

A comparative study of efficacy and safety of luliconazole cream (1%) and sertaconazole nitrate cream (2%) in the treatment of patients with Tinea corporis and cruris.

Dr. Chundi Sai Saketh Reddy¹, Dr. Shiva Kumar. V²,
Dr. Rachamadugu Keerthana³

¹(Post graduate, Department of Dermatology, Venereology and Leprosy, PES Institute of Medical Sciences and Research/ YSRUHS, INDIA)

²(HOD, Department of Dermatology, Venereology and Leprosy, PES Institute of Medical Sciences and Research/ YSRUHS, INDIA)

³(Post graduate, Department of Dermatology, Venereology and Leprosy, PES Institute of Medical Sciences and Research/ YSRUHS, INDIA)

ABSTRACT:

BACKGROUND: Dermatophytosis is a superficial fungal infection occurring in almost 25% of world population. It is usually seen in countries with relatively more humidity and temperature. Different terms are given based on areas affected like Tinea Corporis (body), Tinea Cruris (groin), Tinea Mannum (hand), Tinea Barbae (beard area), Tinea Pedis (foot), tinea capitis (scalp), Tinea Faciei (face), Tinea Unguium (nail).

MATERIALS AND METHODS: This was a randomized open, comparative and prospective study conducted from March 2022 to August 2022 in the department of dermatology, venereology and leprosy at PES Institute of Medical Science and Research, Kuppam. Overall, 80 patients with tinea cruris and corporis were included in the study and divided into 2 groups of 40 patients each. Patients were randomly allocated to group A and group B receiving topical luliconazole 1% cream and topical sertaconazole nitrate 2% cream respectively. The KOH mount and fungal culture were done at the beginning and end of study to assess clinical and mycological cure.

RESULTS: Treatment was of 4 weeks duration. On comparing 2 groups after 2 weeks of treatment, group A receiving luliconazole gave better clinical response compared to group B. Whereas the clinical cure rates were almost same after 4 weeks of treatment in both groups.

CONCLUSION: The present study indicates that topical luliconazole cream (1%) and topical sertaconazole cream (2%) are both potent antifungals in the treatment of tinea corporis and cruris. Topical Luliconazole appears to provide a quicker response compared to topical sertaconazole. Clinical and mycological cure rates were almost similar at the end of treatment phase (4 weeks). Both are equally efficacious and associated with minimal side effects.

KEY WORDS: Tinea cruris, Tinea corporis, Luliconazole, Sertaconazole

Date of Submission: 12-01-2023

Date of Acceptance: 28-01-2023

I. INTRODUCTION

Dermatophytoses is a term for a collection of closely related fungi known as dermatophytes that cause superficial fungal infections of keratinized tissues, specifically the epidermis, hair, and nails.¹

Tinea infections are widespread around the world, although they are more common in the tropics and may become epidemic-scale in regions with increased humidity, excessive population, and unhygienic living circumstances.²

Depending on the meteorological, socioeconomic, and population density factors, the distribution, frequency, and causative agents differ from place to place.³

Currently, there isn't much clinical research evaluating the clinical effectiveness and safety of the two topical antifungals, luliconazole and sertaconazole, in treating tinea corporis and cruris in the Indian population.

Therefore, this study compares the effectiveness and safety of topical luliconazole cream (1%) and topical sertaconazole nitrate cream (2%), both of which are used to treat individuals with tinea corporis and tinea cruris.

II. MATERIALS AND METHODS

This is a prospective comparative study that was conducted from March 2022 to August 2022 at the PES Institute of Medical Sciences And Research, Kuppam. A total of 80 subjects (both males and females) of age >18 years of age taken for this study.

Study design: randomized open comparative and prospective study

Study location: This study was done in the department of dermatology, venereology and leprosy, PESIMSR, Kuppam, Andhra Pradesh.

Study duration: March 2022 to August 2022

Sample size: 80 patients

Sample size calculation: 80 patients were divided randomly into 2 groups, group A and group B receiving luliconazole 1% cream and sertaconazole 2% cream respectively

Inclusion criteria:

1. Patients willing for study
2. Untreated patients with tinea cruris and corporis above 18 years of age.
3. Patients whose diagnosis is confirmed by KOH mount

Exclusion criteria:

1. Patients not willing for study
2. Patients with resolving dermatophytoses
3. Patients already on antifungal treatment
4. Pregnant women and lactating women.
5. Patients on immunosuppressive drugs or having an immunosuppressive disease.

Procedure methodology: 80 patients were randomly allocated to group A and group B with 40 patients each, with group A receiving topical luliconazole 1% cream and group B receiving topical sertaconazole 2% cream. The KOH mount is done at the start of treatment. Treatment was of 4 weeks duration for both groups. Clinical photographs were taken at the first visit , end of 2nd week and at the end of 4th week. Patients were advised to apply the topicals twice daily over affected sites. The patients were followed up every week for adverse effects like itching, erythema, burning, and stinging sensation for a total of 4 weeks. All patients in the study were screened for diabetes mellitus and HIV infection.

Statistical analysis: The data will be entered into MS EXCEL 2019 version and further analyzed using SPSS 21. The data is represented in the form of frequency and percentages using tables and charts.

III. RESULTS

In the study, the majority of patients belonged to the age group of 31-45 years (26 patients- 32.5%) followed by the age group 18-30 (24 patients - 30%), age group 45-60 years (21 patients - 26.25%) and minority being age group >60 years(9 patients - 11.25%). Out of 24 patients in the 18-30 years group, 11 were given luliconazole and 13 were given sertaconazole creams. Out of 26 patients in the 31-45 age group, 14 patients were given luliconazole treatment and 12 patients were given sertaconazole treatment. In the 46-60 age group, 10 patients were given luliconazole treatment and 11 patients were given sertaconazole treatment. In the >60 years age group, 5 patients were given luliconazole treatment and 4 patients were given sertaconazole treatment.

Out of 60 patients, 48 were females (60%) and 32 were males(40%). In 48 females luliconazole treatment was given to 22 patients and 26 patients were treated with sertaconazole cream. Out of 32 males, luliconazole treatment was given to 18 patients and sertaconazole treatment was given to 14 patients.

Solitary lesion of tinea was seen in 18(22.5%) patients in whom luliconazole was given to 10 patients and sertaconazole given to 8 patients. and multiple lesions of tinea were seen in 62 (77.5%) patients in whom 30 were given luliconazole treatment and 32 were given sertaconazole treatment.

On comparing both groups after 2 weeks of therapy, group A patients receiving luliconazole 1% cream showed better cure rates with clinical improvement (30 patients -75%) than group B receiving sertaconazole nitrate 2% cream who showed clinical improvement in 26 patients (65%). However, after 4 weeks of treatment, both groups showed almost equal cure rates with group A showing cure in 38 patients and group B showing clinical cure in 39 patients.

Table no 1:sex distribution vs treatment given

Gender	Luliconazole treated	Sertaconazole treated	Number of patients
Males	18	14	32(40%)
Females	22	26	48(60%)
	40	40	80

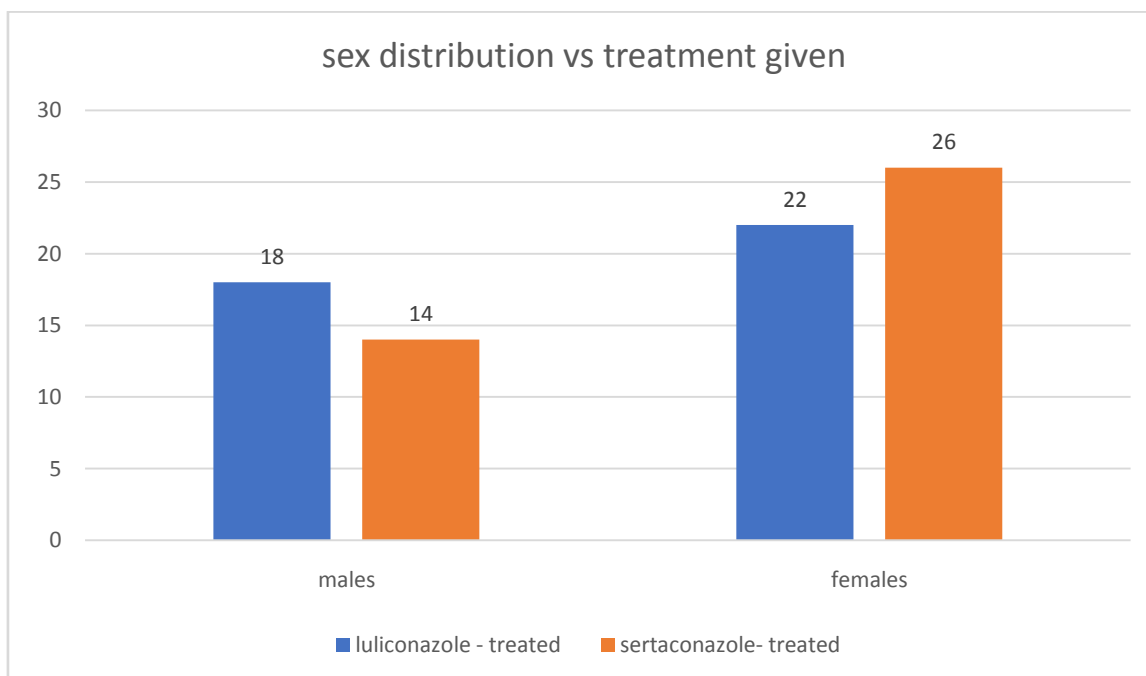


Table no 2: Age group vs treatment given

Age groups	Luliconazole treated	Sertaconazole treated	Total patients
18-30	11	13	24(30%)
31-45	14	12	26(32.5%)
46-60	10	11	21(26.25%)
>60	5	4	9 (11.25%)
	40	40	80

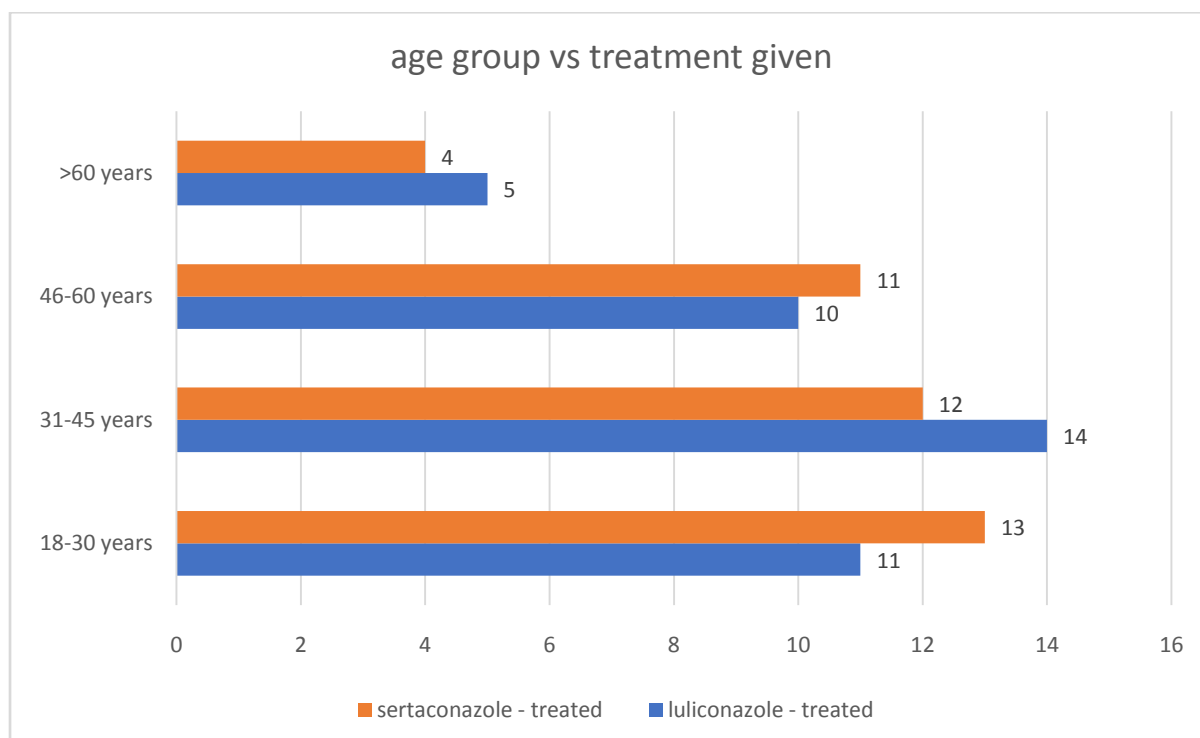


Table no 3: number of lesions vs treatment given

Number of lesions	Luliconazole treated	Sertaconazole treated	Total patients
Multiple lesions	30	32	62(77.5%)
Single lesion	10	8	18(22.5%)
	40	40	80

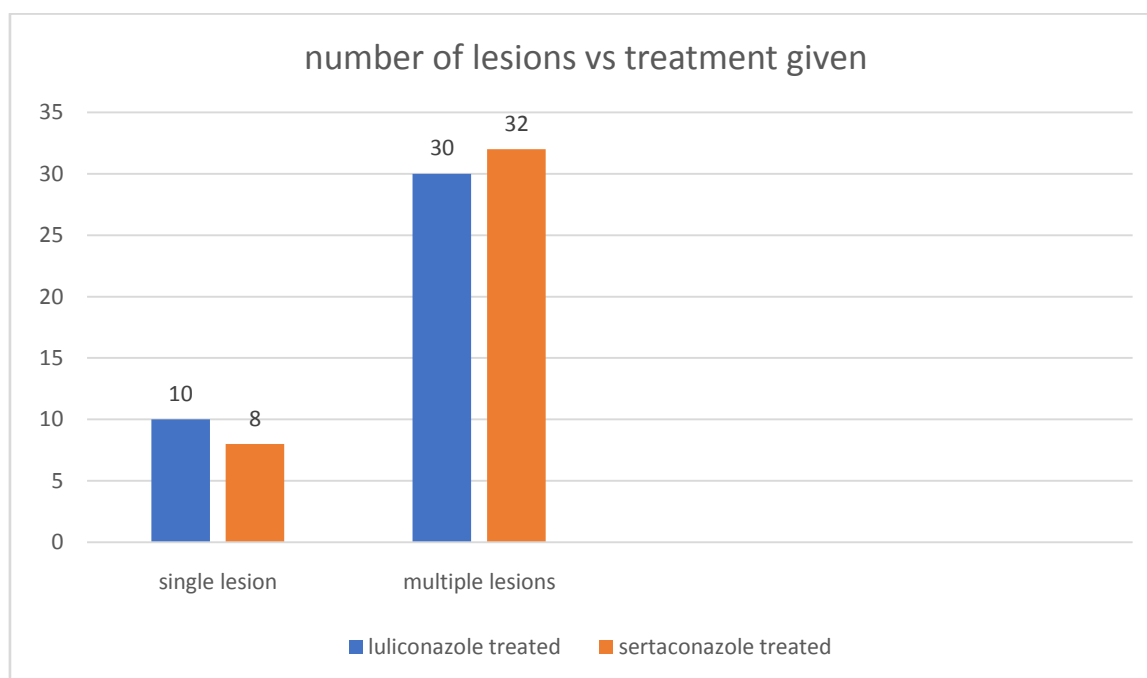


Table no 4: Cure rates based on treatment given

Cure rates	Luliconazole treated	Sertaconazole treated
Clinical Cure seen after 2 weeks	30 patients (75%)	26 (65%)
Clinical Cure seen after 4 weeks	38 patients (95%)	39 (97.5%)

IV. Discussion

A very common superficial fungal infection of the skin and its appendages is dermatophytosis. Its development is known to be predisposed by hot and humid climate conditions that cause excessive sweating. Other risk factors include poor personal hygiene, immunosuppressive conditions, etc.

In our study, we recruited a total of 80 patients diagnosed with Tinea Corporis and Tinea Cruris or both. They were divided into 2 groups of 40 patients each receiving topical luliconazole (1%) cream in group A and topical sertaconazole 2% cream in group B respectively. At the end of 2 weeks, the clinical improvement was seen in 30 patients (75%) in group A and 26 patients in group B (65%). At the end of 4 weeks, the clinical improvement was seen in 38 (95%) patients in group A and 39 (97.5%) patients in group B.

In a study done by Sharma A et al.⁴ on the efficacy and tolerability of sertaconazole nitrate 2% cream vs miconazole 1% cream in the treatment of patients with dermatophytosis, sertaconazole nitrate cream was used twice daily for a total of 2 weeks and they observed clinical improvement in 62.3% patients which is almost similar to our study where clinical improvement at the end of 2 weeks was 65%.

In a study by ESSO et al.⁵, sertaconazole was administered once daily for two weeks to treat pediatric patients with cutaneous dermatophyte infections. It was found that after two and four weeks of treatment, a clinical cure was achieved in 75% and 100% of cases, respectively. There were no local adverse effects noted. At the end of the second and fourth weeks of our trial, we observed cure rates of 65% and 97.5%, respectively.

Choudry SV et al.⁶, in their comparative study between topical terbinafine and sertaconazole found complete cure rates of 73.3% and 100% after 2 and 3 weeks of treatment with sertaconazole topically. In our study, the cure rates were less comparatively where 65% and 97.5% of cure rates were seen after 2 and 4 weeks of treatment with sertaconazole respectively.

In a study conducted by adithya k gupta et al.⁷, once daily application of topical luliconazole was done and results were compared with sertaconazole results. after 4 weeks, sertaconazole showed maximum improvement in 93.3% cases whereas luliconazole showed improvement in 86.6% cases. In our study, at the end of 4 weeks, sertaconazole showed improvement in 97.5% of cases whereas luliconazole showed improvement in 95% of cases.

V. CONCLUSION

The results of the present study indicate that topical luliconazole 1% cream and sertaconazole nitrate 2% cream are both very much potent antifungals in the treatment of tinea cruris and tinea corporis and there is very little differences to choose between them. luliconazole acts a little quicker compared to sertaconazole whereas clinical cure rates were almost similar at the end of 4 weeks. Both antifungals showed almost nil side effects and were almost equally efficacious.

REFERENCES

- [1]. Emmons CW, Binford CH, Utz JP, Kwon-Chung KJ. Dermatophytoses. Medical mycology. 1977;3:117-64.
- [2]. Weitzman I, Summerbell RC. The dermatophytes. Clinical microbiology reviews. 1995 Apr;8(2):240-59.
- [3]. Das K, Basak S, Ray S. A study on superficial fungal infection from West Bengal: A brief report. Journal of Life Sciences. 2009 Jul 1;1(1):51-5.
- [4]. Sharma A, Saple DG, Surjushe A, Rao GR, Kura M, Ghosh S, Bolmall C, Baliga V. Efficacy and tolerability of sertaconazole nitrate 2% cream vs. miconazole in patients with cutaneous dermatophytosis. Mycoses. 2011 May;54(3):217-22.
- [5]. Van Esso D, Fajo G, Losada I, Vilallonga M, Casanovas JM, Clanxet J, Aliaga A. Sertaconazole in the treatment of pediatric patients with cutaneous dermatophyte infections. Clinical therapeutics. 1995 Mar 1;17(2):264-9.
- [6]. Choudhary SV, Bisati S, Singh AL, Koley S. Efficacy and safety of terbinafine hydrochloride 1% cream vs. sertaconazole nitrate 2% cream in tinea corporis and tinea cruris: A comparative therapeutic trial. Indian journal of Dermatology. 2013 Nov;58(6):457.
- [7]. Gupta AK, Daigle D. A critical appraisal of once-daily topical luliconazole for the treatment of superficial fungal infections. Infection and Drug Resistance. 2016;9:1.



Figure 1. Tinea lesions before luliconazole treatment



Figure 2 . tinea lesions after Luliconazole treatment at end of 2 weeks

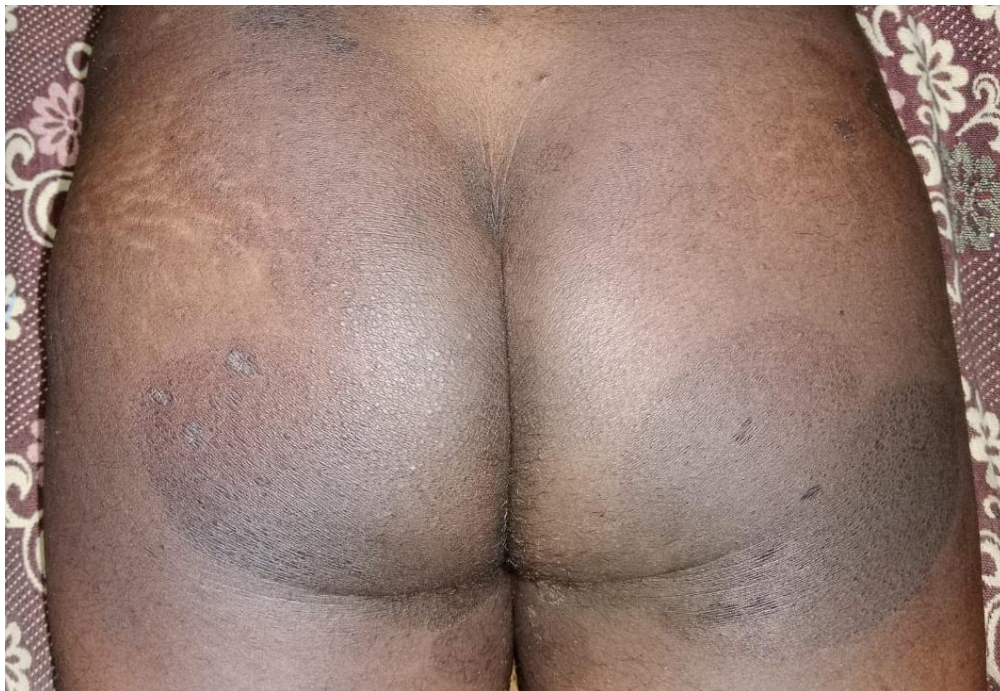


Figure 3 . tinea lesions after Luliconazole treatment at end of 4 weeks



Figure 4. tinea lesion before starting sertaconazole



Figure 5. tinea lesion after 2 weeks of treatment with sertaconazole



Figure 6. tinea lesion at end of 4 weeks of sertaconazole treatment.

Dr. Chundi Sai Saketh Reddy, et. al. "A comparative study of efficacy and safety of luliconazole cream (1%) and sertaconazole nitrate cream (2%) in the treatment of patients with Tinea corporis and cruris." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 22(1), 2023, pp. 35-42.