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Comparative Study between Topical Terbinafine 1% Cream and Topical Aluminum Chloride Hexahydrate 15% in Ethyl Alcohol Solution in Treatment of Interdigital Tinea Pedis

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ABSTRACT

Background: Tinea pedis places a significant burden on patients. The standard treatment is antifungals, e.g., terbinafine. However, the efficacy of the drug has been questioned in the last years with the appearance of resistance to the drug. The introduction of other drugs is essential.

The aim of the work: The aim was to assess and compare the efficacy and safety of topical terbinafine 1% cream versus aluminum chloride hexahydrate 15% in ethyl alcohol solution in treating interdigital tinea pedis.

Patients and Methods: Two groups of patients were included [each 37 patients]. All had been clinically diagnosed with interdigital tinea pedis and scheduled for treatment with terbinafine 1% cream once daily for one month [group A] or aluminum chloride hexahydrate 15% in ethyl alcohol solution once daily for one month [group B]. All patients submitted to standard medical assessment before initiation of treatment and photographs were captured for documents. Then all patients were followed up every two weeks for 3 months after initiation of the treatment. They were assessed for clinical improvement [efficacy], side effects [safety], and recurrence rate.

Results: The mean age was around 40 years, with a high incidence among females. Improvement was higher among group B than group A. But the difference was non-significant. The side effects were more in group B with significant differences [35.13% versus 8.1%]. Burning alone or with redness and dryness were the commonest side effects. The recurrence was higher in B than A groups [20.0% versus 15.38% respectively]. However, the difference was statistically non-significant.

Conclusions: Terbinafine and aluminum chloride are effective in the treatment of interdigital tinea pedis with a superior safety profile for terbinafine. However, the higher success rate with aluminum chloride recommends its use especially since the side effects were mild and resolved with proper care.

Keywords: Antifungal; Terbinafine; Aluminum Chloride; Athlete's foot; Sweat.

INTRODUCTION

Tinea pedis, also known as "-athlete's foot" is an infection of the soles, interdigital clefts of toes, and nails. Its incidence increases with advanced age and it is the most common disease of the feet. The dermatophyte fungi are the principal cause, while some molds and yeast are responsible less frequently. The keratin layer of the skin is invaded by the fungus through keratinase and mannans suppress the body's immune response [1-3].

Risk factors for tinea pedis are diverse and include humidity, tight footwear, and comorbid disease conditions [e.g., diabetes mellitus, obesity, vascular disorder, bone and joint disease] [4-6].

Clinically, tinea pedis is classified into hyperkeratotic, vesicular, interdigital, and ulcerative types. The commonest type is the interdigital one. It affects the interdigital spaces of the fourth and fifth toes and then progresses to the spaces between other toes, leading to maceration, exfoliation, and cracking [1].

For treatment, topical terbinafine is the most commonly used medication. It has a broad-spectrum antifungal action against different fungal infections of the skin. It exerts its action through the inhibition of squalene epoxidase in the fungal biosynthesis of ergosterol. Ergosterol is an essential element for cell membrane growth leading to the accumulation of squalene [2,7].

In patients with chronic tinea pedis, keeping the toes dry is important and beneficial to prevent recurrence [3].

As early as the 1970s, **Leyden and Kligman** [8] recommended aluminum chloride for the treatment of symptomatic tinea pedis. They confirmed the superiority of aluminum chloride over other salts of aluminum in control of superinfected tinea pedis symptoms. They explained these effects by the ability of the solution to dry the skin surface. In addition, a concentration of 20 – 30% of aluminum chloride had a disinfectant action against gram-positive and gram-negative bacteria, yeasts, and other dermatophytes [10,11].

Aluminum chloride hexahydrate is associated with the reduction of sweat production by blocking the lumen of the ducts of the distal eccrine sweat glands, with secondary changes [e.g., atrophy and necrosis] may occur to the sweat glands with destruction of secretory units [12]. However, the data comparing terbinafine to aluminum chloride hexahydrate in the treatment of tinea pedis is deficient. Thus, the current work aimed to assess and compare the efficacy and safety of topical terbinafine 1% cream versus aluminum chloride hexahydrate 15% in ethyl alcohol solution in treating interdigital tinea pedis.

PATIENTS AND METHODS

This was a prospective, double-blinded, double-armed, simple randomized clinical trial. It is carried out at the outpatient clinic of the Department of Dermatology and Venereology, Damietta University Hospital, Al-Azhar University [Damietta, Egypt].

It was completed between April 2023 to January 2024.

It finally included 74 patients with clinical diagnoses of interdigital tinea pedis. They were divided into two groups [37 each] by a simple randomization process. The first group [Group A] received a topical terbinafine 1% cream once daily for one month. The second group [Group B] received topical aluminum chloride hexahydrate 15% in ethyl alcohol solution once daily for one month.

The inclusion criteria were clinical diagnosis with interdigital tinea pedis, of both sexes aged 18 years or more. On the other side, patients with a history of hypersensitivity to terbinafine or aluminum chloride, immunocompromised, pregnant, and lactating females were excluded from the study.

Ethical considerations: The study protocol was reviewed and approved by the institutional review board [IRB] for research and ethics [Damietta Faculty of Medicine, Al-Azhar University, Damietta, Egypt; DFM-IRB00012367-23-01-001]. The study protocol was explained for each patient and an informed consent was signed. The study was completed by the ethical codes of the Helsinki Declaration for research conduct and reporting. Collected data were anonymized and used only for the study. All subjects retain their right to withdraw at any time without any harm or effect on their treatment protocol.

For each patient, a full medical history was reviewed. Then, a clinical examination from head to toe was performed to confirm diagnosis and rule out other associated fungal infections. Finally, a local dermatological examination of the interdigital spaces was performed for all included subjects.

The treatment protocol: according to the classification and grouping of patients, group A received topical terbinafine 1% cream once daily for one month and group B received topical Aluminum chloride hexahydrate 15% in ethyl alcohol solution once daily for one month. All patients were instructed to keep dryness of their legs after washing and to wear sandals.

Clinical evaluation: initial evaluation was done for all patients before initiation of the treatment. Then, regular evaluation was performed every two weeks for 3 months after the initiation of treatment by serial photographs. Finally, the photographs before and after treatment were compared.

The outcome [the result of treatment] was assessed as a complete cure, with a resolution of clinical signs and symptoms of tinea pedis, adverse events [e.g., erythema, burning sensations, and blister formation], where adverse events were related to the used drugs as judged by the investigators, treatment failure, defined as lack of significant clinical improvement after the 4 weeks of treatment and recurrence, where the infection recurred after cure during the follow-up period.

Data analysis: The statistical package for social science [SPSS], version 20 [IBM Inc., Armonk, NY, USA] was used for statistical analysis. Qualitative variables were expressed by their relative frequency and percentages. On the other side, quantitative variables were presented by their mean, minimum, maximum, and standard deviation [SD] when normally distributed. The non-normally distributed data were expressed by their median and interquartile range. The normality Shapiro-Wilk test was used as a test of normality. P value < 0.05 was considered statistically significant. The significance tests were Chi-square tests for qualitative variables. Otherwise, Fisher's Exact or Monte Carlo was used for

correction of Chi-square when > 20% of the cells have expected count < 5. The independent samples student "t" test was used for comparison between the two groups. However, the Mann-Whitney test was used for abnormally distributed quantitative variables.

RESULTS

In the current work, 37 patients with interdigital tinea pedis were included in each group. They were essentially in their fourth decade of life. Females were more represented in both groups than males. Most of them were housewives. The disease onset was gradual in all patients with a progressive course. The disease duration ranged between 3 to 6 weeks and the infection was mainly mild. There were no significant differences between groups A and B regarding demographic characteristics of patients or disease characteristics **[Table 1]. Table [2]** represents the clinical improvement over time of follow-up. Both groups were comparable [no significant differences] in the second and fourth weeks after treatment, although improvement was higher in group B. however, the side effects were more in group B with statistically significant differences. The total side effects were reported among 35.13% and 8.1% in groups B and A respectively. The main side effect was burning with redness or dryness.

Regarding recurrence at the end of the 12th week after initiation of treatment, it was higher in group B than in group A [20.0% versus 15.38% respectively]. However, the difference was statistically non-significant. The recurrence at the 6th and 8th weeks was higher among group B, then it was higher among group A in the 10th and 12th weeks. Again, the difference between groups A and B was statistically non-significant **[Table 3].**

Table [1]: Patient and disease characteristics among study groups

		Group-A	Group-B	Test	p
Age [years] [mean±SD]		38.21±10.34	41±13.11	1.014	0.314
Sex [n,%]	Male	9[24.32]	12[32.43]	0.598	0.439
	Female	28[75.67]	25[67.56]		
Occupation [n,%]	Housewife	18[48.64%]	18[48.64%]	4.876	0.907
	Employee	16 [43.2%]	13 [37.8%]		
	Farmer	2 [5.4%]	3 [8.1%]		
	Student	1 [2.7%]	2 [5.4%]		
Gradual disease onset [n,%]		37 [100.0%]	37 [100.0%]	0.001	1.0
Progressive course [n,%]		37 [100.0%]	37 [100.0%]	0.001	1.0
Disease duration [weeks] [median, IQR]		4 [3-6]	4 [4-6]	1.56	0.118
Degree of Associated symptoms [n,%]	**Mild**	21 [56.8%]	28 [75.7%]	3.13	0.209
	Moderate	15 [40.5%]	8 [21.6%]		
	Severe	1 [2.7%]	1 [2.7%]		

Group- A for terbinafine and group- B for Aluminum chloride hexahydrate

Table [2]: Clinical improvement overtime and side effects among study groups

		Group-A	Group-B	Test	p
Clinical improvement after the second week of treatment [n,%]	Improved	22 [59.45%]	24 [64.86%]	0.230	0.632
	Not-improved	15 [40.54%]	13 [35.13%]		
Clinical improvement after the fourth week of treatment [n,%]	Improved	26[70.27%]	30[81.08%]	1.175	0.278
	Not-improved	11 [29.72%]	7 [18.91%]		
Side effects [n,%]	None	34 [91.9%]	24 [64.86%]	11.557	0.003*
	Burning	1 [2.70%]	7 [18.91%]		
	Burning and redness	2 [5.40%]	1 [2.70%]		
	Burning and dryness	0 [0.0%]	5 [13.51%]		
Total side effects [n,%]		3 [8.1%]	13 [35.13%]	7.97	0.005*

Group- A for terbinafine and group- B for Aluminum chloride hexahydrate

Table [3]: Recurrence rate among study groups over the follow up period

	Group-A	Group B	Test	p
No recurrence	22[84.61]	24[80]	4.54	0.56
Recurrence at the 6th week	0 [0.0%]	3 [10.0%]		
Recurrence at the 8th week	1[3.84%]	2[6.66%]		
Recurrence at the 10th week	2[7.69%]	1 [3.33%]		
Recurrence at the 12th week	1[3.84%]	0 [0.0%]		
Total recurrence	4 [15.38%]	6 [20.0%]	0.463	0.496

Group- A for terbinafine and group- B for Aluminum chloride hexahydrate

In the next section, we presented a photographic assessment of some cases of both groups. We started with group A [terbinafine]. The first pictures were of a 47 years old female, housewife with interdigital tinea pedis. There was clinical improvement at the end of the 4th week of treatment [Figures 1-3] describe the clinical condition before treatment, and 2 and 4 weeks after treatment. The second picture was for a 34 years old male, working as an engineer, with interdigital tinea pedis. Figures 4-6 describe the case before, 2 weeks, and 4 weeks after treatment. There was clinical improvement at the end of the fourth week.

In group B, the first case was for a 23-year-old farmer with interdigital

tinea pedis. Figures 7 to 9 were for the condition before, two weeks, and four weeks after treatment. There was clinical improvement. The second case was for 57 years old female, housewife, with interdigital tinea pedis. Figures 10 to 12 showed the condition before, 2, and 4 weeks after treatment. There was clinical improvement after the 4th week of treatment

Figure [1]: Before treatment

Figure [2]: two weeks after treatment

Figure [3]: Four weeks after treatment

Figure [4]: Before treatment

Figure [5]: two weeks after treatment

Figure [6]: Four weeks after treatment

Figure [7]: Before treatment

Figure [8]: two weeks after treatment

Figure [9]: Four weeks after treatment

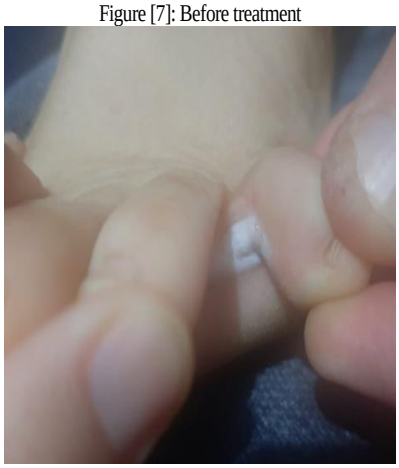

Figure [10]: Before treatment

Figure [11]: two weeks after treatment

Figure [12]: Four weeks after treatment

DISCUSSION

Despite the advances in anti-fungal medication, the incidence of tinea pedis showed a marked increase in recent years. People at risk of dermatophyte infection include miners, marathon runners, and soldiers due to tight footwear [8].

In addition, there was no consensus on the standard medical treatment of athlete's foot. Here we compared topical terbinafine 1% cream versus aluminum chloride hexahydrate 15% in ethyl alcohol solution in treatment regarding the safety and efficacy. Results showed that aluminum chloride hexahydrate 15% in ethyl alcohol solution was more effective than terbinafine 1% cream. However, the difference was statistically non-significant. Interestingly, aluminum chloride hexahydrate 15% had a significantly higher rate of side effects. This could be attributed to the sweat-reduction effect of aluminum chloride due to atrophy of sweat glands [11].

The reported age in the current work comes in line with **Toukabri *et al.*** [12] who conducted a prospective trial for Tunisian subjects with tinea pedis [n=392]. Their age ranged between 31 to 60 years. The average age was 44.7 years [slightly higher than the current work].

In addition, the results are comparable to **El Fekih *et al.*** [13] who reported peak age of tinea pedis is between 16 and 45 years. The average age was 42 years.

This could be explained by the fact that this age is the age of full-time working activity, exposure to nail trauma, chronic medical diseases, and reduced growth of the nails. In addition, reduced proper foot care may predispose to the infection [14-16].

In the present study, we found female predominance among studied patients, as 75.67% and 67.56% were female in terbinafine and aluminum chloride hexahydrate groups respectively. This higher incidence in females may be explained by activities specific to females [e.g., repeated aggressive pedicures and manicures, the use of detergents [with nail trauma], and frequent housework [12].

Different reports had a female predilection among tinea pedis [17-20]. However, other studies reported a higher incidence in males than females [4,21]. This was attributed to more exposure to nail trauma and the usual use of tight footwear.

In this particular study, we found significant improvement among patients after the second and fourth weeks of treatment [59.45%, 70.27% and 64.86%, 81.08%] in terbinafine and Aluminum chloride groups respectively, with no significant differences.

The only available study about aluminum chloride was that of **Leyden and Kligman** [8] who reported effective results in treating tinea pedis. Other studies essentially report on the results of aluminum chloride in the treatment of hyperhidrosis. However, many trials reported the efficacy of topical terbinafine in tinea pedis. For example, **Ward *et al.*** [7] conducted a systematic review of 1042 adult participants [from 7 randomized trials] with tinea pedis to assess the efficacy of pharmaceutical treatment. They concluded that topical terbinafine was more effective than placebo. Other reports also confirmed the efficacy of terbinafine with a cure rate between 81 and 100% within 6 to 8 weeks after initiation of treatment. Terbinafine was administered as 1% cream, solution, gel, or nano-formulations once or twice daily for 1 to 4 weeks [22-23]. However, resistance to terbinafine treatment was reported [25].

Returning to the study **Leyden and Kligman** [8], used aluminum chloride [30.0%] for 11 patients with bilateral, wet, macerated, interdigital tinea pedis. They used a cotton tip to apply the drug two times daily for one week. After this week, 75% of patients showed clinical improvement. In addition, the total flora between the toes showed a significant reduction [the reduction percentage reached 99% in some cases]. The antibacterial and anti-fungal actions of aluminum chloride are explained by the direct killing effect and the drying effect of the drug. The absence of moisture is one of the important factors to guard against fungal infection.

The higher success rate with aluminum chloride in the current study may be explained by the use of alcohol which permits penetration of the active ingredient deeper in the skin and promotes its retention time. Alcohol itself is used as a disinfectant. Aluminum chloride eradicates also commensal flora of the skin, which may affect the resolution of tinea pedis clinical manifestation [7].

Concerning safety, topical terbinafine 1% cream was safe and well tolerated. However, a burning sensation was reported by one patient in the current work, and burning with redness was observed in 2 patients. These effects were mild and resolved rapidly.

These results are in line with **James *et al.*** [22] who evaluated the effectiveness of two concentrations of terbinafine [1 and 3%] emulsion gel, used once daily for 5 days for tinea pedis treatment. Only one patient in each group reported mild burning or irritation. Similarly, one patient in placebo group reported a stinging sensation.

Li RY *et al.* [26] reported mild adverse events with terbinafine when used for the treatment of tinea pedis. The overall incidence of side effects was 4% [2% in each treatment group, terbinafine versus placebo].

The adverse effects were significantly higher among the aluminum chloride group and this could be attributed to alcohol solution which may cause irritation and burning sensations [the commonest side effect was redness or dryness] [8].

The recurrence rate was higher in aluminum chloride than terbinafine group. But the difference was not significant. These findings were by **Ortonne *et al.*** [27] who included 273 patients treated with terbinafine 1%. They reported that the recurrence was reported among 12.5% in the 12th week after treatment.

Schäfer-Korting *et al.* [28] reported less frequent side effects with terbinafine 1%. They reported a relapse rate of 10.0% at 1 week of treatment.

Several factors were responsible for recurrence [e.g., virulence of the fungi, host immunity, environmental and pharmacological factors] [29].

The value of the current work comes from the use of aluminum chloride. As expected, it had a higher success rate, but unfortunately with higher side effects. However, this study had some limitations. One of them is a relatively small sample size. In addition, selection bias was unavoidable, as studied patients were primarily recruited from those attending our clinic only. Therefore, there is a need for larger multi-center research.

Finally, we conclude that terbinafine and aluminum chloride are effective in the treatment of interdigital tinea pedis with a superior safety profile for terbinafine. However, the higher success rate with aluminum chloride recommends its use especially since the side effects were mild and resolved with proper care.

Conflict of interest: none

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