Electrical Stimulation Therapy (EST) of the Lower Esophageal Sphincter (LES): An Effective Therapy for Refractory GERD - Interim Results of an International Multicenter Trial

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Purpose: Previous single-center trial showed that LES-EST significantly improved long-term outcomes in GERD. The aim of this ongoing international multicenter trial is to evaluate the safety and efficacy of LES-EST in refractory GERD patients treated by multiple operators.

Methods: GERD patients partially-responsive to PPI with off-PPI GERD HRQL >20 and >5 point improvement on-PPI, LES end-expiratory pressures of >5 mmHg, % 24-hour esophageal pH<4 for >3%, hialt hernia >5 cm and esophagitis-LA Grade-C were included. Bipolar stitch electrodes and a pulse generator (EndoStim BV, Hague, Netherlands) were implanted. EST at 20 Hz, 220usec, 5mAmp was delivered in12, 30 minute sessions.

Results: Twenty-five patients (median age 52.5; men=14) have been enrolled and implanted to-date. One patient had smallbowel trocar perforation during the implant procedure that was successfully repaired and device prophylactically removed. The remaining 24 patients are continuing with the LES-EST; 20 patients have completed their 3-month and 17, their 6-month evaluation. The median (IQR) off-PPI GERD-HRQL scores at baseline were 32 (28.5-37.0), which improved to 4.0 (3.5-10.3; p<0.001) on EST at months 3, and 5.0 (3.0-9.0; p<0.001) at month 6.

Conclusion: This study shows that LES-EST is effective in treating refractory GERD. There was a significant improvement in patients’ esophageal pH, GERD symptoms, and elimination of PPI use. LES-EST was safe with no GI side-effects or sensations reported.

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Higher Rates of Remission of Esophageal Intestinal Metaplasia Using Photodynamic Therapy Compared to Radiofrequency Ablation

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Purpose: There are few data comparing the efficacy of periforin sodium photodynamic therapy (Ps-PDT) and radiofrequency ablation (RFA) in achieving complete remission of intestinal metaplasia (CIRM) or dysplasia (CRD). The aim of this study was to highlight the differences in time to CRD and time to CRD among patients treated with Ps-PDT compared to RFA.

Methods: This was a retrospective, observational study of patients with BE treated with Ps-PDT or RFA. Information of interest was collected regarding baseline characteristics (age, gender, race, history of smoking, histology, previous statin use, previous NSAID use), previous treatments (EMR, PDT, RFA, APC), length of Barrett’s segment, and follow-up characteristics (date of follow-up visit, procedures performed, biopsy results, complications). The primary endpoint of this study was the occurrence of the first normal biopsy after starting treatment with either the Ps-PDT or RFA CRM.

Results: A total of 233 patients were included in this study. Of those, 103 patients had RFA while 130 patients had Ps-PDT between August 2001 and June 2012. The median follow-up time after Ps-PDT or RFA treatment was 14.3 months. Patients who underwent RFA were younger (median age 65 years vs. 71 years; p<0.001) and less likely to have a history of smoking (67% vs. 82%, p=0.017). There was no difference in other variables between both groups. Median time to CRD was 8.8 months in patients with RFA compared to 2.3 months in patients with Ps-PDT. Patients who were treated with Ps-PDT were more likely to experience a normal biopsy than patients who were treated with RFA (RR 2.42; p<0.001), and this result remained consistent in multivariable analysis (RR 2.67; p<0.001). Kaplan-Meier cumulative incidences CRD are shown in Figure 1 for RFA patients and Ps-PDT patients separately.

Conclusion: When treating patient with BE +/- dysplasia, the rate of CRD is higher in patients treated with Ps-PDT compared to RFA, when controlling for patient age, gender, baseline histology, BE length, use of statins and NSAIDs. Head to head studies may be needed to better quantify this difference and its potential implications.

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Obesity as Risk Factor in Gastroesophageal Reflux Disease in an Asian Population

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Purpose: Over the past years, studies have pointed out the connection between the increasing number of people suffering from acid reflux symptoms and the spreading obesity epidemic. More than one-third of U.S. adults (35.5%) are obese (CDC data). In 1998, using the non-adjusted BMI guidelines for Asians, the WHO Global Database on BMI reported overweight and obesity in the Philippines at 23.5%. In 2003, the Philippine National Nutritional Health Evaluation and Survey showed that there were 19.6% overweight and 34.6% obese people. In the Philippines, the relationship between excessive body weight and GERD is not well established. This study aims to evaluate the relationship of obesity and severity of esophagitis in GERD patients.

Methods: Consecutive patients presenting with typical GERD symptoms, i.e., acid regurgitation, heartburn, and/or epigastric pain, were recruited from June 2012 to January 2013. Demographic and clinical data were collected. We used the 2004, WHO new BMI classification intended for Asian population (normal 18.5-22.9 kg/m2, overweight 23.0-27.4kg/m2, obese I 27.5-32.5 kg/m2, obese II 32.6-37.5 kg/m2). Description of grade of erosive esophagitis (EE) was based on the Los Angeles (LA) Classification, i.e., LA A, LA B and LA C. The prevalence and association of obesity and severity of esophagitis in GERD patients.

Results: Of the 445 GERD patients included in this study, patients were classified in Group A, 116 (26%), normal (BMI 22.8±1.3), Group B, 98 (22%), overweight (BMI 24.9±0.2), Group C, 166 (37%) obese I (BMI 27.9±1.7), and Group D, 65 (14.6%) obese II (BMI 32.9±2.8). Cross group differences were detected for the severity of EE LA class A, for those with normal BMI is 18%, in overweight is 23%, in obese I is 55% and for obese II (p=0.000). Severity of EE LA class B, normal BMI is 11%, in overweight individuals is 25%, in obese I is 57% and in obese II is 39% (p=0.010). For the severity of EE LA class C, those with normal BMI 1%, in overweight is 28%, in obese I 5% is and for obese II is 54%, p=0.04. The extents of esophageal mucosal breaks were more severe in obese patients p<0.001. Obesity is a significant risk factor for EE (odds ratio [OR] 2.9, 1.4-2.3; p>0.001).

Conclusion: Obesity is a strong independent risk factor of EE in GERD patients. The severity of EE is much higher in obese patients.

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Polarization-gated Spectroscopy (PGS) to Detect Tissue Microstructural Alterations in Esophageal Field Carcinogenesis

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Purpose: Experimental data suggest neoplasia may be detected distantly due to epigenetic alterations of adjacent normal tissues (carcinogenesis field effect). This novel fiberoptic probe combines polarization-gating and spectral analysis to depth-selectively quantify the structural and functional tissue properties. The aim of this single center, prospective study was to determine if Barrett’s metaplasia and neoplasia can be detected by PGS measurements taken within the field of a given lesion.

Methods: This IRB approved study was performed at Mayo Clinic Florida in BE patients and normal controls undergoing endoscopy using an optical probe to obtain 6-spectral measurements from the buccal mucosa, esophagus (normal squamous and BE mucosa) andcardia before biopsy. Spectra were correlated with histology using area under the curve algorithms and comparative analysis between controls, BE dysplasia and BE without dysplasia.

Results: Sixty-one patients were enrolled in the study (20 women, median age 67 years, range 33-86) with 17 normal controls, 44 BE patients (19 long segments; 25 IM, 8 LGD, 5 HGD, 6 Ca) with spectral analysis in Figures 1 and 2.