Original Article

The Efficacy of Oral Terbinafine alone and combined with 20% topical Urea in the treatment of Pediatric Dermatophytosis and Prevention of Chronicity and Recurrence: A Double-blind Randomized Controlled Trial

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Abstract

Background Dermatophytosis is a common cutaneous fungal infection, with recurrent and treatment-resistant cases reported increasingly. The limited efficacy of Terbinafine and adverse effects of systemic antifungals underscore the need for safe, cost-effective topical alternatives such as 20% urea.

Objective To assess the efficacy of topical urea in combination with oral Terbinafine vs. oral Terbinafine alone in treating pediatric dermatophytosis, along with its impact on chronicity and recurrence.

Methods One hundred and forty patients were enrolled in this study and divided into two groups. Diagnosis of dermatophytosis was confirmed by clinical as well as potassium hydroxide (KOH) examination. Group A patient used oral Terbinafine on a weight basis for 6 weeks, while patients in Group B applied topical 20% urea in addition to terbinafine. Patients were followed at 2-week interval for 6 weeks and then monthly for 6 months.

Results The mean age in Groups A and B was 6.5±3.6 and 7.21±4.5, respectively. In both groups, male patients were in the predominant number. Both groups were comparable in terms of the number of lesions and site of involvement. At the final assessment, a greater percentage of the patients in Group B achieved remission without recurrence at 6-month follow-up. Similarly, the number of patients in the chronic category was lower in Group B (*P*-value <.05).

Conclusion It is concluded that for the treatment of dermatophyte infections, combination of oral Terbinafine with 20% topical urea yields better outcome in terms of remission, recurrence and chronicity.

Keywords Dermatophytosis; Keratolytics; Terbinafine; Urea.

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Introduction

Cutaneous fungal infection is a public health problem caused by a variety of fungal species. It is classified as superficial, subcutaneous, and deep mycosis.[1] There are many species in the superficial mycosis category, namely Malassezia, Candida, Piedra, but dermatophytes are the commonest, affecting approximately 25% of the world population and could be zoophilic, geophilic, and anthrophilic.[2] Dermatophytes have worldwide prevalence, and more than 30 species contribute to

human infection, but the three main species are Trichophyton, Microsporum, and Epidermophyton, with the former group having the highest prevalence (70- 90%).[3] These species preferentially affect the stratum corneum. The clinical classification is based on the anatomical area involved, e.g. Tinea capitis, Tinea faciei, Tinea barbae, Tinea corporis, Tinea cruris, Tinea manuum, Tinea pedis, and Tinea unguium are the terms used for scalp, face, beard area, body/trunk, groin region, hands, foot, and nails, respectively.[4] In children, T. corporis is the most common clinical subtype, followed by T. facei.[5] Factors predisposing to dermatophytosis include a hot and humid environment, low socioeconomic conditions, overcrowding, poor hygiene, contact sports, tight clothes/ undergarments, and contact with domestic animals/ cattle.[6] In our country, Pakistan, an increase in the number of dermatophytosis cases is noted due to the presence of the above-mentioned factors, especially in rural areas. More importantly, difficult-to-treat cases are emerging, consisting of recurrent or chronic dermatophytosis. Recurrence of the signs and symptoms within a few weeks following apparent cure is known as recurrent dermatophytosis, while chronic dermatophytosis refers to an infection that persists for more than six months to a year in spite of standardized treatment.[7] Drug penetration, patient compliance, the pathogen's susceptibility, the host immune system, and the lack of persistent infection focus are all necessary for a good therapeutic response. Both environmental and host factors contribute to chronicity, such as poverty, poor hygiene, obesity, suboptimal dose or duration of drug therapy, self-medication, quackery/use of topical steroids over the lesions, immunocompromised status, diabetes mellitus, and atopy.[8]

The first-line treatment options for tinea infection are topical or systemic azoles or Terbinafine. Terbinafine is an allylamine and inhibits fungal growth by interfering with sterol biosynthesis. It prevents the synthesis of ergosterol by blocking squalene epoxidase, the catalytic enzyme responsible for converting squalene to 2,3-oxidosqualene (an ergosterol precursor).[9] The ensuing lack of ergosterol damages the integrity of the cell wall and hinders the pathogen's ability to grow. Terbinafine inhibition of squalene epoxidase is species-specific, and human cell wall synthesis is not affected.[10] Mostly Terbinafine is used for superficial fungal infections caused by dermatophyte species, although other fungi are also susceptible with variable sensitivity. Both oral and topical formulations are in use depending on the patient's age, area, and extent of infection. According to recent evidence, very few cases are fully responsive to terbinafine-only therapy; that’s why adding another treatment modality with fewer side effects seems logical in this scenario.[11]

Made up of roughly 20 stacked layers of corneocytes, the stratum corneum is the body's strong, nearly impermeable outer layer. Dermatophytes preferentially inhabit this outer layer of the skin, hair, and nails and require keratin for nutrition.[12] Superficial mycosis is usually associated with hyperkeratosis and epidermal thickening, which in turn provides a favorable environment for fungus growth. Upon binding, keratin inactivates and reduces the availability of antifungal drugs. Because of the physical barrier and lack of thermodynamic activity, epidermal thickness is also linked to decreased penetration of antifungal drugs.[13]

The presence of surface acidity serves as a crucial barrier against the growth of microorganisms; many skin infections are associated with alkaline skin PH. It has been observed that dermatophytes cause significant changes in skin pH from acidic to an alkaline environment. This change in extracellular pH causes damage to host tissue, which increases the dermatophytes' virulence and the development of chronicity. Furthermore, the application of topical

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steroids increases the skin pH and decreases the barrier function.[14]

Keratolytics comprise several chemically non-homogeneous compounds that reduce the corneal layer. The main mechanisms of action include proteolytic cleavage of keratin (leading to thinning of stratum corneum) and dissolution of hydrophobic structures and membrane components in the intercorneocytic lipid matrix via hygroscopic forces (causing hydration of stratum corneum).[15] There are many substances classified as keratolytics, but Hydroxycarboxylic acids (alpha hydroxy acids, AHA), Lactic acid, propylene glycol, Salicylic acid, Tar, and Urea are important and are commonly used in various topical drugs and over-the-counter cosmetic preprations.[16]

Looking at the previous findings, keratolytics use seems logical in superficial fungal infections because of the following: 1; keratolytic actions leading to shedding of pathogens,2; thinning of the epidermis allows better penetration of topical drugs,3; decrease in pH reduces the tissue damage and virulence of fungi, and 4; softening of skin decreases the patients' symptoms.[17]

Methods

It was a double-blinded randomized controlled trial consisting of 140 participants. After obtaining ethical approval from the institutional review board (Ref: No.328.LRH/MTI dated 04.09.2024), the trial was registered in the primary clinical registry/ Thai Clinical Registry (TCTR20250815003). Sample size was calculated using G Power software, t- test (difference between 2 independent means), power 95%, alpha error probability 0.05, effect size 0.6. After obtaining written consent, patients were divided into two groups, each comprising of 70 patients. The consort flow diagram is shown in **Figure 1**.

Participants were randomly assigned to one of the study groups using the lottery method. Equal numbers of slips labelled with the treatment groups were prepared and placed in an opaque container. Each participant selected one slip, determining their group assignment. The allocation process was managed by an independent health care worker not involved in patient recruitment, treatment administration, or outcome assessment. Neither the participants nor the investigators responsible for treatment administration and outcome assessment were aware of the treatment allocation throughout the study period. Diagnosis was made mostly by clinical grounds while KOH smear was used in suspected cases. In order to strengthen the double blinding process, A placebo cream (white petroleum jelly in an unnamed packaging) was given to Group A patients. The study procedure, duration of follow-up, and possible adverse effects were explained. Patients in Group A used once daily oral terbinafine on weight basis (10-20kg:62.5mg/day, 20-40

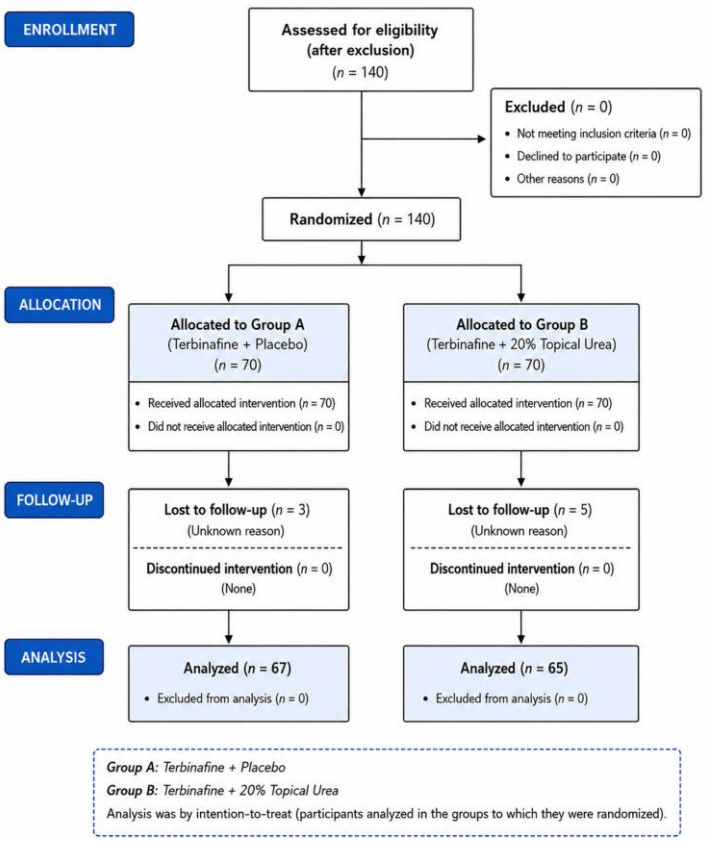


Figure 1 Consort Flow diagram showing patient allocation and follow-up (2 weekly and then monthly)

kg:125mg/day, >40kg:250mg/day) along with placebo cream applied twice a day without occlusion for 6 weeks. Group B followed the same regimen of oral terbinafine in addition to daily application of 20% urea on the lesions. The efficacy was assessed by digital photography as well as a 4-point clinical severity scale for each parameter, i.e. erythema, scaling, and pruritus, (0=no improvement, 1=mild improvement, 2=moderate improvement, 3=excellent improvement). This scoring system is used in other trials on dermatophytosis and inflammatory dermatosis as well and focuses on two objective (scaling and erythema) and one subjective parameter (pruritus).[18] Patients were followed on a fortnightly basis for the first month and then monthly for 6 months. Complete remission was defined by the absence of all signs and symptoms at the end of 6 months. All those patients who achieved excellent improvement initially at 6 weeks but developed new lesions or the older lesions reappeared were included in the recurrent category. Chronic cases consisted of all those patients in whom the lesions persisted or relapsed throughout the follow-up period without significant improvement with drug therapy.

Inclusion Criteria All patients with dermatophyte infection diagnosed on clinical grounds, between the ages of 2 and 16, and willing to participate in the study.

Exclusion Criteria Patients with diabetes mellitus or any other immunosuppressive disease and having a history of sensitivity to terbinafine or topical urea. Similarly, patients with past or current hepatitis or other liver diseases were considered ineligible for the trial. Patients already diagnosed with chronic or recurrent dermatophytosis were also excluded. Finally, patients with T. capitis and onychomycosis were not considered due to altered disease course and prolonged treatment regimens.

SPSS 25 was used to enter and analyse the data. Age and disease duration were computed as mean & SD. At baseline and six months following therapy, digital photography and a standardized questionnaire were used to compare the results. Frequencies and percentages for gender, recurrence, chronicity, and efficacy were determined. A Chi-square test was performed to assess the efficacy of understudy drugs in the two groups, with a two-sided *P*-value of <.05 being considered significant. Age, gender, disease duration, and pattern of body involvement were compared between the two groups.

Table 1 Baseline clinical and demographic data.

Parameter	*Group A*	*Group B*	*P-value*
Number of patients	70	70	
Age (Years)±SD	6.5±3.6	7.21±4.5	0.304
Gender			
Male	61%	55%	0.47
Female	38%	46%	0.33
Disease duration (Days)±SD	45.51±23.41	52.34±29.06	0.128
Family History	43%	39%	0.631
Pattern of Infection			
T. corporis	33%	29%	0.61
T. Faciei	12%	13%	0.85
T. cruris	20%	23%	0.66
T. pedis	4%	3%	0.74
T. manum	6%	4%	0.58
Mixed	25%	28%	0.68
Complete Remission at 6 months	13.4%	38.4%	0.001

P value<0.05=significant, SD=Standard deviation

Result

The basic clinical and demographic data of all patients is shown in **Table 1**. Males outnumbered females in both groups (61% in Group A and 55% in Group B). The mean age and disease duration were comparable in both groups. The most common pattern of skin involvement was T. Corporis (33%) followed Mixed (25%). Among patients achieving excellent improvement in signs and symptoms initially at 6 weeks **(Figure 2)**, 43.5% in Group A and 25 % in Group B become recurrent at 6 months (P-valve=.0258, 95% CI 2.29% - 33.37%) (Figure 3). Similarly at 6 months, 13.4% patients in Group A and 38.4% in Group B achieved complete remission (P-value=.0011, 95% CI 10.12% - 38.64%) while the number of chronic cases was also lesser in Group B (P-value=.0028, 95%CI 8.82% - 40.32%) **(Figure 3)**. In both groups, self-medication was the

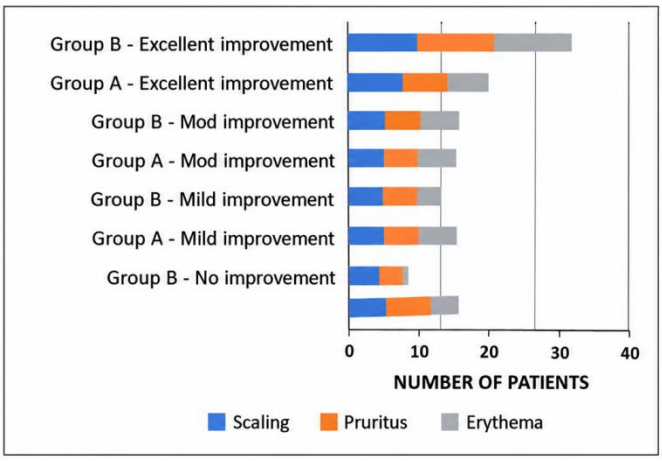


Figure 2 Clinical improvement at 6 weeks.

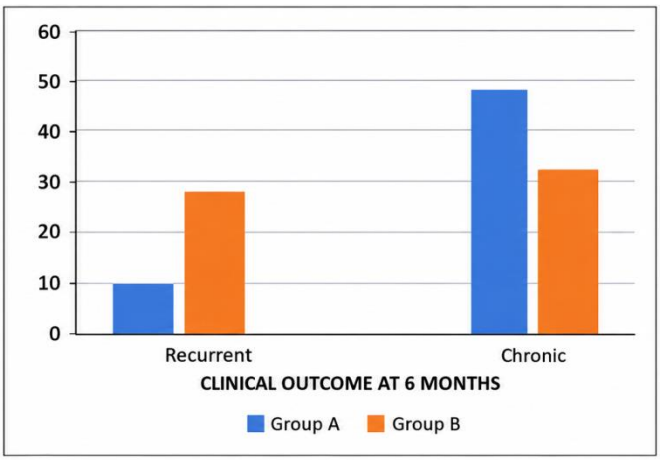


Figure 3 Final outcome at 6 months.

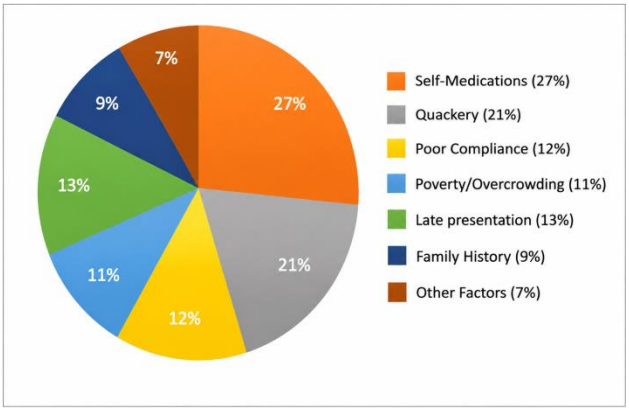


Figure 4 showing g various factors contributing to chronicity and recurrence.

predominant contributing factor to chronicity and recurrence, **(Figure 4)**. Local skin irritation was the main adverse effect in patients using topical urea.

Discussion

Dermatophyte skin infection is a common health issue in developing countries. Despite the availability of multiple treatment options, the number of chronic and difficult-to-treat cases is rising and can pose significant challenges for patients and healthcare providers. These cases often exhibit resistance to standard antifungal treatments, necessitating longer and more specialized therapies, as persistent itching and discomfort can severely impact a patient's quality of life.[19] Additionally, misdiagnosis or delayed treatment can contribute to the development of chronic cases, highlighting the importance of early detection and proper management. Efficacy of various drugs has been reported in chronic cases like Voriconazole, Amphotericin B, a combination of Itraconazole and systemic retinoids, etc. Still, the possible adverse effects and affordability issues may preclude the use of such drugs in children.[20] Therefore, other cost-effective options that reduce the incidence of recurrence and chronicity need to be utilized.

In this study, among 140 patients with superficial mycosis, one group used 20% urea cream in addition to oral and topical terbinafine, while another group used Terbinafine formulation along with a placebo. At final assessment, the patient using topical urea achieved a better rate of remission and lower incidence of recurrence and chronicity, while terbinafine alone was effective in only 13.4% of cases.

A cross-sectional study based on 800 school children was conducted in Nigeria to assess the pattern and demographic features of dermatophytosis. The order of frequency was Tinea corporis, followed by Tinea faciei and Tinea manum, which is comparable to our study, but due to the inclusion of other dermatophytosis subtypes, the overall percentage was low. Similar to our study, male patients outnumbered female patients (male 51 %, female 49%), and most of the patients had an age range between 9 and 12 years (Mean 9.42±2.00).[21] Male patient predominance was also observed in another study conducted by Faizan *et al.* in Lahore.[22] Male

predominance in Pediatric dermatophytosis, as shown in other studies as well, is attributed to more outdoor activities, gathering, and contact sports, etc. Another factor associated with low prevalence in girls may be related to better personal hygiene and self-care.[23]

Earlier studies showed good efficacy of oral and topical antifungals, but the number of resistant cases of superficial dermatophytosis, especially to Terbinafine, is increasing day by day.[24] An Indian study conducted by Ebert *et al*. evaluated Terbinafine resistance in 402 cases of superficial dermatophytosis. T corporis was the commonest form of dermatophytosis, followed by T. cruris and T. faciei. Most of the patients had been treated in the past with various drugs, including superpotent topical steroids. Skin scraping was taken as samples and grown on standard culture media. Trichophyton (T. mentagrophytes) was the most common isolate. Overall, 71% of isolates were Terbinafine resistant.[25] It was an in vitro study showing poor response of various dermatophyte strains to Terbinafine. Our study showed comparable findings as only 25.7% of patients achieved complete remissions, while 74.2% developed recurrence or chronicity as per clinical criteria.

Sanjeewani Fonseka *et al*. assessed the efficacy of keratolytics in combination with antifungals for the treatment of recalcitrant dermatophytosis. Thirty-four patients participated in the trial, all of those had difficult to treat dermatophytosis, defined as non-responsive to at least 2 systemic antifungal drugs received in the past 3 months. Lesions were randomized with modified Whitefield ointment (benzoic acid and salicylic acid, 5% each) applied on one group and an emulsifying agent applied on the other. In addition, all patients received systemic Griseofulvin 500mg daily for 2 months. At final assessment, the objective (erythema, induration, vesicles, pustules, scaling, maceration, papules) and subjective (pruritus, size, scaling, Irritation, overall) improvement was greater in the modified White field ointment arm. After 2 weeks of treatment, mean erythema and pruritus score in White field ointment group & emulsifying agent group, was 1.68±0.78 & 2.19±0.89 and 3.15±3.37 & 6.21±2.95 (*P*-value <.05).[26]

The efficacy of topical urea has been demonstrated in both in vivo and in vitro studies. Thirty-one samples were isolated from various body parts of patients with superficial fungal infections and cultured in multiple tubes with different urea concentrations. After 2 weeks, the growth of several dermatophyte species was inhibited with a positive correlation with higher urea concentration.[27] Similar results were observed in another experimental study conducted by Areeba *et al.*[28]

Clinical studies have shown better efficacy of topical urea in combination with other antifungals in dermatophyte infections associated with hyperkeratosis, like onychomycosis and moccasin foot. A systematic review and meta-analysis compared 130 patients who used 40% urea in addition to antifungal drugs for onychomycosis with 129 patients who used antifungals only. Results revealed better clinical outcomes in the former group of patients (P value<.05).[29] Another prospective study assessed the efficacy of 40% urea in combination with Ciclopirox in the treatment of moccasin tinea pedis. After 2-3 weeks of therapy, a 100% cure rate was observed.[30]

Many drug, host, and microbe-related factors contribute to resistance and hence lower antifungal efficacy. Molecular and genetic factor evaluation was beyond the scope of this study. Among the clinical factors, misuse of over-the-counter available topical steroids either alone or in combination with antifungals was the leading factor contributing to dermatophytosis recurrence and chronicity. Self-medication, poverty, and quackery promote the misuse of potent/ super potent steroids. In developing countries like Pakistan, patients choose the easier and economical options of self-medication or visiting non-Doctors/ general practitioners. Importantly, topical steroids mask the symptoms of superficial fungal infections, leading to delayed diagnosis and a prolonged treatment course. Other

risk factors like positive family history, poor Hygiene, overcrowding, and poor compliance with medications were also associated with lower antifungal efficacy in both groups. Our observations correlate with results from other regional and international studies.[32,33]

Conclusion

Chronic and recurrent dermatophytosis is a debilitating condition not only from a physical perspective, but also has a negative impact on the psychosocial and financial aspects of life. Early diagnosis and prompt treatment are key factors in preventing chronicity. In this study, we used topical 20% urea in combination with oral Terbinafine to treat pediatric dermatophytosis, and based on the results, it is concluded that this combination led to better remission rates as well as decreased the risk of chronicity and recurrence. Therefore, this combination may represent a more effective therapeutic approach than terbinafine alone for the management of pediatric dermatophytosis.

Limitations The small sample size limits the generalizability of the findings. The absence of fungal cultures prevented identification of specific species and their drug-responsiveness. Larger, multicenter trials are needed to validate the efficacy of topical urea and establish its role in dermatophyte infections, particularly chronic cases.

Declaration of patient consent Authors certify that they have obtained all appropriate patient consent.

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Conflict of interest No conflict of interest.

Author's contribution

MF: Substantial contribution conception and design of the study and drafting the manuscript.

MH: Substantial contribution conception and design of the study and critical review of the manuscript.

HK: Substantial contribution analysis and interpretation of data and drafting the manuscript.

SUR,FR,KI,MM: Substantial contribution conception and design of the study, data collection and drafting the manuscript.

Every author has given final approval of the manuscript version to be published and agreed to be accountable for all aspects of the work.

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