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Novel Multidisciplinary Salivary Gland Society (MSGS) Questionnaire: An International Consensus

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    - Department of Otorhinolaryngology-Head and Neck Surgery
  - Pr Marchal's private practice
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Objectives: First, establishment and validation of a novel questionnaire documenting the burden of xerostomia and sialadenitis symptoms, including quality of life. Second, to compare two versions regarding the answering scale (proposed developed answers Q3 vs. 0–10 visual analogue scale Q10) of our newly developed questionnaire, in order to evaluate their comprehension by patients and their reproducibility in time.

Study Design: The study is a systematic review regarding the evaluation of the existing questionnaire and a cohort study regarding the validation of our new MSGS questionnaire.

Materials and Methods: A Multidisciplinary Salivary Gland Society (MSGS) questionnaire consisting of 20 questions and two scoring systems was developed to quantify symptoms of dry mouth and sialadenitis. Validation of the questionnaire was carried out on 199 patients with salivary pathologies (digestive, nasal, or age-related xerostomia, post radiation therapy, post radioiodine therapy, Sjögren's syndrome, IgG4 disease, recurrent juvenile parotitis, stones, and strictures) and a control group of 66 healthy volunteers. The coherence of the questionnaire's items, its reliability to distinguish patients from healthy volunteers, its comparison with unstimulated sialometry, and the time to fill both versions were assessed.

Results: The novel MSGS questionnaire showed good internal coherence of the items, indicating its pertinence: the scale reliability coefficients amounted to a Cronbach's alpha of 0.92 for Q10 and 0.90 for Q3. The time to complete Q3 and Q10 amounted, respectively, to 5.23 min ($\pm$2.3 min) and 5.65 min ($\pm$2.64 min) for patients and to 3.94 min ($\pm$3.94 min) and 3.75 min ($\pm$2.11 min) for healthy volunteers. The difference between Q3 and Q10 was not significant.

Conclusion: We present a novel self-administered questionnaire quantifying xerostomia and non-tumoral salivary gland pathologies. We recommend the use of the Q10 version, as its scale type is well known in the literature and it translation for international use will be more accurate.

Key Words: Chronic obstructive sialadenitis score (COSS), Multidisciplinary Salivary Gland Society (MSGS) questionnaire, oral dryness questionnaire (DMQ), sialadenitis, xerostomia.

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INTRODUCTION

Salivary gland complaints are known to have a major effect on the quality of life (QOL) of patients. In almost all cases, they comprise xerostomia and/or sialadenitis.

Xerostomia is defined as subjective oral dryness in contrast to hyposalivation, which is an objective reduction of the salivary flow.[1–3] The prevalence of xerostomia in the general population varies from 8%[4] to 13%.[5] The range of the underlying medical conditions leading to hyposalivation is increasing. Whereas Sjögren's syndrome, xerostomia after radiation therapy, and xerogenic medication have been known for a long time, there is rising incidence of other pathologies leading to xerostomia including post radioiodine treatment for thyroid cancer,[6] juvenile recurrent parotitis (JRP),[7] IgG4-related disease,[8] and chronic sialadenitis caused by salivary stones or salivary strictures of unknown etiology.[9,10]

Sialadenitis is defined as an infection of the salivary glands, which can be caused by strictures and/or calculus. Strictures, defined as a shrinkage of the salivary excretory ducts, are either idiopathic or induced by bacterial and/or auto-immune diseases, and are most frequently located in the parotid glands.[3,11] Salivary stones are calcified concretions of unknown etiology, most frequently located in the submandibular gland.

Xerostomia and sialadenitis are not rare conditions and can be linked together particularly in case of chronic sialadenitis,[12] especially if they are linked to auto-immune disorders.[13] Symptoms experienced by patients presenting salivary gland pathologies are assessed by questionnaires that evaluate the patient's complaints and their repercussions on their QOL. As of today, over 100 questionnaires regarding xerostomia and oral pathologies are available in the literature; however, none has been validated to assesses completely both sialadenitis and xerostomia regarding any type of treatment (medical, sialendoscopic, or surgical).

The aim of this paper is to propose and validate a new self-administered questionnaire, which could be used to assess salivary gland pathologies and to quantify the burden of symptoms caused by xerostomia and sialadenitis. The secondary aim of this study is to compare two versions regarding the answering scale (proposed developed answers vs. 0–10 visual analogue scale (VAS)) of our newly developed questionnaire, in order to evaluate their comprehension by patients and their reproducibility in time. The purpose of this new questionnaire is to evaluate the patients' global salivary gland symptoms and their QOL before and after medical sialendoscopic-based or surgical treatments. It does not intend to establish a standard or a threshold above which we consider the patients "pathological" or "not pathological," since by definition it is subjective and will vary among patients. Also, its purpose is not establishing a diagnosis of the salivary gland disease.

The main hypothesis of this study would be to be able to distinguish healthy patients from patients with salivary gland disorders with our new questionnaire. The secondary hypothesis was that a questionnaire with proposed detailed answers would be better understood and have less bias regarding its answers than a 0 to 10 VAS, which would be more related to the emotional variable status of patients than to their actual symptoms.

This questionnaire was presented during the second International Sialendoscopy Conference in Dubai in January, 2020, with 125 faculties from 47 countries present. It was discussed by the participants, members of the International Sialendoscopy Society, and Multidisciplinary Salivary Gland Society, and accepted. It was decided during the meeting to name the questionnaire after the Multidisciplinary Salivary Gland Society (MSGS). A prospective multicentric study with 27 countries is under way, as the questionnaire will be translated into different languages and implemented in many countries.

METHODS

Approval for this study was obtained from the local and national Swiss ethical committee (number 2019–00253).

Novel MSGS Questionnaire

Based on the evaluation of existing questionnaires on oral pathologies and our clinical experience, we developed the MSGS questionnaire. We wanted it to be as complete as possible, as short as possible, and mostly easy to understand and fill by patients.

The questionnaire is preceded by open questions regarding tobacco consumption, current medications having effect on xerostomia (diuretics, antidepressants, beta-blockers, sleeping pills, and others), diagnosis of systemic diseases or salivary-gland-specific diseases (Sjögren's syndrome, IgG4-related disease, JRP), and prior radioiodine or radiotherapy treatment. The type of gland affected is also monitored.

The MSGS questionnaire contains 20 questions divided in two groups: 13 regarding xerostomia and 7 regarding sialadenitis. Questions regarding xerostomia are the following: intensity and frequency of dry mouth; saliva quality and taste; need to moisturize during day and night; ability to talk and eat (being the most disabling consequences of dry mouth in daily life); dryness of lips, nose, and eyes (essential to assess systemic immunological disorders, anti-cholinergic drug effects, or adverse effects of radioiodine treatment); and finally QOL in relation to dry-mouth symptoms. Questions regarding sialadenitis are the following: feeling of tenderness; swelling during meals (typical for acute sialadenitis) or between meals, which, being signs of chronic sialadenitis-related, may occur anytime; persistence of swellings and need to take antibiotics (indicating the severity of sialadenitis and helping the comparison before and after treatment); pain and discomfort induced by these swellings (aiming to assess the disability), and QOL encountered by the patients.

We assessed two versions of the MSGS questionnaire using the same questions but different answering scales: one with four detailed possible answers (Q3, Table I), and the other using a VAS (Q10, Table II). We hypothesized that fixed answers might add more objectivity than a 0–10 VAS, which might be influenced by pain or the mood of the patients. The Q3 version had a total score that could vary between 0 and 60 points, as every question had four possible answers which were quoted from 0 to 3 points. The Q10 version had a total score that could vary from 0 to 200 points, as there could be 0 to 10 points attributed to every question.

Validation Method of the MSGS Questionnaire

Patients and volunteers were included in this study from August 8, 2017 until October 1, 2020. Sixty-six healthy volunteers, who were acquaintances of the main authors, nurses and physicians, or colleagues from the Geneva University Hospital, without salivary symptoms or known salivary diseases were selected through an anamnesis including past or actual salivary gland symptoms such as pain, swelling in the area of the salivary glands, and dry mouth. They were also asked about known medical conditions that could be linked to salivary gland disorders and the use of any medication. If any of those criteria was met, they were excluded. Regarding the healthy volunteers, the inclusion criteria were the following: absence of salivary symptoms or known salivary diseases. One-hundred and ninety-nine patients visiting the salivary gland center in Geneva presenting the following conditions were recruited: digestive, nasal, or age-related xerostomia; post radiation therapy and radioiodine therapy; Sjögren's syndrome; IgG4 disease; JRP; and stones and strictures of unknown etiology. As their pathophysiological expression is strictures, patients with Sjögren's syndrome, IgG4 disease, radioiodine therapy, and JRP were included in the stenosis group.

Participants Were Asked to Complete Both Versions Q3 and Q10 of the MSGS Questionnaire.

Time to complete both Q3 and Q10 was assessed in minutes. The aim was to highlight any eventual discrepancy regarding the time needed to complete both versions.

Stenotic pathologies (idiopathic stenosis, Sjögren's syndrome, IgG4 disease, and JRP) generally linked with chronic sialadenitis were analyzed separately using the subscore of items 1–13 regarding xerostomia. As stones refers more frequently to acute sialadenitis, these symptoms were analyzed separately using the second part of the questionnaire, being the subscore of items 14–20.

A subgroup of patients randomly assigned were asked to fill out the two versions of the questionnaire Q3 and Q10 within 15 days after their outpatient clinic visit and asked to send it back for analysis, in order to assess the reproducibility of answering pattern in time.

Sialometry was also performed to test whether the scores obtained by the novel MSGS questionnaire would predict hyposalivation. The method used for sialometry was the following: 5 cm × 5 cm gauze compresses were disposed over each Stensen's papillas and over both Wharton's papillas during 6 min and/or during 15 min. The compresses were weighed before and after saliva collection. We chose to assess the sialometry during 6 min, as it is a standardized time duration used in the Geneva University Hospital, and also to extend the sialometry up to 15 min, as the European–American consensus regarding Sjögren's syndrome has established a duration of 15 min for sialometry to be more accurate.[14]Although the draining and the spitting methods are the most frequent sialometry methods used in the literature, as they have been acknowledged to be reproductible and reliable,[15] we chose to use the swab method in our study because we believe it to be very difficult to ask patients with xerostomia to spit or to drain saliva in a dry mouth.

There is no sialometry consensus cutoff to differentiate normal from low salivary flow; however, most authors agree that below 0.1 ml/min, a diagnosis of hyposalivation can be established and that values below 0.25 ml/min are considered low and below normal.[16–18]

Based on these considerations repeatedly published in the literature, we defined a binary threshold for sialometry of <1.5 g at 15 min[19] and <0.72 g at 6 min.[20] The data collection was performed using case report forms (CRFs) (Appendix 1), which contained both Q3 and Q10 MSGS questionnaires, preceded by open questions regarding any general health condition that could be linked to salivary gland disorders. The time needed to complete the questionnaire and the sialometry values were included in those CRFs. The data abstraction into an Excel file was performed by two authors and then verified by the statistician.

Statistical Analysis

All statistical analyses were done with Stata v16.0. The coherence of the questionnaire items, the time to complete both Q3 and Q10, the reliability of the questionnaire to distinguish pathological patients from healthy volunteers, and its comparison with sialometry were assessed. The two variants of questionnaires Q3 and Q10 were separately analyzed for a subgroup of patients and controls. Groups were compared using one-way ANOVA and Kruskal–Wallis test with Bonferroni adjustments for multiple comparisons. Results are presented as mean ± standard deviation (SD).

To assess the validity of the question selection process, a factor analysis (FA) was performed separately for the Q10 and Q3 questionnaires.

Analysis of the reliability of repeated questionnaires was performed using paired *t*-test and the coefficient of variation (100× standard deviation/mean of two repeated measures), and

TABLE I.
MSGS Salivary Score Q3 (0–3 Detailed Version).

Measure	Items	Scorings
Dry mouth	**Since 1 mo:**	0. No dryness
	1. Evaluate the intensity of your mouth dryness	1. Mild dryness, but no discomfort 2. Moderate, important discomfort 3. Important, handicap for everyday life
	2. Evaluate the frequency of your mouth dryness during the day	0. Never 1. Occasionally during the day 2. Frequently during the day 3. Constantly present during the day
	3. Evaluate the quality of your saliva	0. Normal (even if diminished) 1. Thicker or more watery (serous) than normal but without discomfort 2. Thicker or more watery (serous) than normal but with discomfort 3. Sticky or watery (serous) or no saliva
	4. Evaluate the taste of your saliva	0. Normal 1. A bit salty/sweet/bitter/acid/bad taste 2. Moderate salty/sweet/bitter/acid/bad taste 3. Very salty/sweet/bitter/acid/bad taste
	5. Do you feel the need to moisture your mouth during the day (either by drinking water/chewing gums/or by using moisturizing sprays)?	0. No 1. Yes, occasionally (many times per day) 2. Yes, frequently (many times per hour) 3. Yes, constantly
	6. Do you wake up at night to drink water?	0. No 1. Yes, rarely (one time maximum) 2. Yes, frequently (2–3 times per night) 3. Yes, always (more than 3 times per night)
	7. Do you have difficulties talking?	0. No difficulty 1. Yes, some difficulties, i have to moisturize occasionally while talking 2. Yes, significant difficulties, i have to moisturize frequently while talking 3. Yes, important difficulties, i have to moisturize constantly while talking
	8. Do you have difficulties chewing and swallowing food?	0. No 1. Yes, i need to drink to chew and swallow dry food 2. Yes, i need to drink to chew and swallow moist food, i avoid eating dry food 3. Yes, I need to drink to chew and swallow moist food, it is impossible for me to eat dry food
	9. Do you have dry lips?	0. No 1. Yes, occasionally 2. Yes, frequently 3. Yes, always
	10. Do you have a dry nose?	0. No 1. Yes, occasionally 2. Yes, frequently 3. Yes, always, I need to lubricate it
	11. Do you have dry eyes?	0. No 1. Yes, occasionally 2. Yes, frequently, i need to lubricate them 3. Yes, always, i need to lubricate them
	12. Are your physical activities disturbed because of your dry mouth?	0. No 1. No, but i need to have liquid with me 2. Yes, i exercise less than before 3. Yes, i avoid any physical activity that makes me uncomfortable because of my dry mouth
	13. Evaluate your quality of life regarding to your dry mouth	0. Perfect 1. Satisfying 2. Less satisfying 3. Completely unsatisfying, my quality of life is highly reduced
Salivary glands	**Since 1 mo:**	0. No
	14. Do you experience a feeling of itching/ tightness (tension) in the area of the	1. One to many times per year 2. One to many times per month 3. One to many times per week

(Continues)

TABLE I.
Continued

Measure	Items	Scorings
	salivary glands (in front of the ears or/and under the lower jaw)?	
	15. Do you experience swelling in the area of the salivary glands (in front of the ears or/and under the lower jaw) during meals?	0. No 1. One to many times per year 2. One to many times per month 3. One to many times per week
	16. Do you experience swelling in the area of the salivary glands (in front of the ears or/and under the lower jaw) between meals?	0. No 1. One to many times per year 2. One to many times per month 3. One to many times per week
	17. Evaluate the persistence of this swelling	0. No swelling 1. The swelling healS very quickly/ spontaneously/after a few hours 2. The swelling heals after a few days 3. The swelling heals after a few weeks/ months
	18. How many times have you had to take antibiotics because of an infection of the salivary glands?	0. Never 1. One time per year 2. Many times per year 3. One time per month
	19. Evaluate the pain caused by the salivary gland swelling	0. No pain/no swelling 1. Mild pain 2. Moderate pain 3. Severe pain
	20. Evaluate the discomfort caused by the salivary gland swelling	0. No discomfort/no swelling 1. Mild discomfort 2. Moderate discomfort 3.Severe discomfort

the intraclass correlation coefficient (ICC) was computed along with its 95% confidence interval (95% CI) using one-way random-effect models ("icc" Stata's command). Test–retest reliability was also tested with correlation coefficient and Pitman's test of difference in variance. We computed the scale and subscale reliability coefficient using Cronbach's alpha.

The association between our questionnaire and sialometry was analyzed using linear and quadratic regression models to predict the quantity of saliva (6 and 15 min), with the total score of Q10 and Q3 as the independent variables.The coefficient of determination (R^2) provides the percentage of variance explained by the models. Logistic regression was used to predict binary (yes/no) outcomes (pathological sialometry; the presence of stone/ stenosis) from Q10 and Q3 or their subscores, and the results are expressed as the odds ratio (OR), which can be interpreted as the risk ratio.

RESULTS

The patient group consisted of 65.4% women and 34.6% men, with a mean age of 54.5 years. The control group consisted 65.2% women and 34.8% men, with a mean age of 39.2 years. The baseline characteristics and distribution of different salivary gland pathologies are shown in Table III: 37.26% of the 265 participants had strictures (65.6% of unknown etiology, 28.3% Sjögren's syndrome, 2% IgG4 disease, 2% radioiodine therapy, and 2% RJP), 14.83% had stones, 16% had undergone head-and-neck radiotherapy treatment, 3.42% had nasal, digestive, or age-related xerostomia, 3.42% had medication xerostomia, and 25.1% were healthy controls. Stenosis includes idiopathic etiologies and disease-related etiologies (Sjögren's syndrome, IgG4-related disease, JRP, radioiodine treatment). As there was a reduced number of disease-related stenosis, these patients were included in the stenosis group. The mean age of the participants was 50.5 years ± 16.1, with 68.3% females.

One-hundred and forty-nine patients and 25 healthy volunteers completed both Q3 and Q10 versions of the MSGS.

Consistency of the scores measured by the intraclass correlation coefficient (ICC), were similar for both Q3 and Q10 and their subscore. Test–retest reliability was also assessed, with the correlation coefficient showing similar results as with the ICC and with Pitman's tests of difference in variance, which also show the equivalence of the two repeats.

The scale reliability coefficients amounted to a Cronbach's alpha of 0.92 for Q10 and 0.90 for Q3; as to the subscore for the first 13 items, they amounted to 94.6% for Q10 and 92.6% for Q3; the subscore of the seven last items amounted to 87% for Q10 and 83.2% for Q3. This shows that patients remained consistent with their answers and that neither questionnaire was more reliable than the other. Furthermore, it can be observed that the first 13 items of both Q10 and Q3 have a better internal coherence than the last 7 items and the complete questionnaires.

Factor analysis (FA) was performed separately for Q10 and Q3 questionnaires (added in the statistical analysis section page 13). The clustering of the question corresponds well to our clinical grouping. Loading plot for the Q10 version revealed that the first two factors account for 89.2% of the variance. Loading plot for the Q3 version confirmed that the first two factors accounted for 88.6% of

TABLE II.
MSGS Salivary Score Q10 (0–10 Scale Version).

• Measure	• Items
Dry mouth	**Since 1 mo**
	1. Evaluate the intensity of your mouth drynessNo dryness 0 1 2 3 4 5 6 7 8 9 10 Maximal dryness
	2. Evaluate the frequency of your mouth dryness during the dayNever 0 1 2 3 4 5 6 7 8 9 10 Constantly during the day
	3. Evaluate the quality of your salivaNormal (even if diminished) 0 1 2 3 4 5 6 7 8 9 10 very thick/sticky/watery (serous)/no saliva
	4. Evaluate the taste of your salivaNormal 0 1 2 3 4 5 6 7 8 9 10 very salty and/or sweet and/or bitter and/or acid and/or bad taste
	5. At which frequency do you feel the need to moisture your mouth during the day (either by drinking water / chewing gums / or by using moisturizing sprays)?Never 0 1 2 3 4 5 6 7 8 9 10 constantly
	6. How frequently do you wake up at night to drink water? Never 0 1 2 3 4 5 6 7 8 9 10 Very frequently
	7. Evaluate your talking difficulty related to your dry mouthNo difficulty 0 1 2 3 4 5 6 7 8 9 10 very important difficulty (constant need to moisturize to be able to speak)
	8. Evaluate your level of difficulty to chew and swallow foodNo difficulty 0 1 2 3 4 5 6 7 8 9 10 very important difficulty (constant need to drink water to chew and swallow food)
	9. Evaluate the dryness of your lipsNo dryness 0 1 2 3 4 5 6 7 8 9 10 maximal dryness
	10. Evaluate the dryness of your noseNo dryness 0 1 2 3 4 5 6 7 8 9 10 maximal dryness
	11. Evaluate the dryness of your eyesNo dryness 0 1 2 3 4 5 6 7 8 9 10 maximal dryness
	12. Are you physical activities disturbed because of your dry mouth?No 0 1 2 3 4 5 6 7 8 9 10 yes, i avoid any activity which makes meUncomfortable because of my dry mouth
	13. Evaluate your quality of life regarding to your dry mouthPerfect 0 1 2 3 4 5 6 7 8 9 10 completely unsatisfying
Salivary glands	**Since 1 mo**
	14. At what frequency do you experience a feeling **of itching/tightness** (tension) in the area of the salivary glands (in front of the ears or/and under the lower jaw)? Never 0 1 2 3 4 5 6 7 8 9 10 everyday
	15. At what frequency do you experience swelling in the area of the salivary glands (in front of the ears or/and under the lower jaw) **during** meals?Never 0 1 2 3 4 5 6 7 8 9 10 at every meal
	16. At what frequency do you experience swelling in the area of the salivary glands (in front of the ears or/and under the lower jaw) **between** meals?Never 0 1 2 3 4 5 6 7 8 9 10 at every meal
	17. Evaluate the **persistence** of these swellingNo swelling 0 1 2 3 4 5 6 7 8 9 10 healing after a few months
	18. How many times have you had to take antibiotics because of an infection of the salivary glands?Never 0 1 2 3 4 5 6 7 8 9 10 frequent infections (> one time per month)
	19. Evaluate the pain caused by the salivary glands swellingNo pain 0 1 2 3 4 5 6 7 8 9 10 maximal pain
	20. Evaluate the discomfort caused by the salivary glands swellingNo discomfort 0 1 2 3 4 5 6 7 8 9 10 maximal discomfort

the variance. As questions 1, 2, 3, and 5 are those that contribute the most to the factor 1, we could assume that it concerns mostly xerostomia symptoms. Regarding factor 2, the last seven items are the ones that mostly contribute, meaning that it concerns mostly sialadenitis symptoms.

Regarding the time to complete the MSGS questionnaire, 99 patients and 26 healthy participants were recorded while completing the Q3, and they took respectively 5.23 min (±2.3 min) and 3.94 min (±3.94 min) versus 108 patients and 26 healthy volunteers who were

TABLE III.
Participant's Characteristics by Diagnosis Compared With Healthy

	Healthy	Stones	Idiopathic Stenosis	Sjögren's Syndrome Stenosis	Other Stenosis (IgG4 Disease, Radioiodine Therapy, Juvenile Recurrent Parotitis)	Medication Related	Radiotherapy Treatment	Digestive, Nasal or Age Related	Total
	N = 66	*N* = 40	*N* = 64	*N* = 29	*N* = 6	*N* = 9	*N* = 42	*N* = 9	*N* = 265
	N = 25.1%	*N* = 14.83%	*N* = 24.15%	*N* = 10.94%	*N* = 2.26%	*N* = 3.42%	*N* = 16%	*N* = 3.42%	*N* = 100%
Sex F	43 (65.2%)	23 (57.5%)	51 (79.7%)	27 (93.1%)	6 (100%)	7 (77.8%)	16 (38.1%)	6 (66.7%)	181 (68.3%)
Sex M	23 (34.8%)	17 (42.5%)	13 (20.3%)	2 (6.8%)	0 (0%)	2 (22.2%)	26 (61.9%)	3 (33.3%)	84 (31.7%)
Age (yr)	66; 39.2 ± 13.3	40; 47.8 ± 13.6*	57; 55.3 ± 17.1 **	19; 49.3 ± 16.4 *	5; 46.1 ± 24.5	9; 69.9 ± 15.6 **	42; 62.3 ± 12.0**	9; 52.0 ± 14.8	265; 50.5 ± 16.1
Total Q10 (range 0–200)	63; 19.5 ± 23.3	34; 36.7 ± 31.3	57; 50 ± 30.7 **	23; 62.3 ± 37.1 **	5; 74 ± 35.6 *	7; 78.4 ± 33.3**	32; 49.6 ± 33.3*	8; 76.4 ± 34.1**	229; 43.3 ± 36.6
Total Q3 (range 0–60)	60; 5.5 ± 6.6	37; 12.2 ± 9.4 *	51; 15.9 ± 8.7 **	18; 18.3 ± 10.2 **	6; 19.8 ± 12.6 *	5; 18.4 ± 10.5*	41; 11.4 ± 7.1	4; 28.3 ± 13.6**	224; 12.3 ± 10.2
Q10 items 1 to 13 (range 0–130)	59; 13.8 ± 15.6	32; 18.2 ± 21.1	56; 29.2 ± 25.4	18; 55.6 ± 33.5 **	5; 47.2 ± 29.5	7; 70.1 ± 20.3**	9; 66.0 ± 35.1**	7; 59.4 ± 31.6**	197; 30.9 ± 30.6
Q3 items 1 to 13 (range 0–39)	59; 4.3 ± 4.7	33; 6.4 ± 6.5	49; 8.7 ± 7.2	15; 13.3 ± 7.4 **	6; 12.3 ± 9	3; 17.3 ± 8.6**	6; 13.2 ± 9.2	4; 20.5 ± 11.2*	178; 7.9 ± 7.7
Q10 items 14 to 20 (range 0–70)	58; 3.9 ± 11.1	31; 18.9 ± 15.9**	36; 23.5 ± 15.1 **	13; 17 ± 17.8 *	5; 26.8 ± 21.6 *	4; 7.0 ± 14.0	3; 0.0 ± 0.0	2; 23.0 ± 12.7	161; 13.5 ± 16.1
Q3 items 14 to 20 (range 0–21)	55; 1.2 ± 3.3	33; 6.8 ± 5.2**	42; 7.5 ± 4.2 **	15; 5.7 ± 5.5 **	6; 7.5 ± 6.5	3; 4.0 ± 6.1	3; 0.7 ± 1.2	3; 6.3 ± 3.1	166; 4.9 ± 5.2
Sialometry lasting 15 min (ml/min)	16; 0.33 ± 0.21	29; 0.4 ± 0.15	50; 4.2 ± 2.3	17; 3.8 ± 2.4 *	5; 2.9 ± 1.5	3; 0.07 ± 0.03 *	2; 0.15 ± 0.1	6; 0.24 ± 0.03	
Sialometry lasting 6 min (ml/min)	10; 0.53 ± 0.4	20; 0.75 ± 0.3	26; 3.4 ± 1.7	10; 2.7 ± 1.2 *	3; 2.4 ± 1.4	3; 0.12 ± 0.05 *	No observations	2; 0.3 ± 0.12	

Stenosis includes idiopathic stenosis (*n* = 65), Sjögren's syndrome (*n* = 28), IgG4 disease (*n* = 2), radioiodine therapy (*n* = 2), and juvenile recurrent parotitis (*n* = 2). *N*; mean ± SD.
*$P \leq .05$.
**$P \leq .001$.

recorded completing the Q10 and took, respectively, 5.65 min (±2.64 min) and 3.75 min (±2.11 min). Although not significant ($P = .193$), Q3 was completed slightly faster than Q10. The time to complete Q10 ($P = .0008$) and Q3 was significantly ($P = .0134$) shorter for healthy volunteers in comparison to patients.

Among the 38 participants who completed both questionnaires twice within 15 days, the coefficient of variation was 44.7% for Q10 and 41.5% for Q3, respectively, supporting the limitations of a subjective evaluation, as it is prone to vary among individuals.

The ICCs were not statistically significantly different between Q10 and Q3 regarding total scores and the subscores for questions 1–13 and 14–20, as their 95% CI overlaps. These ranged from 85% to 95% for total and questions 1–13 and were equal to 65% for the subscore questions 14–20. We computed the individual difference between both repeats of the same questionnaire. To compare Q10 and Q3, we divided the difference by the maximum score obtainable by each questionnaire (Q3 = 60; Q10 = 200), expressed in percent. The average difference was 0.7% for Q10 and 1.0% for Q3 and was not P statistically different (= .3022).

Regarding sialometry, 92 patients and 18 healthy volunteers underwent 6-min sialometry and had a mean salivary flow of, respectively, 3.32 g/min (± 1.79 g/min) and 3.95 g/l (±2.56 g/min). The difference of sialometry at 6 min between patients and healthy volunteers was not statistically significant ($P = .2035$). One-hundred and fifty-seven patients and 24 healthy volunteers underwent a 15-min sialometry and had a mean salivary flow of, respectively, 4.2 g/min (±2.33 g/min) and 5.7 g/min (±3.33 g/min). The difference of the sialometry at 15′ min between patients and healthy volunteers was statistically significant ($P = .0067$) and revealed higher values for healthy volunteers in comparison to patients.

Healthy participants had significantly lower Q10 and Q3 scores and higher sialometry values at 15 minutes than the pathological groups. The difference of sialometry values was significant only between healthy volunteers and patients at 15 minutes, possibly because the former need time to produce enough saliva to differentiate them from patients. Moreover, the number of healthy volunteers was limited, which implies that we need to consider those results with caution.

Healthy volunteers had a mean Q10 score of 19.6 (± 23.4) and a mean Q3 score of 5.4 (± 6.4) in contrast to patients who had a mean Q10 score of 52.6 (± 33.8) and a mean Q3 score of 14.9 (± 9.3). Patients had higher scores compared to healthy volunteers, and the difference was statistically significant for Q10 ($P = .049$) and Q3 ($P = .046$).

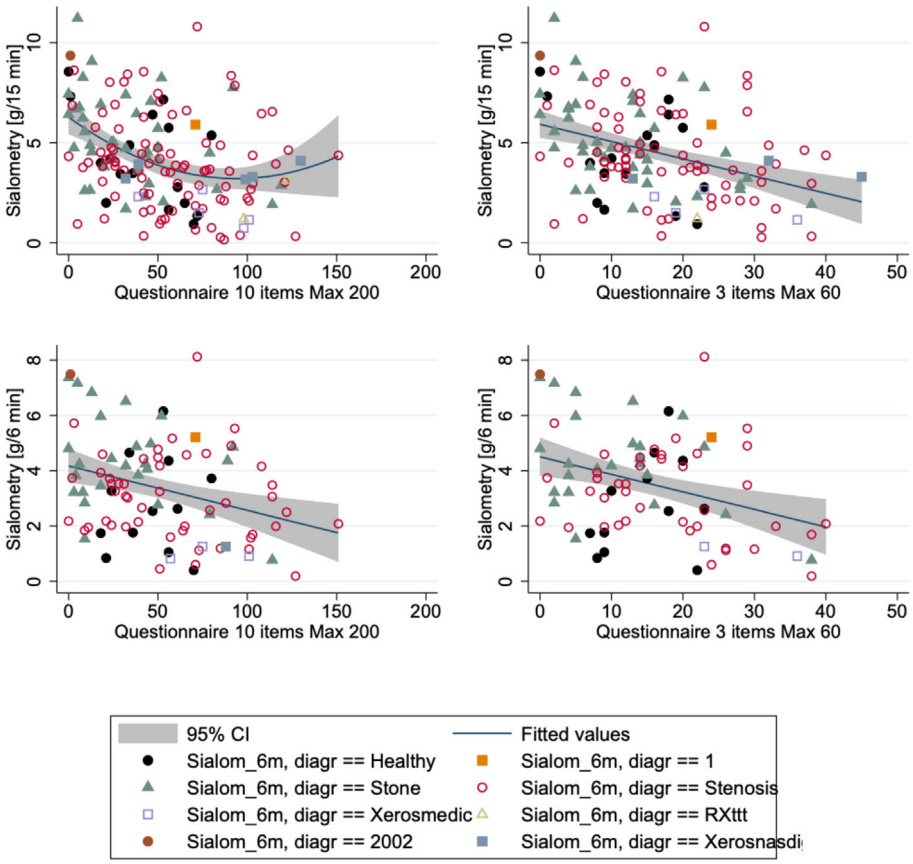

Fig. 1. Regression curve/line of the association between our questionnaires (Q3 and Q10) and sialometry. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

To further validate the questionnaire, patients with stenotic and calculous sialadenitis were analyzed using the first 13 and the last 7 questions separately. Regarding the group of patients with stenosis, assessment with the Q10 (n = 307) 1–13 items subscore revealed no association ($R^2 = 1.5\%$, $P = .110$). However, a better association was found with Q3 ($n = 290$), although not sufficient to predict a stenosis ($R^2 = 2.4\%$, $P = .0018$). Regarding the group of patients with calculous sialadenitis, assessment with the Q10 14–20 items subscore revealed a low positive association for calculus ($n = 254$, $R^2 = 1.5\%$, $P = .036$, OR = 1.019, 95% CI = 1.001–1.04), which was slightly better with Q3 ($n = 263$, $R^2 = 2.4\%$, $P = .007$, OR = 1.075, 95% CI = 1.02–1.12). An OR of 1.075 means that for a one-point increase in the Q3 questionnaire, the risk of stenosis increases by 7.5%. The positive association of Q3 has a higher correlation in the presence of calculus and stenosis compared to Q10. The scores did not predict the presence of stenosis or calculus, thus supporting the notion that the value of the questionnaire lies in quantifying the degree of salivary symptoms and not predicting a particular disease.

Regarding the correlation between the MSGS questionnaire scores and the sialometry results, as shown in Figure 1, the amount of saliva produced at 6 minutes was significantly associated with Q10 ($N = 87$; $P = .0038$; adjusted $R^2 = 8.4\%$) and with Q3 using a linear model ($P = .0013$, adjusted $R^2 = 11.5\%$). At 15 minutes, Q10 was also significantly associated with the linear model, explaining 10.3% of the variance ($N = 139$; $P = .0001$; adjusted $R^2 = 10.3\%$). At 15 minutes, Q3 with the linear model explained 13.6% ($P = .0001$; adjusted $R^2 = 13.6\%$). However, the coefficient of determinations R^2 being below 80% precludes any individual prediction of the sialometry results. From logistic regression, none of the questionnaires (total score or subscore 1–13) was associated with pathological sialometry at 6 and 15 minutes (OR not statistically different from 1.0; P-value ranging from .051 to .08), supporting the importance of an objective evaluation to assess hyposalivation.

DISCUSSION

Many subjective questionnaires assessing symptoms and QOL regarding xerostomia and salivary gland diseases exist in the literature. Most of them assess xerostomia, sialadenitis, or QOL. There is a need for a comprehensive and standardized questionnaire to characterize the symptoms of patients experiencing xerostomia and/or sialadenitis and to evaluate the effect of all treatments.

Regarding QOL, three questionnaires are frequently addressed in the literature: the Health Survey (SF-36, SF-8),[21,22] which evaluates the QOL in regard to the patient's general health; the Glasgow Benefit Inventory,[23] which assesses QOL in regard of treatment in the otolaryngology field; and the Oral Health Impact Profile Questionnaire,[24,25] which evaluates QOL in regard to the patient's oral health. These scores evaluate the QOL of patients but lack specific features regarding the symptoms of xerostomia and sialadenitis. The purpose of the MSGS questionnaire is to target salivary gland pathology symptoms and their consequences on the general QOL. We believed that our questionnaire needed to be exhaustive regarding salivary gland symptoms but also as concise as possible to be able to be used in clinical practice. Therefore, we added only four specific items regarding QOL (questions 12, 13, 19, and 20). Also, we did not want to complicate the study by asking the patients to fill another questionnaire focused only on QOL, as our aim was to evaluate the overall salivary gland burden.

Regarding salivary gland symptoms, two questionnaires address both xerostomia and non-tumoral salivary gland pathologies, and both have been systematically validated: the Xerostomia Inventory (XI)[26] and the Chronic Obstructive Sialadenitis Score (COSS).[27]

XI[26] was first published in 1999 and comprises 11 questions on xerostomia and 4 additional items regarding the burning-mouth syndrome. Although XI comprises many aspects related to dry mouth and has been validated and widely used in the literature,[28,29] it is not exhaustive regarding xerostomia symptoms. Because it does not evaluate the ability to speak, potential taste disturbances, and saliva quality, it does not address QOL and does not evaluate at all sialadenitis features.

The COSS questionnaire[27] was proposed in 2016 to assess using 20 questions the effect of sialendoscopy on general salivary pathologies and dry mouth. It is the first questionnaire addressing sialadenitis features. Since its publication, it has been updated using the results obtained with pre- and post-operative assessment.[30–32] COSS is able to precisely assess sialadenitis features, especially before and after sialendoscopy; however, it remains incomplete to evaluate other pathologies leading to xerostomia and treatment effects.

To validate the MSGS questionnaire, 199 patients and 66 healthy volunteers participated. The control group had significantly lower MSGS questionnaire results than the patient group, supporting its ability to distinguish between pathological and healthy participants. Sialometry at 6 and 15 minutes was also assessed on both groups. The results showed a significant negative association between Q3/Q10 questionnaires and sialometry results, but the amount of variance explained was not sufficient to allow individual predictions of sialometry values and therefore to detect hyposalivation.

We assessed two versions of the MSGS questionnaire (Q3 and Q10) to evaluate whether fixed answers would add more objectivity, allowing better reproducibility of the score over time; however, no differences were found between the answers of patients with Q3 and Q10 questionnaires when completed within an interval of several days. Moreover, the consistency of both versions, measured by ICC, were similar for both Q3 and Q10. Both versions of the MSGS questionnaire showed good internal coherence, confirming that the answers to the questions were consistent among themselves. This was even more accentuated for the first 13 items of the questionnaires.

The time to complete both versions of the MSGS questionnaire was assessed, and no significant difference was found. Moreover, to our knowledge, the time required to fill out questionnaires regarding xerostomia and salivary gland pathologies has not been investigated in the literature.

As both versions Q3 and Q10 remain statistically similar regarding their scale reliability, their ability to distinguish pathological groups from healthy controls, and time to fill out, both would be adequate for use. However, in order to have only one questionnaire as a consensus, we recommend the use of the Q10 version. First, the 1–10 visual analogue scale is widely used and accepted in the literature and has the reputation to be better understood by patients. Second, the Q10 version will be more suitable for an international use, as its translation in different languages might be more accurate than of the Q3 version.

Our study has some limitations. First, we chose to use a less common approach to collect saliva, in contrast to the more frequent methods described by Navazesh et al., as we believed the swab method to be easier to carry out with patients with dry mouth. Based on our clinical experience, we believed it to be very difficult to ask patient with xerostomia to spit or drain saliva from a dry mouth. Moreover, our study had a restricted number of participants, especially in regard of radioiodine therapy and auto-immune salivary gland pathologies such as Sjögren's syndrome, IgG4 disease, and radioiodine.

Therefore, future multicentric studies are needed. The translation of the MSGS questionnaire in other languages and the initiation of a prospective multicentric study using the MSGS questionnaire have been decided during the second International Sialendoscopy Society Meeting. This attempt to use in a multicentric setting a standardized questionnaire in centers dealing with salivary gland diseases may facilitate its improvement and allow a greater consensus in the future. As for an immediate result, it will allow carrying out comparative clinical studies on various treatment modalities (e.g., medical, sialendoscopic, or surgical interventions), comparing pre- and post-treatment scoring. Hopefully, in the future, a wide consensus around a unique screening and assessment tool might be meaningful for all patients suffering from salivary gland diseases.

CONCLUSION

We proposed here a novel, reliable, comprehensive, and self-administered questionnaire addressing benign salivary gland lesions such as xerostomia, sialadenitis, and the associated QOL of the patients. These questionnaires have been statistically validated on a series of patients affected by different pathologies. Even though our questionnaire was not able to predict the presence of stones or strictures, it could discriminate patients from healthy volunteers and demonstrate a good internal coherence of its items. Both versions Q3 and Q10 of the MSGS questionnaire were analyzed and proved to be similar regarding their scale reliability, their ability to distinguish pathological groups from healthy controls, and time to fill out.

We recommend the use of the Q10 version of the MSGS questionnaire, as its scale is better understood by patients and clinicians. In addition, it is more suitable for translation, as we aim to implement its use for international studies.

Further multicentric investigations are in progress to validate and improve it with a larger cohort of patients in 27 different countries.

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