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Effect of personalized caries treatment protocol versus standard of care on salivary flow rate of high caries risk patients

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Abstract--Objective: this study was carried out to assess the effect of different caries prevention protocols on salivary flow in high caries risk patients. Materials and methods: 66 participants were involved in the study (n=22). All of them were considered as high-risk participants. They were randomly divided into three groups according to a proposed caries management system. Group one (I₁) received personalized caries management system. Group two (I₂) received a combined therapy of chlorhexidine and fluoride mouthwash. Group three (I₀) received standard preventive measures (control group). Results: Chi-square test showed that there was no statistically significant difference in the saliva score at baseline between all groups (p>0.05). After one year Chi-square test also showed no statistically significant difference between all groups (p>0.05). Conclusions: No measurable effect was observed for any of the study groups on the salivary flow rate.

Keywords---treatment protocol, salivary flow, personalized caries.

Introduction

The role of saliva in oral health, studied by Stookey (2008). He indicated that the role of saliva includes tissue lubrication and abrasion protection. Saliva has an antibacterial effect on microorganisms, food particles and debris washing effect. Saliva also has a positive role in caries control via chemically supplying a source of phosphate and acid buffering agents. The saliva is secreted from multiple sources: 90% of whole saliva is produced the major saliva glands. The parotid, submandibular and sublingual and 10% is from minor salivary glands in the oral mucosa and from non-glandular sources, such as gingival crevicular fluid.

Saliva is formed of mainly water and less than 1% solid which are mostly protein molecules and electrolytes. These molecules play a major role in maintaining the health and integrity of teeth together with the investing oral structures. Saliva is especially suited to be utilized for monitoring of the patient caries status. This is due to the fact that saliva contains all diet related components of the patient together with the microbiota responsible for the carious process and their biological and chemical byproducts as stated by Gao et al. (2016). They also indicated that using saliva to test for the amount of *S. mutans* has been shown to be as an acceptable alternative for using plaque samples from tooth surfaces as studies support a significant correlation between *S. mutans* amount in plaque and its concentration in saliva. Furthermore, several studies were conducted to find a correlation between caries incidence and salivary *lactobacilli*, however the outcome remains controversial. In a study conducted by Sounah and Madfa (2020), to assess the correlation between dental caries experience and the level of *S. mutans* and *lactobacilli* in saliva, it was found that the level of *lactobacilli* appeared to be higher in carious tissue than in saliva. However, another study carried out on adults revealed a strong relationship between root caries and the level of salivary *lactobacilli* Beighton et al. (1991).

In Scandinavian countries, salivary tests on *S. mutans* and *lactobacilli* levels have been performed routinely for many decades, for identifying elevated caries risk but current evidence indicates that the amount of *S. mutans* or *lactobacilli* alone is a weak predictor for caries risk Sanchez-Perez et al. (2009). The sensitivity and specificity of salivary *S. mutans* levels in predicting caries among preschool children has wide ranges. Also, the reported sensitivity and specificity of tests for salivary *lactobacilli* has wide ranges Gao et al. (2016).

Regarding salivary flow rate, studies have revealed elevated caries prevalence, incidence and activity related to a pathologically low salivary flow rate among patients with medical conditions (most notably the autoimmune disease Sjogren's syndrome), following use of a variety of medications (antihistamines, antihypertensives, antidepressants, etc.) and following therapeutic radiation to the head and neck Flink et al. (2020). Caries lesions developed quickly among these patients and also on tooth surfaces usually not susceptible to caries Leone and Oppenheim (2001). Clinical trials on saliva stimulation by chewing sugar-free gum after meals showed a significant decrease in caries incidence and that the

benefit was attributable to stimulating salivary flow rather than to any chewing gum ingredient Stookey (2008). The null hypothesis tested was that personalized caries treatment protocol will show no significant difference against using tooth brushing and flossing only in affecting salivary flow rate

Materials and methods

Ethics approval

The study was reviewed and accepted by the Research Ethics Committee (REC) – of Faculty of Dentistry, Cairo University in 2018.

Study Design

This study is a parallel group, two tail and superiority frame with 1:1:1 allocation ratio. It was run at the Cairo University Dental Clinics.

Recruitment

An announcement was made at Faculty of Dentistry to inform young students about the study. Students applied for the study were examined in the Conservative Dentistry clinic to check if they were eligible or not to join the study. They were subjected to clinical examination and a sampling frame was prepared of those who were at an increased risk of dental caries. The first 66 eligible students were registered in the study after signing an informed consent.

Randomization

The 66 participants were then randomly divided and allocated into 3 groups (n=22) by choosing a folded paper containing the number of their assigned group

Salivary flow rate testing

Participants were instructed to neither eat nor smoke for one hour prior to sampling. Paraffin wax was used to stimulate saliva for 5 minutes and glass container was used for collection of salivary samples. Each participant was seated in an upright, relaxed position. A paraffin pellet was given to each participant to chew for 30 seconds, then to swallow the accumulated saliva. Participants then continued to chew for 5 minutes, with the accumulated saliva collected continuously into a glass container. After 5 minutes, the amount of saliva was measured, and the secretion rate calculated as milliliters per minute Navazesh et al. (2008)

Based on the salivary stimulated test findings, scores were recorded in the Cariogram software depending on the Cariogram scoring system shown in Table (1) Bratthall and Hansel Petersson (2005)

Table (1)
Salivary flow rate score

Score	Explanation
0	Normal saliva secretion, more than 1.1 ml stimulated saliva per minute.
1	Low, from 0.9 to less than 1.1 ml stimulated saliva per minute.
2	Very low, from 0.5 to less than 0.9 ml stimulated saliva per minute.
3	Dry mouth, less than 0.5 ml stimulated saliva per minute; problem judged to be long-standing.

Grouping

66 participants were involved in the study (n=22). All of them were considered as high-risk participants. They were randomly divided into three groups according to a proposed caries management system.

Group one (I₁) received the intervention of the study which is the personalized caries management system. Group two (I₂) received a combined therapy of chlorhexidine and fluoride mouthwash while Group three (I₀) received standard preventive measures only to be the control group for this study.

Group 1 (Intervention one):

Participants received a caries management plan based on his modifiable caries risk factors in addition to the standard preventive measures which were tooth brushing using 1450 ppm Fluoride tooth paste and interdental cleaning. A summary of the modifiable risk factors and proposed management is presented in Table (2).

Table (1)
Intervention for personalized caries management

Modifiable Risk Factor	Management
Cariogenic Diet	Dietary counselling
Oral hygiene	Biofilm modification
Salivary flow	Salivary stimulation (Xylitol gum, Instruction on hydration)
Fluoride exposure	Fluoride therapy

Group 2 (Intervention two):

For intervention group two participants received a mouthwash containing chlorhexidine (CHX) and fluoride (Emoflour 250ml, Value pharmaceutical, Egypt)

Group 3 (Control Group):

Participants in this group were given only a manual toothbrush (Oral B), fluoridated toothpaste (Signal), dental floss (Oral B)

Follow up period:

All participants were scheduled to follow up every 3 months for one year from their initial visit.

Outcome measured:

The amount of saliva was measured, and the secretion rate calculated as milliliters per minute. Based on the salivary stimulated test findings, scores were recorded in the Cariogram software depending on the Cariogram scoring system shown in Table (1). Salivary flow is measured at baseline and at one year.

Results

Comparison of saliva score at baseline and after one year:

Salivary flow rate scores range from “0” for normal flow rate to score “3” which indicates xerostomia. Chi-square test showed that there was no statistical significant difference in the saliva score at baseline between all groups Table (1) and Table (2) (p=0.4). After one year Chi-square test also showed no statistical significant difference between all groups Table (1) and Table (2) (p=0.1).

Table (3)
Saliva score cross tabulation at baseline

			Group			Total
			ONE	TWO	THREE	
Salivary Flow Rate score at baseline	0	Count	17	21	19	57
		% within Salivary Flow Rate score at baseline	29.8%	36.8%	33.3%	100.0%
		% within Group	77.3%	95.5%	86.4%	86.4%
	1	Count	3	1	1	5
		% within Salivary Flow Rate score at baseline	60.0%	20.0%	20.0%	100.0%
		% within Group	13.6%	4.5%	4.5%	7.6%
	2	Count	1	0	2	3
		% within Salivary Flow Rate score at baseline	33.3%	0.0%	66.7%	100.0%
		% within Group	4.5%	0.0%	9.1%	4.5%
	3	Count	1	0	0	1
		% within Salivary Flow Rate score at baseline	100.0%	0.0%	0.0%	100.0%
		% within Group	4.5%	0.0%	0.0%	1.5%
Total		Count	22	22	22	66
		% within Salivary Flow Rate score at baseline	33.3%	33.3%	33.3%	100.0%
		% within Group	100.0%	100.0%	100.0%	100.0%

Table (2)
Chi-square test for Saliva scores at baseline showing no significant difference between groups

	Value	df ¹	p value ²
Pearson Chi-Square	6.021(a)	6	0.421
Likelihood Ratio	6.875	6	0.333
Linear-by-Linear Association	0.577	1	0.447
N of Valid Cases	66		

¹ df: degrees of freedom

² Significant at p ≤ 0.05

Table (5)
Saliva score cross tabulation at one year

			Group			Total
			ONE	TWO	THREE	
Salivary Flow Rate score at-1y	0	Count	18	22	20	60
		% within Salivary Flow Rate score at-1y	30.0%	36.7%	33.3%	100.0%
		% within Group	81.8%	100.0%	90.9%	90.9%
	1	Count	4	0	2	6
		% within Salivary Flow Rate score at-1y	66.7%	0.0%	33.3%	100.0%
		% within Group	18.2%	0.0%	9.1%	9.1%
Total		Count	22	22	22	66
		% within Salivary Flow Rate score at-1y	33.3%	33.3%	33.3%	100.0%
		% within Group	100.0%	100.0%	100.0%	100.0%

Table (6)
Chi-square test for Saliva scores at one year showing no significant difference between groups

	Value	Df ¹	p value ²
Pearson Chi-Square	4.400(a)	2	0.111
Likelihood Ratio	5.946	2	0.051
Linear-by-Linear Association	1.083	1	0.298
N of Valid Cases	66		

Discussion

Dental caries remains a common and expensive disease for both society and affected individuals. In the work published by Kastenbom et al. (2019). This randomized clinical trial was performed to obtain the best evidence, since the gold standard for examining causation or treatment effect is the randomized clinical trials (RCTs). RCTs have many advantages like prospective data collection, standardization of the intervention, investigation of adverse events, masked outcome measures and examining the effective treatment on secondary outcomes Hariton and Locascio (2018).

Regarding the salivary score, participants in group one received xylitol gum to be used after meals three times daily. Groups two and three did not receive treatment to improve salivary flow. This intervention in group one improved salivary flow. However, there was no statistically significant difference between groups at baseline or after one year. The improvement of salivary flow was in agreement with previous work reported by Stookey (2008), they also reported that the decrease in caries incidence associated with chewing gum was due to improved salivary flow as a result of gum chewing action rather than any the specific ingredient added to the gum.

Saliva contains three buffer systems (bicarbonate, phosphate, and protein) and helps in maintaining acceptable pH range of 6.0-7.5 within the mouth. When a substance is placed in the oral cavity, the flow of saliva will increase depending on its taste, consistency, and concentration. When the volume of saliva is approximately 1.1 ml, a swallowing reflex is triggered. Salivary stimulation, dilution of tasting and swallowing will continue until the concentration of the tastings reaches a point where it ceases to stimulate salivary flow. The oral clearance of various substances will be prolonged in the absence of saliva, resulting in possible harm to intraoral hard and soft tissues. Under normal physiologic conditions the saliva is oversaturated with calcium hydroxyapatite, which prevents dental demineralization. In addition, the salivary protein pellicle protects the teeth against irritants Iorgulescu (2009).

It has been proposed that xylitol due to its organoleptic properties stimulates salivation and that increased masticatory activity due to gum chewing can lead to increased salivary flow rates. The findings of this study is in agreement with previous work which found no significant change in salivary flow rate after chewing xylitol chewing gums for 2-week also other studies did not detect a change in salivary flow rate during a 2-year field trial involving the use of xylitol chewing gum. It can be conjectured that gum chewing may be an effective measure to increase unstimulated salivary flow in the case of hypo salivary individuals. However, in individuals with normal salivary gland function the major effect from chewing gum may only be associated with direct stimulation of salivary flow, which would be of benefit only if the gum is chewed immediately after food consumption according to Aguirre-Zero et al. (1993). The null hypothesis was accepted based on the findings of the current study.

Conclusions

No measurable effect was observed for any of the study groups on the salivary flow rate between baseline and after one year. Xylitol gum did appear to have a measurable effect on the salivary flow rate of high caries risk patients

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