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Predictive Validity and Responsiveness of the Mayo Dysphagia Questionnaire-30 for the Outcome of Erosive Reflux Esophagitis

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Background: In a prior study, the Mayo Dysphagia Questionnaire 30 Day (MDQ-30) demonstrated excellent reproducibility (same response when completed more than once) and concurrent validity (concordance between patients' self-reported written responses and information from a physician interview). The characteristics of predictive validity (does a certain score correlate with a particular phenotype at endoscopy?) and responsiveness (do responses to the items on the questionnaire change in the clinical direction one expects?) of the GERD items would be of further utility in clinical trials. Specific Aim: The aim of this project was to assess the predictive validity and responsiveness of the GERD items on the MDQ-30 for erosive reflux esophagitis. Methods: We consistently collected responses to seven standardized GERD items, including proton pump inhibitor (PPI) use, from adult participants in 5 research studies. Cases had erosive reflux esophagitis, controls did not. Patients with esophageal neoplasm, esophagectomy or fundoplication were excluded. Based on the particular research trial, some participants had a follow-up endoscopy and completed a second MDQ-30. To meet criteria for GERD symptoms a respondent must report heartburn (substernal burning pain) at least once per week and have at least one of the following: heartburn awakens them, radiates to the neck and/or improves with antacids. Respondents also meet criteria for GERD symptoms if they reported experiencing acid regurgitation (bitter or sour-tasting fluid that comes up from the stomach into the mouth or throat) at least once per week. Results: 101 cases with esophagitis (LA grades: A = 6, B = 50, C = 20, D = 25) [mean age 60, 55 (54%) male] were compared to 128 controls [mean age 61, 74 (58%) male]. Predictive validity: Participants who met criteria for GERD symptoms were more likely to have esophagitis at EGD compared to asymptomatic controls [OR 6.5 (CI 3.3, 12.7), p<0.001]. The score was more predictive when the participant was not using a PPI, Interaction Coefficient OR 2.9 (CI 1.4, 6.3), p<0.001. The AUC for GERD symptoms was 0.68. Responsiveness: 17 cases (LA grades: A= 1, B=5, C=5, D=6), underwent repeat EGD. In 2 cases, the patient did not have symptoms at baseline, and hence did not reflect change in esophagitis score when healed at follow up. In 8 patients, the esophagitis score improved as anticipated, however in 7 it did not. Conclusions: The MDQ-30 can be used in research and clinical practice to calculate a reflux esophagitis score. The score demonstrates excellent predictive validity for the presence of reflux esophagitis but its responsiveness is limited.

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"GastroPanel Test" in the Clinical Outcome of GERD

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Background: GERD is claimed to be a chronic acid-related disease, characterized by an high number of relapses (40-85%) in a six-months period withdrawal of antisecretory therapy. Gastropanel is based on a four parameters panel (pepsinogen I, pepsinogen II, gastrin-17 and IgG against H. pylori) assessed by a blood sample. In subjects under antisecretory treatment, both pepsinogen I and II increased as well as gastrin-17, following some well described physiological events in the stomach (acid-pepsin wash-out and acid-gastrin negative feed-back). Aim: To assess the clinical outcome of such parameters as a "Gastropanel test" able to single out patients more growe to an early relapse of GERD after the course of therapy for acute phase of the disease. Methods: 104 consecutive patients (M: 55, mean age: 47 years, range: 27-76) affected by esophagitis (A and B stages, according with Los Angeles Classification) were treated with antisecretory therapy (Rabeprazole 20 mg b.i.d. for 6-8 weeks). After this period 92 patient were asymptomatic and withdrawed the drug, except for antiacids, at low dosages. All patients were requested to contact the endoscopic reference center in case of symptomatic relapse lasting more than 4 days, for a period of six months after stopping therapy. A blood sample was collected for every patient to assess Gastropanel at baseline and at the end of the therapy (ELISA, Biohit, Helsinki, Finland) (normale values: PGI= 30-165 mcg/dl; PGII= 3-10 mcg/dl; G-17: 1-10 mcg/dl; IgG against Hp < 30). Results: Five patients were losted during the follow-up. 55 out of the remaining 87 subjects evaluable at the end of the six-months period of follow-up experienced at least one relapse episode. In the relapser group, the mean values of blood parameters were as follows: Baseline: PGI= 94 ± 38; PGII= 7+ o - 3; G-17= 1.6 + o - 0.7; after therapy: PGI= 164+ o - 48; PGII= 13 + o - 6; G-17= 3.8 + o - 3.7). In the non-relapsers group, the mean values were respectively: Baseline: PGI= 101+ o - 29; PGII= 8.2 + o - 4; G-17= 1.9 + o -1.3; after therapy: PGI= 203 \pm 66; PGII= 27 + o - 8; G-17= 12 + o - 4.7). The Δ of increases for PGI, PGII and G-17 were statistically significant between relapsers and non relapsers (p= 0.01, p<0.001 and p<0.01 respectively). Conclusions: The assessment of PGI, PGII and G-17 before and after a short course of PPIs ("Gastropanel test") relais to be able to single out GERD patients more prove to relapse in a six-months follow-up.

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Demographic and Clinical Features Help to Identify Non Erosive Reflux

Disease (NERD) Patients with Abnormal pH-Impedance Testing
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Introduction: Erosive Esophagitis and Barrett's esophagus are more frequently observed in males and associated with high BMI and hiatal hernia as compared to Non Erosive Reflux Disease (NERD). However, NERD includes patients who differ significantly in terms of pathophysiology and management. Recently, NERD patients have been subclassified by means of pH-impedance testing (MII-pH). Aim: To evaluate differences in demographic and clinical features in subgroups of NERD. Methods: A group of NERD patients underwent ambulatory 24- hour MII-pH while off PPI therapy. 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, $nonacid) and symptom \ association \ probability \ (SAP). \ \textbf{Results}: Of 200 \ patients \ (105F, median) \ and \ (105F, median) \ and$ age 48yrs; range 18-78), 81 (41%) had an abnormal AET. Out of the remaining subjects with normal AET, 65 (32%) had a positive SAP for acid and/or non-acid reflux. Fifty-four patients with normal AET and no symptom association were classified as Functional Heartburn (FH). Demographic and clinical features of these subgroups are shown in Table 1. Conclusions: Male gender, increased BMI and the presence of hiatal hernia are predictors for abnormal pH-impedance studies in the absence of endoscopic visible lesions. Female gender is more associated with FH.

Table 1. Demographic and clinical parameters in NERD patients (n=200)

	pH-POS	pH-NEG/SAP+	pH-NEG/SAP-	P value
	(n=81)	(n=65)	(n=54)	
Female patients, %	40.7% b	53.8% ^c	68.5% b,c	< 0.01
Mean Age	50.9 (20-76)	46.1 (22-77)	45.8 (18-76)	ns
Mean BMI	27 (18-42) a,b	24 (19-41) a	23 (16-34) b	< 0.01
Tobacco Use, %	21.0%	23.1%	25.9%	ns
Alcohol Consumption, %	40.7%	33.8%	35.2%	ns
Coffee Consumption, %	80.2%	73.8%	77.8%	ns
Prevalence of Hiatal Hernia, %	76.5.0% a,b	43.1% a	42.6% b	< 0.01
Prevalence of H. Pylori Infection, %	8.6%	9.2%	9.3%	ns

Statistical analysis a 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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Co-Existing Upper GI Pathologies Among GERD Patients

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Background: Endoscopy is used for diagnosis and assessing response to treatment in GERD patients as well as looking for its complications. However, the importance and necessity of performing endoscopy in these patients is controversial. We assessed the frequency and details of abnormal endoscopic findings in GERD patients. Methods: One-thousand twohundred and thirteen GERD patients (mean age: 39+/-15 years, 54.5% Female) were recruited from the "PARSI" database*. PARSI patients have clinical GERD and all undergo upper GI endoscopy with protocol gastric and esophageal biopsies. Symptoms are recorded in detail & a composite symptom score (SS) is calculated for each, considering frequency and severity of the symptoms. Helicobacter pylori (HP) infection is sought by rapid urease test (RUT) and histopathology. Esophagus, stomach and Duodenum are carefully observed for the presence of SHH, erosions, ulcers, strictures and deformities. Lower esophageal findings are reported according to Los Angeles classification. Results: Erosive reflux disease was found in 57.9% (grade A: 42.6%; grade B: 12.8%, grade C: 2.3% and grade D: 0.2%) & SHH in 62.4% of cases (SHH <1cm: 3.4 %, 1-2cm: 36.4%, 2-3cm: 15.2%, 3-4cm: 2.8%, >4cm: 1.8%). Esophageal ulcer, short segment columnar lined epithelium (SCLE), and long segment columnar lined epithelium (LCLE) were reported in 0.7%, 28.9%, and 1.6%, respectively. Stomach granularity and ulcer were seen in 4.9% and 2.3% (antrum 0.9%, lesser curve 0.3%, greater curve 0.8%, fundus 0.2%, cardia 0.4, multiple sites 0.5%) of patients respectively. Gastric erosions were observed in 22.8%, duodenal ulcers in 10.4%, duodenal erosions in 15.7% and duodenal deformities in 3.0% of cases. RUT was positive in 35.7% of cases. HP was found on histological examination of gastric tissue in 56.7%. HP was found on histology or RUT in 62.0%. No esophageal stricture was found. Conclusion: According to our data important abnormal endoscopic findings mandating therapy are common among patients with clinical GERD. Therefore, performing endoscopy for patients with clinical GERD is recommended, at least in areas where *H. pylori* is prevalent. * Nasseri-Moghaddam S, et al. Prospective Acid Reflux Study of Iran (PARSI): Methodology and study design. BMC Gastroenterology 2007, 7:42.

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Symptoms Characteristics in Patients with Non Acid Reflux

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Background: Multichannel intraluminal impedance-pH (MII-pH) is a method that evaluates gastroesophageal reflux disease (GERD) and differentiates between acid and non acid reflux (NAR). Some patients have persistent reflux symptoms even though they are taking Proton pump inhibitors (PPI). In some of these, the symptoms are due to NAR. Aim: To evaluate the association between NAR and different reflux symptoms on PPI therapy. Methods: Retrospective review of 98 consecutive MII-pH studies performed in our lab on patients with persistent reflux symptoms while on PPI therapy. Study included 39 males, and mean age was 52.8 years. When analyzing symptom association with reflux, a symptom is considered due to NAR if ≥ 50 % of symptoms were reported within 5 minutes of the occurrence of an MII-pH detected reflux episode. Symptoms reported were: Heartburn, Indigestion, Throat clearing, Nausea, Cough, Regurgitation and Chest Pain. Results: Mean percentages of positive symptom association with NAR were as follow: Symptoms Heart Burn Cough Indigestion Throat Clearing Mean 58.6 54.26 78.43 47.64 respectively. Symptoms Regurgitation Nausea Chest Pain Mean 77.95 52.85 55.4 respectively. There was a statistically significant higher association for indigestion and regurgitation with NAR compared to any of the other symptoms (ANOVA: P=0.0003; t test $p\le0.003$). The rest of the symptoms