Evidence Table

Clinical Area: The Stretta procedure for the treatment of GERD.

Keywords: Gastroesophageal reflux, management, radiofrequency, Stretta.


Study Type: Prospective.

Study Aim: To compare the short-term results of radiofrequency treatment of the gastroesophageal junction (Stretta procedure) to the laparoscopic fundoplication (LF) for the treatment of GERD.

Outcomes:
- **Primary**: GERD Health Related Quality of Life score, esophageal acid exposure, reduction in the use of proton pump inhibitors (PPIs), and improvement in physical and mental SF-36 quality of life scores.

Design
- **Number of subjects**: N=140 patients. N=65 underwent Stretta procedure, and n=75 underwent laparoscopic fundoplication (LF).
- **Description of study population**: Study participants were consecutive patients offered a surgical treatment for their GERD condition at Vanderbilt University Medical Center, Nashville, TN, between August 2000 and March 2002.
  - **Laparoscopic fundoplication group**: Mean age 49 ± 14 years, 44% males, 56% females, average Body Mass index (BMI) 28.7 ± 1, 42% had large hiatal hernia, (>2 cm), and 8% had Barrette’s esophagus. Their mean preoperative gastric exposure was 11.3 ± 0.6 %, and LES pressure was 18.2 ± 1.5 mmHg.
  - **Stretta procedure group**: Mean age 46 ± 12 years, 42% males, 58% females, and average Body Mass index (BMI) 30.3 ± 1.1, 59% had no hiatal hernias, and 41% had small hiatal hernias (1-2 cm). Their mean preoperative gastric exposure was 8.5 ± 0.5%, and LES pressure was 25.4 ± 2.9 mm.
- **Setting (clinical or community)**: Outpatient clinic.
- **Inclusion criteria**: Documented GERD either by a positive 24-hour pH study or biopsy-proven esophagitis. There were other predetermined inclusion/exclusion criteria but were not discussed.
- **Consecutive patients?** Yes.
- **Intervention**: All participants underwent upper endoscopy, and pH monitoring for 24 hours, and completed GERD Health Related Quality of Life (GERD-HRQL) questionnaire, and the 12-Item Short Form Health Survey (SF-12), before the procedures. Patients were selected for the Stretta procedure if they did not have a hiatal hernia >2 cm, LES pressure <8mmHg, or Barrette’s esophagus. Those with larger hiatal hernia, LES pressure <8mmHg, or Barrette’s esophagus underwent a LF. **Stretta procedure**: The intervention was performed as an outpatient procedure. Most patients received an intravenous conscious sedation, 8 patients underwent general anesthesia. Endoscopy was initially performed to measure the distance from the incisors to the squamocolumner junction (Z line). A guide wire was then passed through, left in the stomach and the endoscope removed. The Stretta catheter was then introduced transorally over the guide wire and situated at 1 cm proximal to the Z-line. The guide wire was then removed, the Stretta system’s balloon inflated and its four needle electrodes deployed into the muscle of the gastroesophageal (GE) junction, and the radiofrequency energy delivered to each electrode for 90 seconds. The target temperature was 85°C. The catheter was then repositioned and the treatment repeated to create a ring of eight lesions. Three more similar levels of rings were created distally at increments of 0.5 cm. Two other pullback lesions were created by advancing the catheter in the stomach, inflating the balloon, and pulling back till resistance is met. In all six sets of rings were created. Endoscopy was then performed immediately after the procedure to assess the appearance of the mucosal at the GE junction. The average procedure time was 46.5 ± 0.9
minutes. Antisecretory medications were given for at least 21 days after the procedure then gradually discontinued.

Laparoscopic Fundoplication: The five-trocar technique was used with complete mobilization of the gastric fundus, dissection of the distal esophagus and the performance of a fundoplication.

- Source of outcome data (e.g. patient self-report, doctor report, lab results): Follow-up questionnaire at 13, 6, and 12 months after the procedure. Esophageal manometry, and pH monitoring were performed 6 months after the procedure.
- Length of follow-up: 3-15 months for the Stretta procedure patients with a mean of $7.3 \pm 0.6$ months, and 2-10.5 months for the LF patients with a mean of $5.2 \pm 0.5$ months.
- Completeness of follow-up: Not discussed.

Validity
- Is the study type appropriate for the questions being asked? No, a randomized controlled trial would be the ideal type of study.
- Were patients similar with respect to baseline characteristics? No.
- Likelihood of selection bias? Yes.
- Was the intervention and other aspects of patient care similar for all patients (or for all patients in a defined subgroup)? Yes for every procedure.
- Was the process of observation likely to affect the outcome? Yes, mainly for the subjective outcomes, as the study was not blinded.
- Did an objective observer assess outcomes and were outcome measurements consistent? Not discussed.
- Was follow-up duration appropriate? Not for determining the long-term outcomes for the procedure.

Conclusions regarding validity of methods:
The study compared the radiofrequency treatment of GERD to laparoscopic fundoplication, however it has several limitations and potential biases. It was not randomized and the patients were highly selected to each procedure, which is a source of selection bias. There were multiple variations in the baseline characteristics of the patients, and no adjustments we made in the analysis. Moreover, neither the providers nor the patients were blinded to the procedure performed, which introduces an observation bias. The follow-up duration varied among patients and was as short as 2 months for some.

Results:

**GERD-QOL‡ scores for patients in the Stretta, and LF groups**

<table>
<thead>
<tr>
<th>QOL</th>
<th>Stretta procedure ( n=65 )</th>
<th>Laparoscopic fundoplication ( n=75 )</th>
<th>Stretta vs. LF</th>
</tr>
</thead>
<tbody>
<tr>
<td>At baseline</td>
<td>3.9 ± 0.2</td>
<td>4.1 ± 0.2</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>After follow-up**</td>
<td>5.7 ± 0.2</td>
<td>6.2 ± 0.1</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>( P ) value (pre vs. post)</td>
<td>&lt; .01</td>
<td>&lt; .01</td>
<td></td>
</tr>
</tbody>
</table>

*The difference between the 2 procedures was not significant

**3-15 months for the Stretta procedure patients with a mean of $7.3 \pm 0.6$ months, and 2-10.5 months for the LF patients with a mean of $5.2 \pm 0.5$ months.

‡GERD-QOL score is a 25-item questionnaire scored by a 7-point Likert response where 7 is the best score and represents complete absence of symptoms.
SF-12 scores:
Difference between Stretta procedure and LF after follow-up was not significant (p>.05)

PPI use:
58% of patients in the Stretta group were off PPIs, and 31% reduced their dose, compared to 97% of the LF patients who were of PPIs. (P value for difference between the groups is not provided).

<table>
<thead>
<tr>
<th>Esophageal acid exposure and LES pressure</th>
<th>At baseline</th>
<th>After surgery*</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Esophageal acid exposure</strong></td>
<td>8.2 ± 0.9</td>
<td>4.4 ± 0.5</td>
<td>&lt;.01</td>
</tr>
<tr>
<td><strong>DeMeester score</strong></td>
<td>39.4 ± 4.5</td>
<td>26.6 ± 5.2</td>
<td>&lt;.01</td>
</tr>
<tr>
<td><strong>LES pressure</strong></td>
<td>22.8 ± 2.4</td>
<td>23.5 ± 2.5</td>
<td>&gt;.05</td>
</tr>
</tbody>
</table>

* 22 patients returned for esophageal manometry and pH monitoring at a mean of 7.2 ± 0.5 months

Patient satisfaction:
89% satisfied with Stretta procedure vs. 96% with LF

Side effects:

<table>
<thead>
<tr>
<th></th>
<th>Stretta (n=65)</th>
<th>LF (n=75)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transient gastroparesis</strong></td>
<td>1 (1.5%)</td>
<td>2 (2.7%)</td>
</tr>
<tr>
<td><strong>Acute pancreatitis</strong></td>
<td>1 (1.5%)</td>
<td>1 (1.3%)</td>
</tr>
<tr>
<td><strong>Enterotomy</strong></td>
<td></td>
<td>2 (2.7%)</td>
</tr>
<tr>
<td><strong>Pneumothorax</strong></td>
<td></td>
<td>1 (1.3%)</td>
</tr>
<tr>
<td><strong>Slipped Nissen</strong></td>
<td></td>
<td>1 (1.3%)</td>
</tr>
<tr>
<td><strong>Incisional hernia</strong></td>
<td></td>
<td>2 (2.7%)</td>
</tr>
<tr>
<td><strong>Esophageal hernia</strong></td>
<td></td>
<td>1 (1.3%)</td>
</tr>
</tbody>
</table>

Authors’ Conclusions:
The authors concluded that the Stretta procedure is an effective alternative treatment for selected GERD patients. They do not recommend it for patients with large hiatal hernia (>2cm), Barrett’s esophagus or those with LES pressure < 8 mmHg.

Reviewer’s Conclusions:
This study was not randomized and patients were highly selected for each procedure. It was not blinded, not powered, and the follow-up duration was as short as 2 months for some patients, which is insufficient to determine the long-term durability of benefits or harms of the procedure.

Overall the study shows that both the radiofrequency therapy and laparoscopic fundoplication were associated with significant improvement in the patients’ quality of life, esophageal acid exposure time, and daily use of PPIs. Both procedures had high rates of patient satisfaction.

The study was supported by a grant from Curon Medical, the manufacturer of the Stretta System.