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LARYNGOLOGY

Usefulness, acceptation and feasibility of electronic medical history tool in reflux disease

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Abstract

Objectives To investigate usefulness, feasibility, and patient satisfaction of an electronic pre-consultation medical history tool (EPMH) in laryngopharyngeal reflux (LPR) work-up.

Methods Seventy-five patients with LPR were invited to complete electronic medical history assessment prior to laryngology consultation. EPMH collected the following parameters: demographic and epidemiological data, medication, medical and surgical histories, diet habits, stress and symptom findings. Stress and symptoms were assessed with perceived stress scale and reflux symptom score. Duration of consultation, acceptance, and satisfaction of patients (feasibility, usefulness, effectiveness, understanding of questions) were evaluated through a 9-item patient-reported outcome questionnaire.

Results Seventy patients completed the evaluation (93% participation rate). The mean age of cohort was 51.2 ± 15.6 years old. There were 35 females and 35 males. Patients who refused to participate ($N = 5$) were > 65 years old. The consultation duration was significantly lower in patients who used the EPMH (11.3 ± 2.7 min) compared with a control group (18.1 ± 5.1 min; $p = 0.001$). Ninety percent of patients were satisfied about EPMH easiness and usefulness, while 97.1% thought that EPMH may improve the disease management. Patients would recommend similar approach for otolaryngological or other specialty consultations in 98.6% and 92.8% of cases, respectively.

Conclusion The use of EPMH is associated with adequate usefulness, feasibility, and satisfaction outcomes in patients with LPR. This software is a preliminary step in the development of an AI-based diagnostic decision support tool to help laryngologists in their daily practice. Future randomized controlled studies are needed to investigate the gain of similar approaches on the traditional consultation format.

Keywords Reflux · Laryngopharyngeal · Gastroesophageal · Medical history · Artificial · Intelligence · Head neck · Future · Laryngology · Otolaryngology

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Introduction

Laryngopharyngeal reflux (LPR) is an inflammatory condition of the upper aerodigestive tract tissues related to direct and indirect effect of gastroduodenal content reflux, which induces morphological changes in the upper aerodigestive tract [1]. LPR-related symptoms are found in 10 to 30% of outpatients consulting in otolaryngology department [2] and up to 50% of patients in laryngology office [3]. Patient diet habits, stress, medical, surgical and therapeutic histories are all important points for the management of LPR patients [1]. The non-specificity of symptoms and findings associated with LPR led many authors to recommend the use of standardized patient-reported outcome questionnaires or clinical instruments to improve the management of LPR [4, 5]. In a personalized consultation approach [6], the time dedicated to the consultation may be longer when the physician has to consider all above-mentioned epidemiological, medical and clinical outcomes and the use of standardized clinical instruments. However, the consideration of these outcomes remains important for the overall quality of the consultation, the patient satisfaction, and its adherence to treatment [7].

In the present study, we investigated the usefulness, the feasibility, and the patient satisfaction of an electronic pre-consultation medical history assessment (EPMH) software in LPR outpatients.

Methods

From January 2021 to July 2021, 75 patients with LPR symptoms, findings and positive 24-h hypopharyngeal–esophageal multichannel intraluminal impedance pH-monitoring (HEMII-pH) were prospectively recruited from the European Reflux Clinic [8] of the Departments of Otolaryngology–Head and Neck Surgery of CHU Saint-Pierre (Brussels, Belgium) and Foch Hospital (Paris, France). The LPR diagnosis was based on the occurrence of > 1 acid or nonacid pharyngeal reflux evens at the HEMII-pH during the 24-h period (OFF medication) [9]. The probe placement and configuration features were detailed in previous publication [10].

In our departments, patients with suspected LPR diagnosis are referred to the reflux clinic where two physicians (JRL, LDM) offer patients to perform additional examination(s) (HEMII-pH or gastrointestinal endoscopy) or to follow an empirical therapeutic trial. The consultation in the reflux clinic also included diet anamnesis and recommendations. The decision is based on a clinical algorithm considering the history of patients, the severity of reflux and its impact on quality of life (Appendix 1). Patients who benefit from HEMII-pH are seen again by laryngologists to perform a baseline clinical evaluation (symptoms, findings), and to explain the HEMII-pH findings and the personalized treatment. During this consultation, laryngologists systematically collect the following information: demographic and epidemiological data; allergy, tobacco, medication, medical and surgical histories; diet habits; stress findings; symptom and sign scores (Fig. 1). The IRB approved the study protocol (n°BE076201837630). The informed consent was obtained.

Hypopharyngeal-esophageal multichannel impedance pH monitoring

The characteristics of HEMII-pH device, placement and analyses have been described in previous publications [10]. The HEMII-pH was composed of 8 impedance segments and 2 pH electrodes (Versaflex Z®, Digitrapper pH-Z testing System, Medtronic, Europe). Six impedance segments were placed along the esophagus zones (Z1 to Z6) and they were centered at 19, 17, 11, 9, 7 and 5 cm above the lower esophageal sphincter (LES). Two additional impedance segments were placed 1 and 2 cm above the upper esophageal sphincter (UES) in the hypopharynx. The pH electrodes were placed 2 cm above LES and 1–2 cm below UES. Hypopharyngeal reflux event was an episode that reached two impedance sensors in the hypopharynx. Acid reflux episode was defined as an episode with pH ≤ 4.0. Nonacid reflux episode consisted of an episode with pH > 4.0. The LPR diagnostic consisted of the occurrence of > 1 proximal episode [10].

Software development and collected data

A digitized data collection tool designed for ear, nose and throat (ENT) consultations was developed with MDs (JRL, SH, LDM). This tool supports the collection and summarizes all patient's data to use during medical consultations. Digitized questionnaires were sent to patients to fill before each consultation focusing on medical background, diet habits, reflux symptom score (RSS) [12]. The questionnaires were based on validated patient reported outcome measures like perceived stress scale (PSS) [11] and RSS. The web interface of the software used PHP and Javascript. Submitted data were securely saved in a database compliant with the General Data Protection Regulation (GDPR). These data were accessed by the laryngologist through a desktop application implemented using Python (Appendix 2). Additional information can be filled in the software by the MD during the consultation, such as reflux sign assessment (RSA) and, in case of hoarseness, GRBASI scale. According to MDs

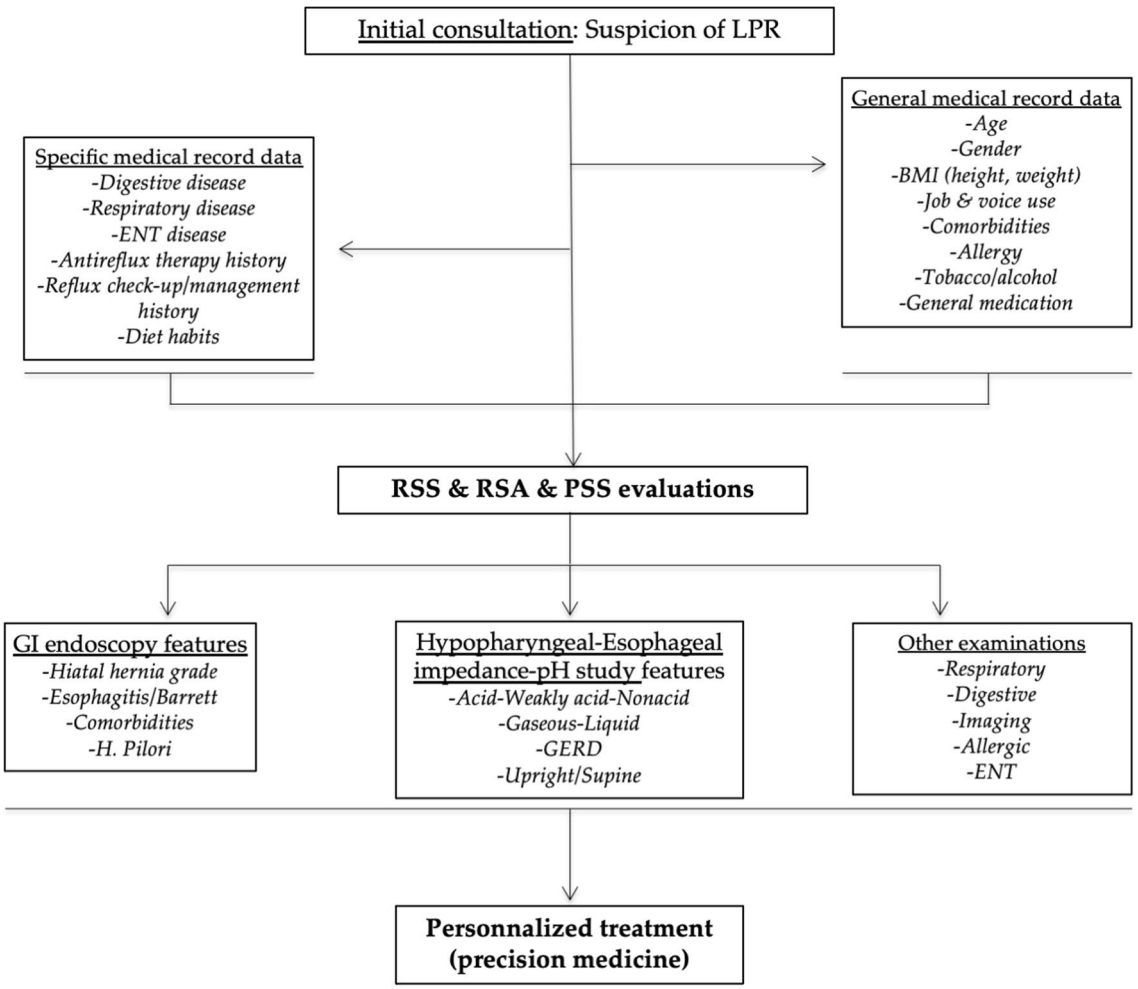

Fig. 1 Key points considered in the precision medicine consultation of patients and the related personalized treatment. *BMI* body mass index, *ENT* ear, nose, throat, *GERD* gastroesophageal reflux disease, *GI* gastrointestinal, *LPR* laryngopharyngeal reflux, *PSS* perceived stress scale, *RSA* reflux sign assessment, *RSS* reflux symptom score

(JRL, SH, LDM), comorbidities, previous examinations, drugs or confounding conditions were selected to be evaluated through a multiple-choice list of answers. The following patient-reported outcome questionnaires were optionally available for LPR patients with sinonasal symptoms, severe dysphagia or dysphonia: sinonasal outcome tool 22 (SNOT-22), [13] voice handicap index [14], eating assessment tool-10 [15]. At 3-month posttreatment, the following outcomes were evaluated: weight changes; adherence to diet and medication; PSS and RSS evolution. PSS, RSS and RSA evolutions throughout treatment were represented in a graphic that was generated by the software (Appendix 2).

Demographic and epidemiological data

Age, gender, body mass index, and job features are considered in the reflux check-up because they may have significant impact on the LPR presentation and therapeutic response. Obese patients reported more severe LPR symptoms, higher proportion of acid reflux and gastroesophageal reflux disease (GERD) and, therefore, may require more frequently gastrointestinal (GI) endoscopy and proton pump inhibitor (PPI) therapy [17]. The influence of age and gender has already been studied in LPR disease [18]. Elderly LPR patients have few symptom scores and require more time to cure, while females report significant higher baseline symptom scores compared with males [18]. The patient occupation and voice use are additional parameters that may be important in the management of LPR. Voice professionals have a higher prevalence of LPR and related dysphonia compared with non-professionals [19], which may require qualitative voice assessments throughout treatment and, in some cases, the consideration of speech therapy.

Medication, medical and surgical histories

Many patients evaluated at the reflux clinic have a long-history of PPI intake or many therapeutic failures with several courses of anti-reflux medication. Others want to stop long-term PPIs according to the adverse events [18]. Consequently, the medication history is important in the management of LPR of patients with positive diagnosis at the HEMII-pH. Because LPR symptoms and signs are non-specific, the identification of confounding conditions that are associated with similar LPR symptoms and findings makes sense in the management of patients. Precisely, the presence of the following conditions was investigated by the senior laryngologist at the first consultation: laryngopharyngeal or nasal infection, tobacco consumption, alcohol dependence, asthma and use of inhaled corticosteroids, neurological or psychiatric illness, previous history of neck trauma, surgery, malignancy or radiotherapy, active seasonal allergies, lactose or histamine intolerance, and the presence of bowel disease [19–21].

Symptoms, findings, and stress severities

The use of patient-reported outcome questionnaires is particularly important in LPR disease regarding the non-specificity of symptoms and findings. In the present study, patients were invited to fulfill reflux symptom score (RSS) [12], and PSS [11], prior to the consultation. RSS evaluates frequency and severity of ear, nose, throat, digestive, and respiratory complaints as well as the impact of symptoms on quality of life (QoL). PSS is a ten-item patient reported outcome questionnaire assessing the impact of stress on the daily live. Findings were electronically assessed during the consultation with RSA [16]. Patient may provide additional information (symptom) in a specific box in the EPMH.

Diet habits and treatment

According to the involvement of diet in the development of LPR [20, 21], patients benefited from a complete diet evaluation. They had to specify their weekly food and beverage consumption through a predefined list of foods and beverages that are associated with a high refluxogenic potential [20]. The identification of foods and beverages associated with a high risk of LPR is, at baseline, important to give personalized diet recommendations.

Patient satisfaction and outcomes

The following outcomes were evaluated in patients who benefited from the EPMH: acceptance of patients, duration of consultation, and patient satisfaction. The duration of consultation was evaluated on two groups of patients: patients using EPMH versus those who had a conventional consultation. Patient satisfaction was evaluated through a 9-item patient-reported outcome questionnaire assessing the patient perception about the EPMH (feasibility, usefulness), the consultation (effectiveness, understanding, and quality of management) and the generalization of such approach (Table 1). The questionnaire was developed by a multidisciplinary team including otolaryngologists, linguists, and patients. Appendix 2 shows the information found in the EPMH dashboard.

Statistical methods

Statistical analyses were performed with the Statistical Package for the Social Sciences for Windows (SPSS version 24.0; IBM Corp, Armonk, NY, USA). Chi-square, Mann–Whitney *U* test were used to compare outcomes between groups. The relationship between patient features, symptoms and findings, and response to the satisfaction questionnaire was

Table 1 Satisfaction patient-reported outcome questionnaire

For the questions 1–5, 7–9, respond with a visual analog scale ranging from 0 (totally disagree) to 10 (totally agree)
1. It was easy to answer to the questions of the medical history software
2. Do you think that it is useful to provide to the physician the information included in the software?
3. Do you think that it would be as easy as providing these information in a classical consultation?
4. Do you think that the use of medical history software approach may improve the availability of physician for potential questions or explanations?
5. Is useful the use of standardized and validated patient-reported outcome questionnaires for stress, diet and symptom evaluations?
6. Do you think that it would be better to provide medical history information in a classical consultation (yes/no)
7. Do you think that this medical history software approach may improve the overall management of your disease?
8. Would you recommend similar approach to other patients consulting in otolaryngology units?
9. Do you think that this approach could be generalized in medicine to improve the quality of the office consultation ?
At the exception of the question 6, patients had to answer through a visual analog scale ranging from 0 (totally disagree) to 10 (totally agree)

investigated with Spearman analysis and multiple linear regression. A level of significance of $p < 0.05$ was used.

Results

Seventy consecutive patients completed the evaluations (93%). Five patients did not complete the information because they preferred a classical consultation. All of them were > 65 years old and did not frequently use internet. The mean age of cohort was 51.2 ± 15.6 years old. There were 35 females and 35 males. The clinical features of patients are described in Table 2.

Table 2 Epidemiological and clinical features of patients

Characteristics	
Mean age (SD)	51.2 ± 15.6
Gender (*N*, %)	
Male	35 (50)
Female	35 (50)
Gastrointestinal endoscopy	*N* = 17
Normal	10
Esophagitis	3
Hiatal hernia	1
LES insufficiency	1
Gastritis	2
Helicobacter Pylori	2
HEMII-pH feature (m ± SD)	
Pharyngeal reflux episodes	46.2 ± 84.8
Pharyngeal reflux episodes upright	43.1 ± 81.8
Pharyngeal reflux episodes supine	3.2 ± 5.0
GERD	
Number of patients (%)	18 (26)
Percentage of time with distal pH < 4	16.8 ± 26.1
DeMeester score	46.4 ± 75.4
Reflux Symptom Score	94.6 ± 66.8
Reflux Sign Assessment	29.1 ± 6.8
Perceived Stress Scale	27.4 ± 8.5

GERD gastroesophageal reflux disease, *HEMII-pH* hypopharyngeal multichannel intraluminal impedance-pH monitoring, *LES* lower esophageal sphincter, *SD* standard deviation

The duration of the consultation was recorded in 30 LPR patients who benefited from a classical consultation. The mean durations of the consultation (from the medical history evaluation to the laryngoscopic examination and treatment) in electronic medical history evaluation versus classical consultation groups were 11.3 ± 2.7 and 18.1 ± 5.1 min, respectively ($p = 0.001$).

The software generated electronic report for all patients. The accuracy of software content was systematically verified with each patient. Indeed, otolaryngologists (JRL & LDM) summarized the findings at each consultation and patient checked the findings. There was no mismatch between the software report and the patient explanations.

The patient perception about the electronic medical history evaluation was described in Tables 3 and 4. More than 90% of patients reported adequate satisfaction evaluations about both easiness to respond to questions and usefulness of the EPMH. Patients assessed the EPMH as easier as the questions in classical consultation in 45.7% Moreover, 97.1% of patients believed that this approach may improve the disease management. Patients would recommend similar approach for otolaryngological or other specialty consultations in 98.6 and 92.8% of cases, respectively. Only 12.9% of patients reported that they would prefer to provide information in a classical consultation. The easiness to provide medical information through EPMH was judged as more difficult than in a classical consultation in 28.6% of cases. There were no significant associations between the patient satisfaction scores and the following outcomes: gender, age, and PSS.

Discussion

Precision medicine, formerly called personalized medicine, is an innovative approach considering the characteristics of individuals in the management of a disease. According to

Table 3 Mean scores and standard deviations of satisfaction questionnaire evaluation

Satisfaction outcomes	Mean ± SD
1. Easiness to respond to questions	8.8 ± 2.1
2. Usefulness of electronic medical history	9.4 ± 1.6
3. Similar easiness than classical consultation	5.7 ± 3.2
4. Improvement of the availability of physician/time dedicated to explanations	8.0 ± 2.6
5. Usefulness of patient-reported outcome questionnaires	8.8 ± 1.6
6. Better to provide information in a classical consultation (yes / no)	9/61
7. Improvement of the disease management	9.3 ± 1.4
8. Recommendation of similar approach for patients consulting in otolaryngology units	9.6 ± 1.1
9. Generalization of the software approach in medicine	8.9 ± 2.0

SD standard deviation

Table 4 Numbers and proportions of patient response in the satisfaction questionnaire outcomes

Satisfaction outcomes	Totally disagree–disagree	Neutral	Agree–totally agree
1. Easiness to respond to questions	3 (4.3)	2 (2.9)	65 (92.8)
2. Usefulness of the medical history software	2 (2.9)	1 (1.4)	67 (95.7)
3. Similar easiness than classical consultation	20 (28.6)	18 (25.7)	32 (45.7)
4. Improvement of the availability of physician/time dedicated to explanations	7 (10.0)	6 (8.6)	57 (81.4)
5. Usefulness of patient-reported outcome questionnaires	1 (1.4)	3 (4.3)	66 (94.3)
6. Better to provide information in a classical consultation (yes / no)	Yes: 9 (12.9) No: 61 (87.1)		
7. Improvement of the disease management	1 (1.4)	1 (1.4)	68 (97.1)
8. Recommendation of similar approach for patients consulting in otolaryngology units	1 (1.4)	0 (0)	69 (98.6)
9. Generalization of the approach in medicine	3 (4.3)	2 (2.9)	65 (92.8)

the impact of age, gender, stress (autonomic nerve dysfunction), diet and lifestyle habits on reflux, it is increasingly suggested that the consideration of these outcomes makes sense to improve GERD [22] or LPR [10, 17, 18, 23, 24] management. Because the consideration of these outcomes may be time-consuming in a classical consultation, especially the diet evaluation, we developed EPMH to save time.

In the present study, the mean duration of consultation of patients benefiting from EPMH was 11.3 min, which was significantly shorter than the consultation duration of the control group. The laryngologists had direct access to the patient information, refluxogenic foods and beverages that are important to avoid, while the patients have had time to provide the requested information at home. Interestingly, according to more than 90% of patients, EPMH was deemed useful, easy to use, and improved LPR management. The high degree of satisfaction led patients to recommend similar approaches for other clinical specialties. In medicine, the most important outcomes associated with high degree of satisfaction in patients included cure or symptom relief, understanding, confirmation, reassurance, physician communication skills, expertise, and time dedicated to patients [25, 26]. Through EPMH, the laryngologist may dedicate more time in the explanations of personal etiological factors of LPR (patient foods, beverages, and stress score), which may improve the understanding of patients. Moreover, the availability of clear information about the etiological factors may help the laryngologist to propose the more adequate treatment regimen, considering medication history and patient diet habits. Similar approaches were found to improve the quality of management in medicine, leading to better patient reassurance and satisfaction [27, 28]. Another potential factor that may explain the high degree of patient satisfaction is the adequate explanations provided by physician about the aim of the EPMH and the development of future artificial intelligence approach. Indeed, it was recently supported that the patient trust and acceptance regarding technology and artificial intelligence depend on the explanations provided by physicians about the interest to use such software [28]. About symptom relief and therapeutic management effectiveness, we observed in the present study that RSS, RSA and PSS curve evolution may help the laryngologist to evaluate more rapidly the degree of symptom and sign changes, and, therefore, tailor the treatment.

The main limitation of the present study is the low number of patients. The involvement of only two otolaryngologists in the assessment of the software accuracy is another limitation. The satisfaction patient-reported outcome questionnaire used was not validated, which may be considered as an additional limitation. However, we did not find similar validated questionnaire in the current literature.

This study is a preliminary report that raises more perspectives than findings. First, in a context of specific consultation (standardized medical history evaluation approach, same questions, patient-reported outcome questionnaires), the use of EPMH makes sense to save time that may be made to patient explanations and assurance. In that context, it is important to keep in mind that technology, such as EPMH, may improve but not replace important human skills needed for patient care in laryngology.

Second, the digitized data collection tool presented in this work is still under development. New features are planned to be implemented, including one relying on automated processing with machine learning. The data are currently preprocessed before they are stored, and the constructed database is directly usable for AI applications. Several approaches of machine learning are currently considered through clustering techniques that identify subgroups among LPR patients, or classification ones used for clinical decision-making by suggesting the most suitable treatment for patients.

Third, to date, the technology and artificial intelligence remain poorly developed in laryngology [29]. The development of similar software collecting important information for the disease management may lead to the development of machine learning process that may improve

the personalized management of patient throughout the therapeutic course in laryngology diseases. The following outcomes may further be analyzed in a machine learning process: analysis of etiological factors, associated conditions, baseline predictors of therapeutic failure or baseline features indicating specific treatment. The better understand of such conditions in LPR may undoubtedly improve the patient care, leading to substantial economies in a field (reflux) where the annual cost are estimated at between US$9.3 to US$50 billion [30, 31].

Conclusion

The findings of the present study support that patients are ready to benefit from home-managed artificial medical history evaluation prior the consultation in laryngology. The use of home-managed electronic medical history evaluation software is associated with adequate feasibility, usefulness, and satisfaction outcomes in patients with LPR. This software is a preliminary step in the development of an artificial intelligence approach able to improve patient care in laryngology and reflux field. Future controlled randomized studies are needed to investigate the gain of similar approaches on the classical consultation.

Appendix 1

See Fig. 2.

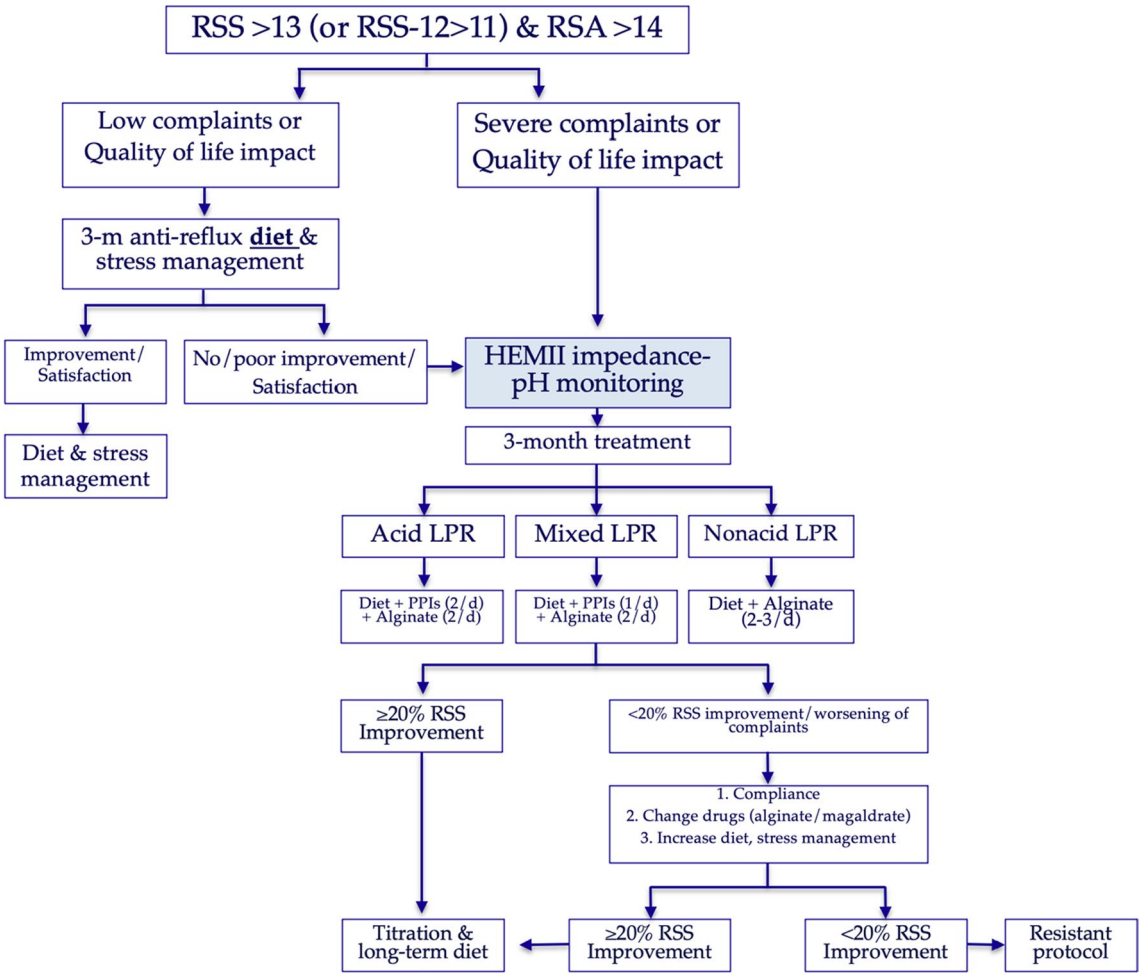

Fig. 2 Laryngopharyngeal reflux management algorithm. Patients addressed to the Reflux Clinic are managed according to this algorithm considering symptom and finding severities and disease impact on quality of life. *LPR* laryngopharyngeal reflux, *PPI* proton pump inhibitor, *RSA* reflux sign assessment, *RSS* reflux symptom score

Appendix 2

See Fig. 3.

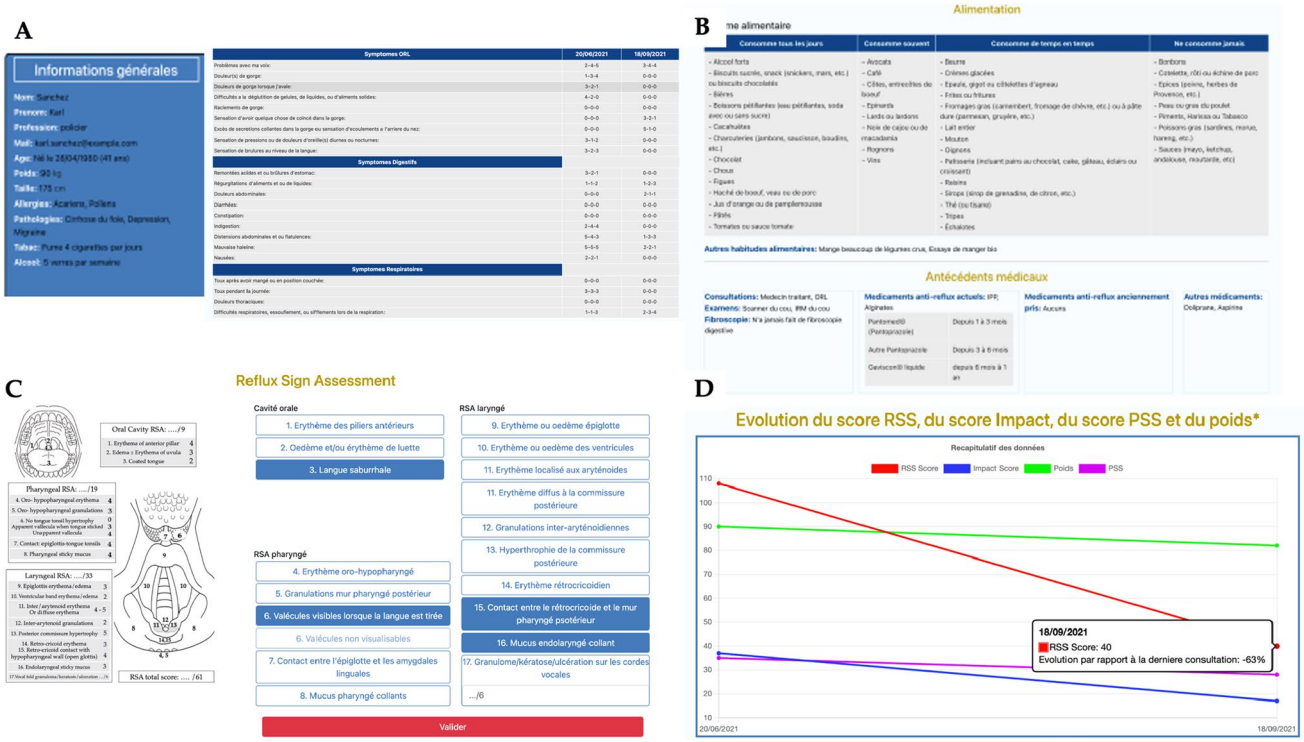

Fig. 3 Electronic medical history software dashboard. The software provides medical record data (age, gender, job, height, weight, comorbidities, allergy, tobacco and alcohol consumption (**A**); Reflux Symptom Score details (**A**); specific diet evaluation (foods and beverages never – sometimes – frequently (1/*w*) – daily (1/*d*) consumed (**B**); general or antireflux medication history (**B**); Reflux Sign Assessment findings to complete electronically by laryngologist during the consultation (**C**); and pre- to -post-treatment changes in perceived stress scale, reflux symptom score, reflux sign assessment and weight (**D**)

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Declarations

Conflict of interest The authors have no conflicts of interest.

Research involving human participants and/or animals IRB was not required for this study.

Informed consent Patients agreed to participate.

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