Original Article

Assessment of Effectiveness of Fluconazole and Clotrimazole in Treating Oral Candidiasis Patients: A Comparative Study

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Aims: One of the most common fungal infections infecting humans is Candidiasis. Belonging to the group of opportunistic infections, it often affects individuals with various debilitating diseases. Fluconazole and clotrimazole are two of the commonly used anti-fungal agents for the treatment of oral candidiasis. Hence, we planned this study to evaluate the effectiveness of fluconazole and clotrimazole in the treatment of patients suffering from candidiasis.

Materials and Methods: A total of 180 participants were enrolled in the present study. All the patients of candidiasis were divided broadly into two study groups. Group I included patients who were treated with fluconazole mouthrinse whereas group II included patients who were treated with clotrimazole mouth paint. Grading of patient discomfort was done as noted from readings given by the patients. Specimen was collection by a swab from the lesional area of the oral cavity from the patients and were incubated in Sabouraud's dextrose agar medium and assessed. All the patients were treated with medication as give to their respective groups. Patients were recalled as assessed. All the readings were recorded and analyzed. Results: For group I patients, the fungal eradication was 89.5%, whereas for group II patients, the fungal eradication was 86.7%. No significant results were obtained

while comparing the mycological eradiation in patients of the two study groups. **Conclusion:** Approximately similar effectiveness in terms of treatment was noted with fluconazole and clotrimazole in treating patients with candidiasis.

KEYWORDS: Candidiasis, clotrimazole, fluconazole

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Introduction

andida genus, in particular Candida albicans, is the one of the common cause of yeast-associated oral infections. [1] There occurrence has been widely described in the literature. Over the last four to five decades, the frequency and incidence of occurrence of candidiasis has significantly increased. The main reason that might attribute for such an increase in its incidence might be the increase in the prevalence of human immunodeficiency virus (HIV) and other immuno-compromising states and diseases. It also occurs more frequently among elderly individuals. [2]

More than 150 different species of asporogenous "yeast-like" fungi comprises *Candida* genus. The distribution of all the members of this genus is ubiquitous and

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consists of inhabitation of soil as saprophytes, aquatic environment, and even colonization of various animal reservoirs. At 37°C, the growth of most of *Candida* spices is prohibited, and therefore, human colonization is not associated with it under normal conditions.^[3]

Within humans, several species persist as commensal microorganism and can act as potential opportunistic pathogen in compromised body status. With respect to the treatment of these oral fungal infections, the most

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common line of treatment is the removal of the etiologic factor along with suitable anti-fungal therapy.^[4]

Few of the routinely employed anti-fungal agents include fluconazole and clotrimazole. There is a paucity of data regarding the comparative evaluation of the abovementioned anti-fungal agents in the treatment of oral candidiasis. ^[5] Hence, we planned this study to evaluate the effectiveness of fluconazole and clotrimazole in the treatment of patients suffering from candidiasis.

MATERIALS AND METHODS

The present study was conducted in the department of oral medicine and radiology of the dental institute and included assessment of 180 participants with chief problem of oral candidiasis from 2010 to 2015. Ethical approval was obtained from the institutional ethical committee and written consent was obtained after explaining in detail the entire research protocol. Complete physical examination of the patients was done before starting the treatment therapy of the patients. Recording of the time duration of the candidiasis was done along with other personal details of the patients. Exclusion criteria for the present study included:

- · Pregnant patients,
- Patients who underwent any kind of anti-fungal therapy in the past 1 month,
- Patients who were on barbiturates or anticoagulants in the past 1 month,
- Patients with any known drug allergy,
- Patients with alcohol history,
- Patients with history of any psychiatric disorder.

All the patients were broadly divided into two study groups. Group I included patients who were under treatment with fluconazole therapy whereas group II included patients who were on clotrimazole therapy. Based on the clinical history, visual examination of the lesion area and presence of clinical signs and symptoms, diagnosis of the candidiasis was made. Both the signs and symptoms of candidiasis were graded by patients into the following categories based on the severity of the lesion and individual perception:

- Mild,
- · Moderate, and
- Severe.

Symptoms' severity was categorized on the basis patient's response to discomfort whereas sign's severity was categorized on the basis of extent of lesion. Mild referred to cases which involved localized involvement to one or two oral sites, moderate referred to localized involvement of more than two oral sites, whereas severe cases involved generalized oral candidiasis.

Microbiological culture assessment was done to confirm the diagnosis of oral candidiasis. Swab was taken from the lesion area of the patients and was transferred to the microbiological laboratory in the transport medium for culturing. They were incubated in Sabouraud's dextrose agar medium for assessment of culture growth characteristics. All the samples were incubated in the culture medium at 37°C for 1–2 days. Counting of the yeast colonies was done 48 hours after incubation.

In group I patients, preparation of fluconazole suspension was done and were given to all the patients in the form of prepared moth rinse. Patients were instructed to use the suspension mouth rinse three times a day. In group II patient, suspension of clotrimazole was given in the form of moth paint and patients were instructed to use it thrice daily. Recalling of the patients was done after 2 weeks of continuation of the treatment therapy and was examined thoroughly for the presence of clinical signs and symptoms; microbial growth was assessed by culturing swab specimens as done earlier before the starting of the treatment. All the results were analyzed by PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc. Chi-square test and student's t-test was used for the assessment of level of significance. P-value of less than 0.05 was taken as significant. All samples were examined twice to avoid intraobserver variability and kappa value came out to be 0.8.

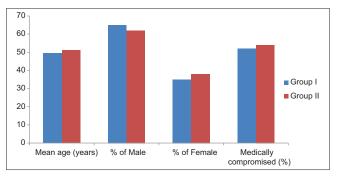
RESULTS

In both the study groups, prolonged antibiotic therapy was the most common compromised state associated with the presence of fungal infections [Graph 1]. Mean age of the patients in groups I and II was 49.5 years and 51.2 years, respectively [Table 1 and Graph 2]. In group I, 65% of the patient population was of males whereas remaining 35% were females. Among group II, 62% of patient population was of males while the reaming was of females. Among group I patients, before starting the treatment, 81% of the patient population had moderate severity of clinical symptoms, whereas in group II, 75% of the patient population had moderate severity of symptoms [Table 2 and Graph 3]. Among group I participants, after commencing the treatment, in 98% of the patients, clinical signs and symptoms were

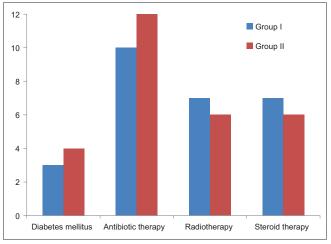
Table 1: Comparative assessment of the two study groups in terms of various parameters

Parameter	Group I	Group II	P
Mean age (years)	49.5	51.2	0.21
Gender			
Male (%)	65	62	0.51
Female (%)	35	38	
Medically compromised (%)	52	54	0.48

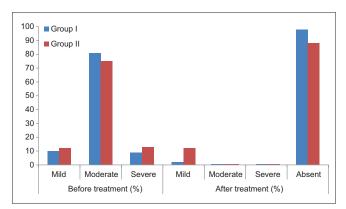
absent whereas in group II participants, 88% of the patients showed absence of clinician signs. Significant results were obtained while comparing the signs and symptoms of the patients in the two study groups after the treatment. In group I patients, before and after the treatment, the colony count was 1325.25 and 9.51, respectively, whereas in the group II patients, the mean colony count was 996.52 and 21.82, respectively [Table 3]. Significant results were obtained while comparing the mean colony count before and after the treatment in both study groups.



Graph 1: Distribution of all the medically compromised patients in the study groups



Graph 2: Comparative assessment of the two study groups in terms of various parameters



Graph 3: Comparison of various clinical signs and symptoms in between the patients of the two study group

DISCUSSION

Over the past few decades, there has been an increase in the incidence of occurrence of fungal infections.^[6] Furthermore, there has been as simultaneous increase in the incidence and occurrence of the predisposing factors. [7] Some of the important predisposing factors included xerostomia, antibiotic therapy for prolonged period of time, local chronic trauma or irritation, endocrinal disorders, medically compromised states, etc.[8] One of the common fungal infection included oral candidiasis. Treatment of the fungal infections included removal of the etiologic systemic or local factor along with antifungal therapy. Fluconazole and clotrimazole are the two commonly used anti-fungal agents for the treatment of fungal lesions. [9-11] Hence, we aimed to evaluate the effectiveness of fluconazole and clotrimazole in the treatment of patients suffering from candidiasis.

In the present study, we observed significant results while comparing the mean difference of colony culture growth before and after the treatment in both the study groups. Similar results were obtained by Sholapurkar *et al.* who observed similar findings in their study. O-Prasertsawat *et al.* comparatively evaluated the effectiveness of fluconazole and clotrimazole in the treatment of vulvovaginal candidiasis. They assessed 103 female patients in a single blinded randomized trial and divided them broadly into two study groups. First group consisted of 53 patients and included participants

Table 2: Comparison of various clinical signs and symptoms in between the patients of the two study group

Parameter	Group I	Group II	P
Before treatment (%)			
Mild	10	12	0.51
Moderate	81	75	
Severe	9	13	
After treatment (%)			
Mild	2	12	0.01*
Moderate	0	0	
Severe	0	0	
Absent	98	88	

^{*}Significant

Table 3: Comparison of colony counts before and after the treatment therapy

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Group	Mean colon	Mean colony count				
I	Before treatment	1325.25	0.01*			
	After treatment	9.51				
II	Before treatment	996.52	0.01*			
	After treatment	21.82				

^{*:} Significant

in whom treatment was done by fluconazole, while the other group consisted of 50 patients and included those in which treatment was done by clotrimazole. They did not observe any significant difference in relation to the clinical characteristic in between the two study groups. They observed approximately 79% and 80% mycological cure rates in the two study groups, respectively. They concluded that for the treatment of cases of vulvovaginal candidiasis, fluconazole can be given as an alternative line of treatment.^[13]

Sekhavat *et al.* comparatively evaluated the effectiveness of single dose of fluconazole and intravaginal clotrimazole 200 mg per day for 6 days in the patients undergoing treatment for the acute episode of vulvovaginal candidiasis (VVC). They prospectively analyzed 142 patients with were diagnosed with VVC and divided them randomly into two study groups. First group consisted of 70 patients and included those patients who received intravaginal tablet whereas the other group included 72 patients and consisted of participants who were given single dose oral fluconazole. They observed that, at the time of follow-up, during the second visit of the patients, approximately 85% and 81% of the patients of the group receiving fluconazole were cured clinically and mycologically, respectively. Similarly in the other study group, approximately 83% and 70% of the study group patients were cured clinically and mycologically, respectively. From the results, they concluded that for the treatment of cases of VVC, oral fluconazole single dose appeared to be a valid mode of treatment.[14]

Goins et al. compared the effectiveness of nystatin and fluconazole in treating the cases of oral candidiasis. One of the common conditions affecting the young infant group of individuals is oral thrush. One of the frequent problems associated with the administration of nystatin is the frequent cases of recurrence and difficulty encountered in its administration. They randomly analyzed 34 infants and were randomly subjected to either nystatin oral suspension four times a day for 10 days or fluconazole suspension 3 mg/kg in a single daily dose for 7 days. They observed that among the patients treated with nystatin, the clinical curing rate was 32%, while in the other group, a success rate of 100% was observed. Significant results were obtained while comparing the two anti-fungal agents. From the results, they concluded that superior action of treatment is associated with fluconazole.[15] Sholapurkar et al. assessed the efficacy of fluconazole mouthrinse and

clotrimazole mouthpaint in the treatment of cases of oral candidiasis. They observed significant difference while comparing the fungal growth on culture media before and after the treatment.^[12]

STRENGTH OF THE STUDY

Authors advocate the use of fluconazole and clotrimazole for treating oral candidiasis patients, thereby helping in improving the quality of life of the patients.

LIMITATIONS OF THE STUDY

- Sample size was small
- Underlying etiologic factors for the occurrence of candidiasis were not explored.

CONTROVERSY

The treatment therapy might differ depending upon the etiologic cause of candidiasis which was not taken as a parameter for the present study.

CONCLUSION

From the above results, the authors obtained significant results while using both the fluconazole and clotrimazole in treating patients with oral candidiasis. However, future studies are required in the same field for better exploration of results.

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Nil.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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