

Initial Experience with the Stretta Procedure for the Treatment of Gastroesophageal Reflux Disease

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ABSTRACT

Background: The Stretta device (Curon Medical, Sunnyvale, CA) is a balloon-tipped four-needle catheter that delivers radiofrequency (RF) energy to the smooth muscle of the gastroesophageal junction. It can be used for the endoscopic treatment of gastroesophageal reflux disease (GERD).

Patients and Methods: Data prospectively collected on the first 25 consecutive patients undergoing the Stretta procedure at Vanderbilt University Medical Center between August 2000 and March 2001 are reported. Patient evaluation included esophageal manometry, ambulatory 24-hour pH testing, a standard GERD-specific quality-of-life survey (QOLRAD), a general quality-of-life survey (SF12), and endoscopy. Stretta surgery was performed following a standardized protocol. Thermocouple-controlled RF energy was delivered to the lower esophageal sphincter (LES) after endoscopic location of the z-line. Patients were followed up 3 months after endoscopic treatment. Results are presented as mean \pm SEM.

Results: Prior to treatment, patients had a mean DeMeester score of 31.0 ± 11.4 , an LES pressure of 24 ± 2 mm Hg, and normal esophageal peristalsis. Of the 25 outpatient procedures, 19 were done under conscious sedation and 6 under general anesthesia. There was a small learning curve (76 ± 8 min for the first three procedures; 50 ± 2 min for the subsequent 22). The mild to moderate pain during the first 24 postoperative hours was controlled with over-the-counter medication. Two complications were noted: one patient presented with ulcerative esophagitis and gastroparesis 10 days after the Stretta treatment, and one patient developed pancreatitis on postoperative day 27, which was probably unrelated to the Stretta procedure. Eight of the thirteen patients (62%) available for 3-month follow-up were off all antisecretory medication. The other five patients were still taking medications but had been able to reduce the amount considerably. The average daily dose of proton pump inhibitors was 43.0 ± 5.0 mg/preoperatively and 6.4 ± 2.2 mg/3 months postoperatively ($P < 0.001$). Other classes of GERD treatment such as metoclopramide had been completely abandoned. In all patients, QOLRAD scores improved (3.5 ± 0.4 to 5.5 ± 0.5 ; $P < 0.001$) as did SF12 physical (23.7 ± 3.0 to 31.0 ± 3.4 ; $P < 0.008$) and mental (40.5 ± 2.9 to 47.7 ± 3.2 , $P < 0.017$) scores. All patients would undergo a Stretta procedure again except one 78-year-old man with progressive Alzheimer's disease.

Conclusion: The Stretta procedure is a promising new modality in the management of GERD. It can be safely performed in one short session with gastroesophageal endoscopy under conscious sedation in an outpatient setting. It improves GERD symptoms and quality-of-life scores in patients at 3 months and eliminates or significantly reduces the need for antisecretory drugs.

INTRODUCTION

GASTROESOPHAGEAL REFLUX DISEASE (GERD) is a common entity, with about 10% of the general population experiencing significant daily symptoms¹ resulting in a substantially affected quality of life.^{2,3} Complications of GERD include Barrett's esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture.⁴ The primary causes of GERD are transient inappropriate relaxation or an abnormally low resting pressure of the lower esophageal sphincter (LES). This episodically exposes the esophageal body to gastric acid and enzymes.⁵ Current therapy for GERD begins with lifestyle changes and medical treatment, which prove to be effective in about 80% of patients. However, the cumulative costs are high, and the recurrence rate of symptoms is as high as 90% after cessation of medication.⁶ Patients who do not tolerate or respond inadequately to medication or who wish to avoid life-long drug therapy are surgical candidates. Nissen fundoplication is the most commonly employed antireflux procedure, with response rates as high as 90% at 5-year follow-up.^{7,8}

Radiofrequency (RF) energy has been used for the general surgical application of tissue coagulation for more than 70 years. The energy is delivered to tissue using an electrode, a return electrode pad, and an RF generator. The recent implementation of thermocouple feedback within certain RF systems has permitted precise regulation of tissue temperature during energy delivery. The effects of RF energy-induced tissue heating can be categorized as tissue contraction through collagen shrinkage and subsequent remodeling, leading to tightening and reduction of tissue compliance, or specific and permanent ablation of nerve pathways.

Today, RF application has found different clinical uses, including ablation of aberrant conduction pathways in Wolf-Parkinson-White syndrome and other myocardial dysrhythmias,⁹ tightening of lax joint capsules in chronic subluxation,¹⁰ transurethral submucosal prostate tissue ablation for benign prostate hyperplasia,¹¹ endometrial ablation for dysfunctional uterine bleeding,¹² and ablation of nerve pathways for chronic pain.¹³ Powell and associates¹⁴ reported submucosal RF ablation of the soft palate musculature with resultant thermal lesion shrinkage and palatal tightening, which led to lessening of disordered breathing during sleep.

Utley and colleagues¹⁵ have pioneered RF application to the gastroesophageal junction (GEJ). In two animal models, they were able to demonstrate an increase in gastric yield pressure (pig) and reduction of transient LES relaxation (dog).¹⁶ Using the new Stretta system (Curon Medical, Sunnyvale, CA), the preliminary results of a recently initiated multicenter trial have shown that the application of RF energy in humans is practical with favorable short-term outcomes regarding GERD.¹⁷

We provide an overview of the practical application of

the Stretta procedure and report our experience with the short-term outcome of RF energy delivery to the LES in the treatment of GERD.

PATIENTS AND METHODS

Preoperative patient evaluation

Data were prospectively collected on the first 25 consecutive patients undergoing the Stretta procedure at Vanderbilt University Medical Center between August and March 2001. The mean age was 48 ± 4 years (range 22–78 years), height 68 ± 1 inch, and weight 200 ± 14 lbs (range 135–385 lbs). All patients had long histories of GERD and were taking proton pump inhibitors (PPIs). Patient work-up included esophageal manometry, ambulatory 24-hour pH testing, completion of a standard GERD-specific quality-of-life survey (QOLRAD) and general quality-of-life survey (SF12), and endoscopy. Manometry was performed using a standard six-channel catheter (Sandhill Scientific) and the pull-through technique. Once the LES was manometrically localized, the pH probe (Sandhill Scientific) was placed transnasally with the most distal port 5 cm above the LES. Esophageal data were recorded for 24 hours using the GERD checker system (Sandhill Scientific). Patients with esophagitis on previous endoscopy did not undergo 24-hour pH testing. Patients with Barrett's esophagus, significant motility disturbances (<70% peristaltic contractions, <30 mm Hg average contraction amplitude), and hiatal hernia >2 cm were not offered the Stretta procedure (Table 1).

Stretta procedure

The Stretta system consists of the RF control module and the flexible Stretta catheter. The catheter has a 20F soft bougie tip and a balloon, which opens a surrounding basket (max. 3 cm). On the widest area after balloon inflation, the catheter has four NiTi needle electrodes (5.5 mm), which can be extended into the LES muscle tissue. The catheter simultaneously aspirates and irrigates the

TABLE 1. EXCLUSION CRITERIA FOR STRETТА THERAPY

Hiatal hernia >2 cm
Motility disorder <70% peristalsis, <20 mm Hg average amplitude
LES <10 mm Hg
Barrett's esophagus
Failure of LES relaxation in response to primary peristalsis (LES relaxation to a pressure >10 mm Hg above gastric baseline)
ASA IV or poor surgical candidate in the event of complications necessitating operative intervention

LES, lower esophageal sphincter; ASA, American Society of Anesthesiologists (classification).

esophageal lumen with water. The four-channel, thermocouple-controlled generator provides 60 to 300 J of RF energy to each needle, heating the surrounding muscle tissue to the target temperature between 65° and 85°C while cooling the mucosa with its integrated irrigation system. While RF energy is employed, the system monitors the temperature and the impedance of the tissue surrounding the needle tips.

The Stretta procedure was performed following a standardized protocol. After completion of the diagnostic endoscopy, the endoscope was used to identify the position of the squamocolumnar junction (z-line). The Stretta catheter was passed transorally and positioned 1 cm above the z-line. Once it was in position, the suction tubing was connected to the catheter, and cooled sterile water was infused through the inflow port of the Stretta catheter. The balloon was inflated, and the needles were simultaneously deployed to the full position (Fig. 1). The settings of the control module were 1.5-minutes' delivery time, target temperature 85°C, and maximum wattage 5W. Radiofrequency energy delivery and irrigation commenced at the same time. The generator continued delivering energy to each needle until 1.5 minutes had elapsed or the needle tip temperature exceeded 100°C, the mucosa temperature exceeded 50°C, or the impedance exceeded 1000 Ω . After treatment, the needles were

retracted, the balloon was deflated, and the catheter was rotated 45°. Treatment was repeated, creating a ring of lesions 1 cm above the z-line.

The catheter was moved distally in 5-mm increments to create four levels of lesions with two lesion sets per level. Pull-back lesions were then created by advancing the catheter into the stomach, inflating the balloon fully to 25 cc, then gently retracting the catheter against the hiatus until it met resistance. The needles were deployed, and RF energy was delivered for 1.5 minutes. Three sets were made in this manner with 45° left and right rotations between sets. A second set of pull-back treatments was then performed. The balloon was inflated to 22 cc and retracted in the same manner to rest in the hiatus about 1 cm higher than before. Three more sets were created at this location.

After the procedure, patients were advised to continue their antireflux medication for 3 weeks. At a follow-up visit, they were asked to gradually taper the use of these drugs over the next weeks.

Postoperative follow-up

Data regarding anesthesia, operative procedure, and postoperative complications were collected. At 3-month follow-up, patients completed the QOLRAD and SF12

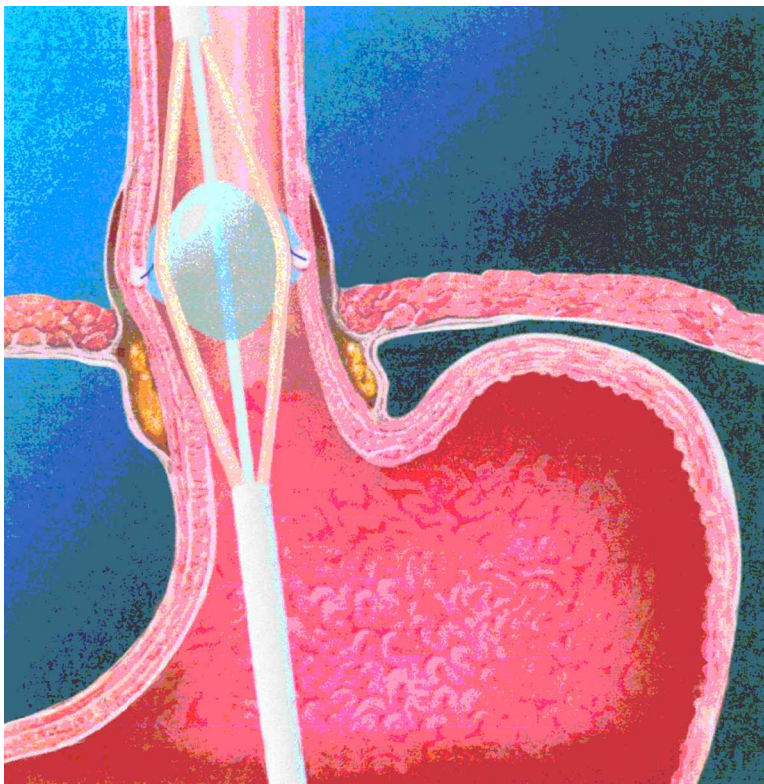


FIG. 1. Stretta catheter 1 cm above z-line at gastroesophageal junction with balloon inflated and four needles deployed to deliver RF energy to submucosal and muscular tissue.

survey forms. The patients were asked about complications, medication use, and overall satisfaction with the procedure.

RESULTS

In nine patients (36%), esophagitis was found on endoscopy prior to the Stretta procedure, and preoperative pH testing was not performed. One patient did not tolerate the pH probe. The remaining 15 patients had a 24-hour pH study performed with a Johnson-DeMeester score of 31.0 ± 11.4 (normal ≤ 22) and a total time of acid exposure of $7.0 \pm 1.3\%$ (normal $\leq 4.2\%$). Preoperatively, esophageal pathologies such as achalasia were excluded by esophageal manometry, which assured normal peristalsis of the esophagus. The LES pressure was 24 ± 2 mm Hg with a mean intra-abdominal length of 2.7 ± 0.3 cm.

All patients were classified as ASA II or III and treated as outpatients. Twenty procedures (80%) were done under conscious sedation, and five patients underwent general anesthesia. Three had comorbidities necessitating tighter physiologic control, and conscious sedation was inadequate because of pain in two patients.

Two surgeons on staff at Vanderbilt University Medical Center performed all 25 Stretta procedures. There was a small initial learning curve for the first three cases, where the average operative time was 76 ± 8 minutes. This was reduced to 50 ± 2 minutes in the following 22 sessions.

All patients under conscious sedation reported moderate pain during the application of RF energy. Patients experienced mild postoperative pain for about 24 hours, which was controlled with over-the-counter pain medication (acetaminophen). No other postoperative complaints were noted.

Complications were noted in two patients. One 22-year-old man developed gastroparesis and ulcerative

esophagitis and was readmitted on postoperative day (POD) 12 with hematemesis. Endoscopy confirmed ulcerative esophagitis, and 1.5 L of brownish fluid was evacuated from his stomach. Four weeks later, the ulcerative esophagitis resolved and the patient felt that his GERD-related symptoms were improving. He was off all medications without symptoms 3 months later. One 36-year-old mentally retarded patient with bipolar disorder, obsessive-compulsive disorder, hypertension, and suspected Ehlers-Danlos syndrome presented with nausea and vomiting on POD 26. After initial work-up, he was admitted for necrotizing pancreatitis with a pseudocyst and remained in the hospital for 1 month. His pancreatitis was thought to have been caused by clozapine, which he had been using for more than 18 months prior to the admission. Four months after the Stretta procedure, he remained on PPIs for GERD. Diagnostic endoscopy showed erosive gastritis but no esophagitis with normal gastric emptying.

Excluding the two patients with complications, 13 procedures (57%) were performed prior to December 31, 2000, and had 3-month follow-up. All but one patient would undergo the treatment again. The single patient who would not repeat the procedure again was a 78-year-old man with progressive Alzheimer's disease. However, his family felt that his symptoms were improved, which was supported by higher QOLRAD (3.2 to 5.3) and SF12 physical (26 to 54) scores but a reduced SF12 mental score 3 months after the procedure.

Including the Alzheimer patient, 5 of the 13 patients (38%) remain on antisecretory medication (PPIs) 12 weeks after the Stretta procedure. The patient with Alzheimer's disease and one other patient reduced omeprazole use to once a day. The other three patients were able to reduce their PPIs to every other day or as needed. The average preoperative dose of PPIs was 43.0 ± 5.0 mg/day, which was decreased to 6.4 ± 2.2 mg/day ($P < 0.001$) 3 months after the Stretta procedure (Fig. 2). Other classes of GERD medications such as

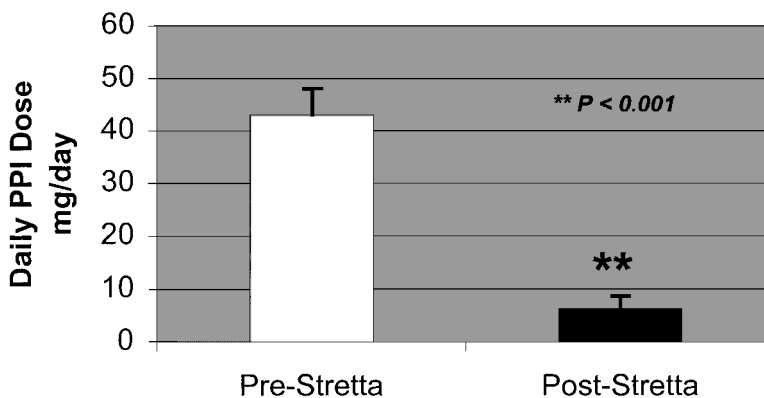


FIG. 2. Daily PPI dose before and 3 months after Stretta procedure (N = 13). Error bars indicate SEM.

TABLE 2. MEAN (\pm SEM) QUALITY OF LIFE SCORES BEFORE AND AFTER STRETTA PROCEDURE

	<i>Pre-Stretta</i>	<i>Post-Stretta</i>	<i>t-test</i>	<i>Normal</i>
QOLRAD	3.5 \pm 0.4	5.5 \pm 0.5	<0.001	7 ^a
SF12 physical	23.7 \pm 3.0	31.0 \pm 3.4	<0.017	49.7 \pm 0.5 ^b
SF12 mental	40.5 \pm 2.9	47.7 \pm 3.2	<0.008	50.5 \pm 0.5 ^b

QOLRAD, Quality of Life in Reflux and Dyspepsia.

^aMaximum score possible is 7 points.

^bNormal scores are taken from the general U.S. population, age 45 to 54 years.

metoclopramide or H₂ blockers were completely abandoned. One patient underwent 24-hour pH testing 6 month postoperatively. Her Johnson-DeMeester score decreased from 29.6 to 4.7 and her acid exposure time from 6.6% to 0.7%.

The quality of life scores improved 3 months after the Stretta procedure. The mean QOLRAD score increased from 3.5 \pm 0.4 to 5.5 \pm 0.5 ($P < 0.001$), as did the SF12 physical (23.7 \pm 3.0 to 31.0 \pm 3.4; $P < 0.008$) and mental (40.5 \pm 2.9 to 47.7 \pm 3.2; $P < 0.017$) scores (Table 2, Fig. 3).

DISCUSSION

Gastroesophageal reflux disease continues to be one of the major medical challenges of modern society. The

prevalence of adults who report at least one significant episode of heartburn per month is estimated to be as high as 40%.¹⁸ Patients with severe GERD may develop serious complications such as stricture, aspiration pneumonia, and carcinoma. Affected individuals report a reduction of their quality of life comparable to the reduction caused by angina pectoris.

Although effective treatment options such as medical therapy with PPIs or laparoscopic fundoplication are available, a totally endoscopic approach could open up a new chapter in the treatment of GERD. An endoscopic technique that eliminates GERD would be less invasive and potentially more cost-effective, while being more acceptable to patients, physicians, and health insurers.

The intensive research efforts of the last decade and the multitude of proposed procedures demonstrate the strong drive to develop a less invasive treatment for

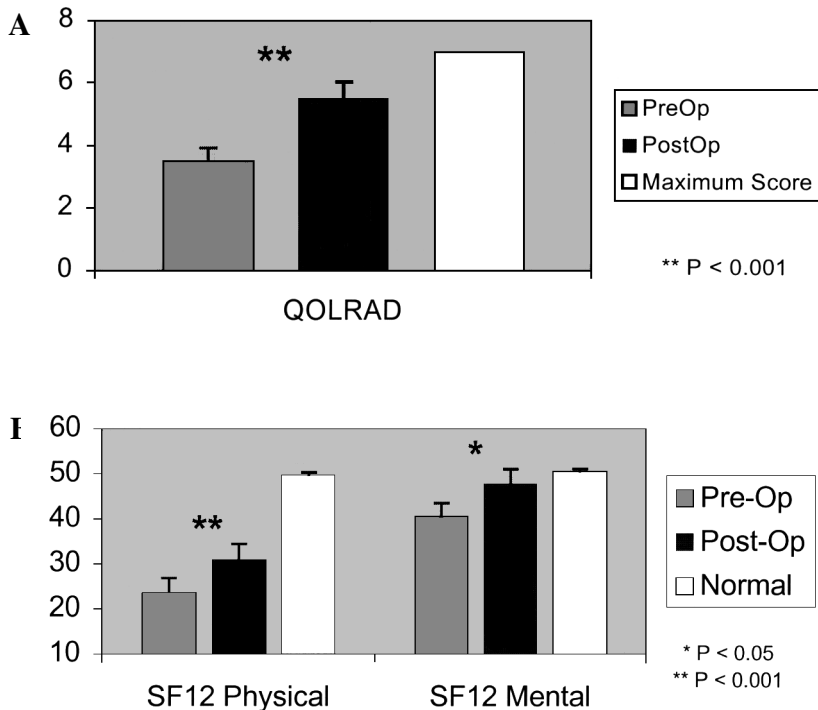


FIG. 3. Quality of life scores before and 3 months after Stretta procedure. Error bars indicate SEM. (A) GERD-specific scores. (B) General scores.

GERD. Many endoscopic procedures to treat GERD have been investigated, with variable outcome.¹⁹ To some degree, these procedures aim to mimic the antireflux mechanisms of fundoplication by augmenting the LES pressure, increasing LES length, or reducing the number of transient LES relaxations.²⁰ Experimental endoscopic techniques altering the GEJ include injection of collagen,²¹ sclerosing agents,²² or polytetrafluoroethylene (Polytef).²³ Important disadvantages of these techniques have been production of antibodies against the injection material (bovine collagen) and only short-term effectiveness of about 6 months (Polytef injection) with the need to repeat the procedure. Other endoluminal techniques such as laser scarring²⁴ and intraluminal valvuloplasty²⁵ have been tested only in animals so far.

Radiofrequency energy delivery to the submucosa and the muscle of the GEJ is a novel modality in the canon of endoluminal approaches targeting GERD. The Stretta catheter has recently been approved by the U.S. Food and Drug Administration for clinical use in the United States. The underlying mechanism is thought to be twofold: tissue contraction and remodeling, leading to tightening and reduced compliance of the GEJ, and ablation of nerves that trigger transient LES relaxations.¹⁶

The Stretta operation is a true outpatient procedure and can be performed in most patients under conscious sedation in less than an hour. The procedure is associated with minimal postoperative pain for 24 to 48 hours. Moderate amounts of analgesics and sedatives must be administered during the procedure to control the pain of RF energy treatment, and some patients are best treated under general anesthesia. Prior to the Stretta procedure, thorough diagnostic evaluation, including manometry, is essential to exclude esophageal motility disorders, achalasia, and larger hiatal hernias. After treatment, the patients were usually able to gradually reduce their antireflux medication over the next 4 to 6 weeks.

The cause of our single complication (gastroparesis and ulcerative esophagitis) is not completely clear. Two explanations were suspected: (1) temporary paralysis of the vagal nerve leading to increased reflux and following ulcerative esophagitis; or (2) direct superficial burn through insufficient mucosal cooling during the Stretta procedure. The incident happened in one of the first patients treated at Vanderbilt and may be a result of the learning curve for the Stretta device.

At 3-month follow-up, the majority of patients were very enthusiastic about the results of the procedure. Not a single patient needed the original amount of antireflux medication. The five patients who were still on PPIs either decreased their daily dose by half (two patients) or were able to take it every other day (two patients) or as needed (one patient) (see Fig. 2). No difference in drug intake was detected according to the weights of the patients.

Corresponding to their reduced or eliminated need for drugs, all 13 patients reported improved quality of life with higher scores in reflux and general surveys (see Table 2; Fig. 3). Most patients were enthusiastic about the results of the procedure, which their responses reflect: all but one would have the Stretta procedure again. The one patient who underwent pH testing 6 months after the procedure had normalization of her Johnson-DeMeester score (from 29.6 to 4.7) and total acid exposure time (from 6.6% to 0.7%).

These very promising results of our patient group correspond well with the only other clinical publication about the Stretta procedure.¹⁷ Triadafilopoulos and coworkers reported their experiences with 47 patients who had 3 and 6 months of follow-up in a multicenter study. After 6 months, the median survey scores and the acid exposure time had improved. Eighty-seven percent of their patients no longer required PPIs. However, the long-term outcome of the Stretta procedure needs to be elucidated.

CONCLUSIONS

Radiofrequency energy delivery to the GEJ (Stretta procedure) is a very promising new modality in the management of GERD. It can be safely administered in one short session combined with gastroesophageal endoscopy under conscious sedation in an outpatient setting. The Stretta approach is appreciated by patients as an alternative to invasive surgery or continuous medical therapy. It improves symptoms and quality of life scores in patients by 3 months and eliminates or reduces the need for antisecretory drugs in most cases.

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