Learning Objectives, Part II

1. Participant will be able to identify main diagnostic protocols in current use for GERD and LPR.

2. Participant will be familiarized with new probe technology for identifying extraesophageal reflux using the Restech pharyngeal probe.

3. Participant will be able to discuss the role of the SLP in relationship to behavioral management of reflux and its impact on voice and swallow issues.
Diagnosis for GERD

- Gastroenterology diagnostic procedures
  - Esophagogastroduodenoscopy (EGD) – mucosal changes, strictures, Zenker's diverticulum, cancer
  - Manometry and Barium swallow – function, dysmotility/achalasia, stricture, Zenker's diverticulum
  - Dual probe pH esophageal monitoring – usually a 24 hour catheter probe though can be up to 48 hours with a probe positioned at the distal esophagus and a proximal probe at the level just below the UES – use of DeMeester Score to quantify presence of reflux
  - BRAVO pH monitoring – 24 or 48 hour – requires endoscopy for placement with or without sedation
  - Multichannel intraluminal impedance testing (MII) – alone or in combination with 24 hour esophageal pH probe – can detect both acidic and nonacidic reflux
Diagnosis of LPR

- Evidence that dual pH esophageal probe is not adequate for reliable diagnosis of LPR (combined with MII, testing is more effective)
- **Reflux Symptom Index** – can be administered by physician/SLP
- **Laryngoscopy** – can be administered by physician/SLP – has both positives and negatives
- **Reflux Finding Score** – conducted by physician/SLP in conjunction with Laryngoscopy
- **Restech Pharyngeal pH Probe** – can be administered by physician or SLP
Problems with Dual pH Esophageal Probe

- Together with EGD, often referred to as the gold standard for GERD diagnosis but can demonstrate poor sensitivity for diagnosis of LPR
- False negative results are common due to problems of placement of proximal probe, the proximal probe drying out or fouled by mucus
- Debate as what acidity level constitutes reflux (levels from <4.0pH to 5.0pH)
- Trials of a triple placement with additional probe in hypopharynx continue to demonstrate variable results
- M. Vaezi (2011) suggests pH monitoring, while valuable in identifying absence or presence of acid, it does not necessarily suggest causal link for symptoms
Reflux Symptom Index

- Developed by Belafsky, Postma and Koufman, the RSI is a self-administered nine-item outcomes instrument for LPR in 2002 with demonstrated construct-based and criterion-based validity.

- Scoring is on a psychometric Likert scale of 0-5 with “0” designated as “no problem” and “5” as “severe problem”.

- Initial results indicated that a cumulative score above “13” is abnormal. However, in some sources, the cutoff score is “10”.

- Follow-up treatments with BID PPI's suggest best results are achieved with a 6 month treatment course.

- Some suggest that the RSI is better at delineating improvement after treatment. It is also suggested that those with symptoms of GERD will score higher on the RSI than those with only symptoms of LPR. (Overall, 2006)
# Reflux Symptom Index

<table>
<thead>
<tr>
<th>Within the last MONTH, how did the following problems affect you?</th>
<th>0 = No Problem</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hoarseness or a problem with your voice</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. Clearing your throat</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. Excess throat mucous or postnasal drip</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. Difficulty swallowing food, liquids, or pills</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Coughing after you ate or after lying down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. Breathing difficulties or choking episodes</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7. Troublesome or annoying cough</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. Sensations of something sticking in your throat or a lump in your throat</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. Heartburn, chest pain, indigestion, or stomach acid coming up</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**TOTAL**
Laryngoscopy as Diagnostic Tool for LPR

- As presented by Vaezi et al. (2011), typical laryngeal signs associated with GERD-related LPR include:
  
edema and hyperemia of larynx; hyperemia and lymphoid hyperplasia of posterior pharynx (cobblestoning);
  granuloma; contact ulcers; laryngeal polyps;
  interarytenoid changes; Reinke's edema; tumors;
  subglottic stenosis; and posterior glottic stenosis.

- However, Vaezi suggests that laryngoscopy demonstrates good sensitivity but poor specificity for LPR diagnosis - identified irritants may be result of smoking and/or environmental allergens

- Findings demonstrate that as many as 50% of patients with laryngoscopic signs suggesting LPR do not respond to aggressive acid suppression or do not have abnormal esophageal acid reflux values on esophageal pH monitoring.
Reflux Finding Score

- Developed by Belafsky et al. in 2001, this tool attempts to assist the examiner performing a laryngoscopy to quantify the signs of possible LPR by grading eight specific physical exam findings.
- Some of the components are scored as whether or not they are present while others are graded with regards to severity.
- The RFS can range from 0 to 26, and the authors concluded that a score greater than 7 suggested a 95% statistical likelihood of a positive dual-probe pH study. This is also applicable for asymptomatic patients.
- At least one study (Jonaitis et al., 2006), while supporting laryngeal examination as a credible diagnostic procedure for LPR, suggests that there are some inconsistencies with the development of the RFS. They suggest that the combination of three laryngoscopic findings – lesions of vocal fold mucosa, lesions of interarytenoid mucosa (roughness, hypertrophy, granuloma) and edema of vocal folds will reliably distinguish LPR from healthy patients in 95.9% of cases.
# Reflux Finding Score

<table>
<thead>
<tr>
<th>Finding</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subglottic edema</td>
<td>2 = present</td>
</tr>
<tr>
<td></td>
<td>0 = absent</td>
</tr>
<tr>
<td>Ventricular obliteration</td>
<td>2 = partial</td>
</tr>
<tr>
<td></td>
<td>4 = complete</td>
</tr>
<tr>
<td>Erythema/hyperemia</td>
<td>2 = arytenoids only</td>
</tr>
<tr>
<td></td>
<td>4 = diffuse</td>
</tr>
<tr>
<td>Vocal cord edema</td>
<td>1 = mild</td>
</tr>
<tr>
<td></td>
<td>2 = moderate</td>
</tr>
<tr>
<td></td>
<td>3 = severe</td>
</tr>
<tr>
<td></td>
<td>4 = polypoid</td>
</tr>
<tr>
<td>Diffuse laryngeal edema</td>
<td>1 = mild</td>
</tr>
<tr>
<td></td>
<td>2 = moderate</td>
</tr>
<tr>
<td></td>
<td>3 = severe</td>
</tr>
<tr>
<td></td>
<td>4 = obstructing</td>
</tr>
<tr>
<td>Posterior commissure hypertrophy</td>
<td>1 = mild</td>
</tr>
<tr>
<td></td>
<td>2 = moderate</td>
</tr>
<tr>
<td></td>
<td>3 = severe</td>
</tr>
<tr>
<td></td>
<td>4 = obstructing</td>
</tr>
<tr>
<td>Granuloma/granulation</td>
<td>2 = present</td>
</tr>
<tr>
<td></td>
<td>0 = absent</td>
</tr>
<tr>
<td>Thick endolaryngeal mucus/other</td>
<td>2 = present</td>
</tr>
<tr>
<td></td>
<td>0 = absent</td>
</tr>
</tbody>
</table>

**TOTAL (a score greater than 11 is strongly suggestive of LPR)** (Belafsky et al., 2002)
RFS – Visual Examples

- Subglottic vocal fold edema/pseudosulcus; ventricular obliteration; posterior arytenoid thickening

Pre-PPI treatment

Post-PPI treatment
Reflux Signs

Granuloma

Diffuse laryngeal edema
28 Yr. Female Pt. with Severe Hx of VCD, Reflux and Dysphonia

- Prior to therapy and 3 months post-therapy
Airway pH:

Measuring Aerosolized Acidity and Alkalinity

New Product Technology Review

*The following slides courtesy of Restech Technologies
1974

**The Johnson – DeMeester Score**

Table 1. De Meester’s Score Table.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration (HH:MM)</td>
<td>23:59</td>
</tr>
<tr>
<td>Number of episodes</td>
<td>50 3.4</td>
</tr>
<tr>
<td>Number of episodes &gt;5</td>
<td>3 2.8</td>
</tr>
<tr>
<td>Longest episode (min)</td>
<td>12.0 1.7</td>
</tr>
<tr>
<td>Total time pH &lt; 4 (%)</td>
<td>3.2 2.2</td>
</tr>
<tr>
<td>Time pH &lt; 4 orthostatism (%)</td>
<td>3.6 1.6</td>
</tr>
<tr>
<td>Time pH &lt; 4 supine (%)</td>
<td>1.2 1.6</td>
</tr>
<tr>
<td>De Meester Score</td>
<td>13.3</td>
</tr>
</tbody>
</table>

There are 6 parameters:
(1) number of refluxes,
(2) number of prolonged refluxes,
(3) longest reflux,
(4) total acid exposure time,
(5) total acid exposure time while standing,
(6) total acid exposure time while lying down.
1998

San Diego based Endonetics

Young engineer / inventor
Ross Tsukashima

Medical Advisor
Dr. Tom DeMeester

Sold to Medtronics
2006

Restech patented
Oropharyngeal Probe

RYAN Score for LPR
Developed by Dr. Tom DeMeester USC

Score Calculation
- Components used:
  - % Time Below Cutoff
  - Number of Episode
  - Duration of the Longest Episode
- Cutoffs:
  Upright  5.5
  Supine   5.0
Light Emitting Diode simplifies positioning
No Manometry
No xray
Esophageal pH Probe Placement

Esophagus (20-24 cm)

Dual Channel Catheter

Upper Esophageal Sphincter

Lower Esophageal Sphincter
Sensor Design of Esophageal pH Catheters

»Reference Sensor must be in direct fluid contact with pH sensors.

Dryout can cause:

»Loss of Signal, which shows up as...

»Drift, Artifact or Pseudo Reflux
Problems Using Esophageal Sensor in the Pharynx

- Esophageal Sensors too low for detection of LPRD
- If the 2nd channel is placed higher it dries out due to air contact
- Sensor can be fouled by mucus
- Mucosal contact can mask reflux events
Restech Sensor Technology

» Coplanar Ionic Bridge pH sensor
» Does not require immersion in Liquid
» Designed to work in the Oropharynx
Sensitivity Improvements

- 1 mm size requires less fluid to measure pH
- Reference electrode next to Antimony sensor allows for measurement of aerosolized events
- Downward aim reduces masking
- Teardrop shape reduces fouling
- Comfort allows for 48 hour studies at 2 Hz sampling rate
Manometry Free Positioning

Light Emitting Diode simplifies positioning
Data Feed Adapter

- Design allows for comfort during sleep
- Direct connection to PSG monitors
- Works well with CPAP
- Plugs into any device with an analogue 0-1v port
Clinical Validation

Tom DeMeester, MD
Advanced Esophageal Function Laboratory
Keck School of Medicine,
University of Southern California

Greg Postma, MD
Center for Voice and Swallowing Disorders
Medical College of Georgia

Michael Vaezi, MD, PhD
Digestive Disease Center
Vanderbilt University Medical Center
Triple probe conventional study –
checking for Extraesophageal Reflux – what do the results indicate? No LPR?

**Patient 18B**
- 63 year old female
- Bravo not performed
- Esophagitis with main symptom cough
- Normal Esophageal pH with one Dx-pH Probe episode in upper airway
- Pharyngeal probe 1 cm > pharynx missed an acidic meal period that the Dx-pH Probe picked up

---

<table>
<thead>
<tr>
<th>Dx-pH Oropharynx</th>
<th>Pharyngeal</th>
<th>Proximal Esophageal</th>
<th>Distal Esophageal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

![Graph showing pH levels in different regions of the esophagus and pharynx.](chart.png)
Hypopharyngeal Monitoring   --- Restech

Many clinicians are interested in assessing the patient with ENT manifestations of GERD using pharyngeal pH monitoring. Traditional pH electrodes have been of limited utility in this group for a number of reasons. A new device was recently developed for measuring pharyngeal pH, which uses a technology designed to protect the pH electrode from drying out and is placed in the hypopharynx as a single electrode at a standard measuring position. This novel pharyngeal pH probe was evaluated in 20 patients and 10 controls for the ability to detect the presence of pH drops in the pharynx. All participants were studied simultaneously with the pharyngeal pH probe as well as a dual-channel pH probe using a traditional pH catheter; pH events in the pharynx were characterized as weak acid (pH 4-6) or acid (pH < 4) if they coincided with a pH drop in the distal esophagus. Most pharyngeal pH events observed were weakly acidic and there was no significant difference in the number of pharyngeal pH events between normal controls and patients. Most important, the study authors concluded that this novel pharyngeal pH probe provided reliable pH monitoring and that perhaps the percentage of time of pharyngeal pH events will be useful in distinguishing symptomatic patients from those who are normal. This device represents an exciting new tool for the evaluation of pharyngeal pH, and further study regarding its clinical utility is awaited.
USE OF A NOVEL OROPHARYNGEAL pH DETECTION DEVICE FOR THE DIAGNOSIS OF SUPRAESOPHAGEAL REFLUX DISEASE

A. N. Williams, T. Hui, R. A. Simon – Scripps Clinic, San Diego, CA.

ABSTRACT

OBJECTIVES

To assess the presence of pharyngeal reflux in patients presenting to the allergy department with upper airway symptoms not attributable to other causes

To characterize the clinical features of patients presenting to the allergy department with upper airway symptoms referred for 24-hour pharyngeal pH testing

To prospectively assess changes in symptoms of patients with abnormal 24-hour pharyngeal pH testing results treated with acid suppressive therapy

METHODS

Prospective, observational pHt study

25 patients presenting to the allergy department for evaluation of upper airway symptoms

Referral for 24-hour pH monitoring with the Delphi Measurement System™ (Delstech Corp., San Diego, CA).

“positive”:

Sustained supra-pH decrease >1
2 or more upright supra-pH events to pH <5.5

Symptom assessment baseline and 3 months

Intrabody Surface Spectral Index (ISS) scores

Visual analog scale (VAS) total symptom severity scores

Protocol approved by MDC and all patients provided informed consent

RESULTS

<table>
<thead>
<tr>
<th>TABLE 1: BASELINE DEMOGRAPHIC DATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Patients</td>
</tr>
<tr>
<td>Mean Age, years (range)</td>
</tr>
<tr>
<td>Male, % (n)</td>
</tr>
<tr>
<td>GERD, % (n)</td>
</tr>
<tr>
<td>Atopy, % (n)</td>
</tr>
<tr>
<td>Allergy rhinitis, % (n)</td>
</tr>
<tr>
<td>Asthma, % (n)</td>
</tr>
<tr>
<td>Mean Total RSI Score, (range)</td>
</tr>
<tr>
<td>Mean VAS Symptom Score, (range)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FIGURE 1: PRESENTING SYMPTOMS</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>TABLE 2: 24-HOUR OROPHARYNGEAL pH RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter (pH values)</td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td>&lt;5</td>
</tr>
<tr>
<td>&lt;5.5</td>
</tr>
<tr>
<td>&lt;5</td>
</tr>
<tr>
<td>decrease &gt;1</td>
</tr>
<tr>
<td>decrease &gt;1.5</td>
</tr>
<tr>
<td>sustained supra-pH decrease &gt;1</td>
</tr>
</tbody>
</table>

CONCLUSIONS

Patients presenting to allergists with upper airway symptoms consistent with GERD have evidence of decreased pharyngeal pH

Most patients with abnormal pharyngeal pH results who were treated with proton pump inhibitors had improved symptom scores as compared to baseline

These data suggest allergists should consider pHt in evaluating patients with upper airway symptoms and support the need for additional study of this novel device

BIBLIOGRAPHY

(References to be added)
Preliminary Comparison of an Oropharyngeal Aerosolized pH Probe and a Standard Dual pH Probe for Diagnosis of Laryngopharyngeal Reflux

Justin S. Golub, BA; Michael M. Johns III, MD; John M. DelGaudio, MD; Adam M. Klein, MD

The Emory Voice Center, Department of Otolaryngology—Head and Neck Surgery, Emory University School of Medicine, Atlanta, GA

The work is supported by an investigator-initiated grant from Motus. pH Probes were donated by Motus and Medtronic Hybrid.

Introduction

- Up to 50% of patients with voice disorders and 40-100% of patients seen in otolaryngology practice experience laryngopharyngeal reflux (LPR).
- LPR has been implicated in the pathogenesis of numerous laryngeal disorders, including subglottic stenosis, laryngeal carcinoma, laryngeal contact ulcers, laryngospasm, asthma, and sinusitis.
- Common LPR symptoms include hoarseness, vocal fatigue, globus pharyngeus, cough, postnasal drip, chronic throat clearing, and dysphagia.
- LPR is often linked to esophagitis and related symptoms such as heartburn and regurgitation.
- Diagnosis of LPR is challenging, as symptoms are nonspecific and may overlap with other conditions.
- The most widely used diagnostic modality for LPR is endoscopy; however, this is not adequate for a therapeutic diagnosis.
- The most widely used diagnostic modality for LPR is endoscopy; however, this is not adequate for a therapeutic diagnosis.

Methods

- Subjects were non-smokers with symptoms consistent with LPR as measured by a reflux symptom index (RSI) > 15.
- Subjects were not receiving medication treatment (including H2 blockers or proton-pump inhibitors) or had no other voice or swallowing pathology on clinical exam.
- All subjects had 24 hours simultaneous placement of the Medtronic 7.0 measurement system (San Diego, CA) and the standard dual pH probe.

Results

- The mean pH measurement over 24 hours (excluding meals and sleeping) were 6.6 (UES reading from standard dual probe) and 7.0 (aerosolized probe).
- The aerosolized probe successfully registered 15 of 20 reflux events (95%) in two subjects measured by the UES probe.
- The mean (±SD) differences in pH measured by the two probes immediately before, during, and immediately after reflux events were 1.0 (±4.4), 2.3 (±1.2), and 1.1 (±0.4), respectively.
- The aerosolized probe consistently recorded higher pH than the UES probe. (Figure 2)

Discussion

- These preliminary data suggest that the aerosolized probe has a high likelihood of identifying LPR events when compared to the standard dual probe.
- Event severity is less when measured with the aerosolized probe, which is expected given the method and location of pH acquisition. A different event threshold may therefore be necessary.

Conclusion

- The aerosolized probe is highly sensitive and specific in registering reflux events when compared to the standard dual probe.
- The aerosolized pH probe is very well tolerated and appears able to reliably diagnose LPR.
- The availability of a well-tolerated, reliable pH device would allow otolaryngologists to readily acquire objective data in the workup of LPR. Further studies are currently being tested.
Comparison of Restech Dx-pH Probe to Sandhill pH monitoring device in patients with GERD
Eric Hill, MD; Farnoosh Farrokhi, MD; Sean Casey, MD; George Sun, MD; Chris Slaughter, Dr.PH; and Michael Vaezi, MD, PhD, MSc(Epi), FACG. Digestive Disease Center, Vanderbilt University Medical Center, Nashville, TN.

BACKGROUND
- Restech Dx pH monitoring device allows for continuous monitoring of intragastric pH.
- Restech Dx pH monitoring device has a significantly larger number of observations below each pH threshold in comparison to Sandhill device.

AIMS
- Compare the internal consistency and agreement of the Restech Dx-pH monitoring with Sandhill pH probes.

METHODS
- 31 patients (18 male and 13 female) with GERD underwent simultaneous intragastric pH monitoring.
- Both probes were positioned free above the gastroesophageal junction.
- Restech data was analyzed using restech Dx pH monitoring software.
- Device agreement was assessed using the Bland-Altman method.

RESULTS

<table>
<thead>
<tr>
<th>pH Interval</th>
<th>Restech (Gastric)</th>
<th>Sandhill (Gastric)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5-6.0</td>
<td>32 (62.2%)</td>
<td>24 (46.2%)</td>
<td>0.07</td>
</tr>
<tr>
<td>5.0-5.5</td>
<td>40 (75.9%)</td>
<td>40 (75.9%)</td>
<td>1.00</td>
</tr>
<tr>
<td>4.5-5.0</td>
<td>33 (61.8%)</td>
<td>33 (61.8%)</td>
<td>1.00</td>
</tr>
<tr>
<td>4.0-4.5</td>
<td>21 (39.6%)</td>
<td>21 (39.6%)</td>
<td>1.00</td>
</tr>
<tr>
<td>3.5-4.0</td>
<td>13 (24.5%)</td>
<td>13 (24.5%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

For each subject, restech pH values were compared to sandhill pH values.

CONCLUSION
- Restech Dx-pH monitoring device has a better agreement with sandhill pH probes in the distal esophagus.
- Future studies will focus on clinical utility of the Restech Dx-pH monitoring device.
Measurement of Pharyngeal pH: A New Technology and Normal Values

S. Ayazi, JC. Lipham, JM. Leers, AL. Tang, A Oezcelik, E Abate, F Banki,
J.A. Hagen, SR. DeMeester, TR. DeMeester
Department of Surgery, University of Southern California, Los Angeles, CA

Introduction

Patients with respiratory and laryngeal complaints often have gastroesophageal reflux but classic symptoms are frequently absent and clinical findings are nonspecific. Current methods of measuring pharyngeal acid exposure are often inaccurate due to technical artifacts or probe malfunction. A newly designed pharyngeal pH probe has been introduced which detects sessileized acid and is placed under direct vision. The aim of this study was to determine normal values for pharyngeal acid exposure using this catheter.

Methods

Seventy eight asymptomatic volunteers were recruited. All had esophageal manometry and a video esophagogram. Dual channel esophageal pH monitoring was performed with the distal probe 5 cm above the lower esophageal sphincter and the proximal probe 1-4 cm below the upper esophageal sphincter. Simultaneously, pharyngeal pH was monitored in the new probe positioned 0.5-1 cm below the uvula. Subjects with abnormal distal esophageal acid exposure, a hiatal hernia larger than 2 cm, or a poor technical recording were excluded.

Pharyngeal pH was analyzed using the standard components of esophageal pH monitoring at pH thresholds from 4 to 6 in 0.5 increments, and a composite score was calculated. A separate analysis was performed for the upright and supine periods and the 95th percentile was determined.

Results

The study population consisted of 55 subjects (28 M/27F) with a mean age of 31 years (range 19-72). The 95th percentile values for pharyngeal acid exposure are shown (Table). In the upright period, 5.5 is the best pH threshold to define abnormal acid exposure (data not shown). Pharyngeal acid exposure is considerably higher in the supine period and a lower threshold is necessary. For this period, pH < 5.0 would maximize sensitivity and pH < 4.5 would maximize specificity (data not shown). The 95th percentile values for the composite score were: 9.4 for the upright period, and 4.8 and 6.7 for the supine period at pH < 5 and pH < 4.5 respectively.

Normal Values for Pharyngeal pH Components and Composite Score Using Recommended Thresholds.

<table>
<thead>
<tr>
<th>Component</th>
<th>Upright</th>
<th>Supine</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Time Below Threshold</td>
<td>pH &lt; 5.5</td>
<td>pH &lt; 5.0</td>
</tr>
<tr>
<td>0.13</td>
<td>5.15</td>
<td>1.54</td>
</tr>
<tr>
<td>Number of Episodes</td>
<td>1.20</td>
<td>4.0</td>
</tr>
<tr>
<td>Longest Episode (min)</td>
<td>0.71</td>
<td>13.97</td>
</tr>
<tr>
<td>RYAN Score</td>
<td>9.41</td>
<td>6.79</td>
</tr>
<tr>
<td>DeMeester score for pharyngeal acid exposure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Conclusion

A newly designed pharyngeal pH probe may overcome the shortcomings of current techniques. Using this probe we have defined normal values for pharyngeal acid exposure in a large series of normal volunteers. These values can be used to determine if patients with laryngeal or respiratory symptoms have abnormal pharyngeal acid exposure.
Published Manuscripts

Annals of ORL
- Greg Postma, MD Medical College of Georgia - March 2009
- Michael Johns, III, MD Emory Medical College – January 2009

Awaiting Publication Normative Study
- Tom DeMeester, MD USC Keck School of Medicine

Allergy and Asthma Proceedings
- Ron Simon, MD, Adam Williams, MD, Sinusitis and Chronic Progressive Exercise-induced Cough and Dyspnea – December 2008

Journal of Voice
- Michael Vaezi, MD, PhD Vanderbilt University School of Medicine – Fall 2008
- Gregory Wiener, MD Private Practice
Current Diagnostic Techniques

• Endoscopy, EGD
• Bravo
• Esophagram/Barium Swallow
• Empiric Therapeutic Trial with H2 Blockers or PPIs
• Refer for 24 hr pH esophageal probe testing
• Restech pH probe
  - Highly sensitive pH probe specifically developed to detect aerosolized reflux
A New pH Probe For The Detection Of Laryngopharyngeal Reflux (LPR) In Children

Annual Meeting of the
American Society of Pediatric Otolaryngology
Orlando, Florida
4 May 2008

David J. Malis, MD, FACS, FAAP
Melbourne, Florida
Normal Study
Patient 1

7 year old male

Initial eval Jan 2007 for chronic rhinitis and snoring

• Pediatrician ordered MRI: maxillary “sinusitis” and adenoid hypertrophy
• PMH: RAD, ADHD, Developmental Delay, Bipolar Disorder
• PSH: None
• Medications: Singulair, Risperdal
• Exam: 2+ Tonsils, 80% obstructing adenoids
Patient 1

Feb 2007: Adenoidectomy

May-Aug 07: Recurrent rhinitis, headaches without improvement despite addition of Flonase

Aug 07: pH probe: marked AM/PM LPR; Rx Prevacid
Patient 1

Nov 07: Clinical resolution of all sinus symptoms
Dec 07: Repeat pH probe: Normal (on Rx)
Patient 2

- 8 year old male
- Initial evaluation June 07 for hoarseness
  - Hx: 2 years duration hoarseness w/o voice abuse
  - No Allergic Rhinitis or LPR sx
  - PMH / PSH / Medications: None
  - Exam: NPL showed lymphoid aggregates lining upper airway to hypopharynx; posterior glottic and TVC erythema and edema w/o nodules
Patient 2

Treatment Course:

- Jun 07: pH Probe: PM LPR; Rx Pepcid
Patient 2

Sept 07: Hoarseness markedly improved
Sept 07: Repeat pH probe: Normal (on Rx)
Application of Ambulatory Supraesophageal pH Probe Monitoring in Infants and Children

Chris Landon, M.D.
FAAP, FCCP, CMD
Ventura County Medical Center
Pulmonary Manifestations of Gastroesophageal Reflux Disease

- Apnea
- Aspiration Pneumonia
- Atelectasis
- Bronchiectasis
- Bronchitis
- Chronic Asthma
- Hemoptysis
- Hoarseness or Laryngitis
- Pulmonary Fibrosis
- Seizures relate to Hypoxia
Age 3 months

- **Diagnosis:** Cystic Fibrosis, failure to thrive

- **Presenting Symptoms of Cough**

- Evaluation UGI no GERD/anatomic obstruction, mildly prolonged gastric emptying scan

- **Course Hospitalization and PICU**
  - Study site: Outpatient

- SE Result Drops to pH<4 associated with respiratory symptoms

- **Intervention** *Nissen and G tube*

- Course resolution at six week follow-up
Age 4 months

- Diagnosis: Infant in foster care with cough, no records

- Presenting Symptoms 3 months of cough

- Evaluation Hyperinflation on CXR

- Course Hospitalization and ER visits

- Study site: Hospital

- SE Study Result Drops to pH<4 associated with respiratory symptoms

- Intervention Proton pump inhibitor and H2 blocker

- Course resolution at six week follow-up
Age 15 months

- Diagnosis: 26 week premature, Infant in foster care, spitting up, asthma

- Presenting Symptoms 3 months of cough

- Evaluation UGI - No GERD/anatomic obstruction. No delay on gastric emptying scan

- Course Hospitalizations for asthma
- Study site: Hospital

- SE Study result Nocturnal pH>7, drop to 4.5 one half hour post daytime feeds

- Intervention Prokinetic agent and H2 blocker, decrease volume feeds (overfeeding)

- Course resolution at six week follow-up
Age 5 years

- Diagnosis: Normal child
- **Presenting symptoms Hoarse voice**
- Evaluation: Vocal cord erythema on endoscopy
- Course: ENT consultation, multiple office visits
- Study site: Outpatient
- SE Study Result: No drop in pH <6.5
- **Intervention Behavioral intervention re:screaming**
- Course resolution at six week follow-up
Elements of the RYAN Score

Score Calculation

Components used

- % Time Below Cutoff
- Number of Episode
- Duration of the Longest Episode

Cutoffs

Upright 5.5 Confirmatory Threshold

Supine 5.0 Confirmatory Threshold
Clinical Value of Restech’s Dx-pH System?

- This is a ‘measuring stick’ that provides a definitive measure of acid / alkaline levels in the airway.
- Co-occurring events are captured at a point in time and marked with the real time capture of the pH of patients breath.
- Dx provides the ability to “see” what is happening during sleep and throughout the patients day.
- Visual report has an impact on patient or parents.
- Etiology for cough / recurrent laryngitis / sinusitis / otitis / lesions / edema can be better studied.
- Acid can be ‘ruled in’ or ‘ruled out’ without using an empirical trial.
- Improvement or progression of disease / symptoms can be monitored.
- Dual purpose – can be used for esophageal monitoring if the case requires.
- Accelerates the diagnostic pathway.
Exposure / Penetration

BEST OF DDW 2006

Highlights From Digestive Disease Week and the 107th Annual Meeting of the American Gastroenterological Association Institute, May 20–25, 2006, Los Angeles, California

Complete abstracts available in Gastroenterology. 2006;130:4(suppl 2).

Presentations in GERD
Reviewed by Joel E. Richter, MD
Richard L. Evans Professor of Medicine
Chairman, Department of Medicine
Temple University School of Medicine

Dx–pH Measurement System:
A Sensitive Device for Detecting Liquid and Aerosolized Supraesophageal Gastric Reflux

2007 North America Respiratory Devices
Product Innovation of the Year Award
Award Recipient: Respiratory Technology Corporation
Case Study 1, male 53 – Report
Lump in throat sensation for 2 years; chronic throat clearing; ear pain/tinnitus
Case Study 1, Graph

53 yr. old male, chronic throat clearing and dysphagia

Graph shows data on pH levels over time with annotations for meals and events.
Case Study 1, Diary
Case, Study 1, Ryan Score

<table>
<thead>
<tr>
<th>Upright pH &lt; 5.5</th>
<th>Patient's Value</th>
<th>Normal Value</th>
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</thead>
<tbody>
<tr>
<td>% Time Below Baseline</td>
<td>1.4</td>
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<tr>
<td>Number of Episodes</td>
<td>17</td>
<td>&lt;1.20</td>
</tr>
<tr>
<td>Longest Episode</td>
<td>3.47</td>
<td>&lt;0.71</td>
</tr>
<tr>
<td>RYAN Score</td>
<td>64.33</td>
<td>&lt;9.41</td>
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<table>
<thead>
<tr>
<th>Supine pH &lt; 5.0</th>
<th>Patient's Value</th>
<th>Normal Value</th>
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</thead>
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<td>Longest Episode (Min)</td>
<td>0</td>
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<td>RYAN Score</td>
<td>2.17</td>
<td>&lt;6.80</td>
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</table>
Case Study 2, 53 Yr. Old Male
Longstanding hoarseness/voice loss; frequent heartburn; belches sour tasting material into throat, swallowing difficulty; change in sense of smell and taste
Case Study 2, Graph
## Case Study 2, Ryan Score

<table>
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<tbody>
<tr>
<td><strong>% Time Below Baseline</strong></td>
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<tr>
<td><strong>Number of Episodes</strong></td>
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<td><strong>Longest Episode</strong></td>
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<td><strong>Normal Value</strong></td>
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<td><strong>Normal Value</strong></td>
<td>&lt;1.20</td>
</tr>
<tr>
<td><strong>Normal Value</strong></td>
<td>&lt;0.71</td>
</tr>
<tr>
<td><strong>Normal Value</strong></td>
<td>&lt;9.41</td>
</tr>
</tbody>
</table>

![Graph showing pH levels over time](image-url)
Case Study 3, Female, 62 yrs.
10 years post Nissen fundoplication; chronic back pain; hoarseness; loss of singing range; food sticking in throat; dyspnea, VCD/PVFM; belching of nonsour tasting food; episodes of sneezing leading to spasms. Pertinent negative: chronic cough, heartburn;
Case Study 3, Graph
Case Study 3, Ryan Score

<table>
<thead>
<tr>
<th></th>
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<th>Supine pH &lt; 5.0</th>
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<tr>
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<td>Patient’s Value</td>
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<td>% Time Below Baseline</td>
<td>20.42</td>
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<td>Number of Episodes</td>
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<td>781.83</td>
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</table>

Graph showing pH values over time with highlighted areas.
Case Study 4, Female, Age 55
Primary complaint of lump in throat sensation with swallowing difficulty and discomfort, chronic and acute cough, frequent hoarseness, sore throat. Denies heartburn. Hx remarkable for anxiety/depression with chronic back pain currently treated with morphine (5 times during study) with surgery scheduled.
Case Study 4, Graph
# Case Study 4, Diary

## Symptoms / Patient Diary / Button Presses

<table>
<thead>
<tr>
<th>Symptom Name</th>
<th>Start Time</th>
<th>End Time</th>
<th>Notes</th>
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<tr>
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<tr>
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<td>03/01/2012 04:26:27</td>
<td></td>
</tr>
</tbody>
</table>
Case Study 4, Ryan Score
Behavioral Strategies to Manage LPR

- Avoid tobacco, alcohol, caffeine, foods high in fat, spices, acidic based foods (tomato based, citric juices, sodas). Decaffeinated drinks are better than caffeinated but soda is still acidic and decaffeinated coffee can still contribute to reflux.

- Avoid foods that can relax the LES – (chocolate, mints)

- If you are overweight, lose weight

- Don't overeat at meals and avoid lying down after meals or eating 3 hours before bedtime

- Don't exercise immediately after eating

- Elevate the head of the bed 4-6-8 inches (20 degree angle) with bed blocks or mattress wedge (not an extra pillow) if reflux during the night is an issue

- Avoid tight belts and other restrictive clothing

- Chewing bicarbonate (baking soda) gum – good for teeth and increased salivary bicarbonate may help prevent reflux
Further SLP guidelines

• Understand the way anti-reflux medications are designed to work and make sure the patient understands

• H2 Antagonists (Pepcid, Zantac, etc.) – histamine blockers designed to reduce acid secretion

• Proton Pump Inhibitors (Prilosec, Nexium, Protonix, etc) are generally considered a stronger class of meds which inhibit acid production - most effective when taken 30 minutes to one hour before the meal and then you must eat to activate the meds.

• Antacids may be taken 30 minutes after meals, before bedtime, and PRN.

• Prokinetic agents (Metoclopramide, Cisapride) improve esophageal motility but are complicated by side effects.

• Alginate-based reflux suppressants (Gaviscon Advance – only available in Europe) – reacts with acid to produce a “raft” in stomach that acts as a physical barrier to reflux (US Gaviscon does not contain same level of alginate (derived from seaweed))
Explore Recipes to Target Reflux!

  - cookbook which explores diet choices that lower risk of reflux compiled by Dr. Jamie Koufman together with Dr. Jordan Stern and Marc Bauer.
References


