

# Oropharyngeal pH Monitoring for the Detection of Liquid and Aerosolized Supraesophageal Gastric Reflux

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**Summary:** The association between gastroesophageal reflux disease (GERD) and extraesophageal symptoms is poorly understood and difficult to document. pH monitoring in this group of patients has resulted in conflicting data due to lack of diagnostic sensitivity. Recently, a new sensitive pH device for detection of liquid and aerosolized droplets in the oropharynx (The Dx-pH Measurement System [Dx-pH]) has become available. Our hypothesis is that we will be able to improve our ability to identify and understand this group of patients with this device. The aim of this preliminary observation study was to compare the results of this new device to the standard esophageal and pharyngeal pH probes in a small group of patients with extraesophageal symptoms. Patients with suspected extraesophageal GER symptoms underwent traditional 24-hour esophago-pharyngeal pH monitoring (24pH) simultaneous with Dx-pH monitoring in the oropharynx. Tracings were reviewed for comparison and correlation between the two probes, with an event in the Dx-pH Probe being defined as a rapid drop >3 standard deviation from baseline. Fifteen patients (10 females, 5 males) with mean age of 57.5 years (range, 25–75) were studied. The predominant chief complaint included 12/15 chronic cough, 2/15 asthma; and 1/15 throat clearing. All Dx-pH events were preceded and associated with distal esophageal pH drops in a progressive ante grade manner. Ten patients had 1–13 abnormal oropharyngeal pH events as measured by Dx-pH monitoring with a total of 48 events. The median pH of reflux events had a statistically significant increase from 3.1 at the distal esophageal probe to 5.2 at the pharynx and 5.6 at the oropharynx, the latter being 80% higher than the distal esophageal probe ( $P < 0.001$ ). The percentage of acid events decreased in a cephalad manner from 66.7% at distal esophagus to 25% at the pharynx and only 6.25% at the oropharyngeal Dx-pH Probe, with the remaining events being weakly acidic. Dx-pH Probe is a new sensitive oropharyngeal pH device whose values correlate well with the gold-standard 24-hour pH device, and appears to accurately detect pH events that begin at the distal esophagus and travel upward to the oropharynx. This device suggests that supraesophageal events manifest themselves as rapid pH drops (>10%), which are likely not to be identified using the standard criteria of pH <4 due to the gradient of increasing pH from the lower esophagus to the oropharynx.

**Key Words:** Reflux–Laryngopharyngeal reflux–Supraesophageal gastric reflux–Extraesophageal reflux–Pharyngeal reflux–Reflux laryngitis–Oropharyngeal reflux–Proton pump inhibitors–pH Monitoring.

## INTRODUCTION

Gastroesophageal reflux disease (GERD) is a common disorder affecting close to 40% of the population.<sup>1</sup> In addition to heartburn and regurgitation, GERD may present with other less typical symptoms. These symptoms when above the upper esophageal sphincter (UES) have multiple names including laryngopharyngeal reflux (LPR), atypical GERD, high reflux, and extraesophageal reflux. We have chosen the term “supraesophageal gastric reflux” (SEGR) because it encompasses the entire anatomic area of involvement, above the esophagus, including the larynx, pharynx, tracheo-bronchial tree, sinuses, oral, and nasal cavities. The most common clinical manifestations of SEGR may include ear, nose, throat (ENT), pulmonary (chronic cough or asthma), or cardiac (noncardiac chest pain)

symptoms.<sup>2</sup> The nature of the association between GERD and extraesophageal symptoms has been difficult to elucidate.<sup>3,4</sup> Clinical and animal data have documented deleterious effects of acidic (pH <4) and weakly acidic (pH 4–7) reflux above the UES, even in small amounts.<sup>5,6</sup>

Many patients with extraesophageal manifestations often do not complain of the “typical” GERD symptoms. Classic reflux symptoms are absent in 40–60% of asthmatics, in 57–94% of patients with ENT complaints, and in 43–75% of patients with chronic cough. This “silent” nature of reflux contributes to the difficulty in establishing the diagnosis.<sup>7</sup> Studies have shown that traditional pH monitoring is not sensitive in detecting the association between GERD and extraesophageal symptoms.<sup>8</sup> Therapeutic studies of proton pump inhibitors (PPIs) in extraesophageal GERD have shown mixed results leading to further confusion in the literature in regard to the association between the two entities.<sup>9</sup> The diagnostic value of a PPI test has not been helpful, which is not surprising, because it has even been poor in patients with classic symptoms of GERD.<sup>10</sup> A more sensitive detection device that may predict response to acid suppressive therapy is currently lacking. The Dx-pH Measurement System (Dx-pH; Restech Corp., San Diego, CA) is a new highly sensitive and minimally invasive device for detection of acid reflux in the posterior oropharynx.<sup>11,12</sup>

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It uses a transnasal, catheter with a sensor that is able to measure pH in either liquid or aerosolized droplets. The probe is a 1.5-mm diameter oropharyngeal catheter with wireless digital Zig-Bee transmitter (CC2420 transceiver, Texas Instruments Corp., Dallas, TX), which is worn on the shirt collar. The catheter tip uses a 3.2-mm teardrop tip to aid in insertion and to assure that the sensor is positioned in the airway. The tip also has a colored Light Emitting Diode (LED), for oral visualization (Figure 1). The sensing element consists of a circular 1-mm antimony surface and a reference electrode separated by a 0.05-mm polymer insulator (Figure 2). Moisture from exhaled air condenses on the sensor surface creating a fluid layer, which bridges the gap between the antimony and reference sensor elements. The sensor records pH values twice every second (2 Hz) and it features a hydration monitor to eliminate data if the tip dries out. Special circuitry monitors each individual reading to assure sufficient sensor hydration. This circuitry prevents the inclusion of dry-out related “pseudo-reflux” events in the data.

Our hypothesis is that we will be able to detect, characterize, and improve detection of reflux above the UES and identify the specific group of patients with supraesophageal reflux, using the new oropharyngeal device. This preliminary observational study verifies the data collected using this device comparing it to that obtained using the present gold-standard 24-hour multichannel pH catheter.

## MATERIALS AND METHODS

### Patients and questionnaire

Patients in a gastroenterology private practice (GJW) were selected randomly based on the criteria of chronic extraesophageal symptoms, suspected by the investigator to be due to reflux.<sup>4</sup> All patients underwent detailed evaluation of medical history, physical examination, consent (WIRB protocol # 20041846), and diagnostic procedures. Reflux medications including PPIs, H<sub>2</sub> blockers, promotility agents, sucralfate, and antacids were discontinued 4–7 days before the study (7 days for PPIs, 4 days for H<sub>2</sub>RAs, and 24 hours for antacids). GERD questionnaire was administered to all patients assessing type, frequency, duration, and severity of reflux symptoms.

### pH Testing

A standard ambulatory 24-hour pH monitoring test (24pH) was performed using a triple-channel pH catheter (Sandhill Scientific PHI-10V; Highlands Ranch, CO). The multichannel probe and the Dx-pH Probe (Restech Corp., San Diego, CA) were both soaked in pH 7 buffer solution for a minimum of 10 minutes. They were then calibrated in pH 7 and pH 4 buffer solutions according to the manufacturer’s instructions.

The Dx-pH Probe was advanced into the oropharynx and slowly withdrawn until the patient did not feel the tip on swallowing. Tip of the probe location in the oropharynx, behind the uvula was then confirmed by visualization of the red LED on the tip of the catheter (Figure 1). The triple-channel pH catheter was then positioned in the following locations: distal sensor—5 cm above the lower esophageal sphincter (LES), pharyngeal sensor—1 cm above the UES (P), and midesophageal sensor—10 cm below

pharyngeal probe (M). The location of the sphincters (LES and UES) was determined using the builtin pressure indicator.

Data from both catheters were transmitted to separate monitors worn by the patient on the belt, and simultaneous data recordings were graphed together. Monitors contained event markers for meals, position, and chief complaint. Because both probes showed similar pH drops with acidic food ingestion, pH data 5 minutes before and after meals were deleted and all data were visually evaluated by one investigator (GJW). For comparison, % time pH <4 was used due to convention and its reliable and reproducible characteristic.<sup>13</sup> Symptom index was calculated based on accepted criteria.<sup>14</sup>

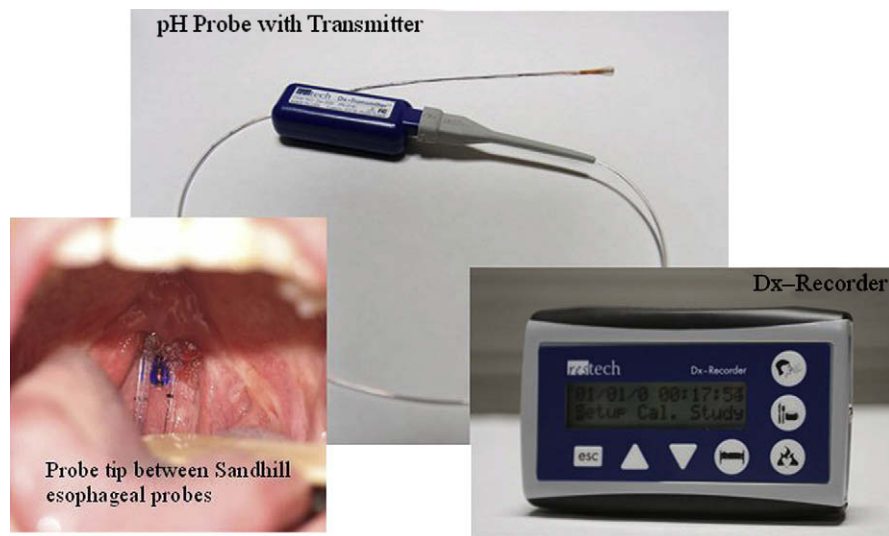
### Reflux event definitions

For the traditional distal pH sensor positioned 5 cm above the LES, the accepted (gold standard) DeMeester-Johnson criteria<sup>15</sup> was used to define abnormal esophageal acid reflux. At the pharyngeal probe, abnormal reflux was defined by the accepted criteria of greater than one episode of pH <4.<sup>16</sup> For oropharyngeal reflux (OPR), there are no normative data; therefore, an event was considered to have occurred if there was a rapid (0.5–2 seconds) vertical pH drop at the Dx-pH Probe of >3 standard deviation (SD) from a running pH baseline. Because these pH drops of >3 SD always corresponded to at least 10% drop in pH, this % value was used to compare Dx-pH data to the 24pH esophageal and pharyngeal probe data. All tracings were expanded and a reflux event was confirmed, if the rapid drop in pH >10% from baseline was preceded by sequential pH drops in the distal, midesophageal, and pharyngeal pH electrodes in a cephalad fashion. Because some of the latter pH drops were not below the cutoff value of pH 4, for tabulation and comparison, they were not considered true pH events.

A patient was considered abnormal at the Dx-pH Probe, if one or more events were detected. This criterion, which is more liberal than criteria for the traditional pharyngeal pH probe (P), was used due to the fact that the sensor was located 2–5.5 cm (mean = 3.8 cm) further from the stomach acid source than the P probe, and minimal increases in distance from the UES have been shown to clearly decrease sensitivity.<sup>17</sup> On the tracings of the Dx-pH and traditional Sandhill probes, events were classified as acidic reflux (AR), if the pH of the lowest nadir was less than 4.0, or weakly acidic reflux (WAR), if the nadir was from 4.0 to less than 7.0. Abnormal Dx-pH results were termed “Dx Abnormal” and normal results were termed “Dx Normal.” Slow progressive drops in pH with rapid return to baseline were not considered significant and, if prolonged, classified as pseudoreflux.<sup>8</sup>

### Statistical analysis

The median pH nadirs of the three sensors (Dx, P, and LES) were compared in the total, supine, and upright time periods with nonparametric repeated-measure analysis of variances (the Friedman test). The abilities to detect events at the Dx, P, and distal esophageal probes were compared descriptively. Because there is no universally accepted true “gold-standard” test for reflux above the UES, values of sensitivity and specificity of



**FIGURE 1.** Oropharyngeal pH probe with transmitter and LED tip in the posterior aspect of the mouth sandwiched between the two Sandhill probes going down into the esophagus.

the Dx-pH were determined by comparing it to the distal esophageal 24pH results, understanding that these are two different anatomic locations.

## RESULTS

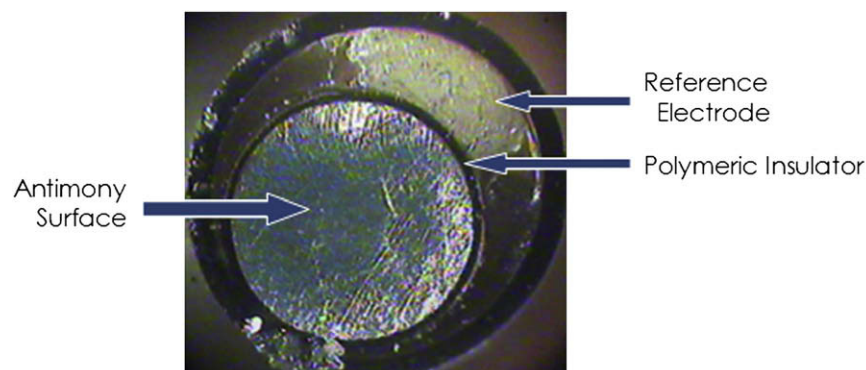
### Patient demographics

Fifteen patients (10 females, 5 males) with mean (range) age of 57.5 years (range, 25–75) constituted the study population. Of the 15 patients, 12 (80%) had chronic cough as the chief complaint symptom, two (13%) had asthma, and one (7%) had throat clearing (Table 1). Patients often had other associated symptoms occurring at least several time per week; of the 15 patients, nine (60%) reported heartburn, 12 (80%) reported throat clearing, and five (33%) reported presence of regurgitation. Most (87%) patients were nonsmokers. Symptom duration ranged from 6 months to 22 years with 11 patients reporting symptom duration for greater than 5 years. Of the 15 patients, 14 (93%) had symptoms on a daily basis and one patient reported symptoms only weekly.

Endoscopy had been performed in 12 out of 15 (80%) patients (Table 2). Among the patients with normal Dx-pH findings (Dx Normal) no esophagitis was noted, whereas

among the Dx-Abnormal group, five patients had Barrett's esophagus and three patients had normal endoscopies. In the absence of a reliable pharyngeal reflux parameter, sensitivity and specificity of the Dx-pH Probe was estimated using the distal esophageal 24pH results plus presence of esophagitis as gold standard (Methods). Using this classification, the estimated sensitivity of the Dx-pH Probe was 90% (9/10) and specificity 80% (4/5). Heartburn was present in 40% of Dx Normals and 70% of patients with abnormal Dx.

**Ambulatory 24-hour pH results.** Standard ambulatory pH results were evaluated as a function of Dx-pH findings: Dx-Normal and Dx-Abnormal groups (Table 2). Of the 10 patients with abnormal events on Dx-pH Probe (Dx-Abnormal group), eight (80%) also had abnormal distal esophageal pH parameters in total, upright, or supine positions (Table 2). In the Dx-Normal group, three (60%) out of five had corresponding normal distal esophageal acid measurements. There was a statistically significant difference in the pH values between the three recording sites ( $P < 0.001$  for upright, supine, and total categories). Of interest is the observation that the median value was zero in all patients at the standard 24-hour pH pharyngeal probe site.



**FIGURE 2.** Magnified cross-section view of the Dx-pH Probe (Magnification: 75X).

**TABLE 1.**  
**Demographics of Study Patients**

Demographics of Study patients (n = 15)								
Patient Number	Dx-pH Results	Age (y)	Gender	Smoking	Chief Complain	Heartburn	Additional Symptoms (Daily Occurrence)	Endoscopy Findings
1	Dx-	61	F	No	TC	No	None	—
2	Dx-	56	F	1 pack/d	Cough	Yes	CP, DYS, WHZ, DYSPP, TC	HH
3	Dx-	42	M	No	Cough	No	HRS, TC	Norm
4	Dx-	25	M	No	Asthma	No	WHZ, DYSPP, TC	—
5	Dx-	42	F	No	Cough	Yes	TC	Norm
6	Dx+	58	F	No	Cough	Yes	HRS, TC	Esophagitis
7	Dx+	49	F	No	Cough	No	RGR, DPHG, HRS, TC	HH/B
8	Dx+	62	F	1 pack/d	Cough	Yes	WHZ, HRS, TC	HH/B
9	Dx+	74	M	No	Cough	Yes	RGR, CP, WHZ, DYSPP, TC	HH/B
10	Dx+	69	M	No	Cough	No	RGR, HRS, TC	Norm
11	Dx+	75	F	No	Cough	Yes	TC	HH/B
12	Dx+	74	F	No	Cough	Yes	RGR, DYSPP, TC, OSA	HH/B
13	Dx+	62	M	No	Cough	No	TC	Norm
14	Dx+	72	F	No	Cough	Yes	CP, HRS	Norm
15	Dx+	41	F	No	Asthma	Yes	RGR, WHZ, DYSPP, C, TC	—

Abbreviations: CP, chest pain; DYS, dysphagia; WHZ, wheeze; DYSPP, dyspepsia; TC, throat clearing; HRS, hoarseness; RGR, regurgitation; OSA, obstructive sleep apnea; C, cough; HH, Hiatal Hernia; B, Barrett's esophagus; Norm, normal.

**Oropharyngeal supraesophageal events.** In the patients who had Dx-pH findings in the hypopharynx (Dx-Abnormal group), there were 48 Dx-pH events with a range of 1–13 events per patient. These 48 Dx-pH events represent 7.8% of 660 ep-

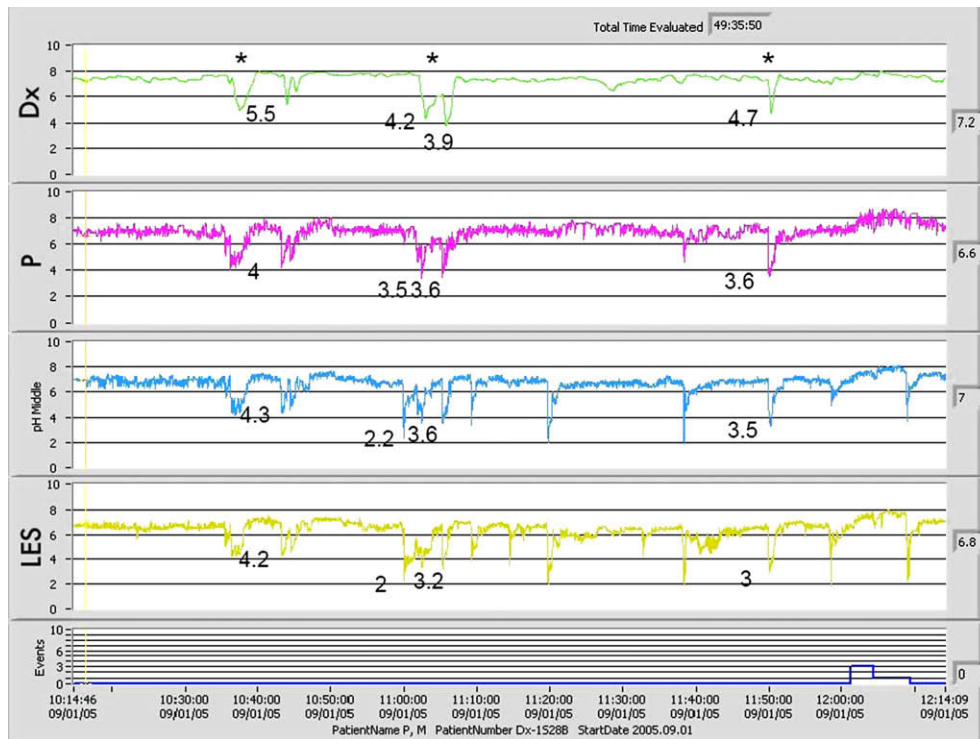
isodes of pH <4 at the distal esophageal probe site. All events had an abrupt pH drop, with gradual return to baseline and were preceded by and sequential to esophageal pH events. There were no Dx-pH events without a corresponding pH

**TABLE 2.**  
**Ambulatory 24-h pH Results as a Function of Dx Findings**

General pH Results (Three Channel Sandhill Probe)												
Patient Number	Dx-pH Probe Results	Distal Sensor 5 cm >LES				Proximal Sensor			Pharyngeal Sensor			DeMeester Score
		% Time pH <4				% Time pH <4			% Time pH <4			
		Upright	Supine	Total	DeMeester	Upright	Supine	Total	Upright	Supine	Total	
1	Norm	2.6	7.1*	5.2*	20.8*	0.9	6.1	3.9	0	0	0	20.8
2	Norm	4.2	0	2.4	9.03	1.9	0	1.1	0	0	0	9.03
3	Norm	4.4	0	3	8.51	0	0	0	0	0	0	8.51
4	Norm	1.5	1.6	1.5	7.33	0.4	1.1	0.8	0.3	0	0.1	7.33
5	Norm	0.4	0.3	0.4	2.35	0	0	0	0	0	0	2.35
6	Abn	2.3	3.7*	3	11.88	0.9	3.8	2.3	0	0	0	11.88
7	Abn	5	0.1	2	6.93	1.1	0	0.5	0.2	0	0.1	6.93
8	Abn	2.2	0.4	1.6	4.36	0.1	0	0.1	0	0	0	4.36
9	Abn	22.8*	52.7*	37.7*	131.41*	18.6	58.2	38.4	0	0.1	0	131.41
10	Abn	1	2.7	2	8.41	0.9	1.2	1.1	0.4	0	0.2	8.41
11	Abn	11*	3.8*	8.3*	27.52*	4.3	0.3	2.8	0	0	0	27.52
12	Abn	6.7	0.6	5*	14.47	3.9	0	2.8	0	0	0	14.47
13	Abn	13.8*	15.7*	14.3*	51.13*	4	1.5	3.3	0	0	0	51.13
14	Abn	14.2*	42.3*	19.3*	89.64*	0.4	14.3	2.9	0	0	0	89.64
15	Abn	1.8	7.4*	4.2	19.22*	0.4	1.1	0.7	0	0	0	19.22

Abbreviations: Norm, normal; Abn, abnormal.

\*Abnormal value.<sup>15</sup>



**FIGURE 3.** Multiple episodes of PR in an asthmatic patient with Dx–pH Probe positive events marked with asterisks (Key: 5 cm >LES yellow, mid esophagus—blue, pharynx—purple, Dx—green).

drop at the distal esophageal sensor (false positives). The cephalad progression of the reflux event is shown in Figure 3.

Characteristics of the 48 Dx–pH events with respect to standard 24-hour pH sites are summarized in Table 3. The events were divided into “acidic reflux” and “weakly acidic reflux,” and median and quartile pH at each sensor were tabulated. In the distal esophagus, most events (66.67%) were AR, and the remaining of the events (33%) were weakly acidic gastric reflux. The median pH at this site was 3.1. However, at the pharyngeal site (P), only 25% of the reflux events were acid gastric reflux, with a median pH in this site of 5.2, whereas at the oropharyngeal Dx–pH site, only 6.25% of the reflux events were acidic with the highest median pH of 5.6. There was an 80% cephalad increase in median pH between the distal esophageal and the Dx–pH Probes. There was a corresponding decrease in AR events in the cephalad direction, with most events being WAR. There was a statistically significant difference in the pH values between the three recording sites ( $P < 0.001$ ) for upright, supine, and total categories. When comparing specifically the Dx–pH Probe to the standard 24pH pharyngeal probe values (Table 4), one sees that of the 48 Dx–pH events, only seven (15%) were detected at the pharyngeal site using the DeMeester and Johnson cutoff of  $\text{pH} < 4$ . If one applies to the pharyngeal site the Dx–pH Probe criteria of individual pH drops  $> 3$  SD (10%) from baseline as “abnormal,” the detection rate would increase to 35 out of 48 or 73% of events, still missing 27% of supraesophageal reflux at this site. Of the 11 pharyngeal events with  $\text{pH} < 4$ , seven had corresponding Dx–pH events. The four events missed were all in one patient whom we suspected had a migration of Dx–pH Probe into the nose with a baseline that did not have the characteristic changes on eating.

**DISCUSSION**

This is the first preliminary report comparing a new oropharyngeal pH catheter to a conventional 24-hour pH system during simultaneous recording to detect supraesophageal reflux. Data from pharyngeal pH recordings, laryngoscopic examinations, and therapeutic trials have not helped to clarify the characteristics of atypical GERD and even questioned its existence.<sup>15</sup> Our findings show events compatible with supraesophageal reflux originating in the distal esophagus and migrating all the way to the oropharynx as detected by this new device. A direct temporal correlation with conventional esophageal pH testing, the

**TABLE 3.** Characteristics of the 48 Dx-Reflux Events

pH Sensor	AR (pH<4) (acid reflux)	WAR (pH 4–7) (weakly acid reflux)	Median pH (25–75%)
Dx	(n=3) 6.25% Median pH 3.5 25–75% (3.5–3.8)	(n=45) 93.75% Median pH 5.75 25–75% (5.1–6.3)	5.6 (5.0–6.2)
Pharynx (P)	(n=12) 25% Median pH 3.9 25–75% (3.8–4.0)	(n=36) 75% Median pH 5.75 25–75% (4.8–6.4)	5.2 (4.1–6.2)
5 cm > LES (LES)	(n=32) 66.67% Median pH 2.8 25–75% (2.2–3.1)	(n=16) 33.33% Median pH 5.4 25–75% (4.4–6.2)	3.1 (2.5–4.3)



**TABLE 4.**  
**Correlation Between Dx-pH and Pharyngeal Sensor Results in Patients With Positive Dx-pH Test**

Patient Number	Pharyngeal and Dx Sensor Data						
	Dx-pH	Pharyngeal Sensor			Dx Sensor		
	Sensor	# Events	# Events	Lowest pH	# Events	# Events	Lowest pH
	Results	10% Drop	pH <4	Reached	10% Drop	pH <4	Reached
1	Norm	0	0	N/A	0	0	N/A
2	Norm	0	0	N/A	0	0	N/A
3	Norm	0	0	N/A	0	0	N/A
4	Norm	0	4	3.7	0	0	N/A
5	Norm	0	0	N/A	0	0	N/A
6	Abn	6	1	3.8	6	0	5.2
7	Abn	2	2	3.1	2	0	5.4
8	Abn	0	0	N/A	1	0	6.4
9	Abn	3	1	3.7	3	1	3.5
10	Abn	6	0	4.4	13	0	4.8
11	Abn	1	0	5.3	1	0	5.2
12	Abn	1	0	4	1	0	4.5
13	Abn	5	1	3.9	8	0	4.5
14	Abn	2	0	4.3	4	0	5.8
15	Abn	9	2	3.3	9	2	3.5

Abbreviations: Norm, normal; Abn, abnormal.

present gold standard for GERD, was established in all events classified as supraesophageal reflux using the present Dx-pH criteria. This helps to substantiate the reliability of a positive Dx-pH finding and the existence of SEGR.

The existing quantitative and qualitative pharyngeal pH data since our first report in 1987,<sup>18</sup> followed by others,<sup>19,20</sup> were essential to define the pH environment in the pharynx, but was flawed by relying on the cutoff value of pH <4. This value of pH <4 was originally designed for defining and understanding the nature of GERD and acid exposure strictly at the distal esophagus.<sup>14</sup> Using these criteria, false negative data have ranged from 20 to 50%, when compared to 24-hour pH and endoscopy, which in themselves are known to be poor tests for SEGR.<sup>4,21</sup> Our study, along with recent impedance data<sup>6,20</sup> have shown that there is a gradient of increasing pH from the distal esophagus to the oropharynx, the latter usually weakly acidic, rarely with pH <4 (Table 3). This might help explain why the previous attempts at defining normals and the specific subset of patients with atypical symptoms using quantitative pH <4 cutoff values have not been reliable or fruitful. Mildly AR above the UES has been shown to be deleterious,<sup>5,6</sup> with evidence of cell damage and pepsin activity.<sup>22</sup> In this area, there is decreased tissue resistance to pepsin and acid along with depletion of laryngeal defenses like carbonic anhydrase III, in response to reflux.<sup>23</sup> Therefore, the confusion surrounding LPR may be potentially clarified by using our criteria of inspecting individual pH drops with morphologic characteristics of acid reflux associated with a value or % pH drop from baseline. We proposed using pH drops of >3 SD from a baseline to define an event, because it is a statistical criterion used to define significance in normal distribution curves, and simplified it to 10% because all values exceeded this percent drop

(Wiener-Vaezi criteria). This value of pH drop, with its limitations, is difficult to test or compare to determine reliability, because there is no accepted normative pharyngeal pH data at present.<sup>18-20</sup> In our study, pharyngeal probe false negative data were significant, suggesting the Dx-pH Probe is more sensitive than the latter. On the other hand, events recorded at the pharyngeal probe were all picked up by the Dx-pH Probe, except for four events in one patient, where the data were questionable, because we suspect the probe was above the palate. This increased likelihood of detecting events with the Dx-pH Probe may be due to sampling every 0.5 seconds along with its downward facing orientation, teardrop shape, and proximity of reference to antimony electrodes. In view of this, redefinition of significant pH events above the UES merits reevaluation and studies defining normative values with the Dx-pH Probe and its quantitative and qualitative criteria are essential and presently being performed.

This catheter is easy to use and comfortable due to the tip location in the upper oropharynx, where interference with swallowing and awareness is minimal. In studying patients with this device, it is important to record oral intake because many foods will produce significant false positive data, and that is one of the most significant limitations. Close examination of the tracings by a qualified physician is essential to identify true events and avoid artifact or pseudoreflux events.<sup>9</sup> We identified significant nighttime pseudoreflux in only one patient, but other atypical nighttime saw tooth-like events were noted and will need further study. The mechanism for pseudoreflux is not well understood but may be due to drying out of the probe, although unlikely because hydration of the probe tip occurs on every exhalation of moist air (witnessed during video-bench testing). The new definition of "significant pH events," unrelated to

specific pH cutoff values, and the use of 3 SD below baseline, are arbitrary and will need further testing. The patient group is small and with obvious selection bias, but we believed that these types of patients were needed to test and study the device. The study was not intended to deal with incidence, clinical features, or usefulness of this device, although we feel that the findings will be very helpful in clinical practice. This is clearly a preliminary pilot study with minimal statistical power, and will need further validation and clinical testing. Hopefully, the findings will help validate a new device that is desperately needed to understand and detect patients with supraesophageal reflux, and encourage further research.

In conclusion the Dx-pH Probe, with its novel criteria for defining SEGR, may be useful in assessing patients with extraesophageal symptoms. The data substantiate the concept that SEGR truly exists in the oropharynx and confirm that there is an increasing pH gradient from the distal esophagus to the oropharynx, the latter rarely less than 4. Evaluation of the clinical predictive potential of this device along with further normative data is needed and encouraged.<sup>24,25</sup>

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