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Feature Article

Influence of oral moisturizing jelly as a saliva substitute for the relief of xerostomia in elderly patients with hypertension and diabetes mellitus

Supranee Dalodom, MS, DDS [a], Aroonwan Lam-ubol, PhD, DDS [b], Sutha Jeanmaneechotechai, MS, DDS [a], Lalana Takamfoo, DDS [c], Watanyoo Intachai, DDS [d], Kochaporn Duangchada, DDS [e], Buakhao Hongsachum, MS, BS [f], Panitnart Kanjanatiwat, MS, BS [f,g], Piamkamon Vacharotayangul, PhD, DDS [b], Dunyaporn Trachootham, PhD, DDS [h,*]

[a] Bureau of Dental Health, Department of Health, Ministry of Health, Nonthaburi, Thailand
[b] Faculty of Dentistry, Srinakharinwirot University, Bangkok, Thailand
[c] Lampang Provincial Public Health Office, Lampang, Thailand
[d] Lampang Hospital, Lampang, Thailand
[e] Jaehom Hospital, Lampang, Thailand
[f] The Dental Innovation Foundation under Royal Patronage, His Majesty the King's Dental Service Unit, Bangkok, Thailand
[g] Food innovation and Packaging Center, Faculty of Agro-industry, Chiang Mai University, Chiang Mai, Thailand
[h] Institute of Nutrition, Mahidol University, Thailand

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ABSTRACT

Dry mouth is common in elderly patients. However, the use of saliva substitute has been limited due to its inedibility. This study investigated the efficacy of oral moisturizing jelly (OMJ), a novel edible saliva substitute. A pre-post design was conducted in 118 elderly patients diagnosed with hypertension and/or diabetes mellitus. After using OMJ, signs and symptoms of dry mouth were compared with baseline data. The properties of saliva were compared between the OMJ use and non-use periods. The use of OMJ for 2 weeks significantly reduced symptoms of dry mouth, while the use for 1 month reduced the signs of xerostomia, prevented the decline of salivary pH(s) and improved buffering capacities. OMJ was equally effective in patients taking 1 to 2 and 3 to 7 medications. Furthermore, 65% of patients preferred OMJ over a commercial product. OMJ could be new edible saliva substitute for elderly patients suffering from dry mouth.

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Introduction

Xerostomia (dry mouth) is a common complaint of almost 50% of elderly population.[1] Although salivation decreases with age, the actual causes of xerostomia in elders are likely drug-induced hyposalivation, head and neck irradiation and systemic conditions, such as Sjögren's syndrome and type 2 diabetes mellitus.[2] Many types of medicine cause dry mouth as a side effect e.g. anti-hypertensive drugs, anti-diabetic drugs, psychotherapeutic drugs and anti-histamines.[3] Owing to the multiple functions of saliva, hyposalivation leads to speech problems, taste disorders, chewing and swallowing difficulties, ill-fitting dentures and consequently poor qualities of life.[4,5] Furthermore, hyposalivation results in decreased oral clearance, declined salivary pH and buffering capacity, and reduced immune defenses.[6] These symptoms may increase risks of developing infectious oral diseases such as cervical caries, periodontitis and oral candidiasis.[6] Current interventions for xerostomia include systemic therapies such as cholinergic agonists; topical interventions such as saliva

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* Corresponding author. Institute of Nutrition, Mahidol University, 999 Phutthamonthon 4 Rd., Salaya, Phutthamonthon, Nakhon Pathom 73170, Thailand. Tel.: +66 2 800 2380x326; fax: +66 2 441 9344.
E-mail address: dunyaporn.tra@mahidol.ac.th (D. Trachootham).

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stimulants and saliva substitutes, and non-pharmacological interventions such as acupuncture and electrostimulation.[7–9] Recent evidence-based reviews concluded that systemic salivary stimulants e.g. pilocarpine and cevimeline are recommended only for primary and secondary Sjögren's syndrome.[7] No topical therapies have strong evidence to support their efficacies.[8] Evidences for acupuncture or electrostimulation devices are insufficient.[9] Thus, the development of novel effective approaches for alleviating xerostomia is essential.

In recent years, saliva substitutes have gained much attention. Saliva substitutes are available in various formulations e.g. lozenges, sprays, mouth rinses, gels, oils, chewing gums or toothpastes. However, no single product could adequately reproduce the properties of the natural saliva.[10] This is likely due to the inedibility of those saliva substitutes. The saliva substitute products usually contain preservatives. Therefore, their uses are limited only to oral cavity and they are not recommended to be swallowed.[10] This constraint has become critical and thus limited the uses of commercially available saliva substitutes. Saliva swallowing is a normal reflex to maintain a proper clearance by eliminating gram-negative bacilli from oropharynx.[11] In fact, oropharyngeal infection and sputum accumulation in patients with xerostomia could increase the risk of aspiration pneumonia.[11] Furthermore, saliva swallowing is critical for food ingestion since the flow of saliva through oropharyngeal isthmus stimulates swallowing process and taste perception in oropharyngeal area.[12] Therefore, the general properties of ideal saliva substitutes should be inexpensive, edible, hydrating, easy-to-swallow but retainable in the mouth.

Recently, oral moisturizing jelly (OMJ) was successfully developed by joint collaborators from various disciplines including dentistry, nursing, medicine and food sciences. OMJ is a ready-to-eat gel with semi-solid appearance but could be melted under oral environment temperature.[13] Upon biting or spooning, the gel will release some water due to syneresis.[14] Since patients with xerostomia often have chewing and swallowing problems,[4] the texture and gel strength of OMJ were designed based on a previous research and development of Nutri-jelly,[15] a nutritious edible gel proven to be effective in improving quality of life in head and neck cancer patients with chewing and swallowing difficulties.[16] Unlike Nutri-jelly, OMJ has no nutrients but contains buffering agents and high water content. In addition, OMJ has neutral pH (6.8–7) and normal buffering capacity, imitating the natural saliva.[13] The most severe xerostomia was found in head and neck cancer patients undergoing radiation therapy. A home-use-test of OMJ was conducted in 36 cancer patients with xerostomia.[13] The patients used the OMJ products for two weeks and recorded their uses and satisfactions in their diaries. The study showed that 82.3% of the cancer patients were satisfied with the texture, flavor and moisture of OMJ.[13] In addition, the satisfaction of OMJ was higher than that of a commercially available saliva gel.[13] After taking one spoon of OMJ, most patients required an additional spoon after 2 h and 45 min, suggesting that OMJ can retain in the mouth for almost 3 h.[13] Although dry mouth is common in elderly population, the intervention studies for treatment of dry mouth in these patients have been limited.[17] Therefore, the aim of this study was to investigate the efficacy of OMJ in elderly patients.

Methods

Intervention

Oral moisturizing jelly (OMJ) products were provided by Dental Innovation Foundation under Royal Patronage, a non-profit organization. The OMJ products passed food safety test (free of pathogenic micro-organisms and hazardous metals), according to the regulation of Thai Food and Drug Administration (FDA). The OMJ products were manufactured in a clean room by hot-filling. The OMJ products have 6-month shelf life at room temperature. Besides, the products are available in two flavors: strawberry and lime mint (Fig. 1a), and their biochemical properties are not different.[13] The products are semi-solid with consistency comparable to National Dysphagic Diet (NDD) level 1,[18] non-nutritive, water-releasing and ready-to-eat by spoon (Fig. 1b).

Participants

Patients were recruited from the out-patient departments of two hospitals located in Lampang province of Thailand. Prior to the recruitment, all patients were screened based on the following inclusion criteria: being diagnosed with hypertension or diabetes mellitus and receiving medical therapies for at least 1 year; having complaint of xerostomia. Exclusion criteria were as follows: having subjective dry mouth score <3 or objective dry mouth score <2; having oral candidiasis; being unable to make reliable decisions or communications. All patients signed their written informed consents prior to data collection. Their identities had been protected, following Good Clinical Practice guidelines of International Conference on Harmonisation (ICH-GCP).

Sample size calculation

Sample size was identified by priori power analysis using G Power 3.1.[19] The effect size was calculated from the pilot data of 10 patients using their mean subjective dry mouth scores and standard deviations at baseline, 2 weeks and 1 month after OMJ use. Based on repeated measure analysis of variance (repeated measure ANOVA), it was necessary to enroll 70 patients to achieve 90% power at 2-sided 1% significance level. To account for an up to 30% drop-out rate, at least 100 patients were required. Initially, 126 patients agreed to be enrolled in the study. Finally, completed data were presented from 118 patients (93.6%).

Study procedures

This study was approved by the institutional ethic committee for research in human of Department of Health, Ministry of Health, Thailand, and performed according to Declaration of Helsinki. To investigate the possible benefits of OMJ, a pre-post design was used. At the beginning, all patients who passed the inclusion criteria signed their written informed consents. Then, all of them received their favorite flavored OMJ products in a volume of 50 ml (10 ml $\times$ 5 times) per day. After using the OMJ for 2 weeks and 1 month, their signs and symptoms of xerostomia were measured as objective and subjective dry mouth scores, respectively, and compared with their baseline data (prior to use). Their properties of saliva, including salivary pH(s), buffering capacities and flow rates, were subsequently compared with their baseline data. Since, the patients were also taking other medicines with potential side effects on saliva qualities during the study period, their changes of saliva properties during 'OMJ use period' were monitored and compared within the same patients during 'OMJ non-use' period. The data for 'OMJ non-use' period were collected within the same patients three months later. To ensure that the baseline data of "OMJ use and non-use" periods was comparable, the history of medication uses was rechecked. It was confirmed that all patients received similar medications and doses in both periods.

Measures

The primary outcome measures were satisfaction and subjective dry mouth scores. The secondary outcomes measures were