Clinical Findings, Feasibility, and Patient Tolerance of Nasopharyngeal Dx-pH System for Detecting Nasopharyngeal Reflux Disease[☆]

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Summary: Objective. To investigate the feasibility, patient tolerance, and clinical findings of the Dx-pH system for detecting nasopharyngeal reflux disease (NRD).

Methods. Patients with idiopathic and chronic nasal complaints were recruited from the European Reflux Clinic between July 2022 and July 2024. Patients underwent 24-hour nasal Dx-pH system for detecting NRD. Reflux symptom score, sinonasal outcome tool-22, and reflux sign assessment were used to document symptoms and findings. A tolerance 19-item questionnaire was used to evaluate the symptom prevalence and severity of the probe placement and position throughout the 24-hour testing, ranging from 0 (no annoyance) to 95 (severe annoyance). **Results.** Twenty-three patients completed the evaluations (11 females). The mean age was 51.5 ± 17.0 years. Eighteen (78.3%) patients had NRD with a mean number of nasopharyngeal reflux events of 67.1 ± 65.9. Mulberry inferior turbinate was reported in 15 patients (65.2%), nasal dryness in nine patients (39.1%), and crusting in six patients (26.1%). The mean tolerance score was 15.2 ± 11.9. The most prevalent symptoms during the 24-hour pH-testing included nasal discomfort during probe placement (73.9%), throat discomfort during probe placement (69.6%), overall discomfort throughout the testing period (69.6%), cough during the testing day (65.2%), and postnasal drip sensation during the monitoring period (60.9%). Patients reported the highest discomfort scores for overall discomfort during the testing night and throat discomfort during probe placement. Significant positive correlations were observed between patient-reported tolerance difficulties and otolaryngological reflux symptom severity ($r_s = 0.644$, P = 0.002) and mulberry inferior turbinate ($r_s = 0.432$; P = 0.045). **Conclusion**. The Dx-pH system effectively detects NRD with acceptable patient tolerance, though discomfort correlates with symptom severity. This diagnostic approach suggests a high NRD prevalence among chronic nasal complaint patients.

Key Words: Nasopharyngeal—Nasal—Laryngopharyngeal—Reflux—Otolaryngology—Head neck surgery— Impedance—PH—Monitoring.

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INTRODUCTION

Laryngopharyngeal reflux disease (LPRD) is defined as a disease of the upper aerodigestive tract resulting from the direct and/or indirect effects of gastroduodenal content reflux, inducing morphological and/or neurological changes in the upper aerodigestive tract. Recent findings supported that LPRD can be associated with nasopharyngeal and nasal mucosa irritation through the deposit of digestive enzymes and the related development of mucosa inflammation.²⁻⁴ This field of research dedicated to "extralaryngopharyngeal" manifestations of LPRD is poorly investigated, and there is no objective testing device developed for documenting nasopharyngeal reflux events. Indeed, to date, the most objective approaches for documenting pharyngeal reflux events consist of impedancepH probes with esophageal and hypopharyngeal sensors.

The oropharyngeal pH metry (Dx-pH system; Restech®) is an alternative objective approach designed for assessing oropharyngeal reflux events. While this approach cannot document the full esophageal reflux column before reaching the pharynx, its single probe detecting acid, weakly acid, and alkaline reflux events can be placed at several levels of the upper aerodigestive tract. This unique

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characteristic and the lack of hypopharyngeal-esophageal multichannel intraluminal impedance-pH testing probe with nasopharyngeal sensors led experts of the Confederation of the European Otorhinolaryngological Societies to suggest the Dx-pH system as a potential method for detecting nasopharyngeal reflux disease (NRD) when placing the sensor in the nasopharynx.⁷

This preliminary study aimed to investigate the feasibility, patient tolerance, and clinical findings of nasopharyngeal impedance-pH testing (Dx-pH system) for detecting NRD.

MATERIALS AND METHODS

Setting and patients

Patients with idiopathic rhinitis were recruited from July 2022 to July 2024 at the European Reflux Clinic (CHU Saint-Pierre, Brussels, Belgium). According to the literature, the diagnosis of idiopathic rhinitis consisted of the presence of two or more cardinal symptoms, including nasal running, nasal congestion, sneezing, and itching for more than an hour per day, lasting > 2 weeks. All patients underwent a sinus CT-scan, skin prick test or RAST, in their initial clinical evaluation. Patients with the following conditions were carefully excluded: acute, recurrent, or chronic rhinosinusitis, active allergic rhinitis, medicamentosa rhinitis, infectious rhinitis, tobacco-induced rhinitis, vasomotor rhinitis, occupational rhinitis, use of antireflux therapy, neurological or psychiatric diseases, head and neck malignancy, history of head and neck radiotherapy, and uncontrolled asthma. Patients with a history of functional endoscopic sinus surgery without recurrence of rhinosinusitis were included. The Dx-pH System (Respiratory Technology Corp, San Diego, CA) was proposed as nasopharyngeal pH testing for patients. According to the European Consensus paper, and normative data paper, the NRD diagnosis was based on the presence of more than eight pharyngeal reflux events at the 24-hour Dx-pH system off acid-suppressive medication.

This study has been approved by the ethics committee of CHU Saint Pierre (reference B0762022220217). Patients consented to participate.

Nasopharyngeal pH testing (Dx-pH system)

The Dx-pH measurement system (Restech®) includes a single transnasal probe, a reusable transmitter, and a wireless recorder system (Respiratory Technology Corp, San Diego, CA). The catheter was initially calibrated in solutions of pH 7 and pH 4. The probe was inserted through the nasal cavity until the sensor light became visible transorally at the posterior wall of the oropharynx. It was then carefully retracted to position the sensor in the nasopharyngeal cavity, with proper placement confirmed by visualization of the probe light. Patients were instructed to maintain their normal daily activities throughout the 24-hour monitoring period. The Dx-pH system sensor continuously recorded reflux characteristics, including type (aerosolized and/or liquid), pH levels, frequency, duration,

and temporal distribution of nasopharyngeal reflux episodes. The catheter was placed in the morning before breakfast. The Restech® data were analyzed by the DataView software (AEMC Instruments, Foxborough, MA), which generated a graphical tracing and a report of the reflux events. Time spent eating and drinking was excluded from the analyses. The RYAN score was measured, considering the number of reflux episodes, the duration of the longest reflux episode, and the percent time of pH below the pH threshold of 5.5 in the upright and 5.0 in the supine periods. The normal composite upright and supine RYAN scores are < 9.4 and < 6.8, respectively. The diagnosis of gastroesophageal reflux disease was based on the Lyon consensus. 11

Safety, tolerance and clinical evaluations

Laryngopharyngeal symptoms were evaluated with the Reflux Symptom Score (RSS). Sinonasal symptoms were assessed with the sinonasal outcome tool-22 (SNOT-22). The Reflux Sign Assessment (RSA) was used to document oral, laryngeal, and pharyngeal findings. Two blinded practitioners evaluated signs (G.M. and J.R.L.). The following nasal findings were documented in the additional findings section of the RSA: mulberry inferior turbinate, nasal crusting, and mucosal dryness.

Safety was evaluated by the practitioner responsible for probe placement (G.C.). Following the 24-hour monitoring period, patients completed a comprehensive 19-item survey designed to assess their experience and any discomfort associated with the nasopharyngeal pH testing procedure. The survey was designed by investigators considering the annoyance/symptoms at the placement time, during the day and night of the 24-hour testing period (Appendix 1). Patients rated each item from 0 (no symptom/annoyance) to 5 (very severe symptom/annoyance). A total score was calculated ranging from 0 to 95.

Statistical methods

Statistical analyses were conducted using the Statistical Package for the Social Sciences for Windows (SPSS version 29.0; IBM Corp, Armonk, NY). The outcome associations were evaluated with the Spearman correlation coefficient, which was considered as low (k < 0.40), moderate (k = 0.40-0.60) and strong (k > 0.60), respectively. A level of significance of P < 0.05 was used.

RESULTS

Twenty-three patients were included (11 females). The mean age was 51.5 ± 17.0 years (Table 1). The mean body mass index was 24.2 ± 3.2 . Twelve patients had a gastrointestinal endoscopy, which reported three hiatal hernias, seven lower esophageal sphincter insufficiency, three esophagitis (LA grade A), and four gastritis. The examination was normal in three cases.

The nasopharyngeal sensor placement was successful in all cases, with no technical failures in event detection or

TABLE 1. Patient Features	
Characteristics	Patients (N = 23)
Age (range; years old)	51.5 ± 17.0
Body mass index (m; SD)	24.2 ± 3.2
Gender (N, %)	
Male	12 (52.2)
Female	11 (47.8)
Dx-pH system features	
Thesholds	10 (70 0)
Patients with > 8 pharyngeal reflux	18 (78.3)
events	
Nasopharyngeal events (mean, SD) Nasopharyngeal pH < 6.5	67.1 ± 65.9
Nasopharyngeal pH < 6.0	23.0 ± 28.0
Nasopharyngeal pH < 5.5	10.1 ± 17.8
Nasopharyngeal pH < 5.0	4.0 ± 10.4
Number of events > 5 minutes	8.8 ± 8.1
pH < 6.5	0.0 1 0.1
Number of events > 5 minutes	4.5 ± 6.1
pH < 6.0	
Number of events > 5 minutes	2.1 ± 2.9
pH < 5.5	
Number of events > 5 minutes	0.7 ± 2.5
pH < 5.0	
Percentage of time (%)	
Total % pH below baseline $P < 6.5$	32.7 ± 32.0
Total % pH below baseline $P < 6$	13.1 ± 18.0
Total % pH below baseline $P < 5.5$	5.3 ± 9.6
Total % pH below baseline $P < 5$	1.1 ± 3.6
Ryan score upright	46.2 ± 130.9
Ryan score supine	1.9 ± 4.9

data analysis during the monitoring period. Eighteen (78.3%) patients had NRD. The mean number of nasopharyngeal reflux events was 67.1 \pm 65.9. The mean number of nasopharyngeal reflux events at pH < 6.5, < 6.0, < 5.5, < 5.0, the mean number of events lasting more than 5 minutes (long reflux events), and the total percentage of time with pH below baseline pH < 6.5, < 6.0, < 5.5, < 5.0 are reported in Table 1. The mean Ryan score upright was 46.2 \pm 130.9.

Abbreviation: SD, standard deviation.

The symptoms and clinical signs observed in the patient cohort are summarized in Table 2. Patients with a positive NRD diagnosis exhibited RSS > 13 and RSA > 14 in 18/18 (100%) and 17/18 (94.4%) cases, respectively. Mulberry appearance of the posterior part of the inferior turbinate was observed in 15 patients (65.2%), nasal dryness in nine patients (39.1%), and crusting in six patients (26.1%).

There was no difficulty related to the placement of the Dx-pH measurement probe. The mean tolerance score was 15.2 ± 11.9. The prevalence of symptoms during the 24-hour nasopharyngeal pH testing is reported in Table 3. Regardless of type or severity, 57.7% of patient responses indicated no discomfort related to the 24-hour Dx-pH testing. Regarding symptom prevalence during the

Clinical Presentation Scores	Mean score (SD	
Otolaryngological RSS	73.3 ± 52.8	
Digestive RSS	56.5 ± 47.5	
Respiratory RSS	22.8 ± 20.6	
Quality-of-life RSS	40.6 ± 23.7	
Reflux Symptom Score	152.6 ± 99.6	
SNOT-22	37.6 ± 28.5	
Reflux Sign Assessment	23.0 ± 9.1	
Oral RSA	4.7 ± 1.9	
Pharyngeal RSA	9.0 ± 3.0	
Laryngeal RSA	13.3 ± 4.7	
Prevalence of Nasal Signs (N, %)		
Mulberry inferior turbinate	15 (65.2)	
Crusting	6 (26.1)	
Dryness	9 (39.1)	

procedure, the most commonly reported complaints included nasal discomfort during probe placement (73.9%), throat discomfort during probe placement (69.6%), overall discomfort throughout the testing period (69.6%), cough during the testing day (65.2%), and postnasal drip sensation during the monitoring period (60.9%) (Table 3). In terms of severity, patients reported the highest discomfort scores for the following symptoms: overall discomfort during the testing night, throat discomfort during probe placement, excessive nasal secretions during the testing day, and nasal discomfort during probe placement (Table 4).

The tolerance total score was significantly associated with the otolaryngological RSS ($r_s = 0.644$, P = 0.002), the RSS-Quality of life ($r_s = 0.605$; P = 0.005), and the presence of mulberry inferior turbinate ($r_s = 0.432$; P = 0.045). The severity of otolaryngological RSS was associated with the documentation of nasal mucosa dryness ($r_s = 0.579$; P = 0.009).

There was no significant correlation between SNOT-22 and nasopharyngeal reflux event findings.

DISCUSSION

The place of the Dx-pH system in the management of LPRD remains undetermined, with a large number of practitioners preferring to use 24-hour HEMII-pH, which can reliably identify the full esophageal column of reflux events before reaching the pharynx. However, the current HEMII-pH probes are not developed for detecting pharyngeal reflux events above the hypopharynx, which limits practitioners in the identification of a potential association between reflux and nasopharyngeal or nasal disorders. The development of an alternative objective approach for detecting NRD is mandatory, considering the emerging literature demonstrating the role of reflux disease

l olerance Evaluation						
	No problem	Very mild	Mild problem	Moderate	Severe	Very severe
Tolerance items	(0)	problem (1)	(2)	problem (3)	problem (4)	problem (5)
Nasal discomfort during probe placement	6 (26.1)	9 (39.1)	4 (17.4)	3 (13.0)	(0) 0	1 (4.4)
Nasal pain during probe placement	11 (47.8)	7 (30.3)	1 (4.4)	2 (8.7)	1 (4.4)	1 (4.4)
Throat discomfort during probe placement	7 (30.4)	5 (21.7)	7 (30.4)	3 (13.0)	1 (4.4)	(0) 0
Throat pain during probe placement	14 (60.9)	4 (17.4)	1 (4.4)	4 (17.4)	0 (0)	(0) 0
Overall discomfort during the testing day	7 (30.4)	9 (39.1)	5 (21.7)	(0) 0	2 (8.7)	(0) 0
Overall pain during the testing day	17 (73.9)	5 (21.7)	(0) 0	1 (4.4)	0 (0)	(0) 0
Overall discomfort during the testing night	10 (43.5)	2 (8.7)	4 (17.4)	5 (21.7)	2 (8.7)	(0) 0
Overall pain during the testing night	17 (73.9)	3 (13.0)	1 (4.4)	2 (8.7)	0 (0)	(0) 0
Discomfort while eating and swallowing	11 (47.8)	6 (26.1)	5 (21.7)	1 (4.4)	0 (0)	(0) 0
Pain while eating and swallowing	16 (69.6)	5 (21.7)	2 (8.7)	(0) 0	0 (0)	(0) 0
Choking sensation during the testing day	17 (73.9)	4 (17.4)	1 (4.4)	1 (4.4)	0 (0)	(0) 0
Choking sensation during the testing night	17 (73.9)	4 (17.4)	(0) 0	2 (8.7)	0 (0)	(0) 0
Excessive nasal secretions during the testing day	9 (39.1)	4 (17.4)	5 (21.7)	4 (17.4)	0 (0)	1 (4.4)
Excessive nasal secretions during the testing night	13 (56.5)	2 (8.7)	4 (17.4)	2 (8.7)	1 (4.4)	1 (4.4)
Cough during the testing day	8 (34.8)	7 (30.4)	5 (21.7)	3 (13.0)	0 (0)	(0) 0
Cough during the testing night	14 (60.9)	4 (17.4)	4 (17.4)	1 (4.4)	0 (0)	(0) 0
Nausea during the testing day	20 (87.0)	2 (8.7)	1 (4.4)	(0) 0	0 (0)	(0) 0
Nausea during the testing night	21 (91.3)	2 (8.7)	(0) 0	(0) 0	0 (0)	(0) 0
Reduced appetite	17 (73.9)	2 (8.7)	(0) 0	2 (8.7)	2 (8.7)	(0) 0
TOTAL	252 (57.7)	86 (19.7)	50 (11.4)	36 (8.2)	9 (2.1)	4 (0.9)

TABLE 4.
Severity of Symptoms Related to the 24-hour Dx-pH Testing

Tolerance Items	Mean (SD)	
Nasal discomfort during probe placement	1.35 ± 1.27	
Nasal pain during probe placement	1.04 ± 1.43	
Throat discomfort during probe placement	1.39 ± 1.20	
Throat pain during probe placement	0.78 ± 1.17	
Overall discomfort during the testing day	1.17 ± 1.15	
Overall pain during the testing day	0.35 ± 0.71	
Overall discomfort during the testing night	1.43 ± 1.47	
Overall pain during the testing night	0.48 ± 0.95	
Discomfort while eating and swallowing	0.83 ± 0.94	
Pain while eating and swallowing	0.39 ± 0.66	
Choking sensation during the testing day	0.39 ± 0.78	
Choking sensation during the testing night	0.43 ± 0.90	
Excessive nasal secretions during the testing day	1.35 ± 1.40	
Excessive nasal secretions during the testing night	1.09 ± 1.50	
Cough during the testing day	1.13 ± 1.06	
Cough during the testing night	0.65 ± 0.93	
Nausea during the testing day	0.17 ± 0.49	
Nausea during the testing night	0.09 ± 0.29	
Reduced appetite	0.70 ± 1.36	
The score was from 0 (no symptom) to 5 (severe symptom). Abbreviation: SD, standard deviation.		

in the development and recurrence of some nasal, Eustachian tube, otological, and eye syndromes. 2-4,16-18

To the best of our knowledge, this preliminary study is the first to demonstrate the usefulness of Dx-pH testing for detecting nasopharyngeal reflux events and disease. The high prevalence of NRD in patients with idiopathic chronic rhinitis indirectly corroborates some research demonstrating the potential role of reflux in the development of nasal disorders. 19,20 In 1999, Ulualp et al reported that 7/11 (63.9%) patients with chronic rhinosinusisits reported positive detection of acid pharyngeal reflux events, while 2/11 (18.2%) volunteers reported more than one pharyngeal reflux events. The authors used a 3-site ambulatory esophagopharyngeal pH monitoring technique (probe location: 2 cm proximal, 3-4 cm distal to the cricopharyngeal sphincter, and 5 cm proximal to lower esophageal sphincter high-pressure zones). 19 Other studies reported indirect findings of LPRD (eg, pepsin detection, laryngeal signs, hypopharyngeal reflux event detection) in patients with recalcitrant rhinitis or rhinosinusitis.²⁰

The other pH-metry probe systems placed in the nasal cavity reported in the literature were just used to measure the nasal mucosa pH in experimental research dedicated to the variability of mucosa pH in some diseases or drug delivery. The advantage of using the Dx-pH system rather than triple-probe pH monitoring devices is the capability of this system to detect weakly acidic reflux events. Indeed, an increasing number of studies have demonstrated that LPRD is characterized by the occurrence of gaseous,

weakly acidic, or alkaline pharyngeal reflux events^{23,24} in patients with a mucosa pH more alkaline than controls.^{25,26} In this context, the use of a pH sensor, which cannot detect weakly acidic or alkaline events, does not make sense.

The second part of this study consisted of the evaluation of patients' tolerance of the nasopharyngeal pH-testing device. The tolerance can be considered acceptable, with 57.7% of patients reporting no discomfort related to the 24hour Dx-pH testing. The severity of discomfort, which was more pronounced during the 24-hour testing period rather than during placement, corroborated the results of Lee et al, who reported the highest discomfort during the examination period in 55 patients undergoing 24-hour multichannel intraluminal impedance-pH testing (MII-pH).²⁷ Although they did not use the same tolerance questionnaire as we did, the findings of this study tended to suggest more severe symptoms, including globus pharyngeus, nausea, dyspnea, and vomiting in patients undergoing 24-hour MII-pH compared to our patients, which could be related to the absence of a probe in the oro-, hypopharynx, and esophagus. Notably, Lee et al reported that 43.6% of MIIpH patients refused to be tested again when investigators asked if they would be willing to undergo repeat testing.²⁷ While several points in Lee et al's study suggest a moderate degree of discomfort related to MII-pH, our assumption that nasopharyngeal pH testing should cause less annovance remains theoretical due to the lack of a control group with MII-pH probe in the present study. The lack of studies evaluating the discomfort associated with 24-hour Dx-pH testing limits the comparison of our findings with the literature.

In this study, the discomfort severity (tolerance score) was correlated with the otolaryngological RSS. This observation may be related to the presence of sensory disorders induced by reflux disease in laryngopharyngeal mucosa, ²⁸ with patients having the highest symptom scores also exhibiting high mucosal sensitivity.

SNOT-22 scores did not correlate with nasopharyngeal reflux event findings, including the number and duration of events at various pH thresholds. This observation aligns with LPRD literature, as most studies have not found significant correlations between laryngopharyngeal symptoms, findings, and HEMII-pH testing results. The variability in sensory mucosa across patient populations and related confounding factors not controlled in the present and other studies (eg, tobacco consumption, pollution, microbiome differences) may explain the lack of significant association between symptoms, signs, and objective reflux event measurements.

The lack of a control group including asymptomatic individuals is the primary limitation of this study. Asymptomatic individuals were not included because of the cost of the procedure and the availability of normative data for oropharyngeal pH testing. However, it should be noted that normative data can differ between oropharyngeal pH-testing and nasopharyngeal pH-testing. In this study, most patients with a positive NRD diagnosis

exhibited RSS > 13 and RSA > 14, which is associated with a high sensitivity for LPRD diagnosis. 12,14 However, RSS and RSA-related symptoms and signs remain non-specific, and the lack of additional objective evaluation supporting the reflux diagnosis is another limitation. Pepsin, cholesterol, and elastase measurements should be additional objective tests supporting the reflux disease diagnosis in patients with positive Dx-pH testing.

CONCLUSION

The Dx-pH system effectively detects NRD with acceptable patient tolerance, though discomfort correlates with symptom severity. This diagnostic approach suggests a high NRD prevalence among chronic nasal complaint patients.

Ethical Approval

The local IRB approved the study. Patients consented to participate.

Declaration of Competing Interest

The author has no financial interest in the subject under discussion. All authors have read and approved the manuscript. Would you be so kind to consider the present manuscript and send us the Reviewer's comments.

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None.

Author Contributions

Glenda Mantione: Design, acquisition of data, data analysis and interpretation, drafting, final approval, and accountability for the work; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Gaetan Cavelier: Design, acquisition of data, final approval, and accountability for the work; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Alexandra Rodriguez, Luigi Vaira, Didier Dequanter, Sven Saussez, Giannicola Iannella, Stephane Hans, Antonino Maniaci, and Giovanni Dapri: Final approval and accountability for the work; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Luigi Bonavina: Drafting, final approval, and accountability for

the work; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. **Jerome R. Lechien**: Design, acquisition of data, data analysis and interpretation, drafting, final approval, and accountability for the work; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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