daily topical Calcipotriol treated patients and once daily combination of topical Calcipotriol plus Betamethasone treated patients respectively after 4th week of treatment. However, betterment in PASI score of 59.6% and 60.7% was seen in twice daily topical Calcipotriol treated patients and once daily combination of topical Calcipotriol plus Betamethasone treated patients respectively after 8th week of treatment, showing more or less same betterment in PASI scorein the end of treatment in both groups but drug dosage benefit of combination of topical Calcipotriol plus Betamethasone over topical Calcipotriol was prominently reported.[17] Our study is comparable to these highly significant (p<0.0001) results.Most of the patients don't do regular follow-ups as they satisfied with their initial recovery and/or because of poor social economic status, it isn't easier for them to continue their treatment. This is the main flaw of long term research and better results.

Conclusion

It is concluded that topically applied Calcipotriol ointment was more efficacious and can replace topically applied Betamethasone valerate ointment in the treatment of both mild and moderate psoriasis vulgaris.

Author's Contribution

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