International Journal of Research in Dermatology
Sumyuktha J et al. Int J Res Dermatol. 2017 Mar;3(1):59-63
http://www.ijord.com

DOI: http://dx.doi.org/10.18203/issn.2455-4529.IntJResDermatol20170082

Original Research Article

A comparative trial between the therapeutic efficacy of topical 2% sertaconazole cream and 1% terbinafine cream in the treatment of tinea cruris/tinea corporis

Sumyuktha J., Murali Narasimhan*, Parveen Basher Ahamed

Department of Dermatology, SRM Medical College and Research Centre, Kattankulathur, Potheri – Kanchipuram, India

Received: 28 December 2016
Revised: 08 January 2017
Accepted: 13 January 2017

***Correspondence:**
Dr. Murali Narasimhan,
E-mail: leecutis@gmail.com

ABSTRACT

Background: Skin infections caused by dermatophyte fungi account for 6% of dermatology consultations at our hospital and 3 to 4% worldwide. A variety of antifungal agents are available for topical use. Terbinafine 1% cream is considered the first line topical medication in the treatment of dermatophytosis. Sertaconazole 2% cream is a relatively new drug having antifungal as well as antiflammatory property. In this prospective study we sought to compare the safety and efficacy of topical 2% Sertaconazole and 1% Terbinafine creams in the treatment of localized tinea cruris and/or tinea corporis.
Methods: In this study, 80 patients were randomized into two groups of 40 each. Group A received 2% Sertaconazole cream while group B received Terbinafine 1% cream topical application twice daily for 4 weeks. Patients were followed up at the end of 2nd and 4th weeks for clinical, mycological (KOH mount and fungal culture) and complete cure (both clinical and mycological).
Results: The mean age of the patients studied was 27.97 years. Complete cure was achieved in 59.5% and 80% in group A and 71.4% and 90.9% in group B at the end of 2nd and 4th weeks respectively. Significant P values were observed if the results were compared within the group, between baseline and 2 weeks, baseline and 4th week and also 2nd and 4th week. Clinically significant side effects were not observed in both the groups.
Conclusions: Although higher cure rates were observed in the Terbinafine treated group, the results were not statistically significant. It can be concluded from our study that Sertaconazole 2% cream is similar in efficacy to Terbinafine 1% cream in the treatment of localized tinea cruris and corporis.

Keywords: Sertaconazole, Terbinafine, Dermatophytosis

INTRODUCTION

Fungal skin diseases are very common and account for 6% of patients seen in our outpatient department. Dermatophytosis is a superficial fungal infection of skin, hair and nails caused by dermatophytes, a group of related fungi belonging to 3 genera namely *Epidermophyton*, *Microsporum* and *Trichophyton*. In India the most commonly occurring clinical type of dermatophytosis is tinea corporis and tinea cruris for adults, that is involvement of the glabrous skin of trunk and groin.[1,2] In spite of the increasing prevalence of these infections, specific guidelines on the management of tinea cruris and corporis are in fact two decades old.[3] Updated Cochrane reviews on the use of topical therapies in tinea corporis and cruris have helped to bridge this gap.[4]

Topical antifungal agents belonging to groups such as azoles, polyenes and allylamines are available and are considered generally as first line therapy for dermatophytosis owing to their high efficacy and low potential for systemic side effects. Shadomy and colleagues reported Terbinafine to be 2 to 30 times more potent than Ketoconazole and 10 times more potent than Clotrimazole against common dermatophytes.[5] The in vitro anti dermatophyte potency for topical antifungal agents in descending order of potency is Butenafine >Terbinafine >ciclopirox = naftifine >azoles.[6]

Terbinafine is a fungicidal allylamine that inhibits squalene epoxidase that results in intracellular accumulation of toxic squalene and causes fungal cell death. Azoles are mainly fungistatic as they block lanosterol 14-α demethylase which prevents the formation of ergosterol, the primary sterol component of the fungal cell membrane. Sertaconazole, a newer lipophilic benzothiophene imidazole derivative, not only blocks lanosterol 14-α demethylase but also binds to non-sterol cell membrane lipids leading to altered membrane permeability and leakage of intracellular contents. This dual mechanism means that depending on the exact organism and drug concentration, Sertaconazole can be either fungistatic or fungicidal.[7]

There is a paucity of studies regarding the clinical efficacy of Sertaconazole in the treatment of tinea corporis and cruris. Hence this study was carried out to compare the efficacy of Sertaconazole nitrate 2% and Terbinafine hydrochloride 1% creams in the treatment of localized tinea corporis and/or tinea cruris.

METHODS

Source of data

Clearance from institutional ethical committee was obtained and this prospective comparative study was conducted on 80 patients presenting to the dermatology department of SRM medical college hospital and Research Centre, Potheri from January 2012 to July 2014.

Inclusion criteria

All patients clinically diagnosed as tinea corporis and/or tinea cruris with less than 20% body surface area involvement and skin scraping positive for dermatophyte filaments on 10% KOH mount, were included in the study.

Exclusion criteria

Pregnant and lactating women and age <18 years, immune-compromised patients including HIV, uncontrolled diabetes, malignancies, cancer chemotherapy, and transplant recipients, Patients with prior history of intolerance or hypersensitivity to imidazole, allylamine compounds or vehicle, Patients using medications such as topical antifungal or topical steroid or topical steroid-antifungal combination in the treatment area within 2 weeks of baseline visit, systemic antifungal agents a within 4 weeks of baseline visit, systemic corticosteroids within 30 days of baseline visit, were excluded from the study.

Sample collection

80 consecutive patients satisfying the inclusion criteria were recruited and were alternatively assigned to two groups A and B of 40 patients each. Group A patients were treated with 2% Sertaconazole nitrate cream and Group B were treated with 1% Terbinafine hydrochloride cream. Both groups were advised to apply the cream twice daily on the affected sites for four weeks and were recalled at the end of 2nd and 4th weeks to note the clinical improvement and adverse effects like local erythema, swelling, stinging sensation or increased itching. Clinical photographs were taken at each visit. Clinical cure was assessed by clinical improvement in signs and symptoms of the parameters like pruritus, erythema, papules and scaling which was graded at 0, 2 and 4 weeks as shown below in Table 1.[10]

Table 1: Clinical assessment of tinea corporis and cruris.

Score	Pruritus	Erythema	Scaling	Papules
0	Absent	Absent	Absent	Absent
1	Mild, occasionally disturbing daily activities	Mild redness	Mild, scarcely visible only in some areas	Mild, scarcely distributed
2	Severe, frequently disturbing daily activities and sleep.	Severe, bright redness easily visualised	Severe, thick covering large area	Severe, densely distributed and/or presence of plaques

Cured: 0; Mild: <4; Severe: 4-8.

Mycological cure was assessed by doing skin scraping for 10% KOH mount and culture on Sabouraud's dextrose agar with chloramphenicol and cycloheximide at 0, 2 and 4 weeks. Mycological cure was defined as negative KOH and culture. Complete cure was defined as mycological cure with complete absence of clinical signs and symptoms.

Statistical analysis

Descriptive and inferential statistical analysis was carried out in the study. Results on continuous measurements are presented on mean±SD (min-max) and results on categorical measurement are presented in numbers (%). Significance is assessed at 5% level of significance student T test has been used to find the significance of study parameters for continuous measurement and Chi square/Fisher exact test has been used for categorical measurement between the 2 groups.

RESULTS

The study population consisted of 80 patients including 51 males (63.7%) and 29 females (36.3%). The mean age of the population was 27.97 years. Students comprised a majority group accounting for 52% of the study population. The mean duration of symptoms in the two groups was 16.28±15.96 and 20.63±19.20 days. Though the duration is more in Terbinafine group it is not statistically significant. Tinea corporis was more common with 65% and 57.5% in the groups, while tinea cruris was seen in 35% and 40% of the 2 groups respectively. Both tinea cruris and tinea corporis was seen in 1 subject. 12 persons dropped out of the study, which included 7 in Sertaconazole group and 5 in Terbinafine group. Culture positivity was seen in 92.5% and 95.0%, 5.4% and 2.9%, 2.9% and 0% in group A and B respectively at baseline 2nd and 4th weeks. *Trichophyton rubrum, Trichophyton mentagrophytes, Microsporum canis* and *Microsporum gypseum* were the culture isolates in the order of frequency in both groups. Clinical assessments at 2nd and 4th week are depicted below in Table 2.

Table 2: Comparison of clinical assessment between the two groups

	Group A (Sertaconazole)		Group B (Terbinafine)	
	2nd week	4th week	2nd week	4th week
Cured	59.5%	80%	71.4%	90.9%
Mild	29.7%	17.1%	28.6%	9.1%
Severe	10.8%	2.9%	0%	0%
Total	100	100	100	100
P value	0.0173		0.0387	

At the end of the 2nd week as well as the 4th week, Terbinafine group showed higher cure rates. There were no severe cases at the end of the treatment period in the Terbinafine group while 10.8% of severe cases persisted at the end of the study period in the Sertaconazole group. Mycological assessment at the end of 2nd and 4th weeks is depicted below in Table 3.

At baseline KOH is positive in all patients and is negative in all the patients tested in both the groups at 4 weeks. However at 2 weeks KOH is negative in 91.9% of patients in group A as compared to 97.1% in group B. All patients in group B are culture negative at the end of 4 weeks where as one patient remained culture positive in group A. A majority of our patients in both the groups showed *Trichophyton rubrum* (53.75%) followed by *T. mentagrophytes* (36.25%) growth on culture.

Table 3: Mycological assessment at the end of 2nd and 4th weeks.

Groups	KOH Mount				Culture		
		0	2nd week	4th week	0	2nd week	4th week
Group A (Sertaconazole)	Negative	0 (0%)	34 (91.1%)	35 (100 %)	3 (7.5%)	35 (94.6%)	34 (97.1%)
	positive	40 (100%)	3 (8.1%)	0 (0%)	37 (92.5%)	2 (5.4%)	1 (2.9%)
	FIF	0	3	5	0	3	5
Group B (Terbinafine)	Negative	0 (0%)	34 (97.1%)	33 (100%)	2 (5%)	34 (97%)	33 (100%)
	Positive	40 (100%)	1 (2.9%)	0 (0%)	38 (95%)	1 (2.9%)	0 (0%)
	FIF	0	5	7	0	5	7
P value		1.00	0.615	1.000	0.995	0.995	0.997

Table 4: Comparison of complete cure at 4 weeks between the two groups.

Completely cured at 4 weeks	Group A		Group B		Total	
	N	%	N	%	N	%
Cured	28	80	30	90.9	58	85.3
Not cured	7	20	3	9.1	10	14.7
Total	35	100	33	100	68	100
Chi squares tests		Value	P- value			
Fishers Exact Test		-	0.307			

Figure 1: Treatment responses to terbinafine and Sertaconazole. Complete clearance of lesions with post inflammatory pigmentation at the end of the treatment period.

DISCUSSION

In our prospective comparative study, we have studied the efficacy of topical 2% Sertaconazole cream and 1% Terbinafine cream in treatment of localised tinea corporis and tinea cruris. The majority of the total study population was between 20 to 30 years of age with a male preponderance. A male preponderance was also noted in a similar study done by Jerajani et al, where 65% were males and 35% were females.[11]

We have assessed the response to treatment both by clinical observation (rating them by giving a scoring pattern), as well as with mycological study i.e. 10% KOH mount and culture which was done at base line (zero day),end of 2 weeks & 4 weeks respectively for both the drug groups.[10] Clinical cure i.e. clinical score equals to zero was achieved in 59.5% and 80% of patients in group A (Sertaconazole) as compared to 71.4% and 90.9% in group B (Terbinafine) at the end of two and four weeks respectively which is similar to a study done by Choudhary et al.[14]

Complete cure is clinical score =0 with KOH and culture negativity. In group A (Sertaconazole) complete cure was noted in 59.5%, and 80% of patients at the end of 2nd and 4th week of treatment, respectively. Significant P value was observed if the results were compared between baseline to 2nd week (<0.001), baseline to 4th week (<0.001) and 2nd to 4th week (0.008).

In group B (Terbinafine) complete cure was noted in 71.4% and 90.9% patients at the end of 2nd and 4th week of treatment, respectively. Significant P value was observed if the results were compared between baseline to 2nd week (<0.001), baseline to 4th week (<0.001) and 2nd to 4th week (0.016).

A comparison between Group A and Group B for complete cure is not statistically significant (at 2 weeks P value = 0.286, at 4 weeks P value = 0.307) even though the complete cure rate for Terbinafine was higher at the end of 2nd and 4th weeks. These observations indicate that in our study Sertaconazole nitrate 2% cream is similar in efficacy to Terbinafine hydrochloride 1% cream at the end of 2nd and 4th weeks.

Table 5: Comparison of present study with other Indian studies.

	Complete cure at 2 weeks		Complete cure at 4 weeks	
	Sertaconazole	Terbinafine	Sertaconazole	Terbinafine
Present study	59%	71.4%	80%	90.9%
Jerajani et al[11]	___	91.2%	97.31%	--
Sumitha et al[13]	63.3%	80%	96.7%	--
Choudhary et al[14]	62.3%	80%	100% (3weeks)	100% (3weeks)
Tamilselvan et al[15]	93% (1week)	83.3% (1 week)	__	__

Jerajani et al compared the efficacy and safety of Sertaconazole (2%) cream versus Terbinafine cream (1%) versus Luliconazole (1%) cream in tinea corporis and tinea cruris and showed that at the end of 'treatment phase', there was a greater reduction in mean total composite score in Sertaconazole group (97.1%) as compared to Terbinafine (91.2%). Composite score in their study was based on clinical symptoms and signs namely pruritus, erythema, vesicle and desquamation.[11] This study was in contrast to ours in which the clinical

cure of Terbinafine (90.9%) was better than Sertaconazole (80%) at the end of 4 weeks of treatment. However in their study the 'treatment phase' was different for both the groups. Sertaconazole nitrate 2% cream was given twice daily for 4 weeks whereas Terbinafine 1% cream was given once daily for 2 weeks hence possibly the difference in efficacy.

Choudhary et al in their comparative study between the same two drugs in tinea cruris and corporis used Terbinafine hydrochloride 1% and Sertaconazole nitrate 2% cream twice daily for 3 weeks and observed statistically non-significant results when the two groups were compared for complete cure at the end of 1st, 2nd and 3rd week. At the end of 2nd week, complete cure rate for Terbinafine was 80% as compared to 73.35% for Sertaconazole with no statistical significance.[14] However in their study they observed a statistically significant difference in complete cure in Sertaconazole group when the results between 2nd and 3rd week was compared, which was not observed in Terbinafine group unlike our study in which statistically significant results were obtained within the group for both the groups when compared for complete cure between 2nd and 4th week.

Tamilselvan et al compared the efficacy of Sertaconazole, Luliconazole, Terbinafine, Amorolfine and Eberconazole and found that Sertaconazole showed higher efficacy with 93.3% as compared to Terbinafine which showed 80%. The treatment duration was only one week only but Sertaconazole showed greater clinical symptom relief as compared to Terbinafine.[15] This is in contrast to our study as well as other studies where Terbinafine gives earlier and better results than Sertaconazole. Adverse reactions were not noted in any of the treated patients in both the groups.

CONCLUSION

This study showed that the clinical cure and complete cure rate was found to be higher in Terbinafine 1% compared to Sertaconazole 2%, though it is not statistically significant. Thus it can be said that topical Sertaconazole 2% cream is similar in efficacy to topical Terbinafine 1% cream in the treatment of tinea corporis and tinea cruris. The main drawback of this study was that there was no follow up phase to evaluate the recurrences.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

REFERENCES

1. Mohanty JC, Mohanty SK, Sahoo RC, Sahoo AS, Prahraj CH. Incidence of Dermatophytosis in Orissa. Indian J Med Microbiol. 1998;16:78-80.
2. Singh S, Beena MP. Profile of Dermatophyte infections in Baroda. Indian J Dermatol Venereol Leprosy. 2003;69:281–3.
3. Sahoo AK, Mahajan R. Management of Tinea Corporis, Tinea Cruris and Tinea Pedis: A Comprehensive review. Indian Dermatol online J. 2016;7:77-86.
4. El – Gohary M, Van Zurren EJ, Fedorowickz Z, Burgess H, Doney L, Stuart B, et al. Topical antifungal treatments for tinea cruris and tinea corporis. Cochrane database system Rev. 2014;8:CD009992.
5. Shadomy S, Esoingel Ingroff A, Gebhart RJ: Invitro studies with SF 86-327, a new orally active allylamine derivative. Sabouraudia 1985;23:125-32.
6. Rhea MP, Theodore R. Topical antifungal agents. In: Wolverton SE. Comprehensive dermatologic drug therapy. 2nd edition. WB Saunders; 2001: 508-9.
7. Croxtall JD, Plosker GL. Sertaconazole: A review of its use in superficial mycoses in dermatology and gynaecology. Drugs. 2009;69:339-59.
8. Liebel F, Lyte P, Garay M, Babad J, Southall MD. Anti-inflammatory and anti-itch activity of Sertaconazole nitrate. Arch Dermatol Res. 2006;298:191-9.
9. Lakshmi V, Bengalorkar GM, Kumar S. Clinical efficacy of topical terbinafine versus luliconazole in the treatment of Tinea corporis / Tinea cruris patients. Br J Pharmacol. 2013;3(4);1001-14.
10. Budimulja U. Terbinafine 1% cream Vs Bifonazole 1% cream in the treatment of Tinea cruris. In J Dermatol. 1998;37:871-3.
11. Jerajani HR, Janaki C, Kumar S, Phiske M. Comparative assessment of the efficacy and safety of Sertaconazole 2% cream versus Terbinafine 1% versus Luliconazole 1% cream in patients with Dermatophytoses: A pilot study. Indian J Dermatol. 2013;58:34–8.
12. Rotta I, Ziegelmann PK, Otuki MF, Riveros BS, Bernardo NL, Correr CJ. Efficacy of topical antifungals in the treatment of Dermatophytosis. A mixed treatment comparison Meta-analysis involving 14 treatments. JAMA Dermatol. 2013;149:341-9.
13. Sumitha A, Geetha M, Shashikala GH, HS Somashekar, KS chandarn. Efficacy and safety of 1% terbinafine hydrochloride versus 2% Sertaconazole cream in the treatment of tinea corporis. Int J Basic Clin Pharmacol. 2015;4:474–8.
14. Chaudhary SV, Bisati S, Singh A, Koley S. Efficacy and safety of Terbinafine hydrochloride 1% cream Vs Sertaconazole nitrate 2 % Cruris: A comparative therapeutic trial. Indian J Dermatol. 2013;58:457-60.
15. Tamilselvan A, Girisha G, Bhaskar V, Suthakaran R. Comparative evaluation of newer topical antifungal agents in the treatment of superficial fungal infections (Tinea or Dermatophytic). Int Res J Pharm. 2013;4(6):224–8.

Cite this article as: Sumyuktha J, Narasimhan M, Ahamed PB. A comparative trial between the therapeutic efficacy of topical 2% sertaconazole cream and 1% terbinafine cream in the treatment of tinea cruris/tinea corporis. Int J Res Dermatol 2017;3:59-63.