



First year experience of patients undergoing the Stretta procedure

H. Houston, L. Khaitan, M. Holzman, W. O. Richards

Department of Surgery, Vanderbilt University Medical Center, D-5219 MCN, Nashville, TN 37232, USA

Received: 22 July 2002/Accepted: 31 July 2002/Online publication: 20 November 2002

Abstract

Background: The Stretta procedure is a new, totally endoscopic treatment for GERD, where radiofrequency energy is delivered to the smooth muscle of the gastroesophageal junction.

Methods: Forty-one patients undergoing the Stretta procedure between August 2000 and August 2001 were prospectively evaluated. Under an IRB-approved protocol, patients were studied preoperatively and postoperatively with esophageal manometry, 24-h pH testing, SF12 surveys, and GERD-specific questionnaires (QOLRAD).

Results: Results are reported as mean \pm SEM. All procedures were performed on an outpatient basis; 33 were under conscious sedation and 8 were under general anesthesia. Prior to treatment, patients had a mean LES pressure of 25 ± 2.4 mmHg, Johnson–Demeester score of 32.8 ± 4.6 mmHg, and % time reflux $8.4 \pm 0.9\%$. The quality-of-life scores were significantly improved at 6 months: QOLRAD score increased from 3.7 ± 0.2 to 5.1 ± 0.2 ($p = 0.002$), SF12 mental score increased from 44.3 ± 2.0 to 51.8 ± 1.7 ($p = 0.001$), and SF12 physical score increased from 26.2 ± 2.4 to 33.1 ± 3.8 ($p = 0.001$). Eighteen patients returned for esophageal manometry and 24-h pH testing at a mean of 6.8 ± 0.5 months. There was a significant decrease in esophageal acid exposure time ($8.4 \pm 0.9\%$ to $4.4 \pm 1.3\%$, $p = 0.03$) and Johnson–Demeester score (32.8 ± 4.6 to 22.9 ± 5.3 , $p = 0.04$). There was no significant change in mean LES pressure (25.3 ± 2.4 mmHg to 26.8 ± 2.6 mmHg, $p = 0.63$). Twenty of 31 patients (65%) available for 6 months follow-up were completely off proton pump inhibitors. The only complication related to Stretta was a case of gastroparesis 10 days post-operatively that resolved completely.

Conclusions: The Stretta procedure is a promising new endoscopic treatment for GERD. It significantly improves GERD symptoms and quality of life while eliminating the need for proton pump inhibitors in the majority of patients.

Key words: Gastroesophageal reflux disease — Radiofrequency energy — Stretta procedure

Gastroesophageal reflux disease (GERD) is one of the most common disorders of the gastrointestinal tract [4]. Forty percent of adults in the United States have occasional heartburn and 10% experience heartburn daily [3]. Chronic reflux may cause serious complications, such as ulceration, stricture, and Barrett's esophagus [4]. Both medical and surgical treatment options for GERD exist. Although medical therapy may be effective in 80% of patients, discontinuation of medications often results in early recurrence of symptoms [1]. Laparoscopic anti-reflux surgery has been shown to be safe and effective for the treatment of GERD with excellent symptom control in 90% of patients at 5-year follow-up [6]. However, many patients do not want surgery because of its potential complications.

The endoscopic delivery of radiofrequency energy to the gastroesophageal junction (Stretta, Curon Medical, Sunnyvale, CA) has recently been shown to be safe, well tolerated, and highly effective [8–10]. In a multicenter trial, the Stretta procedure significantly improved GERD symptoms, quality of life, and esophageal acid exposure while eliminating the need for anti-secretory medications in the majority of patients [8, 9].

We report our experience with the Stretta procedure over the past year.

Materials and methods

Patient evaluation

Forty-one patients undergoing the Stretta procedure between August 2000 and August 2001 were prospectively evaluated under an IRB approved protocol. All patients had a long history of GERD and were on proton pump inhibitors (PPIs). Preoperative evaluation included upper endoscopy, esophageal manometry, 24-h pH monitoring, short-form health surveys (SF12), and GERD-specific quality-of-life questionnaires (QOLRAD). Inclusion criteria were esophageal amplitude >30 mmHg, LES pressure >5 mmHg, normal LES relaxation, and esophageal acid exposure time $>4.0\%$. Exclusion criteria were hiatal hernia >2 cm, erosive esophagitis, Barrett's esophagus, severe

dysphagia, and poor surgical candidates (ASA III or IV). Patients with erosive esophagitis were treated medically, and, if resolved at subsequent endoscopy, they were able to undergo the Stretta procedure. Hiatal hernias were defined endoscopically by measuring the distance between the squamocolumnar junction (Z-line) and the diaphragmatic compression on the stomach.

Stretta procedure

All procedures are performed on an outpatient basis in the same-day surgery center or endoscopy suite. Most patients receive preoperative baseline doses of midazolam and Dilaudid. Subsequent incremental doses of fentanyl or Demerol are required during the procedure because the delivery of RF energy is painful. Diagnostic endoscopy is performed to identify the distance from the incisors to the Z-line. The procedure is terminated if prior endoscopy failed to reveal a hiatal hernia >2 cm, severe esophagitis, or findings suggestive of Barrett's esophagus. The Stretta catheter is inserted transorally and positioned 1 cm above the Z-line. Simultaneous irrigation and suctioning of cooled sterile water is begun to maintain adequate mucosal temperature. Four NiTi needle electrodes (5.3 mm) are deployed from a balloon-basket assembly into the muscle of the gastroesophageal (GE) junction. A 4-channel radiofrequency (RF) generator delivers RF energy to each electrode for 1.5 min with a target temperature of 85°C. The catheter is repositioned 45° and the treatment repeated at this level to create a ring of 8 lesions. The generator has an intrinsic mechanism for the constant monitoring of temperature and tissue impedance. If the base of the needle (mucosal temperature) exceeds 50°C, the tip of the needle (muscle temperature) exceeds 100°C, or impedance exceeds 1000 ohms, the generator shuts off power to that particular needle.

Next, the catheter is moved distally in 5-mm increments to create three more levels of rings in a similar fashion. Pull-back lesions are then created by advancing the catheter into the stomach, inflating the balloon with 25 cc of air, and pulling back the catheter until resistance is met at the GE junction. The needles are deployed and RF energy delivered for 1.5 min. This is repeated two more times at the same level by rotating 45° to the right and 45° to the left. A second pull-back technique is performed by inflating the balloon with only 22 cc of air. At the completion of the procedure, there are 6 sets of rings. Four are created in the antegrade fashion and 2 using the pull-back technique. Immediately after the procedure all patients undergo repeat endoscopy to assess the appearance of the mucosa and GE junction.

Postoperative care and follow-up

Data regarding the operative procedures and postoperative complications were collected. Anti-secretory medications were continued for 3 weeks after the procedure and then gradually weaned off. After consenting to an IRB-approved protocol, patients were studied 6 months postoperatively with esophageal manometry and 24-h pH testing. Patients still requiring anti-secretory medications at 6 months were asked to discontinue use 1 week prior to pH testing. Patients were also mailed QOLRAD and SF12 questionnaires and queries about medication use and overall satisfaction with the procedure.

Statistical analysis

Data were analyzed with STATA statistical software. Continuous outcomes from medication use, questionnaires, pH testing, and motility studies were computed using the Wilcoxon signed rank test. Statistical significance was reported for $p < 0.05$.

Results

Results are reported as mean \pm SEM. The mean age was 46 ± 3 years (range, 22–78). There were 16 males and 25 females. All procedures were performed on an

Table 1. Comparison of quality of life before and 6 months after Stretta procedure

N = 31 (6.2 \pm 0.5 mo)	QOLRAD ^a	SF12 MCS ^b	SF12 PCS ^c
Pre-op	3.7 \pm 0.2	44.3 \pm 2.0	26.2 \pm 2.4
Post-op	5.1 \pm 0.2	51.8 \pm 1.7	33.1 \pm 3.8
p-value	0.002	0.001	0.001

^a Maximum score possible is 7 points

^b Normal score in the U.S. population is 50.5 \pm 0.5

^c Normal score in the U.S. population is 49.7 \pm 0.5

outpatient basis. Thirty-three procedures were performed under conscious sedation and 8 were under general anesthesia. Five patients required general anesthesia secondary to comorbidities, while 3 were converted to general anesthesia secondary to inadequate pain control during RF delivery. The average operating time was 76 ± 8 min for the first 3 cases, as compared to 46 ± 3 min for the last 38 cases. Patients received midazolam (6.2 ± 0.8 mg, range, 3.5–14), Dilaudid (1.75 ± 0.4 mg, range, 1–3.5), and either fentanyl (168 ± 6.9 mcg, range, 75–250) or Demerol (111 ± 5.2 mg, range, 50–125).

Prior to treatment, patients had a mean LES pressure of 25.3 ± 2.4 mmHg, Johnson–Demeester score of 32.8 ± 4.6 (normal < 22), and percent time acid exposure $8.4 \pm 0.9\%$ (normal < 4.0%). All patients had normal peristalsis and complete relaxation of the LES by esophageal manometry.

The only complication related to the Stretta procedure was a 22-year-old man who developed gastroparesis and ulcerative esophagitis on postoperative day 12. He required nasogastric tube decompression and endoscopy confirmed the diagnosis. Four weeks later the esophagitis resolved, and he was off all medications without symptoms in 3 months.

Thirty-one patients (76%) completed questionnaires at a mean of 6.2 ± 0.5 months. The quality-of-life scores were significantly improved at 6 months: QOLRAD scores increased from 3.7 ± 0.2 to 5.1 ± 0.2 ($p = 0.002$), SF12 mental scores increased from 44.3 ± 2.0 to 51.8 ± 1.7 ($p = 0.001$), and SF12 physical scores increased from 26.2 ± 2.4 to 33.1 ± 3.8 ($p = 0.001$) (Table 1). Of patients, 89% were highly satisfied with the procedure and would have it performed again (Fig. 1). In addition, there were no reported procedure related complications such as dysphagia or gas bloat.

The mean PPI dose before the Stretta procedure was 37.8 ± 4 mg/d, as compared to 5.8 ± 1.6 mg/d at 6 months follow-up ($p = 0.003$) (Fig. 2). Twenty of 31 (65%) patients were completely off PPIs. Six patients reduced their PPI use to once a day and 3 were taking them only PRN. Two patients were still taking their PPIs twice a day.

Eighteen patients returned for esophageal manometry and 24-h pH testing at a mean of 6.8 ± 0.5 months. There was a significant decrease in esophageal acid exposure time ($8.4 \pm 0.9\%$ to $4.4 \pm 1.3\%$, $p = 0.03$) (Fig. 3) and Johnson–Demeester score (32.8 ± 4.6 to

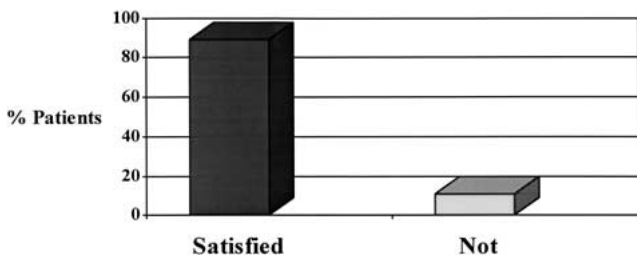


Fig. 1. Patient satisfaction.



Fig. 2. Medication use before and 6 months after Stretta procedure.

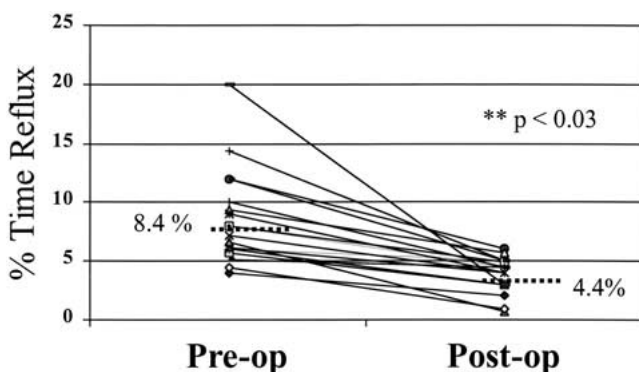


Fig. 3. Percent total time reflux before and 6 months after Stretta procedure.

22.9 ± 5.3 , $p = 0.04$). There was no significant change in mean LES pressure (25.3 ± 2.4 mmHg to 26.8 ± 2.6 mmHg, $p = 0.63$) (Table 2). Of these 18 patients who underwent repeat manometry and pH testing, 10 (55%) were off PPI's, as compared to 10 of 13 (76%) in the group not studied postoperatively.

In order to assess the effect of a hiatal hernia (0–2 cm) on the response to the Stretta procedure, we divided patients into two groups: complete responders (no PPI use) and non-responders (PPI use BID or QD). There was no significant difference between the response rates for patients with (60%) or without (67%) a hiatal hernia (Fig. 4).

Discussion

Gastroesophageal reflux disease is a common disorder affecting many Americans on a daily basis [3]. Severe GERD can lead to serious complications and have an adverse impact on patients' quality of life [12]. Effective

Table 2. Comparison of esophageal manometry and 24-h pH testing before and 6 months after Stretta procedure

$N = 18$ (6.8 ± 0.5 mo)	LESP	Demeester	%Reflux
Pre-op	25.3 ± 2.4	32.8 ± 4.6	8.4 ± 0.9
Post-op	26.8 ± 2.6	22.9 ± 5.3	4.4 ± 1.3
<i>p</i> -value	0.63	0.04	0.03

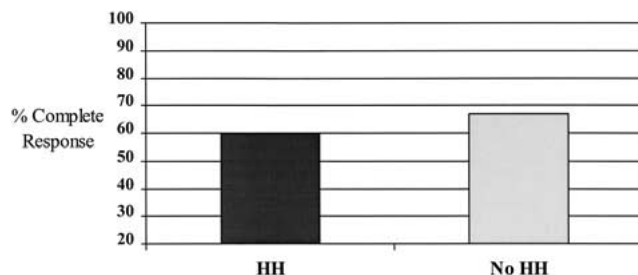


Fig. 4. Percent of complete responders with and without hiatal hernias.

treatment options are available; however, controversies exist. Medical therapy with PPIs relieves GERD symptoms and heals esophagitis in the majority of patients; however, long-term therapy is costly and difficult to maintain [1, 4]. Discontinuation of medication results in recurrence of symptoms in 80% of patients [1]. Laparoscopic Nissen fundoplication improves symptoms and normalizes acid exposure in 90% of patients; however, the risks of surgery and potential postoperative complications discourage many patients from undergoing surgery [6, 7].

The ideal endoscopic procedure for GERD should be safe and effective, control long-term symptoms, and not complicate future surgical options. Many techniques have been tested, such as endoscopic suturing and injection of sclerosing agents; however, only the Stretta procedure has accomplished all these goals. One-year follow-up of the U.S. open label trial has recently been reported [9]. GERD-specific quality-of-life and satisfaction scores were significantly improved over the baseline on-medication scores, and there was a significant reduction in median esophageal acid exposure time (10.6% to 6.2%). There were no major complications, no mortality, and no long-term adverse outcomes. Six patients underwent subsequent Nissen fundoplication secondary to incomplete symptom control and no scarring could be identified at the GE junction.

One proposed mechanism of action for the Stretta procedure is mechanical alteration of the GE junction. Utley and colleagues [11] have shown an increase in LES pressure and gastric yield pressure (resistance to reflux during gastric distension) following treatment with RF energy in animal models. In addition, histologic examination revealed a thickening of the GE junction musculature. These effects are attributable to heat-induced tissue contraction, followed by fibroblast and collagen deposition.

Ablation of the neural pathways responsible for transient LES relaxations (tLESRs), a predominant

cause of GERD, is felt to be a second mechanism of action. Kim and associates [5] reported a 54% reduction in tLESRs following RF delivery in a canine model, while Dibaise et al. [2] found a similar reduction in humans.

In this study, the Stretta procedure was well tolerated with one self-limiting complication (2.4%). All procedures were performed on an outpatient basis, and most were performed under conscious sedation in less than an hour. At 6 months follow-up, only 2 patients (5%) were on their original anti-reflux medication; 20 patients (65%) were completely off PPIs; and 9 patients had either reduced their dose to once a day (6 patients) or as needed (3 patients). QOLRAD and SF12 score were significantly improved, and mean esophageal acid exposure was significantly decreased from 8.4% to 4.4%. In addition, patients were highly satisfied with their procedure (89%) and reported no long-term complications.

Although we did not obtain 100% objective follow-up manometry and pH data, the group studied post-operatively had fewer patients off PPIs (55%), as compared to the rest of the group (76%). This can be explained by the fact that patients who were doing well were reluctant to return for repeat 24-h pH testing, and those who had less than satisfactory results were more willing to return because they were looking for something further to be done. Thus, we feel that, if anything, our objective data may be skewed toward those patients who were not doing as well.

Current exclusion criteria for the Stretta procedure is a hiatal hernia > 2 cm. This was established because of concerns for injuring vital structures in the mediastinum in patients with larger hiatal hernias. In this series, there was no significant difference in clinical outcome in patients with hiatal hernias up to 2 cm. Therefore, we believe small hernias are acceptable in patients undergoing the Stretta procedure.

Conclusions

The Stretta procedure is a safe and effective endoscopic treatment for GERD. It significantly improves GERD symptoms and quality of life, decreases esophageal acid exposure, and eliminates the need for proton pump inhibitors in the majority of patients. We are performing

longer-term assessments of the Stretta procedure and currently engaging in ongoing clinical trials of patients with failed Nissen funduplications and extraesophageal manifestations of reflux to further define the role of the Stretta procedure in patients with complicated GERD.

References

1. Chiba N, De Gara CJ, Wilkinson JM, Hunt RH (1997) Speed of healing and symptom relief in grade II to IV gastroesophageal reflux disease: A meta-analysis. *Gastroenterology* 112: 383–387
2. Dibaise JK, Akromis I, Quigley EM (2000) Efficacy of radiofrequency energy delivery to the lower esophageal sphincter in the treatment of GERD [abstract]. *Gastrointest Endosc* 51: AB96
3. Isolauro J, Laipala P (1995) Prevalence of symptoms suggestive of gastroesophageal reflux disease in an adult population. *Ann Med* 27: xx
4. Kahrilas PJ (1996) Gastroesophageal reflux disease. *JAMA* 276: 983–988
5. Kim MS, Dent J, Holloway R, Utley DS (2000) Radiofrequency energy delivery to the gastric cardia inhibits triggering of transient lower esophageal sphincter relaxation in a canine model [abstract]. *Gastroenterology* 118: A860
6. Lafullarde T, Watson DI, Jamieson GG, Myers JC, Game PA, Devitt PG (2001) Laparoscopic Nissen fundoplication: Five-year results and beyond. *Arch Surg* 136: 180–184
7. Peters JH, Heimbucher J, Kauer WKH, Incarbone R, Bremner CG, DeMeester TR (1995) Clinical and physiologic comparison of laparoscopic and open Nissen fundoplication. *J Am Coll Surg* 180: 385–393
8. Triadafilopoulos G, Dibaise JK, Nostrant TT, Stollman NH, Anderson PK, Edmundowicz SA, Castell DO, Kim MS, Rabine JC, Utley DS (2001) Radiofrequency energy delivery to the gastroesophageal junction for the treatment of GERD. *Gastrointest Endosc* 53: 407–415
9. Triadafilopoulos G, Dibaise JK, Nostrant TT, Stollman NH, Anderson PK, Wolfe MM, Rothstein RI, Wo JM, Corley DA, Patti MG, Antignano LV, Goff JS, Edmundowicz SA, Castell DO, Kim MS, Rabine JC, Utley DS (2002) The Stretta procedure for the treatment of GERD: 6 and 12 month follow-up of the U.S. open label trial. *Gastrointest Endosc* 55: 149–156
10. Triadafilopoulos G, Utley DS (2001) Temperature-controlled radiofrequency energy delivery for gastroesophageal reflux disease: The Stretta procedure. *J Laparoendosc Adv Surg Tech* 11: 333–339
11. Utley DS, Kim MS, Vierra MA, Triadafilopoulos G (2000) Augmentation of lower esophageal sphincter pressure and gastric yield pressure after radiofrequency energy delivery to the gastroesophageal junction: A porcine model. *Gastrointest Endosc* 52: 81–86
12. Valle C, Broglia F, Pistorio A, Tinelli C, Perego M (1999) Prevalence and impact of symptoms suggestive of gastroesophageal reflux disease. *Dig Dis Sci* 44: 1848–1852