Effect of Miconazole Oral Gel in the Treatment of Denture-Induced Stomatitis

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ABSTRACT

Objective: The aim of this study is to assess the efficacy of Miconazole Oral Gel in the treatment of denture - induced stomatitis and to compare it to the use of corrective and hygienic measures only.

Method: Forty two prosthodontic patients, wearing removable prosthesis and presenting with denture stomatitis, were divided equally and randomly into two groups. Group A received Miconazole Oral Gel in addition to oral hygiene instructions, denture cleansers, and correction of denture faults, and group B received the same treatment with the exception of Miconazole Oral Gel. Clinical and mycological examinations using Sabourauds Dextrose Agar Media were done for each patient in both groups, and were repeated for each in the follow up visits. Data were collected, tabulated, and statistical analysis was done to find inter- and intra-group differences.

Results: Results revealed that candidal count and the erythema of the underlying mucosa were significantly reduced in both groups at follow-up visits compared with the pretreatment condition, but the reduction was significantly more in the group that received Miconazole Oral Gel.

Conclusions: Oral hygiene instructions play an important role in reducing severity of the condition, but they should be used in combination with Miconazole Oral Gel to gain the best results.

Key words: Candidal count, Denture-induced stomatitis, Miconazole Oral Gel.

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Introduction

The human oral cavity contains a variety of species of bacteria and fungi, which can sometimes be the cause of different kinds of inflammation.[1] The most common inflammatory changes of mucosa seen under the denture are named stomatitis prosthetic, denture sore mouth or denture stomatitis.[2]

Candida albicans, the most commonly isolated opportunistic human fungal pathogen, can cause different skin and mucosal infections as well as life-threatening systemic infections.[3,4] The involvement of *C. albicans* as a potential causative agent in denture-induced stomatitis was extensively described, and it remains the most frequently isolated yeast in the oral cavity, nevertheless, other species have been isolated and are involved in various diseases.[5] *C. albicans* associated stomatitis is a common disease that occurs in 50–60% of denture wearers. [6-8]

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Fig. 1a: Type1: Pin point stomatitis

Fig. 1b: Type2: diffuse denture stomatitis

Fig. 1c: Type3: Papillary stomatitis

Fig. 1.(a, b, and c) Clinical Newton's classification of denture- induced stomatitis cases

Newton[9] had sorted this condition into three stages:

Stage 1: local or pin-point hyperaemia. (Fig. 1a)

Stage 2: diffuse hyperaemia. (Fig. 1b)

Stage 3: diffuse and hyperplastic. (Fig. 1c)

Denture stomatitis, caused mainly by *C. albicans*, can be observed in a high percentage of people wearing dental prosthesis.[10] *C. albicans*, which exist in the oral cavity as saprophyte, increase in number and gain pathogenicity after a prosthesis is used.[11]

Attachment of *C. albicans* to dental prostheses is believed to be an important step in the development of denture stomatitis. Many factors are involved in the adhesion of *C. albicans* to dental prosthesis like presence of sucrose in the medium, material characteristics like surface roughness, surface hydrophobicity, electrostatic forces, composition of the material, type of matrix, size of fillers, and configuration of fillers.[12-17]

However, the etiology of denture stomatitis appears to be multifactorial; its development is influenced by the presence of a dental prosthesis, *C. albicans* and other microorganisms, but also by other local and systemic factors such as an acid salivary pH, high carbohydrates ingestion, long-term antibiotic therapy, hormonal therapy as well as systemic illnesses such as diabetes mellitus or arterial hypertension.[19]

Treatment of denture stomatitis involves three measures: correction of the denture, oral hygiene, and antifungal drugs, although many practitioners try to keep off medications in general and antifungal medications in these cases to avoid their elderly patients any extra cost or health burden. Therefore, this research was done to evaluate the benefit of adding antifungal medication specifically Miconazole Oral Gel to treat a relatively poor socioeconomic class and medically impaired group of patients.

Methods

This study was performed at Princess Haya Al-Hussein Hospital and Prince Ali Hospital after obtaining ethical approval from the Royal Medical Services Human Research Ethics Committee.

Our sample was selected from the patients that attended the Prosthodontic clinic complaining from signs and symptoms of denture stomatitis. The sample was collected over the period from the 3rd of January, 2012 to the 26th of April, 2012.

The original sample consisted of 50 patients, eight were excluded because of missed follow up visits. The final study sample consisted of 42 Jordanian patients (24 (57.1%)) females and 18 ((42.9%) males) ranging in age from 33 to 85 years, wearing heat-curing acrylic removable prosthesis, presenting with denture stomatitis, and reported wearing their dentures for more than 12 hours a day. Exclusion criteria included: smoking, alcoholism, diabetes, autoimmune diseases, immunosuppression, and drugs. The observers were two trained prosthodontists who examined the patients and directly observed the swabbing and inoculation procedures in the lab.

The patients were informed about the study course and they were asked to sign a written consent. Patients were divided equally and using simple randomization into two groups regardless of their gender. Those in group A, with the mean age was 63.7 ±5.8 years, were treated with Miconazole Oral Gel in addition to correction of denture faults, oral hygiene instructions, and using hypochlorite denture cleanser once daily and normal saline mouth wash three times daily. Instructions were given for all patients in group A

Table I: Age and gender distribution of both groups A and B

Variable	Gender	n (%)	Age (Years)	
			Mean	S. D.
Group A	F	13 (31)	63.7	5.79
	M	8 (19)		
Group B	F	11 (26.2)	62.5	13.34
	M	10 (23.8)		
Total		42 (100)	63.1	10.178

Table II: Clinical findings and dental status at presentation among patients of the whole sample

	Group A				Group B			
Clinical Newton's stage	Stage I	Stage II	stage III	Total	Stage I	Stage II	stage III	Total
Number (%)	6(28.6)	12(57.1)	3(14.3)	21(100)	7(33.3)	12(57.1)	2(9.5)	21(100)
Dental status								
Edentulous		18				14		
Partially dentate		1		21		3		21
Combination		2				4		
Prostheses								
CU*/CL**		19				15		
PU^/PL^^		0		21		2		21
Combination		2				4		
Oral /denture hygiene								
Good	0	0	0	0	0	0	0	0
Moderate	4	3	0	7	5	0	0	5
Poor	2	9	3	14	1	12	2	16

*CU complete upper, **CL complete lower, ^PU partial upper, ^^PL partial lower

to use the Miconazole Oral Gel on the palatal mucosa and on the denture base twice daily.

Those in group B, with mean age 62.5 ±13.3 years, were treated with corrective measures only (all the previously mentioned means but without Miconazole). Mean ages and gender distribution of both groups are summarized in Table I.

Clinical Examination

Personal data of the patients including name, gender, age, occupation, and social status was collected. A detailed medical and dental history was obtained from each subject in both groups. Intra-oral examination included assessment of the dental status, oral and denture hygiene (according to the degree of cleanness of the prosthesis), and a detailed clinical examination of the oral mucosa.

The erythematous lesions in the palatal mucosa in the sample were grouped according to the clinical appearance into stages I, II or III, according to Newton's classification.

The dentures in all subjects were evaluated for their retention, stability, maxillomandibular relationships, and occlusion. Clinical examinations were performed by prosthodontists. The clinical examination and Newton's staging were done at presentation visit, after two weeks, and after four weeks, for both groups and are shown in Table II. Examination of the palatal mucosa clinically revealed that 13 cases (31%) were presenting in Newton's stage I, 24 cases (57.1%) were in stage II, and five cases (11.9%) were in stage III.

At presentation, 30 patients (71.4%) had poor oral/denture hygiene and 12 patients (28.6%) had moderate oral/denture hygiene. Prosthesis examination of the whole sample was investigated and found to have 34 patients (81%) were completely edentulous patients, and two patients (4.8%) were partially dentate patients, and six cases (14.3%) were combined cases.

Table III: The frequency of clinical and mycological scores in both groups

	Group A							
	Clinical Scores			Mycological scores				
Newton Staging	Start n (%)	2 wks n (%)	4 wks n (%)	Start n (%)	1 wk n (%)	2 wks n (%)	3 wks n (%)	4 wks n (%)
0	0(0)	13(61.9)	18(85.7)	0(0)	0(0)	8(38.1)	14(66.7)	18(85.7)
1	6(28.6)	5(23.8)	3(14.3)	6(28.6)	7(33.3)	8(38.1)	7(33.3)	3(14.3)
2	12(57.1)	3(14.3)	0(0)	10(47.6)	11(52.4)	5(23.8)	0(0)	0(0)
3	3(14.3)	0(0)	0(0)	4(19.0)	3(14.3)	0(0)	0(0)	0(0)
4	-	-	-	1(4.8)	0(0)	0(0)	0(0)	0(0)
Total	21(100)	21(100)	21(100)	21(100)	21(100)	21(100)	21(100)	21(100)
	Group B							
	Clinical Scores			Mycological scores				
Newton Staging								
0	0(0)	1(4.8)	6(28.6)	0(0)	0(0)	1(4.8)	1(4.8)	1(4.8)
1	7(33.3)	11(52.4)	11(52.4)	7(33.3)	8(38.1)	11(52.4)	13(61.9)	14(66.7)
2	12(57.1)	7(33.3)	4(19.0)	10(47.6)	9(42.9)	8(38.1)	7(33.3)	6(28.6)
3	2(9.5)	2(9.5)	0(0)	3(14.3)	4(19.0)	1(4.8)	0(0)	0(0)
4	-	-	-	1(4.8)	0(0)	0(0)	0(0)	0(0)
Total	21(100)	21(100)	21(100)	21(100)	21(100)	21(100)	21(100)	21(100)

Table IV: The mycological and clinical response to treatment in both groups

(Group A)	Mycological Scores Mean			Clinical Newton's Scores Mean		
	Mean	SD	S.E.M.	Mean	S.D.	S.E.M.
At presentation	2.00	.183	.837	1.57	.163	.746
One week	1.81	.148	.680			
Two weeks	.86	.173	.793			
Three weeks	.33	.105	.483			
Four weeks	.14	.078	.359	.14	.078	.359
(Group B)						
At presentation	1.90	.181	.831	1.52	.148	.680
One week	1.81	.164	.750			
Two weeks	1.43	.148	.676			
Three weeks	1.29	.122	.561			
Four weeks	1.24	.118	.539	.90	.153	.700

Table V: Inter and intra- group comparison regarding both of the mycological and clinical scores.

Group	Test type	Time Interval	Mean	S.D.	S.E.M.	t-value	P value
	Mycological	Starting visit	2.00	.183	.837		
A		Four weeks	.14	.078	.359	13.000	.000
	Clinical	Starting visit	1.57	.163	.746		
		Four weeks	.14	.078	.359	10.954	.000
	Mycological	Starting visit	1.90	.181	.831		
B		Four weeks	1.24	.118	.539	5.292	.000
	Clinical	Starting visit	1.52	.148	.680		
		Four weeks	.90	.153	.700	5.701	.000
		Starting visit	2.00	.183	.837		
	Mycological		1.90	.181	.831	-.357	.724
		Four weeks	.14	.078	.359		
A-B			1.24	.118	.539	9.312	.000
		Starting visit	1.57	.163	.746		
			1.52	.148	.680	-.237	.815
	Clinical	Four weeks	.14	.078	.359		
			.90	.153	.700	4.985	.000

Laboratory investigation

Swabs were used to collect samples from the fitting denture surface and the underlying mucosa from the rugae area, and were directly inoculated on *Sabourauds Dextrose Agar Culture Medium*, and were then incubated at 37°C for two days as shown in Fig. 2.

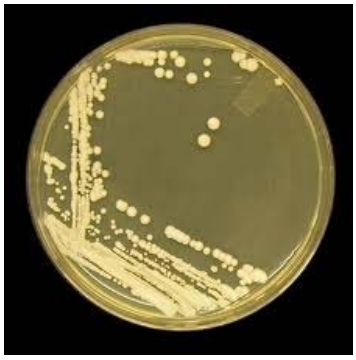

Fig. 2: Colonies of Candida were counted after its inoculation in Sabouraubs Dextrose Agar plate at 37 C° for two days

Colony counts were made according to the following scale to obtain the yeast score: 0 (no growth), 1 (low growth), 2 (medium growth), 3 (high growth), and 4 (confluent growth).

Study Course

Each patient in both groups was seen after one, two, three, and four weeks. Laboratory examination was done at these time intervals. While the clinical examination and Newton's staging were performed at two and four week intervals.

Data were collected, tabulated, and proper statistical analysis were done. Paired Sample Student t-test was used to compare inter and intra- group mean differences. Statistical Package for the Social Sciences (SPSS) software, version 16 was used in this study.

Results

The erythema of the underlying mucosa was significantly improved in both groups at follow-up visits compared with the pretreatment condition. Data of Newton's staging at presentation, at two, and at four week intervals were compared for both groups as shown in Table III. Amounts of yeast colonies were calculated for both groups A and B at each visit and were summarized in Table III. The mycological and clinical score means were analyzed, and summarized in Table IV for both groups.

The number of colonies was reduced more significantly in group A than in group B as shown in Table IV. During follow up, the patients in group A, who were using Miconazole Oral Gel, were noticed to have a significant improvement. At the end of treatment the percentage of patients showing complete clinical cure was 85.7%. The Percentage of patients showing complete mycological cure was 85.7% (Table III). While for group B, after four weeks of oral hygiene instruction (cleaning the denture and using normal saline mouth wash) and corrective measures (correction of base and occlusion errors), there was a significant reduction in yeast count in 66.7% of patients, while there was no change in yeast count in 33.3% of cases. Complete cure was difficult to achieve in group B, as only one case (4.8%) was recorded to have negative mycological result (Table III).

There were no significant differences between both groups at the presentation visit in both the mycological and the clinical tests ($p>0.05$). While, after four weeks there was reduction in *C. albicans* count in both groups, but for group A, there was a more significant reduction than in group B (Table V).

Discussion

The results of this study revealed that there was a direct proportional relation between *C. albicans* colonies count found in the mycological test and the Newton staging for the same case. This result was similar to other results of studies which concluded that there is a significant relation between Newton staging of stomatitis and amount of yeast colonies.[20-23]

In some patients of the sample in this study, *C. albicans* showed to be resistant and was still exhibited even in low numbers in group A in 14.3% of patients or in low to moderate numbers in 95.3% in group B patients. This scene has been studied by many authors.[7]

Results of this study showed that, the relationship between denture cleanliness and denture stomatitis is well established. Denture cleanliness did not cure denture stomatitis completely, as evidenced by both the clinical and the microbiological scores.

Inter-group differences showed highly significant decrease in *C. albicans* counts in group A more than in group B ($p<0.01$), this indicates that educating patients to improve their denture hygiene without providing adjunctive antifungal therapy is an impractical denture stomatitis treatment. The *C. albicans* count of dentures in group B was greater than in the group A at all review visits.

In this study oral hygiene and the corrective measures of the prosthesis showed a significant reduction in number of yeast colonies, but gave no cure for the lesions. On the other side, using Miconazole Oral Gel, in group A, induced a more significant reduction in numbers and gave cure in 85.7% of the patients. This result was very close to the result of Dias *et al.*[25] who found that, Miconazole Oral Gel is an efficient drug of choice for treatment of denture stomatitis.

The overall results of this study revealed that, Miconazole Oral Gel oral gel could be a beneficial drug for the management of denture stomatitis, on the other hand, oral hygiene instructions and corrective measures may reduce yeast count to a lesser extent. These results concerning the efficacy of Miconazole Oral Gel in treatment of denture stomatitis were consistent with the results of other studies.[24-26]

Conclusions

Miconazole Oral Gel oral gel plays an important role in reducing the severity of denture stomatitis but it should be used in combination with oral hygiene instructions and correcting any denture faults.

Recommendations:

First:

1. Correcting any denture faults.
2. Advising patients to avoid nocturnal denture wear.
3. Oral hygiene instructions.

Second:

Instructing the patient to use Miconazole Oral Gel oral gel twice daily, by painting

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