Association between salivary secretary function and laryngopharyngeal reflux: a prospective study

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Objectives. This study aimed to demonstrate the prevalence and risk factors of laryngopharyngeal reflux (LPR) in patients with xerostomia and to investigate the association between salivary function and LPR.

Study Design. The prevalence of LPR among patients with xerostomia was analyzed and the clinical and salivary gland function were compared between 2 groups; the non-LPR and the LPR groups.

Results. The prevalence of LPR was 82.2% in patients with xerostomia. The presence of LPR was correlated with the unstimulated or stimulated salivary flow rate (SFR). LPR did not correlate with scintigraphy findings except time to the minimum count of the parotid gland. Low stimulated SFR and unstimulated SFR were recognized as independent risk factors of LPR. A significant correlation was observed between the Reflux Symptom Index and the xerostomia symptoms score. Furthermore, RFS also correlated with unstimulated and stimulated SFR.

Conclusions. This finding supports that salivary secretory function has an impact on LPR. (Oral Surg Oral Med Oral Pathol Oral Radiol 2019;128:615−620)

Xerostomia is a subjective complaint of dry mouth, which affects speech, chewing, swallowing, denture wearing and, sometimes, irritation in the throat.[1,2] Usually, about 1 L of saliva is secreted daily, mostly from the parotid and submandibular glands. In the resting state, saliva is secreted at a low basal rate. The flow of saliva increases during eating and mastication as a result of cholinergic stimulation.[3] Saliva is essential for the neutralization of gastric contents in the pharynx and larynx and may act as an endogenous antacid to protect against symptomatic gastroesophageal reflux (GER) and laryngopharyngeal reflux (LPR).[4] The normal stimulated salivary flow rate (SFR) averages 1.5 to 2.0 mL/min, whereas unstimulated SFR averages approximately 0.3 to 0.4 mL/min.[1,5] Hyposalivation is said to occur when the stimulated SFR is less than 0.5 to 0.7 mL/min, and the unstimulated SFR is less than 0.1 mL/min.[5]

The loss of the lubricating and buffering function of saliva in patients with hyposalivation results in oral cavity infection, pharyngitis, and high incidences of mucosal inflammation and irritation of the larynx.[6] LPR symptoms, such as globus sensation, voice change, contact granuloma, cough, and excessive mucus, could be the result of following possible mechanisms: (1) local chemical irritation, and/or (2) vagal reflex from esophageal irritation.[7] LPR and GER are highly prevalent in patients with Sjögren syndrome (SS), which is, therefore, the chosen clinical model of salivary deficiency.[8] The relationship between xerostomia (hyposalivation) and LPR is poorly understood. No prospective study has previously analyzed the qualitative and quantitative measurements by using questionnaires, ^{99m}Tc-pertechnetate salivary gland scintigraphy, and laryngoscopic findings.

The goal of the present study was to demonstrate the prevalence and risk factors of LPR in patients with xerostomia and to correlate the association of subjective and objective findings in salivary hypofunction and LPR.

MATERIALS AND METHODS

Ethical considerations

This study was approved by the institutional ethical review board of the University of Groningen and by the ethical committee of Inha University Hospital Institutional Review Board. Investigators read and complied with the tenets of the Helsinki Declaration.

Study population

Between 2014 and 2016, patients with xerostomia were enrolled in this study after completing a questionnaire on xerostomia symptom scores. A study flowchart is presented in Figure 1. Inclusion criteria were having symptoms of dry mouth and providing written informed consent to enroll in this study. Of the 67 patients who completed the xerostomia questionnaire,

Statement of Clinical Relevance

There is a high prevalence of laryngopharyngeal reflux, as evaluated by the Reflux Symptom Index, among patients with xerostomia and low stimulated and unstimulated salivary flow rates. This finding supports that salivary secretory function has an impact on laryngopharyngeal reflux.

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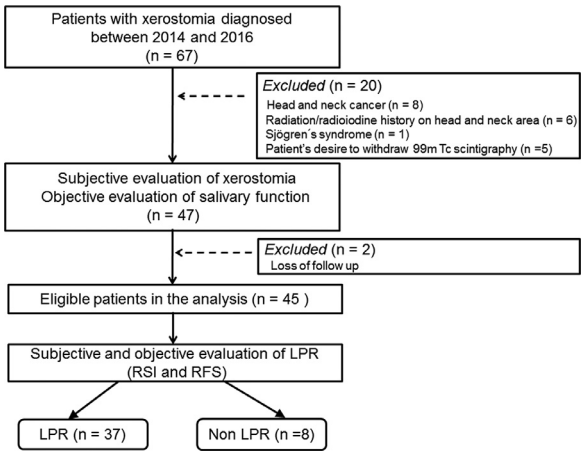

Fig. 1. Enrollment and analysis. *LPR,* laryngopharyngeal reflux; *RFS,* reflux finding score; *RSI,* reflux symptom Index.

22 patients with SS; a history of head and neck cancer and radiation exposure; or incomplete objective evaluation, for reasons of refusal to undergo scintigraphy and follow-up loss; were excluded. The remaining 45 patients who completed the subjective and objective evaluations of LPR were therefore considered eligible for this study.

Xerostomia inventory

The patients performed self-evaluation of dry mouth symptoms through self-rating, with scores ranging from 1 (very mild) to 5 (very severe). Self-reported symptoms were recorded by using a detailed questionnaire (Table SI). The xerostomia symptom questionnaire comprised 21 conditions, including symptoms of obstructive sialadenitis and hyposalivation.

Salivary gland scintigraphy

After a minimum 2 hours of fasting, the patients were administered an intravenous bolus injection of 370 MBq ^{99m}Tc-pertechnate, and dynamic salivary gland scintigraphy was performed. At 20 minutes after injection, ascorbic acid was orally administered to stimulate the salivary gland. The time−activity curve for glandular activity represents the uptake and secretion of ^{99m}Tc-pertechnetate. Parameters, such as uptake ratio (= gland-to background ratio at the maximum count); time to minimum count (Tmin) (= interval time from stimulation to minimum count); maximum accumulation (= [maximal count − starting basal count] / maximal count × 100 [%]), and maximum secretion accumulation (= [maximal count- minimum count] / maximal count × 100 [%]) were calculated.

Follow-up and LPR evaluation

After conservative management of xerostomia, patients were asked to answer the symptoms questionnaire, namely, the Reflux Symptom Index (RSI). The scale for each item ranges from 0 (no problem) to 5 (severe problem), with a maximum score of 45, and an RSI score greater than 13 is considered as abnormal. Furthermore, 2 independent examiners judged the reflux finding score (RFS). The symptoms questionnaire and the classification proposed by Belafsky et al. (Tables SII and SIII) were used.[9,10] Patients presenting a score of 7 or greater were considered to have LPR.[11]

Statistical analysis

Continuous variables were expressed as median (range) or mean ± standard deviation. Categorical variables were expressed as numbers and percentage. Comparisons among different groups were performed by using the Mann-Whitney U test for continuous variables and Fisher's exact test for categorical data. Univariate analyses were used to identify the predictive factors of LPR by using Fisher's exact test and the binary logistic regression test. To determine the area under the curve, we used the receiver operating characteristic (ROC) curve analysis. Two different cutoff values of stimulated and unstimulated SFR for discrimination of LPR were determined by cross-validated predicted probabilities; the optimal cutoff values were obtained by calculating the sensitivity and specificity of each value, and plotting sensitivity against 1 − specificity. Differences between the groups were evaluated by using the χ^2 or the Student t test and logistic regression analysis. Pearson's correlation test was performed for determining the correlations between each salivary function parameter and the subjective or objective finding of LPR. P values less than .05 were considered statistically significant. All statistical analyses and data presentations were performed in R language 3.1.3 and SPSS version 24 (SPSS Inc., Chicago, IL).

RESULTS

Patient characteristics

The characteristics of the 45 eligible patients are summarized in Table I. Patients include 10 men and 35 women (mean age 58 years; range, 33−81 years). Of these patients, 37 patients (82.2%) showed the LPR objective finding. Except body mass index, there was no difference in gender, age, or underlying diseases, such as diabetes and hypertension, between the LPR and non-LPR groups.

Salivary flow rates correlate with the presence of LPR

A strong association was observed between the presence of LPR and unstimulated and stimulated SFR (P = .004, P = .016, respectively). However, there was no association between the subjective findings of xerostomia and LPR (P > .05). Also, there was significant

Table I. Clinical characteristics of study patients ($n = 45$)

Variable	*Non-LPR (n = 8)*	*LPR (n = 37)*	*P value*
Gender, male/female (%)	3/5 (37.5/62.5)	7/30 (18.9/81.1)	.498
Age at diagnosis, median (range), years	59 (33−81)	56 (33−81)	.468
DM, yes (%)	2 (25)	2 (5.4)	.280
Hypertension, yes (%)	4 (50)	8 (21.6)	.228
Smoking, ≥ 20 pack × years (%)	2 (25)	7 (18.9)	1.000
Alcohol, yes (%)	2 (25)	9 (24.3)	1.000
BMI	21.9 ± 1.3	23.5 ± 3.0	**.023***
≥ 23 kg/m^2 (%)	1 (12.8)	20 (54.1)	

*$P < .05$.
BMI, body mass index; *DM,* diabetes mellitus; *LPR,* laryngopharyngeal reflux.

difference in scintigraphy findings between the LPR and non-LPR groups. However, of the scintigraphy parameters, only Tmin of both parotid glands were found to be significantly different between the 2 groups ($P = .012$, $P = .021$, respectively) (Table II). Of the 45 patients, 21 patients showed salivary hypofunction, which indicated that the SFR is less than 0.1 mL/min at rest or less than 0.7 mL/min under stimulation. Among the 21 patients, 20 (95.2%) were regarded as having LPR, and 17 of 24 (70.8%) in the non-LPR group showed an incidence of LPR.

Univariate analyses of factors involving LPR

Initially, values that differentiated between the LPR and non-LPR groups and discovered stimulated or unstimulated SFR were sought. The cutoff points obtained from the ROC curve (data not shown) were unstimulated SFR = 0.245 mL/min and stimulated SFR = 0.745 mL/min. Using these cutoff values, we found that high body mass index and low stimulated and unstimulated SFR were significantly associated with an increased incidence of LPR ($P < .05$, each) (Table III).

Correlations of salivary function parameters with subjective and objective findings of LPR

Correlations between each salivary function parameter and the subjective or objective findings of LPR are summarized in Table IV. A significant correlation was found between the RSI and xerostomia symptoms score

Table II. Comparisons of salivary flow rates and salivary gland scintigraphic parameters between the non-LPR and LPR groups

Variable	*Non-LPR (n = 8)*	*LPR (n = 37)*	*P value*
Unstimulated SFR (mL/min)	0.4 ± 0.2	0.2 ± 0.2	**.004***
Stimulated SFR (mL/min)	1.3 ± 0.5	0.8 ± 0.4	**.016***
Xerostomia symptom score	37.4 ± 11.5	44.9 ± 21.0	.334
Right parotid			
UR	6.7 ± 2.9	5.9 ± 2.9	.460
Tmin	1.2 ± 0.5	2.5 ± 2.7	**.012***
MA	83.1 ± 5.9	78.2 ± 13.5	.125
MS	68.0 ± 9.1	59.7 ± 22.7	.102
Left parotid			
UR	6.8 ± 2.4	5.5 ± 3.2	.219
Tmin	1.2 ± 0.5	2.4 ± 2.8	**.021***
MA	85.5 ± 5.5	80.5 ± 6.7	.053
MS	64.0 ± 9.1	59.3 ± 23.8	.366
Right submandibular gland			
UR	6.2 ± 2.3	6.2 ± 3.2	.967
Tmin	2.5 ± 3.1	2.4 ± 2.4	.946
MA	81.6 ± 7.2	80.0 ± 9.3	.663
MS	44.8 ± 11.5	46.7 ± 17.8	.768
Right submandibular gland			
UR	7.0 ± 3.3	5.6 ± 2.9	.237
Tmin	2.5 ± 3.1	2.2 ± 2.1	.703
MA	82.8 ± 7.1	78.2 ± 9.1	.187
MS	45.7 ± 13.8	46.8 ± 16.7	.864

*$P < .05$, respectively.
LPR, laryngopharyngeal reflux, *MA,* maximum accumulation; *MS,* maximum secretion; *SFR,* salivary flow rate; *Tmin,* time to minimum count; *UR,* uptake ratio.

Table III. Relationships between variables and laryngopharyngeal reflux ($n = 45$)

Variable	*Univariate*	
	OR (95% CI)	*P value*
Age, > 60 years	0.63 (0.13−3.04)	.567
Gender, female	2.57 (0.49−13.40)	.252
DM, yes	0.17 (0.02−1.46)	.077
Hypertension, yes	0.28 (0.06−1.36)	.100
Smoking, ≥ 20 pack × years	0.70 (0.12−4.23)	.697
Alcohol, yes	0.96 (0.17−5.65)	.968
BMI ≥ 23 kg/m^2	8.24 (0.92−73.79)	**.033***
Unstim SFR, ≥ 0.245 mL/min	0.06 (0.01−0.55)	**.013***
Stim SFR, ≥ 0.745 mL/min	0.12 (0.01−1.09)	**.033***

*$P < .05$, respectively.
BMI, body mass index; *CI,* confidence interval; *DM,* diabetes mellitus; *OR,* odds ratio; *SFR,* salivary flow rate; *Stim,* stimulated; *Unstim,* unstimulated.

(Pearson's correlation coefficient r = 0.354; $P = .017$) (Figure 2A). Furthermore, the RFS correlated with the stimulated (r = −0.352) and unstimulated (r = −0.423) SFR ($P = .018$ and $P = .004$, respectively) (Figures 2B and 2C).

DISCUSSION

Our present study findings confirm the association between xerostomia and LPR. The role of saliva in esophageal defense has been described in several studies.[12,13] However, there are few studies on the effects of salivary secretary function on the incidence of LPR. Lee et al. showed that atrophic laryngeal change and low lubrication as a result of irradiation induces damage to the laryngeal mucosal barriers and alters the laryngeal liquid homeostasis in a rat model with salivary damage.[14] The goal of this study was to determine whether there is an association between clinical factors and the LPR-specific health-related quality of life (QOL) measurement tool, and whether pretreatment of the xerostomia QOL index is an independent prognostic factor in patients with successfully treated LPR. Our results showed an association between LPR and several factors, including clinical or salivary gland function test variables. In this prospective study, we performed qualitative and quantitative analyses by using questionnaires, salivary scintigraphy, and laryngoscopic RFS findings.

No previous reports have indicated the prevalence of LPR in adults with dry mouth symptoms, except in those with SS and radiation history. However, Corvo et al. demonstrated a very high prevalence of LPR in patients with SS, which is probably the result of reduced salivary volume and contents.[15] In this study, the prevalence rate of LPR is greater than 80%. Copper et al. reported that only 17% of patients had neither pathologic LPR nor GER in patients with head and neck cancers.[16] Eguchi et al. also demonstrated that

Table IV. Correlation of subjective and objective findings between xerostomia and laryngopharyngeal reflux ($n = 45$)

Variable	*Unstim SFR*	*Stim SFR*	*Symptom score*	*Right PG*			*Left PG*			*Right SMG*			*Left SMG*		
				UR	*Tmin*	*MA*	*MS*	*UR*	*Tmin*	*MA*	*MS*	*UR*	*Tmin*	*MA*	*MS*	*UR*	*Tmin*	*MA*	*MS*
RSI	0.025	−0.037	**0.354***	−0.023	0.027	0.067	−0.083	−0.103	0.068	−0.005	−0.061	0.000	−0.223	0.024	−0.076	−0.039	−0.170	−0.155	−0.114
RFS	**−0.423**†	**−0.352***	0.053	0.004	0.223	−0.002	−0.138	−0.204	0.153	−0.104	0.028	0.015	0.069	−0.009	0.044	−0.124	0.009	−0.067	0.036

*$P < .05$.
†$P < .01$, respectively.
PG, parotid gland; *MA,* maximum accumulation; *MS,* maximum secretion; *RFS,* reflux finding score; *RSI,* reflux symptom Index; *SFR,* salivary flow rate; *SMG,* submandibular gland; *Stim,* stimulated; *Tmin,* time to minimum count; *Unstim,* unstimulated; *UR,* uptake ratio.

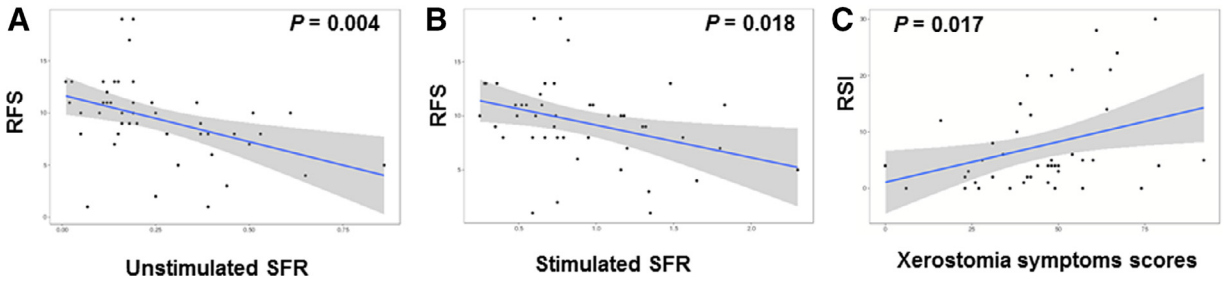

Fig. 2. Correlation subjective **(A)** and objective **(B** and **C)** findings between xerostomia and laryngopharyngeal reflux. *RFS,* reflux finding score; *RSI,* reflux symptom Index; *SFR,* salivary flow rate.

many patients were categorized as high RFS (LPR-likely) among patients with head and neck cancer treated with radiation therapy alone and that high RFS (i.e., increased likelihood of LPR) appeared to be a potential risk factor for developing severe radiation-induced mucositis.[17] We investigated the tendency to LPR among patients with xerostomia without a history of SS and radiotherapy, and our data showed an association between LPR and xerostomia. Furthermore, obesity and high abdominal pressure are also associated with LPR, and our study results are in accordance with those of other studies.[11]

Furthermore, we found that there was a strong association between the presence of LPR and unstimulated and stimulated SFR. These findings suggest that salivary volume influences mucosal injury and reflux laryngitis. This result supports the hypothesis that a decrease in salivary volume can result in LPR. However, in the present study, most scintigraphic parameters, including uptake ratio, maximum accumulation, and maximum secretion, were not related to LPR. Interestingly, the Tmin of the parotid glands in both groups showed meaningful differences. Bozzato et al. found that salivary stimulation with ascorbic acid is more sensitive in evaluating obstructive salivary gland diseases in the parotid glands than those in the submandibular glands.[18] Because of the difference in salivary components and the duct diameter between the parotid glands and the submandibular glands, the Tmin of the parotid glands in patients with LPR was longer than that in the non-LPR group. Further investigations are required for confirmation. Salivary scintigraphy is widely used for investigating multiple diseases affecting the salivary glands. In SS, ^{99m}Tc-pertechnate imaging measures the severity of salivary gland involvement, which may otherwise not be accurately reflected by the symptoms (i.e., xerostomia and other features of sicca syndrome).[19]

Alcohol intake, smoking, and obesity are well-known risk factors for LPR, and therefore, lifestyle modification is vital in treating LPR.[11] We demonstrated that objective decrease in salivary flow (low stimulated and unstimulated SFR) could be a probable risk factor and suggest that effective management of hyposalivation could prevent LPR. Although the cutoff value was set through the ROC curve, future studies are required for validation with the use of significant larger data sets. Furthermore, we found various correlations between xerostomia and LPR with regard to each subjective and objective finding. This result further supports the hypothesis of an association between these 2 disease entities and the reliability of the questionnaire with regard to the association between hyposalivation (xerostomia symptoms scores) and LPR (RSI).

This study has some limitations. In our study design, we included patients with RFS scores above 7 points in the LPR group. Even though RFS has demonstrated high probability, reproducibility, and reliability, proton pump inhibitors offer a better option for diagnosing LPR.[7] We excluded patients with a history of use of proton pump inhibitors from the process of ruling out the bias affecting the prevalence of LPR. Furthermore, we did not perform a double-channel 24-hour esophageal pH probe, and sometimes it is not possible to correlate high RFS with LPR. However, several studies have shown high correlation coefficients between LPR and RFS values greater than 7.[7,20] With regard to the validity and reliability of the xerostomia symptoms score questionnaire used at our institution, the questionnaire was in accordance with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), which has been applied in several previous studies.[5,21] EORTC QLQ-C30 is a widely used questionnaire and contains QOL issues relevant to a broad range of patients with cancer, including those with xerostomia.[22] Furthermore, Eguchi et al. investigated the association between LPR and radiation-induced mucositis and concluded that high RFS (suggesting the increased likelihood of LPR) appears to be a potential risk factor for developing radiation-induced mucosal inflammation.[17] However, the etiology of xerostomia is quite variable and includes several drugs; aging; systemic diseases, such as SS; and radiotherapy. We did not investigate

the history of drugs in all cohorts. Potential drugs that cause salivary dysfunctions can influence the basal salivary secretary function. Eventually, it can affect the incidence of LPR. Finally, the size of the sample was too small to allow multivariate analyses. Further studies with a larger sample size are needed for more robust multivariate analyses.

CONCLUSIONS

Salivary secretion may be associated with LPR. Active management of xerostomia could, therefore, help alleviate the symptoms of LPR.

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Table SI. Xerostomia questionnaire containing 21 conditions related to obstructive salivary symptoms and salivary hypofunction

Xerostomia questionnaire	*1*	*2*	*3*	*4*	*5*
My chin and cheek often has swelling					
Pain in my chin and cheek often develops					
I have trouble swallowing solid food					
I wake up while sleeping for a cup of water					
I feel dryness in my mouth while eating					
I have dryness in my mouth now					
I need a sip of water to swallow solid food					
I usually drink water to reduce dryness					
I have trouble eating dry food					
I eat sweets to reduce dryness					
I feel dryness in my mouth while speaking					
I feel dryness in my mouth while chewing					
I have pain or burning sense in my tongue					
I have bad breath					
I usually have ulcers around my lips					
I have throat discomfort					
I often experience hoarseness					
I have trouble with taste					
My lips often run dry					
My nasal cavity often runs dry					
I have visited the dentist for oral carries or gingivitis					

Table SII. Reflux Symptom Index (RSI)

Within the last month, how did you the following problems affect you?	*1*	*2*	*3*	*4*	*5*
Hoarseness or a problem with your voice					
Clearing your throat					
Excess throat mucous or postnasal drip					
Difficulty swallowing food, liquids, or pills					
Coughing after you ate or after lying down					
Breathing difficulties or choking episodes					
Troublesome or annoying cough					
Sensations of something sticking in your throat or a lump in your throat					
Heart burn, chest pain, indigestion, or stomach acid coming up					

Table SIII. Reflux finding scores (RFS)

Reflux finding score (RFS)	
Subglottic edema	0 = absent, 2= present
Ventricular obliteration	2 = partial, 4 = complete
Erythema/ hyperemia	2 = arytenoids only, 4 = complete
Vocal fold edema	1 = mild, 2 = moderate, 3 = severe, 4 = polypoid
Diffuse laryngeal edema	1 = mild, 2 = moderate, 3 = severe, 4 = obstructing
Posterior commissure hypertrophy	1 = mild, 2 = moderate, 3 = severe, 4 = obstructing
Granuloma/granulation tissue	0 = absent, 2= present
Thick endolaryngeal mucus	0 = absent, 2= present