*Original articles*

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# Treatment of refractory gastroesophageal reflux disease with radiofrequency energy (Stretta) in patients after Roux-en-Y gastric bypass

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**Abstract**
*Background:* Morbid obesity is associated with gastroesophageal reflux disease (GERD), which, in most cases, completely resolves after Roux-en-Y gastric bypass (RYGB). Patients with persistent or recurrent symptoms have limited surgical options. This study sought to evaluate the application of the Stretta procedure for patients with refractory GERD.
*Methods:* The medical records of all patients who underwent Stretta for refractory GERD after RYGB were reviewed. Demographic, preoperative, and postoperative reflux data were collected. Data are presented as mean ± standard error of the mean. The *t*-test was used for comparison purposes.
*Results:* Of 369 patients, 7 received Stretta 27 ± 6 months after RYGB. All were women with a mean age of 49 ± 2 years. All the patients had experienced prebypass GERD symptoms for a duration of 45 ± 8 months. The mean prebypass body mass index was 45 ± 2 kg/m$^2$, and this was reduced to 29 ± 2 kg/m$^2$ after laparoscopic RYGB ($p < 0.001$). Before Stretta, all patients underwent a 48-h Bravo pH study, which demonstrated reflux with a mean fraction time of 7% ± 2% for pH lower than 4. After Stretta, five patients had complete resolution of their symptoms, with normalization of pH studies (mean fraction time of 3% ± 0% for pH < 4). The follow-up period after Stretta was 20 ± 2 months. One patient did not have adequate relief of symptoms after Stretta, and one patient was lost to follow-up evaluation.
*Conclusion:* Stretta is a valid option in the treatment of persistent GERD for patients who have undergone gastric bypass. Further study is required to evaluate the long-term efficacy of this procedure.

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**Key words:** Gastric bypass — GERD — Morbid obesity — Radiofrequency — Stretta

Morbid obesity continues to increase in epidemic proportions. Patients who are severely overweight experience comorbidities that exert a negative impact on their health status and curtail their life span. Among these comorbid factors, gastroesophageal reflux disease (GERD) is symptomatic in about 58% of morbidly obese individuals, and is proven objectively in 21% [10]. A body mass index (BMI) greater than 30 confers an adjusted odds ratio of 2.8 for experiencing at least weekly symptoms of reflux [4]. Many authorities recognize surgical therapy, in the form of hiatal reconstruction and fundoplication, as definitive treatment, particularly for the mechanical features of this disease, such as regurgitation and its attendant complications. Although this strategy carries a high success rate for lean individuals, it is associated with a poorer outcome for obese patients [12].

Weight loss that results in a BMI less than 30, on the other hand, has been associated with favorable results in alleviating GERD. Of all the available methods for achieving significant weight loss, the operative option has proved to be the most effective and durable [5, 8]. In the United States, the Roux-en-Y gastric bypass is the most commonly performed procedure for weight loss, and this operation has been found to resolve GERD symptoms in the vast majority of patients [2, 3]. As a result, recent reports recommend its adoption as the most favored approach for effective treatment of GERD in obese patients [6, 7].

Nevertheless, despite the established proven success of gastric bypass, we have identified a subgroup of patients who experience GERD after the procedure and often require escalating doses of antisecretory medication. Available therapeutic options for these patients are limited because of their altered gastric anatomy.

Patients whose heartburn persists despite maximum doses of medication and those who report severe regurgitation pose a particularly challenging management problem.

The recent development and progressive adoption of endoluminal technology represent a potential breakthrough. Of the available options, radiofrequency ablation (Stretta) has shown the most promise, with up to 55% of patients not requiring any medications at a 2-year follow-up evaluation. Some authors have documented Stretta success rates of 91% for patients with typical GERD [1, 13].

However, the potential application and outcome of endoluminal strategies for the management of recurrent or persistent GERD in patients after laparoscopic Roux-en-Y gastric bypass (LRYGB) are not known. In this report, we present our experience using Stretta to manage recurrent GERD in patients who had undergone prior LRYGB.

## Methods

After receiving approval from the Institutional Review Board of the University of Pittsburgh, prospective data on all patients who had undergone Stretta for recurrent reflux after LRYGB for morbid obesity were reviewed. The data sources included our prospectively designed electronic database (Microsoft, Redmond, WA, USA), all available medical records, and direct patient interviews. Demographics, duration of symptoms, pre- and post-Stretta objective pH data, and subjective symptomatic relief were evaluated. Data are presented as mean ± standard error of the mean. The Student's *t*-test was used for analysis.

Demographic data collected included age, gender, preoperative and current BMI, duration and severity of preoperative GERD-type symptoms, and the use of antisecretory medication. Postoperatively, consenting patients were interviewed regarding their symptoms and use of antisecretory medication.

## Measuring GERD

Objective measurement of GERD was performed for all the patients in a serial manner (Fig. 1). All morbidly obese patients who initially presented with symptoms of GERD underwent preoperative evaluation with ambulatory 24- or 48-h pH monitoring. Postoperative patients who experienced recurrent or persistent GERD while on maximal protein pump therapy underwent 48-h ambulatory pH monitoring with the wireless Bravo probe (Medtronic, Minneapolis, MN, USA). Finally, after a minimum period of 6 months, all the patients who underwent Stretta therapy received a follow-up Bravo test for objective documentation of Stretta's residual effect.

### *Laparoscopic Roux-en-Y gastric bypass*

All patients underwent LRYGB as previously described [11]. Briefly, this operation entails producing a 4-to 5-cm-long gastric pouch anastomosed end-to-side to the efferent limb of a Roux-en-Y-fashioned segment of jejunum. Great care is taken to ensure that the gastric pouch is limited to the cardia of the stomach, and that it does not include any portion of the fundus. This critical portion of the operation is uniformly performed for all patients regardless of BMI. The angle of His is exposed and taken down in all patients to reduce tension across the anastomosis. Patients whose diagnosis involves large hiatus hernias undergo reduction of the herniated distal esophagus, repair of the hiatal defect, and creation of a gastric pouch, as described earlier.

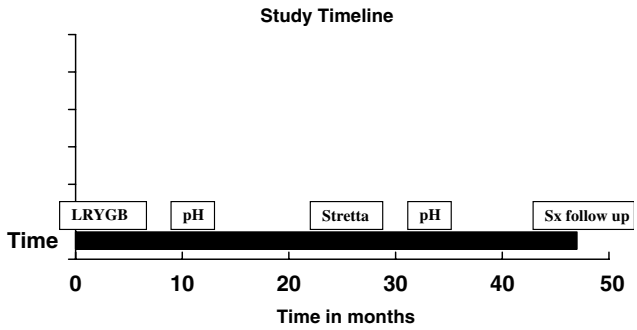


**Fig. 1.** Schematic outline of temporal events of study patients.

### *Stretta procedure*

The procedures were performed on an outpatient basis using either intravenous conscious sedation or general anesthesia. Initially, an upper flexible endoscopy was performed to assess mucosal integrity, and to determine the positions of the gastroesophageal junction and the gastrojejunal anastomosis, as measured from the incisors. The length of the gastric pouch was calculated by determining the difference between the gastrojejunal and gastroesophageal measurements. Under endoscopic guidance, a soft-tip guidewire was advanced into the jejunum several inches past the anastomosis. After removal of the endoscope, the Stretta catheter was advanced over the guidewire until the graduations on the catheter denoted that the Stretta balloon was situated 1 cm above the gastroesophageal junction. The balloon was inflated; wires were deployed; and radiofrequency energy was delivered for 90 s with continuous irrigation using chilled sterile water.

Once the energy was delivered, the balloon was deflated, the Stretta device rotated 45°, and the treatment repeated, creating a ring of eight lesions. The radiofrequency energy was produced by a generator that constantly monitored tissue temperature and impedance, with imposed automatic shutoff at limitations of 50°C for mucosal temperature and 100°C for muscle temperature, as well as tissue impedance of 1,000 ohms. The process was repeated at 5-mm intervals, resulting in four rings that began 1 cm above the Z-line and progressed toward the cardia. At this point, the therapy was terminated.

Typically, the Stretta is completed after an additional two rings have been created in a retrograde fashion by pulling the inflated balloon back into the cardia (the pullback technique). However, in most of our patients, the capacity of the gastric pouch was smaller than that of the inflated balloon (25 ml), thereby making it impossible to perform this portion of the treatment. At the end of the procedure, the endoscope was once again advanced to document the appropriateness of the lesions.

## Results

Seven patients received post-LRYGB Stretta for refractory GERD. One patient was lost to follow-up evaluation after Stretta, and therefore was excluded from the study, resulting in a study group of six patients. All were women with a mean age of 49 ± 2 years who had undergone LRYGB for morbid obesity during the period 1999 to 2001. In these years, 369 gastric bypass operations were performed, giving us a postoperative 1.6% incidence of medically refractory GERD. The mean prebypass BMI was 45 ± 2 $kg/m^2$, which had been reduced to 29 ± 2 $kg/m^2$ 21 months after LRYGB ($p < 0.001$). The patients had experienced prebypass GERD symptoms for 45 ± 8 months before the gastric bypass, and all but two patients reported immediate resolution of their symptoms for at least 10 ± 3 months after bypass. However, all the study patients resumed

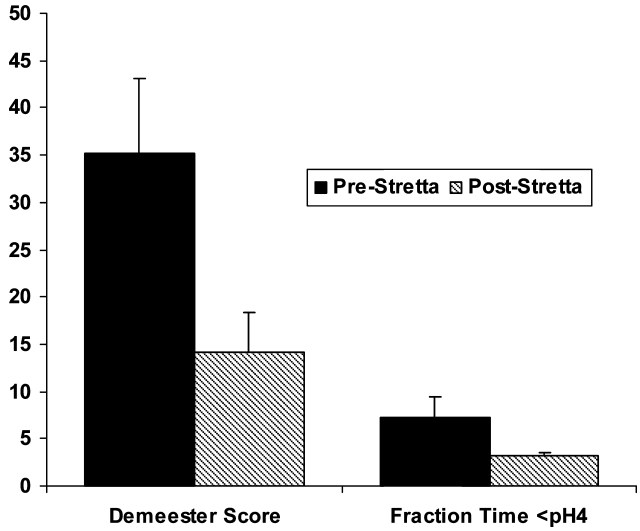


**Fig. 2.** The 48-h Bravo pH monitoring before and after Stretta (*$p < 0.05$).

use of either an H-2 blocker or proton pump inhibitor within 1 year after LRYGB for symptoms of GERD, and all eventually became tolerant to maximal doses of antisecretory medication.

All the patients underwent Stretta 27 ± 6 months after LRYGB. These procedures, all completed on an outpatient basis, were free of any complications. The mean length of gastric pouches at endoscopy was 4.14 cm (range, 3–6 cm). The follow-up data represent a post-Stretta time point of 20 ± 2 months (range, 15–28 months), and pertain to only six patients because one patient was lost to follow-up evaluation. Five (83%) of the six patients had complete resolution of symptoms and discontinuation of all medications. One patient experienced no improvement. Pre-Stretta Bravo was performed for all the patients, and post-Stretta Bravo was performed at a mean of 7 months after Stretta. As can be seen in Fig. 2, the total DeMeester score and fraction of time during which the pH was less than 4 dramatically improved after Stretta. The average DeMeester Score was reduced from 35 ± 7 to 14 ± 4, whereas the average fraction of time the pH was less than 4 decreased from 7% ± 2% to 3% ± 0. As demonstrated in Table 1, one patient (number 4) whose symptoms did not improve had a DeMeester score of 34 and an 8.4% for the fraction of time that pH was less than 4. Interestingly, patients 5 and 7 experienced de-novo GERD after gastric bypass. Figures 3 and 4 graphically illustrate the changes in these parameters for individual patients.

## Discussion

Although LRYGB is recognized for its superior efficacy in treating GERD, it is not universally successful. Even the most exultant reports describe a GERD resolution rate of 72%, meaning that at least 28% of postoperative patients experience persistent or recurrent GERD [3, 10]. In fact, we have identified patients who experience de novo GERD after LRYGB (unpublished data). This probably is attributable to the fact that an integral component of our technique involves disruption to the angle of His, an action that eliminates an important contributor to the antireflux mechanism in the gastroesophageal region. The angle of His is routinely freed to optimize gastric pouch length and to achieve a tension-free gastrojejunostomy.

As the obesity epidemic continues to generate more candidates for LRYGB, it can only be assumed that the number of patients with postoperative GERD will increase, and that some of these will have GERD refractory to maximal medical therapy. Furthermore, although pharmacologic therapy may help to alleviate acid-related symptoms such as heartburn and chest pain, these methods are less effective in controlling the mechanical effects of GERD, such as regurgitation and aspiration. Some patients do gain symptomatic relief, but in many cases, this may be a transient phenomenon because of drug tolerance, rendering these patients dependent on ever-increasing doses of antisecretory medication. Such patients experience a diminution in quality of life and actively seek alternative options.

Nonpharmacologic therapeutic options for managing GERD for post-LRYGB patients are limited because of the anatomic constraints imposed by the operation. The fundamental need for restriction mandates the construction of a small gastric pouch (15–20 ml) based on the lesser curvature that completely excludes the distensible fundus. Additionally, modern principles of gastric bypass stipulate the complete division and separation of the gastric pouch from the remaining stomach. Although these surgical components of LRYGB are effective in optimizing food restriction and in minimizing recontinuity of gastric lumen, they render the stomach nonamenable to traditional antireflux operations.

The recent advent of endoluminal strategies for managing GERD offers a promising method for post-LRYGB patients. Current endoluminal technology is based on the principle of increasing bulk at the gastroesophageal junction by controlled scarring or biopolymer injection, or by valvuloplasty with plication of gastric folds [9]. By engaging the gastroesophageal junction and delivering therapy endoscopically, these approaches avoid the hazards and difficulties of manipulating the fibrosed extraluminal tissue found in patients with prior gastric and esophageal surgery. These methods produce their effect without the need for a traditional fundoplication, a pertinent factor for post-LRYGB patients for whom the fundus has been excluded. Our decision to offer Stretta to these patients was based on our favorable experience treating traditional patients with GERD (unpublished data). Stretta offers a safe alternative for patients who may be considered a high operative risk, or who may prefer a lesser invasive option.

In this study, we report our experience applying radiofrequency energy delivered endoluminally (Stretta) to treat recurrent and refractory GERD in post-LRYGB

**Table 1.** Testing for pH of patients before gastric bypass as well as before and after Stretta

| Patient | Age (years) | Pregastric bypass pH | Pre-Stretta DeMeester score | Post-Stretta DeMeester score | Pre-Stretta pH < 4 | Post-Stretta pH < 4 |
|---|---|---|---|---|---|---|
| 1 | 54 | + | 20.5 | 3.3 | 4% | 0.8% |
| 2 | 47 | + | 37.3 | NA | 7% | NA |
| 3 | 53 | – | 46.5 | 5.8 | 5.3% | 1.3% |
| 4 | 41 | + | 20.2 | 34 | 4.8% | 8.4% |
| 5 | 60 | NA | 20.2 | 14.1 | 4.8% | 3.2% |
| 6 | 46 | + | 66.9 | 26.6 | 17.9% | 2.5% |
| 7 | 45 | NA | 42.7 | 3.60 | 16.9% | 0.5% |

NA, not available

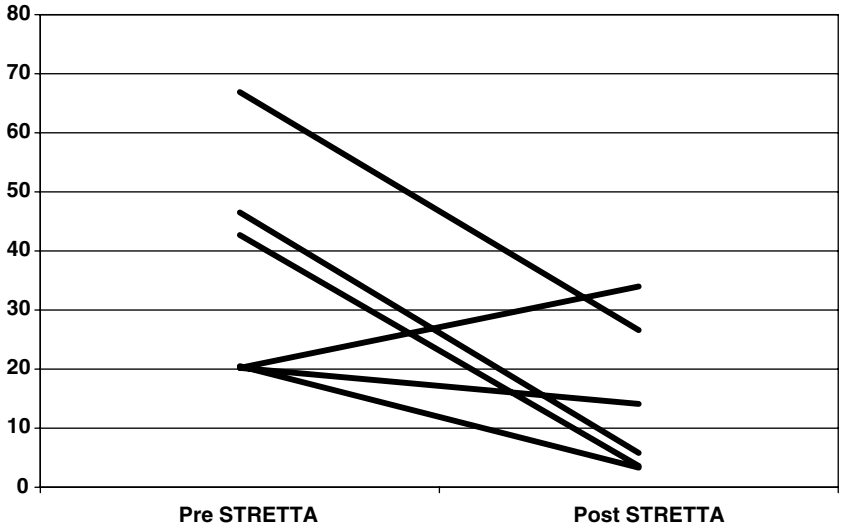


**Fig. 3.** DeMeester Scores before and after Stretta.

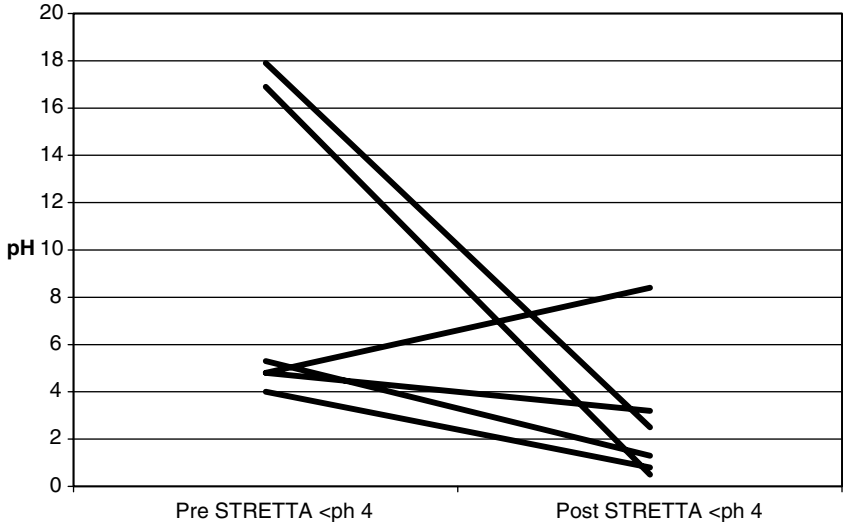


**Fig. 4.** Percentage of pH less than 4 before and after Stretta.

patients. With this method, we have been able to achieve significant symptomatic relief and objective reversal of GERD in a safe and truly minimally invasive manner. Ambulatory pH monitoring performed before Stretta and repeated after a postprocedure interval of at least 6 months showed normalization of pH values in five (83%) of six patients. After a mean follow-up period of 20 months, all of the patients except one were asymptomatic. The one patient with persistent symptoms produced an ambulatory pH profile consistent with GERD. Repeat or so-called "booster" Stretta therapy for typical GERD patients with persistent reflux has resulted in pH neutralization and symptomatic resolution, and this may be a valid option for patients who have achieved suboptimal results.

Patient selection for Stretta after gastric bypass must include careful review of symptoms, an upper gastrointestinal (UGI) series, upper endoscopy, and pH moni-

toring. The UGI series will document the size of the gastric pouch and confirm normal anatomy. Upper endoscopy is required to identify esophagitis and gastric ulcers, whereas pH monitoring will document true reflux. Patients with severe (grade 3 or 4) esophagitis or active ulcer disease are not offered Stretta until disease resolution. Additional patient selection criteria include the ability to tolerate general or intravenous anesthesia.

Initially, we performed the Stretta procedures with the patient under conscious sedation, but we modified this to general anesthesia to enhance airway security and safely eliminate patient discomfort. General anesthesia allows delivery of radiofrequency energy in a smooth and uninterrupted manner. Patients should be cognizant of the attendant risks, which, although rare, include mucosal injury, bleeding, perforation, infection, and dysphagia [14].

This study had some limitations. As a result of the altered gastric anatomy in post-LRYGB patients, we were not able to complete the Stretta procedure as classically described. The procedure typically includes a pullback component that involves applying tension to the inflated balloon of the catheter against the distal surface of the Lower Esophagel Sphincter (LES). The capacity of this balloon is 22 to 25 ml, an amount that surpassed the capacity of the gastric pouches, making us unable to perform this component for fear of producing treatment scars on the distal surface of the gastrojejunostomy anastomosis instead of the LES. Nevertheless, it seems that even this abridged version of Stretta resulted in the required effects for our patients.

Another limitation of this study is the relatively short interval until objective reassessment of GERD after Stretta. The 6-month interval may be construed as insufficient time to allow for potential remodeling and perhaps diminution of the scarring that results from the treatment, an event which may lead to gradual deterioration of the antireflux barrier. However, the elimination of GERD symptoms in our patients for a mean period of 20 months indicates persistent and effective therapy.

In conclusion, we present objective evidence for the efficacy of applying endoluminal technology, specifically radiofrequency energy, for the treatment of patients with recurrent GERD after LRYGB. This method represents a valid option for patients whose gastric anatomy was altered. Furthermore, this outpatient therapy has been delivered safely and, in the current study group, without morbidity. Additional studies are required to determine the long-term effect of Stretta in this patient population, and also to compare its outcomes with those of other endoluminal methods.

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