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Original Research Article

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 treatments are the initial therapeutic option among individuals with palmoplanter psoriasis that affects both the palms and soles. Despite being used for over a decade, there are no reports of research directly comparing the effectiveness of calcipotriol with tazarotene.

Aim: The objective is to assess the relative effectiveness and safety of calcipotriol and tazarotene for treating palmoplantar psoriasis.

Methodology: This study was an observational, open-level, comparative study with two groups. It was conducted over a period of 12 weeks, with follow-up visits every 4 weeks. Group A consisted of 40 patients who administered calcipotriol 0.005% ointment twice daily, whereas Group B consisted of 40 patients who applied tazarotene 0.1% ointment once daily. The effectiveness of the treatment was evaluated by assessing the severity of psoriatic lesions using the ESIF score, which measures erythema, scaling, fissuring, and infiltration on a scale from 0 to 3. The evaluation was conducted at the beginning of the therapy (0 week), as well as after 4 weeks, 8 weeks, and 12 weeks into the treatment. After 12 weeks, the reduction in the ESIF score was compared between patients in both groups. The safety of this trial was assessed by comparing the incidence of adverse medication reactions in each group.

Results: A total of forty-one patients in group A, also known as the Calcipotriol group, successfully finished the research. The group of patients treated with topical calcipotriol showed a substantial reduction in ESI score after 12 weeks, resulting in a moderate-to-marked improvement ($P < 0.0001$). Lesions treated with calcipotriol in group B (Tazarotene group) showed similar improvement to those treated with 0.1% tazarotene after 12 weeks of topical therapy. The detected adverse effects, including burning, pruritus, and irritation, were modest. These symptoms were more frequently observed in the lesions treated with tazarotene compared to those treated with calcipotriol. However, the difference in occurrence between the two treatments was not statistically significant. Nevertheless, no patients discontinued the therapy due to adverse effects.

Conclusion: Overall, both topical 0.005% Calcipotriol and topical 0.1% Tazarotene are effective in treating palmoplanter with similar safety profiles.

Keywords: Efficacy, Safety, Calcipotriol, Palmoplanter Psoriasis, Tazarotene.

Introduction

Psoriasis is a prevalent skin condition characterised by inflammation and excessive skin cell growth. It is caused by hereditary factors and affects around 1% to 3% of the global population. [1] Palmoplantar psoriasis (PPP) is a specific clinical subtype of psoriasis that affects the palms and soles.

PPP impacts around 14% of those who have been diagnosed with psoriasis. [2] While a cure for the condition is not now available, it can be effectively managed through a range of treatment alternatives, either taken alone or in combination. [3,4] Topical treatments are the initial therapeutic option for people with palmoplanter psoriasis that affects both the palms and soles. Calcipotriol and tazarotene are topical treatments that have been used for over a decade to treat palmoplantar psoriasis. Although studies have been conducted to compare the effectiveness of calcipotriol and tazarotene with standard topical treatments (such as coal tar, topical steroids, and anthralin) for palmoplanter psoriasis, no direct comparisons have been found between calcipotriol and tazarotene used as standalone treatments. [4-8]

Aim and objectives: The objective of this study was to assess the relative effectiveness and safety of these two treatments for palmoplanter psoriasis.

Material and Methods

A total of 81 patients, consisting of 38 males and 43 females, with an average age of 45.45± 7.97 years (ranging from 20 to 70 years), were selected for the study. These patients had almost symmetrical lesions of palmoplanter psoriasis (PPP) on their limbs. This study was a 12-week long prospective interindividual, observational comparative groups study. It compared the effects of applying calcipotriol 0.005% ointment twice daily vs applying tazarotene 0.1% gel once daily. The study included two groups, each consisting of 40 patients. Group A administered calcipotriol 0.005% ointment twice daily on the psoriatic lesions on their palms and soles. In contrast, Group B applied Tazarotene 0.1% once daily at bedtime, which was the same frequency as the application of 0.005% calcipotriol. Except for antihistamines, all previous drugs were discontinued 4 weeks before to the commencement of the trial. The only allowed treatment on both sides was the application of an emollient, namely coconut oil. Measurement of serum calcium and phosphate levels was conducted both before and after the treatment. The examination and monitoring of psoriatic lesions during therapy were conducted using the erythema, scaling, induration, and fissuring (ESIF) score. The efficacy was assessed by evaluating target psoriatic lesions using the ESIF score, a point-based severity scale ranging from 0 to 12, which measures erythema, scaling, and infiltration. Individuals without any disease received a score of 0, while those with a severe condition received a score of 12. The evaluation was conducted at the beginning of the therapy (0 week) and again at 4 and 8 weeks into the treatment. The statistical comparison of scores was conducted using both paired and unpaired t-tests to compare quantitative values. Patients who experienced a decrease of more than 75% in ESIF score after 12 weeks were classified as having remarkable improvement. Those with a reduction of 51% to 75% were regarded to have moderate improvement, while those with a reduction of 26% to 50% were classified as having modest improvement. Patients with a reduction of less than 25% were judged to have no response.

Observation and Results

The trial was completed by all patients, with 41 in group A and 40 in group B. The lesions treated with calcipotriol in group A showed a considerably greater reduction in ESIF score at 12 weeks, leading to a noticeable improvement (P< 0.0001). [Table 1] After 12 weeks, all 41 patients who received calcipotriol treatment saw a reduction of more than 75% in their ESIF score, with 11 showing moderate improvement and 30 showing notable improvement. After 12 weeks of therapy, all patients in group B who received topical 0.1% tazarotene demonstrated a comparable decrease in scaling and infiltration of the lesions. The calcipotriol treatment resulted in a greater reduction in erythema compared to the other treatment. However, there was no statistically significant difference in the ESIF score between the two groups when compared to the initial score (P≤ 0.0001). After 12 weeks, the ESIF score decrease in this group exceeded 76%, which is similar to the reduction observed in lesions treated with calcipotriol in group B. [Table 1] additionally, all patients exhibited significant recovery at the end of 12 weeks. [Table 2] Mild adverse effects, such as burning, itching, and irritation, were detected more frequently in the lesions treated with tazarotene (0.1%) compared to those treated with calcipotriol. However, this difference was not statistically significant. Nevertheless, no individuals ceased the therapy due to undesirable consequences.

Table 1: Comparison 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)	
	N	%	N	%
Itching	3	7.3	2	5
Irritation	2	4.8	3	7.5
Burning Sensation	2	4.8	3	7.5
Hyperpigmentation	1	2.4	1	2.5
Total	8	19.3	9	22.5

Discussion

This research aimed to assess the effectiveness of topical 0.05% calcipotriol compared to topical 0.1% tazarotene as a single treatment for individuals with palmoplantar psoriasis. This study distinguishes itself from the prior research

conducted by Bijal H Mehta et al. [9] (with a male-female ratio of 63% to 37%) and Kaur I et al. [10] (with a male-female ratio of 60% to 40%). The mean reduction in ESIF score from baseline to the 12th week was compared across both treatment groups. Both therapy groups achieved significant reductions in the ESIF score throughout the research period.

The average ESIF score at the beginning of the study in the group using topical calcipotriol was 9.29 ±1.29. The ESIF score at baseline in the tazarotene group was 9.17 ± 1.4, which was not statistically significant (p value = 0.352). This was similar to the score in the other group. The results obtained in the present investigation differed from those reported by J. BERTH-JONES et al. [11] for the group treated with calcipotriol. The baseline PASI score for this group was 9.4 ±0.69 on a scale of 72 points. Following treatment, the average ESIF score in the group treated with topical 0.005% calcipotriol was decreased to 2.4 ±1.2 (Table 1). Our study demonstrates a reduction of 75.1% from the initial value in the group treated with topical 0.005% calcipotriol.

The research conducted by J. BERTH-JONES et.al.[11] revealed that after applying topical 0.005% calcipotriol, there was an average reduction of 63.8% in ESIF. The average ESIF score in the group using topical 0.1% tazarotene was decreased to 2.15 ± 0.88, indicating a reduction of 76.3%. In the research conducted by Bijal H Mehta et al.[9], it was shown that the use of Tazarotene resulted in an average reduction of 83.1% in the ESIF Score. The findings of this study indicate that both topical 0.005% calcipotriol and topical tazarotene 0.1% are effective in treating palmoplanter psoriasis. Furthermore, there is no significant distinction between the two treatment groups in terms of the average reduction in ESIF score.

The study found that out of the participants treated with topical 0.005% calcipotriol, 8 cases (19.3%) of adverse drug reactions were reported. Similarly, in the group treated with topical 0.1% tazarotene, 9 cases (22.5%) of adverse drug reactions were reported. These reactions were of mild to moderate intensity and occurred during the first 1-2 weeks of therapy. However, they subsided after the participants continued with the topical therapy in both groups. The study conducted by Kaur I et al. [10] found no statistically significant difference in the occurrence of adverse effects between the two groups, as shown in Table 2. The detected side effects, including burning, itching, and irritation, were classified as minor. These effects were more frequently observed in the lesions treated with tazarotene (0.1%) compared to those treated with calcipotriol (0.005%). However, it is important to note that this difference was not statistically significant. Nevertheless, no individuals ceased the therapy due to undesirable effects. The study showed that patients who received treatment with Topical 0.005% Calcipotiol had a significantly reduced incidence of adverse medication responses compared to those treated with topical 0.1% Tazarotene. However, Tazarotene had a more effective maintenance effect after the treatment was stopped. Both topical Calcipotriol and topical tazarotene, utilised in this investigation, seem to yield a suitable treatment outcome in palmoplanter psoriasis.

Both of these used medications shown comparable negative consequences. Out of the entire number of patients, 81 successfully finished the research, including 41 patients in the topical Calcipotriol group and 40 patients in the topical tazarotene group. Three patients in the group using topical Calcipotriol and four patients in the group using topical tazarotene were excluded from the trial based on the analysis set before the study.

Conclusion

To summarise, both topical 0.005% Calcipotriol and topical 0.1% Tazarotene are effective in treating palmoplanter with similar safety profiles. The use of topical 0.005% calcipotriol ointment resulted in a positive clinical outcome for the patients, with minimal side effects of localised irritation and itching that were addressed with further therapy. Both calcipotriol and tazarotene are considered to be aesthetically pleasing, but, there is a significant disparity in cost, particularly in settings with limited resources. Nevertheless, the primary constraint of this experiment is the limited number of participants, and it is imperative to carry out a more extensive investigation in a manner where the participants and researchers are unaware of the treatment assignments.

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