Salivary Substitutes and Xerostomia Related Quality of Life Among Type II Diabetic Patients - A Randomized Controlled Trial

[1]Dr. Krishnaprakash G, [2]Dr. Rekha P Shenoy, [3]Dr. Imran Pasha M, [4]Dr. Junaid, Dr. Supriya A

Postgraduate, Professor and Head, Reader, Senior lecturer, Senior lecturer
Department of Public Health Dentistry, Yenepoya Dental College

Abstract:
Aim: The aim of this study was to assess the efficacy of salivary substitutes in type II diabetic patients.
Materials and Methods: The randomized, a single-blinded study conducted at the institutionalized old age homes in Karnataka. Participants aged >35 years old with type II diabetes mellitus were recruited. Dry mouth conditions were assessed using CODS Index at baseline. The salivary flow rate and pH was assessed. To compare the salivary flowrate and pH in xerostomia among type II diabetic patients - Wilcoxon-signed rank test was used. The level of significance was set at p<0.05.
Result: The mean (±Standard Deviation) salivary flowrate level has increased from 0.17± 0.078 at baseline to 0.41±0.166 at end of 21st day. So, the weekly comparison between baseline and final evaluation showed statistically significant difference in salivary flowrate ($p < 0.001$)
Conclusion: Dry mouth is a persistent problem in many clinical settings, and clinical trials should evaluate how well treatments diminish xerostomia as well as their effects on patients' quality of life who have long-term, chronic dry mouth symptoms.

Keywords: Salivary substitute, flowrate, quality of life

Introduction

For optimal oral and overall health, saliva is necessary. While the majority of saliva is made up of water, which lubricates and comforts the oral mucosa, a small portion also contains various minerals and chemicals that serve as a natural defence mechanism.[1] The unstimulated salivary flow (SF) averages 0.25 to 0.35 mL/min. Hyposalivation is characterised by a flow rate of less than 0.1 mL/min.[2] Hyposalivation individuals have both a subjective and an objective reduction in salivary secretions, placing these patients at increased risk for cariogenic activity.[3] Reduced salivary flow or a change in the composition of saliva are two common symptoms of xerostomia.[4]

Diabetes mellitus (DM) is a metabolic disorder caused by a persistent hyperglycemia state. Nowadays, DM has spread over the world and its complications have an impact on the quality of life for those who have it.[5] One of the oral symptoms of diabetes mellitus is the subjective sensation of dry mouth (xerostomia), and its prevalence varies from 76.4% in elderly type II DM patients.[6] The burning and itching of the tongue and oral mucosa are among the symptoms that people with reduced salivary flow may experience. Along with having difficulty in speaking, they also had difficulty to taste, chew, and swallow food.[5] Since there is no cure for xerostomia, the major goals of treatment are to reduce clinical symptoms and enhance patients' quality of life.[1]

To reduce the signs and symptoms of dry mouth, many different products are employed.[7] Artificial saliva has received a lot of interest recently. Salivary substitutes come in a variety of forms, including lozenges, sprays, mouthwashes, gels, oils, chewing gum, and toothpastes.[8] Therefore, the aim of this study was to assess the efficacy of salivary substitute in type II diabetic patients.

Materials and Methods

Study Design

This is a randomized clinical trial, a single-blinded study conducted at the institutionalized old age homes in Karnataka. The selected participants were randomly selected as per requirements of the study following the Consolidated Standards of Reporting Trials recommendation as shown in **Flowchart 1**.

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, Karnataka. This study has received approval from the ethical committee of the institution and the study was registered in the Clinical Trials Registry India (CTRI).

Sample Size Calculation

Sample size is 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 is 24. Expected dropout is 10% by considering the dropout rate the sample size is 28 which is rounded off to 30 (n=30).

Study Group

Study population comprised 30 participants aged >35 years old in institutionalized old age 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 will be eligible.

Exclusion Criteria

- Patients having allergy to oral moisturizers.
- Patients who are under medications for 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.

The participants were randomly selected based on the inclusion and exclusion criteria (n=30) and salivary substitutes [Owet spray (West coast Pharmaceutical Works Ltd)] were provided.

Method

Participants dry mouth conditions were assessed using CODS Index at baseline. The salivary flow rate and pH was assessed. The examination was done by a single examiner with assistance from a trained recorder in institutionalized old age homes in Karnataka. The examiner 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. Samples of unstimulated saliva (3ml) was collected in sterile container by passive drool method. Salivary flow rate and pH was assessed.

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 and pH in xerostomia among institutionalized type II diabetic patients - Wilcoxon-signed rank 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 assess the efficacy of substitute saliva in type II diabetic patients. The study was conducted among 30 participants in four different institutionalized old age homes in Karnataka.

The mean age of the study participants was 57.2 ±12.7. Among the participants, 11 (36.7%) were male and 19 (63.3%) were females. Upon completion of the study 3 participants were lost to follow-up. Based on Clinical Oral Dryness Scale (CODS) index 23% of them had mild xerostomia, 50% of them had moderate xerostomia and 26% of them had severe xerostomia.

The mean (±standard Deviation) salivary flowrate level has increased from 0.17± 0.078 at baseline to 0.41±0.166 at end of 21st day. So, the weekly comparison between baseline and final evaluation showed statistically significant difference in salivary flowrate ($p < 0.001$). The mean (±standard Deviation) pH has increased from 5.70 ± 1.0 at baseline to 6.20 ± 2.1 at end of 21st day. Therefore, there is no significant difference in salivary pH ($p > 0.05$) **(Table 1; Figure 1)**.

Discussion:

An important issue for elderly persons is dry mouth. It could raise the risk of oral diseases, taste disorders, difficulty swallowing and chewing food, difficulty speaking, and poor quality of life. One of the most frequently suggested treatments for the management of xerostomia is intra-oral topical medications.

The majority of the negative symptoms of xerostomia and those that are associated are treated symptomatically. To compensate for the decreased saliva production, many artificial salivary substitutes have been developed. It is challenging to substitute saliva because it is such a complicated molecule. Additionally, most patients discover that frequent hydration helps with symptom relief, and artificial saliva substitutes work well in this regard.[14]

The justification for the selection of items and patients is significant when assessing the potential clinical implications of these findings. Owet spray provides various benefits, including a pleasant lemon flavour and an alcohol- and sugar-free formula that is safe for long-term use. 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.

According to the results, daily use of these novel topical dry mouth treatments dramatically increased unstimulated whole salivary flowrate for the course of the product's usage week. The current study found that diabetes patients had lower baseline levels of salivary flow. This outcome is consistent with the findings of other earlier studies. The decrease in salivary flow in diabetes individuals may be brought about by a variety of factors, including fatty infiltration of the salivary glands, hyperglycemia, glycosuria, dehydration brought on by polyuria, and neuropathy of the salivary glands.[11,12]

Studies have showed that diabetes patients had statistically significant higher salivary flow at the end of the study ($p<0.05$). The results show that the adverse effects of xerostomia on QoL and symptoms are significantly mitigated by using salivary substitutes. These cutting-edge topical dry mouth treatments considerably boosted unstimulated whole saliva when used on a regular basis. These results are in line with numerous other studies that have shown that topical dry mouth treatments can reduce xerostomia in a range of patient populations.[10] A study contracting with our results (villa et al).[13] found no compelling proof that any salivary substitute can lessen the signs and symptoms of dry mouth by accelerating salivary flow or changing the makeup of saliva.

Our ability to generalize from this study is limited. The study sample was relatively small and only a few variables were explored. Nevertheless, the sample size was still sufficient for adequate statistical analyses, and increasing the sample size would have been extremely demanding. The findings of this study suggest the significance of providing salivary substitutes to treat diabetic patients' feelings of dry mouth.

Conclusion

Importantly, dry mouth is a persistent problem in many clinical settings, and clinical trials should evaluate how well treatments diminish xerostomia as well as their effects on patients' quality of life who have long-term, chronic dry mouth symptoms.

Conflict of Interest: None

Acknowledgement: We sincerely extend our gratitude to secretaries of all the four institutionalized old age home in Karnataka.

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

References:

1. Assery, Mansour K A. "Efficacy of Artificial Salivary Substitutes in Treatment of Xerostomia: A Systematic Review." *Journal of pharmacy & bioallied sciences* vol. 11,Suppl 1 (2019): S1-S12.
2. Dost, F, and C S Farah. "Stimulating the discussion on saliva substitutes: a clinical perspective." *Australian dental journal* vol. 58,1 (2013): 11-7.
3. Delgado, Alex J et al. "pH and Erosive Potential of Commonly Used Oral Moisturizers." *Journal of prosthodontics : official journal of the American College of Prosthodontists* vol. 25,1 (2016): 39-43.
4. Vinke, Jeroen et al. "Dry mouth: saliva substitutes which adsorb and modify existing salivary condition films improve oral lubrication." *Clinical oral investigations* vol. 24,11 (2020): 4019-4030.
5. Sinjari, Bruna et al. "Artificial Saliva in Diabetic Xerostomia (ASDIX): Double Blind Trial of Aldiamed® Versus Placebo." *Journal of clinical medicine* vol. 9,7 2196. 11 Jul. 2020
6. Busato, Ivana Maria Saes et al. "Impact of xerostomia on the quality of life of adolescents with type 1 diabetes mellitus." *Oral surgery, oral medicine, oral pathology, oral radiology, and endodontics* vol. 108,3 (2009): 376-82.
7. Kvalheim, Siri F et al. "Randomized controlled trial of the effectiveness of three different oral moisturizers in palliative care patients." *European journal of oral sciences* vol. 127,6 (2019): 523-530.
8. Dalodom, Supranee et al. "Influence of oral moisturizing jelly as a saliva substitute for the relief of xerostomia in elderly patients with hypertension and diabetes mellitus." *Geriatric nursing (New York, N.Y.)* vol. 37,2 (2016): 101-9.
9. 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.
10. Matear DW, Barbaro J. Effectiveness of saliva substitute products in the treatment of dry mouth in the elderly: a pilot study. J R Soc Health. 2005;125:35–41
11. 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. doi:10.17219/acem/37067
12. 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
13. Villa A, Connell CL, Abati S. Diagnosis and management of xerostomia and hyposalivation. Therapeutics and clinical risk management. 2015;11:45.

Flowchart 1

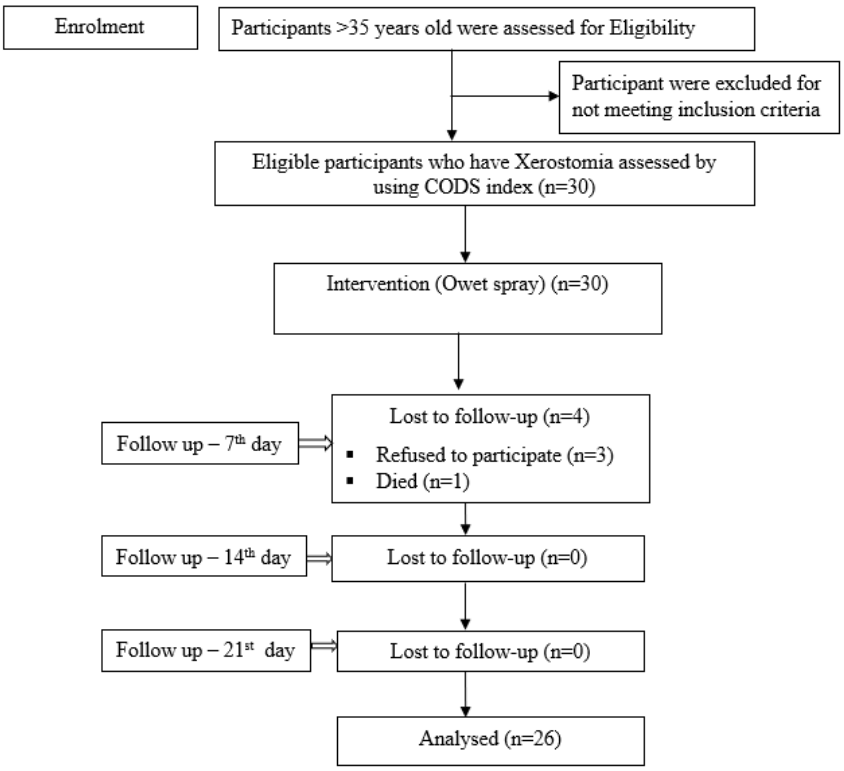

Table 1 Intra group comparison of Salivary flowrate and pH within Group

	Baseline				Final				
	Mean	Standard Deviation	Median	IQR	Mean	Standard Deviation	Median	IQR	p Value
Salivary Flowrate	0.17	0.078	0.20	0.1	0.41	0.166	0.45	0.2	**0.001***
Salivary pH	5.70	1.088	6	2	6.20	2.172	7	1	0.065

p-value based on Wilcoxon signed rank test
***** Statistically significant ($p<0.05$)

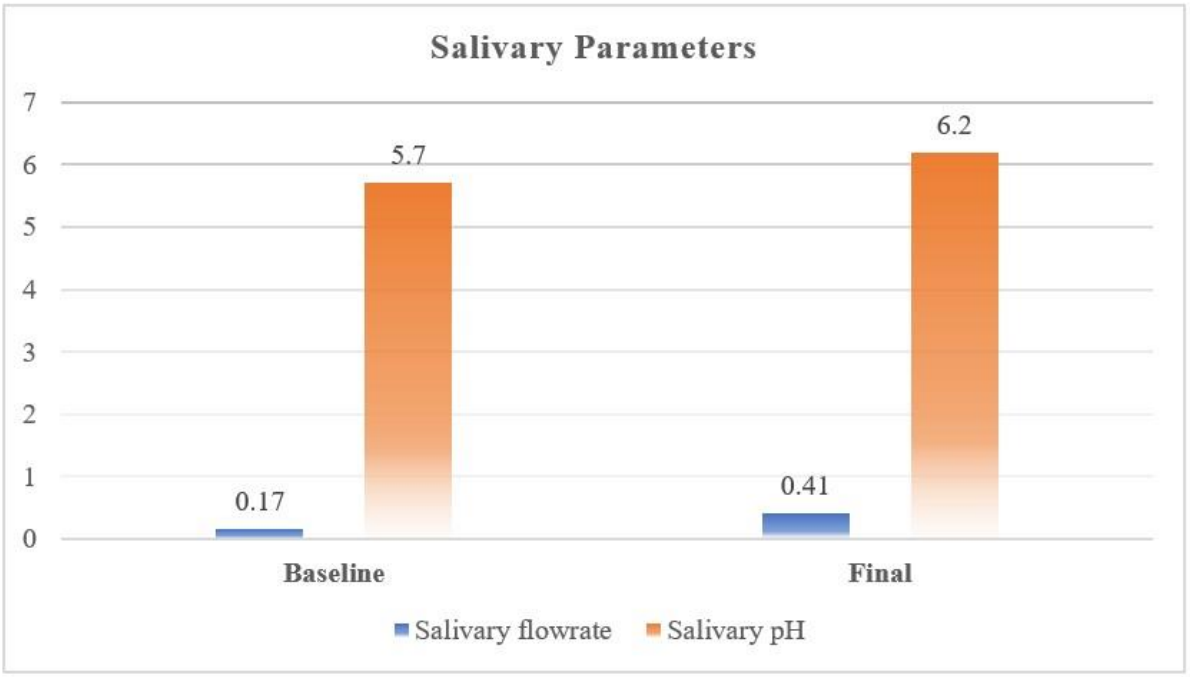

Figure 1 Intra group comparison of salivary flowrate and pH