Influence of oral moisturizers for the relief of Xerostomia among Institutionalized Type II Diabetic patients - A Randomized Controlled Trial

- **Krishna prakash G**. Assistant Professor, Department of Public Health Dentistry, SRM Kattankulathur Dental College & Hospital, SRM Institute of Science and Technology, Kattankulathur, Tamil Nadu-603203, India.
- **Praveen Jodalli.** Associate Professor, Department of Public Health Dentistry, Manipal College of Dental Sciences Mangalore, Manipal Academy of Higher Education, Manipal, Karnataka, India-576104
- **Rekha P Shenoy.** Professor and Head of the Department, Department of Public Health Dentistry, Yenepoya Dental College, Yenepoya (Deemed to be University), Mangalore, Karnataka, India.
- **Imran Pasha M**. Reader, Department of Public Health Dentistry, Yenepoya Dental College, Yenepoya (Deemed to be University), Mangalore, Karnataka, India.
- **Junaid.** Reader, Department of Public Health Dentistry, Yenepoya Dental College, Yenepoya (Deemed to be University), Mangalore, Karnataka, India.
- **Supriya A.** Senior Lecturer, Department of Public Health Dentistry, Yenepoya Dental College, Yenepoya (Deemed to be University), Mangalore, Karnataka, India.

Abstract:

Aim: The aim of the study was to investigate the efficacy of oral moisturizers for the relief of xerostomia among institutionalized type II diabetic patients in Mangaluru, South India. **Materials and Methods:** A parallel group, single blinded randomized control trial was conducted. A total of 90 participants from four institutionalized old age home participated in the study. Dry mouth conditions were assessed using CODS Index. Samples of unstimulated saliva was collected at baseline, 7th, 14th and 21st day from which salivary flow rate was assessed. **Results:** The mean age of the study participants was 58.9 ±12.2. Among the 90 participants, 20 (22.2%) participants were male and 70 (77.8%) participants were females. Inter and intra group comparison of mean score among the three different groups was performed. To compare the salivary parameters in xerostomia among institutionalized type II diabetic patients. - Kruskal-Wallis test was used. The level of significance was set at $p<0.05$. **Conclusion:** The present study reveals that all the three oral moisturizers showed significant improvement within the groups. However, a comparison between the groups showed no significant difference among the three different oral moisturizers in xerostomia among type II diabetic patients. **Clinical significance:** The results from this study imply the importance of prescribing oral moisturisers to relieve the dry mouth symptoms as a result of diabetics.

Keywords: Xerostomia, oral health, oral moisturizers.

Introduction

Saliva plays a fundamental role in maintaining oral health. Healthy individuals produce resting (unstimulated) whole saliva at a rate of 0.3-0.4 ml/min.[1] The term hyposalivation is used, when the whole salivary secretion is 0.1–0.2 ml/min at rest and under 0.5 to 0.7 ml/min of stimulated saliva.[2] Reduced salivation causes problems with speaking, mastication, swallowing, taste alterations, dental caries, difficulty using removable prostheses, microbiological infections, bad breath, soft tissue degradation, and a reduced quality of life.[3]

Xerostomia is a term used to describe the subjective symptoms of a dry mouth deriving from a lack of saliva. Drugs, ageing, other systemic disorders, and anxiety/depression are risk factors for xerostomia in diabetes. Additionally, the act of chewing and swallowing may be hampered, which may have an impact on an older person's nutritional condition.[4]

Numerous research has looked at how common oral lesions and xerostomia are in diabetic individuals.[5] Additionally, it was discovered that this condition could have a significant impact on quality of life. As a result, it is important to appropriately diagnose xerostomia in this group of patients in order to treat its detrimental effects on oral health and to improve quality of life.[6]

Saliva substitutes, often known as oral moisturisers, work by hydrating the dehydrated oral tissue.[7] Oral moisturisers are available in a variety of forms, including liquids, sprays, gels, oils, mouthwash, gum, and toothpaste.[8]

The results of this study can be used by medical and dental professionals in deciding which oral moisturizers will be more effective in reducing the dry mouth symptoms and it also can promote the oral health, and thus enhance the general health of the patients. The aim of the study was to investigate the efficacy of oral moisturizers for the relief of xerostomia among institutionalized type II diabetic patients in Mangaluru, South India.

Materials and Methods

Study Design

This is a randomized clinical trial, a single-blinded study conducted at the institutionalized old age homes in Mangaluru, Karnataka. The selected subjects were randomly allocated into 3 groups as per requirements of the study viz group 1, group 2 and group 3 following the Consolidated Standards of Reporting Trials recommendation as shown in **Flowchart 1.** The participants were not aware of patient allocation.

Ethical Consideration and Registration

The participants were explained the procedure, purpose, risks, and benefits of the study before they signed an informed consent for recruiting in the study. Permission to conduct the study was obtained from the institutionalized old age home, Mangaluru, South India. This study has received approval from the ethical committee of the institution and the study was registered in the CTRI (Clinical Trials Registry India/2021/09/036995).

Sample Size Calculation

Sample size was calculated by using G* power software for ANOVA. At 5% level of significance and 85% power with standard effect size 0.40. So, the total sample size in each group is 24. Expected dropout is 10% by considering the dropout rate the sample size is 28 which is rounded off to 30 (n=30). Thus, the total sample required for intervention were 90 (30 in each group).

Study Group

Study population comprised 90 participants aged >35 years old in institutionalized old age people were recruited by trained and calibrated dentists according to following inclusion and exclusion criteria as follows.

Inclusion Criteria

- Patient diagnosed with diabetic mellitus
- Patients with mild, moderate, severe xerostomia were eligible.

Exclusion Criteria

- Patients who are under medications for other systemic diseases.
- Patients who had a salivary gland removal, and patients with Sjogren's syndrome.
- Patients who had received radiation therapy to the head and neck region.

Randomization

A total of 90 subjects who fulfilled the inclusion and exclusion criteria. The selected participants were randomly allocated into 3 groups (n=90), group 1- Owet spray (West coast Pharmaceutical Works Ltd) provided, group 2: Saleva mouth rinse (Global Dent Aids Pvt Ltd) provided, group 3- Wet mouth rinse [ICPA Health products Ltd] provided. Primary investigator was involved in the random allocation sequence and enrolment of participants to the assigned interventions.

Method

Participants dry mouth conditions were assessed using CODS index[9] at baseline. The salivary flow rate was assessed.

Procedure

The primary investigator visited an institutionalized old age homes every weekend for a period of 21 days. All the participants were assembled and instructed to use the mouth rinse (10 ml to be rinsed for 1 minute) in front of the examiner. Participants were advised to restrict from eating and gargling the mouth for half an hour after the use of mouth rinse. Patient compliance was assessed by checking of the level of mouthwash left in the bottle. Samples of unstimulated saliva (3ml) was collected in sterile container by passive drool method. Salivary flow rate was assessed by volumetric analysis.

Statistical Analysis:

Statistical tests were done using SPSS 27.0 (Statistical Package for Social Sciences; IBM Statistics, 2020). Mean, standard deviation, frequencies and percentage distribution were obtained from the data using descriptive statistics. To compare the salivary flowrate in xerostomia among institutionalized type II diabetic patients - Kruskal-Wallis test was used. The level of significance was set at $p<0.05$.

Results

The present study was conducted from October 2021 to January 2022 to investigate the efficacy of oral moisturizers for the relief of xerostomia among institutionalized type II diabetic patients in Mangaluru, South India. The study was conducted among 90 participants in four different institutionalized old age homes in Mangaluru

The mean age of the study participants was 58.9 ±12.2. Among the participants, 20 (22.2%) were male and 70 (77.8%) were females. **(Table 1)**. Upon completion of the study 81 participants remained out of the initial 90 recruited in the study, 9 (10%) were lost to follow-up. Based on Clinical Oral Dryness Scale (CODS) index 17% of them had mild xerostomia, 44% of them had moderate xerostomia and 39% of them had severe xerostomia.

Among 90 participants intergroup comparison (Kruskal Wallis test) of mean salivary flow rate levels between group 1 (Owet spray) was 0.41, group 2 (Saleva mouth rinse) was 0.40 and group 3 (Wet mouth) was 0.38 showed there was no statistical difference between the three different groups ($p = 0.794$).

The mean (±Standard Deviation) salivary flowrate level has increased from 0.17± 0.078 at baseline to 0.41±0.166, 0.14± 0.056 to 0.40±0.147, 0.18± 0.075 to 0.38±0.186 in group 1, 2, 3 at end of 21st day respectively. So, the weekly comparison between baseline and final evaluation showed statistically significant difference in salivary flowrate ($p < 0.001$) **(Table 2)**.

Discussion

A metabolic disease called diabetes mellitus impairs the function of numerous organs, including the salivary glands.[10,11] Saliva production can be reduced as a result of changes to the salivary glands. It could increase the risk of oral diseases, taste disorders, difficulty in swallowing and chewing food, speech problems, and poor quality of life.[10]

The subjective sensation of having a dry mouth, or xerostomia, is one of the most typical symptoms associated to diabetes mellitus. The prevalence of xerostomia in diabetic patients ranges from 12.5% to 76.4%.[12] Type 2 diabetics had a higher prevalence of xerostomia than type 1 diabetics.

Based on Clinical Oral Dryness Scale (CODS) index 17% of them had mild xerostomia, 44% of them had moderate xerostomia and 39% of them had severe xerostomia. In research by Lima et al. on 120 elderly diabetic patients, moderate to severe xerostomia was reported by 50% women and 47.4% men. The findings of the investigations by Narhi et al. and Collin et al., in which more than 50% of the respondents reported experiencing xerostomia, are similar to those of this study.

The majority of xerostomia and associated side effects are treated symptomatically. To counteract for the decreased saliva production, numerous oral moisturizers have been developed. It is challenging to replace saliva because it is such a complicated molecule. Oral moisturizers work well to relieve symptoms, and most patients also find that drinking water frequently is helpful.[13]

Owet spray has many properties that includes alcohol free, sugar free solution, safe for long term treatment, relieves dry mouth and pleasant lemon flavour. Wet mouth rinse is alcohol free, pleasant peppermint flavour and it contains carboxymethylcellulose. Saleva mouthwash is non-drying, alcohol-free, sugar free solution and has a mint flavoured formula with antiseptic action. The patients who used these dry mouth products for a week showed a favourable safety profile because no adverse events were noticed during the clinical trial.

The key outcomes of this randomised controlled trial study were the short-term efficacy of all three oral moisturisers. The patients preferred each of the three products. Elderly individuals' saliva quality increased after using oral moisturisers consistently every day for a month, which was reported to lessen the signs and symptoms of dry mouth.

According to the current study, diabetes patients had baseline levels of reduced salivary flow ($p<0.05$). This result is in line with a large number of earlier investigations. Numerous reasons, including fatty infiltration of the salivary glands, hyperglycemia, glycosuria, dehydration spurred on by polyuria, and neuropathy of the salivary glands, can be responsible for the decrease in saliva output in diabetic patients.[14,15] This finding is consistent with earlier research that suggested that oral disorders, particularly salivary flow and composition, and poor glycaemic management may be related in some way. A number of pathological alterations driven on by hyperglycemia might impair salivary gland function and decrease salivary production.[16]

Studies have showed that diabetes patients had statistically significant higher salivary flow at the end of the study ($p<0.05$). The findings demonstrate that the use of oral moisturisers considerably lessens the negative effects of xerostomia on QoL and symptoms. Regular use of these cutting-edge topical dry mouth therapies significantly increased unstimulated whole saliva. This was comparable to the research done by Dirix P et al.[13] According to a study by Villa et al.[17], there is no conclusive evidence that any saliva substitute may reduce the symptoms of dry mouth by increasing salivary flow rate or altering the composition of saliva.

The present study revealed that there is no statistically significant difference in the intergroup comparison of salivary flowrate between the three different groups ($p>0.05$). Hence, we can prove in our trial that all three oral moisturisers are equally effective in improving the salivary flow rate and total protein levels among institutionalized type 2 diabetic patients experiencing xerostomia.

Regular water consumption, combined with avoiding specific foods and substances including alcohol, caffeine, and sodium lauryl sulphate (SLS), may help to reduce xerostomia in mild cases to a manageable level. Another natural treatment for xerostomia is olive oil, which not only has lubricating qualities but also has shown anti-inflammatory and antibacterial capabilities.[18]

The present study had limitations. First of all, it must be taken into consideration, the period of observation was short, which was only 21 days. Surely, it would be interesting to observe the same parameters after a longer study period than 21 days.

The strength of the present study was the study design and the random allocation of subjects to the intervention arms which ensured that there was no selection bias. Other strength includes the intervention being supervised by the primary investigator personally which ensured that all participants were following the proper intervention protocol. No adverse effects for the mouth rinses were reported by participants to primary investigator.

There are limited clinical trial data for xerostomia among diabetic patients. Therefore, the results from this study imply the importance of prescribing oral moisturisers to relieve the dry mouth symptoms as a result of diabetics.

Conclusion

Patients in all the three groups showed a significant improvement within the groups. Hence, we can prove in our trial that all three oral moisturisers are equally effective in improving the salivary flow rate among institutionalized type 2 diabetic patients experiencing xerostomia. Importantly, dry mouth is a chronic issue in many clinical settings, and clinical trials should assess not only how effectively treatments reduce xerostomia but also how they affect the quality of life of patients who experience chronic dry mouth symptoms over the long term.

Conflict of Interest: None

Acknowledgement: The author would like to acknowledge all the secretaries of institutionalized old age home in Karnataka.

Manufacturers Name

Owet spray (West coast Pharmaceutical Works Ltd), Saleva mouth rinse (Global Dent Aids Pvt Ltd) and Wet mouth rinse [ICPA Health products Ltd]

Funding: This work was supported by Indian Association of Public Health Dentistry (IAPHD) Financial Assistance under PG category.

References

1. Kvalheim SF, Marthinussen MC, Haugen DF, Berg E, Strand GV, Lie SA. Randomized controlled trial of the effectiveness of three different oral moisturizers in palliative care patients. Eur J Oral Sci. 2019 Dec;127(6):523-530.
2. Lapiedra RC, Gomez GE, Sanchez BP, Pereda AA, Turner MD. The Effect of a Combination Saliva Substitute for the Management of Xerostomia and Hyposalivation. J Maxillofac Oral Surg. 2015 Sep;14(3):653-8.
3. Ship JA, McCutcheon JA, Spivakovsky S, Kerr AR. Safety and effectiveness of topical dry mouth products containing olive oil, betaine, and xylitol in reducing xerostomia for polypharmacy-induced dry mouth. J Oral Rehabil. 2007 Oct;34(10):724-32
4. Wolff A, Joshi RK, Ekstrom J et al. A guide to medications inducing salivary gland dysfunction, xerostomia, and subjective sialorrhea: A systematic review sponsored by the World Workshop on Oral Medicine VI. Drugs R D 2017; 17: 1– 28.
5. Mauri-Obradors E, Estrugo-Devesa A, Jané-Salas E, Viñas M, López-Lopez J. Oral manifestations of Diabetes Mellitus. A systematic review. Med Oral Patol Oral Cir Bucal. 2017; 22(5): e586-94.
6. Carda C, Mosquera-Lloreda N, Salom L, Gomez de Ferraris ME, Peydro A. Structural and functional salivary disorders in type 2diabetic patients. Med Oral Patol Oral Cir Bucal. 2006; 11(4): E309-14.
7. Lysik D, Niemirowicz-Laskowska K, Bucki R, Tokajuk G, Mystkowska J. Artificial saliva: Challenges and future perspectives for the treatment of xerostomia. Int J Mol Sci 2019;20:3199.
8. Marcinkowska-Gapinska A, Linkowska-Swidzińska K, Swidziński T, Surdacka A. Rheological parameters of saliva in comparison with taste examination. Biorheology 2018;55:51-60.
9. Challacombe SJ, Osailan SM, Proctor GB. Clinical scoring scales for assessment of dry mouth. In Dry mouth 2015 (pp. 119-132). Springer, Berlin, Heidelberg.
10. Gil CL, Hooker E, Larrivee B. Diabetic kidney disease, endothelial damage, and podocyte-endothelial crosstalk. Kidney Med. 2021;3 (1):105–115.

11. Homoud B, Alhakami A, Almalki M, et al. The association of diabetes with ischemic stroke and transient ischemic attacks in a tertiary center in Saudi Arabia. Ann Saudi Med. 2020;40 (6):449–455.
12. Lopez-Pintor, Rosa María et al. "Xerostomia, Hyposalivation, and Salivary Flow in Diabetes Patients." *Journal of diabetes research* vol. 2016 (2016): 4372852.
13. Dirix P, Nuyts S, Vander Poorten V, Delaere P, Van den Bogaert W. Efficacy of the BioXtra dry mouth care system in the treatment of radiotherapy-induced xerostomia. Support Care Cancer. 2007 Dec;15(12):1429-36.
14. Malicka B, Kaczmarek U, Skośkiewicz-Malinowska K. Prevalence of xerostomia and the salivary flow rate in diabetic patients. Adv Clin Exp Med. 2014;23(2):225–233.
15. Rahiotis C, Petraki V, Mitrou P. Changes in saliva characteristics and carious status related to metabolic control in patients with type 2 diabetes mellitus. J Dent. 2021;108:103629. doi:10.1016/j.jdent.2021.103629
16. Díaz Rosas CY, Cárdenas Vargas E, Castañeda-Delgado JE, AguileraGalaviz LA, Aceves Medina MC. Dental, periodontal and salivary conditions in diabetic children associated with metabolic control variables and nutritional plan adherence. Eur J Paediatr Dent. 2018;19(2):119–126.
17. Villa A, Connell CL, Abati S. Diagnosis and management of xerostomia and hyposalivation. Therapeutics and clinical risk management. 2015;11:45.
18. Dost, F, and C S Farah. "Stimulating the discussion on saliva substitutes: a clinical perspective." *Australian dental journal* vol. 58,1 (2013): 11-7.

Flowchart 1: Flowchart of participants over 21 days of study period

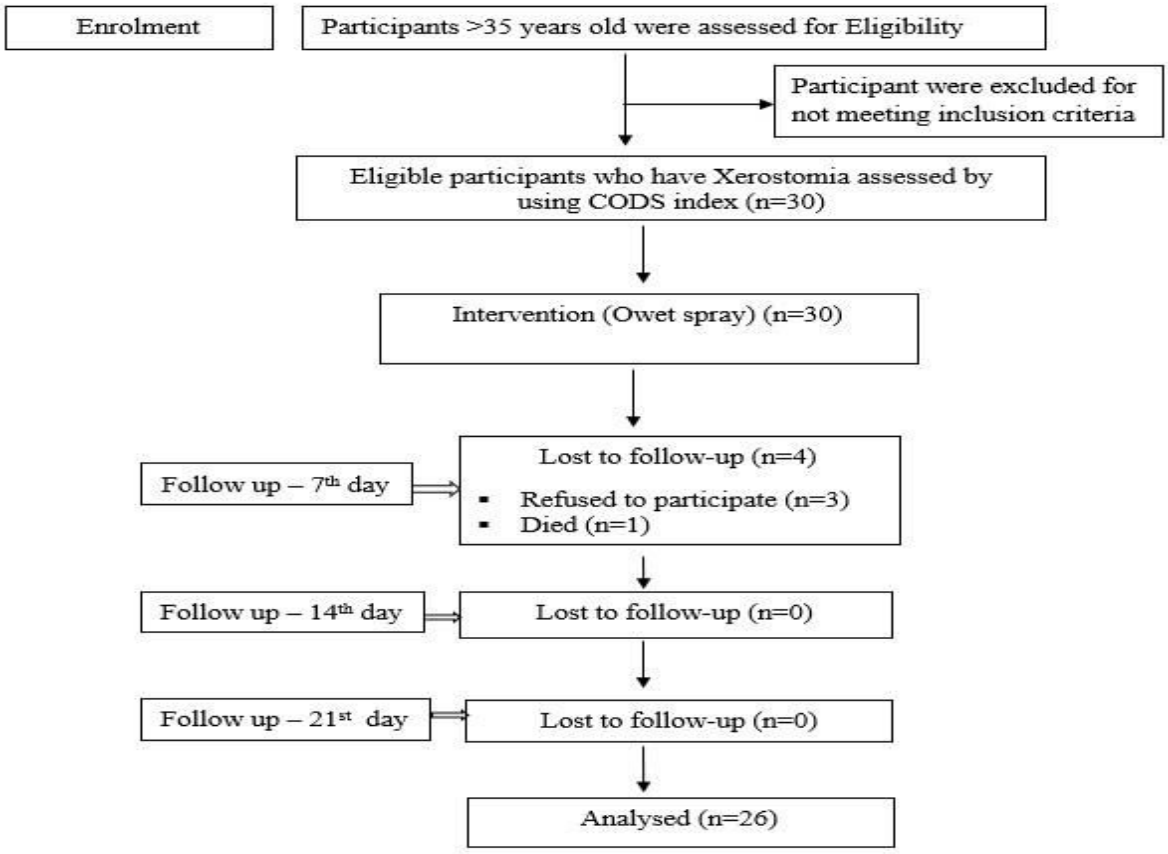

Table 1 Sociodemographic characterises of the respondents (n=90)

Variable	*n (%)*
Mean age (±SD)	58.9 ±12.2.
Gender	
Male	20 (22.2%)
Female	70 (77.8%)
Study site	
1. Olavina Halli - Rehabilitation and Community Development Centre, Kinya	20 (22.2%)
2. Seva Ashrama, Belma barke, Deralakatte	21 (23.4%)
3. Paschim RE-HAB Charitable Trust, Kotekar post, Someshwara	20 (22.2%)
4. Snehalaya Charitable Trust, Bachalike, Manjeshwar	29 (32.2%)

Table 2 Intra group comparison of Salivary flowrate within Group

Salivary flowrate					
	Baseline		**Final**		
	Mean	Standard Deviation	Mean	Standard Deviation	p - value
Group 1 (Owet spray)	0.17	0.078	0.41	0.166	< 0.0001
Group 2 (Saleva mouth rinse)	0.14	0.056	0.40	0.147	< 0.0001
Group 3 (Wet mouth)	0.18	0.075	0.38	0.186	< 0.0001

p-value based on Kruskal Wallis Z test

* = Statistically significant ($p<0.05$)