

Long-term results of the stretta procedure in patients with gastroesophageal reflux: A single-center experience

Gastroözofageal reflü hastalarında uzun dönem stretta sonuçlarımız: Tek merkez deneyimi

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Background and Aim: Gastroesophageal reflux disease is a common disease that is usually treated with medications. A group of patients who is unresponsive to lifestyle changes and medications or does not want to use long-term medications is referred for endoscopic treatments and surgery. In this study, we aimed to present the results of our patients who were followed up after the diagnosis of gastroesophageal reflux disease and Stretta treatment in our clinic. **Materials and Methods:** The study included a total of 25 patients with gastroesophageal reflux disease with ages between 18 and 80 years who underwent the Stretta procedure. Patients were followed up for 4 years. **Results:** Of 25 patients, 16 were men (mean age: 38±7.59 years) and 9 women (mean age: 38.2±7.74 years). The heartburn scores were 3.7±0.66 and 1.6±1 (p <0.05) in women and 4±0.70 and 1.68±1.19 (p <0.05) in men before and 12 months after the procedure, respectively. In the 4th year, there was a significant improvement in the reflux symptoms and quality of life of the patients, and 15 (60%) of 25 patients continued their life without using proton pump inhibitors. **Conclusion:** The Stretta procedure may be a good alternative for patients who do not respond to medicines or respond but refuse to take continuous medications.

Keywords: Stretta, gastroesophageal reflux, heartburn

INTRODUCTION

Gastroesophageal reflux (GER) is defined as the passage of gastric contents into the esophagus. GER becomes a disease when it causes macroscopic esophageal damage or symptoms. GER disease (GERD) is divided into physiological and pathological GERD (i.e., GERD is considered physiological to some extent). Physiological GERD attacks are usually short term, occur after meals, do not cause symptoms (asymptomatic), and rarely occur in sleep. On the other hand, pathological GERD can cause symptoms or mucosal damage and is frequently seen in sleep (1). Although the prevalence of GERD varies by country, its prevalence is 10%-20% in Western societies and less than 5% in Eastern societies (2). The classic symptoms of GERD are heartburn (pyrosis) and regurgitation. Heartburn is described as a retrosternal burning sensation that occurs after a meal, whereas regurgitation is defined as the escape of stomach contents into the esophagus, hypopharynx, or mouth. Dysphagia, chest pain, water brash,

Giriş ve Amaç: Gastroözofageal reflü yaygın bir hastalıktır ve genellikle ilaçlar ile tedavi edilir. Yaşam tarzı değişikliklerine ve ilaçlarına cevap vermeyen ya da uzun süreli ilaç kullanmak istemeyen bir grup hastaya, endoskopik tedaviler ve cerrahi müdahale önerilir. Bu çalışmada kliniğimizde gastroözofageal reflü tanısı ile takip edilen ve Stretta uygulanmış hastaların sonuçlarını sunmayı amaçladık. **Gereç ve Yöntem:** Çalışmaya, Stretta işlemi uygulanan 18-80 yaşları arasında gastroözofageal reflü hastalığı olan toplam 25 hasta alındı. Hastalar 4 yıl takip edildi. **Bulgular:** 25 hastanın 16'sı erkek (yaş ortalaması: 38±7.59) ve 9'u kadındı (yaş ortalaması: 38.2±7.74). Mide ekşimesi skoru (tedaviden önce) kadınlarda 3.7±0.66, erkeklerde 4±0.70 idi. Stretta işleminden sonraki 12. ayda, heartburn skoru kadınlarda 1.6±1 (p <0.05) ve erkeklerde 1.68±1.19 (p <0.05) idi. Dördüncü yılda reflü semptomlarında ve hastaların yaşam kalitesinde belirgin bir düzelme görüldü ve 25 hastanın 15'i (% 60) proton pompa inhibitörü kullanmadan yaşamlarına devam etti. **Sonuç:** İlaçlara cevap vermeyen veya ilaçlara cevap vermeyen ancak sürekli ilaç almak istemeyen hastalarda Stretta prosedürü iyi bir alternatif olabilir.

Anahtar kelimeler: Stretta, gastroözofageal reflü, heartburn

globus sensation, odynophagia, nausea, and extraesophageal symptoms (cough, hoarseness, and wheezing) are also GERD symptoms (3). GERD can be diagnosed clinically in the presence of classic GMRH symptoms such as heartburn and regurgitation. In some cases, such as atypical symptoms, the presence of alarm symptoms in individuals at risk for Barrett's esophagus and among others may require additional tests to diagnose GERD (endoscopy, pH meter, etc.). Endoscopically, GERD is divided into erosive and nonerosive forms. Lifestyle changes, medications [proton pump inhibitors (PPIs), antihistamines, antacids, etc.], endoscopic procedures, and surgery are used in the treatment of GERD. Although most patients with GERD can be treated with lifestyle changes and medications, a group of patients who is unresponsive to these therapies or do not want to use long-term medications is referred for endoscopic treatments and surgery (2,3).

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The Stretta procedure is a popular endoscopic treatment modality, which has become widespread in recent years. A Stretta is a flexible catheter with a nickel-titanium needle and an inflatable balloon. During the procedure, radiofrequency (RF) is applied to the lower esophagus region (4). In this study, we present the results of our patients who were followed up after GERD diagnosis and Stretta treatment in our clinic.

MATERIALS and METHODS

The study included a total of 25 patients with GERD between the ages 18 and 80 years. Patient data for this retrospective study were obtained from hospital records. All of the patients underwent upper gastrointestinal system endoscopy. Because of the retrospective nature of the study, ethics committee approval was not obtained. The study was done in accordance with the Declaration of Helsinki (1975) and ethical guidelines.

Criteria used for GERD diagnosis were as follows: endoscopy-proven esophagitis, abnormal esophageal pH result, a DeMeester score of ≥ 14.7 with symptom correlation of $\geq 50\%$, and/or more than 73 reflux episodes during 24 h of ambulatory impedance monitoring.

Inclusion criteria included a diagnosis of GERD according to the criteria above, age of >18 years, duration of symptoms (heartburn and/or regurgitation) must be 6 months or more, completely or partially responsive to PPIs, and refused reflux surgery.

Exclusion criteria included comorbidities (central nervous system diseases, connective tissue diseases, autoimmune diseases, and coagulation disorders), gastrointestinal surgery history (previous esophageal or gastric surgery, esophageal stricture, and shortened esophagus), impaired distal esophageal peristalsis, and Barrett's esophagus.

Stretta Procedure

The Stretta RF ablation system (Mederi Therapeutics Inc., Greenwich, CT, USA) consists of a four-channel RF generator

with a catheter system that delivers pure sine-wave energy (465 kHz, 2 to 5 Watts per channel, and 80 Volts maximum at 100 to 800 ohms). Each needle tip incorporates a thermocouple connection to prevent heat damage. Patients were prepared for an upper gastrointestinal system endoscopy. All procedures were completed at an endoscopy unit with sedo-analgesia. Upper gastrointestinal endoscopy was performed to identify the distance from the incisors to the Z-line. The endoscope was then removed, and the RF catheter was localized 1 cm above the Z-line through the mouth. The four-needle electrodes were placed at a predetermined length of 5.5 mm, and RF transmission was initiated. Each electrode transmitted RF energy for 60 s to reach the target temperature of 85°C. Then, the procedure was completed by removing the catheter. Control endoscopy was performed after the Stretta procedure.

Statistical Analysis

Descriptive statistics are presented as means, standard deviations, and percentages. Pearson's correlation coefficients were calculated for relationships between all quantitative variables. Statistical Package for Social Sciences version 18 (IBM Corp., Armonk, NY, USA) was used. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 25 patients were included in the study: 16 men (mean age: 38 ± 7.59 years) and 9 women (mean age: 38.2 ± 7.74 years).

The pretreatment heartburn score was 3.7 ± 0.66 in women and 4 ± 0.70 in men. In the upper gastrointestinal system endoscopy, six of nine female patients had erosive esophagitis (Los Angeles grade A to B), one had hiatal hernia (3 cm), and two had normal upper gastrointestinal system findings.

Table 1 presents the patients' demographic characteristics and evaluation results before the procedure. After the Stretta procedure, the patients were hospitalized for 1 day. Six

Table 1. Demographics of the patients

Characteristics	Women (n = 9)	Men (n = 16)
Age (years; mean \pm SD)	38.2 \pm 7.74	38 \pm 7.59
Continuous use of medications	5	10
Intermittent use of medications	4	6
Erosive esophagitis (Grade A–B)	6	7
Hiatal hernia (<3 cm)	1	0
Hiatal hernia + esophagitis	0	5
Normal endoscopy	2	4
48 h wireless pH meter	3	4
Heartburn score (before Stretta)	3.7 \pm 0.66	4 \pm 0.70

SD: Standard deviation.

of the patients did not manifest any complications or symptoms within the first 24 h after the procedure. None of the remaining 19 patients had life-threatening complications. Gastrointestinal complaints such as abdominal pain, nausea, and bloating were observed in 18 patients with spontaneous recovery and did not last more than 24 h. Gastroparesis was observed in one patient 2 weeks after the procedure. Medical treatment was initiated in patients who developed symptoms, and all of the complaints improved after treatment.

In the 12th month after the Stretta procedure, the heartburn score was 1.6 ± 1 ($p < 0.05$) in women and 1.68 ± 1.19 ($p < 0.05$) in men. Follow-ups of 24 patients were conducted for 4 years and one patient for 3 months. In the fourth year of follow-up examinations, it was determined that there was a significant improvement in the reflux symptoms and quality of life of the patients, and 15 (60%) of 25 patients continued their life without using PPIs (Table 2).

Table 2. Complications after the Stretta procedure

	N
No complications	6
Chest pain	6
Dyspepsia	3
Bloating	6
Nausea	3
Gastroparesis	1

DISCUSSION

GERD is a common disease in Turkey, as well as in the rest of the world. In studies investigating the prevalence of GERD in Turkey, the Mayo questionnaire has often been used. According to such studies, the frequency of GERD in Turkey is 19.3-22.8% (5-8). GERD affects patients' quality of life and increases hospital visits. PPIs are used in the treatment of GERD, and some patients may need to use these drugs for a long time. Long-term treatment and follow-ups are cost effective. There is a need for reliable nonsurgical methods to provide effective symptom relief and treat damaged mucosal lesions.

Endoscopic methods, such as the minimally invasive Stretta procedure, seem to be a good alternative in patients with refractory GERD who do not want surgical treatment or long-term medication use (9,10). In 2002, Corley et al. performed the first randomized controlled study comparing Stretta and sham procedures. In this study, 35 patients with GERD were treated with the Stretta procedure and 29 with a sham procedure. After 6 months, heartburn symptoms were reduced in the Stretta group compared with the sham group (61% vs. 33%, $p = 0.05$). No significant difference was found between

the two groups in terms of esophageal acid exposure time and PPI use (drug use 55% vs. 61%, $p = 0.67$) (11).

In another study, Liu et al. applied the Stretta procedure to 90 patients with GERD who had endoscopic esophagitis or abnormal esophageal pH. They found that reflux symptoms decreased by 70% in less than 2 months and by 16.7% in 2-6 months after treatment (9).

In a meta-analysis performed by Perry et al., 18 studies with a total of 1,441 patients were examined. Stretta treatment was found to improve heartburn and dyspepsia scores and quality of life ($p < 0.05$). In the same meta-analysis, a significant reduction was observed in DeMeester scores after the Stretta procedure (44.4 to 28.5, $p < 0.05$) (10).

In another study, Reymunde et al. performed the Stretta procedure to 83 patients with GERD symptoms, and follow-up evaluations were done for 48 months. The validated quality of life scores were 2.4, 4.6, and 4.3 ($p < 0.001$) and the GERD symptom scores were 2.7, 0.3, and 0.6 ($p < 0.001$) at 12, 36, and 48 months, respectively. In the same study, the rate of drug use was 100% before the procedure and 13.6% at 48 months (12).

Dughera et al. applied the Stretta procedure to 69 patients diagnosed with GERD between 2002 and 2007. They followed up 56 patients for 48 months. Heartburn scores, GERD-specific quality of life scores, and general quality of life scores were significantly improved in 52 patients (92.8%) at 24 and 48 months ($p < 0.001$). In the same study, 41 out of 56 patients (72.3%) were completely off PPIs (13). Meanwhile, in a prospective study conducted by Noar et al. in 217 patients with GERD, 99 patients were followed up for 10 years. Of the patients, 72% had normalized GERD-health-related quality of life scores, and 41% had entirely eliminated the use of PPIs (14).

In our study, we evaluated 25 patients with GERD for 48 months after treatment with the Stretta procedure. The mean heartburn scores were 3.7 ± 0.66 and 1.6 ± 1 ($p = 0.05$) in women and 4 ± 0.70 and 1.68 ± 1.19 ($p = 0.05$) in men before and 12 months after the procedure, respectively. Of the patients, 24 were evaluated for 4 years and one for 3 months. We determined that there was a significant improvement in reflux symptoms and quality of life, and 15 (60%) of 25 patients continued their lives without requiring the use of PPIs.

The retrospective nature of the study and the fact that it was performed in a small population constitute the most important limitations. However, the fact that the majority of patients are still being followed up in our outpatient clinic facilitates access to new data.

Most patients with GERD respond to medical treatment. There are, however, many patients who do not respond or do not want to take medication continuously. Thus, the Stretta procedure may be a good alternative for them. The Stretta proce-

sure may also be more effective in patients with nonerosive GERD or grade A–B esophagitis, particularly those with heartburn and regurgitation, who have to use long-term and/or intermittent PPI-type medications. Prospective and randomized controlled studies in larger populations are needed.

Conflict of Interest Statement: For all authors of this manuscript, there is no financial arrangement (e.g., employment,

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