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Article History
Received 8 October 2013
Accepted 5 November 2013

Abstract
The purpose of this study was to develop a Japanese questionnaire for subjective oral dryness and reveal factors associated with xerostomia among Japanese youth. A sample of 237 male and 144 female Japanese students (mean age: 20.8 years) was selected. The validity of the questionnaire was assessed through factor analysis, while its reliability and internal consistency were assessed with Cronbach’s alpha. The impact of health, daily life, food intake, and oral dryness on xerostomia was assessed. To this end, subjects responded to questions on oral dryness, health, daily life, and food intake; unstimulated saliva was also collected from the subjects. Unstimulated salivary flow rate ranged from 0.02 to 1.8 ml/min (mean: 0.32 ml/min.). Factor analysis revealed that the questionnaire comprised 12 items making up four factors, namely, “at swallowing the food particle,” “oral dryness during mastication,” “dryness of the lips or facial surface,” and “dryness at night.” All factors had a Cronbach’s alpha of 0.6 or more. In addition, subjects with an unbalanced diet had a threefold susceptibility to xerostomia.

The questionnaire is deemed a valid and reliable measure of subjective oral dryness among Japanese youth. By using this questionnaire, the relationship between xerostomia and a self-reported unbalanced diet was suggested.

Introduction
Saliva plays an important role in general and oral cavity health(1, 2). Sufficient, good-quality saliva enables the smooth capturing of food, wetting or softening of food to facilitate mastication, swallowing, and digestion. The role of saliva also includes enabling the mechanical protection of soft and hard oral tissues both at rest and during a particular oral process (e.g., mastication). Furthermore, salivary antibodies offer protection against various types of bacteria, viruses, and fungi. With regard to its oral functional role, salivary flow rate affects speech, taste, and denture retention (3). Inefficient salivary gland function may lead to severe oral health impairment (4). Examples of these are dental caries, mucous membrane alterations, speech difficulty, dysphagia, and microbial infections. Aging and a general decrease in salivary flow has several effects on an individual’s daily life, particularly with regard to aspects such as food intake, treatment modalities, and oral care.

The mean flow rate of unstimulated whole saliva is approximately 0.3 ml/min, but this rate can range widely—from 0.008 to 1.85 ml/min (5). An objective unstimulated salivary flow rate that falls below 0.1 ml/min is diagnosed as “hyposalivation” (5). There are various conjectures regarding the possible causes of hyposalivation. Examples of these are systemic disorders, duration of the potential medications (6), and the possible effects of radiotherapy for the treatment of tumors in the head and neck region (7). Although the amount of saliva secreted might objectively be within the normal range, subjective experiences may be contrary to objective measures; xerostomia is a condition involving subjective oral dryness (8). No less than 20% to 65% of the population over 65 years of age complains of xerostomia (3, 9–12), and up to one-third of individuals with xerostomia do not show a decrease in the salivary flow rate (3). Thus, in order to
discriminate between hyposalivation and xerostomia, the objective salivary flow rate, accompanied by the use of a valid and reliable measure of subjective dryness, must be used as diagnostic test. Although there are validated questionnaires for the measurement of oral dryness in various countries (13-15), none have been found in Japan. In this study, an existing English questionnaire is translated into Japanese and administered to a sample of Japanese youth for validation and reliability testing, with a view towards developing a valid Japanese questionnaire measuring subjective oral dryness. Additionally, the questionnaire is used to determine the prevalence of hyposalivation and xerostomia among Japanese youth, as well as reveal factors that are associated with xerostomia, despite there not being a decrease in the salivary flow rate.

Materials and Methods

Subjects

The sample comprised 381 students at Nihon University School of Dentistry at Matsudo, including 237 men and 144 women aged between 18 and 34 years (mean age: 20.8 yrs, standard deviation: 2.1 yrs). All of the subjects were healthy and not using any medication. The subjects were required to complete the questionnaire on oral dryness. Subsequently, unstimulated saliva was collected. Informed consent was obtained from each subject prior to participation. The study protocol was approved by the ethics committee at Nihon University School of Dentistry at Matsudo (#: EC 10-035).

The questionnaire

Seventeen items relating to oral dryness, chosen after referring to several English articles (13-15) (Table 1), were used for the construction of the Japanese version of the questionnaire. The items were translated into Japanese and back-translated to English, so as to verify the accuracy of the translation. Responses were made on a five-point Likert scale: “1=Never,” “2=Hardly ever,” “3=Occasionally,” “4=Frequently,” and “5=Always.” Additionally, ten items related to health, daily life, and food (Table 2) were presented along a dichotomous scale requiring “Yes/No” responses. The items inquired about factors that are related to xerostomia.

Collection of unstimulated saliva

Unstimulated whole saliva was collected through the spitting method from 11:00 to 11:45 a.m. from June to July 2011. Prior to the collection of saliva, the subjects attended a 60-minute lecture, during which they had refrained from food, beverages, and smoking (14, 16). Before the collection, the subjects were asked to sit in an upright position and swallow all the saliva in their oral cavity. They were then asked not to swallow for 5 minutes and subsequently expectorate the accumulated saliva into a disposable cup after the session. Flow rates of whole saliva were expressed in ml/min.

Data Analysis

The validity and reliability of the questionnaire

Construct validity was assessed through factor analysis, while reliability, in the form of internal consistency, was determined through Cronbach’s alpha after the factor and constructed items had been defined. The scree plot revealed that 4-factors was determined as valuable numbers of common factors. Promax rotation was conducted for ease of interpretation. The items were classified into four, inter-
interpreted factors. Items with a factor loading of 0.40 or above were extracted and grouped into their respective, relevant factors. Once the factors and their constituent items had been defined, Cronbach’s alpha was calculated to assess internal consistency.

The association between objective assessment and subjective saliva flow

Participants whose unstimulated saliva rate fell below the overall group average were classified into the objective dryness (OD) group, while those with an above-average unstimulated saliva rate were classified as the non-objective dryness (NOD) group. In the same way, when a participant’s total score on the constructed questionnaire fell below the overall average rate, that participant was classified into the subjective dryness (SD) group. In instances of an above-average total score, the concerned subject was classified into the non-subjective dryness (NSD) group. Furthermore, $2 \times 2$ contingency tables were generated to express the prevalence of hyposalivation and xerostomia.

Health, daily life, food intake, oral dryness, and xerostomia without a decrease in salivary flow

Subjects presenting with xerostomia and forming part of the NOD group ($n=154$) were assessed, since the etiology of their condition is unclear. By generating $2 \times 2$ contingency tables comprising 10 questions, a chi-square test was used to determine the difference between the SD and NSD groups in terms of the proportion of “Yes” responses given for each question. Odds ratios were also calculated to indicate the strength of the impact of health, daily life, and food intake on xerostomia. StataTM version 12.0 (College Station, TX, USA) was used for all of the analyses.

Results

Validity and reliability of the questionnaire

Factor analysis revealed that the questionnaire consisted of four factors with 12 items (Table 3). Factor 1 comprised three items (Q3, 10, and 17), interpreted as “swallowing the food particle.” Factor 2 comprised three items (Q1, 2, and 15), interpreted as “oral dryness during mastication.” Factor 3 comprised three items (Q11, 12, and 13), interpreted as “dryness of the lips or the facial surface.” Factor 4 comprised three items (Q5, 7, and 16), interpreted as “dryness at night.” Items 4, 6, 8, 9, and 14 were excluded because their factor loadings were below 0.4. The internal consistency of the respective four factors ranged from moderate to sufficient: Cronbach’s alpha was 0.72 for Factor 0.73 for Factor 2, 0.62 for Factor 3, and 0.63 for Factor 4 (Table 4).

The association between objective saliva flow and subjective assessment by questionnaire

The participants’ unstimulated salivary flow rate ranged

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**Table 3** Factor structure of the oral dryness questionnaire after promax rotation

<table>
<thead>
<tr>
<th>Item</th>
<th>Factor 1</th>
<th>Factor 2</th>
<th>Factor 3</th>
<th>Factor 4</th>
<th>Uniqueness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have difficulties swallowing any foods?</td>
<td>0.42</td>
<td>0.38</td>
<td>0.05</td>
<td>-0.07</td>
<td>0.55</td>
</tr>
<tr>
<td>Do you have difficulties swallowing certain foods?</td>
<td>0.76</td>
<td>0.11</td>
<td>-0.15</td>
<td>-0.06</td>
<td>0.47</td>
</tr>
<tr>
<td>Do you have difficulties eating any dry foods?</td>
<td>0.60</td>
<td>0.26</td>
<td>-0.14</td>
<td>0.13</td>
<td>0.45</td>
</tr>
<tr>
<td>Do you sip liquids to aid in swallowing dry foods?</td>
<td>0.01</td>
<td>0.74</td>
<td>-0.03</td>
<td>-0.04</td>
<td>0.48</td>
</tr>
<tr>
<td>Does your mouth feel dry when eating meal?</td>
<td>0.03</td>
<td>0.44</td>
<td>0.16</td>
<td>-0.02</td>
<td>0.73</td>
</tr>
<tr>
<td>Do you need liquids when swallowing foods?</td>
<td>0.10</td>
<td>0.79</td>
<td>0.04</td>
<td>0.00</td>
<td>0.27</td>
</tr>
<tr>
<td>Does your skin of face feel dry?</td>
<td>-0.09</td>
<td>-0.01</td>
<td>0.76</td>
<td>-0.09</td>
<td>0.53</td>
</tr>
<tr>
<td>Does your eyes feel dry?</td>
<td>0.09</td>
<td>0.00</td>
<td>0.50</td>
<td>-0.09</td>
<td>0.73</td>
</tr>
<tr>
<td>Does your lips feel dry?</td>
<td>-0.20</td>
<td>0.11</td>
<td>0.70</td>
<td>-0.05</td>
<td>0.60</td>
</tr>
<tr>
<td>Does your mouth feel dry at night or on awakening?</td>
<td>-0.18</td>
<td>0.1</td>
<td>0.25</td>
<td>0.44</td>
<td>0.70</td>
</tr>
<tr>
<td>Do you keep a glass of water by your bed?</td>
<td>-0.01</td>
<td>-0.09</td>
<td>-0.07</td>
<td>0.72</td>
<td>0.56</td>
</tr>
<tr>
<td>Do you get up to drink at night?</td>
<td>0.05</td>
<td>0.00</td>
<td>-0.14</td>
<td>0.75</td>
<td>0.50</td>
</tr>
<tr>
<td>Does the amount of saliva in your mouth seem to be little?</td>
<td>0.23</td>
<td>0.19</td>
<td>0.05</td>
<td>0.17</td>
<td>0.75</td>
</tr>
<tr>
<td>Does your mouth feel dry in the day time?</td>
<td>0.04</td>
<td>0.11</td>
<td>0.30</td>
<td>0.31</td>
<td>0.64</td>
</tr>
<tr>
<td>Do you chew gum daily to relieve oral dryness?</td>
<td>0.30</td>
<td>-0.15</td>
<td>0.28</td>
<td>0.02</td>
<td>0.78</td>
</tr>
<tr>
<td>Do you use candies to relieve oral dryness?</td>
<td>0.35</td>
<td>-0.20</td>
<td>0.29</td>
<td>-0.01</td>
<td>0.75</td>
</tr>
<tr>
<td>Does your inside of nose feel dry?</td>
<td>0.26</td>
<td>-0.04</td>
<td>0.25</td>
<td>0.13</td>
<td>0.73</td>
</tr>
</tbody>
</table>

**Table 4** Internal consistency of respective factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>Question Interpretation</th>
<th>Cronbach’s α</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor 1</td>
<td>Swallowing the food particle</td>
<td>0.72</td>
</tr>
<tr>
<td>Factor 2</td>
<td>Oral dryness during eating</td>
<td>0.73</td>
</tr>
<tr>
<td>Factor 3</td>
<td>Dryness of lips or facial surface</td>
<td>0.62</td>
</tr>
<tr>
<td>Factor 4</td>
<td>Dryness at night</td>
<td>0.63</td>
</tr>
</tbody>
</table>
from 0.02 to 1.8 ml/min (mean: 0.32 ml/min, 95% confidence interval: 0.30 to 0.35). Figure 1 shows all the responses on the questionnaire, with respect to each of the four factors; the response options were organized on a Likert-type scale. The total scores on the questionnaire ranged from 14 to 46 (mean: 28.5, 95% confidence interval: 28.0 to 29.1). The cut-off point for the subjective and objective values relating to oral dryness was set according to the respective mean values; to this end, a 2×2 contingency table was generated (Table 5). The prevalence of SD within the OD, xerostomia, and hyposalivation groups was 58% (131/227), and was 55% (84/154) within the NOD and xerostomia without hyposalivation groups. This indicated an equivalent prevalence of SD among subjects with xerostomia and hyposalivation, and those with xerostomia only (OR: 1.14, 95% CI: 0.75 to 1.72, p=0.54, chi-square test). This further indicates that the disagreement between objective and subjective assessment is not rare.

Impact of health, daily life, food intake, and oral dryness on xerostomia

Table 6 shows the impact of health, daily life, and food intake on xerostomia. Subjects who had an unbalanced diet were more likely to have xerostomia than those who had not (odds ratio=3.04; 95% CI: 1.41 to 6.69, p=0.002, chi-square test).

Discussion

The objectives of this study were to construct a valid and reliable questionnaire measuring subjective oral dryness, and identify the factors that are associated with xerostomia. The results revealed that the Japanese version of the questionnaire on subjective oral dryness comprised four factors, with 12 items. Approximately 22% of the subjects reported dryness, despite the above-average objective unstimulated salivary flow values. These findings indicated xerostomia. Additionally, the subjects who had an unbal-
anced diet had three times the odds of xerostomia than those who had a balanced diet. This suggests that an unbalanced diet may play an important role in the etiology of xerostomia.

The questionnaire consisted of four factors. Two of these each comprised three questions, tapping into oral function during mastication and swallowing. The remaining two factors also each comprised three questions on perceived oral dryness during the day and at night. Thomson et al. (14) also carried out factor analysis of the current questionnaire but found a two-factor structure: one related to xerostomia and the second related to burning-mouth syndrome. These constituted symptomatic interpretations. Other studies were informed by Thomson et al.'s (14) questionnaires, structuring items independently without interpretation or grouping the items into domains. Furthermore, no other studies have incorporated the domain of oral dryness, as ours did. Thus, the four-factor domain derived from the current study could enable a detailed assessment of how and when people experience oral dryness.

The general, average mean flow rate of unstimulated whole saliva is 0.3 ml/min among older populations (5). This study indicated a slightly higher average that, nonetheless, can be considered low for a younger population. This could be due to the lecture that the subjects had attended earlier, and having been confined to a lecture room for almost an hour, as well as seasonal effects, given the high temperatures typical of early summer at the time of the study. Elishoov et al. (16) reported that parotid and submandibular/sublingual salivary flow rate is significantly higher in winter than in summer.

In practice, it is typically not easy to assess hyposalivation or xerostomia using either an objective or subjective measure, since xerostomia is a subjective feeling, and up to one-third of the cases does not reflect a real reduction in the salivary flow rate (3). In this study, 39% of subjects (84 out of 215 who subjectively experienced oral dryness) did not show an actual decrease in the rate of unstimulated saliva. Thus, the use of both objective and subjective assessment to obtain the relevant information leading to accurate diagnosis of xerostomia with or without hyposalivation, is important for the development of a treatment plan against this complex pathology. For example, xerostomia patients with a low salivary flow rate are initially required to induce an increase in salivary flow through, for instance, the use of a powered toothbrush (2) or insertion of suitable den-

ures (17). However, xerostomia patients who do not experience a decrease in the salivary flow rate require a different approach. The results from this study indicate that by obtaining information on the health, daily life, and food intake of individuals with subjective dryness and a salivary flow rate considered to be within the normal range, clinicians may determine the factors that are associated with these symptoms, thereby advancing towards the development of an appropriate treatment plan for each patient (e.g., dietary change).

However, the exact effects of individual food intake or eating habits is unclear; this serves as a limitation of this study. Further studies must clarify the effects of an unbalanced diet on xerostomia, and whether an improvement in eating habits would improve the symptoms, especially among patients without objective dryness. In addition, future research could focus on the development and implementation of appropriate treatment modalities for this condition.

References