

A randomized, double-blind trial of amorolfine 0.25% cream and sertaconazole 2% cream in limited dermatophytosis

Anirban Das, Amrita Sil¹, Tushar Kanti Sarkar², Arpita Sen², Sriparna Chakravorty³, Manideepa Sengupta³, Anupam Das², Somodyuti Chandra², Santasmita Pal⁴, Debabrata Bandyopadhyay², Nilay Kanti Das⁵

Department of Dermatology, Murshidabad Medical College and Hospital, Berhampore, ¹Department of Pharmacology, Rampurhat Government Medical College, Rampurhat, Departments of ²Dermatology, ³Microbiology and ⁴Biochemistry, Medical College and Hospital, Kolkata, ⁵Department of Dermatology, Bankura Sammilani Medical College, Bankura, West Bengal, India

Abstract

Background: Dermatophytosis is becoming increasingly unresponsive to conventional antifungals. Newer topical antifungals may be more effective in these patients.

Aims: To evaluate and compare the efficacy and safety of amorolfine 0.25% cream and sertaconazole 2% cream in limited tinea cruris/corporis.

Methods: A single-center, randomized (1:1), double-blind, parallel group, active-controlled trial (CTRI/2014/12/005246) was performed. Sixty-six untreated adults with acutely symptomatic tinea cruris/corporis were included in the study. All patients had limited cutaneous involvement and were KOH mount positive. Group A received amorolfine 0.25% cream, and group B received sertaconazole 2% cream twice daily application to the lesions for 4 weeks. After the baseline visit, four follow-up visits were carried out. The outcome measures for effectiveness were clinical and mycological cure. Safety parameters studied were treatment-emergent adverse events and changes in routine laboratory parameters.

Results: Both sertaconazole and amorolfine significantly reduced symptoms ($P < 0.001$) in both groups. However, improvement in symptoms (pruritus, burning sensation, erythema, scaling and crusting) was significantly greater in the sertaconazole group at every follow-up visit. Sertaconazole cream was also more effective than amorolfine cream in reducing the number of lesions ($P = 0.002$ at 12 weeks) and improving the Dermatology Life Quality Index ($P < 0.001$) at all the follow-up visits. Adverse events were similar in the two groups ($P = 0.117$). Fungal cultures became negative in 92.3% of the sertaconazole group as compared to 80% in the amorolfine group ($P = 0.010$).

Limitations: Antifungal susceptibility testing could not be done.

Conclusion: Sertaconazole 2% is superior to amorolfine 0.25%, both in terms of effectiveness and tolerability. Improvement can be appreciated from second week onwards.

Key words: Amorolfine, randomized controlled trial sertaconazole, tinea corporis, tinea cruris

Correspondence:

Dr. Amrita Sil,
Flat 3I, Block 4,
83A Cossipore Road,
Kolkata - 700 002,
West Bengal, India.
E-mail: drsilamrita@gmail.com

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Introduction

Dermatophytoses are among the commonest of infections occurring worldwide. They are particularly widespread in tropical countries owing to the warm and humid climate, crowded living conditions and other socioeconomic factors.¹ Although not life-threatening, they produce significant symptoms and frequently diminish the quality of life. Dermatophytosis unresponsive to conventional antifungal drugs is becoming more common, resulting in frequent treatment failure.²

Despite the advent of newer antifungal agents, treatment remains challenging. Many clinical trials have been conducted to assess these drugs for efficacy and safety.³ In the past terbinafine 1% cream has been compared with butenafine 1% cream⁴ and sertaconazole nitrate 2% cream,⁵ and one study evaluated the efficacy of oral fluconazole with Whitfield's ointment to topical 1% butenafine.⁶

Amorolfine and sertaconazole have recently been marketed in India for the treatment of dermatophytosis. Sertaconazole is an imidazole antifungal that inhibits lanosterol 14- α demethylase, leading to disruption in ergosterol biosynthesis.⁷ Ergosterol is a major component of the fungal cell membrane and its deficiency is responsible for fungistatic and fungicidal properties of sertaconazole. Amorolfine interferes with the synthesis of ergosterol at the delta 14 reduction and the delta 7-8 isomerization steps, leading to both the accumulation of the delta 14 sterol ignosterol in the cell membrane and the depletion of ergosterol.⁸

This study was undertaken with the objectives of evaluating and comparing the efficacy, safety and tolerability of amorolfine 0.25% cream and sertaconazole 2% cream. Improvement in the quality of life in the two treatment arms was also assessed.

Methods

The study was carried out over a period of 8 months at the Medical College, Kolkata, as a single-center, randomized (1:1), double-blind, parallel group, active controlled trial. Permission from the Institutional Ethics Committee was obtained and the study was registered (No CTRI/2014/12/005246). Written informed consent was obtained from all study participants. Untreated males and females (>18 years) with acutely symptomatic tinea cruris/corporis with limited involvement (i.e. restricted to a single-body region) attending the Dermatology Outpatient Department of the hospital. All patients had positive KOH mounts. Patients were excluded from the study if they had received 1 week of topical therapy or 4 weeks of systemic therapy for tinea corporis/cruris, had a history of hypersensitivity to the study medications, were immunosuppressed due to drug or disease or were suffering from advanced disease of vital organs. Patients who refused consent and women who were pregnant or lactating were also excluded.

Visits and follow-ups

After the initial visit, follow-up visits were carried out at 1, 2 and 4 weeks. The treatment was then discontinued and patients were examined again at 12 weeks both clinically and with 10% KOH mounts for detection of relapses.

Randomization and blinding

Eligible patients were randomized into either group A or B with an allocation ratio of 1:1 utilizing a computer-generated randomization sequence. Allocation concealment was achieved by the use of a sequentially numbered opaque-sealed envelope (SNOSE) technique. Patients in group A received amorolfine 0.25% cream [Loceryl cream, Manufacturer Galderma, Lot no. TD0764, Date of manufacture February 2014, Date of expiry January 2016] while patients in group B received sertaconazole 2% cream [Onabet 2%, Manufacturer Glenmark Pharmaceuticals, Lot no. 11170792, Date of manufacture May 2014, Date of expiry April 2016]. Both groups were instructed to apply the cream twice daily to the lesions for 4 weeks. Both the groups were also given cetirizine (10 mg tablets) [Brand name: CIT-Z, Manufacturer: Square Pharmaceuticals, Central Medical Store Supply, supplied free of cost to the patients from the institutional pharmacy] to be taken once daily at bedtime for 4 weeks.

The medicine tubes were painted in opaque white color, kept in an opaque envelope and coded "medication A" and "medication B" by the drug dispenser. The codes were kept securely and were to be broken only when a serious adverse event was faced. The evaluator who assessed the effectiveness and safety parameters at baseline and at follow-ups was another dermatologist who was seated in a separate room and not involved in randomization, drawing blood, scraping and KOH mount, thus making the trial double-blind.

Effectiveness and safety parameters

The primary outcome measures for effectiveness were clinical cure, mycological cure and global cure. Clinical cure quantifies the disease activity depending on number of lesions, pruritus, burning, erythema, scaling, grade of improvement (Grade 0: No improvement, Grade 1: Few lesions/erythema + mild-to-moderate itching, Grade 2: Scaly lesions $\pm$ itching, Grade 3: No lesions $\pm$ residual pigmentation). Mycological cure was determined by the results obtained by KOH mount and fungal culture in Sabouraud dextrose chloramphenicol agar medium followed by microscopic examination. Global cure was calculated by combining the results of clinical and mycological cure. The secondary effectiveness parameters were Patients' Global assessment of disease activity and Physicians' Global assessment of disease activity improvement; both were recorded on a five-point Likert scale (0: No improvement, 1: Mild improvement, 2: Moderate improvement, 3: Marked improvement and 4: Excellent improvement).⁹ These parameters were assessed at baseline and at the end of weeks 1, 2, 3 and 4 following randomization. Safety parameters assessed included both

spontaneously reported adverse events and adverse events elicited by physician at each follow-up visit. Routine hemogram, liver function tests, serum urea, creatinine, fasting blood glucose were recorded at baseline and at the end of treatment. The quality of life improvement was assessed by the validated vernacular version (Bengali) of Dermatology Life Quality Index at baseline and study end.¹⁰

Sample size

The target sample size was 60 patients, with 30 evaluable subjects in each treatment group. This was calculated considering mycological cure of 78.9% with amorolfine cream³ and 100% with sertaconazole cream,⁵ with 80% power and 0.05 probability of Type 1 error. Considering possible 10% dropout rate, this translated to a recruitment target of approximately 33 subjects per group or 66 subjects overall.

Statistical analysis

Continuous variables were compared within groups by the paired *t*-test and between groups by the independent *t*-test. For comparison of unpaired and paired nonparametric data, the Mann–Whitney U test and the Wilcoxon’s matched pairs signed rank test were employed respectively. Freidman’s analysis of variance was carried out with nonparametric data for within group repeated measures comparisons, followed by the *post hoc* Dunn’s test. Categorical data were compared between groups by the Chi-square test or the Fisher’s exact test, as applicable. MedCalc version 11.6 [Mariakerke, Belgium: MedCalc Software, 2011] and Graph-pad Prism version 5 [San Diego, California: GraphPad Software Inc., 20057] software were used for statistical analysis.

Results

Among 70 patients screened, 66 were randomized equally into two groups. Six patients in the sertaconazole group and 10 patients in the amorolfine group were lost to follow-up thus leaving 27 patients in the sertaconazole group and 23 in the amorolfine group to be analyzed by the per protocol analysis [Figure 1].

Most of the study participants were educated, middle-aged males with an income above the poverty line. The area of residence of the groups (rural and urban) was not significantly different. Tinea corporis was diagnosed in 58% patients, tinea cruris in 26% and the rest had both tinea cruris and corporis [Table 1].

The number of tinea lesions in the two study arms were similar ($P = 0.436$) at baseline. A significant decline in the number of lesions was noted in both the groups from the first follow-up onwards ($P < 0.001$) which continued till the end of treatment. However, the reduction in number of lesions significantly greater in the sertaconazole group as compared to the amorolfine group at all follow-ups [Table 2]. Complete

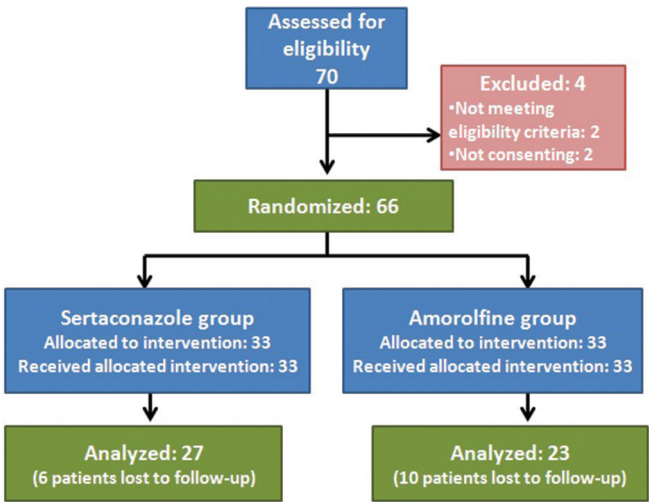


Figure 1: Flow of study participants

Table 1: Clinicodemographic profile of study participants			
Category	Group A Sertaconazole (n=27)	Group B Amorolfine (n=23)	P (between groups)
Age (years)			
Range	18, 64	18, 51	0.498
Mean±SD	34.18±13.45	31.91±9.31	
Median (IQR)	32 (22, 43.5)	32 (23, 40)	
Sex, n (%)			
Male	16 (59.3)	16 (69.5)	0.559
Female	11 (40.7)	7 (30.5)	
Residence, n (%)			
Urban	12 (48)	10 (43.5)	0.780
Rural	13 (52)	13 (56.5)	
Education, n (%)			
Illiterate	5 (18.6)	8 (34.8)	0.215
Literate	22 (81.4)	15 (65.2)	
Income group, n (%)			
APL	22 (81.4)	15 (65.2)	0.215
BPL	5 (18.6)	8 (34.8)	
Diagnosis, n (%)			
Tinea corporis	16 (59.2)	13 (56.5)	0.752
Tinea cruris	6 (22.2)	7 (30.4)	
Both	5 (18.6)	3 (13.1)	

P value between groups by Student’s unpaired *t*-test for age, Fisher’s exact test for gender, residence, education, income, Chi-square test for diagnosis. APL: Above poverty line, BPL: Below povert line SD: Standard deviation, IQR: Interquartile range

cure of lesions was seen in 17 (62.96%) patients treated with sertaconazole at the end of active treatment and 6 (26.09%) patients in the amorolfine group.

All symptoms (pruritus, burning sensation) and signs (erythema, scaling and crusting) decreased progressively at each follow up in both the groups from the first follow-up onwards ($P < 0.001$). The improvement in both signs and symptoms was more marked in the sertaconazole group at each follow-up [Table 3a and b].

Table 2: Comparison of the number of lesions between groups

Number of lesions	Group A Sertaconazole (n=27)	Group B Amorolfine (n=23)	P (between groups)
Baseline			
Mean±SD	2.59±0.93	2.91±1.08	0.436
Median (IQR)	3 (2, 3)	3 (2, 4)	
1 st follow-up			
Mean±SD	1.40±0.97*	2.34±1.19	0.006
Median (IQR)	2 (1, 2)	2 (2, 3)	
2 nd follow-up			
Mean±SD	0.48±0.65*	1.57±1.04*	0.0005
Median (IQR)	0 (0, 1)	2 (1, 2)	
3 rd follow-up			
Mean±SD	0.41±0.57*	1.30±0.97*	0.002
Median (IQR)	0 (0, 1)	1 (0, 2)	
P (within group)	<0.001	<0.001	

P value between groups by Mann-Whitney test, P value within group by Friedman's ANOVA followed by *post hoc* Dunn's test. *Significant difference of the particular follow-up from baseline. SD: Standard deviation, IQR: Interquartile range, ANOVA: Analysis of variance

The Dermatology Life Quality Index value significantly reduced to 1.37 ± 1.49 from 12.29 ± 3.05 in the sertaconazole group ($P < 0.001$) and to 4.43 ± 3.26 from 11.74 ± 3.98 in the amorolfine group ($P < 0.001$). The improvement was greater in the sertaconazole arm than the amorolfine arm from first follow-up onwards ($P < 0.001$) [Table 4]. The grade of improvement too was significantly greater in sertaconazole group at both the first follow-up ($P = 0.002$) and at the end of the study ($P = 0.0005$) [Table 5].

In the amorolfine group burning was seen in 3 patients, oozing/vesiculation in 2 patients and pigmentation in 3 patients while in the sertaconazole group 4 patients developed postinflammatory hyperpigmentation. There was no difference in the incidence of adverse events in the two groups ($P = 0.117$).

Pretreatment mycology showed predominance of *Trichophyton rubrum* and *Epidermophyton floccosum* followed by *T. mentagrophytes*. A greater number

Table 3a: Comparison of the symptoms pruritus, burning sensation over lesions between groups

Parameter	Group A Sertaconazole (n=27)	Group B Amorolfine (n=23)	P (between groups)
Pruritus			
Baseline			
Mean±SD	2±0.39	2±0.67	0.823
Median (IQR)	2 (2, 2)	2 (2, 2)	
1 st follow-up			
Mean±SD	0.89±0.5*	1.17±0.78*	0.224
Median (IQR)	1 (1, 1)	1 (1, 2)	
2 nd follow-up			
Mean±SD	0.59±0.5*	1.04±0.56*	0.022
Median (IQR)	1 (0, 1)	1 (1, 1)	
3 rd follow-up			
Mean±SD	0.59±0.5*	0.86±0.63*	0.176
Median (IQR)	1 (0, 1)	1 (0, 1)	
P (within group)	<0.001	<0.001	
Burning sensation over lesions			
Baseline			0.815
Mean±SD	1.52±0.70	1.48±0.73	
Median (IQR)	1.5 (1, 2)	1 (1, 2)	
1 st follow-up			
Mean±SD	0.07±0.27*	0.87±0.76	0.0003
Median (IQR)	0	1 (0, 1)	
2 nd follow-up			
Mean±SD	0*	0.21±0.52*	0.293
Median (IQR)	0	0	
3 rd follow-up			
Mean±SD	0*	0.17±0.49*	0.431
Median (IQR)	0	0	
P (within group)	<0.001	<0.001	

P between groups by Mann-Whitney test, P within group by Friedman's ANOVA followed by *post hoc* Dunn's test. *Significant difference of the particular follow-up from baseline. SD: Standard deviation, IQR: Interquartile range, ANOVA: Analysis of variance

Table 3b: Comparison of the signs erythema, scaling/crusting over lesions between groups

Parameter	Group A Sertaconazole (n=27)	Group B Amorolfine (n=23)	P (between groups)
Erythema			
Baseline			
Mean±SD	0.89±0.32	0.96±0.21	0.683
Median (IQR)	1 (1, 1)	1 (1, 1)	
1 st follow-up			
Mean±SD	0.07±0.27*	0.61±0.5	0.001
Median (IQR)	0	1 (0, 1)	
2 nd follow-up			
Mean±SD	0.04±0.2*	0.13±0.34*	0.572
Median (IQR)	0	0	
3 rd follow-up			
Mean±SD	0*	0.13±0.34*	0.431
Median (IQR)	0	0	
P (within group)	<0.001	<0.001	
Scaling/crusting			
Baseline			
Mean±SD	0.96±0.20	1	0.823
Median (IQR)	1 (1, 1)	1 (1, 1)	
1 st follow-up			
Mean±SD	0.52±0.51	0.83±0.39	0.063
Median (IQR)	1 (0, 1)	1 (1, 1)	
2 nd follow-up			
Mean±SD	0.11±0.32*	0.48±0.51*	0.027
Median (IQR)	0	0 (0, 1)	
3 rd follow-up			
Mean±SD	0.11±0.32*	0.44±0.51*	0.050
Median (IQR)	0	0 (0, 1)	
P (within group)	<0.001	<0.001	

P between groups by Mann-Whitney test, P within group by Friedman's ANOVA followed by *post hoc* Dunn's test. *Significant difference of the particular follow-up from baseline. SD: Standard deviation, IQR: Interquartile range, ANOVA: Analysis of variance

Table 4: Comparison of Dermatology Life Quality Index between groups

DLQI	Group A Sertaconazole (n=27)	Group B Amorolfine (n=23)	P (between groups)
Baseline			
Mean±SD	12.29±3.05	11.74±3.98	0.748
Median (IQR)	12 (10, 14.75)	12 (9, 14)	
1 st follow-up			
Mean±SD	4.26±2.47*	9±4.36	<0.001
Median (IQR)	5 (2, 6)	10 (7, 12)	
2 nd follow-up			
Mean±SD	1.44±1.48*	5.17±3.24*	<0.001
Median (IQR)	1 (0, 2)	5 (3.25, 6.75)	
3 rd follow-up			
Mean±SD	1.37±1.49*	4.43±3.26*	<0.001
Median (IQR)	1 (0, 2)	5 (1.5, 6)	
P (within group)	<0.001	<0.001	

P value between groups by Mann-Whitney test, P value within group by Friedman's ANOVA followed by *post hoc* Dunn's test. *Significant difference of the particular follow-up from baseline. SD: Standard deviation, IQR: Interquartile range, ANOVA: Analysis of variance, DLQI: Dermatology Life Quality Index

of culture-positive growths became negative in the sertaconazole group (100%) as compared to the amorolfine group (80%) ($P = 0.010$) [Table 6].

Clinical and mycological relapse was seen in 3 patients (11.11%) in the sertaconazole group and in 1 patient (4.34%) in the amorolfine group at the end of the study, but this was not statistically significant ($P = 0.722$).

Limitations

A limitation of this study was that antifungal susceptibility testing could not be done due to logistic reasons.

Discussion

Increasing resistance of tinea to the older antifungals has led to distressing relapses in patients in recent times. A hit-and-trial method is often adopted by dermatologists since the results of studies of antifungal effectiveness conducted many years ago cannot be extrapolated to the current scenario. We evaluated the efficacy of two newer options, sertaconazole 2% and amorolfine 0.25% in a comparative trial.

Table 5: Comparison of the grades of improvement of lesions between groups

Grades of improvement	Group A Sertaconazole (n=27)	Group B Amorolfine (n=23)	P (between groups)
1 st follow-up			
Mean±SD	2.22±0.75	1.30±1.02	0.002
Median (IQR)	2 (2, 3)	1 (1, 2)	
2 nd follow-up			
Mean±SD	2.78±0.51*	2±0.74*	0.0005
Median (IQR)	3 (3, 3)	2 (1.25, 2.75)	
3 rd follow-up			
Mean±SD	2.85±0.36*	2.08±0.73*	0.0005
Median (IQR)	3 (3, 3)	2 (2, 3)	
P (within group)	<0.001	<0.001	

P value between groups by Mann-Whitney test, P value within group by Friedman's ANOVA followed by *post hoc* Dunn's test. *Significant difference of the particular follow-up from baseline. SD: Standard deviation, IQR: Interquartile range, ANOVA: Analysis of variance

Table 6: Comparison of the mycological data between groups

Mycological data	Group A Sertaconazole (n=27)	Group B Amorolfine (n=23)	P (between groups)
Pre-treatment, n (%)			
<i>T. rubrum</i>	8 (29.63%)	6 (26.1%)	
<i>T. mentagrophytes</i>	7 (25.93%)	4 (17.4%)	
<i>E. floccosum</i>	9 (33.33%)	5 (21.73%)	
Negative culture	3 (11.11%)	8 (34.78%)	
Post-treatment, n (%)			
Became culture negative which were positive in pretreatment	24 (100%)	12 (80%)	0.010

P value between groups from Chi-square test. *T. rubrum*: *Trichophyton rubrum*, *T. mentagrophytes*: *Trichophyton mentagrophytes*, *E. floccosum*: *Epidermophyton floccosum*

Both sertaconazole and amorolfine were effective in reducing the number of lesions from the second week onwards but sertaconazole 2% was superior to amorolfine 0.25% in effectiveness and tolerability. The antiinflammatory effects of sertaconazole may help in providing rapid relief thus improving the quality of life in these patients.¹¹ However, at the end of active treatment both sertaconazole and amorolfine groups showed similar improvement in symptoms.

At the end of the study, 3 patients relapsed (one in the amorolfine group and 2 in the sertaconazole group) and in all 3 patients *Epidermophyton floccosum* was isolated. This has clinical implications, and in patients with *E. floccosum* infection alternative strategies (such as the addition of an oral antifungal) should be employed to prevent relapses.

There is an urgent need for further clinical trials with a longer follow-up period and using different antifungal drugs in combination to determine more effective and safer regimens.

Conclusion

Both sertaconazole and amorolfine provide relief with acceptable adverse effects in limited tinea. However, sertaconazole 2% cream was significantly better than amorolfine 0.25% cream with regard to earlier relief of symptoms and improved quality of life. Relapses and unresponsiveness are seen with both the topical agents.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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