

Clinical Studies using the Restech Dx-pH Measurement System™

A new technique for measurement of pharyngeal pH: normal values and discriminating pH threshold.

Ayazi S, Lipham JC, Hagen JA, Tang AL, Zehetner J, Leers JM, Oezcelik A, Abate E, Banki F, DeMeester SR, DeMeester TR. J Gastrointest Surg. 2009 Aug; 13(8):1422-9.

INTRODUCTION: Identifying gastroesophageal reflux disease as the cause of respiratory and laryngeal complaints is difficult and depends largely on the measurements of increased acid exposure in the upper esophagus or ideally the pharynx. The current method of measuring pharyngeal pH environment is inaccurate and problematic due to artifacts. A newly designed pharyngeal pH probe to avoid these artifacts has been introduced. The aim of this study was to use this probe to measure the pharyngeal pH environment in normal subjects and establish pH thresholds to identify abnormality.

METHODS: Asymptomatic volunteers were studied to define the normal pharyngeal pH environment. All subjects underwent esophagram, esophageal manometry, upper and lower esophageal pH monitoring with a dual-channel pH catheter and pharyngeal pH monitoring with the new probe. Analyses were performed at 0.5 pH intervals between pH 4 and 6.5 to identify the best discriminating pH threshold and calculate a composite pH score to identify an abnormal pH environment. RESULTS: The study population consisted of 55 normal subjects. The pattern of pharyngeal pH environment was significantly different in the upright and supine periods and required different thresholds. The calculated discriminatory pH threshold was 5.5 for upright and 5.0 for supine periods. The 95th percentile values for the composite score were 9.4 for upright and 6.8 for supine.

CONCLUSION: A new pharyngeal pH probe which detects aerosolized and liquid acid overcomes the artifacts that occur in measuring pharyngeal pH with existing catheters. Discriminating pH thresholds were selected and normal values defined to identify patients with an abnormal pharyngeal pH environment.

Normal values for pharyngeal pH monitoring.

Chheda NN, Seybt MW, Schade RR, Postma GN. Ann Otol Rhinol Laryngol. 2009 Mar;118(3):166-71.

OBJECTIVES: We performed a prospective study of asymptomatic adult volunteers to establish normative values of pharyngeal pH using a novel pH probe.

METHODS: The Dx-pH probe is a novel pH device capable of measuring liquid and aerosolized acid levels. Twenty asymptomatic patients (Reflux Symptom Index less than 10 and Reflux Finding Score less than 6) underwent simultaneous investigation with this probe placed in the oropharynx and a dual antimony probe placed in the hypopharynx and esophagus. The reflux parameters measured from the oropharyngeal probe included the percentage of time and the number of events in which the pH was less than 5.5,5.0,4.5, and 4.0.

RESULTS: The upper limits of normal (95th percentile) for the number of events below pH of 5.5, 5.0, 4.5, and 4.0 per 24-hour

period were 16.6, 10.7, 7.4, and 0.2, respectively. The upper limits of normal (95th percentile) for an acid exposure time below pH of 5.5, 5.0, 4.5, and 4.0 per 24-hour period were 820 seconds, 385 seconds, 75 seconds, and 3 seconds, respectively. CONCLUSIONS: Normative pharyngeal pH values are presented. Further studies are required to determine clinical relevance.

Oropharyngeal pH monitoring for the detection of liquid and aerosolized supraesophageal gastric reflux.

Wiener GJ, Tsukashima R, Kelly C, Wolf E, Schmeltzer M, Bankert C, Fisk L, Vaezi M. J Voice. 2009 Jul;23(4):498-504.

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.

Sinusitis and chronic progressive exerciseinduced cough and dyspnea.

Williams AN, Simon RA, Woessner KM. <u>Allergy Asthma Proc. 2008 Nov-Dec;29(6):669-75.</u>

We present the case of a 47-year-old man with exercise-induced dyspnea, cough, chest tightness, and recalcitrant chronic rhinosinusitis. Evaluation revealed IgE sensitization to grass, tree, and weed pollen, no evidence of obstruction on spirometry, and a negative methacholine challenge. Diagnostic considerations included allergic and nonallergic rhinitis, asthma, aspirin-exacerrespiratory disease, vocal cord dysfunction, extra-esophageal manifestations of acid reflux, and vasculitits. Further evaluation with sinus imaging, laryngoscopy, ambulatory pharyngeal pH testing, upper endoscopy, and bronchoscopy led to a diagnosis. Key issues surrounding the diagnostic and therapeutic approaches to this patient's condition are reviewed.

Tracheal pH monitoring: a pilot study in tracheostomy dependent children.

Brigger MT, Sipp JA, Hartnick CJ. Int J Pediatr Otorhinolaryngol. 2009 Jul;73(7):999-1001.

OBJECTIVES: 1. Determine the feasibility of measuring tracheal pH with a novel non-aqueous probe designed for oropharyngeal pH monitoring. 2. Correlate clinical and subclinical laryngopharyngeal reflux aspiration events with esophageal pH measurements.

METHODS: Five children with chronic indwelling tracheostomies undergoing routine endoscopy and pH probe monitoring at a tertiary care pediatric aerodigestive center between October 2007 and January 2008 were identified for this prospective feasibility pilot study. The non-aqueous Restech Dx-pH probe was subsequently affixed to each child's tracheostomy with the probe tip confirmed to be within the tracheal lumen. Esophageal and tracheal probe pH measurements were subsequently recorded until the child was unable to tolerate the study or 24h elapsed. Tracheal pH tracings were compared directly to esophageal pH tracings. Esophageal biopsy and bronchoalveolar lavage data were reviewed for each child.

RESULTS: 3/5 children tolerated the tracheal probe for greater than 18h. Adequate tracheal pH tracings were demonstrated for all children while the probe was in position. Mean baseline tracheal pH was 7.8. One child demonstrated direct correlation between acidic esophageal reflux events and decreased tracheal pH. Esophageal biopsy confirmed the presence of active inflammation consistent with reflux in this child.

CONCLUSION: Tracheal pH can be accurately recorded with the Restech Dx-pH probe. The technology may allow further investigations to determine the impact of gastroesophageal refluxate aspiration and empiric antireflux therapy in children with aerodigestive symptoms.

The relationship of Restech pH probe results with laryngopharyngeal reflux symptomatology and examination findings.

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OBJECTIVES: To determine the utility of the new Restech pHprobe in diagnosis of laryngopharyngeal reflux by showing that patients with higher Reflux Symptom Indices and Reflux Finding Scores will have positive Restech studies

Subjects: Patients with suspected laryngopharyngeal reflux.

METHODS: The charts of all patients who presented between 1/2007 and 4/2008 to the Indiana University Clinic for Swallowing and Voice Disorders and underwent Restech evaluations were reviewed. Initial Reflux Symptom Indices and Reflux Finding Scores were recorded, as well as initial Restech findings. The association between abnormal Restech findings and elevated scores and indices were then determined, with student t-test used to determine statistical significance.

RESULTS: Twenty patients were included in the study. Of these, thirteen patients (65%) had positive pH events during Restech evaluation. Sixteen patients (80%) of patients had Reflex Symptom Index of 10 or greater. Eighteen patients (90%) had Reflux Finding Scores of 7 or greater. There was a trend toward a higher scores and indices in the patients (n=9) with the abnormal Restech results, but this difference did not reach significance when all patients were included. When those patients who had diffusely elevated review of systems (greater than 10 complaints) were excluded, those patients with abnormal Restech (n=6) had significantly higher scores and indices (p=0.047 and p=0.030, respectively) than those patients with normal studies (n=10).

CONCLUSIONS: The Restech pH-probe may be a useful diagnostic tool for patients with laryngopharyngeal reflux in correlation with symptoms and examination finding.

A new pH catheter for laryngopharyngeal reflux: Normal values.

Sun G, Muddana S, Slaughter JC, Casey S, Hill E, Farrokhi F, Garrett CG, Vaezi MF. Laryngoscope. 2009 Aug; 119(8):1639-43.

OBJECTIVES/HYPOTHESIS: Laryngopharyngeal reflux (LPR) represents a challenging field. Therapeutic studies of proton pump inhibitors in LPR have shown mixed results. The Restech pH catheter (Respiratory Technology Corp., San Diego, CA) is a minimally invasive device for detection of oropharyngeal acid reflux. The aim of this study was to provide normative data using this device in both distal esophagus and oropharynx. Study Design: Prospective observational study.

METHODS: Normal volunteers were recruited to undergo pH monitoring. A custom made longer catheter was used to assess distal esophageal pH. Oropharyngeal pH catheter was placed at the level of uvula. The distribution of % time was summarized using the 5th, 25th, 50th (median), 75th, and 95th quantiles for

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pH < 6, pH < 5, and pH < 4 for both upright and supine positions. RESULTS: A total of 20 normal, healthy volunteers underwent pH monitoring for 14 to 24 hours (median 20.5 hours). The 95th percentile for % total time pH < 4, pH < 5, pH < 6 for the distal esophageal pH catheter were 4.52%, 10.91%, and 42.99%, respectively. For the oropharynx pH probe, the 95th percentile for % total time pH < 4, pH < 5, and pH < 6 were 0.02%, 2.33%, and 21.41% respectively. The 95th percentile for number of reflux events for total pH < 4, pH < 5, and pH < 6 were 1.3, 8.1, and 128.0, respectively.

CONCLUSIONS: Oropharyngeal acid reflux is an infrequent occurrence in healthy volunteers without LPR. The normative data for Restech pH catheter may now be compared to those with suspected LPR.

Comparison of an oropharyngeal pH probe and a standard dual pH probe for diagnosis of laryngopharyngeal reflux.

Golub JS, Johns MM 3rd, Lim JH, DelGaudio JM, Klein AM. Ann Otol Rhinol Laryngol. 2009 Jan; 118(1):1-5.

OBJECTIVES: We compared the ability of an oropharyngeal (OP) aerosol-detecting pH probe and a standard dual pH probe in measuring laryngopharyngeal reflux (LPR).

METHODS: Fifteen subjects with LPR symptoms had 24-hour simultaneous placement of the OP probe and a standard dual pH probe. Acid exposure was defined as a 10% pH decrease below baseline for the OP probe or a pH of less than 4 at the upper esophageal sphincter (UES) probe of the dual pH probe.

RESULTS: The mean duration of acid exposure was 650 seconds (SD, 619) or 0.75% of the total time for the OP probe and 438 seconds (SD, 511) or 0.51% of the total time for the UES probe. When we excluded meals and sleep, the mean duration of acid exposure was 271 seconds (SD, 356) or 0.31% of the total time for the OP probe and 271 seconds (SD, 359) or 0.31% of the total time for the UES probe. The correlation coefficient (R) between the two probes for measurement of the duration of acid exposure was 0.50 (p < 0.05). When we excluded meals and the supine position, the R was notably higher, at 0.95 (p < 0.0001).

CONCLUSIONS: The OP probe reliably documented LPR events when meals and sleep were eliminated and was better tolerated than the standard dual probe.

Influence of Anxiety and Depression on the Predictive Value of the Reflux Symptom Index.

Samuel L. Oyer, MD; Lauren C. Anderson, MD; Stacey L. Halum, MD. Ann Otol, Rhinol, Laryngol October, 2009.

OBJECTIVES: Although the Reflux Symptom Index (RSI) is a validated laryngopharyngeal reflux (LPR) outcomes tool, its predictive value for LPR is controversial. Because psychiatric problems may lead to exaggerated patient-perceived symptoms and RSI values, the aim of this study was to determine whether the positive predictive value of the RSI for pH probe-documented LPR is influenced by anxiety and depression. Methods: We reviewed the charts of all patients who underwent pH probe

testing for LPR between January 2006 and July 2008 at our institution. The RSI, Reflux Finding Score (RFS), medical history, and pH probe findings were recorded.

Patients with anxiety or depression were included in the psychiatric disorder (+PSY) group, and those without anxiety or depression comprised the non-psychiatric disorder (-PSY) group. Predictive values of the RSI for pH probe-documented LPR were determined for each group.

RESULTS: We included 51 patients: 30 patients (59%) in the -PSY group and 21 patients (41%) in the +PSY group. The mean RSI of the +PSY group was higher than that of the -PSY group (p <0.05), but the +PSY patients actually had a lower incidence of abnormal probe studies (p < 0.02). The positive predictive value of an elevated RSI for an abnormal pH probe study was poor in the +PSY patients (p = 0.495), but strong in the -PSY group (p = 0.004).

CONCLUSIONS: The presence of anxiety and depression impairs the predictive value of the RSI for LPR. This finding potentially explains some of the controversy over the diagnostic utility of the RSI.



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