COMPARATIVE EFFICACY OF TOPICAL OXICONAZOLE CREAM (1%) VERSUS TOPICAL CLOTRIMAZOLE CREAM (1%) IN THE TREATMENT OF TINEA CRURIS

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ABSTRACT

OBJECTIVES

To compare the clinical efficacy of topical Oxiconazole 1% cream with topical clotrimazole 1% cream in patients with KOH-confirmed tinea cruris.

METHODOLOGY

The study was conducted in the Department of Dermatology, MTI-Hayatabad Medical Complex, Peshawar, from 12 May, 2025 to 12 Nov, 2025. A total of 386 patients aged 18–60 years with clinically diagnosed tinea cruris confirmed by potassium hydroxide mount were consecutively recruited and randomly allocated into two equal treatment groups. Group A received topical Clotrimazole 1% cream, while Group B received topical Oxiconazole 1% cream, applied twice daily for four weeks. Clinical severity was assessed at baseline and at Week 4 using a composite symptom score comprising pruritus, erythema, vesicles, and desquamation, each graded from 0 to 3. Clinical response was defined as ≥50% reduction in total symptom score at Week 4. The primary analysis was performed according to the randomized groups. Mean differences with 95% confidence intervals were calculated for symptom scores, and the risk difference with 95% confidence interval was calculated for clinical response. Data were analyzed using IBM SPSS version 25, with $p \leq 0.05$ considered statistically signific ant.

RESULTS

All 386 randomized patients were included in the Week-4 analysis, with 193 patients in each group. Baseline symptom scores were comparable between the groups. At Week 4, pruritus score was significantly lower in the oxiconazole group than in the clotrimazole group (0.74±0.63 vs. 0.93±0.58; mean difference -0.19, 95% CI -0.31 to -0.07; p=0.003). Week-4 erythema, vesicles, and desquamation scores did not differ significantly between the groups. Overall clinical response was achieved in 165/193 patients (85.5%) in the oxiconazole group and 157/193 patients (81.3%) in the clotrimazole group, with a risk difference of 4.1% (95% CI -3.3% to 11.6%; p=0.274). Clinical response remained comparable across gender strata.

CONCLUSION

Topical Oxiconazole 1% and Clotrimazole 1% creams showed comparable overall clinical response in KOH-confirmed tinea cruris after four weeks of treatment. Oxiconazole produced a statistically greater reduction in pruritus; however, the magnitude of difference was small. As Week-4 mycological cure, antifungal susceptibility, quality-of-life assessment, adverse-event profile, and recurrence after treatment were not assessed in the available dataset, the findings should be interpreted as short-term clinical response rather than confirmed microbiological eradication.

KEYWORDS: *Tinea cruris; Dermatophytosis; Clotrimazole; Oxiconazole; Topical antifungal; Randomized controlled trial; Clinical response; Pruritus*

INTRODUCTION

Dermatophytosis is one of the commonest superficial fungal infections worldwide and affects approximately 20-25% of the global population.[1] It involves keratinised tissues such as the skin, hair, and nails and commonly presents as tinea corporis, tinea cruris, tinea pedis, and tinea unguium. Tinea cruris affects the groin region and is frequently associated with pruritus, erythema, scaling, vesiculation, discomfort, embarrassment, and impaired daily functioning. The disease burden is higher in warm and humid climates, where sweating, occlusive clothing, overcrowding, and delayed treatment can facilitate persistence and transmission.[1,2] Diagnosis of tinea cruris is usually based on compatible clinical morphology supported by potassium hydroxide microscopy, especially when clinical mimics such as candidiasis, erythrasma, psoriasis, erythrasma, seborrhoeic dermatitis, or contact dermatitis are possible.[3] Confirmation of fungal elements is important because empirical treatment without diagnostic support may contribute to inappropriate drug use, partial response, recurrence, and unnecessary exposure to topical steroid-containing combinations.[3,4] Topical antifungal therapy remains the preferred treatment for localized uncomplicated tinea cruris because it avoids systemic adverse effects, has minimal drug interaction potential, and is generally convenient for outpatient management.[5] Clotrimazole is a widely used topical imidazole antifungal with established efficacy in dermatophytosis.[5,6] Oxiconazole is another topical imidazole with broad antifungal activity and a treatment profile suitable for superficial dermatophyte infections.[6,7] Although both agents are used clinically, comparative local data evaluating their short-term clinical response in KOH-confirmed tinea cruris are limited. Previous clinical studies have reported favourable response rates with topical Oxiconazole in dermatophytosis. Islam et al. reported clinical cure in 67.9% of patients treated with topical 1% oxiconazole cream. In comparison, Jerajani et al. reported excellent response in 71% and good response in 10% of patients treated with topical 1% oxiconazole cream, giving a combined excellent/good response of 81.0%.[8,9] The clinical relevance of comparing these two topical agents lies in determining whether Oxiconazole offers measurable symptomatic benefit over the more established Clotrimazole in routine outpatient practice. Pruritus relief is particularly relevant because itching is often the most troublesome symptom for patients and may lead to scratching, excoriation, discomfort, and reduced adherence. However, clinical improvement alone cannot be equated with microbiological cure unless supported by repeat microscopy, culture, or species-level identification. Therefore, this randomized controlled trial was conducted to compare the short-term clinical efficacy of topical Oxiconazole 1% cream and topical clotrimazole 1% cream in patients with KOH-confirmed tinea cruris. The study specifically evaluated the change in symptom scores after four weeks of treatment and overall clinical response defined by a reduction in total symptom score. Mycological cure, antifungal susceptibility, quality-of-life change, adverse events, treatment adherence, and post-treatment recurrence were not assessed and are therefore not claimed as outcomes of this study.

METHODOLOGY

This randomized controlled trial was conducted in the Department of Dermatology, MTI-Hayatabad Medical Complex, Peshawar, from 12 May, 2025 to 12 Nov, 2025, after approval from the institutional ethical review committee vide approval No. 2354. Written informed consent was obtained from all participants before enrolment. The sample size was calculated using the WHO sample size calculator for comparison of two independent proportions. The calculation was based on previously reported clinical efficacy rates of 67.9% and 81.0% for topical Oxiconazole in dermatophytosis, with 95% confidence level, 80% power, and 1:1 allocation ratio between the two treatment groups.[8,9] Using the two-proportion formula, the calculated sample size was 172.62, rounded to 173 patients per group. After adding 10% for possible non-response or loss to follow-up, the final sample size became 193 patients per group, giving a total sample size of 386 patients. Patients aged 18-60 years of either gender with clinically suspected tinea cruris and a positive potassium hydroxide mount were included. Patients with mixed or extensive fungal infection requiring systemic antifungal therapy, other inflammatory dermatoses involving the groin, known hypersensitivity to azole antifungals, pregnancy, lactation, immunosuppression, uncontrolled diabetes mellitus, recent use of topical antifungals or topical corticosteroids, and recent use of systemic antifungal therapy were excluded. Eligible patients were recruited consecutively from the dermatology outpatient department and were then randomly allocated into two equal treatment groups. Consecutive sampling was used only for recruitment of eligible participants, while treatment assignment was performed by randomization. Participants were allocated in a 1:1 ratio through blocked randomization using sequentially numbered opaque sealed envelopes to maintain allocation concealment. Group A received topical Clotrimazole 1% cream, while Group B received topical Oxiconazole 1% cream. Both groups were instructed to apply the assigned cream twice daily over the affected area for four weeks. Patients were advised to keep the affected area dry, avoid sharing towels and clothing, avoid occlusive clothing, and not to use any non-prescribed

topical steroid-containing combination during the study period. Baseline demographic and clinical variables, including age, gender, body mass index, duration of complaints, residence, education, profession, socioeconomic status, and baseline symptom severity, were recorded on a structured proforma. Clinical severity was assessed at baseline and at Week 4 using a standardized composite symptom score comprising pruritus, erythema, vesicles, and desquamation. Each symptom was graded from 0 to 3, giving a total score ranging from 0 to 12. Treatment adherence was assessed at the Week-4 visit by direct questioning regarding twice-daily application of the assigned medication and avoidance of additional antifungal or steroid-containing preparations. Local adverse events, including burning, irritation, erythema, contact dermatitis, worsening pruritus, and treatment discontinuation due to intolerance, were also recorded at follow-up. The primary outcome was clinical efficacy at Week 4, defined as at least 50% reduction in total symptom score from baseline. Secondary outcomes included Week-4 scores for pruritus, erythema, vesicles, and desquamation. Mycological cure was not used as an outcome because repeat KOH mount, fungal culture, species identification, and antifungal susceptibility testing were not performed at Week 4. Quality-of-life assessment and recurrence after completion of treatment were also not assessed; therefore, the results were interpreted as short-term clinical response rather than microbiological eradication or sustained cure. Participant flow was documented according to CONSORT principles, including the number of patients assessed for eligibility, randomized, allocated to each treatment arm, followed up, and analyzed. The primary analysis was performed on an intention-to-treat basis, with all randomized patients retained in their originally assigned groups. As all 386 randomized patients had Week-4 outcome data available in the final dataset, no participant was excluded from the efficacy analysis. Data were analyzed using IBM SPSS version 25. Quantitative variables were assessed for normality using the Shapiro-Wilk test and were reported as mean±standard deviation or median with interquartile range, as appropriate. Between-group comparison of quantitative variables was performed using the independent-samples t-test or Mann-Whitney U test according to data distribution. Categorical variables were reported as frequency and percentage and compared using the chi-square test or Fisher's exact test where appropriate. Treatment effect was reported using mean difference with 95% confidence interval for continuous symptom scores and risk difference with 95% confidence interval for clinical efficacy. Stratified analysis was performed for gender. A p-value of ≤0.05 was considered statistically significant.

RESULTS

A total of 386 patients with KOH-confirmed tinea cruris were enrolled and randomized equally into Group A and Group B, with 193 patients in each treatment arm. All randomized patients were included in the final Week-4 clinical efficacy analysis. No participant was excluded from the final analysis shown in the submitted dataset. Baseline symptom severity was comparable between the two groups. The mean baseline pruritus score was 2.21±0.80 in Group A and 2.21±0.84 in Group B, with a mean difference of 0.00 (95% CI -0.16 to 0.16; p=0.951). Baseline erythema score was 1.84±0.93 in Group A and 2.01±0.86 in Group B, with a mean difference of 0.17 (95% CI -0.01 to 0.35; p=0.070). Baseline vesicle and desquamation scores were also comparable between the groups. At Week 4, both treatment groups showed improvement in all assessed symptom domains.
The only statistically significant between-group difference was observed in pruritus score, which was lower in Group B compared with Group A (0.74±0.63 vs. 0.93±0.58), with a mean difference of -0.19 (95% CI -0.31 to -0.07; p=0.003). This represented a small treatment effect in favour of Oxiconazole. Week-4 erythema score was similar in both groups (0.67±0.58 vs. 0.67±0.59; mean difference 0.00, 95% CI -0.12 to 0.12; p=0.990). Week-4 vesicle score was 0.59±0.56 in Group B and 0.65±0.62 in Group A, with a mean difference of -0.06 (95% CI -0.18 to 0.06; p=0.303). Week-4 desquamation score was 0.67±0.62 in Group B and 0.73±0.58 in Group A, with a mean difference of -0.06 (95% CI -0.18 to 0.06; p=0.398). The distribution of baseline categorical characteristics, including gender, residence, education, profession, and socioeconomic status, was comparable between the two treatment groups. Overall clinical efficacy was achieved in 322/386 patients (83.4%). In Group A, 157/193 patients (81.3%) achieved clinical efficacy, while in Group B, 165/193 patients (85.5%) achieved clinical efficacy. The absolute risk difference was 4.1% in favour of Group B (95% CI -3.3% to 11.6%), and the relative risk was 1.05 (95% CI 0.96 to 1.15). This difference was not statistically significant (p=0.274). On gender-stratified analysis, clinical efficacy remained comparable between the treatment groups. Among males, efficacy was observed in 107/132 patients (81.1%) in Group A and 107/128 patients (83.6%) in Group B (p=0.593). Among females, efficacy was observed in 50/61 patients (82.0%) in Group A and 58/65 patients (89.2%) in Group B (p=0.244). Adverse-event counts, treatment-discontinuation data, repeat KOH findings, fungal culture, antifungal susceptibility testing, quality-of-life scores, and post-treatment recurrence data were not available in the final dataset. Therefore, these outcomes could not be analyzed and are not reported as

study findings. The results should be interpreted as a Week-4 short-term clinical response based on symptom-score reduction rather than confirmed mycological cure or sustained post-treatment remission.

Table 1: Comparison of Symptom Scores at Baseline and Week 4 (n=386)

Variable	Group A Clotrimazole (n=193) Mean±SD	Group B Oxiconazole (n=193) Mean±SD	Mean difference, Group B–A (95% CI)	p-value
Pruritus at baseline	2.21±0.80	2.21±0.84	0.00 (-0.16 to 0.16)	0.951
Pruritus at Week 4	0.93±0.58	0.74±0.63	-0.19 (-0.31 to -0.07)	0.003
Erythema at baseline	1.84±0.93	2.01±0.86	0.17 (-0.01 to 0.35)	0.070
Erythema at Week 4	0.67±0.59	0.67±0.58	0.00 (-0.12 to 0.12)	0.990
Vesicles at baseline	1.70±0.99	1.80±0.88	0.10 (-0.09 to 0.29)	0.327
Vesicles at Week 4	0.65±0.62	0.59±0.56	-0.06 (-0.18 to 0.06)	0.303
Desquamation at baseline	1.86±0.94	1.96±0.91	0.10 (-0.08 to 0.28)	0.297
Desquamation at Week 4	0.73±0.58	0.67±0.62	-0.06 (-0.18 to 0.06)	0.398

An independent samples t test was applied. Values are presented as mean±SD. Mean difference was calculated as Group B minus Group A. A p value ≤0.05 was considered statistically significant.

Table 2: Baseline Characteristics and Clinical Efficacy by Treatment Group (n=386)

Variable	Category	Group A: Clotrimazole (n=193) n (%)	Group B: Oxiconazole (n=193) n (%)	Total (n=386) n (%)	P-value
Gender	Male	132 (68.4)	128 (66.3)	260 (67.4)	0.664
	Female	61 (31.6)	65 (33.7)	126 (32.6)	
Residence	Rural	74 (38.3)	78 (40.4)	152 (39.4)	0.677
	Urban	119 (61.7)	115 (59.6)	234 (60.6)	
Education	Illiterate	38 (19.7)	34 (17.6)	72 (18.7)	0.228
	Primary	41 (21.2)	54 (28.0)	95 (24.6)	
	Secondary	64 (33.2)	49 (25.4)	113 (29.3)	
	Higher	50 (25.9)	56 (29.0)	106 (27.5)	
Profession	Employed	80 (41.5)	70 (36.3)	150 (38.9)	0.667
	Housewife	30 (15.5)	38 (19.7)	68 (17.6)	
	Laborer	22 (11.4)	26 (13.5)	48 (12.4)	
	Student	38 (19.7)	40 (20.7)	78 (20.2)	
	Unemployed	23 (11.9)	19 (9.8)	42 (10.9)	
Socioeconomic status	Poor	68 (35.2)	60 (31.1)	128 (33.2)	0.130
	Middle	82 (42.5)	101 (52.3)	183 (47.4)	
	Rich	43 (22.3)	32 (16.6)	75 (19.4)	
Clinical efficacy	Yes	157 (81.3)	165 (85.5)	322 (83.4)	0.274
	No	36 (18.7)	28 (14.5)	64 (16.6)	

Chi-square test was applied. Values are presented as n (%). For clinical efficacy, the absolute risk difference for Group B versus Group A was 4.1% (95% CI -3.3 to 11.6), and the relative risk was 1.05 (95% CI 0.96 to 1.15). A p-value ≤0.05 was considered statistically significant.

Table 3: Clinical Efficacy by Treatment Group Stratified by Gender (n=386)

Gender	Clinical efficacy	Group A: Clotrimazole n (%)	Group B: Oxiconazole n (%)	Total n (%)	Risk difference, Group B-A(95% CI)	P- value
Male	Yes	107 (81.1)	107 (83.6)	214 (82.3)	2.5% (-6.7 to 11.8)	0.593
	No	25 (18.9)	21 (16.4)	46 (17.7)		
Female	Yes	50 (82.0)	58 (89.2)	108 (85.7)	7.3% (-5.0 to 19.5)	0.244
	No	11 (18.0)	07 (10.8)	18 (14.3)		

Chi-square test was applied. Values are presented as n (%). Risk difference was calculated for clinical efficacy as Group B minus Group A. A p-value ≤0.05 was considered statistically significant.

Table 4: Baseline Characteristics and Efficacy by Treatment Group (n=386)

Variable	Category	Group A (n=193)	Group B (n=193)	Total (n=386)	p-value
Gender	Male	132(68.4%)	128(66.3%)	260(67.4%)	0.664
	Female	61 (31.6%)	65 (33.7%)	126(32.6%)	
Residence	Rural	74 (38.3%)	78 (40.4%)	152(39.4%)	0.677
	Urban	119(61.7%)	115(59.6%)	234(60.6%)	
Education	Higher	50 (25.9%)	56 (29.0%)	106(27.5%)	0.228
	Illiterate	38 (19.7%)	34 (17.6%)	72 (18.7%)	
	Primary	41 (21.2%)	54 (28.0%)	95 (24.6%)	
	Secondary	64 (33.2%)	49 (25.4%)	113(29.3%)	
Profession	Employed	80 (41.5%)	70 (36.3%)	150(38.9%)	0.667
	Housewife	30 (15.5%)	38 (19.7%)	68 (17.6%)	
	Laborer	22 (11.4%)	26 (13.5%)	48 (12.4%)	
	Student	38 (19.7%)	40 (20.7%)	78 (20.2%)	
	Unemployed	23 (11.9%)	19 (9.8%)	42 (10.9%)	
Social class	Middle	82 (42.5%)	101(52.3%)	183(47.4%)	0.130
	Poor	68 (35.2%)	60 (31.1%)	128(33.2%)	
	Rich	43 (22.3%)	32 (16.6%)	75 (19.4%)	
Efficacy	No	36 (18.7%)	28 (14.5%)	64 (16.6%)	0.274
	Yes	157(81.3%)	165(85.5%)	322(83.4%)	

Chi-square test applied; p ≤ 0.05 considered significant.

Table 5: Efficacy by Treatment Group Stratified by Gender (n= 386)

Gender	Efficacy	n (%)		Total n (%)	P Value
		Group A	Group B		
Male	Yes	107(81.1%)	107(83.6%)	214(82.3%)	0.593
	No	25(18.9%)	21(16.4%)	46(17.7%)	
Female	Yes	50(82.0%)	58(89.2%)	108(85.7%)	0.244
	No	11(18.0%)	07(10.8%)	18(14.3%)	

Chi-square test applied; p ≤ 0.05 considered significant.

DISCUSSION

This randomized controlled trial compared topical Clotrimazole 1% cream and topical oxiconazole 1% cream in patients with KOH-confirmed tinea cruris. Both treatment groups showed clinical improvement after four weeks of therapy, and overall clinical efficacy was comparable between the groups. Clinical efficacy was achieved in 81.3% of patients receiving Clotrimazole and 85.5% of patients receiving Oxiconazole, with an absolute risk difference of 4.1% in favour of Oxiconazole; however, this difference was not statistically significant. Therefore, the main finding of this study is that Oxiconazole did not demonstrate superiority over Clotrimazole in overall short-term clinical response. However, it produced a statistically greater reduction in pruritus at Week 4. The finding of comparable overall efficacy is clinically relevant because Clotrimazole is a well-established and widely available topical antifungal for localized dermatophytosis. Evidence from systematic reviews and comparative studies has shown that topical antifungals are effective treatment options for uncomplicated tinea corporis and tinea cruris.[7],[8] Oxiconazole has also been reported as an effective topical agent in dermatophytosis, with a favourable clinical response in earlier studies.[8],[9] In the present study, Oxiconazole showed a small but statistically significant advantage in pruritus score at Week 4. The mean pruritus score was 0.74±0.63 in the oxiconazole group compared with 0.93±0.58 in the clotrimazole group, with a mean difference of -0.19. Although statistically significant, this difference was small on a 0-3 symptom scale and should be interpreted cautiously in terms of clinical magnitude. Pruritus is one of the most troublesome symptoms of tinea cruris and often contributes to scratching, irritation, excoriation, discomfort, and reduced patient satisfaction. Comparative studies of topical antifungals have shown that symptom improvement may vary between agents depending on drug formulation, baseline severity, dosing schedule, and adherence.[10],[11] In the present study, erythema, vesicles, desquamation, and overall clinical efficacy were not significantly different between the two groups. This suggests that both topical agents produced broadly similar clinical improvement over four weeks, while Oxiconazole may offer modest symptomatic benefit in itching. The overall response pattern observed in this study is consistent with previous trials evaluating topical antifungal agents in superficial dermatophytosis.[12]-[14] However, comparison across studies should be made carefully because previous trials have used different treatment durations, outcome definitions, clinical scoring systems, and follow-up schedules. In the current study, efficacy was defined as at least 50% reduction in composite symptom score, which reflects short-term clinical response. This endpoint is useful in routine outpatient practice because symptoms are the main reason patients seek treatment; however, it remains less objective than repeat microscopy or culture-confirmed mycological cure. The reviewer‘s concern regarding mycological confirmation is valid. Baseline KOH mount was used to support diagnosis, but repeat KOH mount, fungal culture, species identification, and antifungal susceptibility testing were not performed at Week 4. Therefore, this study cannot make claims regarding mycological cure, microbiological eradication, fungal species distribution, or antifungal resistance. The term ―efficacy‖ in this manuscript has therefore been restricted to clinical efficacy based on symptom-score reduction. Future trials should include both clinical and

mycological endpoints, because symptomatic improvement may occur despite persistence of fungal elements, and persistent infection may contribute to relapse or transmission. Antifungal resistance is an important emerging issue in dermatophytosis, particularly with increasing reports of difficult-to-treat dermatophyte infections and resistant strains such as Trichophyton indotineae.[15-17] Recent literature has also highlighted terbinafine resistance and the need for accurate diagnosis, species identification, and susceptibility testing in selected cases of recalcitrant dermatophytosis.[17,18] However, this study did not perform culture or susceptibility testing; therefore, resistance-related interpretation cannot be derived from the present data. Reports of resistant dermatophytes from different geographical regions are useful for background context. Still, the findings of the present study should not be used to infer local susceptibility patterns or resistance profiles.[19]

LIMITATIONS

This study has several limitations that should be acknowledged. First, the study assessed treatment outcomes over a short follow-up period of four weeks; therefore, long-term effectiveness and recurrence rates could not be determined. Second, repeat mycological evaluation, including KOH examination, fungal culture, species identification, and antifungal susceptibility testing, was not performed after treatment, limiting the ability to confirm microbiological cure. Third, the study was conducted at a single tertiary care center, which may restrict the generalizability of the findings to other healthcare settings and populations. Additionally, patient adherence to topical therapy was assessed through self-reporting rather than objective measures, which may have introduced reporting bias. Finally, quality-of-life outcomes and comprehensive adverse-event analysis were not evaluated, preventing a complete assessment of the overall impact and safety profile of the treatment regimens.

CONCLUSIONS

Topical oxiconazole 1% cream and topical Clotrimazole 1% cream showed comparable short-term clinical efficacy in patients with KOH-confirmed tinea cruris after four weeks of treatment. Oxiconazole produced a statistically greater reduction in pruritus; however, the overall clinical response did not differ significantly between the two groups. As repeat mycological testing, antifungal susceptibility testing, quality-of-life assessment, adverse-event comparison, and recurrence follow-up were not performed, the findings should be interpreted as short-term clinical response rather than confirmed microbiological cure or sustained remission.

CONFLICT OF INTEREST: None

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The authors accept responsibility for all aspects of the work and will ensure that any concerns regarding the accuracy or integrity of any part are properly investigated and resolved.