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Original Article

Comparison of Efficacy between Topical Luliconazole and Topical Clotrimazole in the Treatment of Tinea Corporis and Tinea Cruris

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Abstract:

Background: The prevalence of Tinea Corporis and Tinea Cruris infections are increasing in Bangladesh due to its tropical climate, along with low socio-economic conditions. In treatment of these infections, Clotrimazole has been used for a long time. But Luliconazole is a newer drug which is offering more efficacy and tolerability with a short duration of treatment.

Methods: An observational comparative study was directed to assess the efficacy of topical Luliconazole over Clotrimazole in the treatment of Tinea Corporis and Tinea Cruris among the 175 OPD patients of Department of Dermatology and Venereology, Sylhet MAG Osmani Medical College Hospital. The patient's score was followed up by using 4-point scale of Global Assessment Score.

Results: The mean age of Group A patients was 33.94±13.95 years and Group B was 32.64±13.15 years and male patients were predominant in both groups (65.2% and 66.3%). Tinea corporis was more prevalent in both groups (65.2% and 70.9%). The mean number of infection lesion was 2.35±1.12 and 2.30±1.13. The mean duration of infections was 3.33±5.98 months and 2.38±3.36 months in respective study groups. Papules found 61.4% and 51.4% among the patients respectively. Based on GAS, at the end of first week of treatment, significant difference in distributions found in case of erythema and papules. At the end of treatment, significant difference in distributions found in case of pruritus and scaling. At the 4 weeks after the end of treatment, significant difference in distributions found in case of pruritus, erythema and scaling ($p<0.005$). The mean GAS of Group A was 6.95±1.05 at baseline, which gradually decreased to 3.16±1.27, 1.02±1.01 and 0.42±1.32 in respective first, second and third visit. On the other side, in Group B, the mean GAS decreased from 7.21±1.27 to 3.87±1.28, 1.33±1.37 and 1.23±2.01 in respective baseline, first, second and third visit. Complete cure observed more patients in Group A (32.6%) compared to Group B (12.8%) after one weeks of treatment, whereas no response to treatment observed in more patients of Group B (55.8%) compared to Group A (28.1%). These changes in distribution were found significant ($p=0.004$). At the second visit, complete cure found in 89.9% patients in Group A and 77.9% patients in Group B. These distributions were reached the level of significance ($p=0.031$). At the last visit, only 2.2% of the completely cured patients of Group A and 16.3% of the completely cured patients of Group B developed relapse of the disease, which was also found significantly ($p=0.001$).

Conclusion: Luliconazole found to be superior in terms of short duration of treatment course, less treatment failure and less relapse compared to that of the Clotrimazole.

Keywords: Efficacy, Luliconazole, Clotrimazole, Treatment, Tinea Corporis, Tinea Cruris.

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Introduction:

Tinea is a fungal infection, which is also known as ringworm infection of the human body.[1]

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Globally, the prevalence of superficial fungal skin infection is 20-25%, and it is comparatively higher in all age groups of both sexes in the tropical regions.[2,3] In India, the prevalence is ranging from 36.6% to 78.4%.[4]

Dermatophytes are the most common organism which causes superficial infections, sometimes it's named as Tinea infection or dermatophytosis. It has three genera- Trichophyton spp., Microsporum spp., and Epidermophyton spp.[5,6] Tinea infections are mostly cutaneous and restricted to non-living confide layers as the dermatophytes cannot able to penetrate the deeper tissues or organs of immunocompetent hosts.[3] The characteristic lesion is a circular, single or multiple sites and usually well demarcated; edge become raised with pink to slightly erythematous patch. In progressive cases, central area become clear and scaling may present at the border. Based on the presence of types of dermatophytes, scaling, vesicles, papules or even pustules may develop.[7] In case of Tinea cruris, it also produces similar lesion; but the lesion is most often bilateral and spare the skin of the scrotum. Pruritus is more common than the lesion of other sites and as sweat macerates the irritated skin.[8]

Tinea corporis and Tinea cruris are usually well responsive to topical anti-fungal preparations. Several groups of topical anti-fungal agents are available in local drug market, such as Imidazole, Triazoles, Allylamines etc. Although several preparations are available, their comparative efficacy is not well documented.[9] Systemic antifungals, like fluconazole, Itraconazole, Terbinafine etc., were useful in Tinea lesions with extensive involvement.[9]

Clotrimazole, a member of Imidazole anti-fungal drug, is one of the oldest known and most widely used topical agent that require twice daily application for at least four weeks. On the other hand, Luliconazole is relatively newer agent to this family, which requires applying once daily for two weeks provide more effectivity.[10] Both the drugs act by inhibiting lanosterol 14-α-demethylase enzyme, which play important role in the formation of Ergosterol. Ergosterol is a major component of fungal plasma membrane to maintain membrane fluidity, asymmetry and integrity.[11,12] Luliconazole has higher lipophilic and reservoir property in the stratum corneum than that of Clotrimazole, which facilitate more invading property and provide more duration of action compare to Clotrimazole.[13,14] The development of Clotrimazole resistance, which occurs due to overexpression of efflux pump, makes its efficacy under question.[15] Based on the favorable efficacy and safety profile of Luliconazole is becoming popular rapidly in several countries of the world.[4,10,16]

Materials and methods:

Study design and settings

This study was an observational comparative study was conducted to assess the efficacy of topical Luliconazole over Clotrimazole in the treatment of Tinea corporis and Tinea cruris in the Department of Pharmacology and Therapeutics, Sylhet MAG Osmani Medical College; in collaboration with Department of Dermatology and Venereology, Sylhet MAG Osmani Medical College Hospital, Sylhet during the study period from 1st January 2021 to 31st December 2021.

Patient's selection

All patients of diagnosed Tinea corporis and Tinea cruris attended the Outpatient Department (OPD) of Dermatology and Venereology, Sylhet MAG Osmani Medical College Hospital and fulfilled the inclusion criteria were the study population in this study. Inclusion criteria were patient's age >12 years, patients whose score was ≥5 in global assessment scores and patients whose KOH wet mount test was positive. Patient with immuno-compromised, extensive dermatophytosis, super added bacterial infection, atopic dermatitis, contact dermatitis, psoriasis and pregnant & lactating mother were excluded from this study. Detail history, clinical examination was taken and relevant investigations were performed. The diagnosis was confirmed by skin scraping for fungus.

Procedures of data collection

A pre-tested semi-structured questionnaire was used for interviewing total 175 patients, who was divided into two groups (3 patients dropped out in the course of treatment). For starting the treatment, the participants of Group A were given topical Luliconazole cream, n=89 and

Group B were given topical Clotrimazole cream, n=86 by physicians. In both groups, patients were advised to come back at end of 1st week, end of treatment (at the end of 2nd week in Luliconazole treated patients and 4th week in Clotrimazole treated patient) and 4 weeks after completion of the treatment for evaluation. At each follow up 4-point scale of 'Global Assessment Score' (GAS) was calculated, skin scraping results were assessed and any drug related adverse effects were noted.

Clinical assessment of the patients

A 4-point GAS of pruritus, erythema, scaling and papules was used to assess the severity of the lesion. Visual analogue scale was used to assess the severity of pruritus. Based on the guideline, an assortment of scale of 10cm long, ruler shaped mono-dimensional scale marked from 0 as "no itch" to 10 as "severe itch" provided to the patient to mark a number according to the intensity of feeling of itching. For this research, marking on "0" considered as "grade-0" that means "no itching", marking from 1 up to 3 considered as "grade-1" means "mild itching", marking from 3 up to 6.9 considered as "grade-2" meaning "moderate itching", and marking ≥7 considered as "grade-3" that mean "severe itching".

Severity of erythema assessed according to the score '0' was considered if there is no erythema when color of the skin lesson similar to the surrounding skin color. Score '1' (mild degree) considered when there was faint erythema present, which meant color of the skin lesion became pink or dark with more intensity than the surrounding skin. Score '2' (moderate erythema) considered when there was bright erythema present that meant erythema apparent in bright pink or dark and the border is clearly defined. And score '3' (severe erythema) considered when very bright erythema was present that means skin color of the lesion became very bright or very dark, border became very well defined, capillaries and bruising was visible.

Severity of scaling was assessed according to the score '0' (absent) was considered when there was no scaling present in the lesion. Score '1' (mild) was considered when fine white pattern of scaling was present at the border. Score '2' (moderate) was considered when there was diffuse and thick scaling partially covered most of the lesion area. And score '3' (severe) was considered when very thick scaling covered all over the lesion area.

Severity of papules was assessed according to the score '0' (absent) was considered when there was no papule present in the lesion. Score '1' (mild) was considered when few papules were present at the border. Score '2' (moderate) was considered when there were diffuse papules partially covered the lesion area. And score '3' (severe) was considered when diffuse papules covered all over the lesion area.

Comparison of pre-treatment and post-treatment scores of pruritus, erythema, scaling and papules were performed, skin scraping result were assessed and response obtained were graded as 0= absent, 1= mild, 2= moderate and 3= severe. At the end of each visit, patients were assessed both clinically and mycologically to evaluate: 1= clinical cure, 2= mycological cure, 3= complete cure, 4= relapse and 5= treatment failure.

Statistical analysis

All data were compiled, omissions and inconsistencies were corrected by using SPSS v25. Quantitative data were expressed as mean and standard deviation and comparison was done between the groups by unpaired 't' test. Qualitative data were expressed in frequency and percentage and comparison was done by using chi-square test or fisher's exact test. P-value of <0.05 at 95% confidence interval was considered as statistically significant. The results were presented in tables and diagram.

Ethical consideration

Participation was voluntary and confidentiality was maintained and informed written consent was taken from each patient. The study was validated by the ethical committee of the Sylhet MAG Osmani Medical College, Sylhet 3100, Bangladesh. (Memo no: SOMC/2021/43)

Results

Table 1 outlines most of the patients came from 18-44 years in study groups, 64.0% in Group A and 66.3% in Group B. The mean age of Group A patients was 33.94±13.95 years and Group B was 32.64±13.15 years respectively. Two-thirds

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of the patients were male (65.2% and 66.3%). The patients based on the site of Tinea infections, Tinea corporis was more prevalent in both groups (65.2% and 70.9%).

Table 2 shows differences in mean of the Tinea lesion sites in body and mean duration of infection between the study groups. The mean number of infection lesion was 2.35±1.12 and 2.30±1.13. The mean duration of infections was 3.33±5.98 months and 2.38±3.36 months in respective study groups. Both the mean number of infection lesion and duration of lesion were not significant (p=0.787 and p=0.203).

Figure 1 represents all the patients of both study groups were presented with the complaints of pruritus, erythema, and scaling at their Tinea lesion sites. Papules found in 61.4% and 51.4% of patients of respective Group A and Group B.

Table 1: Patient's outlines of the Tinea infections (n=175)

Outlines	Group A	Group B
	n (%)	n (%)
Age groups (years)		
12-18	9 (10.1)	7 (8.1)
18-44	57 (64.0)	57 (66.3)
45-65	23 (25.8)	22 (25.6)
Mean±SD	33.94±13.95	32.64±13.15
Gender		
Male	58 (65.2)	57 (66.3)
Female	31 (34.8)	29 (33.7)
Site of Tinea infections		
Tinea corporis	58 (65.2)	61 (70.9)
Tinea cruris	31 (34.8)	25 (29.1)

Table 2: Mean number of infection site and mean duration of infection (n=175)

Tinea infections	Group A Mean±SD	Group B Mean±SD	t-value	p-value
Infection site	2.35±1.12	2.30±1.13	t= 0.271	0.787
Duration (in month)	3.33±5.98	2.38±3.36	t= 0.203	0.203

*Unpaired t-test value

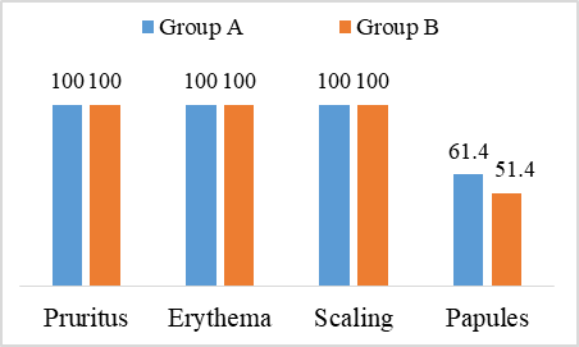

Figure 1: Presenting features of the patients during recruitment (n=175)

Parameters	Group A n (%)	Group B n (%)	χ2 value	p-value
At baseline				
Pruritus				
Mild itching	5 (5.6)	2 (2.3)		
Moderate itching	45 (50.6)	45 (52.3)	2.576	0.276
Severe itching	39 (43.8)	39 (45.4)		
Erythema				
Faint erythema	26 (29.2)	21 (24.4)		
Bright erythema	52 (58.4)	51 (59.3)	0.850	0.654
Very bright erythema	11 (12.4)	14 (16.3)		
Scaling				
Fine white scaling	13 (14.6)	11 (12.8)		
Diffuse and thick scaling	60 (67.4)	56 (65.1)	0.512	0.774
Very thick scaling	16 (18.0)	19 (22.1)		
Papules				
No papules	31 (34.8)	25 (29.1)		
Papules at border	51 (57.3)	48 (55.8)	2.484	0.289
Papules partially covered	7 (7.9)	13 (15.1)		
At first visit (End of 1st week)				
Pruritus				
No itching	10 (11.2)	7 (8.1)		
Mild itching	48 (53.9)	47 (54.7)	0.598	0.778
Moderate itching	31 (34.9)	32 (37.2)		
Erythema				
No erythema	19 (21.4)	10 (11.6)		
Faint erythema	57 (64.0)	49 (56.9)	8.250	*0.016
Bright erythema	13 (14.6)	27 (31.5)		
Scaling				
No scaling	19 (21.3)	9 (10.5)		
Fine white scaling	60 (67.4)	61 (70.9)	4.910	0.085
Diffuse and thick scaling	10 (11.3)	16 (18.6)		
Papules				
No papules	77 (86.5)	59 (68.6)	8.150	*0.004
Papules at border	12 (13.5)	27 (31.4)		

*Statistically significant value

Table 3a demonstrates distribution of patients based on GAS in different parameters before starting the treatment and at the end of first week of treatment. At the end of first week of treatment, statistically significant difference in

distributions found in case of erythema (p=0.016) and papules (p=0.004). Table 3b demonstrates distribution of patients based on GAS in different parameters at the end of treatment and at the 4 weeks after the end of treatment. At the end of treatment, statistically significant difference in distributions found in case of pruritus (p=0.020) and scaling (p=0.005). At the 4 weeks after the end of treatment, statistically significant difference in distributions found in case of pruritus (p=0.003), erythema (p=0.001) and scaling (p=0.001).

Table 4 represents the mean differences of the GAS between the study groups. The mean GAS of Group A was 6.95±1.05 at baseline, which gradually decreased to 3.16±1.27, 1.02±1.01 and 0.42±1.32 in respective first, second and third visit. On the other side, in Group B, the mean GAS decreased from 7.21±1.27 to 3.87±1.28, 1.33±1.37 and 1.23±2.01 in respective baseline, first, second and third visit. The means between the groups were showed significant difference at the first (p=0.001) and third (p=0.002) visit. The means within the groups were compared using ANOVA with post-hoc Tukey HSD test that showed the mean GASs were significantly reduced in every visit compared to their corresponding previous visit within both study groups (p=0.001), except between second and final visit in Group B.

Table 5 interprets distribution of patients based on the mycological cure between the study groups. At the baseline, all the patients of both groups were found positive for the mycological assessment. On the first visit, mycological test negative found in 68.6% patients of Group A and 46.5% patients of Group B, which was found statistically significant (p=0.003). At the end of treatment, mycological test positive patients observed three times more patients in Group B (18.6%) compared to the Group A (5.6%) patients, which was found statistically significant (p=0.008). At third visit, the mycological test positive patients raised in both groups 6.7% in Group A and 29.0% in Group B due to the relapse of disease. The difference between Group A and Group B was found also significant (p=0.001).

Table 6 showed distribution of patients based on the treatment outcome response at different visits between the groups. Complete cure observed more patients in Group A (32.6%) compared to Group B (12.8%) after one weeks of treatment, whereas no response to treatment observed in more patients of Group B (55.8%) compared to Group A (28.1%). These changes in distribution were found statistically significant (p=0.004) between the study groups. At the second visit (at the end of treatment), complete cure found in 89.9% patients in Group A and 77.9% patients in Group B. These distributions were reached the level of statistical significance (p=0.031). At the last visit, only 2.2% of the completely cured patients of Group A and 16.3% of the completely cured patients of Group B developed relapse of the disease, which was found significantly (p=0.001) higher in Group B than that of Group A.

Table 3b: Distribution of patients based on GAS at different stages of study (n=175)

Parameters	Group A n (%)	Group B n (%)	χ2 value	p-value
At second visit (End of treatment: 2 weeks for Group A and 4 weeks for Group B)				
Pruritus				
No itching	61 (68.5)	58 (67.4)		
Mild itching	25 (28.1)	16 (18.6)	7.435	*0.020
Moderate itching	3 (3.4)	12 (14.0)		
Erythema				
No erythema	67 (75.3)	61 (70.9)		
Faint erythema	20 (22.5)	23 (26.7)		†0.847
Bright erythema	2 (2.2)	2 (2.4)		
Scaling				
No scaling	58 (65.2)	37 (43.0)		
Fine white scaling	30 (33.7)	48 (55.8)		*†0.005
Diffuse and thick scaling	1 (1.1)	1 (1.2)		
Papules				
No papules	86 (96.6)	83 (96.5)		†1.000
Papules at border	3 (3.4)	3 (3.5)		
At third visit for identification of relapse (4 weeks after end of treatment)				
Pruritus				
No itching	80 (89.9)	60 (69.8)		
Mild itching	6 (6.7)	15 (17.4)	11.240	*0.003
Moderate itching	3 (3.4)	11 (12.8)		
Erythema				
No erythema	81 (91.0)	59 (68.6)		
Faint erythema	6 (6.7)	17 (19.8)	14.470	*0.001
Bright erythema	2 (2.3)	10 (11.6)		
Scaling				
No scaling	82 (92.2)	61 (70.9)		
Fine white scaling	6 (6.7)	22 (25.6)		*†0.001
Diffuse and thick scaling	1 (1.1)	3 (3.5)		
Papules				
No papules	87 (97.7)	82 (95.3)		†0.438
Papules at border	2 (2.3)	4 (4.6)		

*Statistically significant value, †Fisher's exact test

Table 4: Comparison of mean difference of GAS at different stages

Stages	Group A	Group B	t-value	p-value
	mean±SD	mean±SD		
At baseline	6.95±1.05	7.21±1.27	t = 1.47	0.149
At first visit	3.16±1.27	3.87±1.28	t = 3.68	0.001
At second visit	1.02±1.01	1.33±1.37	t = 1.69	0.103
At third visit	0.42±1.32	1.23±2.01	t = 3.14	0.002
ANOVA value	F= 566.575	F= 296.793		
**p-value	0.001	0.001		

*Unpaired t-test value, **ANOVA

Table 5: Mycological evidence at different visits (n=175)

Visits	Study group	Mycological evidence		χ^2 value	p-value
		Present n (%)	Absent n (%)		
At baseline	Group A	89 (100)	0 (0)		1.000
	Group B	86 (100)	0 (0)		
At first visit	Group A	28 (31.4)	61 (68.6)	8.72	*†0.003
	Group B	46 (53.5)	40 (46.5)		
At second visit	Group A	5 (5.6)	84 (94.4)	6.99	*†0.008
	Group B	16 (18.6)	70 (81.4)		
At third visit	Group A	6 (6.7)	83 (93.3)	14.96	*†0.001
	Group B	25 (29.0)	61 (70.9)		

*Statistically significant value, †Fisher's exact test

Table 6: Clinical response of drug treatments at different visits (n=175)

Parameters	Group A n (%)	Group B n (%)	χ^2 value	p-value
First visit				
Clinical cure	2 (2.2)	0 (0)		
Mycological cure	33 (37.1)	27 (31.4)		*†0.004
Complete cure	29 (32.6)	11 (12.8)		
No response	25 (28.1)	48 (55.8)		
Second visit				
Complete cure	80 (89.9)	67 (77.9)	4.67	*†0.031
Treatment Failure	9 (10.1)	19 (22.1)		
Third visit				
Complete cure	81 (91.1)	56 (65.1)	18.06	*†0.001
Treatment Failure	6 (6.7)	16 (18.6)		
Relapse	2 (2.2)	14 (16.3)		

*Statistically significant value, †Fisher's exact test

Discussion

The mean ages were 33.9±14.0 and 32.64±13.15 years in Luliconazole and Clotrimazole treated groups, and maximum patients (two thirds) of both groups were in between 18-44 years (64.0% in Luliconazole treated group and 66.3% in Clotrimazole treated group). Dermatophytosis was reported in similar age groups (both mean and distribution) in these studies.[4,13,17]

This study showed male predominance, the frequency of male patients was found almost double compare to the female on both study groups (65.2% vs 34.8% in Luliconazole treated group and 66.3% vs 33.7% in Clotrimazole treated group). Male predominance of suffering of both Tinea corporis and Tinea cruris reported in these studies.[3,13] The male predominance might be due to the fact that the males are more commonly engaged in outdoor activity and, hence, they are wearing relatively tight fitted cloth than female. Prolonged wearing of wet cloth (due to sweating) provide risk factor for tinea infection. This factor is supported by the distribution of patients based on their occupation.

Frequency of Tinea corporis found was nearly doubled than that of the Tinea cruris in this study; 65.2% versus 34.8% in Luliconazole treated group and 70.9% versus 29.1% in Clotrimazole treated group. Similar ratio was reported in these studies.[4,10] In contrast, Lakshmi CP et al. and Khan I. observed almost equal frequencies of Tinea corporis and Tinea cruris in their sample.[13,18]

Significant reduction of GAS observed in both Luliconazole and Clotrimazole treated group in this study. Mean GAS reduction was found more prominent in Luliconazole that Clotrimazole treated group at the end of first week of treatment (3.16±1.27 vs 3.87±1.28, p=0.001) and at third visit (0.42±1.32 vs 1.23±2.01, p=0.002). Similar significant mean reduction difference at the end of first week and not significant mean difference at the end of treatment between the groups also reported in the study.[4]

Significantly higher percentage of Luliconazole treated patients achieved mycological cure at the end of first week (68.6% vs 46.5%) and also at the end of treatment period (94.4% vs 81.4%) compared to the Clotrimazole treated group. Prabha et al. observed similar mycological cure at the end of first week and at the end of treatment, those were also statistical significant (p=0.001 at the end of first week and p=0.01 at the end of treatment).[4]

Complete cure at the end of first week of treatment in Luliconazole group achieved by 32.6%, which reached 89.9% at the end of treatment. Prabha et al. reported 22.0% complete cure at the end of first week and 98.0% at the end of treatment.[4] In contrast, another study reported that nearly half of the patients (53 of 94) became completely cured at first visit that become almost 100% (93 of 94 patients) at the end of therapy.[10] Failure rate was found slightly higher in Luliconazole treated group in this study (7.0%) compared to the earlier two studies, it was 2.0% and 1.06%.[4,10]

Among the Clotrimazole treated patients, this study observed 12.8% complete cure at the end of first visit, while 23.58% complete cure observed at first visit[10], but the frequency was zero in study.[4] At the end of treatment, complete cure achieved by 77.9% of patients in this study, which was 95.28% in a study[10] and 72.0% in another study.[4] However, significantly higher cure rate observed in Luliconazole treated group in previous two researches. This study result also follows previous two study results.[4,10] Relapse found in 2.2% of Luliconazole treated patients and 16.3% of Clotrimazole treated patients in this study. It was reported slightly higher relapse in Luliconazole treated group (4.0%) and also in Clotrimazole treated group (20%).[4]

Conclusion

Based on the result of this study, Luliconazole found to be superior in terms of short duration of treatment course, less treatment failure and less relapse compared to that of the Clotrimazole. Both the drugs were found equally safe within the investigating period of treatment.

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