

## Role of Sertaconazole in the Treatment of Dermatophytosis

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### Abstract:

*Dermatophytosis is a major health burden worldwide and is now increasing day by day. Dermatophytosis is also becoming increasingly unresponsive to topical conventional antifungals now a day. Newer topical antifungals may be more effective in these patients. Sertaconazole is a new, broad spectrum, fungicidal and fungistatic imidazole with added antipruritic and anti-inflammatory activity that may be effective and beneficial in improving the quality of life for the patient with dermatophytoses. It is indicated in the European Union(EU) for the treatment of superficial skin mycoses such as dermatophytosis (including tinea corporis, tinea cruris, tinea manus, tinea barbae and tinea pedis), cutaneous candidiasis, pityriasis versicolor and seborrhoeic dermatitis of the scalp, and in the US for tinea pedis only. Sertaconazole has broad-spectrum antifungal activity against dermatophytes of the Trichophyton, Epidermophyton and Microsporum genera, and yeasts of the genera Candida and Cryptococcus; additionally, it is effective against opportunistic filamentous fungi and Gram-positive bacteria. Moreover, the antifungal activity of sertaconazole is maintained in clinical isolates of dermatophytes that show reduced susceptibility to other azoles. While the drug has good dermal penetration, this is not associated with systemic absorption. In clinical trials in patients with superficial mycoses, 2% sertaconazole cream applied twice daily was effective in the eradication of a range of dermatophytoses, and a significantly greater proportion of patients were cured compared with those receiving 2% miconazole cream twice-daily treatment. Both as a topical cream and suppository preparation, sertaconazole was generally well tolerated. Sertaconazole is a well-established antifungal agent, which is now available in a variety of formulations, and remains a useful treatment option particularly in patients with fungal infections resistant to other azoles.*

**Key words:** Sertaconazole, antifungal, dermatophytosis.

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### Introduction:

Dermatophytoses are the superficial fungal infections of skin, hair, and nail, caused by keratinophilic fungi called dermatophytes. ‘Dermatophytes’ which include three genera, namely, Epidermophyton, Microsporum, and Trichophyton<sup>1,2</sup>. 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)<sup>3,4</sup>. Tinea corporis presents as 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<sup>5</sup>. Many topical

antifungals of different groups are available for the treatment of dermatophytoses such as azole derivatives, allylamines, benzylamines, morpholine, etc<sup>1,6</sup>. 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<sup>7-9</sup>. Sertaconazole, one of the newer azoles, is structurally unique due to a benzothioephene ring. It is the only azole with a fungicidal action due to its ability to cause direct fungal cell membrane damage<sup>4</sup>. Sertaconazole shows good in vitro fungistatic activity against a broad range of dermatophytes and yeasts of the genera Candida and opportunistic fungi<sup>10</sup>. 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<sup>8</sup>. Sertaconazole has additional anti-inflammatory and antipruritic actions<sup>11</sup>. It has shown efficacy even against dermatophyte isolates resistant to other azoles<sup>12</sup>. Its faster and superior cure rates as compared to other azoles are well documented<sup>13,14</sup>. 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 > or = 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<sup>10</sup>. 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<sup>15,16</sup>.

#### Discussion:

Jerajani et al conducted a study with 83 patients with tinea corporis and tinea cruris infections in a multicentre, randomized, open label parallel study to compare efficacy and safety of sertaconazole, terbinafine and luliconazole in patients with dermatophytoses. The initial 'Treatment Phase' involved 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. They concluded that sertaconazole was better than terbinafine and luliconazole in relieving signs and symptoms during study and follow up period. At the end of 'Treatment Phase' and 'Follow-up' Phase, all patients showed negative mycological assessment in all three treatment groups suggesting no recurrence of the disease<sup>4</sup>. 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. A single-center, randomized (1:1), double-blind, active-controlled trial 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. 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)<sup>9</sup>.

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 randomly allocated to two treatment groups. They were advised to apply the drug topically twice a day for one month on the lesions. They were followed up at an interval of 10 days. Clinical score and Global Evaluation Response were assessed at baseline and during each follow up. A total 125 patients were recruited, out of them 111 completed the whole study. Median Sign and Symptom Score of tinea on the baseline was 9 [5,9] that was reduced to 0 [0,4] by 2% sertaconazole while it was 9 [6,9] in the butenafine group on the baseline that was reduced to 0 [0,6] at the end of the treatment. 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<sup>10</sup>. Choudhary et al conducted a randomized control trial with treatment with terbinafine cream and sertaconazole cream respectively. A majority of their patients in both the group showed Trichophyton rubrum followed by Trichophyton mentagrophytes growth on culture. 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 1<sup>st</sup> and 2<sup>nd</sup> week, statistically non-significant results were observed (P = 0.461 and P = 0.679 respectively). However, at the end of 2<sup>nd</sup> week, complete cure rate for terbinafine was 80% as compared to 73.35% for sertaconazole with no statistical significance. In both Group A and Group B, clinically significant local side effects like erythema, swelling, stinging sensation, or increased itching were not noticed. 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<sup>16</sup>. Chatterjee et al conducted a randomized 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). At 2 weeks, 6 (6.82%) sertaconazole and 10 (10.99%) terbinafine recipients were considered as "clinical failure." Tolerability of both preparations was excellent. The

results suggest that once-daily topical sertaconazole is effective in localized tinea infections<sup>17</sup>. Carrillo-Muñoz et al conducted a clinical trial including patients with vulvovaginal candidiasis, a single dose of sertaconazole produced a higher cure rate compared with other topical azoles such as econazole and clotrimazole, in shorter periods. Sertaconazole had shown an anti-inflammatory effect that is very useful for the relief of unpleasant symptoms<sup>18</sup>. Romaguera et al was conducted a randomized double-blind clinical trial in 78 atopic 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. The other substances did not demonstrate any sensitizing capacity, including sertaconazole and its excipient. 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<sup>19</sup>. 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 cures 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. In the comparative analysis, it was observed that the patients treated with sertaconazole were cured earlier and in a higher proportion than those treated with miconazole, with the difference being significant. The negative result of the microscope examination and culture test confirmed the superiority of sertaconazole over miconazole, already after 14 days of treatment. 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<sup>20</sup>. 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. They were divided into two groups of 30 patients each. First group included patients treated with topical Sertaconazole as test drug whereas the second group constituted patients treated with topical Clotrimazole as standard drug. The patients were advised to apply the drug on affected area twice daily for three weeks. The parameters like erythema, scaling, itching, margins and size of the lesion and KOH mount were taken for the assessment of efficacy. The total score included all grades in erythema, itching, scaling, margins and size of lesion and KOH mount. 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. The p-value on application of students unpaired t- test was  $p < 0.001$  (Highly significant). 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<sup>21</sup>. 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. The full analysis set comprised 160 patients in the solution group and 153 patients in the cream group. The primary efficacy parameter was a combination of culture test result and total clinical score. Efficacy was defined by eradication of the pathogen and reduction of the total clinical score between pretreatment and the final visit. Efficacy was documented in 90.6% of patients using the solution and 88.9% of those using the cream (full analysis set). No adverse events occurred. 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<sup>22</sup>. 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<sup>23</sup>. Savin et al conducted a study to determine the safety and efficacy of topical sertaconazole nitrate cream 2% in the treatment of tinea pedis, 2 randomized, multicenter, double-blinded, parallel group, vehicle-controlled studies. 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 4, mycologic cure was seen in 70.3% of sertaconazole-treated subjects and 36.7% of vehicle-treated subjects ( $P < 0.0001$ ). At week 6, 46.7% of sertaconazole-treated subjects had successful treatment outcomes compared with 14.9% of vehicle-treated subjects ( $P < 0.0001$ ). No serious adverse events were reported, and rates of cutaneous adverse events were comparable between treatment groups. They concluded that sertaconazole nitrate cream 2% was well-tolerated, offered rapid relief of symptoms, and achieved high rates of mycologic cure. The stability of the mycologic cure rates through weeks 5 and 6 (2 weeks after cessation of therapy) indicate that sertaconazole protects against reinfection<sup>24</sup>.

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. A total of 92 participants were included in their analysis. The primary end points were eradication of the pathogen (confirmed by fungal culture results) and reduction in total clinical score (TCS) of at least 2 points. 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<sup>25</sup>.

Nasarre et al was studied in a randomized parallel double-blind clinical trial on 21 patients suffering from Pityriasis versicolor (confirmed by KOH microscopic examination and exploration with Wood's light). The patients were divided into two treatment groups: one with 11 patients receiving sertaconazole 1% cream and the other with 10 patients receiving sertaconazole 2% cream. The cream was applied twice a day during 4 weeks. The data were assessed clinically and microscopically (optical and fluorescence). All the patients were cured (100% cure), showing excellent efficacy. A check-up performed after the end of the treatment showed no relapses of infection. The drug safety was optimum, since no local or general undesirable effects were recorded, nor were there any changes in the analytical parameters studied in the 21 patients<sup>26</sup>.

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<sup>13</sup>. Esso 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<sup>27</sup>.

#### Conclusion:

On the basis of the review of literature, it can be concluded that sertaconazole is highly effective and well tolerated by patients in the treatment of dermatomycoses.

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