e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(3); 1333-1337

Original Research Article

Evaluate the safety and efficacy of Naftifine 2% cream in fungal skin infection among patients in Rajasthan

Neelima Goyal[1], Ashok Hogade[2], Simran Singh Aujla[3], Anjali Agarwal[4]

[1]Associate Professor, Department of Dermatology, Venerology and Leprosy, Pacific Institute of Medical Sciences, Udaipur Rajasthan

[2]Professor, Department of Dermatology, Venerology and Leprosy, Pacific Institute of Medical Sciences, Udaipur Rajasthan

[3]Associate Professor, Department of Dermatology, Venerology and Leprosy, Pacific Institute of Medical Sciences, Udaipur Rajasthan

[4]Junior Resident, Department of Dermatology, Venerology and Leprosy, Pacific Institute of Medical Sciences, Udaipur Rajasthan

Received: 01-01-2026 / Revised: 02-02-2026 / Accepted: 02-03-2026

Corresponding Author: Neelima Goyal

Conflict of interest: Nil

Abstract:

Background: Naftifine hydrochloride is an allylamine topical agent used in treating superficial fungal infections, especially dermatophytosis. The objective of this study was to assess the safety and effectiveness of naftifine 2% cream in patients with superficial fungal skin infection.

Aim: A real-world observational study to evaluate the safety & effectiveness of Naftifine 2% cream in patients with superficial fungal skin infection.

Materials and Methods: It was an observational, prospective study conducted on patients in Rajasthan, where subjects were advised to apply naftifine 2% cream on the affected area by treating physician. Effectiveness was determined by assessing the clinical cure, absence of signs and symptoms and mycological cure viz negative microscopic KOH test, at the end of the treatment. Safety & tolerability were evaluated based on the presence of adverse events and their severity. The patient compliance was recorded based on the investigator's assessment.

Results: A total of 463 patients were enrolled in the study, out of which 82.07% achieved a clinical cure at the end of the treatment. The skin scraping for microscopic KOH mounting was available for 94 patients out of which the mycological cure was observed in 89 patients (94.6%) ($p<0.0001$) at the end of the treatment. Our study recorded a lower incidence of adverse events (2.4%), commonly including dermatitis, pruritis, skin irritation at the application site, and erythema. The reported adverse events were mild or moderate and were cured within 2-7 days. The naftifine 2% cream was well tolerated by 70.8% of the patients. Upon completion of the treatment, 296 patients (64.1%) exhibited 100% compliance to the study drug.

Conclusion: Topical Naftifine 2% cream was safe and effective in Indian patients with tinea cruris and tinea corporis.

DOI: 10.25258/ijcpr.18.3.212

Introduction

The increasing prevalence of fungal infections, affecting almost 25% of the world's population, has debilitated the individual's quality of life, especially in developing countries. [1] It impacts individuals of all ages either living in remote areas or densely populated cities, thriving in warm and humid climates. [2] Though these infections are not life-threatening, the transmission through various routes significantly increases the infection rate, posing a great challenge to healthcare professionals. [3] Also, the visible skin lesions, and itching negatively impact the social interactions and image of the individual causing psychological distress and discomfort.

Dermatophytosis or tinea, a common fungal infection, is caused by dermatophyte fungi that primarily invade human keratinized tissues like hair, nails, and skin. [4] Based on the site of invasion, the infection caused by dermatophyte can be categorized as tinea pedis (foot), tinea corporis (body), tinea capitis (head), tinea faciei (face), tinea barbae (beard), tinea mannum (hand), tinea cruris (groin), and tinea unguium (nail). [2,4] Among these, recent epidemiological studies conducted in India have shown a rising trend in the prevalence of tinea corporis, tinea pedis, and tinea cruris. This rise is attributed to the predominance of the most common isolated trichophyton rubrum [5]. Factors

contributing to the widespread of the infections include increased urbanization, overcrowding, poor hygiene, and tight-fitted clothes. Compromised immunity in patients taking medications like broad-spectrum antibacterials, immunomodulators, immunosuppressants, and cytostatic is another significant factor to cogitate [6]. The misuse of potent topical corticosteroids in the management of fungal infections can lead to severe complications and further spread of the infection [7,8]. Additionally, global warming and increased sweating due to warm and humid climates have also been associated with repeated fungal infections.

The effective pharmacological approach for the treatment of dermatophytosis includes the use of systemic and topical antifungals based on the severity and site of the infection. Though numerous studies have reported the treatment of tinea corporis and cruris with the combination of oral and topical antifungal agents, owing to the better penetration of the topical antifungal well inside the skin, they have contributed to better efficacy and pharmacokinetic profile [9]. This penetration inside the skin inhibits the propagation of fungi and eases the mycological cure.

Naftifine hydrochloride (HCl), an allylamine derivative, is an approved topical antifungal agent available as 1% and 2% cream and gel in various countries. It penetrates the stratum corneum and epidermis of the skin to exhibits fungicidal and fungistatic properties. Naftifine acts by inhibiting the squalene epoxidase responsible for the biosynthesis of ergosterol leading to disruption in cell growth and damaging cell wall. Other effective properties of naftifine include antibacterial, anti-inflammatory, anti- histaminic, and corticosteroid-like activity. [6,10]

Clinically naftifine has proved its efficacy in curing tinea corporis, tinea cruris, and tinea pedis against various azoles like econazole, clotrimazole, oxiconazole, and miconazole in different geographical populations [11-13]. However, comprehensive real-world data concerning the safety and effectiveness of naftifine 2% topical antifungal cream in the Indian population remain scarce. Thus, this prospective study was undertaken to assess the safety and effectiveness of naftifine 2% cream in individuals diagnosed with tinea cruris and tinea corporis.

Materials and Methods

The study was observational, prospective study conducted among patients coming to Dept of Dermatology at PIMS, Udaipur over a period of 01 Year. Both males and females above 18 years of age, clinically and/or mycologically diagnosed with a superficial infection, i.e. tinea corporis and tinea cruris were included in the study. The enrolled patients signed an informed consent before participation. All subjects included in the study were eligible to receive the topical naftifine 2% cream with or without oral antifungal at the discretion of the treating physician. Subjects hypersensitive to naftifine, pregnant women, lactating mothers, and those who were found ineligible by the treating physician to receive naftifine were excluded from the study.

The eligible patients were advised to apply naftifine 2% cream on the affected area. The duration and the frequency of the dosage were prescribed based on the severity of the infection. Other topical or oral formulations were advised along with naftifine 2% cream by the treating physician. Patients underwent initial screening during their first visit, with adherence to specific inclusion and exclusion criteria. Subsequently, comprehensive general and systemic examinations were conducted. Detailed demographic information, medical history, and current medications were documented for each patient. Additionally, clinical scores were appraised, and the total clinical score was computed during each visit. Wherever possible, skin scrapings were collected for KOH mounting to evaluate mycological cure during follow-up visits. Adverse events were monitored during follow-up appointments, and at the end of treatment.

At the end of the study, the patients were assessed for the safety and effectiveness of the given formulation. The effectiveness of 2% naftifine cream was reported based on the clinical cure and mycological cure. The total clinical score was given according to the severity of the clinical symptoms. The clinical cure was defined as an absence of any signs and symptoms except for residual clinical signs such as mild erythema (score = 1) and mild scaling (score = 1) with or without hypopigmentation of the affected skin area. The subjects were considered to have achieved the clinical cure when their TCS was ≤ 2 with no itching at follow-up and end of treatment. The patients achieving the required clinical cure were compared with the baseline. The safety was evaluated by examining adverse events during follow-up visits. The overall tolerability of the naftifine was graded as excellent, good, fair, and poor by the physician (Table 1). At the end of the study, the percentage of patient compliance with the study was assessed by the investigator.

Results

Out of the 463 patients enrolled in the study, 267 (57.7%) were male and 196 (42.3%) were female. The mean age of the patients was 35.9 ±12.9 years. The detailed demographics of the study population is described in Table 2. Among the total patients, 8.2% were presented with one or more illnesses with type-2 diabetes mellitus (43.24%) as the most

common medical condition, followed by thyroid (18.92%), hypertension (16.22%), and tinea pedis (5.41%). Arthritis, vitiligo, scabies, renal failure, onychomycosis and insomnia were other common diseases (Table 2).

Table 1: Adverse Reporting Scale (Tolerability)

Excellent	**No adverse event reported**
Good	Mild adverse event(s) reported which subsided with or without medication and did not necessitate stoppage of study drug
Fair	Moderate adverse event(s) reported which subsided with or without medication and did not necessitate stoppage of study drug
Poor	Severe or serious adverse event(s), or adverse event(s) which necessitated stoppage of study drug

Table 2: Patient Demography

Parameters	**Frequency**	**Percentage**
Total Patients	463	100
Male	267	57.7%
Female	196	42.3%
Age (years)	35.90 ± 12.9	
Weight(kg)	65.36 ± 29.74	
Height (cm)	162.98 ± 8.57	
Presence of any medical history	**Frequency**	**Percentage**
Yes	38	8.2%
No	425	91.8%
Treatment	**Frequency**	**Percentage**
Patients prescribed topical naftifine monotherapy	166	35.85%
Patients prescribed topical Naftifine + oral antifungals	297	64.15%

Among the study cohort, 64.15% of the patients were given other drugs along with the study drug. Notably, the most common drug was oral itraconazole followed by oral levocetirizine, oral fluconazole, topical preparation of ketoconazole, and others. The subjects were given Naftifine in the form of 2% cream, among them 53.6% were recommended to use it once daily (OD), 46.4% twice daily (BD), and 0.2% three times a day (TDS). The mean duration of the study drug given to the patients was 4.4 ± 1.65 weeks.

In the present study, we found a significant difference between the mean of the total score, score for erythema, scaling, and itching at all visits at 95% CI tested by the ANOVA Test ($p<0.0001$) (Table 3). In our study, 82.07% of the patients achieved clinical cures at visit 3 compared to the baseline.

Table 3: Mean Scores of erythema, Scaling and Itching.

Variables	**Visit-1**	**Visit-3**	**p-value***
Erythema	2.51 ± 0.67	0.18 ± 0.53	P<0.0001
Scaling	2.37 ± 0.67	0.14 ± 0.43	P<0.0001
Itching	2.53 ± 0.62	0.17 ± 0.49	P<0.0001
Total score	2.62 ± 0.64	0.22 ± 0.56	P<0.0001

Out of 463 patients, skin scrapping for microscopic KOH mounting was performed for 94 patients. Of these 94 patients, 70.2% (66) patients tested negative at 1st follow- up, while 94.6% (89) tested negative at the end of the treatment with naftifine 2% cream. For the assessment of the safety of the study drug, the patients were followed up for any adverse events developed till the end of the treatment, and in our study, we found that 11 patients developed AEs. These AEs were resolved within 2 to 7 days, demonstrating the safety of the drug in patients with superficial fungal infections.

The tolerability of topical naftifine 2% cream, as assessed by the physician, was found to be excellent in 70.8% of the patients, good in 27.6%, and fair in 1.5%. Upon completion of the treatment, the investigators determined that 296 (64.1%) of the total patients exhibited 100%, 155 (33.3%) patients showed >80%, and 12 (2.6%) patients demonstrated 50-80% compliance to the study drug.

Discussion

The search for effective approaches for treating superficial infections poses a significant challenge when dealing with those caused by dermatophytes invading the keratinized tissues like skin, hair, and nails. Most of the imidazole antifungals available in the market are fungistatic and inhibit the fungal growth on the skin, causing patients to observe the

vanishing signs and symptoms of the infections. This improvement often prompts them to discontinue the treatment. Once the patient ceases medication, the fungus may surface again and develop spores, resulting in symptoms to resurface, leading to relapse and the onset of chronic tinea infections [14]. Therefore, owing to their enhanced penetrating property and greater binding affinity to keratin, allylamines are often recommended to achieve a complete cure. The lipophilic nature of the allylamines allows them to penetrate deep inside the stratum corneum and inhibits the growth of fungi within, exhibiting fungicidal activity. [15]

Naftifine HCl, an allylamine derivative, has shown to be effective in patients with tinea pedis, corporis, and cruris when prescribed as gel or cream. The reported increase in the clinical and mycological cure post naftifine treatment supports the findings of this prospective study conducted in Indian patients with tinea cruris and tinea corporis. [10,16]

In this study treatment with naftifine, 2% cream in the patients who presented with tinea corporis and tinea cruris resulted in a significant reduction in the clinical signs and symptoms at the end of the treatment ($p<0.0001$). In our study, 82.07% of the patients achieved clinical cure at the end of the treatment. Additionally, 94.6% of patients wherein KOH mounting data was available showed mycological cure at the end of the treatment ($p<0.0001$). The response of our study was in line with the previously conducted efficacy and safety study of naftifine 2% cream in patients with tinea corporis by Gold et al. 2016 [17]. Moreover, treatment-related adverse events were observed only in 2.4% of the patients enrolled in the study, which resolved within 2-7 days through proper treatment. The adverse event rates observed in this study are consistent with the low incidence of adverse events (2%) documented in a previous randomized, double-blind trial on patients with tinea cruris conducted by Parish et al., 2011. The most reported adverse events in the Parish et al. study were mild in nature, including dermatitis, pruritus, and other skin reactions. These findings suggest that the topical treatment used in the current study has a favorable safety profile for patients with tinea cruris [18]

Although specific clinical trials focusing solely on Indian patients may be limited, the collective evidence from diverse populations consistently demonstrates the safety and efficacy of naftifine in treating dermatophytosis, including tinea infections, which are prevalent in India. Naftifine 2% cream has demonstrated excellent tolerability in most patients enhancing compliance, and satisfaction with the treatment regimen. Overall, the favorable real-world effectiveness and safety profile of naftifine 2% cream together highlight its acceptance in the clinical management of superficial fungal infections like tinea cruris and tinea corporis in Indian patients.

Conclusion

In conclusion, the favorable result of this observational study provides a promising therapeutic option for patients with tinea cruris and tinea corporis, among the Rajasthan population. Future studies focusing on the long-term clinical benefits of naftifine 2% cream in a larger population, would bolster our understanding of the management of superficial fungal infections in the Indian population.

References

1. Manickam N, Manimaran PT, Gopalan K, Somasundaram K, Vellaisamy SG. A Clinico Epidemiological Study with Assessment of Impact on Quality of Life and Financial Burden in Patients with Dermatophytosis. Journal of Communicable Diseases;56(1):36–4
2. Maryam jassim mohammad. Epidemiological study of dermatophytes spread in Anbar Governorate. Int Tinnitus J. 2023;S1:80-86.
3. Garber G. An Overview of Fungal Infections. Drugs. 2001;61(Suppl 1):1–12. [Accessed May 28, 2025].
4. Sahoo AK, Mahajan R. Management of tinea corporis, tinea cruris, and tinea pedis: A comprehensive review. Indian Dermatol Online J. 2016;7(2):77–86.
5. Lakshmanan A, Ganeshkumar P, Mohan SR, Hemamalini M, Madhavan R. Epidemiological and clinical pattern of dermatomycoses in rural India. Indian J Med Microbiol. 2015;33:134–6. doi:10.4103/0255-0857.150922.
6. Gusliakova O, Verkhovskii R, Abalymov A, Lengert E, Kozlova A, Atkin V, et al. Transdermal platform for the delivery of the antifungal drug naftifine hydrochloride based on porous vaterite particles. Mater Sci Eng C Mater Biol Appl. 2021;119:111428. doi:10.1016/j.msec.2020.111428.
7. Verma S, Madhu R. The Great Indian Epidemic of Superficial Dermatophytosis: An Appraisal. Indian J Dermatol. 2017;62(3):227– 36.
8. Havlickova B, Czaika VA, Friedrich M. Epidemiological trends in skin mycoses worldwide. Mycoses. 2008;51(4):2–15.
9. Rotta I, Ziegelmann PK, Otuki MF, Riveros B, Bernardo N, Correr CJ, et al. Efficacy of topical antifungals in the treatment of dermatophytosis: a mixed-treatment comparison meta-analysis involving 14 treatments. JAMA Dermatol . 2013;149(3):341–9.
10. Gupta AK, Ryder JE, Cooper EA. Naftifine: A Review. J Cutaneous Med Surg. 2008;12(2):51–8. [Accessed May 28, 2024].
11. Godse K, Vidya TS, Adhikari P, Prasad AK, Raj C, Bhaskar G, Mapare A, Jaiswal AD, Chinda M. A real-world observational study to evaluate the safety & effectiveness of Naftifine 2% cream in patients with superficial fungal skin

infection. IP Indian J Clin Exp Dermatol 2024;10(3):260-265.
12. Millikan LE, Galen WK, Gewirtzman GB, Horwitz SN, Landow RK, Jr LN, et al. Naftifine cream 1% versus econazole cream 1% in the treatment of tinea cruris and tinea corporis. J Am Acad Dermatol. 1988;18(1 Pt 1):52–6.
13. Walsh JA, Jones H, Mallbris L, Duffin KC, Krueger G, Clegg DO, et al. The Physician Global Assessment and Body Surface Area composite tool is a simple alternative to the Psoriasis Area and Severity Index for assessment of psoriasis: post hoc analysis from PRISTINE and PRESTA. Psoriasis (Auckl). 2018;8:65–74.
14. Plaum S, Verma A, Fleischer-Jr AB, Olayinka B, Hardas B, Hardas B, et al. Detection and relevance of naftifine hydrochloride in the stratum corneum up to four weeks following the last application of naftifine cream and gel, 2%. J Drugs Dermatol. 2013;12(9):1004–8.
15. Kyle A, Dahl M. Topical Therapy for Fungal Infections. Am J Clin Dermatol. 2024;5:443–51. doi:10.2165/00128071-200405060-00009.
16. Parish LC, Parish JL, Routh HB, Avakian E, Olayinka B, Pappert EJ, et al. A double-blind, randomized, vehicle-controlled study evaluating the efficacy and safety of naftifine 2% cream in tinea cruris. J Drugs Dermatol. 2011;10(10):1142–7.
17. Gold M, Dhawan S, Verma A, Kuligowski M, Dobrowski D. Efficacy and Safety of Naftifine HCl Cream 2% in the Treatment of Pediatric Subjects With Tinea Corporis. J Drugs Dermatol. 2016;15(6):743–8.
18. Parish LC, Parish JL, Routh HB, Fleischer-Jr AB, Avakian EV, Plaum S, et al. A randomized, double-blind, vehicle-controlled efficacy and safety study of naftifine 2% cream in the treatment of tinea pedis. J Drugs Dermatol. 2011;10(11):1282–8.