

COMPARISON OF EFFICACY OF TAZAROTENE/BETAMETHASONE VERSUS
CALCIPOTRIOL/BETAMETHASONE IN PATIENTS WITH MILD TO MODERATE PLAQUE PSORIASIS

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Abstract: Plaque psoriasis is a chronic inflammatory skin disorder that significantly impacts patients' quality of life. Combination therapies, such as Tazarotene/Betamethasone and Calcipotriol/Betamethasone, are widely used for its management. Evaluating the efficacy of these combination therapies is essential for optimizing treatment outcomes. **Objective:** To evaluate the efficacy of Tazarotene/Betamethasone compared to Calcipotriol/Betamethasone in patients with mild to moderate plaque psoriasis. **Methods:** Following ethical committee approval, this randomized comparative study was conducted in the Department of Dermatology, PIMS, Islamabad, from January 2024 to June 2024. One hundred seventy patients with mild to moderate plaque psoriasis were enrolled and randomly assigned to two groups. Group A received Tazarotene 0.045% cream combined with Betamethasone dipropionate 0.05% ointment, while Group B was treated with Calcipotriol 0.005% combined with Betamethasone dipropionate 0.05% ointment. Both therapies were applied once daily for 12 weeks. The treatment response was assessed by evaluating changes in the Psoriasis Area and Severity Index (PASI) scores and Body Surface Area (BSA) affected. Data were analyzed using SPSS Version 26, and comparisons between the groups were made using t-tests, with significance set at $p < 0.05$. **Results:** The mean age of participants was 39.52 ± 11.07 years. In Group A, 35.3% were male and 64.7% were female, while in Group B, 41.2% were male and 58.8% were female. Baseline PASI scores and BSA affected were comparable between the groups. After 12 weeks, Group A showed a more significant reduction in PASI scores (4.72 ± 1.01 vs. 5.20 ± 0.93 , $p=0.00$) and BSA affected ($3.49 \pm 0.86\%$ vs. $4.21 \pm 0.86\%$, $p=0.00$) compared to Group B. **Conclusion:** Both combination therapies resulted in significant improvements in PASI scores and reductions in BSA affected. However, Tazarotene/Betamethasone was more effective than Calcipotriol/Betamethasone, likely due to the keratolytic properties of Tazarotene. These findings suggest that Tazarotene/Betamethasone may offer superior efficacy in managing mild to moderate plaque psoriasis.

Keywords: Plaque psoriasis, Calcipotriol, Tazarotene, PASI scores.

Introduction

Plaque psoriasis is a chronic inflammatory skin condition characterized by well-defined, scaly plaques. (1) It affects approximately 2-3% of the global population and can significantly impact the quality of life. (2, 3) Psoriasis affects males and females at similar rates, showing no significant gender preference. (4) However, the prevalence of psoriasis varies widely across different populations and regions, ranging from as low as 0.1 percent to as high as 11.8%. (5) These variations in prevalence can be influenced by factors such as genetics, environmental conditions, and healthcare access, highlighting psoriasis's diverse impact on global populations. Psoriasis is a chronic skin condition that can emerge at virtually any stage of life, although it is exceptionally uncommon in children under the age of 10 years. (6) The onset of psoriasis is most frequently observed between the ages of 15 and 30 years, when the immune system and environmental factors may interact to trigger the condition. (7) The clinical presentation of psoriasis varies widely from one individual to another, particularly in terms of the extent of body surface area (BSA) involved. (8) approximately 80% of psoriasis remains a limited disease for most patients, affecting less than 2% of the total BSA. (9) These cases might involve small, localized patches of scaly, inflamed skin that, while bothersome, are more manageable with topical treatments. On the other hand, about 20% of patients experience a more severe form of the

disease, with psoriasis covering more significant portions of the body. (5, 9) In these cases, the skin involvement is more extensive, often requiring systemic treatments and presenting more significant challenges in management. This wide range of severity highlights the complexity of psoriasis, not just in terms of physical symptoms but also in its impact on quality of life. The diverse nature of the disease necessitates personalized treatment plans that consider the severity, location of lesions, and the patient's overall health and lifestyle. Understanding the individual variability in psoriasis is crucial for healthcare providers to optimize treatment outcomes and improve the quality of life for those affected by this chronic condition.

Numerous treatment strategies have been developed for managing psoriasis, each tailored to address the varying severity and symptoms of the condition. (10) Among the options available, topical treatments play a central role, with combination therapies like Tazarotene/Betamethasone and Calcipotriol/Betamethasone standing out for their proven effectiveness and favorable safety profiles. These combination therapies have become increasingly popular as frontline treatments, particularly for patients with mild to moderate plaque psoriasis. The present study aims to provide a comparative analysis of the efficacy of these two widely used topical combinations, highlighting their respective strengths in managing this chronic skin disorder.

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Objective: To evaluate the efficacy of the combination therapy of Tazarotene/Betamethasone compared to Calcipotriol/Betamethasone in patients with mild to moderate plaque psoriasis.

Methodology

Following approval from the hospital's ethical committee, this randomized controlled trial was conducted in the Department of Dermatology at PIMS, Islamabad, between January 2024 and June 2024. The study enrolled 170 patients diagnosed with mild to moderate plaque psoriasis who met the predetermined inclusion criteria. Participants were between 18 and 60 years old, with a Psoriasis Area and Severity Index (PASI) score ranging from 3 to 10. Patients were randomly assigned to two treatment groups. Group A received Tazarotene 0.045% cream in combination with Betamethasone dipropionate 0.05% ointment, while Group B was treated with Calcipotriol 0.005% in combination with Betamethasone dipropionate 0.05% ointment. Both treatments were applied topically once daily for 12 weeks.

Patients were regularly monitored during the trial, and their responses to the treatments were assessed through clinical evaluations at designated intervals. Patients who had used topical treatments such as corticosteroids, vitamin D analogs, or retinoids within two weeks prior to enrollment, those with severe plaque psoriasis, or those with a history of hypersensitivity to the study medications were excluded. Additional exclusions included patients with comorbidities such as diabetes and hypertension, as well as pregnant or

breastfeeding women. Statistical analyses were performed using SPSS Version 26 to evaluate treatment efficacy and compare the outcomes between the two groups over the 12 weeks.

Results

The mean age of all enrolled patients was 39.52±11.07 years. The mean age in Group A was 39.27±11.26 years, while in Group B, it was 39.77±10.94 years. In terms of gender distribution, Group A had 30 males (35.3%) and 55 females (64.7%), whereas Group B had 35 males (41.2%) and 50 females (58.8%). When categorized by age groups, 25.9% of Group A and 22.4% of Group B were between 18-30 years, 21.2% of Group A and 24.7% of Group B were between 31-40 years, 31.8% of Group A and 30.6% of Group B were between 41-50 years, and 21.2% of Group A and 22.4% of Group B were over 50 years old.

At baseline, the mean PASI score for Group A was 7.85±1.49, and for Group B was 8.09±1.32, with a p-value of 0.27, indicating no significant difference between the groups. The Body Surface Area (BSA) affected was 6.40±1.09% for Group A and 6.56±1.07% for Group B, with a p-value of 0.32, also showing no significant difference. After 12 weeks of treatment, the PASI score significantly decreased in both groups, with Group A at 4.72±1.01 and Group B at 5.20±0.93, yielding a p-value of 0.00, indicating a statistically significant difference in favor of Group A. Similarly, the BSA reduced to 3.49±0.86% in Group A and 4.21±0.86% in Group B, with a p-value of 0.00, showing a significant improvement in Group A compared to Group B.

Table 1: Mean age of all enrolled patients (n=190)

Variables	Mean±SD
Age (Years)	39.52±11.07

Table 2: Demographic Characteristics of Both Groups of Patients

	Groups	
	Groups A	Groups B
Age (Years)	39.27±11.26	39.77±10.94
Gender		
Male	30(35.3%)	35(41.2%)
Female	55(64.7%)	50(58.8%)
Age groups		
18-30 years	22(25.9%)	19(22.4%)
31-40 years	18(21.2%)	21(24.7%)
41-50 years	27(31.8)	26(30.6%)
>50 years	18(21.2%)	19(22.4%)

Table 3: Characteristics of both group patients before and after treatment.

	Groups		
	Groups A	Groups B	p-value
Baseline PASI Score	7.85±1.49	8.09±1.32	0.27
Body Surface Area (BSA, %)	6.40±1.09	6.56±1.07	0.32
After 12 weeks of treatment			
PASI Score	4.72±1.01	5.20±0.93	0.00
Body Surface Area (BSA, %)	3.49±0.86	4.21±0.86	0.00

[Citation: Amin, S., Khan, M.R., Saleem, M., Khan, A., Mushtaq, F., (2024). Comparison of efficacy of tazarotene/betamethasone versus calcipotriol/betamethasone in patients with mild to moderate plaque psoriasis. *Biol. Clin. Sci. Res. J.*, 2024: 1088. doi: <https://doi.org/10.54112/bcsrj.v2024i1.1088>]

Discussion

The comparison between Tazarotene/Betamethasone and Calcipotriol/Betamethasone in treating mild to moderate plaque psoriasis offers essential insights into the effectiveness of these two popular combination therapies. Both treatments have shown significant improvements in Psoriasis Area and Severity Index (PASI) scores and reductions in the body surface area (BSA) affected by psoriasis, highlighting their efficacy in managing this condition.

In the present study, after 12 weeks of treatment, the reduction in PASI scores and BSA in both groups highlights the effectiveness of these therapies, but with a clear advantage for Group A. The PASI score in Group A dropped to 4.72 ± 1.01 , while in Group B, it decreased to 5.20 ± 0.93 . The p-value of 0.00 indicates a statistically significant difference between the two groups, favoring Group A. This suggests that the combination therapy used in Group A may offer superior efficacy in reducing the severity of psoriasis compared to the treatment in Group B. The BSA affected by psoriasis also showed a more pronounced reduction in Group A, decreasing to $3.49 \pm 0.86\%$, compared to $4.21 \pm 0.86\%$ in Group B. Again, the p-value of 0.00 confirms that this difference is statistically significant. This outcome is consistent with findings from other studies showing the superior efficacy of certain combination therapies in reducing PASI scores and BSA in patients with plaque psoriasis. These findings are particularly relevant when considering the clinical management of psoriasis, as the PASI score is a critical measure of treatment effectiveness, encompassing both the severity and extent of the disease. The more significant reduction in BSA in Group A also suggests that the treatment regimen may be more effective in clearing psoriatic lesions from more significant areas of the skin, a critical consideration in improving patient outcomes.

The present study described that both combinations are highly effective in treating mild to moderate plaque psoriasis, with significant improvements in PASI scores. However, Tazarotene/Betamethasone may be more effective in patients with thicker plaques and more pronounced hyperkeratosis due to Tazarotene's keratolytic properties. (11) Patient preference is essential in the long-term management of psoriasis. (12, 13) While some patients may favor the quicker onset of action offered by Calcipotriol/Betamethasone, (14) others might benefit more from the deeper penetration and keratolytic effects of Tazarotene/Betamethasone. Selecting between these therapies should be personalized, considering the patient's needs, the characteristics of the plaques, and their tolerance to the treatment.

The present study reveals that the Tazarotene/Betamethasone combination therapy yielded a more significant reduction in PASI scores compared to Calcipotriol/Betamethasone after 12 weeks of treatment. This suggests that Tazarotene/Betamethasone may be more effective in reducing the severity of psoriasis lesions. The higher efficacy of Tazarotene could be attributed to its mechanism of action, which involves retinoid activity that modulates cell proliferation and differentiation, thereby effectively reducing plaque formation and inflammation. (15, 16) Patients receiving this combination also showed a more significant decrease in BSA affected, indicating its

superior ability to clear more significant areas of psoriatic skin.

Psoriasis most commonly begins between the ages of 15 and 30, when interactions between the immune system and environmental factors are likely to trigger the condition. The mean age of all enrolled patients in the study was 39.52 ± 11.07 years, indicating that the population primarily consisted of middle-aged adults. This mean age aligns well with the typical age range for the onset and management of mild to moderate plaque psoriasis, which often emerges in adulthood. The present study was supported by the study conducted by Humaira Afreen et al.(5)

Conclusion

It was concluded that both combination therapies demonstrated significant effectiveness in improving PPASI scores and reducing BSA affected by psoriasis. However, Tazarotene/Betamethasone showed a statistically significant greater reduction in both PASI scores and BSA compared to Calcipotriol/Betamethasone. This suggests that Tazarotene/Betamethasone may be more effective for patients with plaques due to the keratolytic properties of Tazarotene.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate.

Approved by the department concerned. (IRB-PMIS-0139/22)

Consent for publication

Approved

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Not applicable

Conflict of interest

The authors declared an absence of conflict of interest.

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Concept & Design of Study

References

1. Bélanger A, de Oliveira CP, Maheux M, Pouliot R. Plaque psoriasis: understanding risk factors of this inflammatory skin pathology. *Journal of Cosmetics, Dermatological Sciences and Applications*. 2016;6(02):67.

2. Nabieva K, Vender R. Quality of life and body region affected by psoriasis: a systematic review. *Actas dermo-sifiliograficas*. 2023;114(1):33-8.
3. Bhosle MJ, Kulkarni A, Feldman SR, Balkrishnan R. Quality of life in patients with psoriasis. *Health and quality of life outcomes*. 2006;4:1-7.
4. Lesuis N, Befrits R, Nyberg F, van Vollenhoven RF. Gender and the treatment of immune-mediated chronic inflammatory diseases: rheumatoid arthritis, inflammatory bowel disease, and psoriasis: an observational study. *BMC medicine*. 2012;10:1-9.
5. Afreen H, Islam AS, Alam MN, Afroz F, Sultana T. A comparative study of once daily tazarotene versus combination of tazarotene and betamethasone valerate in the treatment of plaque psoriasis. *Journal of Pakistan Association of Dermatologists*. 2019;29(1):93-100.
6. Kuchekar AB, Pujari RR, Kuchekar SB, Dhole SN, Mule PM, Vidyapeeth B, et al. Psoriasis: A comprehensive review. *Int J Pharm Life Sci*. 2011;2(6):857-77.
7. Goldsmith LA, Fitzpatrick TB, Katz SI, Gilchrist BA, Paller AS, Leffell DJ, et al. *Fitzpatrick's dermatology in general medicine*. (No Title). 2012.
8. Henseler T, Schmitt-Rau K. A comparison between BSA, PASI, PLASI and SAPASI as measures of disease severity and improvement by therapy in patients with psoriasis. *International journal of dermatology*. 2008;47(10):1019-23.
9. Gelfand JM, Feldman SR, Stern RS, Thomas J, Rolstad T, Margolis DJ. Determinants of quality of life in patients with psoriasis: a study from the US population. *Journal of the American Academy of Dermatology*. 2004;51(5):704-8.
10. Mrowietz U, Steinz K, Gerdes S. Psoriasis: to treat or to manage? *Experimental dermatology*. 2014;23(10):705-9.
11. Chen Y, Yi M, Pang X, Du M, Chen H, Li Z. Effects of secukinumab combined with tretinoin on metabolism, liver enzymes, and inflammatory factors in patients with moderate to severe psoriasis vulgaris. *Advances in Dermatology and Allergology/Postępy Dermatologii i Alergologii*. 2024;41(1):113-20.
12. Tada Y, Ishii K, Kimura J, Hanada K, Kawaguchi I. Patient preference for biologic treatments of psoriasis in Japan. *The Journal of dermatology*. 2019;46(6):466-77.
13. Schaarschmidt ML, Umar N, Schmieder A, Terris D, Goebeler M, Goerdts S, et al. Patient preferences for psoriasis treatments: impact of treatment experience. *Journal of the European Academy of Dermatology and Venereology*. 2013;27(2):187-98.
14. Navarro-Triviño FJ, Lozano-Lozano M, Ruiz-Villaverde R. Calcipotriol/betamethasone dipropionate aerosol foam for plaque psoriasis: a prospective, observational, non-interventional, single-center study of patient adherence and satisfaction in daily use. *Dermatology Practical & Conceptual*. 2021;11(3).
15. Norris DA. Mechanisms of action of topical therapies and the rationale for combination therapy. *Journal of the American Academy of Dermatology*. 2005;53(1):S17-S25.
16. Heath MS, Sahni DR, Curry ZA, Feldman SR. Pharmacokinetics of tazarotene and acitretin in psoriasis. *Expert opinion on drug metabolism & toxicology*. 2018;14(9):919-27.



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