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Outcome of Stretta in a Tertiary Medical Center: A Safe and Effective Non-Surgical Option for Refractory GERD

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ABSTRACT

BACKGROUND: Multiple treatment modalities exist to achieve symptom relief in Gastroesophageal Reflux Disorder (GERD), but there is mixed evidence for the efficacy of Stretta procedure.

METHODS: 56 patient charts from a single center were reviewed in this retrospective observational study for clinical response to Stretta therapy. Clinical success was defined by an overall decrease in dysphagia, heartburn, reflux and breakthrough symptoms. PPI usage at baseline and post-procedure was also measured. Patients were followed up at 1month post procedure as well as 6-12months post procedure.

RESULTS: 56 total patients underwent Stretta procedure from January 2005 to July 2019. 35 patients (62.5%) responded to Stretta therapy, 16 patients (45.7%) did not respond to Stretta therapy, and 5 patients were lost to follow up. At six months post-procedure, 21 of the 35 responders (60%) reported continued symptomatic relief and reduced their PPI dosage by at least half without reemergence of symptoms. There were no noted long-term complications from the procedure.

Conclusion: Stretta is a safe option for patients suffering from long-term GERD and can potentially offer long term improvement in symptoms and reduction in PPI usage.

INTRODUCTION

Gastroesophageal Reflux Disorder (GERD) is a chronic condition in which stomach contents rise into the esophagus and cause symptoms such as heartburn, halitosis, chest pain, regurgitation, and acid taste, or complications including esophageal stricture, Barrett's esophagus, etc. These symptoms can adversely affect quality of life, activity, and overall productivity.

GERD is one of the most frequent outpatient diagnoses in the United States, with approximately 10-20% of the population affected by reflux [1]. The majority of patients can treat symptoms with lifestyle changes as well as a trial of medication. For a subset of patients, GERD is refractory to multiple medications, including antacids, H2 receptor blockers and Proton Pump Inhibitors (PPIs). These medications target acid production and secretion, but do not address mechanical issues such as sphincter incompetence. In addition, prolonged PPI therapy is associated with several adverse effects including osteoporosis or C difficile infection.

Patients with undertreated GERD often turn to surgical or inter-

ventional options. Laparoscopic Nissen Fundoplication (LNF) is the standard surgical treatment, offering about an 80% success rate at 20-year follow up [2]. In this procedure, the gastric fundus is wrapped in a 360º fashion around the lower end of the esophagus to reinforce the lower esophageal sphincter and close off the esophagus during gastric contractions. However, for patients who have already attempted this procedure with no improvement or do not wish to have surgery, other interventions, such as Stretta, are a valuable option.

The Stretta procedure delivers thermal energy through an endoscopic catheter to the muscles of the lower esophageal sphincter and gastric cardia. This mechanism mechanically alters the Gastroesophageal Junction (GEJ) and modulates neural pathways to reduce the frequency of Lower Esophageal Sphincter (LES) relaxations [3]. Successful procedures result in symptom resolution, esophageal mucosal healing, and/or increased health-related quality of life. In this study, we observed the clinical success of Stretta in patients by overall symptom relief and decrease in PPI usage as well as reviewed the safety of this procedure for patients with chronic GERD.

MATERIALS AND METHOD

After approval by the Institutional Review Board at Emory University, we conducted a retrospective case series study of all patients who underwent Stretta for refractory GERD performed at our institution between January 2005 and July 2019. The procedures were performed by experienced advanced endoscopists in the Division of Digestive Diseases.

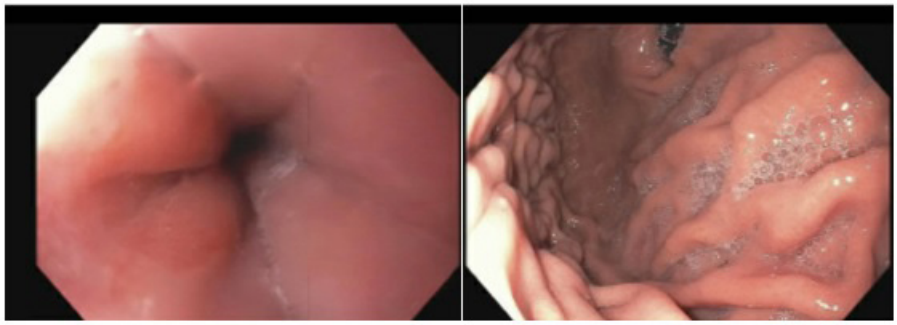
A retrospective chart review of all patients who underwent the Stretta procedure for GERD from 2005 to 2019 at our center was conducted. Demographics; clinically noted GERD symptoms including dysphagia, heartburn, reflux, and breakthrough symptoms; and PPI usage at baseline and post-procedure were reviewed.

OUTCOME MEASUREMENTS

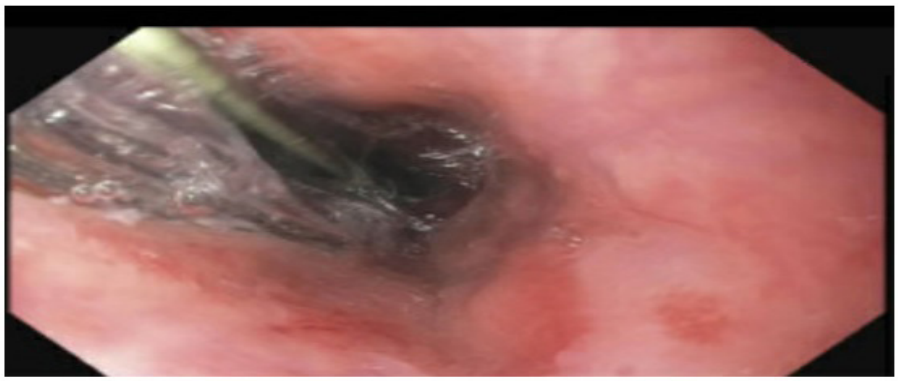
The primary outcome observed was clinical response to Stretta, notably documented changes in clinical GERD symptoms including dysphagia, heartburn, reflux, and breakthrough symptoms; PPI usage at baseline and post-procedure were also measured.

TECHNICAL DETAILS

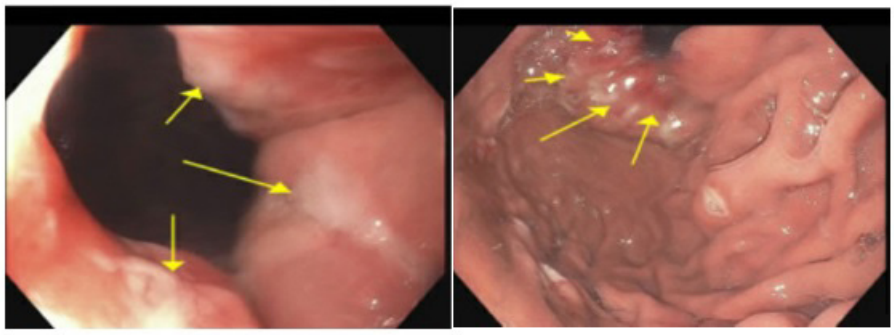
Patients were prepared for an upper gastrointestinal endoscopy and typically were kept NPO for overnight prior to the procedure. Patients were tracheally intubated to protect the airway. Intravenous propofol was used for sedation. For the procedure, an upper gastrointestinal endoscopy is first performed, and the distance from the incisors to the squamo-columnar junction (Z-line) is measured. The endoscope is removed, and the RF catheter is passed through the mouth and positioned 1 cm above the z-line according to the distance previously determined. The four needle electrodes are deployed to a preset length of 5.5 mm and RF delivery is initiated. Each electrode delivers RF energy for 60 s to achieve a target temperature of 85 °C. Additional treatment sites are created by rotating and changing the linear position of the catheter so as to create several rings over a span of 2 cm above and below cardia. The catheter is then removed and the endoscopy repeated. Overall, patients receive RF energy at 56 treatment sites over a period of 35 min. The endoscopic pictures before, during and post Stretta treatment is shown in (Figure 1).



Before therapy



during therapy



Post therapy

Figure 1: Endoscopic Stretta therapy for GERD

FOLLOW UP AND OUTCOME MEASUREMENTS:

Patients were scheduled for a clinic visit one month after the procedure as well as within six to twelve months post-procedure. Documentation of subjective symptoms included on the GERD-Health Related Quality of Life was reviewed, including dysphagia, heartburn, reflux, and breakthrough symptoms. PPI dosages were reviewed as well.

RESULTS

Fifty-nine Stretta procedures were performed on 56 patients (average age 52.3 years, range 20 years to 82 years, women = 40) between January 2005 and July 2019. All procedures were performed on an outpatient basis in the endoscopic suite. ive patients were lost to follow-up following Stretta procedure.

Symptom resolution was determined by the percentage decrease of the number of documented GERD-related symptoms. The average symptomatic improvement was a 54% decrease in number of symptoms. Thirty-five out of 51 patients had decreased symptoms (responders), averaging 78.5% decrease in number of symptoms in this group of responders. One patient who had a decrease in 1 out of 3 symptoms underwent a second Stretta and had a full response after the subsequent procedure. Sixteen out of 51 patients had no symptomatic improvement (non-responders). Two of these 16 patients underwent a second procedure and did not have improvement.

At six months post-procedure, 21 of 51 patients (41.2%), all of whom reported symptomatic improvement, reduced their PPI dosage by at least half without reemergence of symptoms.

PROCEDURE-RELATED OUTCOMES

There were no reported long-term procedure-related complications noted up to the six-month follow-up, including stricture, dysphagia, or worsening GERD. Two patients had resolution of GERD symptoms that unmasked underlying gastric emptying issues. One patient had complete resolution of GERD symptoms but remained on proton-pump inhibitor due to chronic steroid use for an unrelated diagnosis. Two patients underwent a Nissen fundoplication after the Stretta procedure. Five patients were lost to follow-up.

DISCUSSION

Results from this retrospective observational study demonstrate that Stretta has good efficacy and is a valuable tool to help patients with severe and refractory GERD. Our study followed 51 patients with at least 6-month follow-up.

A recent meta-analysis of randomized controlled trials and cohort studies representing over 2400 patients who underwent Stretta showed significant improvements in subjective and objective clinical endpoints, including quality of life, heartburn, PPI usage, incidence of erosive esophagitis, and esophageal acid exposure [4]. Our review focused on clinically relevant subjective endpoints, finding that two-thirds of patients had relevant symptomatic improvement.

Three patients in our review underwent a second Stretta procedure. One patient who had a partial response after one procedure had full symptomatic improvement after a second procedure. However, two patients who did not respond to the initial procedure did not have improvement after a second procedure. One randomized trial that studied single-dose and double-dose Stretta found that patients who underwent a second procedure had non-significant improvement in quality-of-life symptoms and PPI usage, though had a significant increase in the number of patients who had full response in quality-of-life symptoms [5]. Our small sample suggests that partial responders may benefit from a second procedure, but non-responders may not.

Stretta is a less invasive option than Laparoscopic Nissen Fundoplication (LNF), the gold standard surgery for refractory GERD. One study followed 215 patients who underwent either Stretta or LNF for refractory GERD over a 5-year period. They found that both treatments improved symptoms, though LNF had more success in eradicating PPI usage and higher quality of life improvement [6]. Of note, undergoing Stretta procedure does not preclude patients from obtaining LNF in the future if they do not experience desired symptomatic improvement. In our sample, two patients elected to follow-up failed Stretta procedures with LNF.

Other endoscopic therapies provide alternative methods of treat-

ing refractory GERD. Transoral Incisionless Fundoplication (TIF) mechanically repairs defective gastroesophageal valves and can reduce small hiatal hernias [7-8], unlike Stretta.

The cost-effectiveness of Stretta is not as well studied. One Canadian analysis in 2008 estimated that Stretta was less than half as expensive as LNF in cost per symptom-free months [9]. However, this was during the initial years of the procedure without better long-term data for Stretta effectiveness as well as economies of scale given equipment requirements.

Our review had several limitations. First, it is a retrospective study from a single center, which limits generalizability. Next, there is an inherent methodological limitation in determining clinical success based on a chart review of reported symptom improvement in patients. Alternative tools, such as formal GERD-HRQOL surveys, or objective measurements such as baseline and follow-up impedance pH monitoring have been utilized in other studies. Lastly, we had five patients, or 8.9% of our sample, lost to follow-up.

The Stretta procedure is one tool that can help patients with severe and refractory GERD. In our review, two-thirds of patients had a meaningful improvement in symptoms. More than two-fifths of patients were able to reduce their PPI dosage. No long-term procedure-related complications were noted. We acknowledge that the strength of the review was limited due to the small number of patients and lack of objective clinical markers, such as usage of GERD-related quality of life questionnaires. While the review was conducted utilizing a review of symptoms in the chart, this was not directly first-hand data. This can be utilized for future patients to further assess quality of life improvement with the procedure (Table 1) (Figure 1).

Table 1: Outcome of Stretta therapy for GERD

	Responder (n=35)	Non-Responder (n=16)
Male	13 (37%)	3 (19%)
Female	22 (63%)	13 (81%)
Age (mean ± SD) in years	51.4 ± 16.2	56.7 ± 14.4
Decrease in symptoms		
At 1 month follow-up	84.30%	13.70%
At 6 months follow-up	78.50%	0%
PPI Usage Decrease at 6 months	21 (0.60)	0 (0%)

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