GERD at all physiologically). Methods: 296 pts (75% female, 91% Caucasian) with either typical (HB/reg.) (23%) or extra-esophageal (77%) symptom complex (cough-38%, chest pain-30%, hoarseness-22%, asthma-5%, post nasal drip 5%) underwent 48 hour Bravo pH monitoring on week off acid suppressive therapy. % time pH < 4 (total, upright and supine) were measured. Abnormal reflux was defined as % time pH < 4, total > 5.5%, upright > 8.0% and supine > 3.0%. pH profile as well as demographic data (age, gender, BMI) were compared. Results: 216/296 (73%) pts had abnormal esophageal acid exposure: 95/216 (44%) in both upright and supine positions; 82/216 (38%) in the upright only and 39/216 (18%) in the supine only positions. The median (interquartile) number of reflux events was significantly (p<0.001) higher in pts with upright and supine reflux [86 (59 to106)] than those with supine only [52(37 to 73)] or upright only [62 (43 to 93)] reflux pattern. HB and regurgitation were significantly (p=0.03) higher in those with supine only reflux than upright only group. Prevalence of abnormal esophageal acid exposure was similar in those with chief complaint of HB/reg (65%) to those with extra-esophageal symptom's with (54%) or without (68%) concomitant HB/reg. (p=0.3). Conclusions: 1) Reflux disease defined physiologically by abnormal esophageal acid exposure off acid suppressive therapy is common (73%) in pts referred with extra-esophageal symptom's and occurs most commonly in the upright position. 2) The widely held notion that pts with extra-esophageal symptoms without concomitant HB/regurgitation are less likely to have reflux should be re-evaluated.

#### W1070

### Non-Acid Reflux Burden is a Predictor of Bacterial Lung Infections Rachel L. Rosen, Kristen Hart, Mary Warlaumont, Samuel Nurko

Background: A single pediatric study in a general pediatric practice found a higher rate of community acquired pneumonia in patients taking acid suppression therapy. One theory is that non-acid reflux predisposes patients to bacterial overgrowth which results in lung infections. No studies have explored the relationship between non-acid reflux burden and proven pulmonary bacterial or fungal infections diagnosed during bronchoscopy. Methods: We prospectively enrolled 85 children who were not taking acid suppression therapy and were undergoing combined endoscopy, bronchoscopy and pH-MII testing for the evaluation of cough or asthma. We compared the reflux profiles between those patients with positive and negative lung cultures obtained during bronchoscopy. We then performed logistic regression to determine predictors of a positive lung culture. Results: The mean age of patients was 68±43 months. 38% of bronchoscopies grew a single bacterial species from the lung. 16% of bronchoscopies grew yeast or mold. Patients with a positive bacterial culture in the lung had a significantly higher non-acid reflux burden than patients with a negative culture (Table). There were no significant differences in the reflux profiles of patients with and without a positive fungal culture (p>0.09). A positive bacterial culture was associated with a significantly higher percentage of neutrophils (17±15%) in the lung compared to the percentage in patients with negative cultures (11±10%, p=0.04) suggesting that the bacteria presence did not reflect colonization alone. There was no significant difference between the mean lipid laden macrophage index in patients with and without a positive bacterial culture (57±40 versus 52±36, p=0.5). After adjusting for reflux parameters and medication use, non-acid reflux remained a significant predictor of a positive bacterial lung culture (p=0.02) Conclusions: Non-acid reflux may predispose patients to bacterial infections of the lungs.

	Bacterial Culture Positive (N=31)	Bacterial Culture Negative (N=54)	P Value
# Acid Events	25±15	24±15	0.9
# Non-Acid Events	23±18	14±14	0.01
# pH-only Events	7±7	8±7	0.8
Total # Reflux Events	47±23	38±25	0.08
% time pH<4	4.4±5.8	3.9±4.7	0.8
% Full Column Events	27±21	20±19	0.13

## W1071

## Peristaltic Dysfunction in Asthma is Secondary to Increased Gastro-Oesophageal Reflux

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Background: Vagal dysfunction and prolonged intra-oesophageal acidification cause oesophageal hypomotility. Asthmatics have ineffective oesophageal motility, but demonstrate increased vagal activity. Whether oesophageal hypomotility in asthmatics is a primary abnormality or secondary to pathological gastro-oesophageal reflux is unclear. Our aim was to investigate the relationship of oesophageal motility and gastro-oesophageal reflux (GOR)to vagal function in asthmatics. Methods: Thirty consecutive mild, stable asthmatics (ATS criteria) and 30 healthy volunteers underwent 24-hour ambulatory dual-sensor oesophageal monitoring, stationary oesophageal manometry and autonomic function testing. They also underwent gastro-oesophageal reflux disease (GORD) symptom assessment. Twenty seven of the thirty asthmatics underwent gastroscopy. A parasympathetic autonomic function score was calculated from vagal function tests (valsalva manouvre, heart rate variation to deep breathing, heart rate and blood pressure response to standing from a supine position) and correlated with gastro-oesophageal function parameters. Results: Age and sex of asthmatics (mean age(SD), 34.8 years (8.4); 60% female) and controls (mean age(SD), 30.9 years (7.7); 50% female) were comparable. Asthmatics had a higher frequency and severity of GORD symptoms and 10/27 (39%) had oesophageal mucosal damage. Twenty two (69%) asthmatics showed a hypervagal response and none had a hyperadrenergic response. Manometrically, LOS and UOS parameters were similar in the two groups, but 14 asthmatics had ineffective oesophageal motility. Asthmatics with higher GORD symptom scores had a significantly lower percentage of peristaltic contractions and a higher percentage of simultaneous contractions than controls. They also had higher total and upright oesophageal acid contact times in the proximal oesophagus than those with low symptom scores. All reflux parameters were significantly higher in asthmatics. Twenty (66.7%) asthmatics had abnormal distal acid reflux and 22 (73.3%) had abnormal proximal acid reflux. Asthmatics also had significantly prolonged proximal and distal acid clearance times than controls. There was no association between parasympathetic function and either oesophageal motility or reflux parameters. Conclusions: Asthmatics with mild, stable asthma have abnormal oesophageal motility and pathological GOR. The asthmatics did not show any evidence of vagal dysfunction nor did the vagal function score correlate with oesophageal motility parameters. It seems likely that the peristaltic dysfunction is secondary to damage due to GOR and not primary vagal dysfunction.

#### W1072

A Pilot Study Evaluating the Role of Combined Impedance-pH Monitoring in the Evaluation of Asian Patients With Suspected Supra-Esophageal Manifestations of Gastro-Esophageal Reflux Disease (GERD): Establishing the Presence of Acid and Non-Acid Reflux (NAR)

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Introduction: Extra-esophageal manifestations of GERD, including chronic cough, sore throat or positive laryngoscopic findings by an ear, nose and throat (ENT) surgeon are reported to be rare in the absence of typical symptoms of heartburn and regurgitation. Recent studies suggest an association between cough and non-acid reflux (NAR). However, the role of NAR in the genesis of laryngo-pharyngeal manifestatons of GERD has not been well studied. Aim: (1)Assess the yield of intraluminal impedance-pH (MII-pH)monitoring in the evaluation of Asian patients with suspected extra-esophageal GERD in the absence of typical reflux symptoms, and (2)examine the role of acid and NAR in generating extra-esophageal GERD symptoms. Methods: Prospective study of patients referred by ENT surgeons or respiratory physicians for evaluation of possible GERD between January 2009 and October 2009. All patients had a normal baseline gastroscopy. They underwent esophageal manometry and MII-pH monitoring. Data collected included patient demographics, symptom profile, esophageal acid exposure time (AET) based on % total time pH<4.2% and the composite DeMeester score. The association of atypical symptoms and reflux was evaluated by calculating the symptom association probability (SAP)[positive if ≥95%]. Results: Combined MII-pH monitoring was performed in 18 patients (8M, mean age 48.3 ± 15.5) for evaluation of unexplained chronic cough (n=10, 56%), globus (n=4,22%) and sore throat (n=4,22%). Nine (50%) patients had features suggestive of laryngo-pharyngeal reflux (LPR) including vocal cord oedema(n=2) and arytenoids erythema(n=7). All 10 patients who presented with chronic cough had a negative pulmonary evaluation. High esophageal AET and a high DeMeester score was recorded in 3 patients (16.7%), including 2 with chronic cough and 1 with sore throat. A total of 751 reflux events were recorded;347 acid reflux(AR)events (46.2%,range 1-89)and 404 NAR events(53.8%,range7-46). The mean DeMeester score was 8.04 (median 4.35). A positive SAP was recorded in 9(50%) patients, including acid reflux (AR) in 3(16.7%) and NAR in 6(33.3%). MII-pH improved the diagnostic yield in patients evaluated for suspected extra-esophageal GERD by 33%. Conclusion: A high distal esophageal AET is uncommon in patients with only atypical GERD symptoms. In the evaluation of patients with suspected extra-esophageal GERD, adding impedance to pH monitoring increases the diagnostic yield and allows better symptom analysis than pH studies alone. In addition, our preliminary findings suggest that NAR may be involved in the pathogenesis of laryngo-pharyngeal reflux, with therapeutic consequences.

### W1073

# Long-Term, Safe and Effective Treatment of Gastroesophageal Reflux Disease Using a Sphincter Augmentation Device

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BACKGROUND: We have previously demonstrated that laparoscopic placement of the LINX™ bioprosthesis (Torax Medical, Shoreview, MN), at the gastroesophageal junction (GEJ), provides safe and effective GERD therapy on a short-term basis (J Gastrointest Surg 2008). We now extend those observations to 2 year follow-up. METHODS: The LINX device is a series of linked titanium beads with magnetic cores, placed laparoscopically around the GEJ in the region of the z-line. The magnetic bond between adjacent beads augments the lower esophageal sphincter, restoring its barrier function and preventing reflux. With swallowing, belching or vomiting the beads separate to allow bolus, air or fluid transfer across the sphincter. Moreover, magnetic forces are permanent and never decay. PPI-responsive GERD patients with abnormal pH scores, hiatal hernias (HH) 3 cm or less, and esophagitis scores up to LA grade B were enrolled and implanted with the LINX device. GERD-HRQL scores, pH scores, PPI usage, endoscopies, barium swallow studies, esophageal manometries, and CXRs were obtained at baseline, and monitored over 24 months. RESULTS: To date 44 patients (mean age 42.8) have been implanted, with a median duration of 745 days f/ u (range 226-994 days). 39 patients have completed follow-up at 1 year and data is available for 7 patients at 2 years. There were no intra-operative complications and hernias were repaired in only 11% of patients. There have been no observed erosions and no migration of the device. Mild dysphagia was present in the initial post-op period, but resolved in 91% of patients by 6 months. The device was removed uneventfully in 2 patients: one due to persistent dysphagia and the other for a MR study. Mean % time pH < 4 improved from 11.9% to 3.1% (p ≤.001), and DeMeester scores improved from 31.7 to 5.3 (p<.001). 28/ 39 patients (72%) had normal pH scores at 1 year. Median GERD-HRQL scores improved from 26 at baseline to 3.0 at 1 year and 1.0 at 2 years. Endoscopy, barium swallows, and CXRs demonstrated uniform device stability at 1 year with no device-related mucosal injury. Complete cessation of PPI use was seen in 87% of patients at 1 year and 86% at 2 years. Patients reported the ability to belch and vomit. CONCLUSIONS: Restoration of the reflux barrier using the LINX device appears to be a safe, effective, minimally-invasive, longterm GERD therapy. Objective pH scores demonstrate effective acid normalization and the treatment appears to avoid the long-term side effects commonly seen with Nissen fundoplication. The procedure is reversible and preserves the ability to belch and vomit. A large multi-center pivotal trial is currently underway.

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