CONTROL ID: 1746036
AVERAGE SCORE: 2.75
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TITLE: Electrical stimulation therapy (EST) of the lower esophageal sphincter (LES) – an effective therapy for refractory GERD – Interim results of an international multicenter trial

AWARDS:
CURRENT CATEGORY: A. Esophagus
CURRENT SUB-CATEGORY: None
PRESENTATION TYPE: Oral or Poster
ACG Research Grant Support: No

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 < 5%, hiatal hernia < 3 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, 220 µsec, 5 mAmp was delivered in 12, 30 minute sessions. Patients are evaluated at regular intervals. Stimulation sessions are optimized based on residual symptoms and esophageal pH at follow-up.

Results: Twenty-five patients (median age 52.5; men=14) have been enrolled and implanted to-date. One patient had small-bowel 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 (26.5-37.0) 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. There was significant improvement in GERD-HRQL at both month 3 and 6 compared to their baseline on-PPI GERD-HRQL scores of 16.5 (8.8-22.0; p<0.01). Patients’ median esophageal pH at baseline was 11.8% (8.9-15.1) which improved to 3.6% (2.7-12.0; p<0.001) at 3 and 3.5% (2.4-6.8; p<0.001) at 6 months; 88% (15/17) of patients at 6 months reported being able to discontinue ALL PPI medication with one patient using PPI < 50% of diary-days. Fifty AEIs in 17 patients were reported. Two SAEs (trocar perforation and AV nodal reentrant tachycardia – not device or procedure related successfully ablated) were reported; 48 non-serious events include 26 possible/probable device or procedure, and one definite procedure related. There were 2 instances of mild, transient dysphagia in 9/24 patients undergoing hiatus closure at the time of device implant, both resolved within 4 weeks without intervention. There were no stimulation-related GI side effects or sensations reported.

Conclusion: Interim results show that LES-EST is effective in treating refractory GERD. There was a significant improvement in patients’ esophageal pH, GERD symptoms, and elimination of PPI usage. LES-EST was safe with no GI side-effects. Long-term results in a larger group of patients are being collected.

Commercial Products or Services: Yes
Financial Relationships: Yes
Extra Info: P Siersema, J Conchillo, A Escalona, A Bredenoord, J Ruurda, N Bouvy, M van berge Henegouwen, D Cisternas, M Booth, DN Reddy, J Wu - Research Support, EndoStim BV
Initiated Research: Industry
FDA Approval: No
Designed Study: Industry
Performed Analysis: Industry
CONTROL ID: 1733966
AVERAGE SCORE: 3.75
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TITLE: Influence of Reflux and Central Adiposity on Intercellular Space in Squamous Esophageal Epithelium

AWARDS: ACG Obesity Award

CURRENT CATEGORY: A. Esophagus

CURRENT SUB-CATEGORY: None

PRESENTATION TYPE: Poster Only

ACG Research Grant Support: No

Purpose: Central adiposity is associated with esophageal inflammation, metaplasia and neoplasia independent of gastroesophageal reflux and BMI. Mechanisms by which central adiposity may potentiate esophageal inflammation and neoplasia remain incompletely understood. Our aim was to determine the esophageal squamous epithelium intercellular space diameter in patients with increased central adiposity, independent of esophageal reflux.

Methods: Subjects who underwent clinically indicated ambulatory 24 hour pH impedance studies and endoscopy within 48 hours were prospectively recruited. Anthropometric measurements (height, weight, waist circumference, hip circumference) were obtained using standard methods. Biopsies were taken from the squamous mucosa 5 cm above the gastroesophageal junction (GEJ). The patients were divided into the four groups outlined in Table 1. 10 sections were then prepared from the squamous mucosal biopsies. Using a transmission electron microscopy, 4 images at were obtained randomly at the basal and spinous layers. Then, using a computerized image analyzer, 10 transects were randomly drawn across perpendicular cell membranes with each transect no closer than 1 μm apart. The intercellular space (ICS) was calculated at these transecting lines using the software.

Results: 13 subjects were prospectively recruited. 4 (33%) were males. Mean age (SD) was 43.4 (16.9). Group 2, (centrally obese without reflux), had a statistically significant larger ICS diameter than the control group (no central obesity, no reflux) (0.503 μm). The difference between the reflux group and control was 0.223 μm. There was no statistically significant difference between the ICS diameters of groups 2, 3 and 4. Our ICS difference between reflux and non-reflux patients was consistent with the data in the literature.

Conclusion: In this study, we found that subjects with increased BMI and central obesity but no evidence of pathologic reflux on ambulatory pH monitoring, had dilated ICS. The ICS in obese subjects was almost twice the size of the control group (normal BMI and no reflux). Moreover, this was similar to that of subjects with pathologic reflux in the absence of obesity (normal BMI and WHR). This change may potentially increase susceptibility of centrally obese subjects to epithelial injury, inflammation and neoplasia.

Commercial Products or Services: No
Financial Relationships: Not Applicable
Initiated Research: Investigator
FDA Approval: No
Designed Study: Investigator
Performed Analysis: Investigator
Investigator Contribution: No
Study Results: Yes
Secondary Analyses: Not Applicable
Supported by Industry Grant: No
CONTROL ID: 1739028
AVERAGE SCORE: 3
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Christopher Rife: ACG Member
Aaron Clark: ACG Non-Member
Donald Castell: ACG Member

TITLE: A Novel Sleep Assist Device Prevents Gastroesophageal Reflux: A Randomized Controlled Trial

AWARDS:
CURRENT CATEGORY: A. Esophagus
CURRENT SUB-CATEGORY: None
PRESENTATION TYPE: Oral Only

ACG Research Grant Support: No

Purpose: Previous studies show that sleeping with the head of bed elevated or on a wedge reduces gastroesophageal reflux (GER). In addition, while recumbent, left side down reduces GER compared to right side down and supine. We performed a randomized controlled trial evaluating a sleep device (SD) consisting of a two-piece inclined base and body pillow (Medcline, Amenity Health, Inc., San Diego, CA) that maintains a patient in lateral position while elevating the head and torso. We hypothesized that sleeping in a fixed position on the left side with the head and torso elevated would significantly reduce recumbent GER.

Methods: This was a single institution, randomized controlled trial involving 20 healthy volunteers, each subject having 4 impedance-pH tests 6 hours in length. After placement of a reflux probe subjects returned home and ate a standardized meal (1350 kcal, 58g fat). Each subject then lay down in one of 4 randomly assigned positions: SD right side down (SD-R), SD left side down (SD-L), standard wedge any position (W), and flat any position (F). A wireless position monitor documented position during each study. Number of reflux episodes (RE) and esophageal acid exposure (EAE) was blindly calculated for 6 hour periods. Position monitor data was used to compare assigned position to actual position.

Results: Significantly less EAE over 6 hrs occurred sleeping SD-L compared to sleeping W (mean 0.46% vs. 3.59%, p<.01), SD-R (mean 0.46% vs. 4.59%, p<.01), and F (mean 0.46% vs. 3.46%, p<.05). RE over 6 hrs were significantly less SD-L than SD-R (mean 5.55 vs. 13.23, p<.05). Patients assigned to SD-L on average spent 83% of first 2 hrs and 61% of 6 hrs in assigned position. Those assigned to SD-R spent 72% of first 2 hrs and 53% of 6 hrs in assigned position. Over 6 hrs, patients sleeping on W and F averaged significantly more time supine than R or L (p<.05).

Conclusion: The sleep device maintains recumbent horizontal position effectively. Lying left side down, it dramatically reduces recumbent esophageal acid exposure. As in previous studies, right side down position gives the worst results, even with aid of the sleep device.

Commercial Products or Services: Yes
Financial Relationships: Yes
Extra Info: Dr. Erik Person - No financial relationship
Janice Freeman, RN - No financial relationship
Dr. Chris Rife - No financial relationship
Aaron Clark - Employee of Amenity Health, Inc.
Dr. Donald Castell - No financial relationship

Initiated Research: Industry
FDA Approval: No
Designed Study: Investigator
Performed Analysis: Investigator
Investigator Contribution: No
Study Results: Yes
Secondary Analyses: Not Applicable
Supported by Industry Grant: Yes
Extra Info: Amenity Health, Inc.
CONTROL ID: 1727046
AVERAGE SCORE: 3.25
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TITLE: Obesity and Waist Belt Distort the Esophagogastric Junction and Induce Intrasphincteric Acid Reflux
AWARDS: ACG Obesity Award
CURRENT CATEGORY (A. Esophagus)
CURRENT SUB-CATEGORY: None
PRESENTATION TYPE: Oral or Poster
ACG Research Grant Support: No
Purpose: We examined the esophagogastric junction using novel and high-resolution probes in healthy subjects with and without obesity, and the effects of elevating intra-abdominal pressure with a waist belt.
Methods: We recruited 24 subjects with 12 normal and 12 with increased waist circumference, matched for age and gender. A magnet (2x1 mm) was endoscopically clipped to the SCJ. Assembly of 3-D Hall-Effect probe, 12-channel pH catheter and 36-channel 2.7-mm manometer was then passed nasally. A waist belt was applied on a separate study day. All results were in mean.
Results: The SCJ (P < 0.001) and pH transition-point (P = 0.04) were displaced proximally in obese vs. non-obese subjects, but not diaphragm (pLES and PIP). With belt on vs. off, there was proximal displacement of SCJ (P < 0.001), pH transition-point (P < 0.001) and also of diaphragm (P < 0.001) and LES (upper and lower border, P < 0.001 and P = 0.002 respectively). The SCJ relative to the diaphragm (pLES and PIP) was more markedly displaced by obesity than by the belt (3.9 vs. 1.9 cm and 3.4 vs. 1.5 cm respectively). The magnitude of proximal migration of SCJ during TLESRs was less in obese vs. non-obese subjects (4.2 vs. 6.8 cm, P = 0.04) and belt on vs. off (3.9 vs. 5.5 cm, P = 0.01), consistent with its resting position being already proximally displaced. At five cm above LES and 1-2 cm above upper border LES, the mean % time pH < 4 was minimal (< 4%) in all studied groups; however, it was increased (4 – 30%) in belt on vs. off at 1.3 cm above the SCJ (P = 0.02) and in obese subjects with belt on vs. off at 0.5 cm above the SCJ (P = 0.02). In obese subjects with belt on vs. off, there was a greater frequency of TLESRs (7.3 vs. 5.0/hour, P = 0.001), % TLESRs with reflux (56.4% vs. 32.8%, P = 0.01) and a longer acid clearance time (72.3s vs. 23.4s, P = 0.01).
Conclusion: Our findings indicate that obesity and waist belt cause partial hiatus herniation and intrasphincteric short segment acid reflux in asymptomatic volunteers.
Commercial Products or Services: No
Financial Relationships: No
Initiated Research: Investigator
FDA Approval: No
Designed Study: Investigator
Performed Analysis: Investigator
Investigator Contribution: Yes
Study Results: Yes
Secondary Analyses: Not Applicable
Supported by Industry Grant: No
CONTROL ID: 1742999
AVERAGE SCORE: 3.75
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TITLE: Gender Disparities in Remission of Esophageal Intestinal Metaplasia after Radio-frequency Ablation

AWARDS: Naomi Nakao Gender Based Research Award/Radhika Srinivasan Gender Based Research Award

CURRENT CATEGORY: A. Esophagus
CURRENT SUB-CATEGORY: None
PRESENTATION TYPE: Oral or Poster

ACG Research Grant Support: No

Purpose: Among the available ablative modalities, radiofrequency ablation (RFA) is the most commonly used for treatment of Barrett’s esophagus (BE) with dysplasia. Few studies have assessed the effect of gender on remission rates after RFA. Preliminary studies indicate a potential biological difference between males and females with BE. We aim to assess the effect of gender on the time to achieve complete remission of intestinal metaplasia (CRIM) among patients with BE who underwent RFA.

Methods: This was a retrospective, observational study using large RFA database in a tertiary referral center. The primary outcome was time to CRIM compared between males and females. Candidate predictor variables included patient age, sex, race, smoking history, use of endoscopic mucosal resection (EMR), and initial biopsy before RFA. Time to CRIM (in months) was calculated using the Kaplan-Meier method. Log-rank test was used for comparison. We used Multivariable cox-proportional hazard model to assess for any association between time to CRIM and predictor variables.

Results: 257 patients underwent RFA for BE between May 2005 and June 2012. Of those, only 11% (n=26) were females. Males and females were similar in mean age, race, smoking history, median BE length, history of EMR, and baseline histology. Females required less RFA sessions compared to males (p = 0.027). For males, median time to CRIM was 11.7 months [95% CI: 10 – 15]. For females, median time to CRIM was 24 months [95% CI: 10.3 – 60.2]. The Log Rank χ² statistic for the difference in time to CRIM was 4.7, with p = 0.03. Kaplan-Meier curves of the time to CRIM stratified by gender are presented in Figure 1. Using cox-regression analysis, there was no evidence of confounding, collinearity, or effect modification in the final model. When controlling for age, use of EMR, BE segment length, and the number of RFA sessions, female gender was associated with 55% decrease in the rate of CRIM compared to males (HR = 0.45 [95%CI: 0.25 – 0.82], p=0.009).

Conclusion: Female patients take longer time to achieve remission of intestinal metaplasia when treated with radiofrequency ablation with or without endoscopic mucosal resection when compared to males of similar age and BE length. Further studies are needed to understand the potential factors leading to those important differences.

Commercial Products or Services: No

Financial Relationships: Yes

Extra Info: Dr. Wolfsen is a consultant for CSA Medical, Ninepoint Medical, and Oncoscope. He receives research funding from BARRx Medical and Olympus America, Inc. Dr. Wallace is a consultant for Ninepoint Medical. He receives research funding from Olympus America, Inc, American BioOPTICS, and Fujinon.

Initiated Research: Investigator

FDA Approval: No

Designed Study: Investigator

Performed Analysis: Investigator

Investigator Contribution: Yes

Study Results: Yes

Secondary Analyses: Not Applicable

Supported by Industry Grant: No
CONTROL ID: 1734835

AVERAGE SCORE: 4

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PRESENTER (COUNTRY ONLY): United States

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TITLE: Esophageal Eosinophilia and Eosinophilic Esophagitis are Increased in Rural Areas with Low Population Density: Results from a National Pathology Database

AWARDS:

CURRENT CATEGORY: A. Esophagus

CURRENT SUB-CATEGORY: None

PRESENTATION TYPE: Oral or Poster

ACG Research Grant Support: No

Purpose: Eosinophilic esophagitis (EoE) is an increasingly prevalent chronic disease and is thought to arise from an allergy/immune-mediated process. The relationship between population density, EoE, and esophageal eosinophilia is unknown. Our aim was to estimate the association between EoE and esophageal eosinophilia with population density.

Methods: We conducted a cross-sectional study of patients with esophageal biopsies in a U.S. national pathology database between January, 2009 and June, 2012. Using Geographic Information Systems (GIS), the population density (number of individuals per square mile) was determined for each patient zip code. The odds of esophageal eosinophilia and EoE were estimated for each quintile of population density after controlling for age, sex, race and distance traveled for endoscopy. Sensitivity analyses were performed with varying case definitions of EoE.

Results: Of 292,621 unique patients in the source population, 91,929 had normal esophageal biopsies and 14,739 had esophageal eosinophilia with ≥15 eosinophils per high-power field (eos/hpf). Those with esophageal eosinophilia were generally younger (45 vs 54 years), more likely to be male (64% vs 35%) and had more dysphagia (54% vs 26%) than those with normal biopsies (p<0.05 for all). After multivariate analysis, the odds of esophageal eosinophilia decreased with increasing population density (p for trend < 0.001) (Figure). Compared to those in the lowest quintile of population density, odds of esophageal eosinophilia were significantly reduced amongst those in the highest quintile of population density (OR 0.79; 0.73-0.85). A similar dose-response trend was observed across case definitions of EoE (Figure).

Conclusion: Population density is strongly and inversely associated with both esophageal eosinophilia and EoE, with these conditions being more common in rural areas. This association persists in sensitivity analyses. Environmental exposures in rural areas may be key in the pathogenesis of EoE.

Commercial Products or Services: Yes

Financial Relationships: Yes

Extra Info: : Jensen - nothing to disclose
Hoffman - nothing to disclose
Shaheen - nothing to disclose
Genta - employee of Miraca Research Institute and Miraca Life Sciences where the database used in this study is maintained.

Initiated Research: Investigator

FDA Approval: No

Designed Study: Investigator

Performed Analysis: Investigator

Investigator Contribution: No

Study Results: Yes

Secondary Analyses: Not Applicable

Supported by Industry Grant: No