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Comparative study of efficacy and safety of topical 0.005% Calcipotriol and topical 0.1% Tazarotene in patients of Palmo-plantar psoriasis

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Abstract
Background: Topical therapies are the first line of treatment for patients with palmoplanter psoriasis affecting both palms and soles. Although in use for more than a decade yet we could not find any reports of studies directly comparing calcipotriol and tazarotene.
Aim: To evaluate the comparative efficacy and safety of calcipotriol and tazarotene in the treatment of palmoplanter psoriasis.
Methods: This was an observational, open level, two groups comparative, longitudinal follow up(every 4week), 12-week study using calcipotriol 0.005% ointment applied twice daily (group A) versus0.1% ointment tazarotene (group B) applied once daily, each group having 40 patients. Efficacy was determined by the assessment of target psoriatic lesions under evaluation by using the severity scale (0-3) of erythema, scaling, fissuring and infiltration (ESIF score). Evaluation was done at baseline (0 week), 4 weeks, 8 weeks, and 12 weeks of treatment. At the end of 12 weeks reduction in the ESIF score was compared in patients of both groups. Safety of this study was evaluated by comparing the adverse drug reaction in each group.
Results: Forty-one patients in group A (Calcipotriol group) completed the study. In this group reduction in ESI score was significant at 12 weeks in patients treated with topical calcipotriol, producing moderate-to-marked improvement ($P< 0.0001$). In group B (Tazarotene group), improvement was comparable in lesions treated with calcipotriol at the end of 12 weeks after the topical treatment by 0.1% tazarotene. Adverse effects noted were mild - in the form of burning, pruritus, and irritation - and were observed more often in the lesions treated with tazarotene as compared to those in the lesions treated with calcipotriol, but the difference was not statistically significant. However, none of the patients discontinued the therapy because of adverse events.
Conclusion: In conclusion, topical 0.005% Calcipotriol and topical 0.1% Tazarotene both are efficacious in treatment of palmoplanter with almost same safety profile.

Keywords: calcipotriol, palmoplanter psoriasis, tazarotene

1. Introduction
Psoriasis is a common, genetically determined inflammatory and hyper proliferative skin disease with worldwide prevalence of 1% to 3% [1].One clinical subtype of psoriasis localized on the palms and soles is classified as Palmo plantar psoriasis (PPP). PPP affects approximately 14% of patients diagnosed with psoriasis [2]. Though no cure is available, the disease can be effectively controlled by various therapeutic options, used alone or in combination [3, 4]. Topical therapies are the first line of treatment for patients with Palmo planter psoriasis affecting both palms and soles. Calcipotriol and tazarotene are newer topical treatment modalities in use since more than a decade in Palmo planter psoriasis. Though
We have studies comparing their effectiveness in Palmo planter psoriasis with that of various conventional topical treatments (coal tar, topical steroids, anthralin) [4-8], we did not find any studies directly comparing calcipotriol and tazarotene used as monotherapies. The present study was planned to evaluate the comparative efficacy and safety of these two agents in the treatment of Palmo planter psoriasis.

2. Material & Methods
Eighty one patients (38 males, 43 females) of mean age45.45± 7.97 years (range, 20-70 years) having nearly bilateral symmetrical lesions of palmoplanter psoriasis (PPP) on limbs were recruited. This was a prospective inter-individual, observational comparative groups study of 12 weeks' duration using calcipotriol 0.005% ointment applied twice daily versus tazarotene 0.1% gel once daily in two groups, each of 40 patients. In group A, calcipotriol 0.005% ointment was applied twice daily over the psoriatic lesions on palms and soles and in group B, Tazarotene 0.1% was applied once daily at bed time same as 0.005% calcipotiol. All prior medications except antihistamines were stopped 4 weeks before the start of the study, and only application of an emollient (coconut oil) was permitted on both the sides. Serum calcium and phosphate estimation was done before and after therapy. The assessment of target psoriatic lesions under evaluation and progress during treatment were done using the erythema, scaling, induration and fissuring (ESIF) score. The Efficacy was determined by the assessment of target psoriatic lesions under evaluation by using the severity scale (0-12) of erythema, scaling, and infiltration (ESIF score), which is point base scale 0 point was given those having no disease and 12 point was given to those having severe disease Evaluation was done at baseline (0 week) and at 4 and 8 weeks of treatment. The scores obtained statistically compared using paired and unpaired t test was used for comparing quantitative values. At the end of 12 weeks, patients with more than 75% reduction in ESIF score were considered to have marked improvement; 51% to 75%, moderate improvement; 26% to 50%, minimal improvement; and less than 25%, no response.

3. Results

All patients (41 in group A, 40 in group B) completed the study. In group A, the reduction in ESIF score was significantly more at 12 week in the lesions treated with calcipotriol, resulting in marked improvement ($P< 0.0001$) [Table 1]. At 12 week, all 41 patients treated with calcipotriol had more than 75% reduction (moderate improvement in 11, marked in 30) in ESIF score.

In group B, at the end of 12 weeks of treatment, topcal 0.1% tazarotene-treated lesions showed similar reduction in scaling and infiltration in all patients. Reduction in erythema was more with calcipotriol, but there was no statistically significant change in the ESIF score of the two groups as compared to baseline score ($P\leq 0.0001$). At the end of 12 weeks ESIF score reduction in this group was more than 76%, comparable in lesions treated with calcipotriol in group B [Table 1] all patients achieved marked improvement at the end of 12 weeks [Table 2].

Adverse effects noted were mild in the form of burning, pruritus, and irritation and were observed more often in the lesions treated with tazarotene (0.1%) as compared to those in the lesions treated with calcipotriol, but the difference was not statistically significant. However, none of the patients discontinued the therapy because of adverse

Table 1: Comparision of Mean ESIF Score in Both Groups

Duration	Calcipotriol Treated Group (N= 41)	Tazarotene Treated Group (N= 40)	P-Value
Baseline	9.29 ± 1.29	9.17±1.4	.352
12 Weeks	2.4±1.2	2.15 ± 0.88	.142
p-value	<0.0001	<0.0001	

Table 2: Comparison of Adverse Drug Reaction in Both Treatment Groups

Adverse Drug Reaction	Calcipotriol Treated Group (N= 41)		Tazarotene Treated Group (N= 40)	
	No. of Cases	%	No. of Cases	%
Itching	3	7.3	2	5
Irritation	2	4.8	3	7.5
Burning Sansation	2	4.8	3	7.5
Hyperpigmentation	1	2.4	1	2.5
Total	8	19.3	9	22.5

4. Discussion

The present study was undertaken to evaluate the efficacy of topical 0.05% calcipotriol in comparison with topical 0.1% tazarotene monotherapy in patients of palmoplanter psoriasis.). The present study differs from the previous study done by Bijal H Mehta *et al*. [9] (63% Male and 37% Female) and Kaur I *et al*. [10] (60% Males and 40% Females).

Both treatment groups were compared for the mean reduction in ESIF score from baseline to 12th week.Both treatments group were successful in decreasing the ESIF score over the course of the study duration. Mean ESIF score at baseline in topical calcipotriol group was 9.29 ±1.29. This was comparable to tazarotene group in which ESIF score at baseline was 9.17 ± 1.4, which was statistically not significant (p value. 352). These scores were different in comparison with the study done by J. BERTH-JONES *et al*. [11] for the calcipotriol treated group which showed 9.4 ±0.69 on a 72 point PASI score at basline.

After treatment, mean ESIF score in topical 0.005% calcipotriol treated group was reduced to 2.4 ±1.2 (Table1), our study shows a reduction of 75.1% from baseline in topical 0.005% calcipotriol treated group. In the study done by J. BERTH-JONES et.al.after treatment with topical 0.005%calcipotriol, the mean ESIF reduction was 63.8%. The mean ESIF score in topical 0.1% tazarotene group was reduced to 2.15 ± 0.88 which shows a reduction of 76.3%. In the study done by Bijal H Mehta *et al*. 126, after treatment with Tazarotene, the mean ESIF Score reduction was 83.1%. The result of the present study demonstrated that both topical 0.005% calcipotriol and topical tazarotene 0.1% are efficacious in the treatment of palmoplanter psoriassis and that, there is no significant difference between the two treatment groups on the basis of mean reduction in ESIF score.

In the present study, a total of 8 (19.3%) cases of adverse drug reaction were reported in topical 0.005% calcipotriol treated group, while a total of 9 (22.5%) cases of adverse drug reaction were reported in topical 0.1% tazarotene treated group which were mild to moderate in intensity during the 1-2 weeks of therapy and subsided after continuation of the topical therapy in both the group. In the study done by Kaur I *et al*. [10], there is no statistically significant difference in the adverse effect between these two Groups (Table2). These were noted as mild in the form of burning, pruritus, and irritation and were observed more often in the lesions treated with tazarotene (0.1%) as compared to those in the lesions treated with0.005% calcipotriol, but the difference was not statistically significant. However, none of the patients discontinued the therapy because of adverse effect.

Results of this study demonstrated that patients treated with Topical 0.005% Calcipotiol had a substantially lower rate of adverse drug reactions in relations to those treated with topical 0.1%Tazarotene, but tazarotene had a better maintenance effect after the cessation of therapy.

Both topical Calcipotriol and topical tazarotene, used in this study appear to provide an appropriate therapeutic effect in palmoplanter psoriasis. Both of these used drugs had similar adverse effects. A total of 81 patients completed the study out of which, 41 patients in topical Calcipotriol and 40 patients in topical tazarotene group, completed the study. Three patients in topical Calcipotriol group and 4 patients in topical tazarotene group were considered drop outs from the study, on the basis of the analysis set prior to study.

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