markedly improved (from 16 to 16 mm) but the DS only mildly improved (from 52 to 50). Discordant results were recorded in two patients. One patient had a 7 mm stricture with DS 61 initially, and at follow up had a 5 mm diameter stricture with improved DS of 12. In the final patient, the initial diameter was 9.8 mm with DS of 39. At repeat EGD the stricture was measured as 16 mm diameter but the DS was the same at 39, and hence, did not reflect improvement. Conclusions: The MDQ-30 can be used in research and clinical practice to calculate a DS that is responsive and demonstrates excellent predictive validity.

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The Relationship Between Nasopharyngeal pH Environment and Gastroesophageal Reflux

Daniel Luger, John E. Pandolfino, Peter J. Kahrilas, Anita Fareeduddin, Monika A. Kwiatek

Background: Laryngopharyngeal reflux may contribute to supraesophageal symptoms such as chronic cough, hoarseness and throat clearing. However, little is known about the extent of acidification of the pharyngeal area and its relationship to gastroesophageal reflux. **Aim:** To determine the correlation between gastroesophageal reflux events detected by multichannel intraluminal impedance-pH (MII-pH) and nasopharyngeal (NP) acidification measured by the Dx-pH systems. **Methods:** 7 controls and 3 patients (5M, 22 - 58 yr) underwent simultaneous monitoring with nasopharyngeal pH (Dx-pH Measurement System™, Restech) and MII-pH (AccuTracpH-Z™, Sierra Scientific Instruments) monitoring systems for an average 16h. The Dx-pH electrode was positioned behind the soft palate. The MII-pH probe measured impedance at 6 locations along the esophagus (3, 5, 7, 9, 15 and 17 cm above the manometrically localized LES) and pH 5 cm proximal to LES. The MII-pH and Dx-pH recordings were sampled at 50 and 2 Hz, respectively. Both electrodes were calibrated at pH 4 and 7. The automated NP reflux detection scheme of Dx-pH DataView™ signaled an event when the pH dropped 10% from a 15 minute running average baseline pH. The 15 min preceding the onset of an NP reflux event was analyzed for presence of esophageal reflux. Esophageal reflux events were defined as pH drop ≥ 1 pH unit and/or retrograde bolus propagation seen on MII. **Results:** Dx-pH tracings typically showed an upright average baseline pH 7 - 7.5 with frequent rapid deviations < 0.5 pH units. Supine tracings showed smooth and gradual pH drops over extended periods with an indistinguishable baseline. The median time NP pH < 5.5 when upright, pH < 5 and 4.5 when supine were 0%, 0.2% and 0%, respectively. Prolonged NP acidification was noted in 3 subjects mainly when supine (pH < 4.5: 70.7%, 21.8% and 4.0%). A total of 37 NP vs. 537 esophageal reflux events were seen in 10 subjects. 2.7% NP events coincided only with a distal esophageal pH drop, while 16.2% and 13.5% NP events coincided with an acidic and weakly acidic impedance event. The remainder 67.6% had no corresponding GER events. **Conclusion:** There is a weak temporal relationship between nasopharyngeal acidification and esophageal acidic or weakly acidic reflux events. This disconnect indicates that nasopharyngeal acidification and esophageal reflux pathophysiology may not parallel each other. The etiology and clinical significance of nasopharyngeal acidification events is unclear and requires further study in the context of detectable esophageal reflux.

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Reflux and Dyspeptic Symptom Patterns in Patients with Non Erosive Reflux Disease (NERD) Subclassified Using 24-Hour Ambulatory Intraluminal pH-Impedance

Edoardo Savarino, Daniel Pohl, Patrizia Zentilin, Giorgio Sammito, Elisa Marabotto, Luca M. Sconfienza, Andrea Parodi, Simone Vigneri, Radu Tutuian, Vincenzo Savarino

Introduction: Patients with abnormal pH-monitoring, esophagitis or Barrett' Esophagus complain more frequently of symptoms such as heartburn, regurgitation and epigastric pain or burning than patients with normal pH-testing. Non Erosive Reflux Disease (NERD) incorporates different subgroups which have been recently differentiated by means of pH-impedance testing (MII-pH). **Aim:** To evaluate differences in reflux and dyspeptic symptoms in different subgroups of NERD patients. **Methods:** We evaluated NERD patients off-PPI therapy using ambulatory 24-hour MII-pH. Refluxate presence was measured at 3,5,7,9,15 and 17 cm and esophageal pH at 5 cm above the LES. We calculated distal esophageal acid exposure time (AET), number of impedance-detected reflux episodes (acid, nonacid) and symptom association probability (SAP). A validated Dyspepsia Questionnaire was used to quantify individual patients symptoms before examination. **Results:** Data from 200 consecutive patients (105F, median age 48yrs) were analyzed. Subgrouping according to AET and symptom characteristics are detailed in table 1. Fifty-four patients with normal AET and negative SAP were classified as functional heartburn (FH) patients. **Conclusions:** The increased prevalence of dyspeptic symptoms in patients with normal acid exposure and negative symptom association further supports classifying these patients in the group of functional esophageal disorders.

Table 1. Reflux and dyspeptic symptoms patterns in NERD patients (n=200)

	pH-POS	pH-NEG/SAP+	pH-NEG/SAP-	*P value*
Symptoms	(n=81)	(n=65)	(n=54)	*Chi-Square*
Patients with heartburn, %	76.5%	80.0%	79.6%	*ns*
Patients with regurgitation, %	50.6% [b]	50.8% [c]	25.9% [b,c]	*<0.01*
Patients with Postprandial Distress Syndrome, %	24.7% [b]	36.9% [c]	63.0% [b,c]	*<0.01*
Patients with belching, %	36.0%	28.0%	30.0%	*ns*
Patients with bloating, %	20.0% [b]	28.0% [c]	54.0% [b,c]	*<0.01*
Patients with nausea, %	14.0% [b]	20.0% [c]	41.0% [b,c]	*<0.01*
Patients with Epigastric Pain Syndrome, %	34.6%	23.1%	22.2%	*ns*

Statistical analysis [b] pH-POS vs. pH-NEG/SAP + p<0.05; [b] pH-POS vs. pH-NEG/SAP - p<0.05; [c] pH-NEG/SAP + vs. pH-NEG/SAP - p<0.05

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A Placebo-Controlled Trial of Visilizumab in Patients with Intravenous (IV) Steroid Refractory Ulcerative Colitis (UC)

William J. Sandborn, Jean-Frederic Colombel, Matthew Frankel, Daniel Hommes, James Lowder, Lloyd Mayer, Scott E. Plevy, Pieter Stokkers, Simon Travis, Gert A. Van Assche, Stephan R. Targan

Aim: To evaluate the efficacy of visilizumab, an antibody against CD3, for the induction treatment of IV steroid refractory UC. Methods: 127 patients with severely active UC despite 5 days or more of IV steroids were randomized to visilizumab 5 mcg/kg (n=84) or placebo (n=43) infusions X 2 days. Patients were converted to oral prednisone 40 mg and tapered according to disease activity. The primary endpoint was induction of response (decrease in the Mayo score of >/=3 points and a decrease in the rectal bleeding score of >/=1 or a rectal bleeding score of 0-1) at day 45. Secondary end-points included remission (Mayo score </= 2 with no individual subscores >1) at day 45, mucosal healing (endoscopy subscore </=1) at day 45, symptomatic response (Modified Truelove and Witts Severity Index score </=9 with a decrease of >/=3 points from baseline) at day 15, prednisone discontinuation, and time to colectomy. Results: The proportion of patients in response at day 45 was 55% with visilizumab and 47% with placebo, p=0.475. The proportion of patients in remission at day 45 was 8% with visilizumab and 9% with placebo, p=0.704. The proportion of patients with mucosal healing at day 45 was 29% with visilizumab and 26% with placebo, p=0.799. The proportion of patients with symptomatic response at day 15 was 82% with visilizumab and 74% with placebo, p=0.244. The proportion of patients who discontinued prednisone was 14% with visilizumab and 21% with placebo, p=0.255. The median time to colectomy could not be calculated, 15 patients (18%) in the visilizumab group and 3 patients (7%) in the placebo group had a colectomy, p=0.130. Among visilizumab treated patients, CD4+ T-cells decreased to a mean of 10 cells/mcL (approximately 90% recovered by day 90). The proportion of patients with serious adverse events was 17% with visilizumab and 16% with placebo. Infections related to study drug in the visilizumab group included herpes zoster 2%, CMV 1%, and oral candidiasis 1%. The proportion of patients with cardiac disorders was 11.9% with visilizumab (including tachycardia 8.3% (likely due to cytokine release syndrome), angina 1.2%, cardiomyopathy 1.2%, myocardial ischemia 1.2%) and 4.7% with placebo (sinus bradycardia 2.3% and sinus tachycardia 2.3%). The proportion of patients with vascular disorders was 22.6% with visilizumab (including phlebitis 2.4%, thrombophlebitis 2.4%, superficial thrombophlebitis 2.4%, deep vein thrombosis 1.2%, vasculitis 1.2%, other 13%) and 4.7% with placebo (other 4.7%). Conclusions: Among patients with IV steroid refractory UC, visilizumab was not effective and was associated with increased infectious, cardiac, and vascular adverse events.

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Supplementation with the Probiotic VSL#3 in Patients with Mild-to-Moderate Active Ulcerative Colitis: A Double-Blind, Randomized, Placebo-Controlled Study

Antonio Tursi, Giovanni Brandimarte, Alfredo Papa, Andrea Giglio, Walter Elisei, GianMarco Giorgetti, Giacomo Forti, Silvio Danese, Antonio Gasbarrini

Background: VSL#3 probiotic mixture has been show to be effective in supporting standard treatments in active ulcerative colitis (UC) in open-label studies. Aims: Primary end-point of the study was to asses the effect of the supplementation of VSL#3 to a standard pharmaceutical treatment in patients affected by active UC, assessed by a decrease in the UC Disease Activity Index (UCDAI) of 50% or more, from baseline to week 8. Secondary end-points were considered: activity of UC, change in subjective symptoms (rectal bleeding and stool frequency), lack of beneficial effects, concordance between the Physician and Patients Global Assessment Scale, from baseline to week 8. Methods: 144 consecutive patients with diagnosis of mild-to-moderate active UC, and already under treatment with stable doses of 5-ASA, were randomly treated for 8 weeks with VSL#3 3600 billion/day (71 pts) or with placebo (73 pts). UCDAI, and Physician and Patients Global Assessment Scale were assessed at baseline and at week 8. Results: 65 pts in VSL#3 group and 66 pts in placebo group completed the study; 4 pts (3 in VSL#3 group and 1 in the placebo group) were lost to follow-up, 3 pts (2 in VSL#3 group and 1 in placebo group) withdrew consent to the study, 1 pt in VSL#3 group was withdrawn for protocol violation, 5 pts in placebo group were withdrawn for lack of efficacy. As regards the primary endpoint, the decrease in UCDAI of 50% or more after 8 weeks was higher in VSL#3 than in placebo group (63.1 vs 42.9, p<0.019). Looking at the secondary end-points, the number of pts who had an improvement in the UCDAI of 3 point or more was significantly higher in VSL#3 than in the placebo group (60.5% vs 41.4%, p<0.031); rectal bleeding improved significantly in VSL#3 than in placebo group (p<0.017); stool frequency did not show statistical difference between the two groups (50.8% vs 42.9%, p=n.s.); Physician and Patients Global Assessment Scale did not show statistical difference between the two groups (p=n.s.). Finally, the number of pts in remission was higher in VSL#3 than in placebo group (47.7% vs 32.9%, p=0.079). Non side-effects were recorded both in VSL#3 and in placebo group. Conclusions: VSL#3 supplementation is safe and able to reduce UCDAI after 8 weeks of treatment use in patients affected by mild to moderate UC. Moreover, VSL#3 improves rectal bleeding and it seems to be able in inducing remission in UC patients after 8 weeks of treatment, though this latter parameter is borderline significant.