

THE EFFECT OF PILOCARPINE MOUTHWASH ON SALIVA AMOUNT IN STUDENTS OF AHVAZ JUNDISHAPUR UNIVERSITY OF MEDICAL SCIENCES

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ABSTRACT

Dry mouth is a common disorder in the salivary function. Pilocarpine is one of the most common drugs in treatment of this condition. The aim of this study was to evaluate the effect of Pilocarpine mouthwash on the saliva amount in students of Ahwaz Jundi Shapour University of Medical science. The study was designed as a double-blind, clinical trial, involving 86 healthy volunteers students. In the intervention group, the pilocarpine mouthwash 2% was used and the control group received normal saline 0.9%. Results were analyzed by using Mann-Whitney and chi-square ($P < 0/05$ was considered significant). Before intervention, significant differences were not existed between two groups, while immediately and after 60 minutes after using the mouthwash significant differences was seen between intervention group comparing to the control group ($P=0.004$) ($p=0.027$). The results indicate that using pilocarpine mouthwash increased amount of saliva was produced.

Keywords: Saliva, Pilocarpine, Mouthwash, Xerostomia

INTRODUCTION

The most common presentation of salivary gland disease is xerostomia. The feeling that the patient says about his dry mouth is named Xerostomia. THIS is of great importance that any complaint about Xerostomia must not be considered as salivary dysfunction (Guggenheimer and Moore, 2003). The factors contributing in Xerostomia include aging, various medications, radiation therapy, diabetes, anemia, lack of some vitamins and Sjogren's syndrome (Drummond *et al.*, 1995; Zarb *et al.*, 1997; Kreher *et al.*, 1987; Shafer *et al.*, 1987).

Xerostomia is recognized based on the physical examination of the oral cavity and patient history (Sánchez-Guerrero *et al.*, 2002). There is no agreement on normal level of saliva among researchers, which a majority of researchers have mentioned the unstimulated salivary flow rate under 0.1 m/min and/or stimulated salivary flow rate under 0.7 m/min abnormal indicating a reduction in salivation. It is of great importance to mention this point that higher salivary rates do not assure normal function (Navazesh and Kumar 2008).

The most important symptoms from decreased saliva include feeling a dry mouth, excessive thirst and difficulty in swallowing, talking and burning tongue and impaired sense of taste (Liena-Puy 2006). Xerostomia might be often subjective with no evidence for reduction of salivation (Porter *et al.*, 2004; Malpani *et al.*, 1996). Different methods and medications have been used to treat dry mouth, but each has their advantages and disadvantages. The primary treatment to reduce xerostomia is oral pilocarpine.

Pilocarpine is a muscarinic cholinergic agonist which increases salivary output and stimulates remaining gland function.

The majority of patients receiving oral pilocarpine therapy for xerostomia experience adverse events (most commonly sweating) (Zarb *et al.*, 1997; Malpani *et al.*, 1996; Little *et al.*, 2002; Sutherland 1972; Bernardi *et al.*, 2002). The aim of this study was to evaluate the effects of Pilocarpine mouthwash on the saliva level in students of Ahwaz Jund Shapour University of Medical science.

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MATERIALS AND METHODS

The present research is a double blind, placebo- controlled study that has been performed on a group consisting of 86 individuals among the students in Ahvaz Jundishapur University of Medical Sciences. This study has been approved according to the guidelines of the ethics Committee of Ahvaz Jundishapur University of Medical Sciences. Volunteers were referred to the Oral Medicine department, School of Dentistry. 86 healthy individuals with ranging from 19-26 years old were selected. The exclusion criteria of study included Gastrointestinal, hematologic, cardiac, hepatic, renal and respiratory disorders, behavioral disorders, autoimmune diseases (such as Sjogren's syndrome), previous radiotherapy and the use of any medication. Participants were divided into two intervention and control groups randomly, and asked to avoid eating, drinking, brushing and anything which stimulates salivation for 90 minutes then, unstimulated saliva was collected via coachman method for 5 minutes (stage 1). In this method, the patient sits leaning forward resting his or her body weight, elbows, and arms on the tops of the thighs and knees while bending the neck, gently holding a funnel resting in a calibrated tube. The lips are opened and any saliva that is produced during 5 minutes is allowed to passively flow into the funnel and tube (López-Jornet *et al.*, 1996). Pilocarpine mouthwash (Iran, Tehran, Sinadaru) was given to the intervention group and normal saline (Iran, Tehran, Darupakhsh) was given to the control group. At the next step the customised pilocarpine mouthwash contained 1 cc of 2% Pilocarpine diluted in 19 cc of 0.9 % saline (20 cc) and the mouthwash used for control group contained 20 cc 0.9% saline. Before study, there materials were put in the same containers which had been numbered with label. The individuals in these groups were asked to use the mouthwashes for 5 minutes and then saliva was collected for 5 minutes via the coachmans method (stage 2). Followed that, the individuals were asked to avoid eating, drinking, brushing and anything which stimulates salivation for one hour. Then the saliva was collected after one hour (stage3). Ultimately, the participants were asked to chew and swallow a piece of bread and then put a pinch of salt on the right and left borders of the tongue for 30 seconds. Students were asked to fill a questionnaire which has been provided based on Likert scale consisting of five questions about amount of saliva, humidity of mouth, the status of swallowing, speech and salty taste and scored (table 1). Results were analyzed by using Mann-Whitney and chi-square ($P < 0/05$ was considered significant).

RESULTS AND DISCUSSION

Findings

There were 54(62.79%) male and 32(37.21%) female among the 86 participants. The Average age of individuals in intervention and control groups has been 23.57 and 22.76 respectively.

Table 1: Pilocarpine mouthwash questionnaire for xerostomia

In following, several questions have been proposed that your response to them will conduct us in understanding status of xerostomia in your mouth and its intervention in your daily life. Kindly after using the mouthwash, indicate your status in response to the questions by putting a cross inside the square.

Which change has occurred in amount of saliva in your mouth?

Increased ☐ decreased ☐ not changed ☐

Which change has occurred in moisture of your mouth?

Increased ☐ decreased ☐ not changed ☐

Which change do you feel in your speaking status?

easier ☐ harder ☐ not changed ☐

Which change do you feel in your swallowing status?

easier ☐ harder ☐ not changed ☐

Which change has occurred in your salty taste?

Increased ☐ decreased ☐ not changed ☐

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Table 2: The effect of pilocarpine mouthwash on saliva amount

Stage	Group	Mean deviation	±standard	P-value
Stage 1	Intervention(pilocarpine)	2/1±06/24		0/50
	Control	2/1±14/16		
Stage 2	Intervention(pilocarpine)	3/1±15/61		0/004
	Control	2/1±24/24		
Stage 3	Intervention(pilocarpine)	2/1±70/56		0/027
	Control	2/1±07/18		

Stage 1= before intervention

Stage 2 = immediately after intervention

Stage 3 = 1hour after intervention

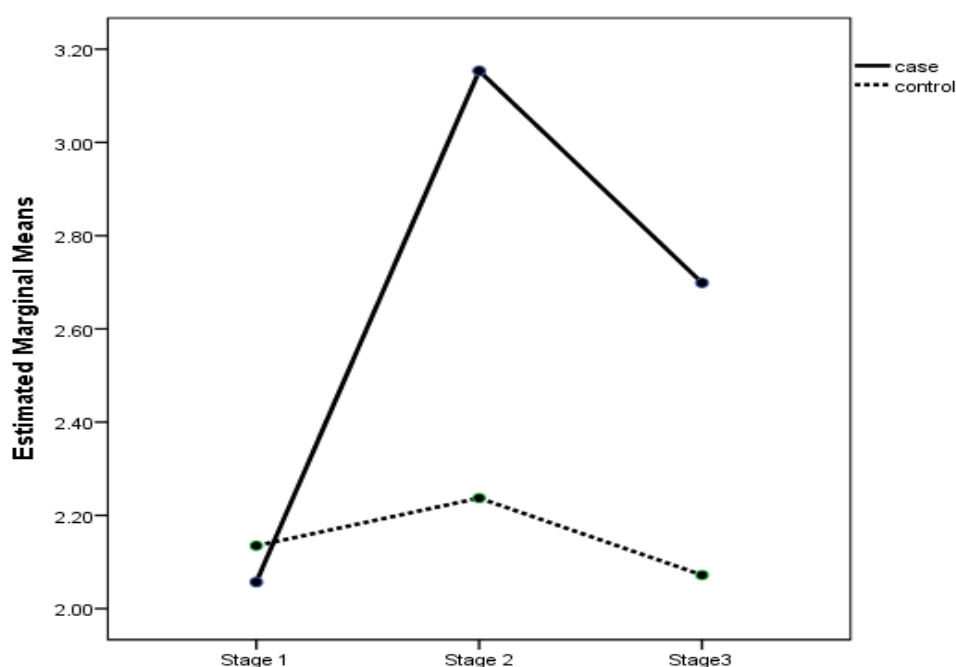


Figure 1: Dispersion diagram for the effect of pilocarpine mouthwash on saliva amount in students of Ahvaz Jundishapur University of Medical Sciences (Stage 1= before intervention; Stage 2 = immediately after intervention; Stage 3= 1hour after intervention)

Mean of saliva amount in both groups under study was compared via Mann–Whitney test. Before intervention (stage 1), significant differences were not existed between two groups, while immediately (stage2) and after 60 minutes (stage 3) after using the mouthwash significant differences was seen between intervention group comparing to the control group ($P=0.004$), ($p=0.027$) (table 2, figure 1). Further, in this study, effect of Pilocarpine mouthwash on amount of saliva, speech status, humidity of mouth, swallowing status and salty taste was evaluated via questionnaire. The results indicated that these factors have improved in intervention group comparing to the control group, which this difference is significant ($p\text{-value}<0.001$).

Discussion

Nowadays, there are a variety of treatments for xerostomia ranging from artificial saliva to systemic medications. The primary treatment to reduce xerostomia is oral pilocarpine.

The results of this study indicate that there has existed a significant difference in amount of saliva between two groups after using pilocarpine mouthwash.

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Previously, a variety of studies have been conducted evaluating the effect of Pilocarpine on xerostomia (Lajtmán *et al.*, 2000; Zimmerman *et al.*, 1997). A study by Brimhall *et al.*, which has been performed to compare the effect of Cevimeline and Pilocarpine on salivation indicated that both these drugs have caused increase of salivation (Brimhall *et al.*, 2013). Chainani-Wu *et al.*, performed a study on 20 patients with Xerostomia to compare the effect of three drugs including Cevimeline, Pilocarpine and Bethanechol, and reported that these drugs caused increasing saliva and improved Xerostomia (Chainani-Wu *et al.*, 2006). In Iran, Karimi and Hadad conducted a study on 18 patients under treatment via 5 mg Pilocarpine three times a day from initiation of radiotherapy to 3 months later. The findings indicated that Xerostomia has been lower in the group receiving pilocarpine compared to the placebo group (Hadad and Karimi, 2002; Kim *et al.*, 2014).

Davies and Singer have compared the effect of Pilocarpine mouthwash and artificial saliva among the patients with Xerostomia due to radiation, whereby the findings indicated that Pilocarpine mouthwash has more effective than artificial saliva in improving the patients status (Davies and Singer, 1994; Ferguson *et al.*, 1991). Bernardi *et al.*, evaluated the effects of topical pilocarpine solutions as mouthwashes on salivary flow and their adverse effects on healthy subjects. There was a dose-dependent increase in salivation. Cardiovascular, visual, gastrointestinal and behavioral symptoms and signs were not changed by topical pilocarpine (Bernardi *et al.*, 2002).

Braga *et al.*, compared the effect of low-dose pilocarpine and cevimeline as stimulants for salivary flow in healthy subjects. Both drugs showed efficacy in increasing the salivary flow, but cevimeline was more effective than pilocarpine (Braga *et al.*, 2009).

In this study, the effect of pilocarpine mouthwash on speech status, humidity of mouth, swallowing status and salty taste was examined. Results indicated that these factors have improved in intervention group significantly.

Saliva plays a critical role in maintenance of oral structure, function and integration, thus reduction of salivation can result in discomfort in the mouth, difficulty in chewing, swallowing, tasting and talking (Brimhall *et al.*, 2013). Few studies conducted to examine these subjective parameters have reported similar results to our study, for example there has existed a significant correlation between subjective and objective results in the study by Hadad and Karimi (Hadad and Karimi, 2002).

Conclusion

The results of this study indicate that using pilocarpine mouthwash increased amount of saliva. Prescription of pilocarpine mouthwash in patients with xerostomia could be helpful.

ACKNOWLEDGEMENT

This work was Financially Supported by Grand: (U-93111) from Vice-chancellor for Research Affairs of Ahvaz Jundishapur University of Medical Science. This Paper Is Issued From Thesis Of (Naeem Alhaei).

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