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Research Article

Efficacy and safety of 1% terbinafine hydrochloride versus 2% sertaconazole cream in the treatment of tinea corporis

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ABSTRACT

Background: Tinea corporis is a common superficial dermatophytosis seen in tropical countries. This study was done to compare the efficacy and safety of topical antifungal agents, terbinafine versus sertaconazole in the treatment of tinea corporis.
Methods: This study was conducted in Babuji Hospital and Chigateri Government Hospital, Davangere. A total of 60 (n=60) patients were included and divided into two groups of 30 patients each in the study. 1st group - received topical 1% terbinafine hydrochloride and 2nd group - received 2% sertaconazole cream. Patients were advised to apply cream twice daily for 4 weeks. Improvement in clinical parameters like erythema, scaling, itching, and potassium hydroxide (KOH) mount were taken for assessing the efficacy of drugs. They were followed-up at the end of 2, 4, and 6 weeks to assess the improvement of the condition. Complete cure rate was defined as mycological cure with a complete absence of clinical signs and symptoms. For safety data of both drugs presence of any local side effects (like stinging sensation, swelling and increased erythema) were analyzed in both groups. Statistical analysis was done using students paired t-test and unpaired t-test.
Results: When two groups were compared at the end of 2 weeks, complete cure rate for terbinafine was 80% as compared to 63.3% for sertaconazole ($p<0.003$). However, at the end of 4 weeks, sertaconazole was as effective as terbinafine and statistically non-significant ($p>0.05$) results were obtained. KOH mount was negative in both groups at the end of 2nd week. Local side effects like erythema, swelling, stinging sensation were not noticed during the study in both the groups.
Conclusion: From this study, it was shown that 2% sertaconazole cream was as effective as 1% terbinafine cream, though 1% terbinafine had higher rates of complete cure at the end of 2 weeks as compared to sertaconazole.

Keywords: Dermatophyte, Ringworm, Potassium hydroxide mount, Itching, Erythema

INTRODUCTION

Dermatophytoses are fungal infections caused by trichophyton, epidermophyton, and microsporum genera of fungi that have the unique ability to invade and multiply within keratinized tissue (skin, hair and nails).[1]

Superficial dermatophytosis of the skin poses a major public health problem especially in tropical countries like India due to hot and humid climate.[2] Tinea corporis is a dermatophyte infection of the skin of trunk and extremities excluding the hair, nails, palm, soles and groin.

Topical antifungals are the first line treatment for many patients with uncomplicated, localized lesions of tinea corporis.[1] Many topical antifungals of different groups are available for the treatment such as azole derivatives, allylamines, benzylamines, morpholine, etc. There has always been a search for better antifungals both topical and systemic.

Terbinafine hydrochloride belongs to allylamine group of drugs with a broad spectrum of antifungal activity. In one of the studies to evaluate the efficacy and safety of topical 1% terbinafine versus placebo in the treatment of tinea corporis/

cruris, terbinafine was effective than placebo for complete cure (clinical and mycological).[3]

Sertaconazole is a newer topical antifungal agent, which belongs to the imidazole class of antifungals. In a double-blind study comparing efficacy and safety of 2% sertaconazole versus placebo in tinea corporis, sertaconazole had shown a higher cure rate than placebo.[4]

Hence, the present study was done to compare the efficacy and safety of topical 1% terbinafine hydrochloride and 2% sertaconazole cream in the treatment of tinea corporis.

METHODS

This study was conducted in the department of Dermatology of Babuji and Chigateri Government Hospitals attached to JJM Medical College, Davangere during the period from June 2014 to November 2014.

A total of 60 patients were enrolled for the study. 30 patients in Group 1 (treatment with 1% terbinafine cream) and 30 patients in Group 2 (treatment with 2% sertaconazole cream). Informed consent was obtained from the patients and Institutional Ethical Committee Approval was taken prior to initiation of the study (Ref No.: JJMMC/IERB/55/2014-15).

Inclusion criteria

1. Patients in age group of 15-60 years of either sex having clinical manifestations of tinea corporis such as erythema, scaling, itching
2. Patients with skin scraping positive for potassium hydroxide (KOH) mount were included in the study.

Exclusion criteria

1.Patient with systemic mycosis or tinea manuum, tinea pedis, tinea capitis
2. Patients with a history of intolerance or hypersensitivity to imidazole and allylamine compounds
3. Patients who were immunocompromised (due to diseases e.g.: HIV or medication), pregnant and lactating women
4. Patients using topical antifungal agent, topical/systemic corticosteroids in treatment area within 30 days of baseline visit
5.Patients with a history of diabetes mellitus and other systemic illness.

Patients were advised to apply cream twice daily on affected sites for 4 weeks. They were followed-up at 2 weeks, 4 weeks to look for efficacy and adverse effects of drugs and also at the end of 6 weeks to look for any relapse of skin lesion. To ensure regular follow-up of patients, they were provided with topical cream every 2 weeks.

Demographic data

All the patients had similar demographic features with respect to age and sex.

Assessment of efficacy and safety

Efficacy parameters were clinical effectiveness and mycological assessment.

Clinical effectiveness

Improvement in clinical signs and symptoms (itching, erythema, and scaling) assessed on a predetermined four-point score as absent (0), mild (1), moderate (2), and severe (3) by the investigator with the assistance of dermatologist.

Mycological assessment KOH mount

Mycological cure was defined as negative KOH mount.

Complete cure was defined as mycological cure with a complete absence of clinical signs and symptoms.

Safety data

Local side effects like increased erythema, swelling, stinging sensation were compared among both the groups.

Statistical analysis

Data collected from both the groups were analyzed using paired and unpaired t-test. Paired t-test was used for comparing the within group differences in signs and symptoms at the end of 2 and 4 weeks and unpaired t-test for comparing complete cure rate between both the groups at the end of 2 and 4 weeks.

RESULTS

Comparison of mean age between the groups did not show any significant difference (t=0.76, non-significant). Both the groups were comparable with respect to their baseline demographic profile (Table 1).

With 1% terbinafine and 2% sertaconazole cream, there was clinical improvement in all the efficacy parameters at the end of 2 weeks, with further improvement continuing till 4 weeks. Mean difference in the scores obtained in signs and symptoms (itching, erythema, scaling) in both 1% terbinafine and 2% sertaconazole cream group at the end of 2 and 4 weeks was shown in Tables 2 and 3, respectively.

KOH mount in both the groups (1% terbinafine and 2% sertaconazole cream) was negative at the end of 2 weeks of

Table 1: Baseline demographic characteristics in both groups.

Variables	Terbinafine n=30	Sertaconazole n=30	Statistical analysis
Age (mean and SD) years	30.93±8.82	32.73±9.55	p=0.76, NS
Age categories			
30 years and below	15	14	p=0.54, NS
More than 30 years	15	16	
Sex			
Male	22	20	p=2.13, NS
Female	8	10	
Duration of illness (mean and SD) days	9.93±2.39	9.60±1.69	p>0.05, NS

NS: Not significant, SD: Standard deviation

Table 2: Comparison of mean difference in the scores obtained for signs and symptoms at the end of 2 and 4 weeks of treatment in terbinafine group (n=30).

Signs and symptoms	Baseline and 2 weeks of treatment	Baseline and 4 weeks of treatment	2 weeks and 4 weeks of treatment
Itching	t=6.59, p<0.001	t=11.0, p<0.001	t=3.8, p<0.001
Erythema	t=2.5, p<0.01	t=2.1, p<0.04	t=10, NS
Scaling	t=6.1, p<0.001	t=10.8, p<0.001	t=3.8, p<0.001

t: Paired t-test

Table 3: Comparison of mean difference in the scores obtained for signs and symptoms at the end of 2 and 4 weeks of treatment in sertaconazole group (n=30).

Signs and symptoms	Baseline and 2 weeks of treatment	Baseline and 4 weeks of treatment	2 weeks and 4 weeks of treatment
Itching	t=9.8, p<0.001	t=15.3, p<0.001	t=3.7, p<0.001
Erythema	t=1.36, NS	t=1.97, p<0.05	t=1.5, NS
Scaling	t=10.9, p<0.001	t=15.7, p<0.001	t=3.27, p<0.003

t: Paired t-test, NS: Not significant

treatment. Improvement in signs in both the groups at the end of 2 and 4 weeks of treatment was shown in Figures 1 and 2.

When both the groups were compared for complete cure at the end of 2 weeks; terbinafine cream showed higher rates of cure (80%) than sertaconazole (63.3%) which was statistically significant (p<0.003). However, at the end of 4 weeks, sertaconazole cream was as effective as terbinafine which was statistically non-significant (p>0.05) shown in Table 4. No relapse of skin lesion was noted in both the groups at the end of 6th week.

Local side effects like local erythema, swelling, increased itching, and stinging sensation were not noticed during study in both the groups.

DISCUSSION

In our study, terbinafine and sertaconazole cream was applied twice daily for 4 weeks; 1% terbinafine had higher rates of complete cure at the end of 2 weeks as compared to sertaconazole; though 2% sertaconazole cream was as effective as terbinafine cream at the end of 4 weeks.

In another study, once-daily course of 1% terbinafine cream for 1-week was significantly more effective than placebo in achieving and maintaining mycological cure (84.2 vs. 23.3%, p<0.001). Terbinafine cream was also significantly more effective than placebo in terms of clinical response, reduction in signs and symptoms scores, and overall efficacy.[5]

Choudhary et al. compared efficacy and safety of twice daily application of 1% terbinafine hydrochloride and sertaconazole 2% cream, terbinafine had higher rates of cure (80%) at the end of 2 weeks as compared to sertaconazole cream (62.3%).[6] Similar to the above study in our study also 1% terbinafine cream showed higher rates of complete cure (80%) at the end of 2 weeks as compared to sertaconazole (63.3%).

Lakshmi and Bengalorkor in their study compared topical terbinafine and topical luliconazole in the treatment of tinea corporis and tinea cruris and found that once-daily application for 2 weeks was equally effective.[7] Croxtall and Plosker had reported that in patients with superficial mycosis, 2% sertaconazole cream applied twice daily was effective in eradicating a range of dermatophytosis, and a significantly greater proportions of patients were cured compared with those receiving 2% miconazole cream twice daily treatment.[8]

In a study done by Sharma et al. on the efficacy and tolerability of sertaconazole nitrate 2% cream versus miconazole 1% cream

Table 4: Comparison of complete cure between terbinafine and sertaconazole group at the end of 2 and 4 weeks of treatment.

Terbinafine and sertaconazole group	Unpaired t-test	
Baseline and 2 weeks of treatment	t=3.14	p<0.003, significant
Baseline and 4 weeks of treatment	t=1.46	p>0.05, not significant
2 weeks and 4 weeks of treatment	t=1.70	p>0.05, not significant

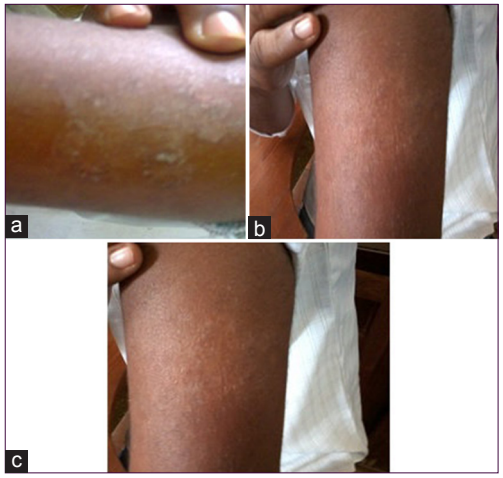

Figure 1: Improvement in signs at the end of 2 and 4 weeks in terbinafine group (a) Baseline, (b) 2nd week of treatment, (c) terbinafine – 4th week of treatment.

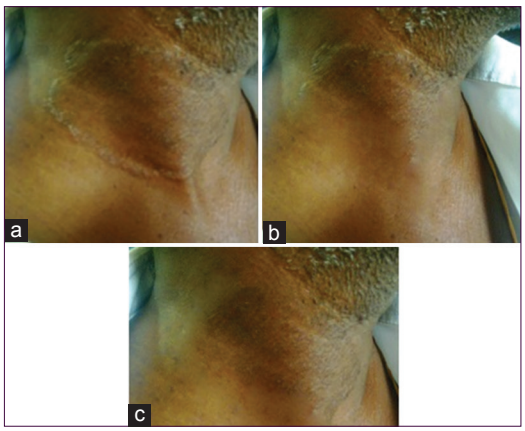

Figure 2: Improvement in signs at the end of 2 and 4 weeks in sertaconazole group (a) Baseline, (b) 2nd week of treatment, (c) sertaconazole - 4th week of treatment.

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.[9] Sertaconazole was well tolerated without clinically significant side effects. In our study, cure rate of 63.3% observed at the end of 2 weeks treatment with sertaconazole cream but we continued the treatment for another 2 weeks and observed cure rate of 96.7% at the end of 4 weeks.

Terbinafine hydrochloride is a fungicidal agent belonging to allylamine group of drugs with broad spectrum of antifungal activity. It interferes with fungal sterol biosynthesis at an early stage. It also inhibits squalene epoxidase enzyme, leading to intracellular accumulation of toxic squalene responsible for fungal cell death.[10]

Sertaconazole is a newer topical fungistatic agent which belongs to the imidazole class of antifungals. Sertaconazole inhibits the synthesis of ergosterol, an essential component of fungal cell wall resulting in disruption of mycelial growth and replication. It inhibits the release of proinflammatory cytokines from immune cells. Sertaconazole also has anti-inflammatory and antipruritic action.[11] This might give the overview why sertaconazole cream was as effective as terbinafine at the end of 4 weeks of treatment.

Limitations of our study being KOH mount was used for mycological assessment rather than a fungal culture which would have been better for mycological assessment. More number of patients should be studied in further studies to support our observation.

CONCLUSION

From this study it can be concluded that 2% sertaconazole cream was as effective as 1% terbinafine cream, though 1% terbinafine cream had shown higher rates of cure at the end of 2 weeks as compared to sertaconazole.

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