

Efficacy and safety of sertaconazole in the treatment of dermatophytoses

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Abstract

Background Dermatophytoses are becoming increasingly unresponsive to topical conventional antifungals now a days. Sertaconazole is a new, broad spectrum, fungicidal and fungistatic imidazole with added antipruritic and anti-inflammatory activity that may be beneficial in efficacy and improving the quality of life for patients with dermatophytoses.

Objective To assess the efficacy and safety of topical sertaconazole cream in the treatment of localized tinea corporis and tinea cruris.

Methods A prospective, clinical trial was conducted with 81 cases of dermatophytosis patients attending outpatient department (OPD) of Dermatology and Venereology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh. Patients were advised to apply sertaconazole cream 2 times per day for 4 weeks and patients were followed up for clinical improvement and side-effects of drug therapy.

Results The improvement of clinical score was from baseline to 41.6% at week 1; 89.3% at week 2 and 91.5% at week 4. On the basis of global response, level of improvement was clear in 55 (67.9%) patients, good in 25 (30.9%) patients and fair in 55 (67.9%) patients. Based on clinical efficacy, cure was observed in 55 (67.9%) patients, improvement in 25 (30.9%) patients and failure in 1 (1.2%) patients. About 78(96.3%) patients didn't suffer from any side effects from application of sertaconazole cream.

Conclusion On the basis of the results, it can be concluded that sertaconazole can be considered effective and a safe drug for the treatment of dermatophytosis.

Key words

Sertaconazole, antifungal, dermatophytosis.

Introduction

Dermatophytoses are superficial fungal infection of keratinized tissue, caused by keratinophilic fungi called dermatophytes. 'Dermatophytes' which include three genera, namely, *Epidermophyton*, *Microsporum*, and *Trichophyton*.^{1,2} Dermatophytoses is commonly

called as tinea. The two varieties of tinea most commonly encountered are tinea corporis (affecting trunk and limbs) and tinea cruris (affecting the inguinal region).^{3,4} Tinea corporis presents as radially advancing, flat, scaly, pruritic macules with a raised border and a characteristic central clearing which earns the sobriquet 'ringworm' for these lesions. Tinea cruris begins in the inguinal folds and presents usually as bilateral, scaly, dull red, pruritic plaques whose leading edge advances in a sharply demarcated, raised, scaly border.⁵ Many topical antifungals of different groups are

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available for the treatment of dermatophytoses such as azole derivatives, allylamines, benzylamines, morpholine, etc.^{1,6} Topical antifungal drugs are usually sufficient and effective in localized infections. The traditional azoles, such as clotrimazole, miconazole, and ketoconazole, which belongs to the imidazole class of antifungals, are fungistatic and most commonly used.^{7,8} Newer topical antifungals may be more effective in these patients.⁹

Sertaconazole, one of the newer azoles, is structurally unique due to a benzothiofene ring. It is the only azole with a fungicidal action due to its ability to cause direct fungal cell membrane damage.⁴ Sertaconazole shows good in vitro fungistatic activity against a broad range of dermatophytes of the Trichophyton, Epidermophyton and Microsporum genera, and yeasts of the genera Candida and opportunistic fungi.¹⁰ Like other azoles, sertaconazole inhibits the synthesis of ergosterol, an essential component of fungal cell walls resulting in disruption of mycelial growth and replication. However, at higher concentrations, sertaconazole binds directly to non-sterol lipids in the fungal cell wall, which leads to increased permeability and subsequent lysis of the mycelium. Thus, depending on concentration, sertaconazole may exhibit both fungistatic and fungicidal activities.⁸ Sertaconazole has additional anti-inflammatory and antipruritic actions.¹¹ It has shown efficacy even against dermatophyte isolates resistant to other azoles.¹² It's faster and superior cure rates as compared to other azoles are well documented.^{13,14}

The geometric minimum inhibitory concentration (MIC) of sertaconazole ranged from 0.06 to 1 microg/mL against a variety of dermatophyte isolates (n = 456), which included 114 isolates with reduced susceptibility to fluconazole (MICs \geq 16 microg/mL). Additionally, sertaconazole showed antibacterial

activity with a geometric MIC of 0.88 microg/mL against 21 isolates of Gram-positive bacteria. When applied topically in experimental models of inflammation, sertaconazole showed some evidence of anti-inflammatory action.¹⁰ In addition to this antifungal efficacy, it has a good safety profile, sustained cutaneous retention, and low systemic absorption, all of which make it ideal for topical applications.^{15,16}

Dermatophytosis is a major health burden worldwide and is now increasing day by day. There is paucity of clinical studies regarding the clinical efficacy and safety of newer antifungal like sertaconazole. To the best of my knowledge, till date no study on efficacy and safety of sertaconazole nitrate have been done in the treatment of tinea corporis and tinea cruris.

Patients and Methods

A prospective, clinical trial was conducted at the Department of Dermatology and Venereology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh from January 2019 to December 2019. About 81 cases of dermatophytosis (Tinea corporis and Tinea cruris) were included. Consecutive type of non-probability sampling technique was followed. Complete history, general physical and dermatological examinations were done for all enrolled patients. Data were collected by face to face interview and history and physical findings were recorded in a semi structured questionnaire. Baseline investigations like complete blood count (total count, differential count), platelet count, Hb%, ESR, urine analysis, random blood sugar (RBS), serum creatinine and liver function test (SGPT) were done. Identification of dermatophytes was done by KOH microscopical examination and culture was done on Sabouraud dextrose agar media and reports received 2 weeks after culture examination. All culture negative patients were

excluded from the study and culture positive patients were included in the study. Finally those patients, who agree freely to give their informed consent, were selected for the study.

Intervention

Patients were advised to apply sertaconazole cream 2 times per day for 4 weeks. Patients were followed up weekly for clinical improvement and side-effects of therapy upto 4 weeks of drug therapy. In each follow up, the patients were evaluated by all investigations and microscopic examination (10% potassium hydroxide) of a skin scraping from site of the lesion and culture. Assessment of clinical improvements by clinical efficacy score and global response evaluations were performed throughout the course of study. Adverse effects of the drugs among all patients were recorded. Statistical analysis of the results was obtained by using window based computer software devised with Statistical Packages for Social Sciences (SPSS-23).

Outcome measure:

Global evaluation responses of the clinical condition compared to baseline were assessed in accordance to the following criteria:

- Clear: 100% remission of clinical signs and symptoms from baseline;
- Excellent: 90-99% improvement of clinical signs and symptoms from baseline;
- Good: 50-89% improvement of clinical signs and symptoms from baseline;
- Fair: 25-49% improvement of clinical signs and symptoms from baseline;
- Poor: 24% improvement of clinical signs and symptoms unchanged from baseline;
- Worse: Clinical signs and symptoms deteriorated from baseline.

Clinical efficacy was categorized as:

- Cure (disappearance of all baseline signs and symptoms of infection; negative 10.0% KOH reading in conjunction with a global response as cleared or excellent);
- Improvement (improvement in or partial disappearance);
- Failure (no change or worsening); or
- Relapse (improvement or cure followed by reappearance or worsening).

Ethical consideration

Prior to the commencement of this study, approval from Institutional Review Board (IRB) were taken. Before enrollment of the patients into the study, the aims and objectives of the study along with proper application of the therapy, possible therapeutic outcomes and adverse effect associated with the therapy, alternative methods, risks and benefits of this study were explained to the patients in easily understandable local language, so that they could make independent decision about their participation. Finally the informed written consent was taken from each patient.

Results

Table 1 showed the distribution of the patients on the basis of age group and sex. There were 29 (35.8%) patients in the age group of 21-30 years, 22 (27.2%) patients in the age group of 31-41

Table 1 Distribution of the patients on the basis of age group and sex (n=81).

<i>Age in years</i>	<i>Number</i>	<i>Percentage</i>
18-20 years	14	17.3%
21-30 years	29	35.8%
31-40 years	22	27.2%
41-50 years	11	13.6%
51-60 years	5	6.2%
<i>Sex</i>	<i>Number</i>	<i>Percentage</i>
Female	46	56.8
Male	35	43.2

Table 2 Distribution of patients by side effects (n=3).

Side effects	Frequency	Percentage (%)
Pruritus	2	2.5
Burning	1	1.2

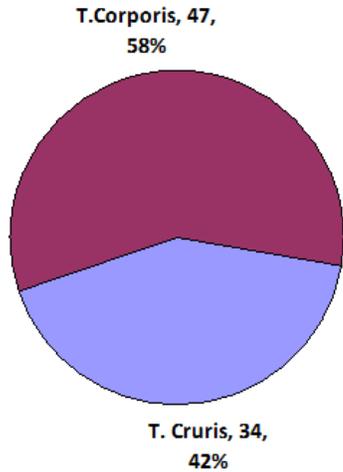


Figure 1 Distribution of the patients by of clinical types of dermatophytosis (n=81).

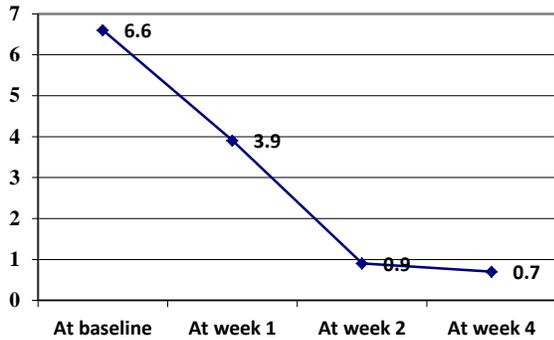


Figure 2 Clinical assessment score at different interval (n=81).

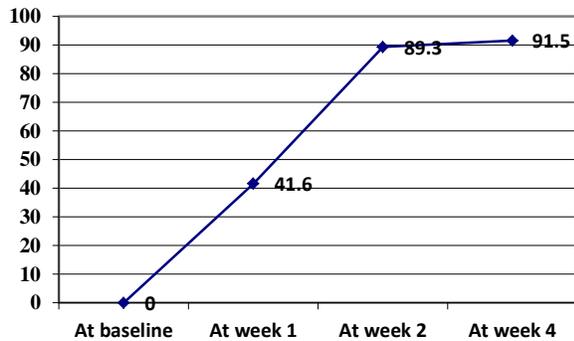


Figure 3 Improvement at different time interval (n=81).

years, 14 (17.3%) patients in the age group of 18-20 years, 11 (13.6%) patients in the age group of 41-50 years and 5 (6.2%) patients in the age group of 51-60 years. Regarding sex, female was 56.8% in the study group.

Figure 1 showed the distribution of the patients by clinical types of dermatophytosis. Among the 81 patients, tinea corporis in 47 (58.0%) patients and tinea cruris in 34 (42.0%) patients.

Figure 2 showed the clinical assessment score at different interval. The mean clinical assessment score declined from 6.6 ± 1.3 at baseline; to 3.9 ± 1.2 at week 1, 0.9 ± 1.3 at week 2; 0.7 ± 1.1 at week 4. Reduction of clinical assessment score from baseline to end of the treatment period was statistically significant ($p < 0.001$). Repeated measure anova was employed to analyze the data.

Figure 3 showed the improvement at different time interval. The improvement of clinical score was from baseline to 41.6% at week 1; 89.3% at week 2 and 91.5% at week 4. Improvement of clinical score from baseline to end of the treatment period was statistically significant ($p < 0.001$). Repeated measure anova was employed to analyze the data.

Distribution of patients by global response was shown in **Figure 4**. Global response was clear in 55 (67.9%) patients, good in 25 (30.9%) patients and fair in 55 (67.9%) patients.

Distribution of patients by clinical efficacy was shown in **Figure 5**. Clinical efficacy was cure in 55 (67.9%) patients, improvement in 25 (30.9%) patients and failure in 1 (1.2%) patients. About 78 (96.3%) patients didn't suffer from any side effects from application of sartaconazole cream. Only 3(3.7%) patients developed side effects. Pruritus occurred in 2 (2.5%) patients and

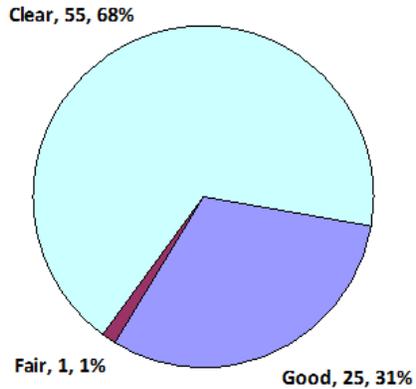


Figure 4 Distribution of patients by global response (n=81).

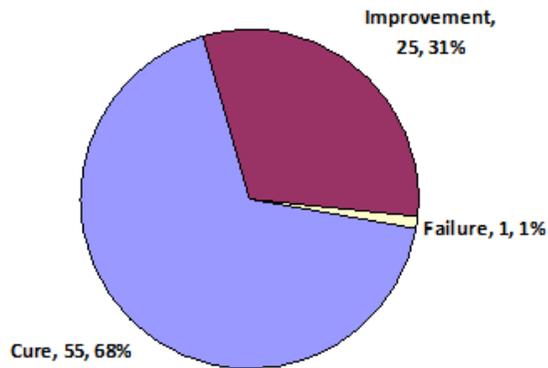


Figure 5 Distribution of patients by clinical efficacy (n=81).

burning in 1 (1.2%) patients after initial application of cream.

Discussion

Patients were applied sertaconazole and followed up for clinical improvement and side-effects of drug therapy. Our study findings were similar to other findings, described here. Jerajani *et al.* conducted a study with 83 patients with tinea corporis and tinea cruris infections to compare efficacy and safety of sertaconazole, terbinafine and luliconazole in patients with dermatophytoses. 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%). They concluded that sertaconazole was better than terbinafine and luliconazole in relieving signs and symptoms during study and follow up period.⁴

Das *et al.* conducted a study to evaluate and compare the efficacy and safety of amorolfine 0.25% cream and sertaconazole 2% cream in limited tinea cruris/ corporis. 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 ($P = 0.117$).⁹

Thaker *et al.* conducted a study to compare the efficacy, safety and cost effectiveness of topical 2% sertaconazole cream and 1% butenafine in tinea infections of skin. Patients were advised to apply the drug topically twice a day for one month on the lesions. Clinical score and Global Evaluation Response were assessed at baseline and during each follow up. About 90% and 98% of the patients got complete clearance of the lesions with sertaconazole and butenafine respectively. Treatment with butenafine was more cost effective as compared to sertaconazole.¹⁰

Choudhary *et al.* conducted a randomized control trial with treatment with terbinafine cream and sertaconazole cream respectively. Comparison showed that at the end of 3 weeks both terbinafine and sertaconazole groups had

100% complete cure. When the two groups were compared for complete cure, at the end of 1st and 2nd week, statistically non-significant results were observed ($P = 0.461$ and $P = 0.679$ respectively). However, at the end of 2nd week, complete cure rate for terbinafine was 80% as compared to 73.35% for sertaconazole with no statistical significance. The newer fungistatic drug sertaconazole nitrate 2% cream was as effective as terbinafine hydrochloride 1% cream which is one of the fungicidal drugs. Both the drugs showed good tolerability with no adverse effects.¹⁶

Chatterjee *et al.* conducted a study with 88 patients on sertaconazole and 91 on terbinafine. At 2 weeks, the clinical cure rates were comparable at 77.27% for sertaconazole and 73.63% for terbinafine ($P = 0.606$). Fourteen patients in either group improved and on further treatment showed complete healing by another 2 weeks. The final cure rate at 4 weeks was also comparable at 93.18% and 89.01% respectively ($P = 0.914$). Tolerability of both preparations was excellent. The results suggest that once-daily topical sertaconazole is effective in localized tinea infections.¹⁷

Romaguera *et al.* was conducted a randomized double-blind clinical trial in 78 volunteers of both sexes. Sertaconazole in 2% dermatological cream form was compared with 5 other commercially available antimycotics (econazole, ketoconazole, bifonazole, clotrimazole and miconazole), using the excipient of the cream without sertaconazole and 2% sertaconazole in vaseline as controls. At the end of the trial, only miconazole showed a positive allergy (vesiculation) in two of the 78 individuals studied. This trial showed that sertaconazole in 2% dermatological cream form does not possess a sensitizing capacity for causing contact dermatitis which confirmed its excellent safety in topical use.¹⁸

Alomar *et al.* carried out a double-blind, controlled multicentre trial with 631 patients suffering from superficial cutaneous mycosis (sertaconazole $n = 317$, miconazole $n = 314$). The rate of clinical cure for both treatments at the end of the follow-up was 95.6% for sertaconazole and 88.1% for miconazole, with the difference being statistically significant. At the end of the follow-up, 98.6% of the patients in the sertaconazole group obtained a negative culture test result, as opposed to 91.7% in the miconazole group, with the difference being highly significant.¹⁹

Shivamurthy *et al.* conducted a study to compare the efficacy of topical antifungal agents, sertaconazole and clotrimazole in Tinea corporis patients. A total of 60 ($n=60$) patients were included in the study. There was significant reduction in erythema ($p<0.02$) and highly significant reduction in scaling ($p<0.001$), itching ($p<0.001$) and margins of lesion ($p<0.001$) among sertaconazole group. The mean difference and the standard deviation of total scores for Clotrimazole were 7.20 and 1.69 and for Sertaconazole group 8.80 and 1.52 respectively. From the present study, it can be concluded that topical Sertaconazole shows better improvement in the clinical parameters than topical Clotrimazole within a span of three weeks in the treatment of T corporis.²⁰

Borelli *et al.* carried out a randomized, controlled study to compare the efficacy of a solution containing 2% sertaconazole with the well-established 2% sertaconazole cream formulation in patients with tinea corporis, tinea pedis interdigitalis. Patients received either sertaconazole solution or cream twice daily for 28 days. Efficacy was documented in 90.6% of patients using the solution and 88.9% of those using the cream (full analysis set). They concluded that solution and cream formulations of 2% sertaconazole applied for 28 days were

associated with comparable efficacy and safety in the treatment of fungal skin infections.²¹

Weinberg *et al.* conducted a small (n=32) clinical trial designed to determine whether sertaconazole nitrate 2% cream, used once daily, is as effective as the traditional regimen. Results demonstrated that sertaconazole is as effective when used once daily for four weeks. Patients showed rapid improvement in pruritus as early as week 2, and at six weeks' follow up, all patients were free of erythema while 93.8 percent were free of pruritus; no relapses had occurred. These encouraging findings suggest that sertaconazole nitrate may be useful in a once-daily regimen.²²

Savin *et al.* conducted a study to determine the safety and efficacy of topical sertaconazole nitrate cream 2% in the treatment of tinea pedis. A total of 588 subjects were enrolled and 383 subjects were randomized to treatment with sertaconazole or vehicle applied twice daily for 4 weeks. Improvements in symptoms were noted at week 1 in the active treatment group. At week 6, 46.7% of sertaconazole-treated subjects had successful treatment outcomes compared with 14.9% of vehicle-treated subjects (P<.0001). They concluded that sertaconazole nitrate cream 2% was well-tolerated, offered rapid relief of symptoms.²³

Borelli conducted a study to evaluate the safety and efficacy of sertaconazole nitrate cream 2%, specifically in participants with tinea pedis interdigitalis (ie, fungal skin disease of the toe web) of dermatophyte origin. After 4 weeks of treatment, 88.8% (79/89) of evaluable participants achieved success on the primary end points. Most participants also demonstrated substantial improvement in signs and symptoms after 4 weeks of treatment: 63.7% (58/91) were free of erythema, 33.0% (30/91) were free of desquamation, and 91.2% (83/91) were free of

itch. The rate of reported AEs was low (8.7% [8/92]), and none were considered serious. These findings indicate that sertaconazole nitrate cream 2% is highly safe and effective in the treatment of tinea pedis interdigitalis.²⁴

In a study done by Sharma *et al.* on the efficacy and tolerability of sertaconazole nitrate 2% cream vs miconazole 1% cream in patients with cutaneous dermatophytosis, sertaconazole nitrate 2% cream was used twice daily for 2 weeks and they observed that 62.3% patients had a complete clinical cure. Sertaconazole was well tolerated without clinically significant side effects.¹³ Ezzo *et al.* in their study of sertaconazole in the treatment of paediatric patients with cutaneous dermatophyte infections used 2% sertaconazole once daily for a period of 2 weeks and observed that clinical cure was achieved in 75% and 100% patients after 2 and 4 weeks, respectively. No local adverse effects were observed in their study.²⁵

Conclusion

On the basis of the results presented, it can be concluded that sertaconazole is highly effective and well tolerated by patients in the treatment of dermatomycoses. Further controlled randomized trial involving multicentre and large sample size should be carried out to draw final conclusion.

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