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Efficacy and Safety of Terbinafine Compared with Other Antifungal Agents in Dermatophytosis: A Systematic Review and Meta-analysis of Randomized Controlled Trials

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ABSTRACT

Background: Dermatophytosis is a frequent superficial fungal infection that causes significant morbidity and is increasingly associated with treatment failure. Terbinafine is frequently used as a first-line therapy; however, its relative efficacy compared with other antifungal agents remains inconsistent. This study aimed to assess the effectiveness and safety of Terbinafine compared to other antifungal agents in patients with dermatophytosis.

Methods: A systematic review and meta-analysis of the past 20 years was conducted following PRISMA 2020 guidelines. The databases used were PubMed, the Cochrane Library, and ScienceDirect. The outcomes assessed included overall cure, mycological cure, clinical cure, treatment failure, and adverse events. Random-effects models calculated risk ratios (RRs) and 95% confidence intervals (CIs).

Results: Thirteen RCTs were analyzed. No notable differences were found between Terbinafine and other antifungal agents in overall cure (RR: 0.87; 95% CI: 0.74–1.02), mycological cure (RR: 1.11; 95% CI: 0.89–1.38), or clinical cure (RR: 1.06; 95% CI: 0.96–1.16). However, Terbinafine was associated with a higher risk of treatment failure (RR: 6.22; 95% CI: 1.50–25.80). Subgroup analyses indicated Terbinafine was less effective for tinea corporis and tinea cruris, but more effective for tinea capitis. There were no significant differences in adverse events between the groups.

Conclusion: Terbinafine demonstrated efficacy comparable to that of other antifungal agents, but it may increase the risk of treatment failure under certain conditions. Its effectiveness appears to be context-dependent and influenced by the type of dermatophytosis and the causative pathogen.

Keywords: antifungals, efficacy, safety, Terbinafine, dermatophytosis.

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INTRODUCTION

Dermatophytosis is among the most prevalent superficial fungal infections globally. Estimates indicate that about 20–25% of the world's population is affected by superficial fungal infections at any given time, highlighting the significant public health challenge they pose.¹ A study at Jagakarsa Regional General Hospital from February 2023 to January 2024 found that infectious skin diseases made up 39.59% of cases, with fungal infections being the most common at 47.63%.² Data from Aisiyiah Islamic Hospital, Malang, indicated that tinea incognito was the most common tinea infection at 26%. This was followed by tinea unguium and

tinea faciei, each at 21%, then tinea capitis and tinea corporis, each at 11%, and tinea pedis and tinea cruris, each at 5% each).³

Dermatophytosis is especially common in tropical and subtropical areas, where high temperatures and humidity create ideal conditions for fungal growth. Its occurrence has reportedly risen in recent years.⁴ Beyond its high prevalence, dermatophytosis is associated with substantial morbidity, including chronic disease courses, frequent recurrence, and reduced quality of life due to persistent symptoms such as pruritus, discomfort, and cosmetic disturbance.⁵ Several studies have also documented increasing rates of therapeutic failure and treatment-resistant infection, which

have been linked to antifungal resistance, inappropriate therapy, and misuse of topical corticosteroid combinations.^{4,6}

Management of dermatophytosis generally involves the use of antifungal agents, either systemic or topical, such as Terbinafine, itraconazole, griseofulvin, and fluconazole. Among these agents, Terbinafine has long been regarded as a first-line therapy because of its fungicidal activity and favorable pharmacokinetic profile.⁷ Therapeutic responses to Terbinafine can differ among individuals, influenced by the causative organism and the type of infection. For instance, Terbinafine tends to be more effective against infections caused by *Trichophyton* species, while other treatments, such

as griseofulvin, may be better for *Microsporum* infections. Additionally, different forms of dermatophytosis exhibit varied clinical outcomes, highlighting the diversity in disease presentation and treatment response.^{8,9}

Despite the availability of various antifungal options, considerable uncertainty remains about their relative efficacy and safety. Randomized controlled trials have yielded inconsistent findings. Some studies have reported comparable efficacy between Terbinafine and itraconazole, whereas others have suggested superiority of alternative regimens or different therapeutic strategies.^{10,11} In addition, studies conducted in endemic settings have shown relatively low cure rates and high recurrence rates across several antifungal therapies, including Terbinafine.⁴ Differences in outcome definitions, such as clinical cure, mycological cure, and recurrence, further complicate direct comparisons across studies. Moreover, drug safety profiles, including the risks of hepatotoxicity and gastrointestinal adverse events, remain important considerations in treatment selection.⁹

Inconsistent evidence can hinder clinical decision-making. Therefore, a thorough review of current studies is necessary to evaluate Terbinafine's effectiveness and safety. This study aims to compare Terbinafine with other antifungal agents for the treatment of dermatophytosis, using data from randomized controlled trials.

METHODS

Study Design

This systematic review and meta-analysis assesses the efficacy and safety of Terbinafine compared to other antifungal agents in patients with dermatophytosis. It was conducted and reported in accordance with the PRISMA 2020 guidelines to ensure transparency, thoroughness, and high reporting quality.

Literature Search Strategy

The database used in this study includes PubMed, the Cochrane Library, and ScienceDirect. A structured search approach was implemented using selected keywords combined with Boolean

operators. Furthermore, including terms related to the intervention, condition, and study design, such as "terbinafine," "dermatophytosis," "tinea corporis," "tinea cruris," "tinea capitis," and "antifungal." The search strategy was adapted for each database by modifying the keywords to optimize sensitivity. Additional restrictions were applied to include only randomized controlled trials and full-text articles published within the past 20 years.

Eligibility Criteria

The inclusion criteria were (1) randomized controlled trials (RCTs) published within the past 20 years; (2) involved patients with dermatophytosis, including tinea corporis, tinea cruris, tinea capitis, tinea pedis, tinea unguium, and tinea faciei; (3) used Terbinafine, either orally or topically, as the intervention; (4) compared Terbinafine with one other antifungal agent used as monotherapy; and (5) reported relevant outcomes, namely cure rates (overall, mycological, or clinical). Exclusion criteria were: (1) unavailability of the full-text article; and (2) use of combination interventions involving more than one antifungal agent.

Study Selection

Multiple steps following the PRISMA guidelines were done in this study. Initially, all records from the database searches were compiled and screened using automated filters for publication year and study type. These records were then merged, and duplicates were removed. The remaining records were screened by title and abstract to assess eligibility against the inclusion criteria, with irrelevant studies excluded at this stage. Those who passed moved on to full-text assessment. During this review, studies that did not meet the criteria or lacked extractable data were excluded. The entire process is summarized in the PRISMA flow diagram. All authors participated in the selection process, and in case of disagreements, the final decision was made by majority vote.

Data Extraction

Data from studies meeting the inclusion criteria were systematically extracted and compiled into a study characteristics table. This table included details such

as the author's name, publication year, average participant age, sample size, study country, dermatophytosis type examined, intervention, and comparator for each study. The outcome data included the number of events and the total sample size in each group for the following outcomes: overall, mycological, and clinical cure rates; treatment failures or worsening conditions; and adverse events.

Risk of Bias Assessment

The included studies' risk of bias was evaluated using the Cochrane Risk of Bias tool version 2 (RoB 2). This evaluation covered five key areas: (1) the randomization process; (2) deviations from the intended interventions; (3) missing outcome data; (4) outcome measurement; and (5) the selection of reported results. Each area was classified as low risk, some concerns, or high risk of bias. The findings are displayed both graphically and in summary form to give an overall view of the studies' methodological quality.

Statistical Analysis

All included RCTs were statistically analyzed using Review Manager (RevMan) version 5.4. Because all outcomes were dichotomous variables, effect sizes were expressed as risk ratios (RRs) with 95% confidence intervals (CIs). Meta-analyses were performed using a random-effects model to accommodate clinical and methodological variation across studies. Between-study heterogeneity was assessed using the Chi-square test and the I^2 statistic. If the I^2 value exceeded 50%, it was considered indicative of substantial heterogeneity. The primary outcome was cure rate, analyzed according to three outcome definitions: overall cure, mycological cure, and clinical cure. Secondary outcomes included treatment failure or worsening of condition, as well as adverse events, grouped into gastrointestinal, dermatological, and neurological categories. Subgroup analyses were performed according to population type and comparator antifungal agent. Population-based subgroups comprised patients with tinea corporis, tinea cruris, and tinea capitis, while comparator-based subgroups compared Terbinafine with itraconazole and Terbinafine with griseofulvin.

RESULTS

Study Selection Results

A total of 3,823 records were identified across databases, including PubMed (n = 1,853), Cochrane (n = 311), and ScienceDirect (n = 1,659). Before screening, 3,051 records were removed, including 2,996 records excluded via automated filtering and 55 duplicate records. The automated filters included publication year and study type, such as randomized controlled trials, trials, and research articles.

A total of 772 records underwent title and abstract screening. Of these, 719 were excluded for not meeting the inclusion criteria, including 681 studies that were not randomized clinical trials and 38 that were not full-text articles. Fifty-three studies were then assessed for eligibility through full-text review. Of these, 40 studies were excluded because they involved combined interventions (n = 12), did not compare Terbinafine with another antifungal agent (n = 23), or did not report cure rates (n = 5). Ultimately, 13 studies met the inclusion criteria and were included in the analysis. The PRISMA flow of study selection is presented in Figure 1.

Risk of Bias Assessment

Overall, methodological quality varied across studies. Most demonstrated a low risk of bias in random sequence generation and allocation concealment, while an unclear risk was more common in blinding of participants, personnel, and outcome assessment, largely due to the predominance of open-label designs. Unclear risk was also observed in incomplete outcome data, primarily due to inadequate reporting of missing data handling or the absence of intention-to-treat analyses. Similarly, selective reporting was often rated as unclear because many studies lacked trial registration or published protocols, limiting the ability to verify prespecified outcomes. Despite some studies showing strong methodological rigor, common limitations included lack of blinding, incomplete reporting, and potential bias related to missing data.

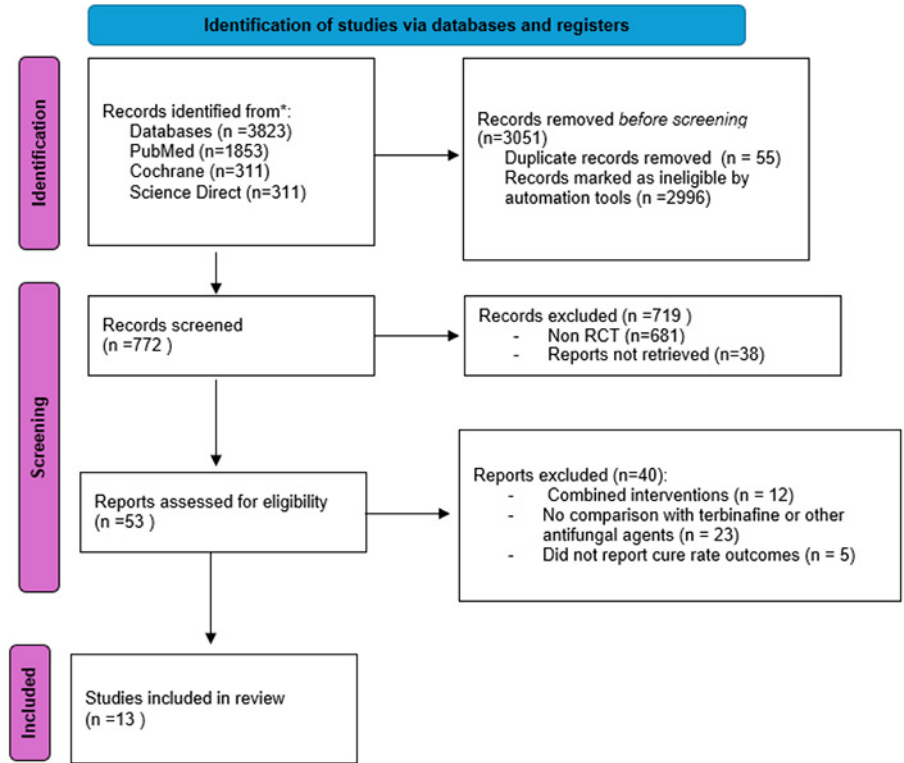


Figure 1. PRISMA diagram

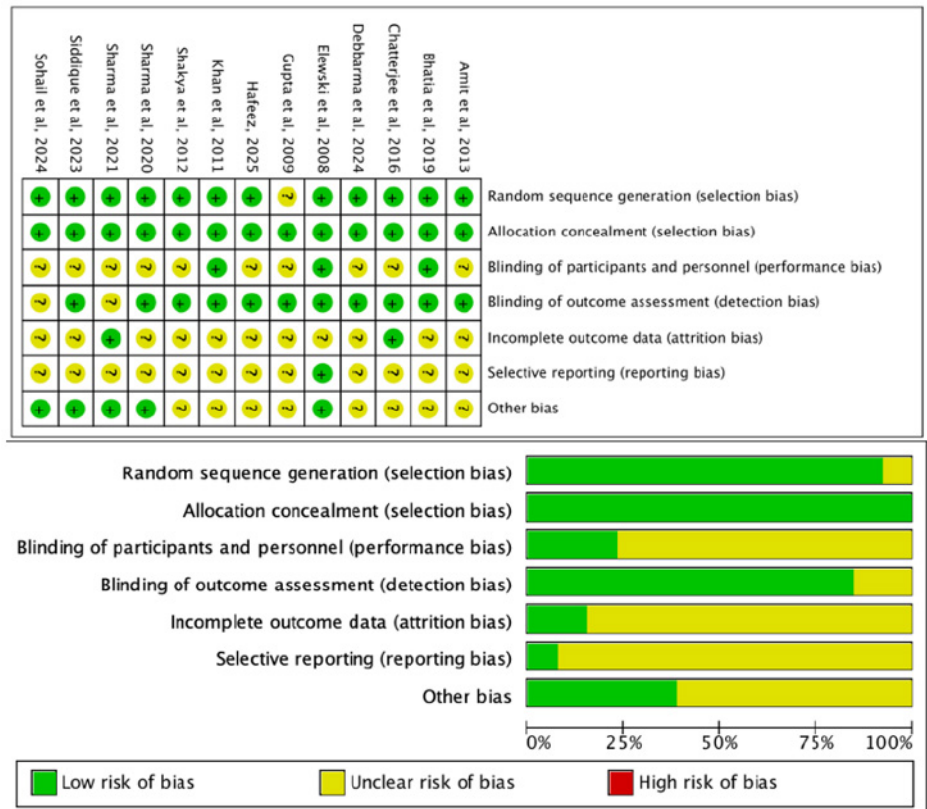


Figure 2. Risk of Bias Assessment

Table 1. Characteristics of the Included Studies.¹²⁻²⁴

Author, Year	Country	Population	Sample Size		Mean Age		Intervention	Comparator	Follow-up Duration (weeks)
			Terbinafine	Other Antifungal	Terbinafine	Other Antifungal			
Kumar et al., 2013 ¹²	India	Tinea corporis	42	50	30.40 ± 6.69	30.32 ± 6.67	Terbinafine 250 mg once daily for 4 weeks	Fluconazole 150 mg once weekly for 4 weeks	4
Bhatia et al., 2019 ¹³	India	Tinea corporis, tinea cruris	160	160	34.97 ± 14.12	34.78 ± 13.04	Terbinafine 500 mg once daily for 4 weeks	Itraconazole 200 mg once daily for 4 weeks	4
Chatterjee et al., 2016 ¹⁴	India	Tinea corporis, tinea cruris	91	88	37.8 ± 13.58	39.3 ± 13.76	Terbinafine 1% cream once daily	Sertaconazole 2% cream once daily	2
Debbarma et al., 2024 ¹⁵	India	Tinea capitis	50	50	9.8 ± 2.6	9.1 ± 2.4	Terbinafine 62.5, 125, 250 mg for 4 weeks	Griseofulvin 10–20 mg/kg body weight for 8 weeks	6 and 8
Elewski et al., 2008 ¹⁶	International multicenter	Tinea capitis	1040	509	6.9 ± 2.29	6.8 ± 2.25	Oral terbinafine hydrochloride granules 5–8 mg/kg body weight/day	Oral griseofulvin suspension 10–20 mg/kg body weight/day	10
Gupta et al., 2009 ¹⁷	Canada	Onychomycosis	43	40	51.2 ± 2.4	62.5 ± 2.6	Intermittent terbinafine	Pulse itraconazole	72
Hafeez, 2025 ¹⁸	Pakistan	Tinea corporis	25	25	35.16 ± 8.76	28.36 ± 10.65	Terbinafine 250 mg orally once daily for 8 weeks	Itraconazole 100 mg orally twice daily for 8 weeks	4
Khan et al., 2011 ¹⁹	Pakistan	Tinea capitis	60	60	7.5 ± 2.6	7.5 ± 2.6	Terbinafine 62.5–125 mg/day	Griseofulvin 15 mg/kg body weight	6
Shakya et al., 2012 ²⁰	Nepal	Tinea cruris	35	35	29.2 ± 5.5	29.4 ± 5.5	Terbinafine 250 mg once daily for 2 weeks	Itraconazole 100 mg orally twice daily for 2 weeks	4
Sharma et al., 2020 ²¹	India	Tinea corporis, tinea cruris	20	20	33.4 ± 11.9	34.05 ± 11.3	Oral Terbinafine 250 mg	Oral itraconazole 200 mg	3
Sharma et al., 2021 ²²	India	Tinea cruris	50	50	36	36	Terbinafine 250 mg orally once daily for 8 weeks	Itraconazole 100 mg orally twice daily for 8 weeks	8
Siddique et al., 2023 ²³	Pakistan	Tinea corporis, tinea cruris	80	80	9.5 ± 2.5	9.5 ± 2.5	Terbinafine 62.5–125 mg/day	Itraconazole 50–200 mg/day	8
Sohail et al., 2024 ²⁴	Pakistan	Tinea corporis	75	75	39.22 ± 10.61	37.36 ± 11.33	Terbinafine 250 mg orally once daily for 4 weeks	Itraconazole 100 mg orally twice daily for 4 weeks	6

Study Characteristics

Thirteen studies meeting the inclusion criteria were analyzed in this review. The studied populations were heterogeneous and encompassed several types of dermatophytosis. Most studies were conducted in Asian countries, particularly India and Pakistan, while several others were conducted in Nepal, Canada, and multinational centers. Sample sizes ranged from 20 to 1,040 participants in the terbinafine group, with generally balanced group allocations with heterogeneity in age characteristics, with mean ages ranging from pediatric populations (6–10 years) in studies of tinea capitis to adult populations (30–50 years) in studies of tinea corporis and onychomycosis. In general, the mean ages of the terbinafine and comparator groups within each study appeared comparable. In terms of intervention, Terbinafine was administered in various forms and regimens, both oral and topical, with doses adjusted according to the type of infection and patient characteristics. The comparator groups received a range of other antifungal agents, including itraconazole, griseofulvin, fluconazole, and sertaconazole, which were also administered in differing formulations and doses. The duration of follow-up differed among studies, ranging from 2 to 10 weeks in most dermatophytosis trials, whereas one onychomycosis study reported a longer follow-up of up to 72 weeks. Such variation may be attributed to differences in study design and disease characteristics **Table 1**.

Efficacy of Terbinafine Compared with Other Antifungal Agents According to Cure Rate

The comprehensive analysis of all included studies indicated no statistically significant difference in overall cure rates between Terbinafine and other antifungal agents (RR: 0.87; 95% CI: 0.74–1.02; P = 0.09; I² = 77%). Concerning the mycological cure rate, no significant difference was observed (RR: 1.11; 95% CI: 0.89–1.38; P: 0.34, I²:86%). The analysis of clinical cure rates similarly revealed no significant difference between Terbinafine and other antifungals (RR: 1.06; 95% CI: 0.96–1.16; P = 0.23; I² = 28%). Overall, there was no statistically significant difference in cure rates between

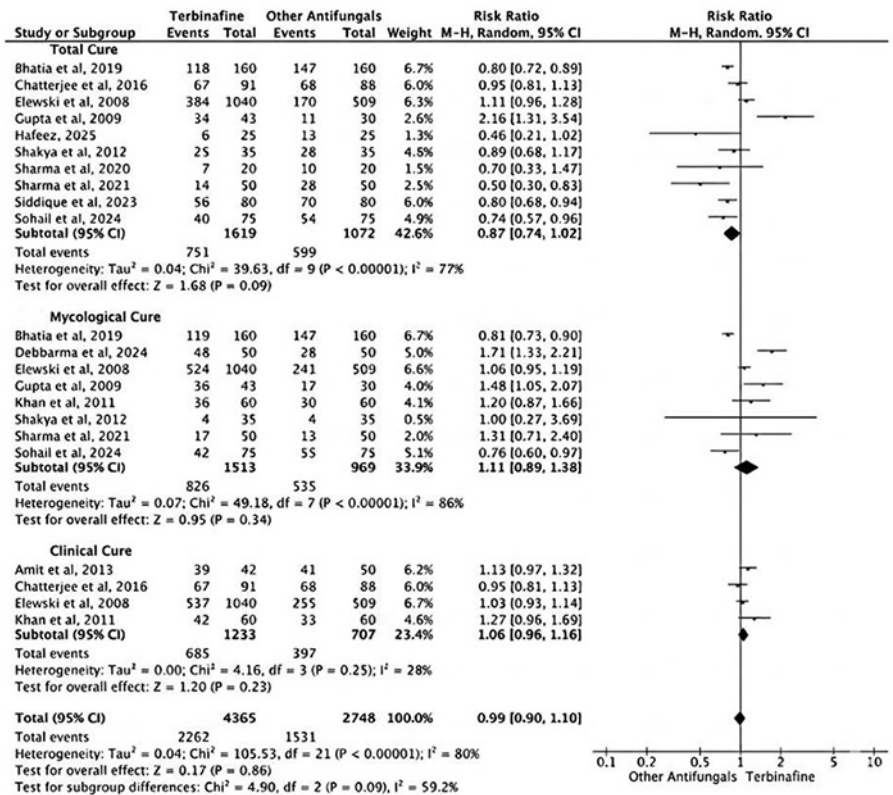


Figure 3. Forest plot illustrating the efficacy of Terbinafine compared to other antifungal agents, based on cure rates.

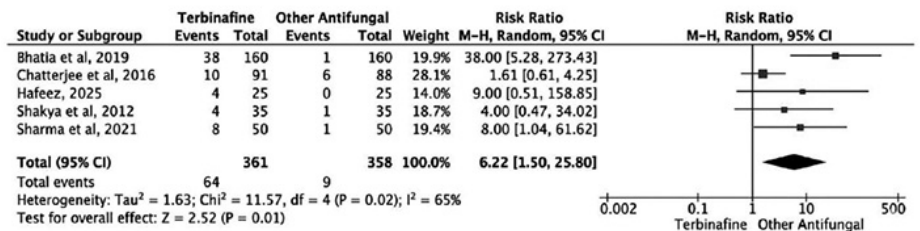


Figure 4. Forest plot of the efficacy of Terbinafine compared with other antifungal agents according to treatment failure or worsening condition

Terbinafine and other antifungal therapies (RR: 0.99; 95% CI: 0.96–1.16; P = 0.86).

Efficacy of Terbinafine Compared with Other Antifungal Agents According to Treatment Failure or Worsening Condition

The clinical reliability of Terbinafine was further scrutinized by evaluating the risk of treatment failure or worsening of the patient’s condition relative to alternative antifungal protocols. The synthesized evidence, as illustrated in the forest plot, indicates a significantly higher propensity for suboptimal outcomes within the Terbinafine cohort, yielding a

pooled Risk Ratio (RR) of 6.22 (95% CI: 1.50–25.80, p = 0.01). From a humanistic standpoint, this pronounced disparity suggests that a substantial subset of patients may experience persistent or exacerbating symptoms when managed with Terbinafine compared to broader-spectrum or newer antifungal alternatives. While individual study weights varied, the overall trend consistently aligns towards the ‘Other Antifungal’ group, emphasizing their superior efficacy in preventing disease progression. Although the moderate heterogeneity reflects variations in study environments and patient demographics, the collective data

serves as a critical clinical indicator that, in specific recalcitrant cases, alternative therapeutic strategies may be more effective in safeguarding patients from treatment refractory states and ensuring sustained clinical stability.

Adverse Events Associated with Terbinafine Compared with Other Antifungal Agents

A. Gastrointestinal Adverse Events

Gastrointestinal adverse events showed no significant difference between Terbinafine and other antifungal agents (RR: 0.93; 95% CI: 0.65–1.32; p: 0.67). Subgroup analyses likewise demonstrated no significant differences for diarrhea (p: 0.58), abdominal pain (p: 0.45), nausea/vomiting (p: 0.71), or anorexia (p: 0.76).

B. Dermatological Adverse Events

The analysis of dermatological adverse events, such as rash and pruritus, revealed no statistically significant difference between Terbinafine and other antifungal agents (RR: 0.94; 95% CI: 0.56–1.59; P: 0.82). In subgroup analyses, the incidence of rash did not differ significantly between groups (RR: 0.98; 95% CI: 0.45–2.14; P: 0.96). Likewise, pruritus showed no significant difference (RR: 0.91; 95% CI: 0.45–1.84; P: 0.80).

C. Neurological Adverse Events

The analysis showed no statistically significant difference between Terbinafine and other antifungal agents in headache occurrence (RR: 1.06; 95% CI: 0.75–1.51; P: 0.73). A higher incidence of headache was discovered in the terbinafine groups.

Analysis of Cure Rate, Treatment Failure, and Adverse Events Associated with Terbinafine Compared with Other Antifungal Agents According to Population

A. Cure Rate in Tinea Corporis and Tinea Cruris

In patients with tinea corporis and tinea cruris, Terbinafine had a lower overall cure rate than other antifungal agents (RR: 0.81; 95% CI: 0.73–0.90; P < 0.0001). For mycological cure, Terbinafine also demonstrated a lower cure rate than other antifungals (RR: 0.81; 95% CI: 0.74–0.89; P < 0.0001). However, no significant

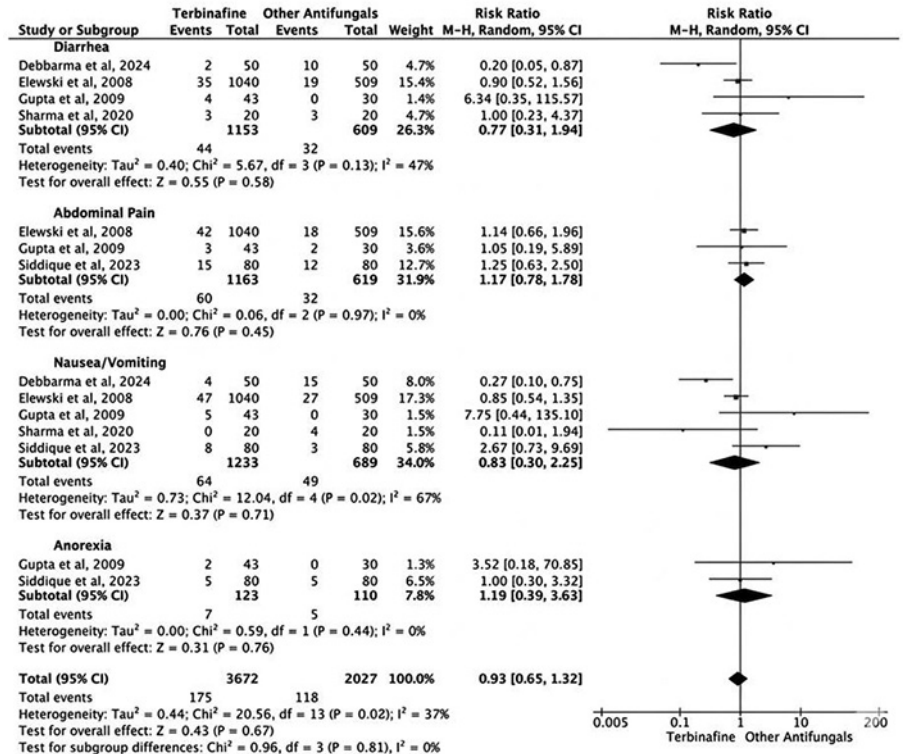


Figure 5. Forest plot of adverse events associated with Terbinafine compared with other antifungal agents in the gastrointestinal system

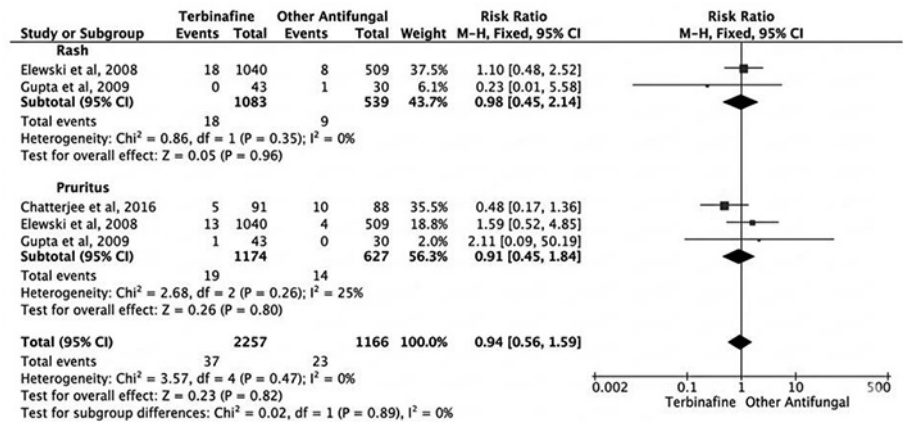


Figure 6. Forest plot of adverse events associated with Terbinafine compared with other antifungal agents in the dermatological domain

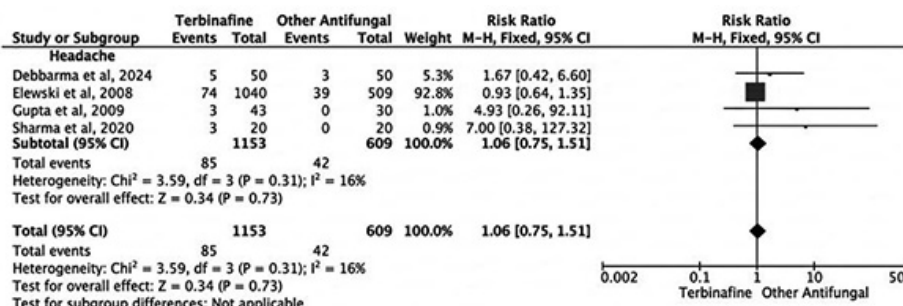


Figure 7. Forest plot of adverse events associated with Terbinafine compared with other antifungal agents in the neurological system

difference in clinical cure was found between the two groups (RR: 1.04; 95% CI: 0.87–1.25; P: 0.65). The pooled analysis indicated that Terbinafine has a lower cure rate compared to other antifungal agents (RR: 0.85; 95% CI: 0.78–0.94; P: 0.0009).

B. Treatment Failure or Worsening Condition in Tinea Corporis and Tinea Cruris

Among patients with tinea corporis and tinea cruris, the analysis indicated that Terbinafine was linked to a higher risk of treatment failure or worsening conditions compared to other antifungal agents (RR: 6.22; 95% CI: 1.50–25.80; P: 0.01)

C. Adverse Events in Tinea Corporis and Tinea Cruris

The safety and tolerability of Terbinafine, compared with alternative antifungal interventions for tinea corporis and tinea cruris, are systematically evaluated in the forest plot of adverse events presented here. Terbinafine maintains a safety profile comparable to that of other antifungal agents with p-values exceeding the threshold for statistical significance (p:0.04).

D. Cure Rate in Tinea Capitis

Among patients with tinea capitis, the mycological cure analysis revealed no statistically significant difference between Terbinafine and other antifungal agents (RR: 1.29; 95% CI: 0.94–1.76; 0.12; I²: 83%). Similarly, the clinical cure analysis showed no significant difference between the two groups (RR: 1.10; 95% CI: 0.91–1.33; P: 0.33; I²: 47%). Overall, the results indicated that Terbinafine was associated with a higher cure rate than other antifungal agents (RR: 1.20; 95% CI: 1.02–1.40; P: 0.03) in patients with tinea capitis.

E. Adverse Events in Tinea Capitis

Among patients with tinea capitis, the overall assessment of adverse events showed no significant difference between Terbinafine and other antifungal medications (RR: 0.85; 95% CI: 0.54–1.35; P = 0.49). In subgroup analyses, the incidence of diarrhea and headache did not differ significantly between Terbinafine and other antifungal drugs, and both adverse events were most observed in the Terbinafine group.

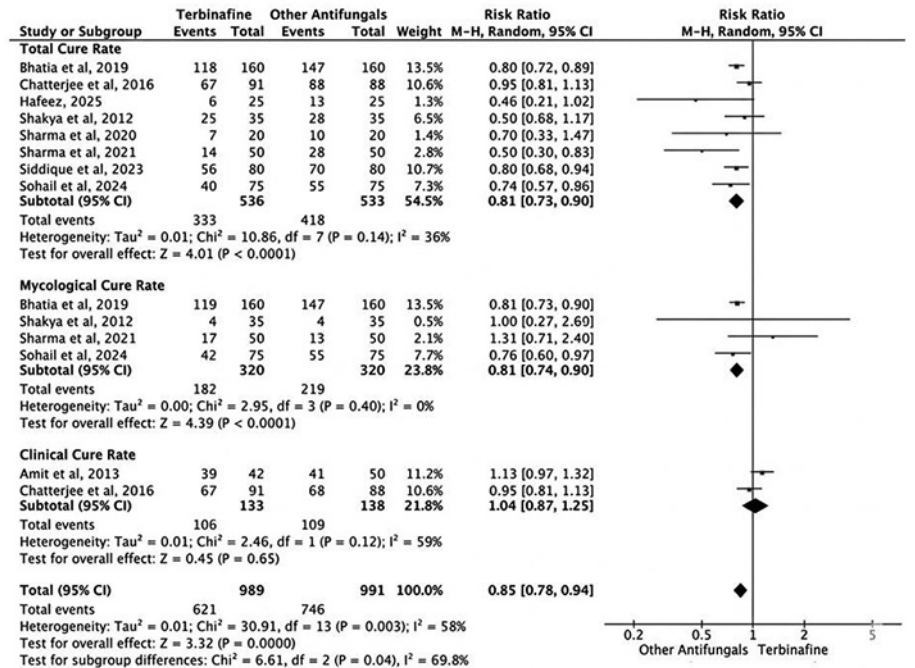


Figure 8. Forest plot illustrating cure rates for tinea corporis and tinea cruris.

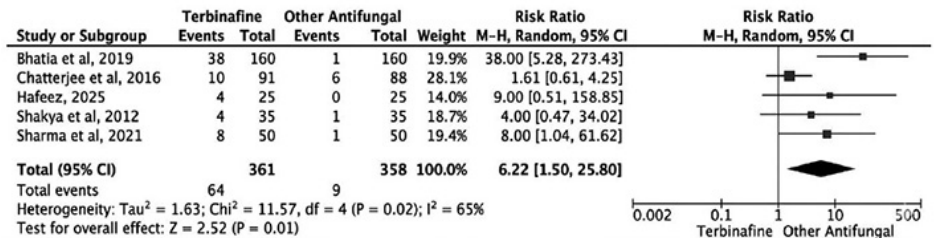


Figure 9. Forest plot of treatment failure/worsening condition in tinea corporis and tinea cruris

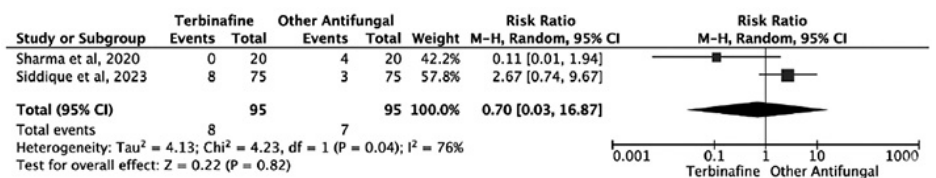


Figure 10. Forest plot of adverse events in tinea corporis and tinea cruris

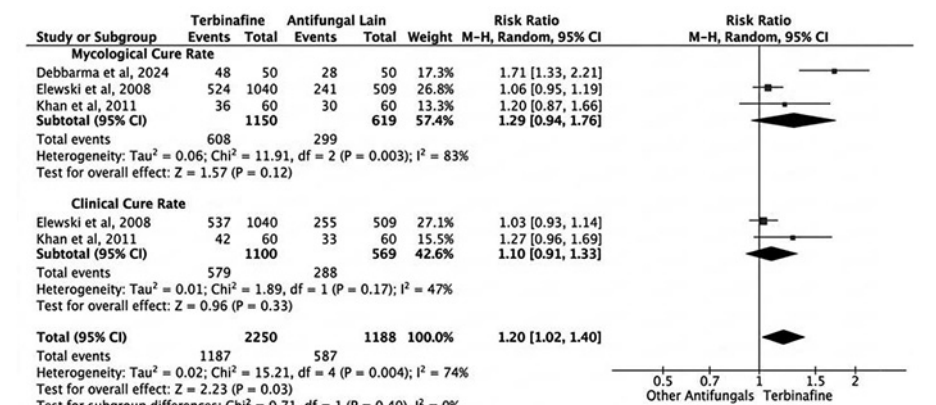


Figure 11. Forest plot of cure rate in tinea capitis.

Analysis of Cure Rate, Treatment Failure, and Adverse Events Associated with Terbinafine Compared with Other Antifungal Agents

A. Cure Rate of Terbinafine and Itraconazole

The overall analysis of cure rates indicated that Terbinafine had a lower success rate than itraconazole (RR: 0.82; 95% CI: 0.68–0.98; P: 0.03). However, for mycological cure, no statistically significant difference was observed between Terbinafine and itraconazole (RR: 0.98; 95% CI: 0.74–1.29; P: 0.89). Overall, the analysis showed a lower cure rate in the terbinafine group than in the itraconazole group (RR: 0.87; 95% CI: 0.76–0.99; P: 0.03).

B. Treatment Failure or Worsening Condition of Terbinafine and Itraconazole

The analysis indicated that Terbinafine is associated with a 15.57-fold higher risk of treatment failure or worsening condition compared with itraconazole (RR: 15.57; 95% CI: 5.34–45.38; P < 0.00001). A total of 54 patients were found in the terbinafine group, and only 3 patients in the itraconazole group had treatment failure or worsening condition.

C. Adverse Events of Terbinafine and Itraconazole

Overall analysis showed no significant difference between the two groups, including subgroup analyses (diarrhea, abdominal pain, vomiting, anorexia). However, a higher proportion of adverse events was observed in the terbinafine groups.

D. Cure Rate of Terbinafine and Griseofulvin

No statistically significant differences were observed between Terbinafine and griseofulvin in terms of mycological cure (RR: 1.22; 95% CI: 0.88–1.70; p = 0.23) or clinical cure (RR: 1.10; 95% CI: 0.91–1.33; p = 0.33). Overall, the pooled analysis also showed no significant difference in cure rates between the two treatments (RR: 1.17; 95% CI: 1.00–1.37; p = 0.05).

E. Adverse Events of Terbinafine and Griseofulvin

The overall analysis showed no statistically significant difference in adverse events

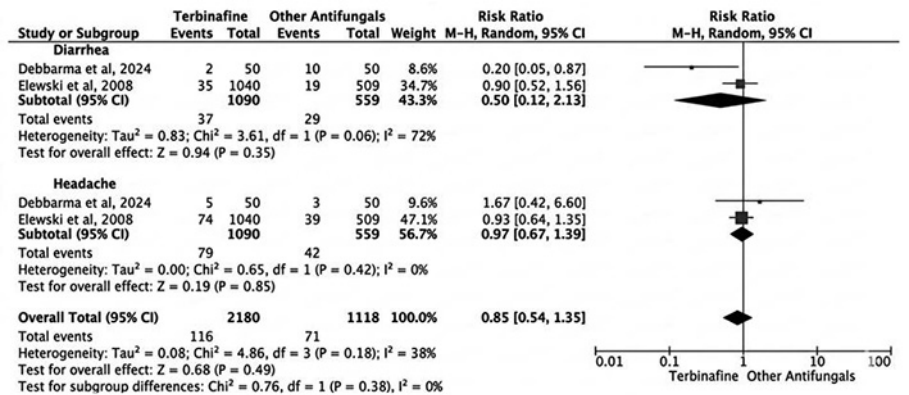


Figure 12. Forest plot of adverse events in tinea capitis

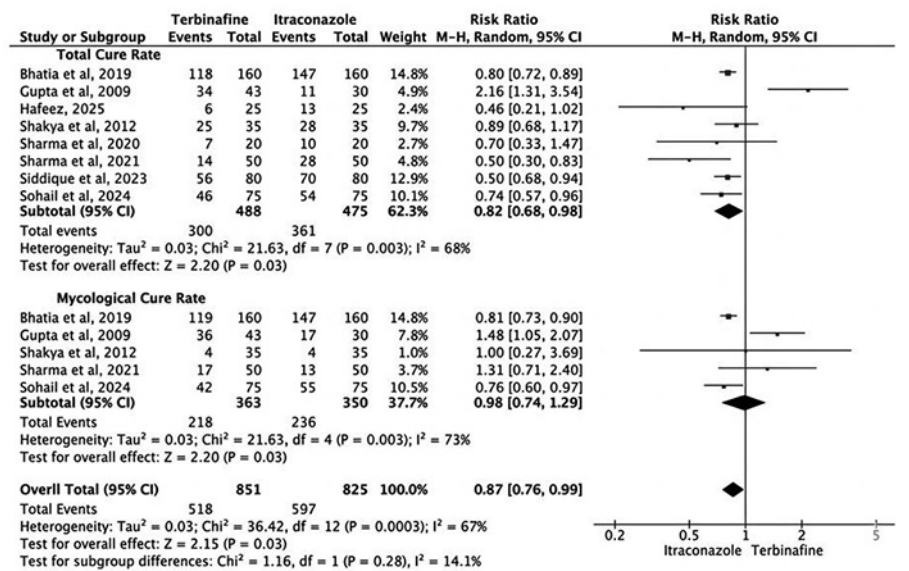


Figure 13. Forest plot of cure rate: Terbinafine and itraconazole

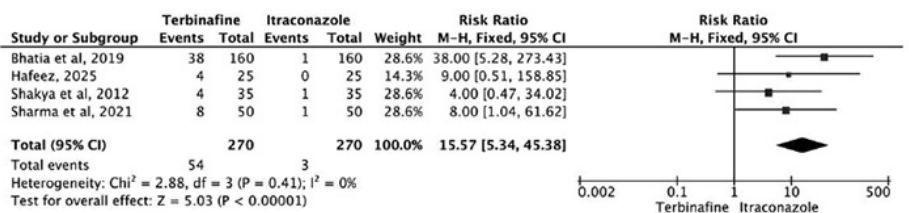


Figure 14. Forest plot of treatment failure or worsening condition of Terbinafine and itraconazole

between Terbinafine and griseofulvin (RR: 0.75; 95% CI: 0.51–1.11; p = 0.15). Subgroup analyses likewise revealed no significant differences for diarrhea (RR: 0.50; 95% CI: 0.12–2.13; p = 0.35), nausea/vomiting (RR: 0.52; 95% CI: 0.17–1.62; p = 0.26), or headache (RR: 0.97; 95% CI: 0.67–1.39; p = 0.85).

DISCUSSION

Most studies were conducted in Asia, particularly India and Pakistan, regions with a high prevalence of dermatophytosis due to climatic and environmental factors. There was also marked variation in age distribution, ranging from pediatric populations with tinea capitis

to adult populations with tinea corporis and onychomycosis. This variation reflects the broad clinical spectrum of dermatophytosis and potential differences in treatment response across populations. In addition, heterogeneity was observed in the interventions themselves, including differences in dosage, treatment duration, and comparator antifungal agents. Such variation may have contributed to the heterogeneity identified in the statistical analyses.

Methodologically, study quality varied, with the main strengths being relatively adequate randomization and allocation concealment in several studies. However, limitations were consistently identified in the blinding domain, as most studies employed open-label designs. This increases the potential for bias, particularly for subjective outcomes such as clinical cure. In addition, several studies provided insufficient reporting of missing-data handling, including a lack of explicit intention-to-treat analyses, which may affect the validity of the findings. The absence of trial registration or previously published protocols also represents an important limitation in assessing the likelihood of selective reporting.

Terbinafine, a member of the allylamine class, exerts its antifungal effects by inhibiting the squalene epoxidase enzyme, which is responsible for converting squalene precursors into ergosterol. By disrupting ergosterol synthesis, a critical structural component of fungal cell membranes, the drug induces membrane instability and increased permeability, ultimately leading to cell death. Furthermore, the accumulation of non-metabolized squalene exerts cytotoxic effects, further precipitating fungal cell lysis. Due to its high lipophilicity, Terbinafine readily achieves high concentrations and binds efficiently to the stratum corneum, sebum, and hair follicles, thereby reducing the likelihood of recurrent infections. Allylamines possess a broad-spectrum antifungal profile and have demonstrated significant clinical efficacy in treating various superficial mycoses, such as tinea corporis, tinea cruris, and tinea pedis.²⁵ In this study, although the cure rate was higher in the terbinafine group compared to other therapies, the difference was not

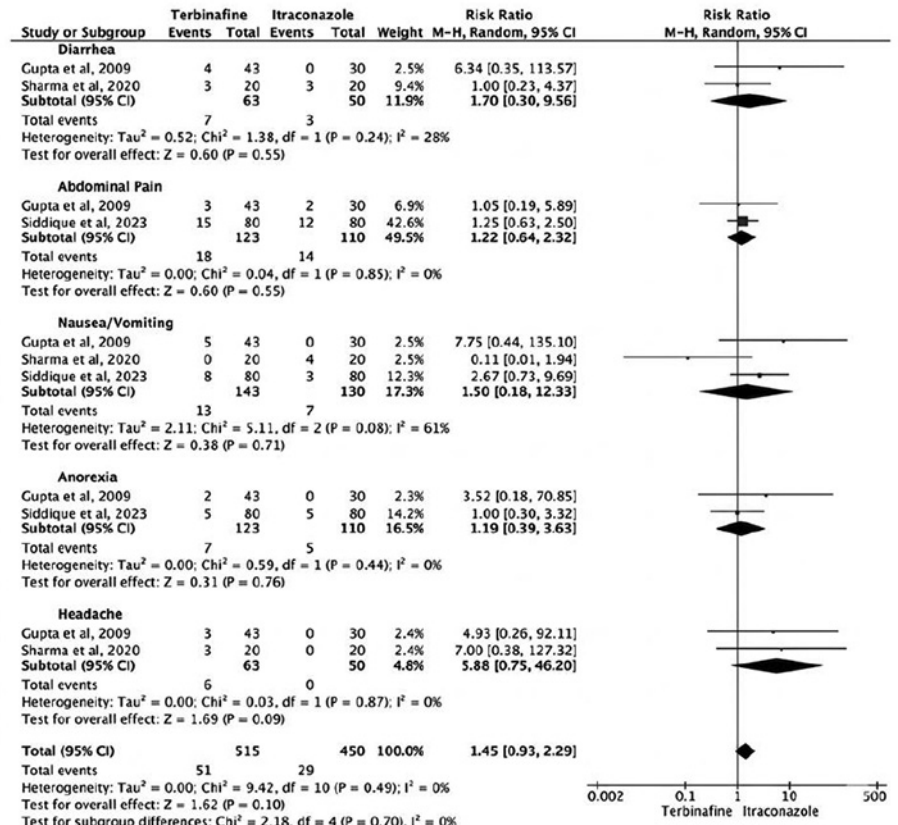


Figure 15. Forest plot of adverse events: Terbinafine and itraconazole

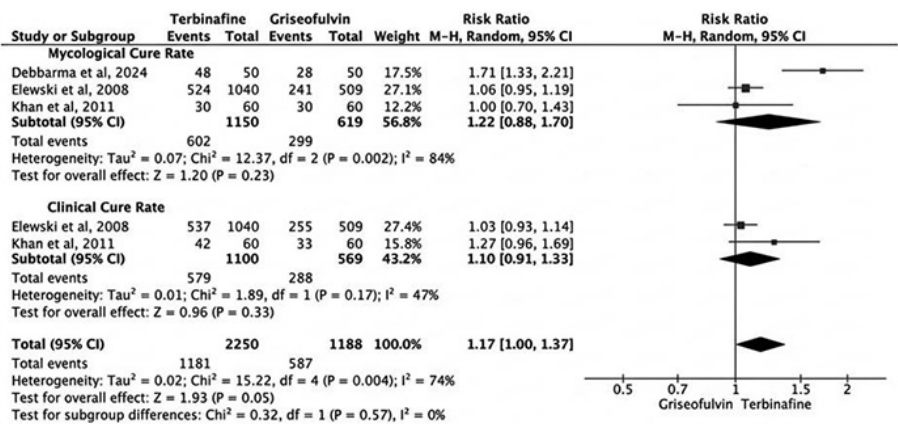


Figure 16. Forest plot of cure rate: Terbinafine and griseofulvin

statistically significant. However, a higher rate of treatment failure was also observed in the terbinafine group, although the number of cases was proportionally smaller than the number of cured patients. In subgroup analyses, treatment response varied by type of dermatophytosis. In this review, Terbinafine appeared to be less effective in tinea corporis and tinea cruris, but tended to perform better in

tinea capitis. These findings suggest that Terbinafine's efficacy is not universal; rather, it depends on the type of infection and possibly on the underlying causative species.

Terbinafine treatment failure may be due to several factors. Factors contributing to terbinafine treatment failure are best understood through an integrated lens that spans molecular resistance,

pharmacological barriers, and patient-centered factors, with careful attention to the nuances and disagreements across the current literature. At the molecular level, the dominant driver of reduced terbinafine susceptibility in dermatophytes is point mutations in the squalene epoxidase (SQLE) gene, notably at hotspots such as Leu393 and Phe397, with additional relevant changes at Phe415 and His440; these alterations can distort terbinafine binding and elevate MICs, sometimes correlating with clinical nonresponse, though the strength of this genotype–phenotype link varies by study and organism.^{26–31} Importantly, several analyses emphasize that SQLE mutations do not uniformly predict clinical failure in all isolates, indicating that concomitant resistance mechanisms such as upregulation of efflux pumps (ABC and MFS transporters), and potentially enzyme overexpression or compensatory metabolic pathways may act synergistically with SQLE changes to foster resistance and treatment relapse.^{32–36} The literature also underscores the role of biofilm formation by dermatophytes in reducing drug penetration and promoting recalcitrance, with biofilms showing higher terbinafine MICs than planktonic cells and potentially requiring higher drug exposures or combination strategies to achieve clearance; while most detailed biofilm data come from dermatophyte species such as *T. rubrum*, *M. canis*, and *T. mentagrophytes*, the translational implication is clear: biofilm-associated resistance can complicate therapy even when SQLE mutations are subclinical or absent.^{31,32,36–39} On the pharmacological front, Terbinafine’s lipophilic distribution yields high concentrations in sebum-rich skin but imperfect penetration into hard keratin in nails or deeper epidermal compartments, potentially leaving sanctuary sites that permit persistence or relapse, coupled with biofilm barriers. Clinically, adherence and dosing strategies further modulate outcomes: prolonged or suboptimal exposure can foster resistance selection and relapse, while antifungal stewardship approaches advocate tailoring therapy guided by species identification, susceptibility testing where feasible, and consideration of alternative agents or

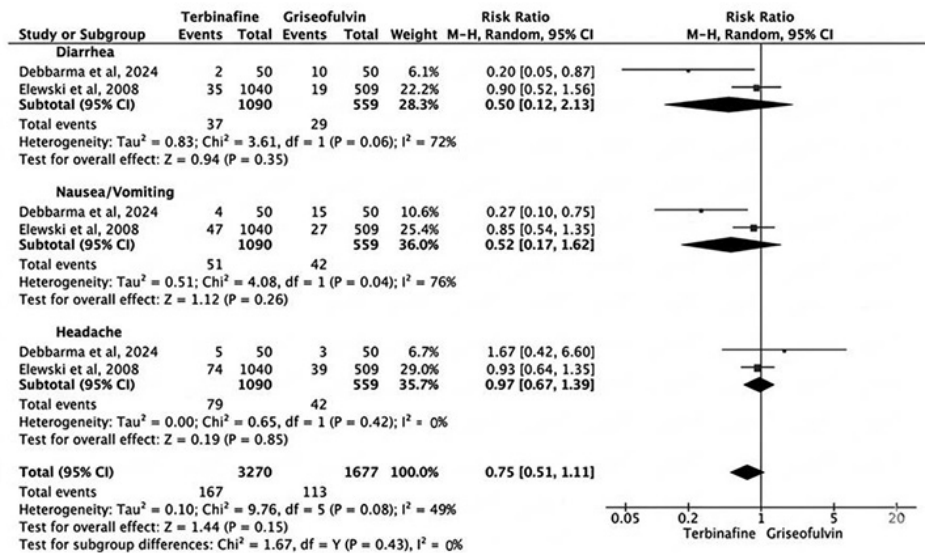


Figure 17. Forest plot of adverse events: Terbinafine and griseofulvin

combination regimens to circumvent resistance^{28,30,37,40,41}.

Patient-level factors such as immune status, comorbidities (e.g., diabetes), and exposure history also influence relapse risk and pharmacodynamic realized exposure, intersecting with pharmacokinetic variability and adherence that shape the ultimate clinical trajectory of terbinafine therapy.^{28,30,40,42} In summary, treatment failure emerges from a complex, multilayered interplay: SQLE mutations and potential coexisting efflux or metabolic adaptations raise intrinsic resistance, biofilms and limited tissue penetration impede drug delivery to the pathogen, and patient-centric determinants—adherence, comorbidity, and drug interactions determine whether sufficient drug exposure is achieved in the infected niche. Recognizing this convergence has practical implications: it justifies integrating rapid molecular or multiplex diagnostic tools to detect SQLE mutations and resistance signatures, reinforces the value of AFST-guided therapy alongside molecular diagnostics in select settings, and supports strategies such as topical/combination regimens or azole alternatives when the clinical context suggests resistance signatures or poor penetration. Where data diverge, including variable correlations between SQLE mutations and clinical outcomes, this heterogeneity highlights the need for standardized susceptibility testing,

surveillance of SQLE variants, and prospective studies linking genotype to pharmacokinetics and clinical response to refine treatment pathways and stewardship efforts.^{26,28,30,31,36}

The findings of this meta-analysis are generally consistent with previous studies showing that Terbinafine is not consistently superior to other antifungal agents across different forms of dermatophytosis. This is illustrated by the meta-analysis conducted by Korting et al., which showed that although Terbinafine was significantly more effective than placebo, no statistically significant difference was observed when it was compared with other active antifungal agents, either in terms of clinical or mycological cure. This is consistent with the present study, which likewise found no significant difference in cure rates between Terbinafine and other antifungal agents. In addition, that study highlighted the advantage of Terbinafine in terms of shorter treatment duration, which was not directly evaluated in the present analysis but may represent an important consideration in clinical practice.⁴³

Conversely, multiple meta-analyses indicate that Terbinafine’s effectiveness varies significantly depending on the dermatophyte species involved. Gupta et al. found no major overall difference between Terbinafine and griseofulvin in the treatment of tinea capitis. However, subgroup analyses revealed that Terbinafine is more effective against *Trichophyton*

infections, while griseofulvin is more effective against *Microsporum* infections. This finding was reinforced by a more recent network meta-analysis, which demonstrated a similar pattern using ranking approaches (SUCRA), indicating that treatment efficacy is highly dependent on the causative organism. This may help explain the variation in findings observed in the present meta-analysis, particularly in subgroup analyses, where differences in therapeutic efficacy were likely influenced by non-uniform distributions of dermatophyte species across studies.⁴⁴

Moreover, in more severe infections, such as onychomycosis, Terbinafine has shown better efficacy than topical therapy, although it is not always superior to other systemic antifungal agents, such as itraconazole.⁴⁴

This meta-analytic synthesis of terbinafine safety data demonstrates a safety profile that is broadly comparable to that of other systemic antifungals across gastrointestinal, dermatological, and neurological domains. This conclusion rests on non-significant pooled risk ratios (RRs) for the principal adverse-event categories examined (gastrointestinal effects (diarrhea RR 0.77, abdominal pain 1.17, nausea/vomiting 0.83, anorexia 1.19; all $P > 0.05$ with 95% CIs crossing 1.0), dermatologic effects (rash RR 0.98, pruritus 0.91; both non-significant), and neurological effects (headache RR 1.06; non-significant). The consistency of non-significance across these domains reinforces the interpretation that Terbinafine does not confer a statistically higher adverse-event burden relative to comparator antifungals, despite its potent mechanism of action as a squalene epoxidase inhibitor.⁴⁵

The potent fungicidal activity of Terbinafine does not correlate with an increased burden of systemic adverse effects in clinical practice. This safety profile is consistent with broader pharmacovigilance data, confirming Terbinafine's favorable tolerability and safety for treating superficial mycoses, such as tinea and onychomycosis, in appropriately selected patient populations.⁴⁶⁻⁴⁸ The absence of a signal for excess harm supports its continued role as a first-line systemic option

for dermatophytic infections, where prolonged therapy is sometimes required and nail or skin involvement necessitates sustained drug exposure.

Clinically, this safety consistency carries meaningful implications for long-term management. Dermatology practice increasingly contemplates extended courses for onychomycosis and chronic superficial infections, contexts in which cumulative adverse events could be limiting if the safety profile were unfavorable. The pooled non-significance across gastrointestinal, cutaneous, and neurological domains suggests that clinicians can prioritize efficacy and pharmacokinetic considerations, such as nail bed penetration and sebum-rich skin distribution, without necessarily increasing patient risk of adverse events compared with alternative agents. In practice, this supports Terbinafine as a viable long-term option for superficial mycoses, particularly when sustained systemic exposure is required to achieve mycological cure and clinical remission, provided baseline liver function and potential drug interactions are considered, in line with established guidelines and reviews that emphasize appropriate patient selection and monitoring when needed.⁴⁷⁻⁴⁹

However, these findings cannot be fully generalized to superficial dermatophytosis such as tinea corporis or tinea cruris, which were the main focus of the present study. Overall, discrepancies across previous meta-analyses indicate that Terbinafine's efficacy is context-dependent and influenced by infection type, anatomical site, and underlying pathogen characteristics.

CONCLUSION

This systematic review and meta-analysis found no significant differences between Terbinafine and other antifungal agents in overall, mycological, or clinical cure rates among patients with dermatophytosis. However, Terbinafine was associated with a higher risk of treatment failure or worsening outcomes. Subgroup analyses indicated that its efficacy varied by infection type, with lower effectiveness in tinea corporis and tinea cruris but more favorable outcomes in tinea capitis. No

significant differences in adverse events were observed across gastrointestinal, dermatological, or neurological systems. Overall, these findings suggest that Terbinafine's effectiveness is context-dependent, and treatment selection should consider infection type and individual clinical factors.

DISCLOSURE

Author Contribution

All authors made substantial contributions to the study.

Conflict of Interest

None

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None

Generative AI statement

The authors declare that no generative artificial intelligence (AI) tools were used at any stage of this study, including manuscript writing, data analysis, or interpretation. All aspects of the work were performed entirely by the authors.

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