

## ORIGINAL RESEARCH

### A comparative study of topical amorolfine, sertaconazole and terbinafine in patients with tinea corporis and tinea cruris

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#### ABSTRACT

**Background:** Superficial mycotic infections such as ‘Dermatophytoses’ is an extremely common infection. The disease is caused by dermatophytes belonging to genera of Trichophyton, Microsporum and Epidermatophyton. The present study was conducted to compare topical amorolfine, sertaconazole and terbinafine in patients with tinea corporis and tinea cruris.

**Materials & Methods:** 90 patients with tinea corporis and tinea cruris of both genders were included. Patients were divided into 3 groups of 30 each. Group I were prescribed topical application of amorolfine (0.25%) once daily, group II were given sertaconazole (2%) twice daily and group III were given terbinafine (1%) twice daily. Response to treatment was assessed after 3 weeks.

**Results:** Group I had 14 males and 16 females, group II had 17 males and 13 females and group III had 12 males and 18 females. The mean value of scaling was 0.92 in group I, 1.14 in group II and 0.78 in group III. The mean value of erythema was 0.94 in group I, 1.42 in group II and 0.56 in group III. The mean value of pruritus was 1.12 in group I, 1.32 in group II and 0.65 in group III. The response was poor seen in 42% in group I, 22% in group II and 44% in group III. Moderate seen in 40% in group I, 46% in group II and 48% in group III and good seen in 18% in group I, 32% in group II and 8% in group III. The difference was non-significant ( $P > 0.05$ ).

**Conclusion:** Sertaconazole found to be effective as compared to other agents in management of cases of tinea corporis and tinea cruris.

**Key words:** Tinea corporis, Tinea cruris, Sertaconazole

#### INTRODUCTION

Superficial mycotic infections such as ‘Dermatophytoses’ is an extremely common infection occurring throughout the world with a reported incidence of 20% in USA.<sup>1</sup> The disease is caused by dermatophytes belonging to genera of Trichophyton, Microsporum and Epidermatophyton. The fungal infections of the skin and its appendages are more common in tropical countries like India due to environmental factors like heat (summer) and humidity (monsoon). The risk factors include socio-economic conditions like overcrowding and poverty leading to poor personal hygiene.<sup>2</sup> The type and frequency of dermatophytoses may

change with time, due to changes in living standards and application of preventive measures like personal hygiene. However, in India, the most commonly occurring clinical type of dermatophytoses for adults includes, tinea corporis (36-59%) and tinea cruris (12-27%).<sup>3</sup> Depending upon the site of infection, dermatophyte infection can be classified as tinea corporis (body), tinea cruris (groin), tinea capitis (head), tinea pedis (feet), tinea manuum (hand), tinea unguium (nail), tinea barbae (beard) etc. The most common factors predisposing to fungal infection still remain poor personal hygiene, immune status and associated illness. The two most important methods used to diagnose dermatophytosis are direct microscopy and isolation of the specific species through culture.<sup>4</sup>

New extended-spectrum triazoles and allylamines have been introduced into market among such are Luliconazole, Sertaconazole, Eberconazole which belong to triazoles and Amorolfine which belong to Allyamine group.<sup>5</sup> The present study was conducted to compare topical amorolfine, sertaconazole and terbinafine in patients with tinea corporis and tinea cruris.

## METHODOLOGY

90 patients with tinea corporis and tinea cruris of both genders were included in present study. All were enrolled with their written consent.

Data such as name, age, gender etc. was recorded. Patients were divided into 3 groups of 30 each. Group I were prescribed topical application of amorolfine (0.25%) once daily, group II were given sertaconazole (2%) twice daily and group III were given terbinafine (1%) twice daily. Parameters such as location of lesion, morphology and symptoms were noted. Scrapings from the edge and/or from the scaly area of the lesions were taken. Response to treatment was assessed after 3 weeks. The improvement in the pruritus, erythema and scaling was recorded as score 0 for no improvement, score 1 for partial improvement and score 2 for complete improvement. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

## RESULTS

**Table I Distribution of patients**

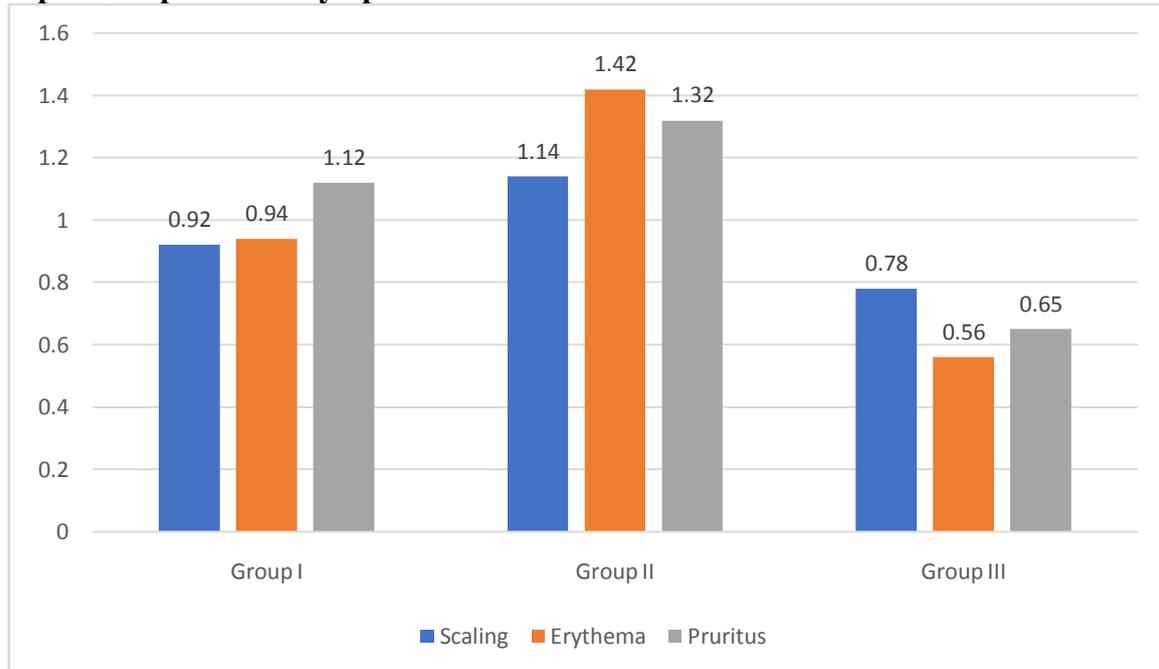
Groups	Group I	Group II	Group III
Drug	amorolfine (0.25%)	sertaconazole (2%)	terbinafine (1%)
M:F	14:16	17:13	12:18

Table I shows that group I had 14 males and 16 females, group II had 17 males and 13 females and group III had 12 males and 18 females.

**Table II Comparison of symptoms**

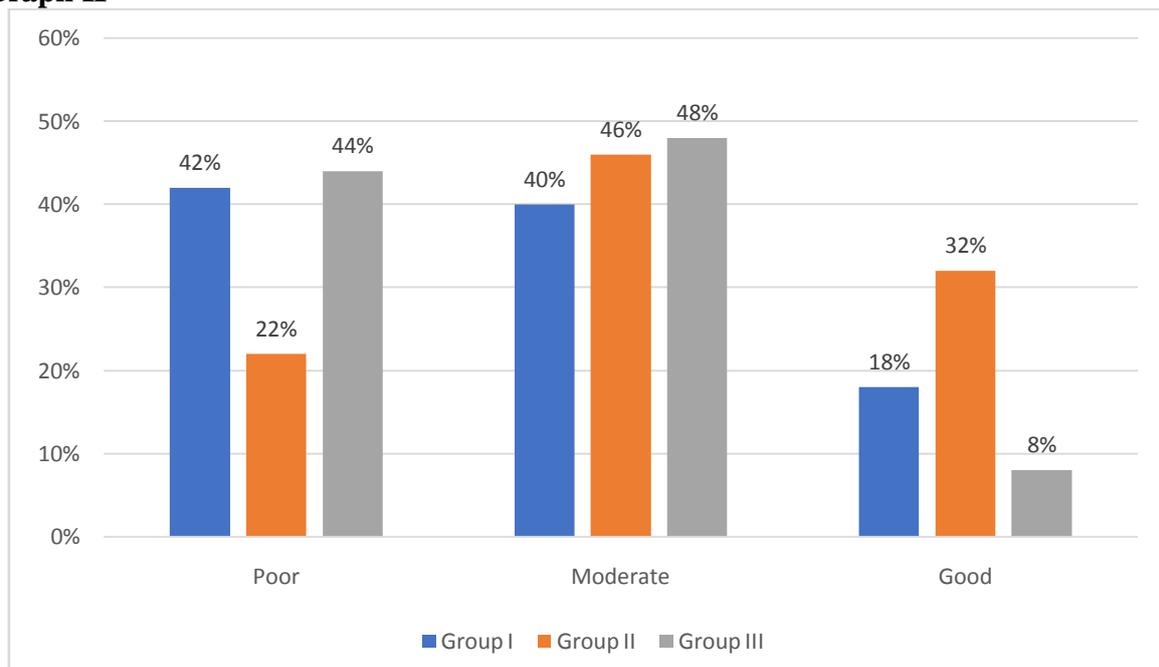
Groups	Scaling	Erythema	Pruritus
Group I	0.92	0.94	1.12
Group II	1.14	1.42	1.32
Group III	0.78	0.56	0.65
P value	0.02	0.04	0.01

Table II, graph I shows that mean value of scaling was 0.92 in group I, 1.14 in group II and 0.78 in group III. The mean value of erythema was 0.94 in group I, 1.42 in group II and 0.56 in group III. The mean value of pruritus was 1.12 in group I, 1.32 in group II and 0.65 in group III. The difference was significant ( $P < 0.05$ ).

**Graph I Comparison of symptoms****Table III Evaluation of response**

Response	Group I	Group II	Group III	P value
Poor	42%	22%	44%	0.91
Moderate	40%	46%	48%	0.96
Good	18%	32%	8%	0.01

Table III, graph II shows that response was poor seen in 42% in group I, 22% in group II and 44% in group III. Moderate seen in 40% in group I, 46% in group II and 48% in group III and good seen in 18% in group I, 32% in group II and 8% in group III. The difference was non-significant ( $P > 0.05$ ).

**Graph II**

## DISCUSSION

Classically dermatophytoses is characterized by the presence of 'ringed lesions' with central healing, concomitant presence of inflammatory symptoms including pruritus is noted in these patients.<sup>6</sup> Pruritus often leads to intense urge to itch affecting the quality of life of the patient. Secondly, intense itching of the lesion increases the chances of secondary bacterial infections and eczematization. Misuse of topical steroids result in unclear morphology of fungal infections (tinea incognita).<sup>7</sup> Imidazoles, allylamines and triazoles are most effective agents for dermatophytoses. Topical daily antifungal therapy usually involves imidazoles (namely, Luliconazole and Sertaconazole) and allylamines (Terbinafine). Terbinafine is a broad spectrum lipophilic antifungal agent showing excellent activity in patients with tinea corporis or tinea cruris.<sup>8</sup> Sertaconazole is a new benzothiofene imidazole derivative that is being used worldwide for varied indications including dermatophytosis, candidiasis, pityriasis versicolor, seborrheic dermatitis of scalp. Sertaconazole has both fungistatic and fungicidal activity against Dermatophytes, *Candida* spp. and *Cryptococcus* fungal infections.<sup>9</sup> The present study was conducted to compare topical amorolfine, sertaconazole and terbinafine in patients with tinea corporis and tinea cruris.

In present study, group I had 14 males and 16 females, group II had 17 males and 13 females and group III had 12 males and 18 females. Kumar et al<sup>10</sup> in their study a total of 100 divided into four groups with 25 patients in each category of antifungal were considered. Consecutive eligible patients were prescribed topical amorolfine (0.25%), luliconazole (1%), sertaconazole (2%) and terbinafine (1%) in a serial order. We evaluated the improvement in the pruritus, erythema and scaling with score 0 for no improvement, score 1 for partial improvement and score 2 for complete improvement. Among 100 patients 44 were treatment naive, 25 were topical steroid (with or without antifungal) modified cases, 23 were partially treated with antifungals and 8 had used home remedies prior to the study. Luliconazole showed best improvement of pruritus, erythema and scaling. Terbinafine showed the least improvement with mean being 0.62, 0.52, 0.77 for pruritus, erythema and scaling respectively. Difference in the mean values of improvement of luliconazole as compared to the other three drugs was significant for pruritus ( $P=0.019$ ) and highly significant for erythema and scaling ( $P=0.003$  &  $0.006$ ). A total of 16 patients (64%) in luliconazole group showed good response as compared to the other drugs. These differences in the improvement of patients was statistically significant as compared to other drugs.

We observed that mean value of scaling was 0.92 in group I, 1.14 in group II and 0.78 in group III. The mean value of erythema was 0.94 in group I, 1.42 in group II and 0.56 in group III. The mean value of pruritus was 1.12 in group I, 1.32 in group II and 0.65 in group III. Jerajaniet al<sup>11</sup> compared efficacy and safety of sertaconazole, terbinafine and luliconazole in patients with dermatophytoses. 83 patients with tinea corporis and tinea cruris infections were divided into three groups receiving either sertaconazole 2% cream applied topically twice daily for four weeks, terbinafine 1% cream once daily for two weeks, luliconazole 1% cream once daily for two weeks. Of the 83 patients, 62 completed the study, sertaconazole ( $n = 20$ ), terbinafine ( $n = 22$ ) and luliconazole ( $n = 20$ ). The primary efficacy variables including change in pruritus, erythema, vesicle, desquamation and mycological cure were significantly improved in all the three groups, as compared to baseline, in the Treatment and Follow-up phase. Greater proportion of patients in sertaconazole group (85%) showed resolution of pruritus as compared to terbinafine (54.6%); and luliconazole (70%), ( $P < 0.05$  sertaconazole vs terbinafine). There was a greater reduction in mean total composite score (pruritus, erythema, vesicle and desquamation) in sertaconazole group (97.1%) as compared to terbinafine (91.2%) and luliconazole (92.9%). All groups showed equal negative mycological assessment without any relapses. All three study drugs were well tolerated. Only

one patient in sertaconazole group withdrew from the study due to suspected allergic contact dermatitis.

We found that response was poor seen in 42% in group I, 22% in group II and 44% in group III. Moderate seen in 40% in group I, 46% in group II and 48% in group III and good seen in 18% in group I, 32% in group II and 8% in group III. Another study conducted by Choudhary et al<sup>12</sup> showed equal efficacy between sertaconazole and terbinafine.

## CONCLUSION

Authors found that sertaconazole found to be effective as compared to other agents in management of cases of tinea corporis and tinea cruris.

## REFERENCES

1. Spanakis E.K, George A, Eleftherios M. New Agents for the Treatment of Fungal Infections: Clinical Efficacy and Gaps in Coverage. *Clin.Dermatology* . 2006; 43:1060–8.
2. Ajello, L. A taxonomic review of the dermatophytes and related species. *Sabouraudia* 1968. 6:147–159.
3. David H. Stein. Tinea- Superficial Dermatophytes. *Infection,pediatrics in review.*1998; 19:368-372.
4. Sahni K, Singh S, Dogra S. Newer topical treatments in skin and nail dermatophyte infections. *Indian Dermatol Online J* 2018;9:149-58.
5. Dogra S, Uprety S. The menace of chronic and recurrent dermatophytosis in India: Is the problem deeper than we perceive?. *Indian Dermatol Online J* 2016;7:73-6.
6. Verma S, Madhu R. The great Indian epidemic of superficial dermatophytosis: An appraisal. *Indian J Dermatol* 2017;62:227-36.
7. Mala MS. Mellow to the malicious: Could Trichophyton mentagrophytes be the malefactor?. *Clin Dermatol Rev* 2017;1(S1):1-2.
8. Dabas R, Janney MS, Subramanian R, Arora S, Lal V S, Donaparthi N et al. Use of over-the-counter topical medications in dermatophytosis: A cross-sectional, single-center, pilot study from a tertiary care hospital. *Indian J Drugs Dermatol* 2018;4:13-17.
9. Rudramurthy SM, Shankarnarayan SA, Dogra S, Shaw D, Mushtaq K, Paul RA, et al. Mutation in the Squalene Epoxidase Gene of Trichophyton interdigitale and Trichophyton rubrum Associated with Allylamine Resistance. *Antimicrob Agents Chemother* 2018;26:62(5).
10. Kumar N, Kumar N. Comparative Assessment of Efficacy Of Four Different Topical Drugs In The Management Of Tinea Corporis And Tinea Cruris. *European Journal of Molecular & Clinical Medicine.* 2021 Jan 28;7(11):4765-9.
11. Jerajani HR, Janaki C, Kumar S, Phiske M. Comparative assessment of the efficacy and safety of sertaconazole (2%) cream versus terbinafine cream (1%) versus luliconazole (1%) cream in patients with dermatophytoses: a pilot study. *Indian journal of dermatology.* 2013 Jan;58(1):34.
12. Choudhary SV, Bisati S, Singh AL, Koley S. Efficacy and safety of terbinafine hydrochloride 1% cream vs. sertaconazole nitrate 2% cream in tinea corporis and tinea cruris: A comparative therapeutic trial. *Indian J Dermatol* 2013;58:457- 60.