Title: Radiofrequency Energy Delivery to theLower Esophageal Sphincter (Stretta Procedure) in Sleeve Gastrectomy Patients with GERD

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ABBREVIATIONS AND DEFINITIONS OF TERMS

GERD	Gastroesophageal Reflux Disease
RYGB	Roux-en-Y Gastric Bypass
SG	Sleeve Gastrectomy
HRQL	Health Related Quality of Life
EMR	Electronic Medical Record
FDA	Federal drug administration
RSI	Reflux Symptom Index
LES	Lower esophageal sphincter
PPI	Proton pump inhibitor

OVERVIEW

1. Background Information and Rationale

1.1 Introduction

Gastroesophageal reflux disease(GERD) is a widely prevalent medical disorder in the United States with a spectrum of treatment options ranging from dietary modification, to various pharmacologic treatments, to an array of available surgical and endoscopic procedures. There is a well-described correlation between obesity and symptoms of GERD. The morbidly obese patients undergoing evaluation for bariatric surgery are to characterize any GERD-like symptoms as this will assist in directing surgical therapy. Generally, it is recommended that patients with severe GERD undergo Roux-en-Y gastric bypass(RYGB) rather than a sleeve gastrectomy (SG) as RYGB has proven to be the most effective surgical treatment for GERD in the morbidly obese patient. The number of bariatric procedures performed in the United States has increased significantly in the recent years. Out of all bariatric procedures SG is the most commonly performed in the United States, as it has proven to be a very safe procedure with excellent weight loss. However, the incidence of de novo GERD and the effect of SG on patients with preexisting GERD remain controversial.Although some authors report high incidence of de novo GERD and worsening of previous reflux symptoms, there is also data showing improvement of symptoms post SG. Management of GERD after SG poses an interesting challenge, as traditional invasive procedures likeNissen fundoplication are not available due to an altered gastric anatomy. The alternative is to perform a conversion to RYGB, which represents increased morbidity to patient and significant cost.

A large number of endoscopic procedures have been introduced in the past for the management of GERD as an alternative to the surgical anti-reflux procedures with various degrees of success. One of the few non-invasive methods for managing GERD that is still available on the market and widely used is Stretta. Stretta delivers Radio Frequency energy (RFe) to the LES resulting in increased LES pressure. In 2000, the FDA approved the Stretta system as treatment for patients diagnosed with GERD. Stretta allowsan alternative for treatment in patients who are not willing or able to undergo surgery. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) published clinical practice guidelines that endorsed Stretta as an appropriate therapy for treatment of GERD in patients >18, with at least 6 months of symptoms partially or completely responsive to pharmacotherapy and who are unable or unwilling to undergo laparoscopic Nissen fundoplication. There are to date no studies evaluating the use of Stretta in management of patients with GERD symptoms after sleeve gastrectomy.

1.2 Compliance Statement

This study will be conducted in full accordance of all applicable Montefiore Medical Center Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, and the HIPAA Privacy Rule. Any episode of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consentand assent when applicable (unless a waiver is granted), and will report unexpected problems in accordance with The Montefiore Medical Center IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

1.3 Relevant literature and Data

Bariatric surgery is an effective long term treatment for morbid obesity. The number of bariatric procedures performed in the United States has increased significantly in the recent years. The American Society for Metabolic and Bariatric Surgery (ASMBS) estimates that in The United Statesin 2013 approximately 179 thousand bariatric caseswere performed. The number of sleeve gastrectomiespreformed in the US has increased from being only 17% of the bariatric cases in 2011 to over 42% in 2013 and continues to increase. This increase in numbers is because SG has proven to be a very safe procedure with excellent weight loss results. There is conflicting data on theeffect of SG on patients with preexisting GERD. Although the pathophysiology is not fully understood, GERD following SG is usually attributed to a decreased lower esophageal sphincter (LES) pressure, disruption of the sling fibers, dissection of the angle of His or elevated intragastric pressure. In cases with severe GERD, patients may have to undergo a revision to RYGB, as this is the only available treatment for refractory GERD after SG.

Studies investigating the incidence of GERD following SG have many limitations and are poorly designed. First, the surgical technique is not standardized. Different techniques can result in various sleeve sizes and can also result in gastric stenosis at the incisura or in a residual large fundus, which can all, affect the incidence of GERD postoperatively. Second, the true incidence of GERD in patients undergoing SG is largely unknown because patients do not routinely undergo preoperatively workup for GERD. Third, many patients develop non-specific gastrointestinal symptoms like regurgitation, bloating and chest pain, which are sometimes attributed to GERD or even hiatal hernia without any confirmationof the diagnosis.The postoperative use of proton pump inhibitors or other antisecretory medications as well as initial healing time followed by relaxation/dilatation of the gastric sleeve a few months following SG can influence symptoms of GERD. Therefore, data regarding the incidence of GERD following SG should be obtained at least 6 months postoperative at which time the majority of weight loss has been achieved, medications stopped and changes have stabilized.

There has been in recent years a large number of endoscopic procedures that have been used as an alternative to the surgical anti-reflux procedures with various degrees of success.The delivery of RFe to the LES by the Stretta device results in increased LES pressure. The Stretta device is FDA approved and has excellent results in the treatment of GERD symptoms in the standard population. The aim of this study is to objectively investigate the effect of RFe to the LES in patients who develop GERD related symptoms after SG. Patients who experience GERD related symptoms 6 months after SG will undergo the Stretta procedure. The data collected from EGD, pHmonitoring in junction with GERD Health-Related Quality of Life (HRQL) questionnaire prior to the Stretta procedure, will be compared with data following the Stretta procedure at 6, 12 and 24 months.

2. Study Objectives

2.1 Primary Objective

The primary objective of this prospective study is to evaluate the treatment success as measured by percent reduction of symptoms. Following the use of radiofrequency energy delivered to the lower esophageal sphincter as a treatment of symptomatic GERD, in patients who have undergone sleeve gastrectomy for morbid obesity. The endpoint of interest is whether patients achieved a 50% reduction in symptoms as measured by RSI and HQRL indices.

2.2 Secondary Objectives

The secondary objectives are:

- To determine the pH findings in patients with symptomatic GERD after SG
- To determine the effects of gastric emptying and its association to GERD in patients after SG
- To follow the long term effect of Stretta in patients with symptomatic GERD after SG

3. Investigational Plan

3.1 General Schema of Study Design

3.1.1 Multicenter prospective study

This is a multicenter prospective study involving ten to fifteen tertiary medical centers. We expect to enroll at least twenty patients per center. Pre-procedure all enrolled patients will undergo a battery of testing in order to ensure that they are an adequate candidate for Stretta. The workup will include:

- pH monitoring(off medication)
- EGD with biopsies
- Barium swallow
- Gastric Emptying study
- RSI and GERD-HQRL
- Manometry, if dysphagia is reported

This will be followed by endoscopic radiofrequency energy delivery utilizing the Stretta system. Patients will be followed and evaluated at 6, 12, and 24 months with RSI and GERD-HRQL scoring as well as interval pH testing. At 6 and 12 months those subjects with initial abnormal pH,Gastric emptying or EGD will repeat pH monitoring,gastric emptying and EGD

3.1.2 Number of sites

10 to 15 tertiary medical centers. The proposed sites that have expressed interest are:

- Montefiore Medical center, Bronx, NY
- Ohio State University, Columbus, OH
- Duke University, Durham NC
- Emory University, Atlanta, GA
- Oregon Health & Science University, Portland, OR
- Loyola University, Chicago, IL
- New York University(NYU), NY, NY
- Oregon Clinic, Portland, OR
- The Methodist Hospital, Houston, TX
- Buffalo General Hospital, Buffalo, NY
- Our Lady of the Lake Hospital, Baton Rouge, LA
- Brigham and Women's Hospital, Boston, MA
- University of California Irvine Medical Center, Orange County, CA
- Memorial Hermann Hospital, Houston, TX

- Cleveland Clinic, Cleveland, OH
- Columbia University Medical Center, NY, NY
- UH Case Medical Center, Cleveland, OH
- Rush University Medical Center, Chicago, IL

3.1.3 Enrollment

Patients may be enrolled prospectively or retrospectively up to 6 months following Stretta procedure.

3.2 Criteria For Evaluation

3.2.1 Primary Endpoint

- Primary endpoint will be based RSI and HQRL indices and will be a determination of whether the patient achieved at least a 50% reduction in symptoms at the 6 12 and 24 month points as compared to baseline.

3.2.2 Secondary Endpoints

- Improvement in esophageal pH exposure.
- Cessation or decreased in use of anti-reflux medication
- Determination of gastric dysmotility as a contributory factor in GERD after SG
- Objective improvement or resolution of esophagitis utilizing LA classification.

3.2.3 Inclusion Criteria

Participants will be men and women between the ages of 18 and 80 who have undergone sleeve gastrectomyat least 6 months prior to enrollment as treatment of morbid obesity and who have one or more of the following:

1. Symptomatic reflux: (heartburn, chest discomfort, asthma/chronic cough, laryngitis, nocturnal aspiration or regurgitation)
2. On a PPI with GERD-related symptoms
3. On a PPI but like to discontinue them

3.2.4 Exclusion Criteria

1. Age <18 or > 80
2. History of a severe psychiatric disorder: including suicidal ideation, or admission to a psychiatric institution.
3. Unable or unwilling to consent for an invasive procedure.

4. History of intestinal leak after surgery.
5. History of revisional bariatric surgery
6. Significant sleeve abnormalities such and twist or large fundus
7. Hiatal hernia(>2cm)
8. Pregnancy
9. Inability to comply with study protocols and procedures
10. Esophageal stricture, Eosinophilic Esophagitis or Achalasia
11. Prior esophageal surgery or therapy for Barrett's Esophagus
12. Grades 3 or 4 esophagitis
13. Gastric or esophageal varices
14. History of obstruction of the small bowel or inflammatory bowel disease
15. Pacemaker or implanted cardiac defibrillator
16. Coagulopathy or use of anticoagulants
17. ASA classification >3
18. Scleroderma or other connective diseases
19. Use of imunosuppressive medications.

4. Study Procedures

A Schedule of Events representing the required testing procedures to be performed for the duration of the study is diagrammed in Appendix 1.

A description of the assessment and work-up to be performed on the initial evaluation, pre-procedure testing, and each of the post-procedural follow-ups is provided in Appendix 2.

Prior to conducting any study-related activities, written informed consent and the Health Insurance Portability and Accountability Act (HIPAA) authorization must be signed and dated by the subject.

4.1 Clinical Assessments

Demographics

Demographic information (date of birth, gender, race) will be recorded at screening.

Medical/Surgical History

Relevant medical history, including history of current disease, information regarding underlying diseases and prior surgical history will be recorded at screening.

Physical Examination

A complete physical examination will be performed by either the investigator or a subinvestigator who is a physician at the participating center. Qualified staff (MD, NP, RN, and PA) may complete the abbreviated physical exam at all other visits. New abnormal physical exam findings must be documented and will be followed by a physician or other qualified staff at the next scheduled visit.

Vital Signs

Standard vital sign measurements will be captured at screening, during pre-procedure workup, peri-procedure and at each subsequent follow-up visit.

Imaging/Endoscopy

The investigator or subinvestigator to assure appropriate inclusion and exclusion criteria are met will review all relevant prior imaging and endoscopic evaluations.

Concomitant Medications

All concomitant medication and concurrent therapies will be documented at initial screening and during pre-procedure evaluation. All changes in medications and doses will be captured at each follow-up visit. Dose, route, unit frequency of administration will be documented.

4.2 Clinical Laboratory Measurements

Pregnancy Test

A urine or serum pregnancy test will be obtained from female subjects who are of childbearing age prior to Stretta procedure. Subsequent pregnancy tests may be performed at follow-up visits, at the discretion of the investigator.

4.3 Pre-procedure Testing

EGD

The upper endoscopy of SG patients with GERD symptoms will be performed under IV sedation per institutional guidelines. Biopsies of any suspicious lesions and of any evidence of esophagitis will be taken. Evidence of esophagitis will be scored by histology and according to LA classification:

Grade A	One or more mucosal breaks < 5 mm in maximal length
Grade B	One or more mucosal breaks > 5mm, but without continuity across mucosal folds
Grade C	Mucosal breaks continuous between > 2 mucosal folds, but involving less than 75% of the esophageal circumference
Grade D	Mucosal breaks involving more than 75% of esophageal circumference

Following upper endoscopy, assuming that there are no contraindications noted, the patient will then undergo a motility and 24 hour pH testing.

pH monitoring

Bravo pH monitoring will be performed off proton-pump inhibitors (PPI) or anti-secretory drugs. Subjects taking any of these medications will be required to discontinue them for at least one week. Subjects who are unable to discontinue their medications will be excluded from the study. At the discretions of each site and pending site availability catheter based pH monitoring can be used.

Barium Swallow

The Barium swallow will be performed per institutional guidelines. Assessment of esophageal motility and any evidence of dilation will be recorded. Subjects who have any evidence of abnormally enlarged sleeve, evidence of twist, or large residual fundus will be excluded from study.

Gastric Emptying Study

The Gastric Emptying study will be performed per institutional guidelines. Assessment of gastric emptying for all patients at 1, 2, 3 and 4 hours, will be documented. Subjects who have severe gastroparesis(over 50% retention at 4 hours) will be excluded from study.

RSI/HQRL

Patients will complete a GERD Health Related Quality of Life questionnaire (HRQL) (Addendum 1) and Reflux Symptom Index (RSI) (Addendum 2) at baseline off medications and following the Stretta procedure at 6,12 and 24 months if patient has required to restart antisecretory medication at any time a new trial to discontinue medication will be attempted and questionnaires shall be completed while off medications for at least 1 week.

Manometry

Esophageal manometry will be performed in any patients who refer any symptoms that may suggest dysphagia or if contrast study shows evidence of severe dismotility, if positive for motility problems it will exclude subject from study.

5. Study administration

Catheter-based manometry and Bravo pH monitoringStudies

The use of manometry will be at the discretion of the physician if there is any suspicion of motility abnormalities. All subjects will have pH monitoringas baseline prior to Stretta procedure if abnormal it will be repeated at 6 month and 12months. Results will be collected and reviewed by the investigators at each site and reported using confidential password protected files.

As part of the submission and review process the studies will be inspected by the designated investigator and evaluated for:

1. Quality of data collected.
2. Correct use of the diary information and patient symptoms entries.
3. Artifacts will be noted and excluded from the calculation.
4. Confirmation of diagnosis regarding the presence or absence of reflux events, and correlation of reflux events with patient symptoms.
5. Data will be collected of the following data entries:
    a. LES length
    b. LES pressure
    c. % normal peristalsis
    d. Total number of reflux events
    e. Time pH < 4 min
    f. Total fraction time % pH < 4
    g. DeMeester Score
    h. Correlation of symptoms with reflux events

Stretta Procedure

Stretta will be performed while patient is on anti-secretory agents. Subjects will continue taking these medications for four weeks post procedure. After the fourth week they will decrease to half dose for 2 week and then discontinue medication.

Stretta is a safe, non-invasive FDA approved procedure performed endoscopically under moderate sedation or general anesthesia which uses radio frequency (RF) energy applied to the lower esophagus over 14 minutes per a specific FDA approved protocol and as per package instructions for the device. Under endoscopic guidance, a soft tip guide wire will be advanced thru the gastric sleeve and into the duodenum. After removal of the endoscope, the Stretta catheter will be advanced over the wire and the Stretta balloon initially positioned 1 cm above the previously located GE junction. Following the established manufacturer required protocol, the balloon is inflated and needles deployed for each successive treatment level, with RF energy applied under the control of the Stretta version 2 generator.

5.1 Data Collection and Management

Data will be obtained through subject interview and survey, and medical records. Privacy and security will be maintained by minimizing the amount of identifiable data as much as possible. All identifiable patient information will be kept at each site in a password protected file and deleted at the conclusion of the study. All de-identified information will be compiled in confidential password protected Access spreadsheets on cloud bases storage that are password protected.

All necessary identifiers will be used only to identify the relevant source documents (as described above). Following this, surrogate numbers will be given to identify the patients for data analysis. All identifiers will be deleted from the file. This information will remain at each institution in a separate password protected file that served as the initial list of cohort patients to be searched until after completion of the study period and analysis, at which point it will be deleted.

As part of the usual standard of patient care for bariatric surgery and reflux corrective procedures, the principal investigator and study coordinator designees have the responsibility to monitor timely collection and regularly examine the results to make sure the study protocol is implemented correctly with no unforeseen side effects. The principal investigator and co-investigators will review data collected every three months, to monitor trends within the different outcome measures, as well as

evaluate side effects and other unforeseen events. The principal investigator will report to the IRB any unexpected and adverse events or other unanticipated problems involving risks to subjects or others within 30 calendar days and within 7 days for serious adverse events.

5.2 Confidentiality

All data and records generated during the process of this study will remain confidential in accordance with all Institutional and HIPAA policies on subject privacy. All documents will be used by the Investigator and other personnel solely for the purposes of this study. All safeguards to maintain subject confidentiality are described above (5.1 Data Collection and Management). No information will leave Montefiore in the event that an investigator leaves during the duration of the study.

5.3 Regulatory and Ethical Considerations

5.3.1 Risk assessment

Stretta is a safe, non-invasive FDA approved procedure performed endoscopically under moderate sedation or general anesthesia which uses radio frequency (RF) energy applied to the lower esophagus over 14 minutes per a specific FDA approved protocol and procedure.

Definition and Reporting of Serious Adverse Events (SAEs)

A serious adverse event (SAE) is a subtype of adverse event. An SAE is any adverse event occurring when the subject outcome is:

- Death
- Life-threatening (i.e., subject was at substantial risk of dying at the time of the AE)
- Inpatient hospitalization or prolongation of existing hospitalization
- Disability or permanent damage
- Other serious medical events that jeopardize the health of the subject and require medical or surgical intervention such as bronchospasm, blood dyscrasias, seizures/convulsions, or development of drug dependency or drug abuse.

The principal investigator or designee must comply with applicable local regulatory authority and IRB/IEC requirements concerning the reporting of SAEs and any safety-related documentation (e.g.., safety letters, revised IB) that may be received from the sponsoring entity. Additionally, the principal investigator will keep safety-related documentation in secured site files.

5.3.2 Potential Benefits of Study Participation

Full resolution or improvement in symptoms related to GERD

5.3.3 Risk-benefit assessment

Patients will be undergoing a procedure that is FDA approved and is an acceptable treatment for GERD. This study is intended to collect data and outcomes in the bariatric population.

5.4 Informed consent

Informed will be obtained from the subjects directly and not through a health care proxy. Qualified interpreter services will be used when appropriate. All risks, benefits, and alternatives of the procedure with be explained in detail by study to the participants and supplemental documentation will be provided to patients for further review.
A copy of the Informed Consent document is provided in Appendix 3

5.5 Payment to subjects/families

No monetary payment will be given to participants.

6. Statistical Considerations

6.1 Statistical Methods

Data will be entered on an excel spreadsheet and analyzed with SAS v9.3. Data analysis will be preceded by quality control of our data which will include checks for accuracy, completeness and internal validity. Rates of achievement of 50% reduction of symptoms will be computed and reported with their 95% confidence intervals. Descriptive data analysis will be conducted and all adverse events and overall patient characteristics will be described. The distribution of change in symptom scores will be examined and the decrease in patient symptoms will also be examined and described. If the distribution of this score approximates normality, symptom reduction will be described using mean and standard deviation. Otherwise we will use median and interquartile ranges. Bivariate analysis will be conducted to examine factors associated with achievement of 50% reduction in symptoms. Categorical variables will be analyzed using the Chi-Square's exact test. Continuous variables whose distribution meets normality assumptions will be analyzed with the t-test. Variables whose distribution does not approximate normality will be analyzed using the Wilcoxon rank sum test. While we recognize that the sample size is modest – an exploratory multivariate logistic regression analysis will be conducted to examine factors associated with 50% symptom reduction

6.2 Sample Size and Power

The target number of patients proposed for this protocol is based on our primary objective of estimating the proportion of patients achieving at least a 50% reduction of symptoms from baseline as measured by RSI and HQRL indices 1 year post treatment. Sample size calculations are based on this primary objective. Our target sample size is 80 unless perforation occurs in more than 2 patients or more than one death directly related to Stretta procedure or the accrual is terminated during interim analysis. A sample size of 50 would produce a two-sided 95% confidence interval with a width of 0.289 for a proportion of 0.5 and a width of 0.267 for proportions of 0.7. Taking into consideration that given improvement of symptoms or other factorswe estimate a 30% patientsdropout prior to completing the 24 month follow-upwe will increase target sample size to a total of 80 patients

6.3 Patient Accrual

Patient accrual will begin shortly after approval of protocol at a rate of approximately 10 to 15 patients per month and estimate patient accrual will be completed 6 months after start of protocol

6.4 Interim analysis and stopping rules:

While Stretta has been extensively used safely, we will consider perforation in more than 2 patients or more than 1 deaths directly related to Stretta procedure as unacceptable since this rate is higher than one would expect from invasive esophageal junction intervention such as dilation. Interim analysis will be conducted in an ongoing manner after treatment of eachand every patient, by the principal investigator and the lead investigator at each site. If more than 1 patientdiesor more than 2 patients suffer perforation attributable to the treatment, we will stop enrolment if no critical adverse events occur we will continue accrual to the target sample size of 80 patients. If a patient suffers a morbid event such as perforation or other life threatening event or event that requires surgical intervention accrual will be suspend and a through investigation be conducted. After the root cause is determined the study team will confer with the IRB and made a determination as to whether to resume accrual. If there is any event or evidence of increased morbidity form the treatment with the device the manufacturer FDA safety information and adverse event program (Medwatch) will be notified.

7. Publication

Once the study is complete and significant conclusions are made, a manuscript will be submitted to a relevant journal for publication.

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