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Research Article

Comparison of efficacy, safety and cost-effectiveness of clotrimazole 1% cream and sertaconazole 2% cream in patients suffering from of mild to moderate tinea corporis, attending tertiary care hospital out-patient department: a randomized, open-labeled, comparative, parallel group trial

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ABSTRACT

Background: Tinea corporis is a common dermatophytic infection of the body involving keratin layer of skin. This lesion presents as an annular plaque with an advancing border along with central clearing. Clotrimazole is topical, conventional imidazole antifungal drug and has given good efficacy in tinea corporis. Sertaconazole is new topical imidazole antifungal claimed to be superior to old topical imidazoles in tinea corporis. The aim of this study was to compare efficacy, safety and cost effectiveness of topical antifungals, clotrimazole 1% cream and sertaconazole 2% cream in patients suffering from mild to moderate tinea corporis attending out-patient department of tertiary care hospital in Vidarbha region of Maharashtra.
Methods: This was a prospective, comparative, randomized trial with 2 parallel treatment arms of 4 weeks duration. Patients were diagnosed on the basis of clinical evaluation and microscopic findings of KOH mount. Hundred patients were randomly assigned into two groups of clotrimazole 1% cream, and sertaconazole 2% cream with 50 patients in each group. Evaluation was carried out at baseline, 1st week, 2nd week and 4th week for efficacy parameters viz. itching, erythema and scaling, physician's global assessment (PGA), safety and cost effectiveness.
Results: Topical sertaconazole 2% cream was highly efficacious and superior to clotrimazole 1% cream in improvement of clinical parameters, PGA and mycological cure at the end of the treatment phase. At end of the follow-up phase both the trial drugs were effective with no recurrence or relapse of tinea corporis. However, clotrimazole 1% cream was safe and cheaper.
Conclusions: Topical clotrimazole 1% cream and sertaconazole 2% were effective and well tolerated in patients of tinea corporis. Effectiveness of sertaconazole was early and superior with tolerable side-effects. However, clotrimazole was cost-effective.

Keywords: Tinea corporis, Clotrimazole, Sertaconazole, Cost effectiveness

INTRODUCTION

"Dermatophytoses" are fungal infections caused by dermatophytes belonging to genera of trichophyton, microsporum, and epidermatophyton; a group of fungi that invade and grow in keratin of skin, hair, and nail. In India, the most commonly occurring clinical type of dermatophytoses includes tinea corporis (36-59%) and tinea cruris (12-27%).[1,2] Tinea corporis refers to tinea anywhere on the body except the scalp, beard, feet, hands, groin, and nails. The incidence of fungal infections is increasing due to widespread use of antimicrobials and immune-suppressants and due to immune-compromised states such as diabetes mellitus, HIV-AIDS etc.[3,4] Both topical and systemic therapies may be used to treat dermatophytic infections. The oral drugs show poor compliance because of the length of treatment, side effects and cost.

Clotrimazole have been widely used topically for the treatment of the superficial dermatophytosis for over 25 years. It is a broad spectrum antifungal agent that is used for the treatment of dermal infections caused by various

species of dermatophytes, yeasts, and *Malassezia furfur*.[5,6] Sertaconazole nitrate is the new topical azole antifungal, found to be more effective than conventional azoles. This recently developed antifungal is characterized by broad spectrum of action against yeasts, dermatophytes and Gram-positive bacteria as well.[7,8] We came across no trials reported in the literature comparing efficacy, safety and cost effectiveness of topical antifungals clotrimazole and sertaconazole in the treatment of tinea corporis.

Hence, this study was undertaken to compare two antifungals, the established medicine clotrimazole and the most recently introduced sertaconazole in patients suffering from tinea corporis of Vidarbha region of the central India, based on efficacy, safety and cost effectiveness.

METHODS

This was a prospective, comparative, randomized, open-labeled, controlled, parallel group study. Totally 100 patients satisfying inclusion criteria were selected at skin out-patient department of tertiary center and randomized in a 1:1 ratio into two groups, each of 50 patients. One group was treated with topical clotrimazole 1% cream while other received topical sertaconazole 2% cream after approval from Institutional Ethics Committee.

Selection of participants

The patients of both genders in age group of 18-65 years, having clinical manifestations of mild to moderate tinea corporis and positive for KOH mount were selected. Patients with systemic mycosis or mycosis of the hands, groin, nails, feet, face and scalp, those received antifungals and immunosuppressive medicines within last 1 month, prior to the onset of study, pregnant and nursing mothers and patients with history of diabetes mellitus and other systemic illness were excluded.

The duration of the study was 4 weeks consisting of two phases; initial "treatment phase" consisted first 2 weeks and "follow-up phase" for next 2 weeks. After a detailed history, general and systemic examination, clinical assessment was done based on parameters of itching, erythema and scaling at base line, 1st week, 2nd week and 4th week. Furthermore, physician's global assessment (PGA) was rated on 4 point scale as poor, satisfactory, good and excellent. Mycological examination was done with KOH mount of skin scrapings. Absence of fungal elements was considered as mycological cure.

Efficacy outcome

Primary efficacy outcome

The primary efficacy outcome was clinical cure at the end of "treatment phase" and "follow-up Phase," which included parameters itching, erythema and scaling, and graded as absent (0), mild (1), moderate (2) and severe (3).[9]

Secondary efficacy outcome

The secondary efficacy outcome was mycological cure.

Safety assessment

The safety of the therapy was monitored by follow-up visits of patients for the emergent of adverse events if any.

Cost-effectiveness analysis

For the calculation of cost effectiveness, direct cost of the therapy was considered. It was calculated by calculating fingertip units (FTU);[10] one FTU is equal to 0.5 g of cream, if the lumen of the tube has diameter of 5 mm. Efficacy outcome parameter was PGA. Cost-effectiveness ratio was calculated by dividing cost with outcome.[11]

Statistical analysis

Sample size was rounded to 100 considering future drop outs. Results were expressed as mean±standard error of the mean. Categorical variable was expressed in actual numbers and percentage. Parametric test used was unpaired t-test. Differences within group were compared by Friedman test with Dunn's multiple comparison *post-hoc* test. Group differences were ascertained by Mann–Whitney Rank Sum test. Two tailed $p<0.05$ was considered as statistically significant.

RESULTS

In the study total, 100 patients underwent randomization and included in the intention to treat groups. Two groups were balanced with respect to baseline characteristics (Table 1). There were total 5 cases who lost to follow-up, 3 in clotrimazole group and 2 in sertaconazole group. The reason of drop outs was failure of the patient to report in follow-up phase after completion of the treatment phase.

Table 1 shows the comparison of baseline demographic characteristics and clinical features of itching, erythema and scaling in treatment groups of clotrimazole 1% cream and sertaconazole 2% cream. There was no statistically significant difference in the mean scores of these parameters in both the treatment groups.

Table 2 shows the intra-group comparison of the efficacy of clotrimazole 1% cream and sertaconazole 2% cream on itching, erythema and scaling at 1st, 2nd and 4th week. At 1st week of follow-up, in clotrimazole group the reduction in mean scores of itching and scaling was statistically significant ($p<0.01$ in itching and $p<0.05$ in scaling) and non-significant of erythema, whereas it was highly significant ($p<0.001$) in sertaconazole group when compared to baseline scores. The reduction in mean scores of itching, erythema

and scaling was statistically highly significant (p<0.001) in both the treatment groups at the 2nd and 4th week when compared with the scores of baseline and 1st week. However, no significant difference was found when 2nd week was compared to 4th week in both the treatment groups. Both the trial drugs achieved complete clinical cure at the end of 4th week.

Table 3 shows the inter-group comparison of mean difference of itching, erythema and scaling scores at 1st week, 2nd week and 4th week from the baseline score in treatment groups of clotrimazole 1% cream and sertaconazole 2% cream. It was found that the mean difference of itching, erythema and scaling was statistically highly significant (p<0.001) in sertaconazole group when compared with clotrimazole group at the end of 1st week. The mean difference of baseline to 2nd week's score was highly significant (p<0.001) in itching, significant (p<0.05) in erythema and statistically non-significant in scaling when sertaconazole 2% cream was compared with clotrimazole 1% cream. However mean difference of the baseline to 4th week's score was statistically significant for erythema, but non-significant for itching and scaling the score when the two trial drugs were compared. This shows that sertaconazole 2% cream was significantly superior in efficacy when compared with clotrimazole 1% cream.

Figure 1 shows the comparison of PGA of patients suffering from mild to moderate tinea corporis at the end of 1st week in treatment groups of clotrimazole 1% cream and sertaconazole 2% cream. It was observed that with clotrimazole 1% cream, response was poor in 21.2% cases, satisfactory in 63.8% cases and good in 14.8% cases. Whereas with sertaconazole 2% cream, response was poor only in 4% cases, satisfactory in 64.5% cases and good in 31.25% cases.

Figure 2 shows the comparison of PGA of patients suffering from mild to moderate tinea corporis at the end of "treatment phase" in treatment groups of clotrimazole 1% cream and sertaconazole 2% cream. It was observed that with clotrimazole 1% cream, response was good in 25.53% cases, whereas with sertaconazole 2% cream, response was good in 6.25% cases.

Complete clinical cure i.e. excellent response at the end of "treatment phase" was observed in 93.75% of patients in sertaconazole group and 74.47% patients of clotrimazole

Table 1: Baseline demographic data and clinical characteristics of patients.

Characteristic	Clotrimazole	Sertaconazole
Number of patients recruited	50	50
Number of patients completed trial	47	48
Age (years)	37.06±1.55	38.02±1.22
Gender		
Male	33	30
Female	17	20
Height (cm)	158.6±1.00	159.7±1.22
Weight (kg)	60.4±0.89	60.8±1.25
Itching	2.72±0.07	2.70±0.07
Erythema	2.45±0.1	2.64±0.08
Scaling	2.57±0.07	2.5±0.09

Values are expressed as mean±SEM. SEM: Standard error of the mean

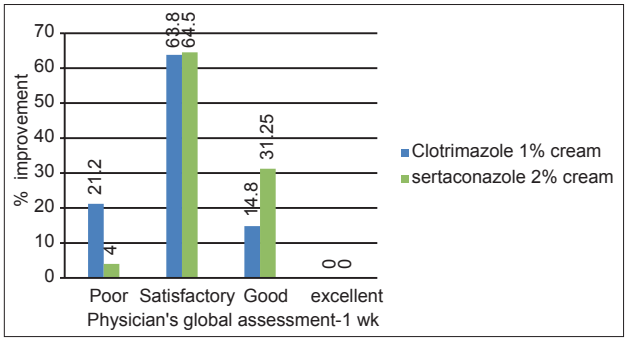

Figure 1: The comparison of physician's global assessment of patients, suffering from mild to moderate tinea corporis at the end of 1st week.

Table 2: Within group comparison of mean scores of itching, erythema and scaling at baseline, 1st week, 2nd week and 4th week in clotrimazole and sertaconazole groups.

Parameter	Baseline	1st week	2nd week	4th week
Clotrimazole (n=47)				
Itching	2.73±0.06	1.69±0.06**	0.60±0.07***	0.19±0.05***
Erythema	2.42±0.01	1.97±0.11	0.21±0.06***	0.08±0.04***
Scaling	2.57±0.07	1.85±0.05*	0.36±0.07***	0.19±0.05***
Sertaconazole (n=48)				
Itching	2.70±0.07	1.10±0.08***	0.041±0.02***	0***
Erythema	2.65±0.08	1.08±0.09***	0.08±0.04***	0***
Scaling	2.5±0.1	1.08±0.1***	0.08±0.04***	0***

Values are expressed as mean±SEM; Friedman test with Dunn's multiple comparison *post-hoc* test. ***p<0.001, **p<0.01, *p<0.05. SEM: Standard error of the mean

Table 3: Inter group comparison of mean differences of scores of itching, erythema and scaling at 1st, 2nd and 4th week from baseline score in clotrimazole and sertaconazole groups.

Duration	Baseline to 1st week		Baseline to 2nd week		Baseline to 4th week	
Parameters	Clotrimazole	Sertaconazole	Clotrimazole	Sertaconazole	Clotrimazole	Sertaconazole
Itching	1.02±0.06	1.6±0.09***	2.1±0.07	2.66±0.07***	2.53±0.08	2.71±0.07
Erythema	0.45±0.08	1.56±0.54***	2.21±0.1	2.56±0.08*	2.34±0.1	2.64±0.08*
Scaling	0.72±0.06	1.41±0.1***	2.21±0.1	2.41±0.09	2.39±0.1	2.5±0.09

Values are expressed as mean±SEM; Mann-Whitney Rank Sum test, *p<0.05 and ***p<0.001. SEM: Standard error of the mean

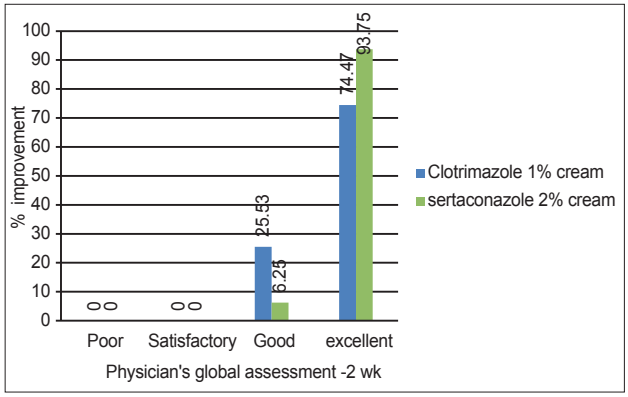

Figure 2: The comparison of physician's global assessment of patients, suffering from mild to moderate tinea corporis at the end of "treatment phase".

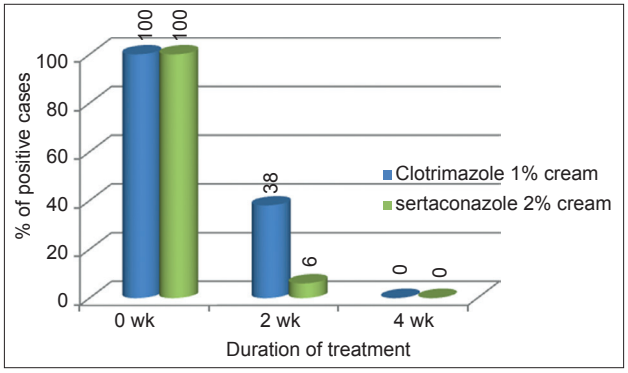

Figure 3: The comparison of percentage of positive cases for fungal elements on KOH mount in patients suffering from mild to moderate tinea corporis at baseline, end of "treatment phase" and "follow-up phase".

group which proves that sertaconazole 2% cream had a cure rate superior to clotrimazole 1% cream. At the end of "follow-up" phase both the groups showed 100% cure rate. There was absence of any relapse recurrence of the disease with both the trial drugs.

Figure 3 shows the comparison of percentage of positive cases for fungal elements on KOH mount in patients suffering from mild to moderate tinea corporis at baseline, end of "treatment phase" and "follow-up phase" in treatment groups of clotrimazole 1% cream and sertaconazole 2% cream. It was observed that at baseline 100% cases were positive on mycological examination. At the end of "treatment phase" 38% and 6% cases were positive in clotrimazole and sertaconazole groups respectively. At the end of "follow-up phase" there was no (0%) positive case in both the treatment groups.

At the end of "treatment phase" complete mycological cure was observed in 94% patients treated with sertaconazole 2% cream and in 62% patients treated with clotrimazole 1% cream. At the end of "follow-up" phase both the drugs showed 100% cure with absence of any relapse and recurrence.

Safety analysis of therapy

Clotrimazole 1% cream and sertaconazole 2% cream were well tolerated with mild application site adverse drug reactions (ADR). No severe adverse events were reported, no participants from the study discontinued due to ADR and no case of non-compliance to the therapy was reported.

One ADR related to treatment of sertaconazole 2% cream during the 1st week was burning the sensation at the site of application of drug.

For assessing the cost-effectiveness, amount of topical drug needed was calculated by averaging requirement for different sites, which came out as two tubes per week of 15 g each. Thus, the average cost of treatment with clotrimazole 1% cream, at the end of "treatment phase" and "follow-up phase" week was INR 92 and INR 184 respectively and with sertaconazole 2% cream, it was INR 420 and INR 840, respectively. Efficacy outcome parameter was PGA. Figure 4 shows that CER of sertaconazole 2% cream was statistically highly significant when compared with clotrimazole 1% cream at end of "treatment phase" and at the end of "follow-up phase." The CER was higher for sertaconazole 2% cream, followed by clotrimazole 1% cream at both the follow ups.

DISCUSSION

Tinea corporis is a common superficial fungal infection occuring in tropical countries, commonly known as "ringworm." Usually, there is a trend towards prescribing combinations of antifungals, corticosteroids and antimicrobials for the treatment of common fungal skin infections without confirming the diagnosis leading to risk of side effects, resistance, excessive cost etc. Efficacy of monotherapy with topical antifungals in the treatment of tinea corporis is controversial due to few studies. Hence, the present study was carried out.

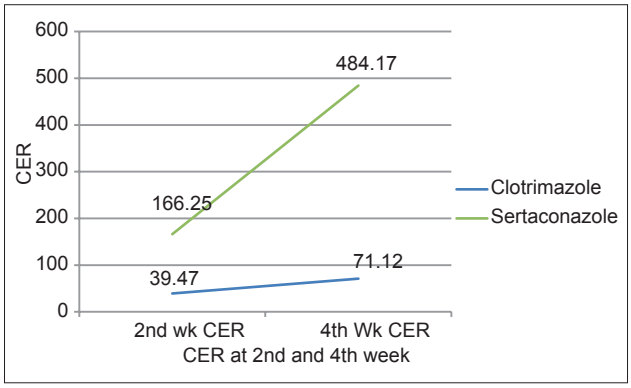

Figure 4: The comparison of mean of cost effectiveness ratio of clotrimazole 1% cream and sertaconazole 2% cream at the end of "treatment phase" and "follow-up phase".

Total hundred patients of both genders were included in the study. The baseline demographic data and clinical characteristics of participants of the study were matching. This proves the homogeneity of our study subjects in the two groups. Most patients were in the age group of 29-46 years.[2,12-14] The percentage of male patients with fungal infection was more than women patients i.e. 63% including both groups,[2,12,15] may be due to higher exposure to sun and heat, schools or colleges, jobs and sporting activities leads to excessive sweating, warm and moist skin; a good medium for the fungal growth.[1,2,12,15]

The effect of topical therapies with clotrimazole 1% cream and sertaconazole 2% cream, twice daily application for 4 weeks was compared in patients suffering from mild to moderate tinea corporis. The initial 2 weeks were "treatment phase" where clinical and mycological outcome was evaluated, and last 2 weeks were "follow-up phase" where recurrence and relapse of tinea corporis were observed.

In the present study based on data of 100 evaluable patients, both the study drugs showed a significant reduction in clinical features (itching, erythema and scaling) of tinea corporis as compared to baseline.[16-18] However, response to therapy was early in onset and higher in sertaconazole group. At end of " treatment phase," significantly higher proportion of patients treated with topical sertaconazole 2% cream had improvement of itching, erythema, and scaling as compared to clotrimazole 1% cream.

The probable superiority of sertaconazole 2% cream over clotrimazole 1% cream may be attributed to its wide range of mechanism of action, described as follows.

Fungistatic activity is resulting from interference with ergosterol synthesis, an essential component of the fungal cell membrane, inhibition of its synthesis results in increased cellular permeability causing leakage of cellular contents. It is a highly selective inhibitor of fungal cytochrome P-450 sterol C-14 α-demethylation via the inhibition of the enzyme cytochrome P450 14 α-demethylase. This enzyme converts lanosterol to ergosterol and is required in fungal cell wall synthesis. The subsequent loss of normal sterols correlates with the accumulation of 14 α-methyl sterols in fungi. Fungicidal activity at high concentrations results from a direct physiochemical effect on the fungal cell membrane. As it binds directly to non-sterol lipids on the fungal membrane and interferes with ligands from the intra-cellular contents, thereby causing cell death. It is an effective fungicidal and fungistatic agent. In addition, anti-inflammatory properties have been described by reducing cytokine secretion from activated lymphocytes, histamine release from mast cells and release of PGE_2, all of which control the inflammatory component of dermatophytosis.[19-21]

PGA showed that complete clinical cure rate i.e. excellent response at the end of "treatment phase" was highest with topical sertaconazole 2% cream (93.75) as compared to clotrimazole 1% cream (74.47%). Complete clinical cure was observed with both the trial drugs at the end of "follow-up phase." A study by Sharma et al., has shown that the sertaconazole produced 62.3% clearance at the end of 2 weeks.[22] In the study by Alomar et al., 95.6% clinical cure rate was seen at the end of treatment with sertaconazole.[23]

Mycological assessment with KOH mount showed that at the end of "treatment phase," 94% patients treated with sertaconazole 2% cream and 62% patients who received clotrimazole 1% cream were negative for fungal elements. This proves topical sertaconazole 2% cream to be superior in mycological cure, followed by clotrimazole 1% cream. However at the end of follow-up phase complete mycological cure (100%) was observed with both the therapies which confirmed absence of recurrence and relapse of tinea corporis. Schopf et al. reported mycological cure rate of 91% with clotrimazole solution in the treatment of tinea pedis.[24] Savin and Jorizzo reported sertaconazole 2% cream showed 70.3% mycologic cure in patients of tinea pedis.[25]

In this study, we found only one ADR related to treatment. One patient from sertaconazole group during the 1st week reported this. It was burning the sensation at the site of application of sertaconazole, which was of mild grade and lasted only for three days. It did not require any stoppage of medication, shift to another therapy or withdrawal of the patient from the trial. Sharma et al. have reported five patients in the sertaconazole group and nine in the miconazole group developing mild to moderate adverse events.[22] del Palacio et al. have reported premature termination of their trial due to adverse effects, which were 26.7% with clotrimazole 1% cream in candida and dermatophyte skin infections.[26]

For pharmacoeconomic analysis, treatment modality having less cost-effectiveness ratio is considered as superior. It was observed that the CER was significantly higher in sertaconazole 2% cream when compared to clotrimazole

1% cream at both the follow ups. Thus, it suggests that clotrimazole 1% cream is cost-effective over sertaconazole 2% cream in the treatment of tinea corporis. No literature on cost-effectiveness of topical clotrimazole 1% cream and sertaconazole 2% cream is reported.

Limitations

Results of the present study cannot be generalized as this was an open labeled (non-blinded) study with smaller sample size. Furthermore, diagnosis of tinea corporis was purely on the basis of clinical examination and microscopic finding of KOH mount. We did not identify the causative organism for the tinea corporis by culture sensitivity. More studies with larger size in future are needed.

CONCLUSIONS

Response to the topical monotherapy with clotrimazole 1% cream and sertaconazole 2% cream was safe, effective and well tolerated in the treatment of mild to moderate tinea corporis. Treatment with sertaconazole 2% cream was early in the onset, required shorter duration of therapy and with tolerable side-effects. Hence, sertaconazole 2% cream should be preferred as a first line topical monotherapy, followed by clotrimazole 1% cream. However, topical clotrimazole 1% cream was cost-effective. Further studies are needed to support the findings of the present study.

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