Clinical Studies using the Restech Dx–pH Measurement System™

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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.

Pharyngeal pH Monitoring May Be Superior to Proximal pH Monitoring in the Detection of Laryngopharyngeal Reflux.

Candice L. Wilshire, Kelly M. Galey, Thomas J. Watson, Carolyn E. Jones, Daniel Raymond, Virginia R. Litle, Jeffrey H. Peters. Digestive Disease Week Presentation, 2011.

BACKGROUND: Determining a causal relationship between abnormal reflux into the proximal esophagus/pharynx and extraesophageal manifestations of gastroesophageal reflux disease (GERD) remains a diagnostic challenge. In this study we aim to determine whether pharyngeal pH monitoring provides superior sensitivity over dual-channel pH testing in detecting laryngopharyngeal reflux (LPR). Methods: 7 control subjects and 17 symptomatic patients, 4 with typical GERD and 13 with primary respiratory symptoms, underwent 24-hour ambulatory esophageal multichannel intraluminal impedance (MII)-dual pH simultaneously with pharyngeal pH monitoring. The distal pH sensor was placed 5cm above the manometrically determined upper border of the lower esophageal sphincter (LES) and the proximal 15cm above. Pharyngeal pH was monitored concomitantly using a separate pH probe positioned 1 cm below the uvula. Data collection was synchronized between the devices. Esophageal reflux was considered present if pH dropped to <4 in either pH sensor, and/or a drop occurred ≥50% from baseline in impedance 3, 5, 7 or 9cm above LES (distal) or 15 and 17cm above LES (proximal). Separate pH thresholds of <5.5, 5.0, 4.5 and 4.0 were defined for reflux episodes detected in the pharyngeal probe.
RESULTS: At a threshold of pH<5.5, an average of 1(±4) pharyngeal reflux event over 24 hours was seen in control subjects. Symptomatic patients had greater pharyngeal pH exposure than controls, averaging 7(±14) episodes/24 hours in those with typical GERD symptoms and 46(±76) in those with respiratory symptoms. Total pharyngeal reflux events (603) were markedly more common in patients with respiratory symptoms than either control (10) or typical GERD symptoms (28). Further, the highest number of pharyngeal reflux episodes recorded across all pH thresholds was observed in subjects presenting with primary respiratory symptoms: 603, 91, 38 and 40 events at pH<5.5, 5.0, 4.5 and 4.0, respectively. 6 of the 11 patients with abnormal distal pH results had corresponding abnormal pharyngeal acid exposure; however, only 3 had concomitant positive proximal esophageal pH results. Pharyngeal pH also appears superior to the proximal esophageal pH in differentiating GERD related respiratory symptoms, as compared to gastrointestinal. Fundoplication normalized pharyngeal pH and markedly relieved symptoms in a single patient with severe respiratory symptoms and normal proximal esophageal acid exposure.
CONCLUSIONS: The more common prevalence of pharyngeal reflux, as compared to proximal esophageal reflux, particularly in subjects with extraesophageal symptoms, suggests that pharyngeal pH monitoring may be a more sensitive diagnostic tool for LPR than proximal pH monitoring. Symptom relief and pharyngeal pH normalization post fundoplication provides further evidence of the utility of ambulatory pharyngeal pH monitoring.

Changes in prevalence, incidence and spontaneous loss of gastro-oesophageal reflux symptoms: a prospective population based cohort study, the HUNT study.

Eivind Ness-Jensen, Anna Lindam, Jesper Lagergren, Kristian Hveem. Gut Journal, December 2011.

OBJECTIVE: Changes in the occurrence of gastro-oesophageal reflux symptoms (GORS) in the population remain uncertain. This study aimed to determine the prevalence changes, the incidence and the spontaneous loss of GORS.

DESIGN: This population-based cohort study was conducted within the Nord-Trøndelag Health Study (the HUNT study), a longitudinal series of population-based health surveys in Nord-Trøndelag County, Norway. The study base encompassed all adult residents in the county, and the participants reported the degree of GORS during the previous 12 months. The number of participants included were 58 869 (64% response rate) in 1995–7 and 44 997 (49%) in 2006–9. Of these, 29 610 persons (61%) were prospectively followed up for an average of 11 years.

RESULTS: Between 1995–7 and 2006–9, the prevalence of any, severe and at least weekly GORS increased by 30% (from 31.4% to 40.9%), 24% (from 5.4% to 6.7%) and 47% (from 11.6% to 17.1%), respectively. The average annual incidence of any and severe GORS was 3.07% and 0.23%, respectively. In women, but not men, the incidence of GORS increased with increasing age. The average annual spontaneous loss (not due to antireflux medication) of any and severe GORS was 2.32% and 1.22%, respectively. The spontaneous loss of GORS decreased with increasing age.

CONCLUSION: Between 1995–7 and 2006–9 the prevalence of GORS increased substantially. At least weekly GORS increased by 47%. The average annual incidence of severe GORS was 0.23%, and the corresponding spontaneous loss was 1.22%. The incidence and spontaneous loss of GORS were influenced by sex and age.

Laryngopharyngeal reflux – the ear, nose and throat patient.

M.G. Watson. Aliment Pharmacol Ther 2011.

Laryngopharyngeal reflux is commonly encountered in UK ENT clinics. This paper describes the diagnosis and management of this condition in a district general hospital setting. Invasive investigations are usually reserved for cases which are diagnostically difficult, who do not respond well to medical treatment or where antireflux surgery is contemplated. New techniques which are less invasive are described. Symptoms should be documented using the Reflux Symptom Index at each visit. Standard medical treatment is described.

The role of poor oesophageal clearance in patients with suspected laryngopharyngeal reflux.

K. Tan, A. Raeburn, A. Emmanuel. Gut Journal, April 2011.

INTRODUCTION: Laryngopharyngeal reflux (LPR) disease is thought to occur in one-third of gastro-oesophageal reflux disease (GORD) patients. Currently there is no gold standard investigation for patients with suspected LPR. The Restech Dx -pH measurement system is reported to be capable of detecting liquid or aerosolized acid reflux in the upper airway, and may be valid objectifiable measure of LPR. We postulated that elevated Restech Dx-pH results may be related to poor oesophageal clearance of acid.

METHODS: Thirty-eight consecutive patients referred for investigations of LPR underwent standard stationary oesophageal manometry and ambulatory dual channel pH-metry with sensors 5cm and 20cm above the lower oesophageal sphincter. The Restech Dx-pH sensor was placed in the oropharynx transnasally. The RYAN composite score was generated by analysis software and was used to determine test outcome. Patients were stratified into two groups based on the total percentage time of pH<4 detected in the distal channel of pH-metry. Group A had a total percentage of time more than 4.5% and Group B less than 4.5%.

RESULTS: Five patients were excluded in the analysis due to technical or equipment errors. In Group A (n=16), 50% of the patients had positive RYAN score. The average age of these patients with positive RYAN score was significant higher (58 ± 12.5 vs 43 ± 12/7 years, p=0.0389) compare to patients with negative RYAN score. The mid oesophageal contraction amplitude was significantly higher in Group A (47 ± 25.9 vs 22 ± 8.1 mmHg, p=0.04894). The LOS pressure was significantly lower in patients with positive than negative RYAN score in Group B (9 ± 2.6 vs 14 ± 3.9 mmHg, p=0.01347).

CONCLUSION: In this tertiary-referred population with LPR symptoms, almost 50% had significant acidification in the upper airway possibly explaining their symptoms. Poor oesophageal clearance of refluxed acid, reflected in reduced contraction amplitude in the oesophageal body may also play a role. Interestingly, patients with normal distal acidification who have high levels of pharyngeal acid exposure tend to have lower LOS pressure and poor body motility.

Pharyngeal pH monitoring for diagnosis of laryngopharyngeal reflux (LPR).

Andrzej Dymek, MD, PhD, Lucyna Dymek, MD, PhD, Liwia Starczewska-Dymek, MD, Tomasz Dymek, MD, Nowak Krzysztof, MD. Alergia 2009.

Respiratory symptoms and pharyngolaryngeal dry as hoarseness, throat clearing, chronic cough, postnasal drip, asthma and laryngospasm can occur in patients suffering from laryngopharyngeal reflux (LPR). Typical Symptoms of GERD may not be present at all. There are no specific pathognomonic clinical or pathological findings allowing for clear diagnosis of LPR. Until recently, diagnostic tests existing lacked sensitivity and specificity sufficient to confirm the diagnosis of LPR. The Restech Dx-pH Measurement System is a new, highly sensitive and non-invasive device for detection of acid reflux in the posterior oropharynx. Advances in technology allow placement of the probe in the pharynx to detect liquid and gaseous both reflux events. Placement can be performed easily without the need for endoscopy and manometers. The probe is well tolerated. It does not interfere with eating, talking or sleeping.

Detecting Nasopharyngeal Reflux: A Novel pH Probe Technique.

Joseph Brunworth, MD, Hamid Djalilian, MD, Rohit Garg, MD MBA. AAO-HNSF Presentation, 2010.

OBJECTIVES: 1) Ascertain the normal pH values in the aerosolized environment of the nasopharynx in healthy subjects. 2) Utilize a novel pH probe which allows measuring acidity in a non-liquid environment.

METHOD: Between Nov 2009 and Feb 2010, healthy volunteers without a history of reflux or eustachian tube dysfunction were enrolled in the study. A total of 21 patients had a DxpH Measurement System Probe (Restech Corp, San Diego, CA 2006) placed near the torus tubarius in the posterior nasopharynx. Once placed, the single-channel DxpH Probe takes a pH reading every 1⁄2 second, and sends the data wirelessly from the attached DxTransmitter to a DxRecorder. Throughout the 24 hour study, the patient records clinically relevant information such as meals and symptoms with the push of a button as well as manually in a written diary. A flexible fiberoptic laryngoscopy was performed to ensure proper placement of the probe, and to assess for laryngopharyngeal reflux using the Reflux Findings Score. Upon completion of the study, the pH data and patient information is downloaded from an SD memory card into DxpH DataView software to be viewed, graphed and analyzed.

RESULTS: For normal individuals with no history of reflux or eustachian tube dysfunction, pH values obtained from the nasopharynx ranged from 6.10 to 7.92. The average pH was 7.03 with a standard deviation of 0.69. Eight subjects (40%) had at least one reflux event during the 24-hour pH study. Decreases in pH were considered reflux events if the pH dropped below 5.5 while in the upright position or below 5.0 in the supine position. The average number of reflux events for subjects in the upright position was 0.6 events over a 24-hour period. In the supine position, the average number of reflux events was 0.5 over 24 hours. One patient was found to have 3 significant reflux events in the supine position, with the longest episode lasting 61.2 minutes.

CONCLUSION: Until recently it has been difficult to detect reflux in the upper airway because available pH catheters were developed to measure reflux in a liquid environment such as the esophagus. By utilizing a novel self-condensing pH probe, we were able to successfully perform a 24-hour pH study in the nasopharynx of 20 healthy individuals. It is our conclusion that the average pH for individuals without symptomatic reflux or Eustachian tube dysfunction is about 7.03. Interestingly, approximately 40% of healthy controls were found to have at least one episode of silent reflux.

Impact of pH Monitoring on Laryngopharyngeal Reflux Treatment: Improved Compliance and Symptom Resolution.

Michael Friedman, MD, Alexander Maley, Kanwar Kelly, MD, JD, Tanya Pulver, MD, Michael Foster, Michelle Fisher, MD, and Ninos Joseph. Otolaryngology-Head and Neck Surgery, April 2011.

OBJECTIVES: Treatment of laryngopharyngeal reflux (LPR) often suffers from poor patient compliance and hence poor symptom improvement. The aim of this study was to determine whether 24-hour oropharyngeal pH monitoring was associated with higher rates of treatment compliance and symptom improvement compared with empirical treatment for LPR. **STUDY DESIGN**: Retrospective, case-control study. **SETTING**: Tertiary care center.

SUBJECTS and METHODS: Charts were reviewed from 170 consecutive adult patients diagnosed with LPR from January 2008 to March 2010. After clinical diagnosis, all patients were offered the option of empiric treatment with a proton pump inhibitor versus treatment based on a 24-hour oropharyngeal pH study using the Dx-pH system (Restech, San Diego, California). Treatment compliance and pretreatment and posttreatment reflux symptom index (RSI) scores were compared for the 2 groups. Only consecutive patients with complete data were included.

RESULTS: One-hundred and seventy patients were included in 2 groups. Group I consisted of 73 patients who underwent pH monitoring. Group II consisted of 70 patients treated empirically. Compliance with medication therapy (68.5% vs 50.0%, $P = .019$) and lifestyle modification (82.2 vs 25.7%, $P = .0001$) were greater among patients in group I. Symptom improvement was greater among patients in group I following treatment compared with patients in group II, with a significantly greater reduction in RSI (36.6% vs 24.4%, $P = .023$).

CONCLUSION: Among our patient population, treatment of LPR based on pH monitoring resulted in greater compliance, as well as greater symptom improvement, compared with empirical therapy alone.

Clinical utility of pharyngeal pH monitoring for hoarseness.

Mary Es Beaver, MD. AAO-HNSF Presentation, 2010.

OBJECTIVES: To evaluate the contribution of 24-hour pharyngeal pH monitoring for the patient presenting with symptoms of hoarseness, globus, throat clearing, and sore throat.

METHOD: Results of 167 pharyngeal pH studies performed for complaints of hoarseness, globus, and throat clearing at the Texas Center for Voice and Swallowing from 5/09–12/09 were analyzed for pharyngeal reflux pattern and severity. Patient records were reviewed for chief complaint, symptom duration, ten-item voice handicap index (VHI-10) and reflux symptom index (RSI) scores. MANOVA was used to compare symptom duration, VHI-10 scores, and RSI scores between those patients with and without abnormal pharyngeal pH studies.

RESULTS: 72 studies (43%) were normal with zero events below pH 5.5. 59 studies (35%), or 60% of all positive studies showed nocturnal pharyngeal reflux only. 34 studies (20%) showed combination upright daytime reflux events and nocturnal reflux. Five studies (2%) had only upright events. There was no significant difference in presenting symptoms, symptom duration, or severity scores in the patients that had negative vs. positive pharyngeal pH studies.

CONCLUSION: 24-hour pharyngeal pH study eliminates the diagnosis of reflux in a significant percentage of patients with hoarseness. Severity or duration of symptoms of hoarseness, globus, or throat clearing do not reliably predict presence of reflux.

Novel methods of ambulatory physiologic monitoring in patients with neuromuscular disease.

Chris Landon, MD, FAAP, FCCP, CMD. Pediatrics 2009;123:S250–S252.

This is a summary of the presentation on novel methods of ambulatory physiologic monitoring in patients with neuromuscular disease, presented as part of the program on pulmonary management of pediatric patients with neuromuscular disorders at the 30th annual Carrell-Krusen Neuromuscular Symposium on February 20, 2008.

RESULTS: Subject 5 was withdrawn after 60 days because of reluctance to follow the measurement and intervention protocol, and subject 8 withdrew after 30 days because of anxiety. Both subjects had excessive sweating at night, which led to difficulties in maintaining the EEG leads. Each individual served as his or her own control. Median respiratory rate over 24 hours improved by 10% within 1 month, and improvement was sustained at the 3-month exit evaluation. Sleep latency and sleep organization parameters of slow-wave sleep, low delta, theta, and alpha activity, showed continuous improvement over the 90-day trial. One patient had an aspiration-related pneumonia during the 90-day study, with a return to improvement from baseline after resolution of the pulmonary exacerbation.

CONCLUSIONS: It is my hope that, with a source of funding for home sleep testing, the expanded data set available to the NMD clinician will become part of the standard of care in assessing epidemiology, progression of disease, and the impact of current and new therapies.

Oropharyngeal pH monitoring for the detection of extraesophageal manifestations of gastroesophageal reflux in children.

Tyler M. Burpee, MD, Dennis L. Christie, MD. J Pediatr Gastroenterol Nutr, Vol. 49, Suppl 1, 2009.

BACKGROUND and AIMS: Verification of gastroesophageal reflux (GER) as the cause of extraesophageal symptoms is challenging. The Restech Dx-pH pharyngeal probe can measure both liquid and aerosolized pH in the pharynx. Our aim was to assess the tolerance of this probe in children and to gain pilot data of the correlation between pharyngeal acid exposure and upper respiratory and oropharyngeal complaints.

METHODS: We performed 24-hour oropharyngeal pH monitoring in 27 children (aged 15 months to 16 years) with extraesophageal complaints suspected to be due to GER, including dental enamel erosions (n¼7), chronic sinusitis (n¼5), vocal hoarseness (n¼1), and chronic lung disease (n¼14) (Table 5). Noted GER symptoms included regurgitation, vomiting, heartburn, and upper abdominal pain. Based on published Restech Dx-pH adult normal values, reflux events were defined as a pH drop below 5.5 when upright and below 5.0 when supine. Number and duration of events and percent time in reflux were calculated. As pediatric values are lacking, published adult discriminatory values were used to determine those with an abnormal pharyngeal pH environment.

RESULTS: The probe was well tolerated in all 27 patients. The number of children with increased pharyngeal acid in each complaint group, stratified by the presence or absence of GER symptoms, is displayed below.

CONCLUSIONS: The Restech Dx-pH oropharyngeal probe is well tolerated in children. The presence or absence of GER symptoms is not predictive of pharyngeal acid exposure, and pharyngeal acid does not always explain upper respiratory and oropharyngeal complaints. Further studies, including normative pH values, are needed in children.

Dx-pH monitoring: How does it compare to the standard pH probe?

Farnoosh Farrokhi, MD, Eric M. Hill, MD, George Sun, MD, Sean P.Casey, MD, Milton O. Ochieng, Gregory D. Ayers, BS, Michael F. Vaezi, MD, FACG. American Journal of Gastroenterology. Vol. 102, No. S2, 2007.

PURPOSE: Physiologic assessment of esophageal acid exposure is often performed utilizing ambulatory pH monitoring. Recently ambulatory Restech Dx-pH probe is designed to record pH changes in the oropharynx in patients with suspected extraesophageal reflux symptoms. However, there are no validations of this instrument against the current standards in clinical practice. Thus, we aimed to compare the internal consistency of the new distal esophageal Dx-pH probe with the standard of care Sandhill pH probe.

METHODS: Patients diagnosed with GERD (esophagitis at endoscopy or prior abnormal pH findings of acid suppressive therapy) underwent simultaneous ambulatory esophageal pH monitoring. The Dx-pH and Sandhill pH probes were positioned at 5 cm above the manometrically measured LES in each patient. Based on the inherent property of the devices, Dx -pH monitor recorded esophageal acid exposure every 0.5 seconds compared to a 5 second interval for the Sandhill probes. Outcomes assessed included episodes below pH 6, pH 5, and pH 4 and % time below pH 4, 5, and 6. The # times that pH fell below the cutoff was manually and electronically measured. The values were compared using the Wilcoxon signed rank test on the differences in the paired data.

RESULTS: A total of 11 patients (5 male and 6 female) with mean (range) age of 40.9 (21–59) constituted the study population. 72.7% and 45.4% of the patients were complaining of daily heartburn and regurgitation, respectively. No statistically significant ($P < 0.05$) differences were found between the Dx-pH and Sandhill devices for the number of times pH < 4, pH < 5, or pH < 6. The Dx-pH probe spent *consistently* more time at pH < 4 ($P = 0.131$), pH < 5 ($P = 0.049$), and pH < 6 ($P = 0.01$) than the Sandhill probe (Table 1.).

Dx-pH catheter vs Sandhill probe performance at different pH cut offs.

Outcomes	Restech (25–75%)	Sandhill (25–75%)	P Value
# Events pH <4	37 (20–53)	34 (17–60)	0.31
% Times pH <4	8.0 (1–15)	6.0 (1–10)	0.13
# Events pH <5	40 (18–55)	46 (31–62)	0.09
% Times pH <5	14.0 (2–29)	13.0 (1–24)	0.04
# Events pH <6	36 (9–62)	41 (15–47)	0.32
% Times pH <6	43.0 (12–56)	23.0 (6–43)	0.01

CONCLUSION: Dx-probe identifies reflux events in the distal esophagus similar to current standard pH catheter but it has less variability. The clinical potential of this diagnostic device will need to be tested in patients with extraesophageal GERD.

Gastroesophageal reflux disease in bronchial asthma: A preliminary report from a developing country.

C. Onyekwere, O. Adeyeye, A. Ogbera. Canadian Association of Gastroenterology. 2010 Abstracts.

AIMS: 1) To determine the prevalence of symptomatic GERD among a population of known bronchial asthma patients and non asthmatic control matched for age and sex. 2) To document endoscopic findings in the patients found to have GERD and compare asthma severity in those asthmatics with and without GERD. 3) To determine GERD prevalence in the study subjects with and without obesity.

METHODS: The subjects were diagnosed Asthmatics attending clinic at a University teaching hospital. Consecutive asthmatics were enrolled into the study after due consent. The control subjects were non-asthmatics and consisted of hospital workers. They were randomly recruited to match the asthmatics for age and sex. Ethical approval was obtained before commencement of the study in September 2007. An interviewer administered validated GERD questionnaire (F-scale) 1 was used. Subjects' biodata, anthropoiemetric indices as well as their pulmonary function results were documented. Patients found to have GERD (F-scale score> 7) were invited to undergo a 24 hour PH study using a new Oropharngeal PH probe (RESTECH) as well as an upper gastrointestinal endoscopy examination. All data were collated and analysed using Microsoft SPSS software package.

RESULTS: Ninety-eight Asthmatics (mean age (SD) 39.8years (17) and male: female ratio of 1:1.5), and 78 control (mean age (SD) 34years (12) and M: F ratio of 1:1.8) were studied.16 (16%) Asthmatics and 11 (16%) controls had a BMI > 30. The prevalence of symptomatic GERD in asthmatics and controls was (42%) and (35%) respectively; the difference was significant (chi square 52.68, p<0.01). Among the asthmatics 69 had abnormal PEFR while it was normal in 15. Of those with abnormal PEFR, 27 (39%) had F scale > 7 while in remaining 42 (61%) F scale was less than 7.

The duration of asthma diagnosis ranged from 1month to 40 years; mean (SD) 7.8years (10).The asthma duration was short (<5years) in 43, medium (<10 years) in 12, and long duration (>10) in 39. F scale > 7 was noted in 13 (30%) with short duration, 6 (50%) medium duration, and 22 (56%) long duration of asthma diagnosis. 10 (37%) of obese subjects (BMI>30) had F -scale >7 while 28 (35%) of non-obese subjects had F scale > 7. The difference was significant (chi square 203, p<0.001.

CONCLUSIONS: The study has shown a significant higher prevalence of symptomatic GERD among asthmatics than a control with obese patients having a higher prevalence than non-obese. Among asthmatics, GERD prevalence appears to be related to the duration of asthma rather than severity as measured by PEFR. The symptom survey are corroborated by endoscopic as well as PH assessment. Further studies on the mechanisms underlying GERD in asthma as well as trial of antisecretory drugs in asthmatics are required.

Treatment of extraesophageal reflux with nasal CPAP in patients with obstructive sleep apnea.

Vichaya Arunthari, MD, Ernest A. Waller, MD, Paul A. Fredrickson, MD, Siong-chi Lin, MD, Pablo R. Castillo, MD, Kenneth R. DeVault, MD, Michael G. Heckman, MS, Nancy N. Diehl, Augustine S. Lee, MD, Joseph Kaplan, MD. Mayo Foundation for Medical Education and Research, 2010.

INTRODUCTION: Nocturnal gastroesophageal reflux disease (GERD) resulting in extraesophageal reflux (EER) may contribute to airway inflammation and worsen obstructive sleep apnea (OSA). Conversely, OSA may aggravate nocturnal EER. We hypothesize that patients with OSA and GERD are at an increased risk for nocturnal EER and that continuous positive airway pressure (CPAP) will lead to its reduction.

METHODS: Consecutive patients with GERD were enrolled if they required a polysomnography (PSG) for suspected OSA. All patients were tested off acid-suppressive medications. Each patient completed a 2-day diagnostic and therapeutic PSG with continuous monitoring of aerosolized pH by a probe placed into the posterior oropharynx through the nares. Wilcoxon signed-rank test was used to analyze paired data on the rate of EER before and after CPAP. Kendall's Tau coefficient was calculated to determine whether any improvement in the EER as a result of CPAP correlated with the baseline severity of EER.

RESULTS: 8 subjects were enrolled. All were confirmed to have OSA with a median apneahypopnea index (AHI) of 54, improving to 6 on CPAP (p=0.008). The severity of EER at baseline was variable with a median reflux rate of 6 (IQR 3.5–23). We observed a non-significant reduction in the EER rate following CPAP (median: 0.8 vs. 0.4 events/hour, p=0.22) in the overall comparison. However, when accounting for the severity of the underlying EER, a statistically significant reduction in EER following CPAP was observed for those with more severe EER at baseline (Tau=0.71, p=0.013).

CONCLUSION: CPAP may be effective in improving moderate to severe nocturnal EER. Its efficacy however is dependent on the severity of the underlying EER. Further prospective study is in need.

Does laryngopharyngeal reflux cause intraoral burning sensations? A preliminary study.

Sven Becker, Christine Schmidt, Alexander Berghaus, Uta Tschiesner, Bernhard Olzowy, Oliver Reichel. Eur Arch Otorhinolaryngol. 2011.

Intraoral burning sensations are a common problem in the otolaryngological practice. The aim of this study was to evaluate if laryngopharyngeal reflux can cause intraoral burning sensations by measuring oropharyngeal acid reflux. Patients with recurring intraoral burning sensations underwent oropharyngeal pH monitoring in our outpatient clinic. The pH catheter was placed at the level of the uvula. The catheter contained an externally worn transmitter, which wirelessly sent the data to a monitor. In addition, patients were instructed to indicate meals or the occurrence of burning sensations by pressing provided buttons on the monitor. Corresponding events of burning sensations and a significant decrease in oropharyngeal pH values should be visualized. Twenty-two patients suffering from recurring intraoral burning sensations underwent oropharyngeal pH measurement for 21–25 h. We could find oropharyngeal reflux episodes in 11 patients. However, we could not detect any episodes of burning sensations in the mouth corresponding with a decrease in oropharyngeal pH values. Our results suggest that there is no causal connection between LPR episodes and the occurrence of intraoral burning sensations in the examined patients. Although further studies with more patients are necessary in the future, we conclude from our findings that recurring intraoral burning sensations are not an indication for proton pump inhibitor therapy.

Reflux in head and neck cancer patients after chemoradiation.

Allis H. Cho, MD, Ellen Lewis, NP, Cherie-Ann O. Nathan, MD. COSM Presentation, 2010.

OBJECTIVES: To determine if reflux is increased in laryngohypopharyngeal cancer patients who have had radiation (XRT) ± chemotherapy compared to non-radiated patients.

DESIGN: Prospective study **SETTING**: State University Hospital

PATIENTS: Twelve patients with advanced head and neck cancer were evaluated for reflux events using a nasopharyngeal 24 hour pH probe in the last year. Three patients had XRT ± chemotherapy as primary treatment and nine patients were newly diagnosed and treatment was not yet initiated before the pH probe reflux study was performed. There were no patients on reflux medications at the time of the pH probe study except one patient who still had considerable reflux despite the medication.

MEASURES: Ryan scores measuring positive reflux events.

RESULTS: The majority of patients had laryngeal cancer (83%). All patients who were treated with XRT ± chemotherapy primarily had significant reflux as indicated by considerably higher Ryan scores (mean of 547.42 ± 303.59 upright) compared to those who did not have XRT ± chemotherapy (mean of 37.42 ± 63.70 upright) (p=0.0004). Two of the three patients treated primarily with XRT ± chemotherapy had reflux in upright and supine positions, while one patient only had reflux in the upright position. Four of the nine nonradiated patients had reflux only in the upright position, and no one had reflux in the supine position. The mean supine Ryan scores of patients treated with XRT ± chemotherapy was 27.88 ± 35.41 compared to 2.88 ± 1.23 in nonradiated patients (p=0.0398).

CONCLUSIONS: This preliminary study demonstrated that XRT ± chemotherapy caused significant increase in Ryan reflux score compared to non-radiated patients. Given that XRT causes xerostomia and the absence of the neutralizing affect of bicarbonate in the saliva, we believe that XRT causes a significant increase in LPR. Although this is a pilot study and the numbers are still small, the results are striking and there is no objective data in literature linking XRT to reflux at this time.

Histologic vs pH probe results in laryngopharyngeal reflux.

Thomas Andrews, MD. AAO-HNSF Presentation, 2011.

OBJECTIVE: Laryngopharyngeal reflux (LPR) is well documented in children. However, methods of obtaining accurate diagnosis are controversial. As a prelude to establishing normative values in children, we retrospectively reviewed comparison data of 63 consecutive children tested by pH probe and post-cricoid biopsy.

METHOD: Sixty-three consecutive patients with symptoms of reflux without evidence of sinusitis, allergic rhinitis, or adenoid disease were studied by pH probe (Restech Dx Measurement System, San Diego, California) simultaneous with posterior cricoid biopsy (our previous diagnostic method). All testing was done through outpatient ambulatory surgery under general anesthesia.

RESULTS: Of the 63 total patients (age 6 months-17 years), 37 (60%) were positive for reflux by probe with a negative biopsy. Eleven (17%) tested negative to probe and biopsy. Ten (15%) were excluded (pulled probe). Five (8%) were positive by probe and biopsy.

CONCLUSION: Normative values in children have not been determined in this instrument. We believe it may offer a satisfactory diagnostic tool. These results, and previous studies, suggest that pH probe testing is superior to histologic diagnosis in determining LPR. However, normative values must be determined in children prior to further comparative studies.

The effect of singing on laryngopharyngeal reflux.

Daniel Steven Fink, MD; Sugam Bhatnagar; Phillip Song, MD; Glenn Bunting, MS. AAO-HNSF Presentation, 2011.

OBJECTIVE: While there has been widespread conjecture regarding the role of laryngopharyngeal reflux in singing, there remains no objective data demonstrating that voice use causes increased reflux. We attempted to objectively analyze pharyngeal pH changes during singing to better understand how it is affected by singing.

METHOD: Eight singers underwent 24-hour pharyngeal pH probe testing with the Restech Dx-pH Measurement System™, one hour of which was spent singing. The mean pH and number of pH drops were recorded. A one-tailed t test was used to compare the mean pH of the time singing with the 2 control values.

RESULTS: The mean pH for the control time was 6.8347, for the control time without the time supine was 6.9164, and for the time singing was 7.0286. We were thus able to reject the null hypothesis that singing decreases laryngeal pH ($P = .035$). There was an increase in mean pH during the time singing as compared with the 2 control groups.

CONCLUSION: While singers may have increased reflux complaints, our data suggest that the singing itself does not cause an increase in acid exposure to the laryngopharynx.

The value of routine pH monitoring in the diagnosis and treatment of laryngopharyngeal reflux.

Michael Friedman, Craig Hamilton, C.G. Samuelson, and Kanwar Kelley. AAO-HNSF Presentation, 2011.

OBJECTIVE: 1) Report the accuracy of subjective Reflux Symptom Index scores (RSI) and objective Reflux Finding Scores (RFS) in identifying patients with laryngopharyngeal reflux (LPR) using ambulatory pH monitoring as confirmation. 2) Present clinical recommendations for the use of subjective and objective tools in the diagnosis of LPR.

METHOD: Retrospective chart review of 300 adult outpatients from January 3, 2009 to December 30, 2010 in a tertiary care setting. Patients with a diagnosis of LPR based on abnormal RSI and positive findings on laryngeal endoscopic examination using RFS were tested for confirmation with a 24-hour oropharyngeal pH study using the Restech Dx-pH system.

RESULTS: Among 300 consecutive patients with an RSI score >5, 58.6% were confirmed to have reflux after undergoing 24-hour oropharyngeal pH-monitoring. Of these 300 patients, 146 had an RFS score >5. Among patients with a RSI >5 and a RFS 5 and RFS >5 the positive predictive value (PPV) increased to 71.9% (105 of 146). Therefore, when combined, an RSI >5 and RFS >5 yields significantly higher PPV than RSI alone.

CONCLUSION: Patients with clinical signs and symptoms of LPR based on RSI alone do not demonstrate significant positive predictive value when confirmed with oropharyngeal pH testing, but predictive value is increased greatly when RSI and RSF are combined.

Detecting reflux in adults with Eustachian tube dysfunction.

Joseph D. Brunworth, MD; Hamid R. Djalilian, MD; Rohit Garg, MD. AAO-HNSF Presentation, 2011.

OBJECTIVE: 1) Ascertain whether adult patients with Eustachian tube dysfunction (ETD) have a higher incidence of reflux into the nasopharynx compared with controls. 2) Utilize recent advances in pH probe technology to detect acidity at the Eustachian tube orifice for direct comparison.

METHOD: A prospective study was performed on 38 adult patients in an outpatient setting between November 2009 and February 2011. Seventeen patients with Eustachian tube dysfunction and 21 control subjects had a Dx-pH probe (Restech, San Diego, California 2006) placed near the torus tubarius in the posterior nasopharynx for 24 hours.

RESULTS: The average pH value obtained from the nasopharynx of adults with no history of ETD was 7.03 (range, 6.10-7.92; SD, 0.69). In comparison, the average pH for patients with ETD was 6.90 (range, 5.33-8.06; SD, 0.77). This P value for this difference was .48. The average number of reflux events for subjects was 0.55 events over a 24-hour period for controls and 2.1 for patients with ETD. Decreases in pH were considered reflux events if the pH dropped below 5.5 while in the upright position or below 5.0 in the supine position.

CONCLUSION: By utilizing a novel pH probe that allows detection of acidity in a non-liquid environment, a comparison of nasopharyngeal pH between control patients and those with ETD was performed. A trend toward higher numbers of reflux events was found in patients with ETD when compared to control subjects.

Gastroesophageal reflux (GER) presenting with obstructive sleep apnea syndrome – Arousal-related activity in excessive daytime sleepiness (EDS).

E. Briese, W. Böhning, G. Glattki, and C. Schaudt. German Society for Sleep Research and Sleep Medicine annual meeting, 2010.

BACKGROUND/ OBJECTIVE: The excessive daytime sleepiness (EDS) with snoring is a core symptom of obstructive sleep apnea syndrome (OSAS). There is however, only a low correlation between the severity of the OSAS and EDS. Resulting from symptomatic GER compounded by arousals, poor sleep quality (s. Lit. 1). EDS, snoring and GER are positively correlated (s. Lit. 2). Asymptomatic GER leads to arousals with insomnia (s. Lit. 3). Can possibly the increased arousal activity explained by the different GER characterizes her EDS in OSAS?

METHODS/PATIENTS: 11 patients (10 men, 1 woman, mean age 46 J (23-74), BMI m 29 (25-39) for the investigation of SRBD after previous outpatient testing were introduced to the SL. Stationary PSG (Alice-V system, Heinen & Loewenstein) evaluated manually AASM with simultaneous and time-synchronous oropharyngeal pH monitoring (Laryngopharyngeal Reflux Measurement, Restech Dx-pH, pH <6, > 5 ', > 5% ↓).

Outpatient Sleep Center Sleep vigilance parameter:

• Epworth Sleepiness Scale (ESS): > 8

• Pupillographic sleepiness test (PST): Pathologic

• Vigilance Quatember-Maly 30 minutes: PR <32

EXCLUSION CRITERIA: Despite pathological Printing and sued EDS unobtrusive vigilance. Symptomatic GER. Taking PPIs. Poor cooperation. Intolerance of the LPR.

CONCLUSIONS: LPR is a frequent event in saturated OSAS. The monopolar method esophageal endoscopy the 2-channel technology superior (s.Abb.3). Reflux events generate a high number of arousals. The CAP-arousals are obvious characteristic of reflux dependence (S.Lit.4). The lengths of reflux episodes leading to arousals lead differ greatly. Short-pH events do not lead conclusively to an arousal. At EDS, with only mild obstructive sleep apnea syndrome (UARS) is to note the form of arousal. A negative reflux history with CAP-arousals which pH monitoring is indicated. In addition to the CPAP therapy is discussion of aggressive use of PPI.

Evaluation of laryngopharyngeal reflux in pediatric patients with asthma using pharyngeal pH-monitoring: The impact of a new technique.

A. Banaszkiewicz, L. Dembinski, A. Zawadzka-Krajewska, M. Dziekiewicz, P. Albrecht, M. Kulus, A. Radzikowski. Advances in Pneumology conference, Bonn, Germany, 2011.

OBJECTIVE: There is constant discussion about the association between asthma and gastroesophageal and/or laryngopharyngeal reflux. Pharyngeal pH-monitoring is a new technique that allows a physician to check whether reflux really crosses the upper oesophageal sphincter barrier. The aim of the study was to assess the prevalence of laryngopharyngeal reflux (LPR) in children with difficult-to-treat asthma.

METHODS: This was an open, prospective study. All patients were asked to fill out a Reflux Symptoms Index questionnaire. In all children, 24-hour pharyngeal pH monitoring was performed using the Dx-pH Measurement System. LPR was diagnosed on the basis of abnormal values in the composite score (RYAN Score), according to the DeMeester criteria. To verify the hypothesis that the reflux is present in 56% to 68% of asthmatic patients, a sequential test was used.

RESULTS: A total of 21 subjects (mean age of 12.74 years old) were enrolled in the study. Laryngopharyngeal reflux was diagnosed in 13 (61.9%) children. The prevalence of LPR was between 56% and 68%. No association was found between the diagnosis of reflux and anthropometric data, spirometry results, age of asthma diagnosis and total IgE level. There was a positive correlation between LPR diagnosis and the degree of asthma control (77% vs. 12.5% at the 4th step of asthma treatment, p=0.0121). LPR was more frequent in higher fluticasone dose users as compared with lower dose users (p=0.01977, OR=17.27) and in montelukast users as compared with nonusers (p=0.0075, OR=19). The mean Reflux Symptoms Index score was almost two times higher in patients with reflux as compared with those without reflux (13.2 vs. 6.75, respectively, p=0.00337).

CONCLUSION: The prevalence of laryngopharyngeal reflux in children with difficult-to-treat asthma is high (between 56% and 68%).

Identifying the causes of reflux events and symptoms – New approaches.

M. Fox. Aliment Pharmacol Ther 2011.

Gastro-oesophageal reflux disease (GERD) is present if the passage of gastric contents back into the oesophagus causes either mucosal disease or symptoms. The aim of clinical investigation in patients with suspected GERD is not only to establish the diagnosis, but also to identify underlying pathology and guide specific management. Unfortunately, standard endoscopy and physiological measurement of oesophageal function by manometry and ambulatory pH measurement rarely meet these ideals. The need to improve clinical management of patients, especially those with endoscopy negative disease and symptoms persisting during acid-suppressive therapy has refocused attention on the pathophysiology of disease. This review summarises new approaches and new technologies that have been introduced for the investigation of GERD. These include high-resolution endoscopy, detection of dilated intercellular spaces on histology, combined pH impedance studies, prolonged wireless pH monitoring, detection of aerosolized acid in the pharynx, detection of pepsin in expectorated saliva, measurement of gastro-oesophageal distensibility and monitoring of gastro-oesophageal function after a meal by high-resolution manometry. The potential role of these advances to improve clinical practice is considered. Throughout, emphasis is given to the need to identify underlying causes of reflux events and symptoms and how the findings of investigation could be used to guide rational and effective treatment.

Reflux revisited: Advancing the role of pepsin.

Karna Dev Bardhan, Vicki Strugla, Peter W. Dettmar. International Journal of Otolaryngology. 2012.

Gastroesophageal reflux disease is mediated principally by acid. Today, we recognise reflux reaches beyond the esophagus, where pepsin, not acid, causes damage. Extraesophageal reflux occurs both as liquid and probably aerosol, the latter with a further reach. Pepsin is stable up to pH 7 and regains activity after reacidification. The enzyme adheres to laryngeal cells, depletes its defences, and causes further damage internally after its endocytosis. Extraesophageal reflux can today be detected by recognising pharyngeal acidification using a miniaturised pH probe and by the identification of pepsin in saliva and in exhaled breath condensate by a rapid, sensitive, and specific immunoassay. Proton pump inhibitors do not help the majority with extraesophageal reflux but specifically formulated alginates, which sieve pepsin, give benefit. These new insights may lead to the development of novel drugs that dramatically reduce pepsinogen secretion, block the effects of adherent pepsin, and give corresponding clinical benefit.

Oropharyngeal pH evaluation to determine the presence of airway reflux in asthmatic patients.

W. Jackson, J.M. Burke, and A.H. Morice. European Respiratory Society Congress, 2011.

INTRODUCTION: Reflux disease can affect the tracheobronchial tree directly, this has been shown to lead to aspiration, until recently pharyngeal pH measuring detects only liquid reflux. A new pharyngeal probe which detects not only liquid acid but more importantly aerosolized acid has been shown to overcome the artifacts that occur in measuring pharyngeal pH with existing oesophageal catheters and it is now commercially available to measure LPR. It is the 'Restech® Dx-pH measurement system' (Respiratory Technology Corporation, San Diego, California, USA). Prior to the introduction of this system, identifying gastroesophageal reflux as a potential origin of certain respiratory complaints using an accurate, real-time measurement of airway pH was not possible.

PURPOSE: To evaluate the presence of gaseous airway reflux in physician diagnosed asthmatic patients, utilising the 'Dx-pH Measurement System'. The Dx-pH probe can detect the pH of aerosolized droplets and liquid.

METHOD: Asthmatic patients with symptoms assessed on the Hull Airway Reflux Questionnaire (HARQ) underwent 24-hour airway pH monitoring with the Dx-pH measurement system. The probe was inserted transnasally in to the oropharynx with the distal end sitting lateral to the uvula. A Ryan score (composite pH score for pharyngeal acid exposure) was calculated for both the upright and supine periods. In the upright period, 5.5 is the best pH threshold to define abnormal acid exposure, while pharyngeal acid exposure is considerably higher in the supine period and a lower threshold is necessary. For the supine period, pH <5.0 maximizes sensitivity and pH < 4.5 maximizes specificity. The 'Ryan Score' was developed and has been incorporated into Restech's pH data analysis software. The values obtained can now be used to determine if patients with laryngeal or respiratory symptoms have abnormal pharyngeal acid exposure.

RESULTS: The study population consisted of 12 asthmatic patients (1 male, 11 female) with a mean age of 50 (range 33-72). Ryan score values for the upright period were 2.12 - 612.57 (normal <9.41) and for the supine period were 2.17 - 38.01 (normal <6.80). The mean Hull Airway Reflux Questionnaire score was 32/70 (normal <13). Airway reflux was present, confirmed by an abnormal Ryan score in 75% of the study population in the upright position and 58% in the supine position.

CONCLUSION: Airway reflux is a frequent condition in asthma patients. It should be recognized as a distinct entity that warrants specialized focus and treatment to improve the symptoms of patients suffering with extraesophageal reflux and asthma. The Dx-pH probe is a useful diagnostic tool for patients with asthma and symptoms suggestive of airway reflux.

Extraesophageal reflux. Overview and discussion of a new method for pH monitoring.

M. Jungheim and M. Ptok. HNO Journal, 2011.

BACKGROUND. Extraesophageal reflux disease often requires diagnosis and treatment by a phoniatry or ear, nose and throat specialist. The disease needs to be differentiated from gastroesophageal reflux disease.

OBJECTIVE. A new oropharyngeal pH mea-suring system with a single channel probe has recently been introduced. The aim of this study was to compare oropharyngeal pH-metry with the existing diagnostic methods for extraesophageal reflux disease and to pres-ent initial results in our own patients.

METHODS. A literature search for oropharyngeal pH-metry was performed in the data-bases NHS EED, HTA, DARE, Clinical trials, Co-chrane reviews and Medline/PubMed. A selective literature search was also carried out on the problem of extraesophageal reflux disease.

RESULTS. Evaluation scales, trial proton pump inhibitor therapy or pH-metry, for example, can be used to diagnose extraesophageal re
flux disease. pH-metry can be performed using a classical two -channel pH-metry system; a new oropharyngeal pH measuring sys-tem has recently been introduced. This new method has been evaluated in initial studies for normative data and has been compared to two-channel pH-metry. Prospective randomised studies to diagnose extraesophageal reflux disease with the new oropharyngeal pH-metry method are still lacking.

DISCUSSION. Oropharyngeal pH-metry has some potential advantages compared to classical two-channel pH-metry; however, a lot of questions remain unanswered. These will be discussed and illustrated with the help of a number of own patient case reports.

First Direct Comparison of Pharyngeal pH Monitoring with Combined pH/Impedance Monitoring in Patients with Suspected Laryngopharyngeal Reflux

Valentin Becker, Alexander Meining, Simone Graf, Florian Durst, Roland M. Schmid, Monther Bajbouj. Gastroenterology, May 2011.

BACKGROUND The origin of laryngopharyngeal reflux (LPR) is unclear. It might be caused by pharyngeal acid exposure and it is thought to be associated with Gastroesophageal Reflux Disease (GERD). To objectify atypical symptoms of

GERD currently the combination of pHmetry and impedance monitoring (pH/MII) seems to be the most sensitive method. However, a recently developed method using a pH measurement system probe which is placed in the oropharynx without passing the upper sphincter of the esophagus (Dx-pH Catheter, Restech, San Diego, USA) allows to measure pH values in the aerosolized environment of the nasopharynx. The aim of this study was primarily to measure the reproducibility of the new Dx-pH device and secondly to compare it with pH/MII in patients with suspected LPR for the first time.

METHODS In a total of 20 patients with oropharyngeal symptoms suspicious for an atypical GERD Proton Pump Inhibitors were stopped for at least 7 days. All patients were examined by using a reflux finding score (RFS). Thereafter pH/MII and a pharyngeal ph monitoring were applied simultaneously. After removal of the 2 probes the next day a single Dx-pH-measurement was performed. All functional tests lasted for at least 22 hours. pH/MII was regarded as pathological if pH dropped below 4 in more than >4% of the recorded time and/or >73 mixed reflux episodes occurred. Dx-pH-measurement was pathological if the Ryan Score was <9.4 in an upright position or <6.8 in a supine position.

PATIENTS AND RESULTS All patients had pathological findings in RFS. The results of the 1st Dx-pH-measurement were verified in the following pharyngeal pH-metry in 14/20 (70%) patients. Hence, at 2 consecutive days, pharyngeal measurement had a good concordance in the same patient.

However, 11/20 (55%) patients had pathological values derived from Dx-pH, whereas pH/MII showed pathological findings in only 5/20 (20%) patients. Overall only 6/20 (30%) results matched with findings in pH/MII.

CONCLUSION Dx-pH-measurement showed satisfying reproducibility on two consecutive days. However, the pathological results of pharyngeal pH monitoring acquired in this case series were not connected to pathological reflux episodes of GERD in most cases. Potentially, other acid producing or acid retaining factors despite from GERD are accountable for atypical reflux symptoms. This should be subject of further studies.

Relationship between gastro-oesophageal reflux and airway diseases: The airway reflux paradigm.

Adalberto Pacheco-Galván, Simon P. Hart, Alyn H. Morice. Arch Bronconeumol. 2011.

Our understanding of the relationship between gastroesophageal reflux and respiratory disease has recently undergone important changes. The previous paradigm of airway reflux as synonymous with the classic gastro-oesophageal reflux disease (GORD) causing heartburn has been overturned. Numerous epidemiological studies have shown a highly significant association of the acid, liquid, and gaseous reflux of GORD with conditions such as laryngeal diseases, chronic rhinosinusitis, treatment resistant asthma, COPD and even idiopathic pulmonary fibrosis. However, it has become clear from studies on cough hypersensitivity syndrome that much reflux of importance in the airways has been missed, since it is either non- or weakly acid and gaseous in composition. The evidence for such a relationship relies on the clinical history pointing to symptom associations with known precipitants of reflux. The tools for the diagnosis of extra-oesophageal reflux, in contrast to the oesophageal reflux of GORD, lack sensitivity and reproducibility. The original methods for measuring pharyngeal pH were not quite right due to technical problems, such as the drying out of the catheter and the accumulation of mucus and food. The Dx-pH measuring system (Dx-pH; Restech Corporation, San Diego, CA) is a highly sensitive and minimally-invasive device for detecting acid reflux in the posterior pharynx. This sensor detects aerosolised or liquid acid, resists drying out and its electrical continuity is not impeded by the contact of liquids or tissues. Ayazi S et al. have shown the characteristics of mean pH in the oropharynx of healthy subjects using the Dx-pH catheter. The pharyngeal pH score (RYAN) for abnormal pH (limit of 5.5 for standing and 5.0 in supine position) has been calculated in a way similar to the DeMeester oesophageal score. Furthermore, an alternative scoring system has been developed based on the changes in pH. Wiener et al. compared traditional 24-hour pharyngo-oesophageal monitoring with Dx-pH monitoring in 15 patients with extra-oesophageal symptoms. All the events measured with the Dx-pH method were preceded by and associated with falls in distal oesophageal pH in a progressive anterograde manner. However, oropharyngeal studies with the Dx-pH catheter showed a growing pH gradient from the distal oesophagus to the oropharynx. The oropharynx usually presents a mildly acidic pH, rarely with a pH less than 4. This could help explain why the previous attempts at distinguishing normal subjects from the subgroup of patients with atypical symptoms using quantitative cut-values of pH < 4 have not been reliable.

Laryngopharyngeal Reflux in patients with persistent hoarseness

Andrzej Dymek, Lucyna Dymek, Liwia Starczewska-Dymek, Andrzej Bozek, Tomasz Dymek, Krzysztof Nowak. Polish Otolaryngology, January-February 2012.

INTRODUCTION: In 2006 the Global Consensus Group in Montreal confirmed that reflux laryngitis is evidence-based related with Gastroesophageal Reflux Disease (GERD).

AIM: To evaluate the frequency of LPR in selected group of patients with chronic hoarseness. We were also interested in assessment of the relationship between Reflux Symptoms Index (RSI) scores, Ryan scores from the pharyngeal pH monitoring and the morphological changes in the larynx according to Reflux Findings Score (RFS). In addition, we wanted to assess the frequency of various clinical symptoms included in the RSI questionnaire among patients with LPR.

MATERIALS AND METHODS: 42 patients from an outpatient ENT clinic with chronic hoarseness and RSI ≥13. All subjects underwent pharyngeal pH monitoring with the Dx-pH System Restech™ and laryngoscopy.

RESULTS: Among 42 patients with chronic hoarseness, LPR was confirmed in 35 patients (83.33%). In 7 subjects pharyngeal pH monitoring was normal. Among all patients with confirmed LPR, only 5 out of 8 elements of RFS laryngoscopic changes were found. The most frequent inflammatory changes observed included erythema of the arytenoids and interarytenoid regions (*posterior laryngitis*). These findings were found in 30/35 patients with LPR. Median value of RFS in patients with LPR was 4.45, which is lower than the cut off value of 7 necessary for recognition of LPR. There is statistically significant positive correlation between Ryan scores and the RFS scale results (correlation coefficient 0.91, $p<0.001$).

CONCLUSIONS: Pharyngeal pH monitoring confirmed LPR in 83.33% selected group of patients with chronic hoarseness and RSI 13. Isolated erythema of arytenoid and interarytenoid region was the most frequent inflammatory abnormality found in the larynx. RFS values below 7 do not exclude the diagnosis of LPR. We can use RFS scales as a prognostic test of severity of LPR – due to statistically significant positive correlation between Ryan score and RFS values. The use of RSI scale revealed that the most frequent symptom among patient with LPR was throat clearing followed by hoarseness.

Sinusitis and chronic progressive exercise-induced cough and dyspnea.

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

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-exacerbated respiratory 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.

Lauren C. Anderson, MD, IUSM Dept. Otolaryngology, Indianapolis, IN USA, Samuel L. Oyer, MD, Medical College of South Carolina Dept. of Otolaryngology, Charleston, SC, USA Stacey L. Halum, MD, IUSM Dept. of Otolaryngology, Indianapolis, IN USA

OBJECTIVES: To determine the utility of the new Restech pH-probe 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

Clinical Studies using the Restech *Dx-pH Measurement System™*

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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