EFFICACY OF ITRACONAZOLE PULSE THERAPY WITH ADJUVANT ISOTRETINOIN IN THE TREATMENT OF RECURRENT AND RECALCITRANT DERMATOPHYTOSIS

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ABSTRACT

Background; There is a significant increase in the number of cases presented with atypical and unusual dermatophytosis. These patients have chronic and recurrent infection and seems to be more resistant to conventional topical and systemic treatments. This necessitates the use of other adjuvant treatment options such as isotretinoin along with itraconazole that would help to cure these challenging cases.

Objective: To determine the efficacy of monthly pulse of oral itraconazole in combination with daily low dose of isotretinoin in the treatment of recurrent and recalcitrant dermatophytosis.

Methods: This study was carried out in department of Dermatology, Shalamar Hospital, Lahore. Sixty patients attending the dermatology outpatient department at Shalamar Hospital Lahore, fulfilling the inclusion criteria were enrolled in the study. Patients were given oral itraconazole 200mg two times a day for 7 days/ month for 3 months with adjuvant 20 mg isotretinoin/day for the same duration. All the patients also received topical white soft paraffin and antihistamines. Patients were followed up monthly for first three months after starting the treatment and then once at the sixth week after stopping the treatment. During each follow up visit, clinical assessment score was recorded. All the information was collected in predesigned proforma.

Results: Mean age of patients was 36.03±6.11 years, duration of disease 6.83±1.86 months, baseline and post treatment clinical assessment score (CAS) was 3.11±0.61 and 0.16±0.49 respectively. There were 55.0% (n=33) males and 45.0% (n=27) females. Among the co-morbidities studied, frequency of diabetes mellitus was 23.3% (n=14) and 15.0% (n=9) had family history of dermatophytosis. Ten percent (n=6) had history of contact with domestic or wild animal. Out of 60 patients, efficacy was achieved in 88.3 % (n=53).

Conclusion: It is concluded that pulse therapy of Itraconazole with adjuvant daily Isotretinoin is an effective treatment regimen in treating recurrent & recalcitrant superficial dermatophytosis.

Keywords: Dermatophytosis, Isotretinoin, Itraconazole.

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INTRODUCTION

Fungal diseases can be divided into superficial mycosis, subcutaneous mycosis, and systemic mycosis.[1] Among superficial mycosis, dermatophytosis is the most common contagious infection caused by keratinophilic fungi affecting approximately 20-25% of the worldwide population.[1,2] It affects the outermost layer of skin and its appendages such as hair and nails.[1,2] Dermatophytic infections are becoming increasingly common and

recent studies showed their prevalence ranging from 36.6% to 78.4% among patients attending dermatology outpatient departments.[3,4]

Dermatophytosis is currently a public health problem deleteriously affecting the quality of life of the patients in many parts of the world particularly in developing countries.[1,2] Over-crowding, low socioeconomic status, inadequate health facilities, hot and humid climate, poor hygiene, sharing of clothing and close contact with affected family members in developing countries have been recognized as potential risk factors for the proliferation of the disease. [1,2,5,6,7]

Diagnosis of dermatophytosis is mainly clinical. When needed, microscopy with KOH preparation and fungal culture are performed. Dermatophytic infections can be treated with both topical and/or systemic antifungal agents which include imidazoles, triazoles, allylamines, morpholines, griseofulvin and polyenes.[7,8] Cases of recurrent and recalcitrant cases of superficial dermatophytosis are on the rise and they are challenging to treat.[9] It has been observed that monotherapy with oral antifungals like terbinafine and fluconazole results in partial clearance or relapse of the lesions.[9] Itraconazole have shown higher cure rates but still there are many cases of relapsing and recurring superficial dermatophytic infection in our daily practice.[5,6,10] Moreover, the resistance against fluconazole and terbinafine has been documented in many studies.[5] So, there emerges a need to have some effective adjuvant therapy or new treatment regimen which reduces recurrences and relapses in superficial dermatophytic infection.[5,9]

Recently, a combination therapy of oral itraconazole and oral isotretinoin was reported to successfully treat recurrent and recalcitrant dermatophytosis.[3,9,11] Isotretinoin was found to be a good adjuvant to systemic antifungals to reduce this recurrences and relapses.[5,9] It works by increasing the epidermal cell turnover and increase in skin pH that would help to eliminate the growing dermatophyte. Moreover, the keratolytic and immunomodulatory effects of isotretinoin play an important role to inhibit the dermatophyte growth.[3,5,9,11]

In a study conducted by Rahman *et al.* in Bangladesh, efficacy of pulse therapy of itraconazole with adjuvant isotretinoin in treatment of recurrent and recalcitrant dermatophytosis was 90%.[9] In another study conducted by Fathia *et al.* in Egypt, the efficacy of similar combination was found to be 70%.[10]

Only few studies have been conducted worldwide to determine the efficacy of this combination in recurrent and recalcitrant dermatophytosis. In this study, we determined the efficacy of monthly pulse of oral itraconazole in combination with daily low dose of isotretinoin in the treatment of recurrent and recalcitrant dermatophytosis in our population.

METHOD

This quasi-experimental study was conducted in department of Dermatology, Shalamar Medical & Dental College/ Shalamar Hospital, Lahore from 20-02-2024 to 20-08-2024. After taking approval from the ethical review board of the hospital, 60 patients with clinical evidence of dermatophytosis fulfilling the inclusion criterion were enrolled from the outpatient department of the hospital by non-probability consecutive sampling technique. (The sample size was calculated with 95% confidence level, 8% margin of error while taking expected efficacy of itraconazole pulse therapy with adjuvant isotretinoin in treatment of recurrent and recalcitrant dermatophytosis as 90%.[9]) An informed consent was taken from all the patients. Patients of both genders, aged more than 18 years, having recurrent (re-occurrence of the dermatophyte infection <6 weeks after completion of approved systemic treatment.[5]) or recalcitrant (when there is no clinical cure in spite of treatment with systemic antifungal agent in an appropriate dose and for the duration of ≥ 6weeks) tinea corporis/ tinea cruris were enrolled. The area of involvement was at least ≥ 30% of the body surface area and they must not have taken any antifungal treatment for the past 4 weeks. Patients with body surface area involvement ≤ 30%, with deranged lipid profile or raised serum alanine transaminase (ALT), having co-morbidities like cardiac, liver or kidney impairments and pregnant / lactating females were excluded from the study.

Details of duration and progression of the disease, previous treatments taken, occupation, co-morbidities and other relevant history was obtained in all patients. Relevant examination was carried out. The percentage of body surface area involved and duration of infection was recorded. Investigations including serum alanine transaminase (ALT), serum creatinine, total cholesterol was done at baseline. Complete blood count (CBC), glycosylated hemoglobin (HbA1c), echocardiogram (ECG) and pregnancy test was carried out when and where needed. Photographic documentation was done at baseline and after the completion of treatment. Patients were given oral itraconazole 200mg two times a day for 7 days/month for 3 months with adjuvant 20 mg isotretinoin/day for the same duration. All the patients also received topical white soft paraffin and oral antihistamine. Patients were followed up monthly for first three months after starting the treatment and at the sixth week after stopping the treatment. Efficacy was labelled as complete clinical cure after 3 months of

treatment and no relapse after six weeks of stopping treatment. Reappearance of the clinical signs of infection like erythema, scaling or pruritus was considered as the relapse of the disease. During each follow up visit, clinical assessment score (CAS) was recorded. CAS was assessed clinically on the basis of 3 parameters; erythema, pruritis and scaling which was graded on 4-point scale (0=absent,1=mild,2=moderate and 3=severe) from baseline to end of treatment period. The worst affected area was selected as a target area. Then the 3 scores of target area were added to get a clinical assessment score.[2,9] Complete clinical cure was considered as zero CAS score. Various adverse effects like skin and lips dryness, photosensitivity, gastritis, liver function tests or lipid profile derangements were also looked for in each follow up visit.

All the information was collected in predesigned proforma. Data was analyzed in statistical package for the social sciences (SPSS) version 26.0.

RESULTS

Out of 60 patients, 33 were males (55%) and 27 were females (45%). Age distribution of the patients showed that 48 of our patients (80%) were in age group of 18-40 years and 12 were in age group of >40 years (20%). Mean age was calculated as 36.03 (±6.11) years.

Mean duration of disease was 6.83±1.86 months.

In terms of occupation, 23 were farmers (38.3%), 18 had office job (38.3%) and 19 were household (31.7%). Among comorbidities, 14 patients had diabetes mellitus (23.3%). Six of our patients had history of contact with domestic or wild animals (10%). Family history of dermatophytosis was found in 9 patients (15%).

Baseline CAS was 3.11 (±0.61) and post treatment CAS was 0.16 (±0.49). Efficacy was achieved in 53, (88.3%) of our patients. Relapse was noted in 3, (5%) of the patients which was not statistically significant

The data was stratified for age, gender, occupation, diabetes, family history, and history of contact with domestic or wild animal. Table No. 1

Efficacy was achieved in 89.6% of the patients in age group (18-40 years) compared to 83.3% achieved in patients who are more than 40 years. Female patients 96.3% responded little better than their male 81.8% counterparts. Similarly, household patients responded better than farmers and service men. When the studied the correlation between the efficacy among diabetic patients versus non-diabetic patients, it came out to be statistically significant with P- value of 0.045.

Non diabetic patients responded better and achieved efficacy better than the diabetic patients. 93% of the non-diabetic patients responded as compared to 71.4% of diabetic patients. Patients without family history of dermatophytic infection responded better than the patients with family history of dermatophytic infection. Ninety percent of the patients without family history of infection were responded while 77.8% of the patients responded who had positive family history of the infection. Similarly, 90% of patients without any history of contact with domestic animals responded as compared to 66% with history of contact with domestic animals.

Table 1: Stratification for Efficacy with various variables using chi-square test N= 60

Age Group	Efficacy N (%)		Total (N)	P-value
	Yes	No		
18-40 years	43 (89.6%)	5 (10.4%)	48	0.619
>40 years	10(83.3%)	2(16.7%)	12	
Gender				
Male	27(81.8%)	6(18.2%)	33	0.116
Female	26(96.3%)	1(3.7%)	27	
Occupation				
Farmer	19(82.6%)	4(17.4%)	23	0.474
Service	16(88.9%)	2(11.1%)	18	
Household	18(94.7%)	1(5.3%)	19	
Diabetes mellitus				
Yes	10(71.4%)	4(28.6%)	14	0.045*
No	43(93.5%)	3(6.5%)	46	
Family history of dermatophytosis				
Yes	7(77.8%)	2(22.2%)	9	0.281
No	46(90.2%)	5(9.8%)	51	
H/O of contact with domestic or wild animal				
Yes	4(66.7%)	2(33.3%)	6	0.140
No	49(90.7%)	5(9.3%)	54	

DISCUSSION

Superficial dermatophytosis is among the common skin conditions which affect the tropical countries like ours due to hot and humid environment. Chronic and atypical dermatophytosis in the form of recurrent and recalcitrant infection is on the rise.[9] Combination therapy with multiple oral antifungals instead of monotherapy showed better outcome.[9] The resistance against traditional antifungals like azoles and terbinafine led to the use of newer treatment options like isotretinoin in such chronic dermatophytic infections. [3,5,9,11]

In the current study, we determined the efficacy of monthly pulsed dose of itraconazole in combination with daily low dose of isotretinoin in the treatment of recurrent and recalcitrant dermatophytosis which proved out to be efficacious in 88.3% of our patients. Comparison of our study with few of the international studies done in the recent past is shown in Table 2 .

Table 2: Comparison of the Current study with various past studies

	Current study	Priyadarshi D et al.,[12]	Alhamdi DK, Alhamdi KI [13]	Khattab F et al.,[14]	Rahman MH [9]
Year of study	2024	2023	2022	2022	2019
Place of study	Lahore, Pakistan	Uttar Pradesh, India	Iraq	Egypt	Bangladesh
Sample	60	180 randomised in 2 groups	81 randomized in two groups	90 randomised in three groups	40
Methodology	200mg oral itraconazole, two times a day for 7 days/month with adjuvant 20mg oral Isotretinoin/ day	Group A: 200 mg oral itraconazole/day Group B: 200mg oral itraconazole daily plus 20mg oral Isotretinoin/day	Group A: 200 mg oral itraconazole for 7 days /month Group B: 200mg oral itraconazole for 7 days/ month plus 10mg oral Isotretinoin on alternate days	Group A: 200mg oral itraconazole/day Group B: 200mg oral itraconazole/day plus 20mg oral isotretinoin/day Group C: oral voriconazole; 800mg 1st day, then 400mg/day	200mg oral itraconazole, twice daily for 7days/ month with adjuvant 20mg oral Isotretinoin/ day
Duration of study	3 months	2 months	2 months	6 weeks	3 months
Age	36 ± 6 years	Group A: 35 ±11years Group B: 34 ± 10 years	Group A: 38.9 ±1.9 years Group B: 39.6 ±1.9 years	Group A: 24 ±16 years Group B: 36±15 Group C: 36±20	21-30years: 27.5% 31-40 years: 52.5% 41-50 years: 20%
Duration of the disease	≥ 3 months	≥ 3 months	≥ 6 months	≥ 3 months	≥ 3 months
Family history of dermatophytosis	15%	N/A	N/A	75.6%	N/A
History of contact with domestic/wild animals	10%	N/A	64.2%	15.6%	N/A
Diabetes Mellitus /immunosuppressive state	23.3%	N/A	N/A	18.8 %	N/A
Efficacy/cure rate	88%	Group A: 89.2% Group B: 97.5%	Group A: 53.7% Group B: 97.5%	Group A: 53.3% Group B: 70% Group C: 83.3%	90%
Relapse rate	5%	Group A: 13.5% Group B: 2.6 %	Group A: 68.1% Group B: 12.8 %	Group A: 62.5% Group B: 33.3% Group C: 8%	15%
Adverse effects	No adverse effects reported	Group A: 7.7% Group B: 12.2 %	No adverse effects reported in both the groups	Group A: no Group B: 66% chelitis, 30% xerosis Group C: blurring of vision 6.7%, headache 3%	No adverse effects reported

The age of the patients in our study is comparable with many of the studies conducted on chronic dermatophytic infections. [9,12,13,14] Family history of dermatophytosis was noticed by Khattab F *et al*. which was quite high.[14] About 70% of his patients had family history of dermatophytic infection compared to 15% of our patients. This difference could be because of the reason that in our social set up, at times, patients did not want to fully disclose the information about other family members and the doctor has to rely on the information provided by the patient. Though different studies endorsed familial dermatophytosis an important factor in resistant and chronic infection.[15,16] History of contact with domestic or wild animals was found in 10% of our patients which is comparable with the study of Khattab F *et al.*[14] who reported it to be 15% but Alhamdi DK & Alhamidi KI[13] reported much higher rates of 64% and Tuknayat A *et al.*[15] reported it to be 37%. The difference could be due to the fact that in our country, we are not fond of pets and many people don't have pets at home.

Diabetes Mellitus was reported by 23.3 % of our patients. Similarly, Khattab *et al*. reported the disease in

18.8 % of his patients.[14] The association of cutaneous fungal infections is very well established with the diabetes mellitus.[17,18]

The efficacy in current study came out to be 88% which is comparable with the study conducted by Rahman MH[9] from Bangladesh who reported cure rate of 90%. He treated his patients with 200 mg oral itraconazole, twice daily for 7days/ month with adjuvant 20mg oral Isotretinoin/ day for the period of 3 months. Slightly higher cure rates were reported by Priyadarshi D *et al*.[12] and Alhamidi DK & Alhamidi KI.[13] Priyadarshi D *et al*.[12] reported 97.5% cure when she gave 200mg oral itraconazole/day plus 20mg oral Isotretinoin/day for the duration of 2 months and the exact similar cure rate of 97.5% was achieved by Alhamidi DK & Alhamidi KI[13] when they administered 200mg oral itraconazole for 7 days/ month plus 10mg oral Isotretinoin on alternate days for 2 months. Slightly lower cure rates of 70% were reported by Khattab F *et al*.[14] He treated the patients for 6 weeks while Priyadarshi D et al and Alhamidi DK & Alhamidi KI treated for 2 months and we in our study treated the patients for 3 months duration.

The relapse rate in our study after 6 weeks of stopping the treatment was 5%. Priyadarshi D *et a.l*[12] reported it to be 2.6% and Alhamidi DK & Alhamidi KI[13] 12.8%. However, Khattab *et al.* reported much higher relapse rate of 33% which could be due to the shorter duration of the treatment in his study.[14] The difference and variability in relapse rate could be due the various social and geographical environments of different areas. Various factors implicated could be non-compliance by the patient, presence of non-treated family member, humid environment and sharing of the clothes and washing the clothes in the same vessel etc.

No serious adverse effects were noted in our study which could have led the patient to stop the treatment. Mild dryness was managed with the moisturizers. Similarly, Alhamidi DK & Alhamidi KI[13] and Rahman MH[9] reported no adverse effects. However, Priyadarshi D *et al*.[12] reported adverse effects in 12.2 % in her patients and Khattab F et al[14] reported that 66% of his patients had chelitis and 30% has xerosis. The reason of higher adverse reactions in these two studies could be due to the reason that they administered itraconazole on daily basis instead of the pulse therapy given by other reference studies. Moreover, there were higher numbers of participants in Priyadarshi D *et al.* study.[12]

The use of low dose isotretinoin as an adjuvant therapy along with pulsed itraconazole proved to be efficacious in resistant and recalcitrant dermatophytic infection. This provides us advantage of decreasing the dose of itraconazole to 7 days instead of 30 days a month, thereby reducing the side effects and increasing the patients' compliance. Moreover, the adjuvant isotretinoin helps in clearing the infection with the mechanisms which still need more understanding. Retinoids increased the cell turnover which would result in clearing of the growing dermatophyte. It also boosts the immunity by playing its immunomodulatory role via B and T cells which fight against the dermatophyte. They keep the pH of the skin more towards alkalinity therefore making it difficult for dermatophytes to thrive, which like acidic pH.[19]

Future studies are required with larger sample size and futher exploring the pharmacokinetics of the retinoids in dermatophytic infections.

CONCLUSION

Our study showed that the combination of low dose isotretinoin and pulsed itraconazole in recurrent and recalcitrant dermatophytosis is efficacious. However, the use of isotretinoin should be limited to recalcitrant and recurrent dermatophytic infections.

ETHICAL APPROVAL

Ethical approval of synopsis was granted by the Institutional review Board of Shalamar Medical & Dental College via reference No. SMDC-IRB/AL/2024-011 dated; 15 February, 2024

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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AUTHOR'S CONTRIBUTIONS

US: Concept, data collection, analysis, interpretation, manuscript drafting, critical review and final approval
AA: Concept, data collection, analysis, interpretation, manuscript drafting, critical review and final approval
AA: Data collection, manuscript drafting, critical review and final approval
WS: Data analysis, critical review and final approval
NBA: Data analysis, critical review and final approval
MG: Data analysis, critical review and final approval
All Authors: Approval of the final version of the manuscript to be published

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