

Assessment of Efficacy & Safety of Topical Eberconazole and Terbinafine in Patients of Tinea Versicolor

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Abstract

Background: To compare the safety & efficacy of Eberconazole and Terbinafine in patients of Tinea Versicolor. **Subjects and Methods:** 100 patients (58 males & 42 females) were selected and they were divided into two study groups. Group I patients were prescribed Terbinafine 1% cream for 15 days and group II received Eberconazole 1% cream for 15 days. Global clinical response assessment and visual analog scale was recorded in both groups. **Results:** There were 30 males and 22 females in group I and 28 males and 20 females in group II. In group I, 44 (88%) and in group II 39 (78%) showed complete healing. Mild residual disease was seen among 6 (12%) in group I and 10 (20%) in group II. Considerable residual disease was seen in 1 (2%) in group II only. A significant difference was observed between both groups ($P < 0.05$). The mean VAS score on baseline was 6.4 in group I and 7.0 in group II, on 7th day was 4.3 in group I and 5.4 in group II and on 15th day was 2.1 in group I and 2.9 in group II. Intergroup comparison showed non-significant difference ($P > 0.05$). **Conclusion:** Both Eberconazole & Terbinafine drugs were effective in management of cases of Tinea Versicolor. Eberconazole, a newer azole can be a new addition in the armamentarium for the treatment of tinea versicolor.

Keywords: Eberconazole, Global clinical response, Tinea versicolor, Terbinafine

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Introduction

Tinea versicolor (TV) (Peter Elam's disease or Pityriasis Versicolor) is a chronically, recurring infectious fungal skin disease of the stratum corneum, commonly seen during summer. As fungus *Malassezia furfur*, an opportunistic organism, live alongside cells of body in symbiotic relationships, so normally doesn't cause any health problems.^[1] It is found on the surface of the skin, with skin cells and tiny organisms supporting and benefiting each other. The scale appears like bran & the multiple colours gives rise to the other part of the name, versicolor. It commonly affects young adults and more prevalent in men than in women. Moreover, it occurs in children, adolescents, and older adults.^[2]

The management of Tinea versicolor involve topical, systemic oral antifungal agent. The topical antifungal therapy has several advantages & fewer side effects over systemic management as it has lower cost & ensures localization of treatment.^[3] For its treatment, the azole antifungal compounds used are: ketoconazole, clotrimazole, econazole, sertaconazole, sulconazole, miconazole, etc.^[4]

Eberconazole, a broad-spectrum antifungal agent & an imidazole derivative is a topical preparation for treatment of cutaneous mycoses.^[5] This antimycotic agent causes holes in the fungal cell membranes (essential for survival as it

prevents entry of undesirable substance into the cells & prevents leakage of cell contents) and kills fungi resulting in treating fungal infection and provides relief from burning, cracking, itching & scaling of the skin caused due to infections.^[6] Terbinafine blocks the biosynthesis of ergosterol by inhibiting the enzyme squalene epoxidase in the fungal cell membrane, & leads to accumulation of squalene (fungicidal activity).^[7] Considering this, present study compared the efficacy and safety of eberconazole versus terbinafine in Tinea Versicolor.

Subjects and Methods

The present randomized, comparative study was conducted on 100 patients diagnosed with Tinea Versicolor of either gender. All the patients who were enrolled for the study, signed an informed consent & completed the study as per protocol. Ethical clearance was obtained before commencing the study.

Demographic data of each patient was recorded in case history proforma. Patients were divided into two study groups of fifty each. Group I patients received Terbinafine 1% cream once a day for 15 days and group II received Eberconazole 1% cream once a day for 15 days. Parameter such as scaling, pruritis and erythema was recorded on 7th day & 15th days with the help of scale of 0-3 (0-absent, 1-

mild, 2-moderate, 3-severe). Patient's assessment on visual analog scale was also done. Data were expressed as mean ± standard error and were analyzed using Chi-square test. P < 0.05 was considered as statistically significant.

Results

Table 1: Distribution of patients

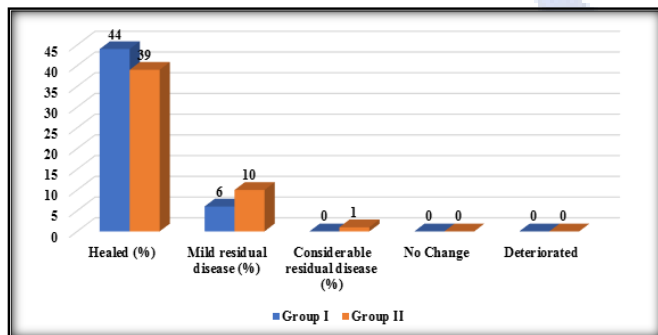
Groups	Group I	Group II
Drug	1% Terbinafine cream	1% Eberconazole cream
M:F	30:22	28:20

There were 30 males and 22 females in group I and 28 males and 20 females in group II (Table I).

Table 2: v Evaluation of global clinical assessment

Parameters	Group I	Group II	P value
Healed (%)	44 (88)	39 (78)	<0.05
Mild residual disease (%)	6 (12)	10 (20)	
Considerable residual disease (%)	0	1 (2)	
No Change	0	0	
Deteriorated	0	0	

It was found that in group I, 44 (88%) and in group II 39 (78%) showed complete healing. Mild residual disease was seen among 6 (12%) in group I and 10 (20%) in group II. Considerable residual disease was seen in 1 (2%) I group II only. A significant difference was observed between both groups (P< 0.05) (Table II, graph I)

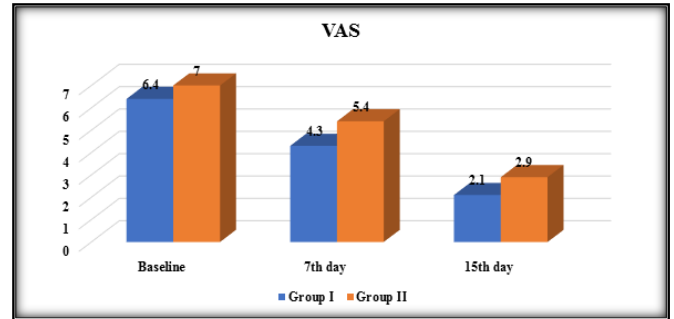


Graph 1: Evaluation of global clinical assessment

Table 3: Assessment of VAS score

VAS	Group I	Group II	P value
Baseline	6.4	7.0	>0.05
7th day	4.3	5.4	>0.05
15th day	2.1	2.9	>0.05

The mean VAS score on baseline was 6.4 in group I and 7.0 in group II, on 7th day was 4.3 in group I and 5.4 in group II and on 15th day was 2.1 in group I and 2.9 in group II. Intergroup comparison showed non- significant difference (P> 0.05) (Table III, graph II).



Graph 2: Assessment of VAS score

Discussion

Pityriasis versicolor, also known as tinea versicolor is a superficial chronically recurring fungal infection of the stratum corneum, characterized by scaly, dyspigmented irregular macules most often occurring on the trunk and extremities.^[8] The organism can easily be diagnosed by treating skin scraping with 10% KOH and shows short, thick hyphae with a large number of variously sized spores.^[9] It is evident that in the brown type of pityriasis versicolor, the yeasts induce enlarged pigment granules called melanosomes and in the white or hypopigmented type of pityriasis versicolor is result of a chemical produced by malassezia that diffuses into the epidermis and impairs the function of the melanocytes.^[10] The pink type of pityriasis versicolor, mildly inflamed is due to dermatitis induced by malassezia or its metabolites. It is characterized by hyper/hypo pigmented, scaly macules located on the trunk and proximal extremities. These patches may be pink, tan, red or brown, lighter (more common) or darker than the surrounding skin, itchy, dry and scaly and more prominent with tanning. Many systemic and topical antifungals in various forms are used in the treatment of pityriasis versicolor with an overall positive result.^[11] The present study compared the efficacy and safety of eberconazole versus terbinafine in Tinea Versicolor.

Our results showed that there were 30 males and 22 females in group I and 28 males and 20 females in group II. Group I patients received Terbinafine 1% cream once a day for 15 days and group II received Eberconazole 1% cream once a day for 15 days. According to study done by Choudhary et al^[12] patients with tinea cruris & tenia corporis were treated with topical 1% eberconazole nitrate cream & 1% terbinafine twice daily for 3 weeks. At the end of 21 days, there was 100% cure rate in both groups. It was found that 1% eberconazole nitrate cream was superior than 1% terbinafine hydrochloride cream in cases of tinea corporis and cruris. Our results showed that in group I, 44 (88%) and in group II 39 (78%) showed complete healing. Mild residual disease was seen among 6 (12%) in group I and 10 (20%) in group II. Considerable residual disease was seen in 1 (2%) I group II only. Chopra and Jain et al^[13] in their study on 25 patients who were treated either with 2% ketoconazole cream (Group A) and 1% terbinafine cream (Group B) once daily for 2 weeks found 100% cure of the patients in both groups whereas 96% patients in terbinafine and 88% in ketoconazole group showed mycological cure. Results showed that 80% in

Group A and 96% in Group B were considered healed, leaving 20% in Group A and 4% in Group B with mild residual disease.

We observed that the mean VAS score on baseline was 6.4 in group I and 7.0 in group II, on 7th day was 4.3 in group I and 5.4 in group II and on 15th day was 2.1 in group I and 2.9 in group II. Repiso Montero et al^[14] compared eberconazole 1% cream with miconazole 2% cream applied twice daily for 4 weeks in the treatment of dermatophytosis and found that clinical efficacy with eberconazole was 76.1% versus 75% in miconazole group. del Palacio et al^[15] found that eberconazole was more efficient than clotrimazole for dermatophytosis treatment with overall efficacy of 61% for clotrimazole & 72% for eberconazole. But both groups showed no significant difference in case of relapse.

Conclusion

Both Eberconazole & Terbinafine drugs were effective in management of cases of Tinea Versicolor. Eberconazole, a newer azole can be a new addition in the armamentarium for the treatment of tinea versicolor.

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