

Role of Fluconazole and Clotrimazole in Treating Oral Candidiasis Patients

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| Received: 17.05.2019 | Accepted: 25.05.2019 | Published: 30.05.2019

DOI:10.21276/sjodr.2019.4.5.15

Abstract

Background: Candida infection today is highly prevalent, especially the increase in carriers of removable dentures and poor oral hygiene society. **Aim:** To evaluate the role of fluconazole and clotrimazole in treating oral candidiasis patients. **Methods:** Two hundred subjects suffering from oral candidiasis formed the study population. Microbiological culture confirmed the diagnosis of oral candidiasis. Study subjects were divided into Group A - subjects who were under treatment with fluconazole therapy, Group B - subjects who were on clotrimazole therapy. Follow up of the study subjects was done after 2 weeks of continuation of the treatment. **Results:** Among group A subjects, before starting the treatment, 164 (82%) of them had moderate severity of clinical symptoms, whereas in group B, 148 (74%) of the subjects had moderate severity of symptoms. After the treatment, most 190 (95%) of them were devoid of any symptom in group A, whereas such proportion was 172 (86%) in group B. In group A subjects, before and after the treatment, the colony count was 1376.4 and 10.8, respectively, whereas in the group B patients, the mean colony count was 854.1 and 23.3, respectively. **Conclusion:** Both fluconazole and clotrimazole were approximately equally effective while treating subjects having oral candidiasis.

Keywords: Oral candidiasis, fluconazole, efficacy, clotrimazole.

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INTRODUCTION

Candida infection today is highly prevalent, especially the increase in carriers of removable dentures and poor oral hygiene society. Over the last four to five decades, the frequency and incidence of occurrence of candidiasis has significantly increased [1]. An increase in incidence of the infections is associated with some predisposing factors as the use of dentures, xerostomia, prolonged therapy with antibiotics, local trauma, malnutrition, endocrine disorders, increased longevity of people, among other states that diminish the quality of defense of the individual [2].

Regarding treatment of these oral fungal infections, the most common line of treatment is the removal of the etiologic factor along with suitable anti-fungal therapy [3, 4]. The treatment of oral candidiasis is based on few concepts- making an early and accurate diagnosis of the infection; Correcting the predisposing factors or underlying diseases; Evaluating the type of Candida infection; Appropriate use of antifungal drugs, evaluating the efficacy / toxicity ratio in each case [5-7].

Few of the regularly used anti-fungal drugs include fluconazole and clotrimazole. There is a paucity of data regarding the comparative evaluation of the aforementioned anti-fungal agents in the management of oral candidiasis. Therefore, the present study was to evaluate the efficacy of fluconazole and clotrimazole in treating oral candidiasis patients.

METHODS

This cross-sectional study was conducted in Oral Medicine and Radiology department of a dental hospital of northern India. Two hundred subjects suffering from oral candidiasis formed the study population. 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. Pregnant females, subjects receiving any kind of anti-fungal therapy in the past 1 month, subjects on barbiturates or anticoagulants in the past 1 month, subjects with any known drug allergy, subjects with alcohol history, and subjects with history of any

psychiatric disorder were excluded from this investigation.

Study subjects were divided into two groups.

- Group A - subjects who were under treatment with fluconazole therapy,
- Group B - subjects who were on clotrimazole therapy.

Diagnosis of the candidiasis was made on the basis of history, examination of the lesion area and presence of clinical signs and symptoms. Both the signs and symptoms of candidiasis were graded as mild, moderate and severe by patients. 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 confirmed 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 A 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 B patient, suspension of clotrimazole was given in the form of moth paint and patients were instructed to use it thrice daily.

Follow up of the study subjects was done after 2 weeks of continuation of the treatment. They were examined 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.

Written and informed consent was obtained from study subjects. Permission of ethical committee was obtained from the Institutional Ethics Committee. All the questionnaires were manually checked and edited for completeness and consistency and were then coded for computer entry. After compilation of collected data, analysis was done using Statistical Package for Social Sciences (SPSS), version 21 (IBM, Chicago, USA). The results were expressed using appropriate statistical variables.

RESULTS

Among group A subjects, before starting the treatment, 164 (82%) of the them had moderate severity of clinical symptoms, whereas in group B, 148 (74%) of the subjects had moderate severity of symptoms. After the treatment, most 190 (95%) of the them were devoid of any symptom in group A, whereas such proportion was 172 (86%) in group B (Table-1).

Table-1: Comparison of various clinical signs and symptoms in between the patients of the two study groups

Variable		Group A	Group B	P value
Before treatment	Mild	22 (11%)	26 (13%)	>0.05
	Moderate	164 (82%)	148 (74%)	
	Severe	14 (7%)	26 (13%)	
After treatment	Mild	8 (4%)	28 (14%)	<0.05
	Moderate	2 (1%)	-	
	Severe	-	-	
	Absent/Nil	190 (95%)	172 (86%)	

In group A subjects, before and after the treatment, the colony count was 1376.4 and 10.8, respectively, whereas in the group II patients, the mean colony count was 854.1 and 23.3, respectively.

Statistically significant results were observed on comparing the mean colony count before and after the treatment in group A and B (Table-2).

Table-2: Comparison of mean colony counts before and after the treatment therapy between study groups

Study group		Mean colony count	P value
Group A	Before treatment	1376.4	<0.05
	After treatment	10.8	
Group B	Before treatment	854.1	<0.05
	After treatment	23.3	

DISCUSSION

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 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* species is prohibited, and therefore, human colonization is not associated with it under normal conditions [8].

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 common line of treatment is the removal of the etiologic factor along with suitable anti-fungal therapy [9].

Fluconazole is water soluble and available in oral capsule, oral solution and saline-based iv solution formulations. All formulations exhibit predictable pharmacokinetics [10]. When given orally, fluconazole is rapidly absorbed, with peak plasma levels occurring 1–3 h after dosing. Absorption is unaffected by food or gastric acidity [11], and peak plasma concentrations are proportional to dose over a wide range (25–400 mg) [12]. The parent compound is active and has a plasma elimination half-life of around 30 h. Bioavailability is consistently high (approximately 90%) and distribution to body sites and tissues is widespread and rapid. This pharmacokinetic profile of fluconazole allows the convenience of once daily dosing, and the treatment of both localized and systemic *C. albicans* infections [13, 14].

In this study we observed that in group A subjects, before and after the treatment, the colony count was 1376.4 and 10.8, respectively, whereas in the group II patients, the mean colony count was 854.1 and 23.3, respectively. Similar results were obtained by Sholapurkar *et al.*, [15] who observed similar findings in their study. O-Prasertsawat *et al.*, [16] 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. 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.

In this study, among group A subjects, before starting the treatment, 164 (82%) of the them had moderate severity of clinical symptoms, whereas in group B, 148 (74%) of the subjects had moderate severity of symptoms. After the treatment, most 190 (95%) of the them were devoid of any symptom in

group A, whereas such proportion was 172 (86%) in group B. Goins *et al.*, [17] compared the effectiveness of nystatin and fluconazole in treating the cases of oral candidiasis. 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.

Sekhavat *et al.*, [18] comparatively evaluated the effectiveness of single dose of fluconazole and intravaginal clotrimazole 200mg per day for 6 days in the patients undergoing treatment for the acute episode of vulvovaginal candidiasis. From the results, they concluded that for the treatment of cases of vulvovaginal candidiasis, oral fluconazole single dose appeared to be a valid mode of treatment.

CONCLUSION

On the basis of findings of this investigation, it can be concluded that both fluconazole and clotrimazole were approximately equally effective while treating subjects having oral candidiasis. However, future studies are required in the same field for better exploration of results.

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