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Original Research Article

EFFICACY AND SAFETY OF 0.1% TAZAROTENE CREAM VERSUS 0.05% BETAMETHASONE DIPROPIONATE OINTMENT IN NAIL PSORIASIS: A RANDOMIZED, PROSPECTIVE, OPEN-LABEL COMPARATIVE STUDY

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ABSTRACT

Background: Nail psoriasis affects approximately 50% of psoriasis patients and imposes a significant negative impact on quality of life. Topical corticosteroids are widely used, yet carry risks of atrophy and tachyphylaxis with prolonged use. Tazarotene, a synthetic retinoid, offers an alternative mechanistic approach with action on both nail matrix and nail bed. The objective is to cossssssssmpare the efficacy and safety of 0.1% tazarotene cream with 0.05% betamethasone dipropionate ointment in mild to moderate nail psoriasis using the modified Nail Psoriasis Severity Index (mNAPSI).

Materials and Methods: A randomized, prospective, open-label study enrolled 60 patients with mild to moderate nail psoriasis at a tertiary care centre in Coimbatore from December 2018 to November 2019. Participants were allocated equally to Group A (0.05% betamethasone dipropionate ointment, n=30) or Group B (0.1% tazarotene cream, n=30), applied once daily for 16 weeks. mNAPSI scores for pitting, onycholysis, and crumbling were assessed at baseline, 1, 2, and 4 months.

Results: Both drugs produced statistically significant reductions in pitting (betamethasone: 4.90 to 0.53; tazarotene: 6.30 to 0.60; $p<0.001$ intragroup) and onycholysis scores (betamethasone: 3.67 to 0.57; tazarotene: 2.83 to 0.27; $p<0.001$ intragroup). Inter-group comparison showed no statistically significant difference (pitting $p=0.26$; onycholysis $p=0.46$). Total mNAPSI score reduced from 9.4 to 1.57 in the betamethasone group and from 10.1 to 1.63 in the tazarotene group. Tazarotene was associated with higher frequency of mild adverse effects (irritation 36.7%, burning 33.3%), whereas betamethasone caused more erythema (16.7%) and periungual infection (6.7%). No serious adverse events were recorded.

Conclusion: 0.1% tazarotene cream is as effective as 0.05% betamethasone dipropionate ointment in treating mild to moderate nail psoriasis, with a comparable safety profile. Tazarotene may serve as a preferred topical alternative, particularly in patients at risk of steroid-related adverse effects.

Keywords: Nail psoriasis, tazarotene, betamethasone dipropionate, modified NAPSI, topical retinoid, randomized controlled study.

INTRODUCTION

Psoriasis is a chronic, immune-mediated, inflammatory skin disorder characterized by T-cell-mediated hyperproliferation of keratinocytes, resulting in thickened, scaly plaques.[1] Its global prevalence ranges from 2–3%, affecting males and females equally.[2] Nail involvement is among the most common extra-cutaneous manifestations, occurring in approximately 50% of psoriasis

patients during the course of their disease, and as an isolated finding in 1–5% of individuals.[3]

Nail psoriasis exerts a profound negative impact on quality of life (QoL). Patients experience both physical impairment—including limitation of manual dexterity, difficulty with fine work such as buttoning clothes and handling small objects, and restriction of housekeeping activities—and significant psychological burden owing to the cosmetic disfigurement of affected nails.[4] Depression and social withdrawal are documented sequelae. Despite this burden, nail psoriasis is frequently under-recognized because clinical attention is predominantly directed toward cutaneous lesions.

Management of nail psoriasis remains challenging for several reasons. The nail apparatus is anatomically protected, limiting drug penetration to the matrix and nail bed. Nail growth is slow, necessitating prolonged treatment courses. Additionally, no universally accepted treatment algorithm exists.[4] Topical potent corticosteroids, particularly betamethasone dipropionate and clobetasol propionate, represent the most widely prescribed first-line agents. However, chronic steroid use is associated with local adverse effects including skin atrophy, telangiectasis, depigmentation, and tachyphylaxis.[5]

Tazarotene is a third-generation, acetylenic class synthetic retinoid, approved by the United States Food and Drug Administration (US FDA) for psoriasis and acne vulgaris. It acts by binding to retinoic acid receptors (RAR-beta and RAR-gamma), thereby normalizing keratinocyte differentiation, inhibiting hyperproliferation, and suppressing inflammation.[5] Its activity on both nail matrix and nail bed lesions, coupled with a manageable adverse effect profile, positions it as a promising alternative topical agent. However, head-to-head comparative data between tazarotene and potent corticosteroids in nail psoriasis in an Indian population remain limited. The present study was therefore designed to compare the efficacy and safety of 0.1% tazarotene cream with 0.05% betamethasone dipropionate ointment in patients with mild to moderate nail psoriasis. In our study our primary objective is to evaluate the efficacy of 0.1% tazarotene cream in nail psoriasis and compare it with 0.05% betamethasone dipropionate ointment using the modified Nail Psoriasis Severity Index (mNAPSI) score. Secondary objective is to record and characterize any adverse events occurring with either study drug during the 16-week treatment period.

MATERIALS AND METHODS

This was a randomized, prospective, open-label, two-arm comparative study conducted at the Outpatient Department of Dermatology, Coimbatore Medical College Hospital (CMCH), Coimbatore, Tamil Nadu, India. The study was conducted between December 2018 and November 2019 after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to enrolment.

Patients diagnosed with nail psoriasis attending the dermatology outpatient clinic were screened. Inclusion criteria were: (i) psoriasis patients with nail involvement with or without concurrent skin lesions; (ii) both sexes; (iii) age 18 years and above; and (iv) willingness to provide written informed consent. Patients were excluded if they were pregnant or lactating; had received systemic agents (methotrexate, systemic retinoids, systemic steroids, or biological agents) within 3 months; had renal or hepatic insufficiency; had known hypersensitivity to either study drug; or had terminal illness, cancer, or HIV/AIDS. A total of 70 patients were screened, 10 were excluded based on criteria, and 60 patients were enrolled.

Enrolled participants were randomized equally into two groups using a computer-generated random number table. Group A (n=30) received 0.05% betamethasone dipropionate ointment once daily at night for 16 weeks. Group B (n=30) received 0.1% tazarotene cream once daily at night for 16 weeks. Patients were counselled on nail care including avoidance of trauma, keeping nails short and dry, and wearing protective gloves.

The primary efficacy outcome was the change in mNAPSI (modified Nail Psoriasis Severity Index) score from baseline to 16 weeks.[6] Each nail was divided into four quadrants and evaluated for nail matrix features (pitting, leukonychia, red spots in lunula, crumbling) and nail bed features (oil-drop discoloration, onycholysis, splinter hemorrhage, subungual hyperkeratosis). Severity was graded 0–3 (absent, mild, moderate, severe) for pitting, crumbling, and onycholysis; other features were graded 0–1 (absent/present), with a total per-nail score of 0–14. Assessments were performed at baseline, 2 weeks, 4 weeks, 8 weeks, 12 weeks, and 16 weeks. Clinical photographs were taken at each visit. Nail scrapings were examined by KOH mount at baseline to rule out onychomycosis. Baseline investigations including complete blood count, liver function tests, renal function tests, random blood sugar, urine routine, ECG, and chest X-ray were conducted and repeated at 2 and 4 months. Adverse events were recorded by patient self-reporting and investigator clinical examination.

Sample size was calculated with statistician guidance. Data were entered into Microsoft Excel and analysed using SPSS version 20. Categorical variables are expressed as frequencies and percentages; continuous variables as mean ± standard deviation (SD). Inter-group comparison of categorical data was performed by chi-square test; continuous variables were compared by independent Student's t-test. Intragroup pre- and post-treatment comparison was done by paired t-test. A p-value of

less than 0.05 was considered statistically significant.

RESULTS

Sixty patients with mild to moderate nail psoriasis completed the study (30 per group). The demographic profiles of both groups were comparable at baseline as shown in [Table 1] The mean age was 50.43 ± 13.2 years in the betamethasone group and 48.9 ± 12.7 years in the tazarotene group. The mean age of onset of psoriasis was 41.3 years and 42.2 years in the betamethasone and tazarotene groups respectively (p=0.78, non-significant). Both groups had a male to female ratio of 3.3:1 (23 males and 7 females per group), confirming male predominance in nail psoriasis. The mean duration of psoriasis was 9.1 years in the betamethasone group and 7.4 years in the tazarotene group, while mean duration of nail psoriasis was 57.83 months and 38.53 months respectively. Positive family history was present in only 3.3% of patients in each group.

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Parameter	Betamethasone Group (n=30)	Tazarotene Group (n=30)
Mean Age (years)	50.43 ± 13.2	48.9 ± 12.7
Age Range (years)	19 – 75	19 – 75
Mean Age of Onset (years)	41.3 ± 14.4	42.2 ± 11.7
Male : Female ratio	23:7 (3.3:1)	23:7 (3.3:1)
Mean Duration of Psoriasis (years)	9.10 ± 10.5	7.43 ± 6.8
Mean Duration of Nail Psoriasis (months)	57.83 ± 87.4	38.53 ± 45.6
Family History of Psoriasis	3.3% (n=1)	3.3% (n=1)
P value (inter-group)	>0.05 (NS)	>0.05 (NS)

NS = Not Significant. Both groups were statistically comparable at baseline (p > 0.05 for all parameters).

[Table 2] summarizes the co-morbidity profile and personal habits of study participants. The prevalence of diabetes mellitus was 13.3% and 26.7% in the betamethasone and tazarotene groups respectively (p=0.19). Hypertension was present in 6.7% and 23.3% of patients in the respective groups (p=0.07). No statistically significant inter-group differences were found for any co-morbidity. With respect to lifestyle factors, alcoholism was observed in 17% of the betamethasone group and 37% of the tazarotene group; smoking in 23% and 37% respectively. Joint pain, suggestive of psoriatic arthritis features, was equally distributed (23% per group).

The predominant type of psoriasis was chronic plaque psoriasis (90%), followed by palmoplantar psoriasis (5%), pustular psoriasis (3%), and scalp psoriasis (2%). Finger nail involvement (97%) was far more common than toe nail involvement (35%). The most common signs of nail psoriasis in descending frequency were pitting (27%), onycholysis (26%), hyperkeratosis (26%), crumbling (7%), longitudinal ridging (7%), Beau's lines (5%), and melanonychia (2%). The most common patient-reported symptoms were work difficulty (49%) and cosmetic handicap (30%).

Table 2: Comparison of Co-morbidities and Lifestyle Habits between Study Groups

Parameter	Betamethasone Group n (%)	Tazarotene Group n (%)	P value
Diabetes Mellitus	4 (13.3%)	8 (26.7%)	0.19
Hypertension	2 (6.7%)	7 (23.3%)	0.07
Myocardial Infarction	1 (3.3%)	0 (0%)	0.31
Alcoholism	5 (17%)	11 (37%)	>0.05
Smoking	7 (23%)	11 (37%)	>0.05
Joint Pain (Psoriatic Arthritis features)	7 (23%)	7 (23%)	1.0

NS = Not Significant. No statistically significant inter-group difference was found for any co-morbidity or lifestyle parameter.

Pitting was present in 70% (n=21) of the betamethasone group and 83.3% (n=25) of the tazarotene group at baseline (p=0.22, non-significant). [Table 3] shows the longitudinal course of pitting scores. In the betamethasone group, the mean pitting score declined from 4.90 ± 5.39 at baseline to 0.53 ± 1.59 at the end of 4 months, a mean difference of 4.36 (p<0.001). In the tazarotene group, the mean pitting score reduced from 6.30 ± 5.59 at baseline to 0.60 ± 1.42 at 4 months, a mean difference of 5.70 (p<0.001). The inter-group comparison at the end of study showed no statistically significant difference (p=0.260), indicating comparable efficacy of both drugs in reducing nail pitting.

Table 3: Comparison of Mean Nail Pitting Score between Study Groups at Different Time Points

Group	Baseline Mean (SD)	1 Month	2 Months	4 Months Mean (SD)	Mean Difference (SD)	P value (Intra)
Betamethasone	4.90 (5.39)	2.83	1.33	0.53 (1.59)	4.36 (4.49)	<0.001*
Tazarotene	6.30 (5.59)	3.37	1.57	0.60 (1.42)	5.70 (4.57)	<0.001*
P value	—	—	—	—	—	0.260 (NS)

*Statistically significant (p<0.001) by paired t-test (intragroup). NS = Not Significant in intergroup comparison. SD = Standard Deviation.

Onycholysis was present in 67% of the betamethasone group (n=20) and 80% of the tazarotene group (n=24) at baseline. As shown in [Table 4], betamethasone reduced the mean onycholysis score from 3.67 ± 3.61 at baseline to 0.57 ± 0.93 at 4 months (mean difference 3.10; p<0.001). Tazarotene reduced the mean onycholysis score from 2.83 ± 3.01 at baseline to 0.27 ± 0.52 at 4 months (mean difference 2.56; p<0.001). The inter-group p-value was 0.46, confirming no statistically significant difference between the two treatments in managing onycholysis.

Table 4: Comparison of Mean Onycholysis Score between Study Groups at Different Time Points

Group	Baseline Mean (SD)	1 Month	2 Months	4 Months Mean (SD)	Mean Difference (SD)	P value (Intra)
Betamethasone	3.67 (3.61)	2.13	1.17	0.57 (0.93)	3.10 (2.99)	<0.001*
Tazarotene	2.83 (3.01)	1.67	0.87	0.27 (0.52)	2.56 (2.59)	<0.001*
Inter-group P value	—	—	—	—	—	0.46 (NS)

*Statistically significant (p<0.001) by paired t-test (intragroup). NS = Not Significant in intergroup comparison.

Crumbling was present in 16.7% (n=5) of the betamethasone group and 23.3% (n=7) of the tazarotene group. The mean crumbling score in the betamethasone group declined marginally from 0.47 ± 1.54 to 0.28 ± 0.70 (p=0.24, non-significant), while in the tazarotene group it declined from 0.50 ± 1.25 to 0.37 ± 0.85 (p=0.103, non-significant). The inter-group comparison showed p=0.70, indicating no significant difference. The total mNAPSI score (reflecting overall disease burden) decreased from a baseline of 9.4 to 1.57 in the betamethasone group and from 10.1 to 1.63 in the tazarotene group, both representing clinically meaningful reductions. Table 5 summarizes adverse effects and overall outcome metrics.

Figure 1: Comparison of onycholysis

Table 5: Comparison of Adverse Effects and Total mNAPSI Outcomes between Study Groups

Adverse Effect / Outcome	Betamethasone Group n (%)	Tazarotene Group n (%)
Erythema	5 (16.7%)	2 (6.7%)
Irritation / Burning	0 (0%)	11 / 10 (36.7% / 33.3%)
Desquamation	3 (10.0%)	2 (6.7%)
Infection (periungual)	2 (6.7%)	0 (0%)
Pain	2 (6.7%)	0 (0%)
Serious Adverse Events	None	None
Baseline Total mNAPSI Score (Mean)	9.4	10.1
End of Study Total mNAPSI Score (Mean)	1.57	1.63

All adverse effects in the tazarotene group were transient and self-limiting, resolving within one week on continuing therapy with supportive emollients. No serious adverse events were recorded in either group.

Figure 2: Comparison of salmon patches

DISCUSSION

The present study provides a direct, randomized head-to-head comparison of 0.1% tazarotene cream and 0.05% betamethasone dipropionate ointment in patients with mild to moderate nail psoriasis. Both agents produced statistically significant intragroup improvement in the two primary mNAPSI parameters—nail pitting and onycholysis—with no statistically significant intergroup difference, confirming therapeutic equivalence in a hospital-based south Indian cohort.

The male predominance (male to female ratio 3.3:1) observed in this study is consistent with published literature. Dogra and Yadav reported a male to female ratio of 2.5:1 in an Indian psoriasis cohort.[7] Augustin et al. similarly documented nail psoriasis being approximately 10% more prevalent in males.[8] The mean age of onset of psoriasis in the study participants (approximately 41–42 years) is concordant with Prabhakar et al., who reported a

mean age of onset of 40.7 years from a tertiary care centre in North Kerala.[9] The age distribution, with peak involvement in the 30–49 year age group, reflects the most productive working years of life, further emphasizing the functional and economic burden of the disease.

Chronic plaque psoriasis was the predominant associated skin type, constituting 90% of cases, consistent with Zargari et al., who reported 91.9% chronic plaque psoriasis among patients with nail involvement.[10] The prevalence of psoriatic arthritis-like joint pain (23.3%) in this study is within the reported range of 5.4–40% among psoriasis patients, reinforcing the known association between nail psoriasis and joint disease.[11] Nail psoriasis is increasingly recognized as a clinical predictor of future psoriatic arthritis through the joint-entheseal-nail apparatus, linking the enthesis of the distal interphalangeal joint extensor tendon to the nail matrix.[11]

The co-occurrence of diabetes mellitus (overall 20%) and hypertension (overall 15%) in this cohort supports the emerging body of evidence linking psoriasis with metabolic syndrome and cardiovascular risk. Chronic systemic inflammation, manifested by elevated TNF-alpha, IL-1, and IL-6, is thought to promote insulin resistance, endothelial dysfunction, and hypertension in psoriatic patients.[12] Smoking (30%) and alcohol use (26.6%) were prevalent, consistent with known associations: smoking amplifies psoriasis severity through increased oxidative stress and elevated cytokine release, while alcohol may exacerbate psoriasis through immune dysregulation and increased susceptibility to infection.[13]

Nail pitting was the most common sign (27%), closely followed by onycholysis and hyperkeratosis (each 26%), with crumbling (7%) being less frequent. This distribution is concordant with the literature—pitting being the hallmark of nail matrix psoriasis and onycholysis the most functionally limiting nail bed feature.[14] Work difficulty (49%) emerged as the most prevalent patient symptom, reflecting the impairment of manual dexterity, a frequently underappreciated dimension of nail psoriasis burden.[15]

Regarding therapeutic outcomes, both betamethasone dipropionate and tazarotene produced highly significant reductions in pitting scores ($p<0.001$ intragroup) and onycholysis scores ($p<0.001$ intragroup), with no significant intergroup difference. These findings align with Rigopoulos et al., who demonstrated that 0.1% tazarotene cream significantly improved pitting, onycholysis, hyperkeratosis, and salmon patch at 12 weeks.[16] Scher et al. similarly reported significant improvement in onycholysis and pitting with tazarotene.[17] In a double-blind study comparing tazarotene 0.1% cream with clobetasol propionate 0.05% cream, both agents showed equivalent efficacy in reducing nail psoriasis scores.[17] The findings of the present study corroborate these observations using betamethasone dipropionate as the comparator. Tosti et al. demonstrated that betamethasone dipropionate was effective in improving subungual hyperkeratosis.[18], consistent with the improvement in overall mNAPSI scores observed in the current study.

With respect to crumbling, neither drug achieved statistical significance in the intragroup analysis (betamethasone $p=0.24$; tazarotene $p=0.103$), likely because crumbling has a lower prevalence and smaller effect size, necessitating a larger sample for adequate power. The total mNAPSI score reductions (betamethasone: 9.4 to 1.57; tazarotene: 10.1 to 1.63) are clinically meaningful and were maintained at 1-month follow-up post-cessation, suggesting durable effects.

The adverse effect profiles differed in character but not severity. Tazarotene produced higher rates of local irritation (36.7%) and burning (33.3%), consistent with its known retinoid-class effects.[5] These were mild, transient, and resolved within one week of initiating supportive emollients, without necessitating drug discontinuation. The betamethasone group had higher rates of periungual erythema (16.7%) and infection (6.7%), the latter managed with topical antibiotics. Notably, no severe corticosteroid-related adverse effects (atrophy, striae, telangiectasia, bone resorption, or hypothalamic-pituitary-adrenal axis suppression) were recorded in the 16-week study period, likely due to the relatively short study duration. The absence of serious adverse events in both groups supports the safety of both treatments for the studied duration.

The study has certain limitations that should be acknowledged. The sample size was relatively small (n=30 per group), which limits the power to detect moderate differences in less prevalent outcomes such as crumbling. The open-label design, while pragmatic, introduces potential for performance and detection bias. The 16-week duration may be insufficient to observe the full treatment effect and the complete steroid adverse effect profile. The follow-up period after drug cessation was only 1 month, precluding assessment of long-term relapse rates. Future studies incorporating larger, double-blind, multicentre designs with extended follow-up would further consolidate these findings.

CONCLUSION

Both 0.1% tazarotene cream and 0.05% betamethasone dipropionate ointment, applied once daily for 16 weeks, are effective and safe in the treatment of mild to moderate nail psoriasis. Both agents produced statistically significant and clinically meaningful reductions in nail pitting and onycholysis scores as measured by mNAPSI, with no statistically significant difference between the two groups. Crumbling scores showed a declining trend in both groups, though without statistical

significance, likely due to low prevalence in the study population. The adverse effects observed with both drugs were mild and self-limiting, with no serious adverse events. Considering the established risks of prolonged corticosteroid use—including skin atrophy, tachyphylaxis, and systemic absorption—tazarotene represents a viable, efficacious, and well-tolerated first-line topical alternative for mild to moderate nail psoriasis, with the additional advantage of activity at both nail matrix and nail bed. It is recommended as a preferred treatment option, particularly in patients at risk of steroid-related adverse effects or requiring long-term topical therapy.

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