

The effect of xerostomia and hyposalivation on the quality of life of patients with type II diabetes mellitusTahereh Molania¹, Mona Alimohammadi², Ozra Akha³, Jaber Mousavi⁴, Ramin Razvini⁵, Maedeh Salehi¹

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Background: Diabetes mellitus is a chronic metabolic disease which can have numerous physical effects for patient. Xerostomia is one of these complications. Compared to healthy people, patients with diabetes mellitus, have a worse quality of life, and complications of diabetes are the main determinants of quality of life in these patients.

Objective: The aim of this study was to determine the effects of xerostomia and hyposalivation on quality of life of patients with type 2 diabetes mellitus.

Methods: This descriptive-analytical epidemiological study was conducted on 200 patients with type 2 diabetes mellitus referred to the diabetes clinic of Shahid Mostafavi in Sari city from October 2015 to January in 2016. A questionnaire containing personal characteristics and medical situation was completed by each person. Then, the Persian Oral Health Impact Profile-14 (OHIP-14-PER) questionnaire was completed by the patients. Eventually, with the use of chewable paraffin for 1.5 min by the patient, stimulated salivary flow rate (SSFR) test was performed, and in order to determine hyposalivation, their saliva amount underwent a gravimetric test. Finally, using statistical software SPSS16, the information was statistically analyzed by independent-samples t-test, Mann-Whitney U, Chi-squared and Fisher exact tests.

Results: The average age of patient was 56.41 years old (43% male and 57% female). Mean SSFR was 0.7 ml/min in patients and xerostomia were confirmed in 112 patients. Difference between age, gender, drug use, years affecting to diabetes and FBS amount in patient with hyposalivation were not statistically meaningful in proportion to patients without it. But difference between HbA1C and SSFR in patients with hyposalivation were statistically meaningful than to patients without it ($p=0.03$, $p=0.001$ respectively). The mean patient score to OHIP-14 were obtained as 38.17. The questionnaire score difference in patients with hyposalivation in proportion to patients without it were not statistically meaningful.

Conclusion: Hyposalivation possibility increases in diabetic patients with low metabolic control which can cause more severe side effects in relation to oral health. Xerostomia in diabetic patients has negative effects on oral health related quality of life. Diabetic control and patients' oral problem improvement is effective in their quality of life promotion.

Keywords: Diabetes mellitus, Xerostomia, Saliva

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1. Introduction

Diabetes mellitus is a chronic metabolic disease that can have physical effects on patients. Xerostomia (dry mouth sensation) is one of these complications. Reduction in salivary flow resulting in xerostomia leads to speaking and chewing problems, mucosal inflammation, candidal infections and atrophic changes of oral mucosa, increase of plaque accumulation, decrease of buffering capacity of the saliva and increase of decay (1). Many studies have examined the prevalence of oral lesions and xerostomia in patients with diabetes. In one study, the prevalence of dry mouth in patients with diabetes was a reported 76.4% (1). In addition, it was found that this complication could have negative effects on the quality of life, so the xerostomia should be diagnosed correctly in this group of patients to treat its negative effects on oral health and to achieve a higher quality of life (2). Xerostomia is the subjective sensation of dry mouth and this definition is based on the presence or absence of individual feeling of dry mouth and not based on actual measurements of salivary flow rate, while hyposalivation is defined as the objective symptoms of a reduced salivary flow rate. Subjective xerostomia can be related to hyposalivation and other physiological factors. Changes in salivary composition instead of changes in salivary quantity may produce xerostomia (3). Narhi reported that dry mouth sensation was not necessarily related with decreased salivary flow and it could be seen in people with normal salivary flow. The prevalence of xerostomia and hyposalivation was reported to be approximately 20%, but the simultaneous existence of both was only 6% (4). The term "quality of life" (QOL) is defined as the patients' feeling of well-being related to various aspects of life. Oral health related quality of life (OHRQoL) consists of individual feelings of the effects of oral health on the quality of personal life. Patients with diabetes mellitus, compared to healthy people, have a worse quality of life, and complications of diabetes are the main determinants of quality of life in these patients (5). In 1997, Slide changed the Oral Health Impact Profile-49 (OHIP-4) questionnaire into the new and short-form version named OHIP-14 questionnaire by maintaining its validity and reliability to evaluate the clinical situation and its effect on the QOL for patients. After that, OHIP-14 questionnaire has been used to evaluate the effects of oral health on the QOL (5). Recent research has examined the relationship between xerostomia and QOL (6-8). In a study that was conducted in 2014, they examined oral health related to quality of life in patients with type 2 diabetes mellitus and found that oral health problems in diabetic patients depend on medical conditions and levels of blood glucose control of which these problems have a negative effect on their quality of life (9). Considering the high prevalence of diabetes among the population and the high percentage of oral complications of disease, particularly xerostomia, the aim of this study was to evaluate the effect of xerostomia and hyposalivation on the QOL of patients with type 2 diabetes mellitus. And finally, the quality of life questionnaire was compared in diabetic patients with xerostomia and hyposalivation.

2. Material and Methods

This descriptive-analytical epidemiological study was conducted on 200 patients with type 2 diabetes mellitus referred to the diabetes clinic of Shahid Mostafavi in Sari city from October 2015 to January in 2016. Inclusion criterion was patients with type 2 diabetes with a dry mouth. Exclusion criteria were illiterate patients or those who did not have the ability to fill out the questionnaire and also those who had systemic conditions such as hypothyroidism, history of radiotherapy in head and neck area or chemotherapy during the past 3 months or consumers of drugs and psychotropic substances, smokers, alcoholics and consumers of medications which cause dry mouth (antihistamines, anticholinergics, anti-hypertensive, tricyclic antidepressants), respectively (10). At first, the plans and aims of the study were explained to the participants, and oral consent was obtained from all patients. Demographic information including age, gender, duration of diabetes, type of medications was written in their records. Fast blood sugar (FBS) level during the study and Hemoglobin A1c (HbA1C) level in less than three months before the study were also recorded (10). Patients with HbA1C \leq 8% were as persons with good control and patients with HbA1c $>$ 8% were as uncontrolled ones. Moreover, FBS level ranged from 90 to 130 mg/dl was defined as control of good blood sugar (10).

2.1. Xerostomia and hyposalivation assessment

To determine the presence of xerostomia, each patient was asked about dry mouth during the day over the last 6 months and a positive response indicated dry mouth in patients, and after that, three additional questions were asked: 1- How would you describe the saliva in your mouth? 2- Do you have trouble in swallowing? 3- Do you need a drink to swallow food? Then their answers to these questions were recorded (10). Hyposalivation was examined via collecting the stimulated saliva. All sampling was conducted in the period from 9 to 11 am. The subjects were asked to avoid smoking, eating food and drinking water at least 2 hours before sampling. Also, patients with partial and complete dentures were asked to remove them before testing the stimulated saliva, and to wash their mouth for 1 minute before sampling, and then their oral cavity was evaluated to ensure no possibility of substances were in their oral cavity. Patients were seated on a chair when swallowing their saliva. Then, 1 × 1 cm paraffin manufactured by

Van (Iran) was put in their mouth and sucked for 1.5 minutes. Afterwards, they spat the saliva into a test tube for 3 minutes (11). Next, the saliva samples were kept in a freezer with -70 °C temperature until their measuring time (11). Stimulated salivary flow rate (SSFR) was evaluated using the gravimetric method, and expressed in milliliters per minute (ml/min). SSFR>0.7 ml/min showed the normal salivary flow and SSFR ≤0.7 ml/min indicated the hyposalivation (10).

2.2. Assessment the effect of xerostomia on quality of life

OHIP-14-Per questionnaire whose validity and reliability had been confirmed by Motalleb Nejad et al. was used to evaluate the effect of xerostomia on QOL in patients (12). The patients were asked to respond to the questions regarding the period of the past 6 months. The questionnaire contained 14 multiple-choice questions with five choices for each question and the five choices with their scores are as follows: Never = 1, seldom= 2, sometimes = 3, almost often = 4, in the majority of cases = 5. This questionnaire covered seven aspects of quality of life related to oral health including functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. All questions were negative in this questionnaire and therefore the scores of all questions had inverse relationship with good oral conditions. Total scores of OHIP-14 per (Additive Score of OHIP = ADD-OHIP) were calculated so that the minimum and maximum scores were 14 and 70, respectively (12). Higher scores indicated the negative impact on QOL. Because some patients might not distinguish among the words "sometimes", "almost often" and "in the majority of cases", the simple count (SC) method was used. It means that, if the patient chose one of two choices (almost often and in the majority of cases), the score of the question would be 1 and if one of three choices (never, seldom and sometimes) was chosen, the score would be Zero and finally the range of all questions was 0 to 14 so that the higher score indicated quality of life related to a lower oral health (12).

2.3. Data Analysis

After collecting the questionnaires, data were analyzed using SPSS-16. OHIP-14 questionnaire was analyzed using Kolmogorov-Smirnov Test and Levene's test was used to analyze the homogeneity of variance. In addition, 25th and 75th percentiles were used to describe the data related to the questionnaire. Other tests used in the study included independent-samples t-test, Mann-Whitney, chi-squared and Fisher's exact tests. P-value less than or equal 0.05 was considered significant.

3. Results

3.1. Characteristics of the study population

Totally, 200 patients with type 2 diabetes mellitus, who had xerostomia over the last 6 months were entered into the current study. The mean age of patients was 56.41 ranged from 22 to 85 years. In total, 85 and 114 patients were male and female, respectively. Mean of diabetes years was 9.75 (for 1-32 years). FBS mean of patients was 128.43 mg/dl (82-210 mg/dl) during the study, and the mean of HbA1C was 7.2% (5.1-9.3%) in patients over the last 3 months. Among them, 108 patients used oral medications to control diabetes, 67 patients took the drugs by injection and 25 cases used the combination of oral and injectable drugs to treat the diabetes. The mean of SSFR also was 0.7 mg/dl and hyposalivation was confirmed in 112 patients (56%) (Table 1).

3.2. Evaluation of the study variables

In a total, 112 of 200 patients with type 2 diabetes mellitus, who complained of xerostomia had hyposalivation after gravimetric measuring of stimulated saliva, and the mean of SSFR was 0.58 in patients with hyposalivation, which suggested that there was a significant relationship between hyposalivation and xerostomia in this study (p=0.001). When hyposalivation as an independent variable compared to its dependent variables was studied, it was found that the difference of age, gender, medication use, years of diabetes and FBS level in patients with hyposalivation was not statistically significant compared to patients without it. However, the maximum level of FBS was 210 mL/min in the current study, observed in diabetics with hyposalivation and patients without hyposalivation, had better control on their FBS. Also in this study, the maximum year of affecting diabetes was 32, which was reported in patients with hyposalivation. However, there was statistically significant difference between the two variables including SSFR and HbA1C in patients with hyposalivation than without hyposalivation (p=0.001 and 0.03 respectively). In studying of qualitative variables including three questions on the flow rate of saliva, difficulty in swallowing and need to drink liquids while eating, interesting results were obtained in the present study. In all the above questions, the difference in answers of patients with hyposalivation compared to without hyposalivation was statistically significant (p<0.001) (Table 2).

Table 1. Characteristics of the studied population

Variable	n	mean \pm SD or %
Age (year)	200	56.41 \pm 13.1
Gender	Female	114
	Male	86
Time with DM ₂ (year)	200	9.75 \pm 5.1
FBS (Mg/dl)	200	128.43 \pm 17.2
HBA ₁ C (%)	200	7.24 \pm 0.8
ADD-oHIP-14	200	38.17 \pm 7.8
SC-oHIP-14	200	11.25 \pm 3.1
SSFR (ml/min)	200	0.7 \pm 0.1
Amount of saliva referred	Low	137
	Normal	63
Difficulty in swallowing	Yes	94
	No	104
Need to drink	Yes	72
	No	128
Hyposalivation	Yes (SSFR \leq 0.7 (ml/min))	112
	No (SSFR $>$ 0.7 (ml/min))	88

Table 2. Analysis of hyposalivation as a dependent variable showing the independent variable in terms of mean \pm SD or number of occurrences and odds ratio (OR) and p-value

Independent variable	Dependent variable					
	Yes	NO	N	OR	p-value	
Age (year); Mean \pm SD	56.64 \pm 14.2	56.13 \pm 11.5	200	-	0.77	
Gender (%)	Female	30.5	26.5	112	1.26	0.41
	Male	25.5	17.5	88		
Time with DM ₂ (year) ; Mean \pm SD	10.44 \pm 6.4	8.89 \pm 5.2	200	-	0.06	
FBS (Mg/dl) ; Mean \pm SD	130.21 \pm 18.8	126.16 \pm 14.9	200	-	0.1	
HBA ₁ C (%); Mean \pm SD	7.35 \pm 0.7	7.1 \pm 0.8	200	-	0.03*	
ADD-oHIP-14; Mean \pm SD	38.38 \pm 9.3	37.9 \pm 9.3	200	-	0.67	
SC-oHIP-14; Mean \pm SD	11.25 \pm 2.8	11.25 \pm 3.5	200	-	1	
Medication	Oral	54	54	108	-	0.17
	Injection	42	25	67		
	Combination	16	9	25		
SSFR (ml/min) ; Mean \pm SD	0.58 \pm 0.1	0.86 \pm 0.9	200	-	0.001*	
Perceived amount of saliva	Low	93	44	137	4.89	0.001*
	Normal	19	44	63		
Difficulty in swallowing	Yes	66	30	96	2.94	0.001*
	No	58	46	104		
Need to drink	Yes	60	20	72	2.77	0.001*
	No	52	68	128		

3.3. Study of the effect of xerostomia and hyposalivation on quality of life

Regarding the study of the OHRQoL, a total of 200 patients responded to all questions. Average score of ADD - OHIP - 14 with a range of (21 to 67) and SC - OHIP - 14 with a range of (0 to 14) was 38.17 \pm 7.84 and 11.25 \pm 3.18, respectively. There was no significant difference between patients with hyposalivation and without it in terms of ADD - OHIP - 14 via statistical analysis using independent-samples t-test. The same results were obtained in relation to SC -OHIP - 14 and the difference was not significant either. OHIP - 14 questionnaire showed that patients had more problem in the field of physical pain so that 58% of patients chose the choices of "almost often" and "in the majority of cases" for two questions concerning this aspect.

4. Discussion

Dry mouth is as an oral manifestation of diabetes that can lead to many clinical or social problems for patients (1). In the present study, diagnosis of xerostomia was confirmed based on the feeling of dry mouth in patients over the last 6 months, then this assessment was completed by three additional questions. Xerostomia is the subjective sensation of dry mouth and can occur in people with normal salivary flow rate. Some believe that saliva compounds can be more effective than its flow in causing xerostomia. However, hyposalivation is the actual reduction in salivary flow rate so the SSFR and unstimulated salivary flow rate are used to diagnose it (3). Unstimulated salivary flow rate is influenced more than a stimulated one by hours of the day, the patient's physical and psychological state. In addition, its collection due to its low flow rate is longer (7). Therefore, in the present study, SSFR was measured to estimate the relationship between hyposalivation and xerostomia. Busato et al. studied 51 patients with type 1 diabetes and they reported that the prevalence of xerostomia was 52.9% although there was no relationship between hyposalivation and xerostomia in their study (10). In other studies, there was relationship between hyposalivation and xerostomia in patients with type 1 diabetes mellitus, and some researchers stated that type 1 diabetes was not as a predisposing factor for hyposalivation (13). Unlike them, Chavez et al. reported that diabetics are more vulnerable to hyposalivation than others (14). The prevalence of xerostomia in patients with type 2 diabetes was reported as 76.4% which was higher than that in patients with diabetes type 1 (10). It seems that hyposalivation due to a higher prevalence of xerostomia is higher in these patients. Hyposalivation in diabetics can lead to many side effects in the oral mucous membrane such as dryness, pain, atrophy, mucositis, ulceration and opportunistic infections (fungal, bacterial and viral), depapillation of tongue and increase of the dental caries (10). In the present study, the difference in the flow of saliva, difficulty in swallowing and the need to drink while eating was higher in patients with hyposalivation than without hyposalivation, and this difference was statistically significant. This represents a real reduction in salivary flow rate and subsequent problems in the swallowing function of patients and a real need to drink in order to facilitate swallowing. The number of affected years of diabetes and its metabolic control can also play a role in creating hyposalivation and xerostomia (10). In the current study, although no significant difference was found between the number of affected years of diabetes and hyposalivation, hyposalivation was observed in people with the maximum years of diabetes. Moreover, the mean years of diabetes and FBS were higher in patients with hyposalivation than without it. Statistically, there was a significant difference between HbA1C and hyposalivation ($p=0.03$), so that its mean was 7.35% in people with Hyposalivation. Given that HbA1C is a good indicator of control and long-term follow-up of diabetes, its higher concentration in hyposalivation group indicates the importance of this indicator in the control of metabolic status of patients with diabetes. In this study, the mean score of ADD - OHIP -14 was 38.17 which represented the negative effect of xerostomia on QOL of diabetics and this effect was found in other studies by using OHIP - 14 and other questionnaires. In order to increase the accuracy of questionnaires and responses of patients, another method was used to score the OHIP - 14 questionnaires, named SC - OHIP - 14. The obtained mean of SC - OHIP - 14 was 11.25. There was no significant difference between the two scoring systems when the patients with hyposalivation were compared to those without it. Moreover, its justification is that any systemic condition such as diabetes mellitus or chronic use of multiple medications can affect oral health (10, 15). All patients participating in the study were suffering from xerostomia. Therefore, their responses to a questionnaire were based on the subjective sensation of dry mouth and its complications, and there was no difference between the questionnaires of patients with xerostomia and those with hyposalivation.

5. Conclusions

Finally, it can be concluded that the possibility of hyposalivation in diabetic patients with poor metabolic control or high number of affected years increases, which can create more serious complications associated with their oral health. Xerostomia in patients with diabetes has a negative effect on quality related to oral health. Further studies are needed to evaluate the association between diabetes control levels and xerostomia leading to hyposalivation in diabetic patients.

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Conflict of Interest:

There is no conflict of interest to be declared.

Authors' contributions:

All authors contributed to this project and article equally. All authors read and approved the final manuscript.

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