

Amorolfine Cream in Comparison with Ciclopirox in Management Efficacy among Individuals with Localized Cutaneous Dermatophytosis

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Abstract:

Background: Dermatophytosis, commonly known as ringworm, is a superficial fungal infection of the skin, hair, or nails caused by dermatophytes. (5) The increasing prevalence of dermatophytosis worldwide has necessitated the evaluation of effective topical antifungal treatments (13). Amorolfine and ciclopirox olamine are two topical antifungal agents commonly used in clinical practice. This study aims to compare the efficacy and safety of amorolfine cream versus ciclopirox olamine cream in the treatment of local cutaneous dermatophytosis. **Methods:** This randomized controlled trial involved 20 participants with localized cutaneous dermatophytosis, who were randomly assigned to two groups. The intervention group (n=10) received topical Amorolfine (twice daily application locally) while the control group (n=10) received topical ciclopirox olamine (twice daily application locally). Efficacy was assessed using Dermatophytosis severity score and mycological cure rate (KOH mount) (10,12) at baseline, 3 weeks, 6 weeks, 9 weeks and 12 weeks where adverse effects were also noted. **Results:** At the end of 12 weeks, clinical and mycological cure rates were significantly higher in the amorolfine group (90%) compared to the ciclopirox olamine group (60%) ($p < 0.05$). Both treatments were well tolerated, with no serious adverse events reported. Mild local irritation was noted in 20% of patients in the amorolfine group and 30% in the ciclopirox olamine group. **Conclusion:** Amorolfine cream is superior to ciclopirox olamine cream in the management of local cutaneous dermatophytosis, offering higher cure rates, faster symptom relief, and lower recurrence rates. Given its efficacy and safety, amorolfine cream should be considered a preferred topical treatment option for dermatophytosis.

Keywords: Dermatophytosis, Amorolfine, Ciclopirox Olamine, Topical Antifungal, Randomized Controlled Trial

INTRODUCTION

Dermatophytosis, also known as tinea or ringworm, is a widespread fungal infection affecting keratinized tissues such as the skin, hair, and nails. (14) Dermatophytes, the causative agents, include species from the genera *Trichophyton*, *Microsporum*, and *Epidermophyton*. (6,7) These infections are common globally and can cause significant discomfort and morbidity. The treatment landscape for dermatophytosis includes various topical and systemic antifungal agents. Topical treatments are preferred for localized infections due to their efficacy and reduced risk of systemic side effects.

Amorolfine and ciclopirox olamine are topical antifungal agents with broad-spectrum activity. (1) Amorolfine, introduced in 1981, is a morpholine derivative with antifungal and fungistatic properties. It works by inhibiting ergosterol synthesis at two levels: it blocks delta 14 reductase and delta 7–8 isomerase. This disruption in ergosterol synthesis affects the fungal cell membrane, depleting ergosterol and causing abnormal spherical sterols to accumulate in the fungal cytoplasmic membranes. (2) Ciclopirox olamine, is a hydroxy-pyridone derivative that has been studied since 1973. It comes in many forms, including cream, suspension, shampoo, gel, solution, powder, and

globules, and is used to treat skin and scalp conditions, as well as nail fungal infections (onychomycosis). Additionally, ciclopirox is used to treat seborrheic dermatitis, pityriasis versicolor, and vaginal yeast infections (vaginal candidiasis). (3,4) Despite their widespread use, direct comparative studies assessing their efficacy and safety are limited. This study aims to fill this gap by providing a comprehensive comparison of amorolfine cream and ciclopirox olamine cream in treating local cutaneous dermatophytosis.

MATERIAL AND METHODS:

Study Design

This study was conducted as a randomized controlled trial at a single dermatology clinic. Ethical approval was obtained from the institutional review board, and all participants provided written informed consent.

Participants

A total of 40 individuals with localized cutaneous dermatophytosis were enrolled. Inclusion criteria included patients with a clinical diagnosis of dermatophytosis confirmed by positive KOH microscopy and fungal culture. (9) Exclusion criteria were hypersensitivity to the study drugs, use of any topical or systemic antifungals within four weeks prior

to the study, pregnancy, lactation, and presence of immunocompromising conditions.

Interventions:

Participants were randomly divided into 2 groups – A and B. Those with odd number serial entry are grouped as A (Amorolfine group) and those with even number entry are grouped as B (Ciclopirox olamine group):
Amorolfine group (n=10) : applied the cream twice a day to affected areas and surrounding 2cm for 8 weeks. (11)

Ciclopirox olamine Group (n=10) : applied the cream twice a day to affected areas and surrounding 2cm for 8 weeks. (11)

Outcomes:

The primary outcome was the clinical and mycological cure measured by Dermatophyte severity score and KOH microscopy respectively at baseline, 3 weeks, 6 weeks, 9 weeks and 12 weeks. Secondary outcomes included adverse effects and patient satisfaction assessed using a standardized questionnaire.

Statistical Analysis:

Qualitative variables were described with frequency and percentage. Quantitative variables were described with mean and SD. Chi-square and unpaired t-test were used according to the type of data. A p-value of <0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS:

A total of 20 patients were enrolled and randomized, with 10 patients in each group. Baseline characteristics, including age, gender was comparable between the two groups ($p > 0.05$).

Table 1: Age and sex distribution of study population

Variables	Amorolfine cream (n=10)	Ciclopirox olamine cream (n=10)	p-value
Age (Mean $\pm$ SD)	35 $\pm$ 4.3	33 $\pm$ 3.9	0.132
Male: Female	4:6	3:7	0.639

Primary outcome:

Effectiveness:

Table 2: Comparison of cure rate between the two treatments

Variables	Amorolfine cream (n=10)	Ciclopirox olamine cream (n=10)	p-value
Cured	9 (90%)	6 (60%)	0.028
Not cured	1(10%)	4(40%)	

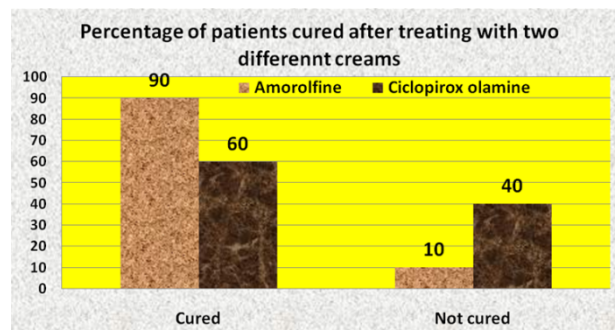


Table 2 shows that the Cure rate was high in patients treated with Amorolfine cream compared to Ciclopirox olamine cream and it was statistically significant ($p < 0.05$)

Secondary Outcomes:

Adverse Effects:

Table 3: Adverse effect after treatment

Adverse effect	Amorolfine cream (n=10)	Ciclopirox olamine cream (n=10)	p-value
Present	2 (20%)	3(30%)	0.465
Absent	8(80%)	7(70%)	

As shown in Table 3, adverse effects reported by the patients treated with Amorolfine cream was 20% and it was 30% in patients treated with Ciclopirox olamine cream. However, the differences in developing adverse effects are not statistically significant between the two treatments ($p=0.465$)

Patient Satisfaction:

Patient satisfaction scores were higher in the amorolfine group, reflecting greater overall satisfaction with the treatment.

DISCUSSION

This study demonstrates that amorolfine cream is more effective than ciclopirox olamine cream in treating local cutaneous dermatophytosis. The higher clinical and mycological cure rates with amorolfine highlight its superior efficacy. The safety profile of both treatments was acceptable, with mild local irritation being the most common adverse effect. The slightly better safety profile of amorolfine may be attributed to its lower incidence of local irritation.

The findings of this study are consistent with previous research indicating the efficacy of amorolfine in treating fungal infections. The superior efficacy of amorolfine may be due to its potent inhibition of ergosterol biosynthesis, leading to more effective disruption of the fungal cell membrane.

Clinical implications:

The study demonstrates that amorolfine cream provides a higher clinical and mycological cure rate compared to ciclopirox olamine cream. This finding suggests that healthcare providers should consider amorolfine as a more effective option for treating local cutaneous dermatophytosis, potentially leading to better patient outcomes and faster resolution of symptoms.

Both treatments were generally well-tolerated, with mild local irritation being the most common adverse effect. However, amorolfine showed a slightly better safety profile with fewer instances of local irritation, making it a safer option for patients, especially those with sensitive skin or a history of adverse reactions to topical treatments.

Patients treated with amorolfine reported higher satisfaction scores, likely due to the faster symptom relief and lower recurrence rates. This indicates that amorolfine not only treats the infection effectively but also enhances the overall patient experience, which can improve adherence to treatment regimens and reduce the likelihood of treatment discontinuation.

The evidence provided by this study can aid dermatologists and primary care physicians in making informed decisions when selecting a topical antifungal treatment for dermatophytosis. The superior efficacy and safety profile of amorolfine may justify its preference over ciclopirox olamine in clinical practice.

Limitations:

study is single centred which is insufficient to generalize the findings to all populations. Shorter study insufficient to evaluate the long-term efficacy and

safety of amorolfine and ciclopirox olamine creams. Although adherence was ensured through monthly follow-up visits, self-reported adherence can be unreliable. The study excluded patients with certain conditions such as immunocompromising diseases, which limits the applicability of the findings to these patient populations.

CONCLUSION:

This randomized controlled trial demonstrates that amorolfine cream is more effective than ciclopirox olamine cream in the management of local cutaneous dermatophytosis. Patients treated with amorolfine cream exhibited significantly higher clinical and mycological cure rates.

Both treatments were well tolerated, with mild local irritation being the most common adverse effect. However, amorolfine had a slightly better safety profile, with fewer patients reporting irritation.

Overall, these findings suggest that amorolfine cream should be considered a preferred option for the topical treatment of dermatophytosis due to its superior efficacy and good safety profile. Further research with larger and more diverse populations, along with longer follow-up periods, is warranted to confirm these results and to evaluate the long-term benefits of amorolfine in the management of dermatophytosis.

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