

Original research article

Comparative Assessment Of Efficacy Of Four Different Topical Drugs In The Management Of Tinea Corporis And Tinea Cruris**Dr. Neeraj Kumar****Assistant Professor & HOD, Department of skin and VD, Vardhman Institute of Medical Sciences, Pawapuri, Nalanda, Bihar, India****Corresponding Author: Dr. Neeraj Kumar****Abstract**

Aim: comparative assessment of efficacy of topical amorolfine, luliconazole, sertaconazole, terbinafine in tinea corporis and tinea cruris.

Material and methods: This was a prospective, randomized study was done in the Department of skin and VD, Vardhman Institute of Medical Sciences, Pawapuri, Nalanda, Bihar, India for one year Total 100 divided into four groups with 25 patients in each category of antifungal were considered. Consecutive eligible patients were prescribed topical amorolfine (0.25%), luliconazole (1%), sertaconazole (2%) and terbinafine (1%) in a serial order. We evaluated the improvement in the pruritus, erythema and scaling with score 0 for no improvement, score 1 for partial improvement and score 2 for complete improvement. Therapeutic response was statistically evaluated using Kruskal Wallis test and Fishers exact test.

Results: Among 100 patients 44 were treatment naive, 25 were topical steroid (with or without antifungal) modified cases, 23 were partially treated with antifungals and 8 had used home remedies prior to the study. Luliconazole showed best improvement of pruritus (mean-1.53), erythema (mean-1.48) and scaling (mean- 1.47). Terbinafine showed the least improvement with mean being 0.62, 0.52, 0.77 for pruritis, erythema and scaling respectively. Difference in the mean values of improvement of luliconazole as compared to the other three drugs was significant for pruritus (P=0.019) and highly significant for erythema and scaling (P=0.003&0.006). A total of 16 patients (64%) in luliconazole group showed good response as compared to the other drugs. These differences in the improvement of patients was statistically significant as compared to other drugs (P= 0.014).

Conclusion: We concluded that the Luliconazole is better as compared to other antifungal.

Keywords: Tinea corporis, Tinea cruris, Topical antifungal.

Introduction

Dermatophytes are a group of taxonomically related fungi.¹ Superficial infection caused by a dermatophyte is termed dermatophytosis or ringworm. They are all moulds belonging to three asexual genera: microsporium, trichophyton and epidermophyton. The common species which causes human infection include *T. rubrum*, *T. mentagrophytes*, *T. tonsurans*, *T. violaceum*, *T. schonleinii*, *E. floccosum*, *M. audouini* etc. Depending upon the site of infection, dermatophyte infection can be classified as tinea corporis (body), tinea cruris (groin), tinea capitis (head), tinea pedis (feet), tinea manuum (hand), tinea unguium (nail), tinea barbae (beard) etc.² The most common factors predisposing to fungal infection still remain poor personal hygiene, immune status and associated illness.³ The two most important methods used to diagnose dermatophytosis are direct microscopy and isolation of the specific species through culture.

Most modern broad-spectrum antifungal agents act by blocking specific steps in the synthesis of fungal cell membrane components. Although the choice of an antifungal agent should be based on an accurate diagnosis.⁴ currently, topical azoles and allylamines are used for the

treatment of Cutaneous mycoses with disadvantages like long duration of therapy, which leads to poor compliance and a high relapse rate. Some of the newer agents require only once-daily application and shorter courses of treatment, and are associated with lower relapse rates.⁵ Within the past few years, new extended-spectrum triazoles and allylamines have been introduced into market among such are Luliconazole, Sertaconazole, Eberconazole which belong to triazoles and Amorolfine which belong to Allyamine group. This report will summarize the studies evaluating new antifungal agents that are approved by the US Food and Drug or that have completed phase 3 clinical trials Administration.⁶ Dermatophytes constitutes a group of about 40 fungal species that are members of the Trichophyton, Microsporium, and Epidermophyton genere and cause superficial infection called dermatophytosis, ringworm, or tinea.^{7,8} The main aim of the study is to comparative study of efficacy of topical amorolfine, luliconazole, sertaconazole, terbinafine in tinea corporis and tinea cruris.

Material and methods

This was a prospective, randomized study was done in the Department of skin and VD, Vardhman institute of medical science Pawapuri, Nalanda, Bihar, India for one year. after taking the approval of the protocol review committee and institutional ethics committee. It was a pragmatic study to assess the therapeutic response to certain topical antifungals in the current scenario of dermatophytosis.

Methodology

Total 100 clinically diagnosed healthy adult patients with tinea corporis and tinea cruris requiring topical antifungal therapy were include in this study. Recurrent, steroid modified and partly treated tinea infections were also recruited in order to represent the current scenario. A detailed history including the duration of disease, associated medical conditions, treatment history and family history were taken. An arbitrary sample size of 100 was considered with 25 patients in each category of antifungal was considered.

Location of lesion, morphology and symptoms were noted. Scrapings from the edge and/or from the scaly area of the lesions were taken. Potassium hydroxide mount (KOH Mount) followed by direct microscopy was undertaken at the beginning of treatment to confirm the diagnosis but not repeated at the end of treatment since clinical improvement rather than a cure was the primary objective of the study. Consecutive eligible patients were prescribed topical amorolfine (0.25%), luliconazole (1%), sertaconazole (2%) and terbinafine (1%) in a serial order. Amorolfine and luliconazole were advised once daily while sertaconazole and terbinafine was twice daily application. They were asked to apply as a thin layer directly to the lesions and also a small area beyond the lesions. Response to treatment was assessed after 3 weeks with no follow-up visit.

We evaluated the improvement in the pruritus, erythema and scaling with score 0 for no improvement, score 1 for partial improvement and score 2 for complete improvement. Therapeutic response was statistically evaluated using Kruskal Wallis test and Fishers exact test. Antihistamine tablet levocetirizine 5 mg at bed time was given for 7 days to all patients as an anti-pruritic medication.

Results

Among 100 patients 44 were treatment naive, 25 were topical steroid (with or without antifungal) modified cases, 23 were partially treated with antifungals and 8 had used home remedies prior to the study (Table 1). Mean age of these patients was 35.5 year with youngest being 18 years and oldest 67 years. Male to female (58 versus 42) ratio was 1.38:1. Luliconazole showed best improvement of pruritus (mean-1.53), erythema (mean-1.48) and

scaling (mean- 1.47). Terbinafine showed the least improvement with mean being 0.62, 0.52, 0.77 for pruritus, erythema and scaling respectively.(Table 2) Difference in the mean values of improvement of luliconazole as compared to the other three drugs was significant for pruritus (P=0.019) and highly significant for erythema and scaling (P=0.003&0.006).

Based on the improvement of all three parameters, we categorized the patients into three groups.(Table 3) Total value of improvement in pruritus, erythema and scaling were calculated and patients were grouped into poor response (total score- 0, 1 & 2), moderate response (total score-3&4) and good response (total score-5&6). A total of 16 patients (64%) in luliconazole group showed good response as compared to the other drugs. These differences in the improvement of patients was statistically significant as compared to other drugs (P=0.014, Fisher's exact test).

Table 1: Previous topical treatment

| Group | Naive | Steroid | Antifungal | Others | Total |
|---------------|-------|---------|------------|--------|-------|
| Amorolfine | 7 | 12 | 4 | 2 | 25 |
| Luliconazole | 14 | 2 | 8 | 1 | 25 |
| Sertaconazole | 11 | 6 | 5 | 3 | 25 |
| Terbinafine | 12 | 5 | 6 | 2 | 25 |
| Total | 44 | 25 | 23 | 8 | 100 |

Table 2: Comparison between pruritus, erythema & scaling

| Parameters | Group | N | Mean | P value | |
|------------|---------------|----|------|---------|-----|
| Pruritus | Amorolfine | 25 | 1.11 | .019 | Sig |
| | Luliconazole | 25 | 1.53 | | |
| | Sertaconazole | 25 | 1.31 | | |
| | Terbinafine | 25 | 0.62 | | |
| Erythema | Amorolfine | 25 | 0.92 | .003 | Hs |
| | Luliconazole | 25 | 1.48 | | |
| | Sertaconazole | 25 | 1.07 | | |
| | Terbinafine | 25 | 0.52 | | |
| Scaling | Amorolfine | 25 | 0.91 | .006 | Hs |
| | Luliconazole | 25 | 1.47 | | |
| | Sertaconazole | 25 | 1.11 | | |
| | Terbinafine | 25 | 0.77 | | |
| Total | Amorolfine | 25 | 2.69 | .007 | Hs |
| | Luliconazole | 25 | 4.62 | | |
| | Sertaconazole | 25 | 3.52 | | |
| | Terbinafine | 25 | 2.21 | | |

Table 3: Group comparison of drugs

| | Amorolfine | | Luliconazole | | Sertaconazole | | Terbinafine | |
|----------|------------|-----|--------------|-----|---------------|-----|-------------|-----|
| | N=25 | % | N=25 | % | N=25 | % | N=25 | % |
| Poor | 10 | 40 | 2 | 8 | 5 | 20 | 12 | 48 |
| Moderate | 10 | 40 | 7 | 28 | 12 | 48 | 12 | 48 |
| Good | 5 | 20 | 16 | 64 | 8 | 32 | 1 | 4 |
| Total | 25 | 100 | 25 | 100 | 25 | 100 | 25 | 100 |

Poor = Total scores 0,1,2, Moderate = Total scores 3,4, Good = Total scores 5,6

Discussion

Topical antifungal therapy is the mainstay in the treatment of dermatophytosis; however increased number of extensive infections in the recent times has been a limiting factor. Newer topical antifungals seem to have certain advantages over the older drugs.⁹ Dermatologist treating dermatophytosis has less information about the efficacy of the currently available topical therapies. Current epidemic of dermatophytosis is complicated by an increased number of chronic and recurrent dermatophytosis.¹⁰ Topical steroid abuse also seems to be a major contributor to the onslaught of extensive and treatment resistant cases.¹¹ There has also been a shift in the dominant pathogen responsible for the infections across India from *Trichophyton rubrum* to *Trichophyton mentagrophytes*.¹² Thus current circumstances are different than a decade ago and we need more information about the response to the therapeutic agents. We conducted this study in 100 adult patients. Among 100 patients 44 were treatment naïve, 25 were topical steroid (with or without antifungal) modified cases, 23 were partially treated with antifungals and 8 had used home remedies prior to the study. We found less OTC drug usage in our patients compared to another study but still it was sizable.¹³

We found that the topical antifungals were effective in majority of the patients, although variable response was seen. Best response at the end of 3 weeks of topical therapy was shown by Luliconazole of pruritus (mean-1.53), erythema (mean-1.48) and scaling (mean- 1.47). Terbinafine showed the least improvement with mean being 0.62, 0.52, 0.77 for pruritus, erythema and scaling respectively, results were statistically significant. Jerajani et al conducted almost a similar study and found sertaconazole exhibiting better response than luliconazole and terbinafine.¹⁴ Another study conducted by Choudhary et al showed equal efficacy between sertaconazole and terbinafine.¹⁵

Improvement was assessed on the basis of total score and 3 groups were made. Out of which luliconazole had 16 patients with good response followed by sertaconazole (8), amorolfine (5) and terbinafine (1) least. This indicates that luliconazole could be the most effective topical antifungal as compared to the other three currently available drugs. These differences in the improvement of patients was statistically significant as compared to other drugs ($P = 0.014$). This high efficacy may be due to its low MIC as compared to certain other antifungals for *T. rubrum* and *T. mentagrophytes*. There seem to be a poor response to the fungicidal drug terbinafine which could be due to various factors that may include drug resistance.¹⁶ Strength of this study lies in replicating the current scenario of dermatophytosis in the study by including naïve as well as partially treated or mistreated cases. We compared currently available relatively new molecules whose efficacy is less known in the current Indian scenario.

Conclusion

We concluded that the Luliconazole may score over other 3 topical antifungals. Although it belongs to azole class, it seems to exhibit fungicidal activity. This study also signifies the role of topical antifungal alone in treating limited tinea corporis and cruris, thus boosting the confidence on topical therapy. Newer topical antifungals are more expensive and hence pharmaco-economical analysis should also be considered while prescribing them.

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