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Original Research Article

Comparative study of topical 0.1% tazarotene cream versus calcipotriol 0.005% ointment in the treatment of palmoplantar psoriasis

Kritika Maria Xess[1,*]

[1] *Dept. of Dermatology, Jawaharlal Nehru Medical College and Hospital, Alligarh Muslim University, Aligarh, Uttar Pradesh, India*

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ABSTRACT

Background: Palmoplantar psoriasis is classified into two types based on morphology- hyperkeratotic palmoplantar psoriasis and pustular palmoplantar psoriasis. Hyperkeratotic palmoplantar psoriasis presents with well defined erythematous scaly plaques with overlying hyperkeratosis without the presence of sterile pustules, predominantly at the palms and/or soles. There is greater physical and functional disability in patients of palmoplantar psoriasis. Patients with palmoplantar disease are more likely to suffer from a significant impact on skin-related QoL, have problems with activities of daily living, and rely on topical prescription medications than patients with moderate-to-severe plaque psoriasis. These differences are important while creating therapeutic strategies and in understanding patients' expectations of the treatment. Objective: To compare the clinical efficacy and study the adverse effects of topical 0.1% tazarotene cream and 0.005% calcipotriol ointment in the treatment of palmoplantar psoriasis.

Materials and Methods: A total of 82 palmoplantar psoriasis cases who attended the OPD of a tertiary care hospital in Northern India for a period of two years formed the study group. The study group was randomized into Group A and Group B. Group A participants were instructed to apply a liquid paraffin-based emollient in night, followed by 0.1 % tazarotene cream under occlusion for 12 weeks. Group B patients were instructed to apply calcipotriol ointment 0.005% twice daily on lesions and a liquid-paraffin based emollient in night daily for 12 weeks. The response to treatment was evaluated by improvement in PPPASI at 2-week interval up to 12 weeks.

Results: At 12 weeks of follow-up 42.9% patients showed an excellent response, 31.4% showed a clear response in group A. In group B 25% patients had an excellent response and 10% patients showed complete clearance. Adverse effects were seen more in group A.

Conclusion: Topical treatment modalities for palmoplantar psoriasis are effective and have a low risk for adverse effects. Both topical calcipotriol 0.005% and tazarotene 0.1% cream are effective in the treatment of palmoplantar psoriasis. While topical tazarotene 0.1% cream showed an excellent clinical response among patients, it was associated commonly with adverse effects such as local irritation and itching in initial weeks of the treatment. Usage of topical 0.005% calcipotriol ointment showed a good clinical response among the patients, with mild side effects of local irritation and itching which resolved on subsequent treatment.

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1. Introduction

Palmoplantar psoriasis is classified into two types based on morphology- hyperkeratotic and pustular palmoplantar psoriasis.[1] Hyperkeratotic palmoplantar psoriasis presents with well defined erythematous scaly plaques with overlying hyperkeratosis without the presence of sterile pustules, predominantly at the palms and/or soles. Palmoplantar pustulosis begins as a unilateral eruption of

* *Corresponding author*.
E-mail address: kritika.xess94@gmail.com (K. M. Xess).

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pin-sized sterile yellow pustules followed by development of hyperkeratosis with erythema, scaling, and fissuring. The most common site in the palms is the thenar, hypothenar, and central portion of the palm. Palmoplantar pustulosis resolves with a residual brown pigmentation.[2]

Palmoplantar psoriasis is associated with the HLA Cw6 gene. There may also be possible linkages to variations in the CARD14 gene and genes in the IL-19 subfamily in palmoplantar pustulosis.[3–5] Environmental triggers in palmoplantar psoriasis include smoking, irritants, friction, and manual or repetitive trauma. The pathogenesis of palmoplantar psoriasis is unknown, but the skin's innate immune system has been implicated. The level of neutrophil-attracting chemokine interleukin 8 (IL-8) is increased in palmoplantar psoriasis.[6] The antimicrobial peptide LL-37 upregulates the cytokines IL-1, IL-8, IL-23, and IL-17.[7] Recent studies identified three distinct subtypes of palmoplantar psoriasis subjects with interleukin 36 receptor agonist gene, adaptor related protein complex 1 subunit sigma 3 gene and Caspase recruitment domain family member 14 gene mutations, which upregulated the IL-36 pathway, favouring differentiation of type 17 helper T cells.[8–10]

A greater physical discomfort and functional disability is seen in patients of palmoplantar psoriasis than psoriasis limited to other body areas.[11] Patients with palmoplantar disease are more likely to suffer from a significant impact on skin-related QoL, have problems with activities of daily living, and rely on topical prescription medications than patients with moderate-to-severe plaque psoriasis.[12] These differences are important while creating therapeutic strategies and in understanding patients' expectations of the treatment.

Tazarotene is a Vitamin A derivative, the first of a new generation of acetylenic retinoids indicated for the topical treatment of psoriasis. It selectively binds to β and γ retinoic acid receptors on the cell membrane of keratinocytes and is then transported to the nucleus, altering transcription of genes in keratinocytes.[13] Tazarotene modulates the pathogenesis of psoriasis through three major mechanisms: normalization of abnormal keratinocyte differentiation, reduction in keratinocyte proliferation, and a decrease in the expression of inflammatory markers.[14] Treatment with topical tazarotene induces expression of TIG1, TIG2, TIG3 on psoriatic skin, their upregulation produces an antiproliferative effect. Tazarotene also causes downregulation of the interferon gamma induced expression of MRP-8, TGase-K, and cornifin. The net result of these effects is normalization of the differentiation pattern of the epidermal keratinocytes.[15] The most common side effect of tazarotene is localized irritation and dryness. Short contact period of 30-60 mins helps in alleviating irritation. FDA has issued a caution regarding the use of tazarotene and exposure to sunlight, patients are advised to use sunscreen while using tazarotene, the dosimetry must be lowered to prevent skin burning in patients undergoing phototherapy.[16]

Vitamin D analogues bind to the intracellular Vitamin D receptor which regulate the genes involved in epidermal proliferation, inflammation, and keratinization.[16] Keratinocyte differentiation and proliferation is inhibited by increasing the calcium ion levels with modulation of ki67, PCNA, involucrin, fillagrin and cytokeratin. Additional inflammatory property is exerted by inhibition of IL 2, IL 6, IFN-γ. Calcipotriene is a synthetic Vitamin D analogue available as 0.005% (5mg/g) cream, ointment, and scalp lotion. Although it is as potent as 1, 25 dihydroxycholecalciferols in the regulation of cell proliferation and differentiation, it is at least 200 times less potent in its effect on calcium metabolism.[16] Side effects include localized skin irritation and systemic side effects such as hypercalcemia, hypercalciuria and parathyroid hormone suppression which is rare and occurs only if maximum dose is more than 100g/week for calcipotriene, 210g/week for calcitriol and 70g/week for tacalcitol. Vitamin D analogues are contraindicated in patients with hypercalcemia and renal impairment. It is not teratogenic and equally effective in children; the dose should not exceed 50g/week in children.[16] Studies in the past have compared the effectiveness of topical vitamin D in psoriasis with that of various conventional topical treatment, however any report of studies directly comparing calcipotriol and tazarotene as a monotherapy for palmoplantar psoriasis is not available. Hence, the present study compares topical tazarotene with topical calcipotriol in the treatment of palmoplantar psoriasis.

2. Aims and Objectives

1. To compare the clinical efficacy of topical 0.1% tazarotene cream and 0.005% calcipotriol ointment in the treatment of palmoplantar psoriasis.
2. To study the adverse effects of topical 0.1% tazarotene cream and 0.005% calcipotriol ointment in the treatment of palmoplantar psoriasis.

3. Materials and Methods

82 patients of palmoplantar psoriasis were enrolled in the study, they were randomized equally into two groups, group A and group B. Group A – Once daily application of 0.1 % topical tazarotene cream under occlusion after application of a standard liquid paraffin-based emollient every night for 12 weeks. Group B - Twice daily application of 0.005 % calcipotriol ointment to the affected area and a standard liquid paraffin-based emollient in night daily for 12 weeks.

3.1. Inclusion criteria

Patients of both sexes above 12 years of age**,** and with psoriasis exclusively localized to palms and soles.

3.2. Exclusion criteria

Patients taking any topical therapy except bland emollients two weeks prior to inclusion in the study, those who have been administered with systemic therapy for psoriasis or intralesional therapy or UV radiation for at least two months prior to inclusion in study. Patients with palmoplantar pustulosis. Pregnant and lactating women were excluded from the study.

The patients were assessed after every 2 weeks during the study period. All the patients were photographed at each visit. The response to treatment was evaluated by an improvement in Palmoplantar Psoriasis Area Severity Index Scores (PPPASI) at 2-week interval up to 12 weeks. Investigations such as renal function test, serum calcium and serum phosphate were done at the baseline and at the end of the study period to look for any adverse effect due to topical calcipotriol. The response to treatment was also assessed by the means of Physicians global assessment scale (PGAS). All the immediate and late adverse effects were evaluated after each treatment session.

4. Results

Majority of the patients belonged to the age group 21-30 years (31.7%). The mean age was calculated as 32.6 ± 4.2 years. Majority of patients seeking treatment in this study were students (26.8%) followed by farmers and housewives (19.5%). Most of the patients belonged to urban area 64.6%. Majority with itching (47.5%) followed by erythemato-scaly plaques in 32.9% patients. A total of 35 (42.7%) patients reported baseline PPPASI score of 5-10 followed by 18 (21.9%) patients with a score of 10-15 and 16 (19.5%) patients scored <5. At 12 weeks, 25 (71.4%) patients in group A reported PPPASI score <5 while in group B 15 (37.5%) patients had a PPPASI score <5.A significant difference with reduction in PPPASI score favored group A over group B at 8^{th} *week,*10^{th} *week and* 12^{th} *week* ($p<0.05$). At 4 weeks, majority of patients in group A showed a fair response 22 (44.7%) while in group B 21 (47.7%) patients had a fair response. (p value >0.05). At 8 weeks, maximum number of patients in group A 21(58.3%) showed a good response followed by fair response in 9(25%) patients, excellent response in 3(8.3%) patients and complete clearance in 1 patient (2.8%). In group B majority of the patients had a fair response 22(52.4%) followed by good response in 12(28.5%) and an excellent response in 2 patients (4.8%). (p value <0.05). At 12weeks of follow-up 15(42.9%) patients showed an excellent response, 11(31.4%) showed a clear response in group A. In group B 10 (25.0%) patients had an excellent response, and 4(10%) patients showed a clear response. Group A patients observed a significant improvement in comparison to group B ($p<0.05$) at the end of the study period. Adverse effects such as itching and burning sensation was noted more in group A patients.

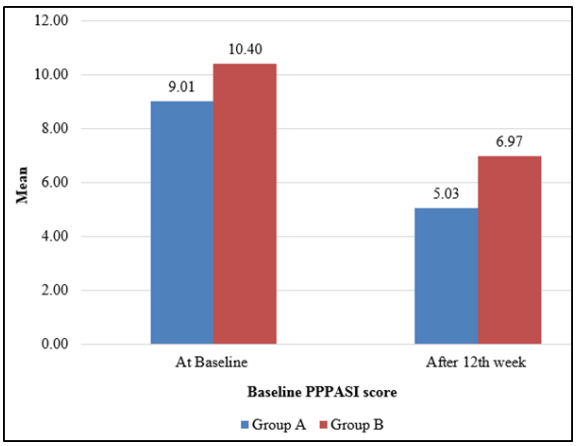

Fig. 1: Association between PPPASI scores of Group A and Group B at Baseline and after 12-week follow-up.

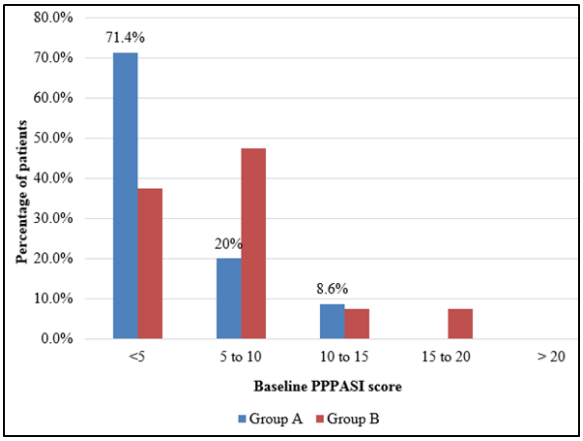

Fig. 2: PPPASI at 12 weeks

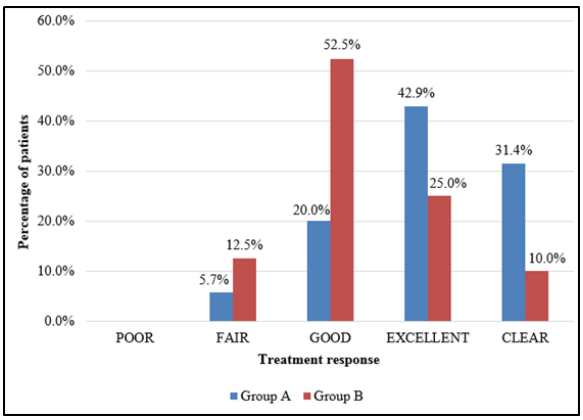

Fig. 3: PGAS at 12 weeks of treatment

Table 1: Baseline PPPASI scores

Baseline PPPASI	Group A		Group B		Total	
	No.	%	No.	%	No.	%
<5	8	21.0%	8	18.2%	16	19.5%
5 to 10	18	47.4%	17	38.6%	35	42.7%
10 to 15	8	21.0%	10	22.7%	18	21.9%
15 to 20	2	5.3%	6	13.6%	8	9.8%
>20	2	5.3%	3	6.8%	5	6.1%
Chi-Square test; p value = 0.732						

Table 2: Association between PPPASI scores of Group A and Group B at Baseline and after 12-week follow-up

PPPASI	Group A	Group B	P value*
At Baseline	9.01±5.32	10.40±5.70	0.262
After 12th week	5.03±3.48	6.97±4.26	0.036

Table 3: PPPASI at 12 weeks

PPPASI at 12 weeks	Group A		Group B		Total	
	No.	%	No.	%	No.	%
<5	25	71.4%	15	37.5%	40	53.3%
5 to 10	7	20.0%	19	47.5%	26	34.7%
10 to 15	3	8.6%	3	7.5%	6	8.0%
15 to 20	0	0.0%	3	7.5%	3	4.0%
20	0	0.0%	0	0.0%	0	0.0%
Chi-Square test; p value = 0.029						

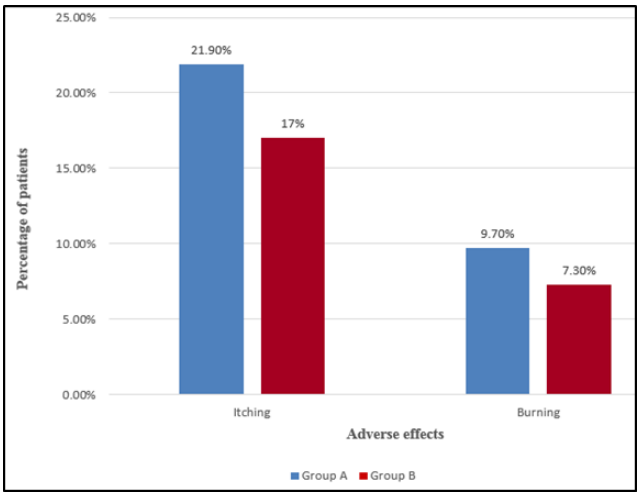

Fig. 4: Adverse effects

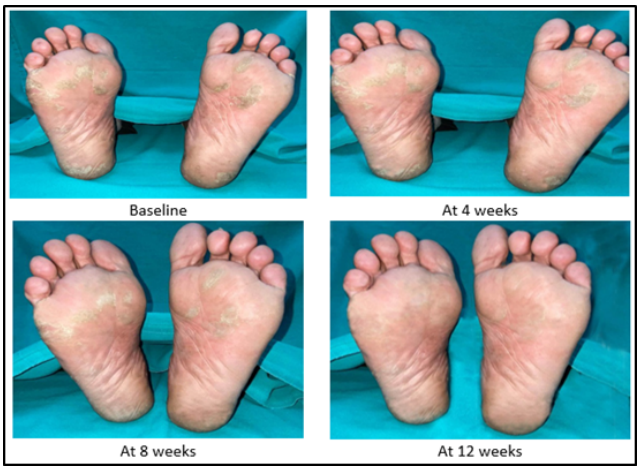

Fig. 5: Group A patients showing 75-99% clearance

5. Discussion

In the present study, mean baseline Palmoplantar Psoriasis Area Severity Index (PPPASI) score for group A was 9.01±5.32 while that for group B was 10.40±5.70, 47.4% and 38.6% of the patients scored between 5-10 (PPPASI score) in group A and group B respectively (Table 1). In a study by Mehta et al.[17] the mean baseline Erythema Scaling Fissuring and Induration (ESFI) score for patients treated with topical tazarotene was 5.69. In a similar study by Kaur et al.[18], the mean baseline Erythema Scaling and Induration (ESI) score was 4.1±1.4 and 3.9±1.2 for patients treated with topical calcipotriol and topical tazarotene cream respectively. In the present study the total number of study participants were 82 in number and PPPASI score was

Table 4: PGAS at 12 weeks of treatment

PGAS at 12 weeks	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Poor (<25%)	0	0.0%	0	0.0%	0	0.0%
Fair (25%-50%)	2	5.7%	5	12.5%	7	9.3%
Good (50-75%)	7	20.0%	21	52.5%	28	37.4%
Excellent (75-99%)	15	42.9%	10	25.0%	25	33.3%
Clear (100%)	11	31.4%	4	10.0%	15	20.0%
Chi-Square test; p value = 0.015						

Table 5: Adverse effects

Adverse Effects	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Itching	9	21.9%	7	17.0%	16	19.5%
Burning	4	9.7%	3	7.3%	7	8.5%
Chi-Square test; p value = 0.015						

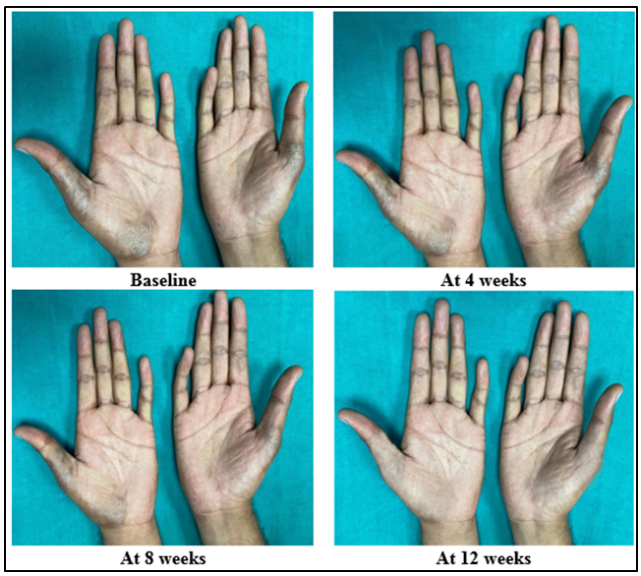

Fig. 6: Group B patients showing 75 to 99% clearance

used for evaluation of patients in contrast to the above studies by Mehta et al.[17] and Kaur et al.[18] where sample size was 17 and a different scoring system was used for evaluation of the patients, hence mean baseline scores were higher in our study. At 4 weeks of treatment, the mean reduction in PPPASI score from the baseline was 7.99±4.88 in group A (30%) and 9.10±5.25 (28.9%) in group B (p value=0.326). Mehta et al.[17] reported reduction in mean ESFI score from the baseline to 4.59 (31%) in tazarotene group (p value =0.029) at 4 weeks. Similarly in a study by Kaur et al.,[18] both calcipotriol and tazarotene treated lesions showed similar reduction in the ESI scores from 4.1±1.4 to 2.1 ±0.3 in calcipotriol group and 3.9 ±1.2 to 2.4 ±0.4 in tazarotene group at 4 weeks, but there was no statistically significant change in the ESI score of both groups as compared to the baseline (p >0.5). The findings of the above studies are consistent with the present study. At 8 weeks of treatment the mean PPPASI scores reduced to 5.65±3.83 and 7.82±4.92 in group A (73%) and group B (70%) respectively (p value =0.033), the reduction in mean PPPASI score was significantly more in the lesions treated with topical tazarotene (Table 2, Figure 2). In a study conducted by Kaur et al.,[18] a reduction in mean ESI scores in both groups was similar and comparable in lesions treated with either calcipotriol (77%) or 0.1 percent tazarotene (75%) (p value <0.005). Guenther et al.[19] revealed marked reduction in ESI score in the tazarotene plus mometasone furoate group (76%) as compared to the calcipotriol group (58%), but there was no statistically significant difference between both the groups (p >0.5). The disparity in the present study, when compared to the results of the above studies is perhaps due to combination therapy used in their studies. At the 12 weeks of the study period, the mean PPPASI scores reduced from 9.01±5.32 to 5.03±3.48 in group A (81.6%) and from 10.40±5.70 to 6.97±4.26 (78.3%) in group B (p =0.036) (Tables 2 and 3Figure 2). The reduction in mean PPPASI score was significantly more in tazarotene group than calcipotriol group. Mehta et al.[17], noted a reduction in mean ESFI score in tazarotene group from 6.65 to 1.12 (83.2%) (p value = 0.019) at the end of the study period. The reduction in mean ESFI score was statistically significant in tazarotene group at 8 weeks, 10 weeks and 12 weeks which could be correlated to the findings of the present study. While at the end of the study, Kaur et al.[18] observed a reduction in mean ESI score from 4.1 ±1.1 to 0.81 ±0.3 in calcipotriol group (77%) and 3.9±1.2 to 1.6 ±0.7 (82.1%) (p value > 0.5) in tazarotene group. The decline in ESI score was comparable in the lesions treated with topical calcipotriol or topical tazarotene in their study. This could be attributed to the usage of 0.05% topical tazarotene in contrast to 0.1% topical tazarotene in our study, as 0.1 % formulation has

an enhanced efficacy over 0.05% formulation. Hence, our patients achieved better clinical improvement. Physician Global Assessment Score (PGAS) at 4 weeks of treatment showed a fair response in 44.7% and 43.2 % of the patients in group A and group B. The findings could be correlated to the study by Mehta et al.[17] where relative majority of the patients showed a fair response in (35.29%) tazarotene group and (33.4%) in calcipotriol group. At 8 weeks of treatment, maximum patients (58.3%) had a good response in PGAS, and 52.4% patients had a fair response in Group B. Group A patients showed a statistically significant better improvement than group B ($p < 0.05$). Similar to the findings by Mehta et al.[17] where at 8 weeks, patients treated with tazarotene showed a good response which was statistically significant (p value <0.05) than the calcipotriol group. At 12 weeks of treatment, PGAS showed an excellent response in 42.9% of patients in group A while 25% had an excellent response in group B. Therefore, in the present study topical tazarotene was found to be superior to topical calcipotriol in improvement in PGAS score (p value=0.015) (Table 4, Figure 3). These findings were almost similar to a study on palmoplantar psoriasis by Guenther et al.[19] in which 82% patients achieved excellent improvement with >75% clearance in tazarotene plus corticosteroid group in comparison to calcipotriol group where 76% of the patients had >75% clearance. In contrary to the findings in the present study, Tzung et al.[20] revealed excellent improvement in equal number of patients in both tazarotene (42%) and calcipotriol group (44%) respectively at the end of 12 weeks treatment period. The disparity in the study findings could be explained by the fact that they used topical gel formulation of tazarotene in their study which is less potent than the topical cream formulation used in our study. In the present study adverse effects such as itching and burning were noted more in patients treated with topical tazarotene than those treated with calcipotriol. The adverse effect of itching (21.9%) and burning sensation (9.7%) was noted more commonly in initial 4 weeks of treatment with tazarotene (Table 4, Figure 4). While 17% and 7.3% patients noted itching and burning sensation with calcipotriol in initial 4 weeks (Table 4, Figure 4). In a study by Mehta et al.[17] 23.5% of patients treated with tazarotene developed itching in initial 4 weeks, similar to the present study. Likewise, Tzung et al.[20] also reported predominance of adverse effects such as pruritus (32%) and local irritation (28%) in patients treated with topical tazarotene than in patients treated with calcipotriol.

6. Conclusion

Palmoplantar psoriasis is also a chronic form of psoriasis with frequent exacerbation, difficulty in management and resistance to therapy. The search for effective topical treatment in palmoplantar psoriasis has been significantly more difficult than the other forms of psoriasis. There are various modalities of treatment in the form of topical, systemic, and phototherapy for palmoplantar psoriasis, many of them have side effects and require combination therapy and strict adherence to treatment. Topical treatment modalities for palmoplantar psoriasis are effective and have a low risk for adverse effects. Topical corticosteroid ointments are preferred as first line, but their long-term usage can lead to atrophy of skin, telangiectasias and tachyphylaxis. Topical therapy with retinoids and vitamin D analogues is devoid of the side effects caused by topical corticosteroids. So far, efficacy of tazarotene cream and calcipotriol ointment has been compared with that of moderate and high potency steroids in chronic plaque psoriasis. However, after extensive research we could not find any study comparing the clinical efficacy of topical tazarotene and topical calcipotriol as a monotherapy in palmoplantar psoriasis. Based on the results obtained in our study, both topical calcipotriol 0.005% and tazarotene 0.1% cream is effective in the treatment of palmoplantar psoriasis. While topical tazarotene 0.1% cream showed an excellent clinical response among patients, it was associated commonly with adverse effects such as local irritation and itching in initial weeks of the treatment. Usage of topical 0.005% calcipotriol ointment showed a good clinical response among the patients, with mild side effects of local irritation and itching which resolved on subsequent treatment. Both topical tazarotene and topical calcipotriol are cosmetically acceptable. More studies on a larger sample and of longer duration of follow-up comparing the efficacy of both modalities are required to demonstrate their effectiveness in the treatment of palmoplantar psoriasis.

7. Source of Funding

None.

8. Conflicts of Interest

There are no conflicts of interest.

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Author biography

Kritika Maria Xess, Resident

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