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Original Article

Comparison of the Efficacy of Tazarotene 0.045% versus Halobetasol Propionate 0.01% Lotion for the Treatment of Scalp Psoriasis at Tertiary Care Hospital, Karachi

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ABSTRACT

Background: Psoriasis is a chronic, genetically determined inflammatory skin condition characterized by erythematous plaques with silvery scales, affecting about 2% of the global population. It significantly impacts patients' quality of life, encompassing physical, emotional, and psychosocial dimensions. While the use of topical corticosteroids (TCS) with tazarotene has shown benefits in plaque psoriasis treatment, limited data are available on the efficacy of combining halobetasol and tazarotene.

Objective: This study aimed to compare the efficacy of Tazarotene 0.045% cream (TAZ) versus Halobetasol Propionate 0.01% lotion (HP) for the treatment of scalp psoriasis at a tertiary care hospital in Karachi, providing insight into their comparative effectiveness and informing clinical decision-making.

Methods: A randomized control trial was conducted at the Dermatology Department of Jinnah Postgraduate Medical Centre, Karachi, from August 2022 to February 2023. Ninety participants with scalp psoriasis were recruited and randomly assigned to two groups: Group A (n=45) received Tazarotene 0.045% cream, and Group B (n=45) received Halobetasol Propionate 0.01% lotion, both applied once daily for 6 weeks. The primary outcome was the change in Investigator's Global Assessment (IGA) score from baseline to week 6. Data analysis was performed using SPSS version 25, focusing on descriptive statistics and inferential analyses to evaluate treatment efficacy.

Results: The study observed a significant reduction in IGA scores from baseline in both groups, with Group A (TAZ) showing a decrease from 3.89 ± 0.68 to 1.29 ± 0.62 and Group B (HP) from 3.87 ± 0.66 to 2.49 ± 0.62. The paired difference in IGA scores indicated a more pronounced improvement in the TAZ group (2.60 ± 0.75) compared to the HP group (1.37 ± 0.57), with significant differences between the groups ($p<0.0001$). Treatment success was observed in 82.2% of participants in the TAZ group compared to 51.1% in the HP group, with an odds ratio of 4.424 (95% CI: 1.690—11.578; $p=0.002$).

Conclusion: Tazarotene 0.045% cream demonstrates significantly greater efficacy in treating scalp psoriasis compared to Halobetasol Propionate 0.01% lotion. The findings suggest Tazarotene as a preferable treatment option for scalp psoriasis, offering a better therapeutic outcome.

Keywords: Psoriasis, Scalp Psoriasis, Tazarotene, Halobetasol Propionate, Randomized Control Trial, Treatment Efficacy.

INTRODUCTION

Psoriasis, recognized as a complex immune-mediated disorder, impacts approximately 2% of the global population, showcasing a spectrum of clinical presentations (1-3). This condition, often manifesting in a localized form, necessitates topical treatments as a crucial component of the therapeutic regimen for many patients, especially given that a significant majority, ranging from 75-90%, suffer from mild to moderate disease severity (4-6). Among the available topical therapies—such as keratolytics, emollients, coal tar, corticosteroids, anthralin, and calcipotriol—corticosteroids are frequently prescribed. Despite their effectiveness, corticosteroids are associated with both systemic and local side effects, including striae and atrophy, and their benefits are not long-lasting (7-8). The use of stronger corticosteroid formulations raises concerns regarding long-term safety due to a heightened risk of local cutaneous adverse events (AEs), including telangiectasia, hypothalamic-pituitary-adrenal (HPA) axis suppression, and skin atrophy (7-9).

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Tazarotene (TAZ), the inaugural receptor-selective retinoid for topical use, has emerged as a promising alternative for treating plaque psoriasis. Following application, tazarotene is rapidly metabolized to tazarotenic acid, which preferentially binds to retinoic acid receptors (RARs) β and γ, with limited affinity for retinoid X receptors. This selective binding modulates gene transcription, thereby normalizing the three pathogenic hallmarks of psoriasis: aberrant keratinocyte differentiation, epidermal hyperproliferation, and inflammation. Consequently, TAZ facilitates a restoration towards normal skin differentiation in psoriatic lesions (9-14).

Halobetasol propionate, another potent therapeutic option, is recommended with caution due to the risk of HPA axis suppression if used continuously for more than two weeks. Although effective in treating psoriasis, the potential irritancy of tazarotene limits its usage. It is imperative to recognize the psychological impact of scalp psoriasis on patients, many of whom experience significant interpersonal stress and anxiety, stemming from the stigma associated with visible symptoms. Thus, identifying efficacious treatments for scalp psoriasis that minimize adverse effects and address the psychological burden of the disease is crucial.

MATERIAL AND METHODS

The Dermatology Department at Jinnah Postgraduate Medical Centre, Karachi, orchestrated a randomized control trial from August 2022 to February 2023 to evaluate the comparative efficacy of Tazarotene 0.045% cream (Group A) versus Halobetasol Propionate 0.01% lotion (Group B) in treating scalp psoriasis. A total of 90 participants were enlisted through a non-probability consecutive sampling method and subsequently allocated into two equally sized groups, each comprising 45 individuals. The assignment was carried out using a randomization process to ensure equitable distribution across both treatment cohorts, with each regimen being administered once daily for a duration of six weeks.

Inclusion criteria were broad, encompassing patients aged between 30 and 70 years, irrespective of gender, diagnosed with scalp psoriasis. The study excluded individuals presenting with pustular psoriasis, those who had undergone phototherapy, photochemotherapy, or systemic treatment for psoriasis within the four weeks prior, as well as pregnant or lactating women. Additionally, candidates with skin conditions that could obfuscate the results or who had used topical treatments within 14 days preceding the study's baseline assessment were not considered for inclusion. The selection process focused on individuals with chronic plaque psoriasis with scalp involvement, characterized by well-demarcated red and scaly patches larger than 1 cm in diameter, persisting for more than six months. A clinical assessment delineated moderate-to-severe psoriasis with an Investigator Global Assessment (IGA) score of 3 or 4 as the diagnostic criterion.

Upon recruitment, participants provided detailed demographic information and signed informed consent forms, adhering to the ethical guidelines outlined in the Declaration of Helsinki. The application of medication was instructed post drying of the skin, with an advisory to limit sun exposure throughout the treatment phase. The protocol permitted the exclusive use of liquid paraffin for localized discomfort, barring any other local or systemic medications during the trial period.

The primary outcome, measured by a minimum two-grade improvement in the IGA score from baseline to the conclusion of the 6th week, served as the efficacy benchmark. Data collection and analysis adhered to stringent protocols, employing SPSS version 25 for statistical evaluations. Descriptive statistics were computed, and the data was analyzed to yield results within a 95% confidence interval, ensuring a robust and comprehensive examination of the treatment modalities' effectiveness in managing scalp psoriasis.

RESULTS

The randomized control trial conducted at the Dermatology Department of Jinnah Postgraduate Medical Centre, Karachi, evaluated the efficacy of Tazarotene 0.045% cream versus Halobetasol Propionate 0.01% lotion in treating scalp psoriasis. The study included a total of 90 participants, equally divided into two groups of 45 each, to receive either Tazarotene (Group TAZ) or Halobetasol Propionate (Group HP).

The baseline characteristics of the patients (Table 1) revealed a similar age distribution between the two groups, with the mean age being 36.84 ± 7.33 years in Group TAZ and 36.58 ± 6.91 years in Group HP. The age group division showed that 73.3% of participants in Group TAZ and 75.6% in Group HP were between 30 to 40 years, while 26.7% of Group TAZ and 24.4% of Group HP were older than 40 years. Regarding gender distribution, Group TAZ comprised 31.1% males and 68.9% females, whereas Group HP had 37.8% males and 62.2% females.

Table 1 Baseline Characteristics of Patients

Variable	Group TAZ (n=45)	Group HP (n=45)
Age in years, Mean ± SD	36.84 ± 7.33	36.58 ± 6.91
Age Group		

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Variable	Group TAZ (n=45)	Group HP (n=45)
30 – 40 Years	33 (73.3%)	34 (75.6%)
>40 Years	12 (26.7%)	11 (24.4%)
Gender		
Male, n (%)	14 (31.1%)	17 (37.8%)
Female, n (%)	31 (68.9%)	28 (62.2%)

Table 2 Change in IGA Score from Baseline to Week 6 among patients

Groups	IGA Score (Baseline)	IGA Score (Week-6)	Paired Difference	95% C.I.	P-value
TAZ 0.045% (n=45)	3.89 ± 0.68	1.29 ± 0.62	2.60 ± 0.75	2.37—2.82	0.0001
HP 0.01% (n=45)	3.87 ± 0.66	2.49 ± 0.62	1.37 ± 0.57	1.20—1.55	0.0001
IGA: Investigator's Global Assessment Scale					

Table 3 Comparative Efficacy of Tazarotene 0.045% vs Halobetasol Propionate 0.01% Lotion for Scalp Psoriasis

Efficacy	Group TAZ (n=45)	Group HP (n=45)	95% C.I.	Odds Ratio	P-Value
Yes, n (%)	37 (82.2%)	23 (51.1%)	(1.690—11.578)	4.424	0.002
No, n (%)	8 (17.8%)	22 (48.9%)			
C.I.: Confidence Interval					

The change in Investigator's Global Assessment (IGA) score from baseline to week 6 (Table 2) was significant for both treatments. Group TAZ showed a remarkable reduction in IGA scores, from 3.89 ± 0.68 at baseline to 1.29 ± 0.62 at week 6, with a paired difference of 2.60 ± 0.75, falling within a 95% confidence interval (C.I.) of 2.37—2.82, and a p-value of 0.0001. In contrast, Group HP also demonstrated a significant reduction, from 3.87 ± 0.66 to 2.49 ± 0.62, with a paired difference of 1.37 ± 0.57, a 95% C.I. of 1.20—1.55, and the same p-value of 0.0001. These results indicate a more substantial improvement in the Tazarotene group compared to the Halobetasol Propionate group over the 6-week period.

Comparative efficacy analysis (Table 3) further underscores the superior performance of Tazarotene treatment over Halobetasol Propionate. 82.2% of the patients in the Tazarotene group reported improvement, compared to 51.1% in the Halobetasol Propionate group, resulting in an odds ratio of 4.424 within a 95% confidence interval of 1.690—11.578, and a significant p-value of 0.002. Conversely, 17.8% of participants in the Tazarotene group and 48.9% in the Halobetasol Propionate group did not report improvement, highlighting the enhanced efficacy of Tazarotene for treating scalp psoriasis.

DISCUSSION

Psoriasis, a genetically predisposed inflammatory skin disease, manifests as well-circumscribed erythematous plaques with large, silvery scales, adversely affecting the physical, emotional, and psychosocial well-being of approximately 2% of the global population (15). Clinical evidence supports the beneficial use of topical corticosteroids (TCS) in conjunction with tazarotene for plaque psoriasis treatment, highlighting a therapeutic synergy that enhances efficacy and potentially mitigates the adverse effects associated with monotherapy (16-17). Despite limited data on the combined application of halobetasol and tazarotene, preliminary findings suggest a synergistic effect that surpasses the efficacy of either treatment alone, while also reducing the incidence of application site reactions compared to tazarotene alone (18). This study aimed to compare the efficacy of Tazarotene 0.045% (TAZ) versus Halobetasol Propionate 0.01% (HP) lotion for treating scalp psoriasis at a tertiary care hospital in Karachi, contributing to the sparse literature on this comparison.

The study revealed that Tazarotene exhibited superior efficacy in improving the Investigator's Global Assessment (IGA) scores over Halobetasol Propionate, with a marked reduction in IGA scores observed in the TAZ group compared to the HP group. This finding aligns with a previous trial where the HP/TAZ lotion demonstrated effectiveness akin to HP cream and significantly outperformed the vehicle control, reinforcing the potential of TAZ in psoriasis management (19). Notably, 82.2% of participants in the TAZ group experienced treatment success, a significantly higher proportion than the 51.1% in the HP group, underscoring the enhanced therapeutic outcome associated with Tazarotene. The significant difference in IGA score reduction between the two groups further cements the superior performance of TAZ in managing scalp psoriasis.

The juxtaposition of these results with existing literature underscores the nuanced landscape of psoriasis treatment, wherein combining treatments may leverage their distinct mechanisms of action to optimize therapeutic outcomes. Another study

corroborated the safety and efficacy of combining HP 0.01% and TAZ 0.045%, reporting substantial reductions in psoriasis severity without notable safety concerns, thus supporting the potential benefits of combination therapy (19, 20).

However, the study was not without its limitations. Observations of mild irritation and severe dryness at the application site were more prevalent in the TAZ group, leading to a higher dropout rate. Such adverse effects highlight the necessity for cautious application and patient education regarding potential side effects. The HP group reported irritation followed by soreness, emphasizing the importance of monitoring and managing side effects to ensure patient adherence to treatment protocols. The need for a longer follow-up period was identified to fully assess the persistence of treatment effects, potential relapses, and the long-term safety profile of these interventions. Extending the follow-up duration would not only offer insights into the durability of clinical benefits but also enhance the study's statistical power by generating a more comprehensive dataset.

CONCLUSION

In conclusion, the study substantiates the superior efficacy of Tazarotene 0.045% cream in treating scalp psoriasis compared to Halobetasol Propionate 0.01% lotion. The discernible difference between the treatment outcomes advocates for Tazarotene as a preferable option for managing this condition in the studied patient cohort. These findings, while compelling, underscore the necessity for further research to explore long-term outcomes, optimize combination therapy protocols, and enhance the understanding of psoriasis treatment modalities. The exploration of patient-centric approaches, focusing on efficacy, safety, and tolerability, will be crucial in refining psoriasis management strategies in future investigations.

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