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Original Research Article

Evaluation of newer imidazoles in dermatophytosis

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ABSTRACT

Background: Eberconazole, a newer Imidazole derivative, antimycotic drug. Similarly, sertaconazole and luliconazole are also newer antifungal which all exhibit fungicidal, fungistatic and anti-inflammatory actions. But, sertaconazole in addition have antipruritic effect also.
Methods: Randomized, open-labelled, prospective study comprising of 75 patients divided into three equal groups A, B, C of 25 patients each. Group A received eberconazole 1%, Group B received sertaconazole 2% and Group C received luliconazole 1% for twice daily topical application for 4 weeks. Patients were asked to review at 2nd and 4th week to record clinical and mycological cure.
Results: In this study out of 75, seventy patients completed the complete course of treatment whereas, five patients were not reported for review citing personal reasons. Parameters included are pruritus, erythema, scaling and vesicles in all three groups. In this study, marked relief of pruritus was achieved clinically with eberconazole (72.7%) followed by luliconazole and sertaconazole with 50.0% and 33.3% respectively at 4th week of treatment phase and reduction of scaling was achieved more with eberconazole (90.9%), sertaconazole (87.5%) and luliconazole (83.3%). All three groups of patients showed successful mycological cure by confirming with negative 10% potassium hydroxide examination at the end of treatment course.
Conclusions: Eberconazole 1% cream was better than sertaconazole 2% cream and luliconazole 1% cream in relieving symptoms like pruritus and scaling at the end of treatment phase and follow up.

Keywords: Dermatophytosis, *Tinea corporis*, *Tinea cruris*, Eberconazole, Sertaconazole, Luliconazole

INTRODUCTION

Dermatophyte infections are one of the earliest known fungal infections of humans and very common throughout the world. The fungal infections of the skin and its appendages are more common in tropical countries due to environment factors like heat and humidity. The risk factors include socio-economic conditions like overcrowding and poverty leading to poor personal hygiene. In India, most commonly occurring clinical type of dermatophytoses for adult is *Tinea corporis* (36-59%) and *Tinea cruris* (12-27%).[1,2] Imidazoles, allylamines, triazoles are most effective antifungal drugs for dermatophytosis. Topical antifungal therapy particularly involves imidazoles (eberconazole, luliconazole and sertaconazole) etc.

Eberconazole, a newer imidazole derivative, antimycotic drug.[3] Luliconazole, an imidazole antifungal agent is active against dermatophytes and non-dermatophyte pathogens. Sertaconazole, a benzothiophene imidazole derivative has both fungistatic and fungicidal activity but

in addition it also has anti-pruritic action.[4] Although they are classified under broad spectrum antifungal agents, there is paucity of studies regarding better efficacy of each of these topical agents in the treatment of dermatophytoses. Hence, this study is undertaken to compare the efficacy and safety profile of eberconazole1%, sertaconazole 2% and luliconazole 1% for the treatment of dermatophytoses. Detailed history and clinical examination of patients will be documented. The aim of the study firstly is to know the efficacy of eberconazole 1%, sertaconazole 2% and luliconazole1% cream and secondly, to know the drug safety profile.

The selected patients were randomized into three groups A, B and C and drugs were given. They were assessed for clinical and mycological improvement and the data was subjected to analysis and the results were interpreted by using SPSS version 20.

METHODS

Study type

A cross sectional, open labelled, prospective study.

Study place

The study was conducted at Bhaskar Medical College, Moinabad, Ranga Reddy District, Telangana state, India.

Study period

The study was conducted for 6 months duration from May 2018 to October 2018.

Selection criteria

Inclusion criteria

- All patients attending DVL OPD of >18 years, both male and female clinically diagnosed as *Tinea corporis* and/or *Tinea cruris* (localized lesions).
- Skin scrapping positive for fungal elements on 10% potassium hydroxide mount.

Exclusion criteria

- Patients who had received topical or systemic antimycotics or corticosteroids <4weeks prior to the study.
- History of Immunocompromised status (diabetes mellitus/hypothyroidism/HIV etc.)
- Pregnant or lactating women.
- Patients who are not willing to give consent.

Procedure

This study comprising of 75 patients divided into three equal groups A, B and C of 25 patients each. The patient selection was randomized successively into three groups. Group A received eberconazole 1%, Group B received sertaconazole 2% and Group C received luliconazole 1% for topical, twice daily application for 4 weeks. Patients were asked to review at 2nd and 4th week to note for clinical and mycological improvement.

Ethical approval

The study was approved by the institutional ethics committee dated 02 May 2018.

Statistical analysis

Data was entered in Microsoft Excel and analysis was done using SPSS version 20. Descriptive statistical analysis was done. Results on categorical measurements are presented as Percentages. Significance was assessed at 5 % level. $p<0.05$ was statistically significant. Chi-square test was used to find out the significance of study parameters on a categorical scale between the three groups.

RESULTS

The study population consisted of 75 patients including 48 males (69%) and 22 females (31%). The mean age of population was 35.03. Five patients were lost to follow up which three in group A, one each in group B and C. Baseline demographic data including age, sex in all 3 treatment groups were comparable as shown in (Table 1). Majority of the patients are labours in all the three groups A, B, and C as shown in (Table 2).

Change in pruritus

At the end of 4th week, the resolution of pruritus was seen in higher proportion of patients in eberconazole group (72.7%) as compared to sertaconazole (33.3%), luliconazole (50%) (Table 3).

Change in erythema

At the end of 4th week, the resolution of erythema was seen in higher proportion in luliconazole (83.3%) as compared to eberconazole (54.5%) and sertaconazole (50%) (Table 4).

Change in desquamation

At baseline, 80 to 100% of total study cases had desquamation in all the three groups. At the end of 4th week 90% desquamation is absent in eberconazole group as compared to sertaconazole (87.5%) and luliconazole (83.3%) (Table 5). At baseline, all patients showed positive potassium hydroxide but at the end of the 4th week, Group B had showed negative 10% potassium hydroxide examination whereas 4 patients (2 each in group A and C) has shown to be positive even at the end of 4 weeks (Table 6).

Table 1: Baseline demographics.

Parameters	Eberconazole	Sertaconazole	Luliconazole
No. of patients	22	24	24
Age (years) mean±SD	35.08±11.899	35.08±15.154	34.71±15.605
Male/ female	12/10	19/5	17/7

Table 2: Occupation of patients.

			Business	Housewife	Labour	Student	Teacher	Total
Drug	A	Count	1	3	15	3	0	22
		% within drug	4.5	13.6	68.2	13.6	0.0	100.0
	B	Count	2	3	12	6	1	24
		% within drug	8.3	12.5	50.0	25.0	4.2	100.0
	C	Count	1	3	12	7	1	24
		% within drug	4.2	12.5	50.0	29.2	4.2	100.0
Total		Count	4	9	39	16	2	70
		% within drug	5.7	12.9	55.7	22.9	2.9	100.0

Table 3: Change in pruritus.

	Group A			Group B			Group C		
	Baseline	**Week 2**	**Week 4**	**Baseline**	**Week 2**	**Week 4**	**Baseline**	**Week 2**	**Week 4**
None	-	-	16 (72.7)	-	-	8 (33.3)	-	-	12 (50)
Mild	-	10 (45.5)	4 (18.2)	-	-	16 (66.7)	-	8 (33.3)	8 (33)
Moderate	10 (45.5)	12 (54.5)	2 (9.1)	9 (37.5)	24 (100)	-	12 (50)	14 (58.3)	4 (16.7)
Severe	12 (54.5)	-	-	15 (62.5)	-	-	12 (50)	2 (8.3)	-

p<0.001.

Table 4: Change in erythema.

	Group A			Group B			Group C		
	Baseline	**Week 2**	**Week 4**	**Baseline**	**Week 2**	**Week4**	**Baseline**	**Week 2**	**Week 4**
None	-	-	12 (54.5)	-	3 (12.5)	12 (50)	-	-	20 (83.3)
Mild	2 (9.1)	8 (36.4)	10 (45.5)	8 (33.3)	3 (12.5)	9 (37.5)	4 (16.7)	12 (50)	2 (8.3)
Moderate	10 (45.5)	14 (63.6)	-	7 (29.2)	12 (50)	3 (12.5)	10 (41.7)	10 (41.7)	3 (7.1)
Severe	10 (45.5)	-	-	9 (37.5)	6 (25)	-	10 (41.7)	2 (8.3)	-

p<0.001.

Table 5: Change in desquamation.

	Group A			Group B			Group C		
	Baseline	**Week 2**	**Week 4**	**Baseline**	**Week 2**	**Week 4**	**Baseline**	**Week 2**	**Week 4**
Present	18 (81.8)	8 (36.4)	2 (9.1)	24 (100)	21 (87.5)	3 (12.5)	22 (91.7)	16 (66.7)	4 (16.7)
Absent	4 (18.2)	14 (36.4)	20 (90.9)	0 (0)	3 (12.5)	21 (87.5)	2 (8.3)	8 (33.3)	20 (83.3)

p<0.001.

Table 6: Mycological assessment (potassium hydroxide mount).

	Group A			Group B			Group C		
	Baseline	**Week 2**	**Week 4**	**Baseline**	**Week 2**	**Week 4**	**Baseline**	**Week 2**	**Week 4**
Positive	22 (100)	12 (54.5)	2 (9.1)	24 (100)	13 (54.2)	-	24 (100)	12 (50)	2 (8.3)
Negative	-	10 (45.5)	20 (90.9)	-	11 (45.8)	24 (100)	-	12 (50)	22 (91.7)

p<0.001.

DISCUSSION

In our study, majority of the total study population was between 30-40 years with male preponderance coinciding with similar findings in a study done by Bindu et al.[5]

Regarding occupational exposure majority of the patients are agricultural labourers (55.7%) followed by students (22.9%) and others (21.5%) in accordance with findings given by Smitha et al.[6]

In the present study, eberconazole proved to be significantly more effective in terms of clinical improvement and in the clearance of fungal pathogens when compared to a study done by Chandana et al.[7]

In a study done by Montero et al in a randomized, double blind, multicentric who observed in his study that eberconazole 1% cream is effective treatment for dermatophytosis with a good safety profile.[8] Eberconazole is clinically effective in the treatment of topical fungal infections, with good safety profile and tolerability.[9,10]

In our study, all three topical drugs were well tolerated and found to be safe. Local side effects such as erythema, swelling, stinging sensation, or itching as mentioned in a few studies were not reported.

Sertaconazole has antipruritic activity in addition to fungicidal activity whereas in this study pruritus is best relieved with eberconazole. Clinical cure at the end of week 4 was better with eberconazole than sertaconazole and luliconazole coinciding with similar findings in study done by Sharma et al.[11]

In this study, at 4 weeks duration all patients in Group B had shown negative 10% potassium hydroxide examination. Whereas, 4 patients (2 each in group A and C) has shown positive even at the end of 4 weeks treatment. These patients were subjected for repeat potassium hydroxide at the end of 6th week.

Limitations

The study sample size was small, and no gross difference was noted. Further studies with larger groups are required.

CONCLUSION

Group A i.e, eberconazole was effective in reducing both pruritus and scaling. Group B i.e, sertaconazole was effective in showing negative potassium hydroxide compared to the other drugs. Group C i.e, luliconazole was found to be more effective in reducing erythema. Among these three drugs, eberconazole was found to be superior both in clinical improvement and fungal clearance when compared to luliconazole and sertaconazole.

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