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Research Article

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Comparison of Safety, Efficacy, and Cost-Effectiveness of Miconazole 2% Versus Sertaconazole 2% in the Treatment of TineaCorporis: A Randomized Control Trial

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Abstract: Tineacorporis is a dermatophytic infection of the body, which involves the keratin layer of the skin. These lesions are present as an annular plaque with an advancing border along with central clearing. Miconazole, a topical antifungal drug and has good efficacy, in anti dermatophyte. Sertaconazole is a highly selective inhibitor of fungal cytochrome P-450 sterol C-14 α-demethylation via the inhibition of the enzyme cytochrome P450 14α-demethylase.It is claimed to be superior to other old topical imidazoles in tineacorporis. .The present study was aimed to compare the safety, efficacy and cost-effectiveness of topical antifungals, where we have compared Miconazole and Sertaconazole 2% creams in the treatment of fungal infection caused by tineacorporis, by assessing the ADR's and therapeutic outcomes, using comparative, unicentered, randomized, non-blinded trial with 2 parallel treatment arms of one-month duration. In this study 106 patients were randomly assigned into 2 groups of Miconazole 2% cream and Sertaconazole 2% with 54 and 52 patients in each group respectively. Measurement is carried out at baseline, 1st, 2nd and 3rd follow-up for desired effects like itching, erythema, pain and lesions, physician's global assessment (PGA), safety and cost-effectiveness. The results showed that sertaconazole 2% cream is efficacious and superior to Miconazole 2% cream in the improvement of clinical parameters and PGA. At the end of the follow-up phase, both groups of drugs are effective and well-tolerated in patients with no recurrence of tineacorporis. Effectiveness of SSertaconazole is early and superior with minor side effects. However, Miconazole is cost effective and safe.

Keywords: Tineacorporis, Miconazole, Sertaconazole, safety, efficacy, cost effectiveness.

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1. INTRODUCTION

Dermatophytoses is a common type of superficial fungal infection that affects as many as 20-25% of the world's population.[1] Dermatophytes are also called tinea /ringworm, majorly causes infections to skin, hair and nails**.** Tineacorporis is the most common fungal infection of the body, which involves keratin layer of the skin. The rate of topical fungal infections is progressively raised due to increase in the number of immunocompromised patients, and increased use of community swimming pools.[2] Recent occurance of dermatophytic infections is due to unhygienic conditions, swimming pools etc.,[3] The incidence of fungal infections is increasing due to widespread use of antimicrobials and immunosuppressants and due to immune-compromised states such as diabetes mellitus, HIV-AIDS etc. [3,4] Several species of fungi causes ringworm, most commonly include trichophyton, microspores and epidermophyton. There are various types of dermatophytes which include-Tineapedis- athlete foot, Tineaunguium-infection to nails, Tineacorporis-infection to arms and legs, Tineacapitis-infection to scalp and hair, Tineafaciei-infection to face, Jock itch(Tineacuris)-infection on inner thighs.[4] The oral drugs show poor compliance because of the length of treatment, side effects and cost. The burden of dermatophytoses is very high in tropical countries like India,mainly due to hot and humid climate conditions.[6]Childrens are at more risk for ringworms due to their unhygienic conditions. The people who own pets are at high risk of getting ringworm.[7]In our country, TineaCorporis(36-59%) is the most common type of dermatophytoses. Dermatophytoses doesn't cause any significant mortality in infected people.[8] But, the infection may interfere with daily routine activities, decreases quality of life, and increases healthcare expenditure. Treatment strategies to deal with dermatophytoses involve the use of a systemic or topical antifungal agent. Dermatophytoses are well managed by using topical or systemic antifungal agents. Topical antifungal agents are predominant option for management of dermatophytoses, because of less adverse effect profile, less cost, good adherence, and less drug-drug interactions.[9] Topical Miconazole is widely used in the management of various types of skin infections caused by *dermatophytes*, yeasts, and *Malassezia furfur*.[11]Sertaconazole nitrate is a new antifungal azole agent that fights against yeasts,*dermatophytes*and Gram-positive bacteria as well. These recently developed antifungal agentsare characterized by broad spectrum action against yeasts, dermatophytes and Gram-positive bacteria as well.[12,13] It has both fungistatic and fungicidal activity against dermatophytes.[14-16] It also has additional anti-inflammatory and antipruritic actions that help to provide better symptomatic relief.[17,18] These additional properties of Sertaconazole are likely to make an impact on the concomitant symptom control and therefore improve the quality of life of these patients with dermatophytoses.[19,20] Evidence shows that, there were no controlled trials to examine the safety, efficacy, and cost-effectiveness of Miconazole 2% cream versus Sertaconazole 2% cream in TineaCorporis infection.[21] The study was undertaken to compare the safety and efficacy of these two topical antifungal agents in the management of patients suffering from TineaCorporis.

2. MATERIALS AND METHODS

2.1. Study site

The study was conducted in an outpatient dermatology unit of a tertiary care hospital located in Anantapur District, Andhra Pradesh, India.

2.2. Study design

This was a prospective, randomized, open labeled comparative study.

2.3. Study criteria

2.3.1. Inclusion criteria

Patients aged between 18-65 years, irrespective gender and having clinical manifestations from mild to moderate *Tineacorporis* infection and positive with potassium hydroxide mount.

2.3.2. Exclusion criteria

Patients suffering from systemic mycotic infection or mycosis of groin, hand, nails, face, feet, and scalp were excluded from our study. Patients with antifungal or immunosuppressive therapy for last one month and pregnant women, nursing mothers are all exempted from this study. Pregnant women and nursing mothers are also not considered for inclusion in our study.

2.4. Study duration

The study was conducted for a period of six months from April 2019 to September 2019.

2.5. Ethical considerations

The study was conducted after approval from the Institutional Review Board (RIPER/IRB/2016/022). Patients who met the study criteria were asked to give oral and written consent. Confidentiality of the subject identifiers were maintained during and after completion of the study.

2.6. Sample size

A total of 115 subjects were recruited and randomized into 2 groups, Miconazole group (n=58) and Sertaconazole group (n=57) by random number generators.

2.7. Study procedure

A data collection form is used to obtain the socio-demographic and clinical profile of the study participants in Miconazole and Sertaconazole groups. Patients were advised to apply Miconazole nitrate 2% cream in one group and Sertaconazole 2% cream in another group. The study was divided into 4 phases; Baseline, first follow-up (after 10 days of enrollment), second follow-up (after 10 days of first follow-up), and third follow-up (after 10 days of second follow-up).

2.7.1. Outcome measures

Primary outcome measures like erythema, itching, pain, and lesion were measured at baseline and consecutive follow-up visits. All these features were graded as; absent (0), mild (1), moderate (2), and severe (3). Secondary outcome measure is the Physician global assessment (PGA) scale. It consists of scoring from 0 to 4, where 0 = Clear (No signs and

symptoms), 1 = Almost clear (only minimal plaque elevation, scaling, and erythema will present), 2 = Mild (slight plaque elevation, scaling, erythema), 3 = Moderate (moderate plaque elevation, scaling, and erythema), and 4 = Severe (very marked plaque elevation, scaling, and erythema). The physician gives the scoring based on the symptoms present in the patient. Mean PGA score and a mean difference of PGA score were compared at each follow-up visit. The safety of each drug was measured by monitoring the possible adverse events.[8]

2.7.2. *Cost effectiveness analysis (CEA)*

CEA was performed by considering direct medication costs incurred by the patient for a complete course of therapy and reduction in PGA score as an effectiveness parameter. The mean cost-effectiveness ratio was calculated by dividing the mean cost of treatment with mean reduction of effectiveness (PGA score) from baseline to final follow-up.

3. STATISTICAL ANALYSIS

Socio-demographic characteristics of the study participants were represented in descriptive statistics like frequency, mean, proportion and standard deviation. Friedman test with Dunn's multiple comparison posthoctest for the comparison of mean scores of all three follow-ups in both groups. Mann-Whitney Rank Sum test for comparison of mean scores of baseline, 1st, 2nd and 3rd follow-ups for both groups. p-value<0.05 was considered as a statistically significant result. Epi-Info statistical software given by the Center for Disease Control (CDC) was used for data analysis.

4. RESULTS

Table 1: Baseline Demographic and Clinical profile of patients

Variable	Miconazole group (Group A)	Sertaconazole group (Group B)	P value
Number of patients recruited	58	57	-
Number of patients completed trial	54	52	-
Age in years (Mean ± SD)	32.31±15.96	33.35±13.09	0.157
Gender, frequency (%)			
Male	31 (57.40)	30 (57.69)	0.976
Female	23 (42.59)	22 (42.30)	
Clinical profile (0-3), Mean ± SD			
Erythema	2.20 ± 0.89	2.13 ± 0.87	0.872
Itching	2.29 ± 0.71	2.34 ± 0.76	0.624
Pain	2.35 ± 0.83	2.36 ± 0.68	0.155
Lesion	1.48 ± 0.86	1.50 ± 0.88	0.867

Values are expressed as mean ± SD, SD: Standard Deviation, % : Percentage

According to table 1, A total of 115 subjects were recruited and randomized into two groups, Miconazole group (n=58) and Sertaconazole group (n=57) by using a random number generator. In Miconazole group, four patients and in Sertaconazole group, five patients fail to attend follow-up visits. The mean age of the study participants was 32.31±15.96 and 33.35±13.09 in group A and group B, respectively. Variables like age, gender, and clinical characteristics (erythema, itching, pain, and lesion) were equally distributed between the two groups.

Table 2: Comparison of mean scores

Parameters	Baseline	1st Follow-up	2nd Follow-up	3rd Follow-up
Miconazole (n=58)				
Erythema	2.20±0.89	1.70±1.41**	0.96±1.26***	0.12±1.18***
Itching	2.29±0.71	1.48±1.26**	0.72±1.21***	0.09±1.18***
Pain	2.35±0.83	1.51±1.21**	0.77±1.23***	0.05±1.17***
Lesion	1.48±0.86	1.01±0.91	0.61±1.04***	0.01±1.16***
Sertaconazole (n=57)				
Erythema	2.13±0.87	1.36±1.30**	0.28±1.15***	0.07±1.12***
Itching	2.34±0.76	1.46±1.16**	0.51±1.13***	0.09±1.15***
Pain	2.36±0.68	1.28±1.06***	0.67±1.11***	0.05±1.17***
Lesion	1.50±0.88	0.86±0.99**	0.65±1.09***	0.01±1.18***

Values are expressed as mean ± SD, Friedman test with Dunn's multiple comparison post-hoc test, ***P value <0.001, ** P value <0.01, *P value <0.05. SD: Standard Deviation.

Table 2 shows comparison of efficacy of Miconazole 2% cream and Sertaconazole 2% cream on erythema, itching, pain and lesions at 1st follow-up, 2nd follow-up and 3rd follow-up visit, which comprises a gap of 10 days for each visit. At first follow-up in Miconazole group, mean score of erythema, itching, and pain were significantly reduced with a *P* value of less than 0.01 and non-significant reduction in mean score of lesions. But in Sertaconazole group reduction in mean score of erythema, itching and lesions were statistically significant (*p* value <0.01) in 1st follow-up compared to baseline. Whereas, the mean score reduction of pain was highly significant (*p* value <0.001). In 2nd and 3rd follow-up, the reduction in mean score of erythema, itching, pain and lesions in both groups were highly significant compared to baseline. All subjects (both groups) were achieved complete cure at 3rd follow-up.

Table 3: Comparison of mean difference

Clinical feature	Miconazole group (Group A)	Sertaconazole group (Group B)	p – value
Baseline to 1st follow-up			
Erythema	0.50±0.50	0.76±0.55	0.033
Itching	0.81±0.56	0.88±0.62	0.624
Pain	0.83±0.50	1.07±0.62	0.092
Lesion	0.46±0.70	0.63±0.48	0.101
Baseline to 2nd follow-up			
Erythema	1.24±0.66	1.48±0.70	0.091
Itching	1.57±0.82	1.67±0.71	0.741
Pain	1.55±0.69	1.82±0.70	0.071
Lesion	0.87±0.70	1.21±0.70	0.034
Baseline to 3rd follow-up			
Erythema	2.07±0.84	2.05±0.88	0.960
Itching	2.20±0.76	2.25±0.78	0.696
Pain	2.77±0.81	2.26±1.41	0.865
Lesion	1.48±1.08	1.48±0.88	0.968

P-value < 0.05.

Table 3 shows that there was a significant improvement in the Sertaconazole group from baseline to 1st follow-up and 2nd follow-up in erythema, and lesions compared to Miconazole group. At final follow-up all features (erythema, itching, pain, and lesions) are equal in both Miconazole and Sertaconazole groups.

Table 4: Comparison of mean cost effectiveness ratio of Miconazole 2% and Sertaconazole 2% at the end of treatment phase.

Drugs	Cost per tube	Mean cost from baseline to final follow-up	Mean difference in PGA from baseline to final follow-up	Mean cost effectiveness ratio
Miconazole (Drug A)	30 INR/20 g of tube	93.2±28.3 INR	1.35±0.23	72.8±48.7
Sertaconazole (Drug B)	85 INR/20 g of tube	198.4±52.3 INR	1.52±0.45	130.7±84.6

PGA: Physician Global Assessment Scale

According to table 4, Sertaconazole mean cost effectiveness ratio is high compared to Miconazole in the management of TineaCorporis infection. The mean difference of PGA from baseline to final follow-up visit in Miconazole group and Sertaconazole group are nearly equal as represented.

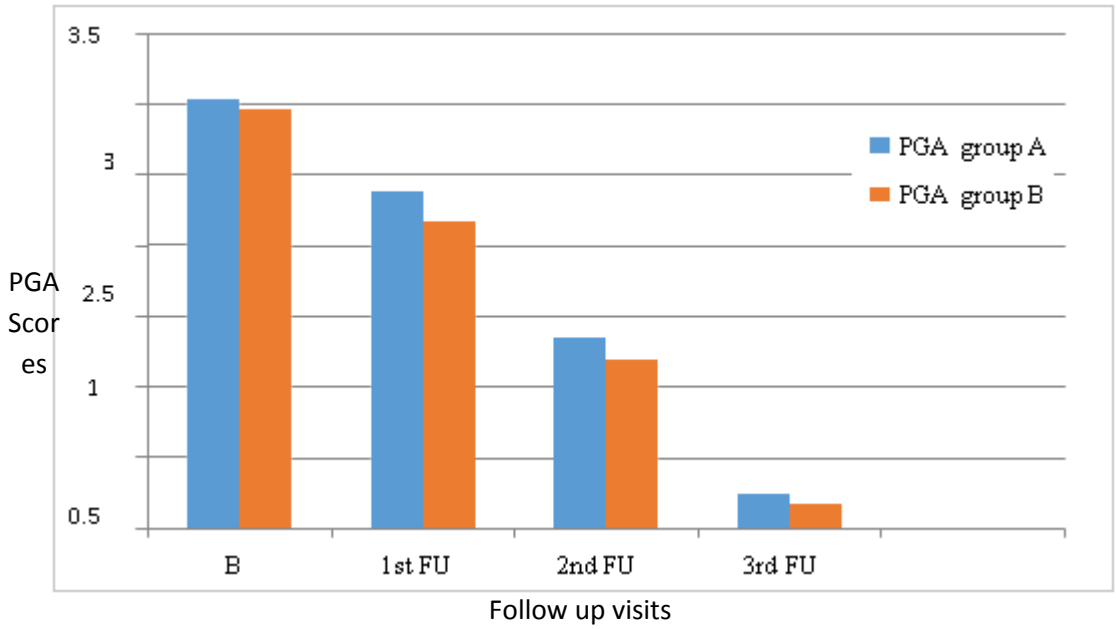

Fig 1: PGA comparison baseline versus follow-up

Fig 1: Shows the comparison of PGA of patients suffering from tineacorporis at baseline to first, second and third follow-up. In these figures it was observed that Sertaconazole 2% cream has slightly higher response than Miconazole 2% cream.

5. DISCUSSION

Dermatophytes are a common fungal infection occurring in tropical countries; it is also known as Ringworm or TineaCorporis. Generally, there is a prescribing trend with the combination of other class of drugs like antifungal, antimicrobials and corticosteroids for general and normal skin infections without diagnosing the actual condition, so it leads to the occurrence of various side effects, excessive cost, and majorly resistance towards that particular drugs. [22] Due to multiple studies, treatment of TineaCorporis became controversial. The study includes one hundred and fifteen (115) patients (both males and females were included). The baseline demographic data and clinical conditions of the patients were similar. It proves the homogeneity of the samples in both the groups. Majority of the people were in the age group of 30-45 years, but we collected data also from six-year-old children. Among all the participants, the percentage of male patients with ring or TineaCorporis was more than the other gender (female), i.e. about 67%, which includes both the groups. It may be due to excess exposure to sun and heat., Schools, colleges, and mainly sports which promote excess sweat, warm and slightly moist skin leads to growth of fungus on various parts of the body[23]. The effect of both Miconazole and Sertaconazole creams were applied two times a day for 30 days (4 weeks/ 1 month) was compared in participants or patients affected from dermatophytes The first 10 days were initial or treatment phase or first follow up and next 10 days were 2nd follow-up and then next 10 days were 3rd follow up, here recurrence and relapse of ringworm were noted. According to the study based on 115 patients, both the drugs (Miconazole-58 & Sertaconazole-57) result in decreased clinical symptoms like itching, erythema, pain and lesions. However, response to therapy was early and higher onset with Sertaconazole when compared to Miconazole. Similarly, most of the patients who were treated with Sertaconazole cream had improved clinical symptoms of itching, erythema, pain and lesions as compared to Miconazole cream[24]. The probable superiority of SSertaconazole 2% cream over Miconazole 2% cream may be attributed to its Fungistatic activity resulting from the interference with ergosterol synthesis, an essential component of the fungal cell membrane, inhibition of its synthesis can result 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.[25]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 physicochemical effect on the fungal cell membrane. It binds directly to non-sterol lipids on the fungal membrane and interferes with ligands from the intracellular contents, thereby causing cell death. It is an effective fungicidal and fungistatic agent. Inaddition, 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. [16,19,26]PGA showed that complete clinical cure rate was observed with both the trial drugs at the end of "follow-up phase." A study by Sharma et al., has shown that Sertaconazole produced 62.3% clearance at the end of the treatment. [9] With the other study by Alomar et al., 95.6% clinical cure rate was seen at the end of treatment with Sertaconazole.[27] However, there is a definite superiority of Sertaconazole cream over Miconazole cream which may be attributed to its wide range of mechanism of action, Physical global assessment scale showed that the complete clinical cure rate was slightly higher with Sertaconazole compared to Miconazole. However, Sertaconazole has more efficacy and safety compared to Miconazole, but in the case of cost-effectiveness Miconazole is cheaper.

6. CONCLUSION

Response to Sertaconazole cream was safe, effective and also well tolerated when compared to Miconazole cream in the treatment of fungal infection caused by TineaCorporis or ringworm or dermatophytes. Therapy with Sertaconazole cream was early in the onset, it requires a lesser duration of treatment with minor side- effects. So Sertaconazole cream must be recommended as a first line choice of drug for fungal infections, particularly it is highly recommended for infection caused by TineaCorporis followed by Miconazole cream. However, Miconazole cream was cost-effective when compared to Sertaconazole cream.

7. AUTHORS CONTRIBUTION STATEMENT

NarayanaGorontla derived the concept and guided this study, Somasekhar Reddy revised the manuscript. Rajkamal, Kartheek Reddy, carried out the research study. ThireeshaThanveer evaluated the results. NeelimaGanzi drafted the manuscript, contributed to the design and implementation of the research to the analysis of the results and to the writing of the manuscript.

8. CONFLICTS OF INTEREST

Conflict of interest declared none.

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