Treatment for severe GERD after Sleeve Gastrectomy: conversion to gastric bypass or endoluminal radiofrequency.

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Disclosures

- Cinemed
- Mederi
Can sleeve gastrectomy cause reflux or making existing reflux worse?

- **Almogy et al.**
  - Symptomatic GERD present in 35 of 119 patients, 17 required PPI preoperatively
  - 13 of 17 required postoperative PPI
  - 12 reported worsening GERD

- **Carter PR et al.**
  - Symptomatic GERD found in 34.6% of 176 patients
  - 47% of patients had symptoms of GERD > 1 month out from SG (majority of these patients were taking medications for GERD)

- **Howard et al.**
  - 28 consecutive patients undergoing LSG
  - 18% had new-onset GERD based on barium swallow

- **Soricelli E et al.**
  - 378 consecutive patients undergoing LSG
  - De novo GERD Symptoms developed in 23% of patients undergoing SG alone

Carter PR et al. SOARD 2011; 7: 569-74.
Soricelli E et al. SOARD 2012.
## Incidence of Post-op GERD after Sleeve Gastrectomy


<table>
<thead>
<tr>
<th>Authors</th>
<th>No. of patients</th>
<th>Follow-up (months)</th>
<th>Postoperative incidence of GERD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nocca et al. [36]</td>
<td>163</td>
<td>24</td>
<td>11.8%</td>
</tr>
<tr>
<td>Himpens et al. [37]</td>
<td>40</td>
<td>36</td>
<td>21.8% (1 year)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.1% (3 years)</td>
</tr>
<tr>
<td>Hamoui et al. [38]</td>
<td>118</td>
<td>13</td>
<td>12.7%</td>
</tr>
<tr>
<td>Menenakos et al. [39]</td>
<td>261</td>
<td>12</td>
<td>24.9%</td>
</tr>
<tr>
<td>Arias et al. [40]</td>
<td>130</td>
<td>24</td>
<td>2.1%</td>
</tr>
<tr>
<td>Cottam. et al. [41]</td>
<td>126</td>
<td>12</td>
<td>20%</td>
</tr>
<tr>
<td>Lakdawala et al. [42]</td>
<td>50</td>
<td>12</td>
<td>9%</td>
</tr>
<tr>
<td>Melissas et al. [43]</td>
<td>23</td>
<td>12</td>
<td>8.7%</td>
</tr>
<tr>
<td>Present series</td>
<td>245</td>
<td>24</td>
<td>7.8%</td>
</tr>
</tbody>
</table>

Range: 2.1-24.9%
A total of 4832 patients underwent LSG and 33,867 underwent GB, with pre-existing GERD present in 44.5% of the LSG cohort and 50.4% of the GB cohort.
Potential causes of GERD after sleeve gastrectomy

- **Inevitable**
  - Decrease in gastric compliance (lead pipe)
  - Increased intraluminal pressure with intact pylorus
  - Lowers LES pressure and shortens abdominal length of esophagus

- **Preventable**
  - Missing hiatal hernias
  - “Pouch” effect in the proximal part of the sleeve and the shape of the sleeve

SG lowers LES pressure and shortens abdominal length of esophagus

SG lowers LES pressure and shortens abdominal length of esophagus

Table 1  Lower esophageal sphincter length before and after sleeve gastrectomy

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal length</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>Total &gt;3.5 cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal length &gt;1 cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incompetent</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>Total length &gt;3.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal length &lt;1 cm</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Total length &lt;3.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal length &lt;1 cm</td>
<td></td>
<td>9</td>
</tr>
</tbody>
</table>

Paradigm shift in the management of GERD post-sleeve resection

1. Lifestyle Changes
2. Medications
3. Conversion to RYGB
4. Minimally Invasive Therapy
5. Invasive Surgery
Stretta Catheter

- Soft, flexible, bougie tip (20 French)
- 65 cm operating length
- Balloon/basket (max 3 cm) with four 5.5 mm NiTi electrodes
- Temperature and impedance monitoring
- Irrigation and suction
Temperature-controlled RF

Thermocouples
Temperature-controlled RF

- Thermocouple monitoring
- Target temperature
- Power output is regulated by computer algorithm
Stretta Procedure
Baseline and 6 months after Stretta
<table>
<thead>
<tr>
<th>RF MECHANISMS OF ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INCREASED WALL THICKNESS</strong></td>
</tr>
<tr>
<td>“EUS demonstrates that LES muscle is significantly thickened after RF delivery...thickening may result in reduced compliance of the GE junction and contribute to its mechanism of action.”</td>
</tr>
</tbody>
</table>

| **INCREASED LES PRESSURE - DECREASED TLESRs** |
| “RF reduced the rate of postprandial transient LOS relaxations from 6.8 (5.7–8.1) (median (interquartile range) per hour to 5.2 (4.2–5.8) per hour (p<0.01), and increased mean basal LOS pressure from 5.2 (SEM 0.3) mm Hg to 8.0 (SEM 0.4) mm Hg (p<0.01).” |

| **DECREASED TISSUE COMPLIANCE** |
| “Stretta improved GERD symptoms and decreased GEJ compliance. Decreased GEJ compliance, which reflects altered LES neuromuscular function, may contribute to symptomatic benefit by decreasing refluxes volume.” |

| **DECREASED ACID EXPOSURE** |
| “At 12 months, the mean HRQL scores of those off medications, the LES basal pressure, the 24-h pH scores, and the proton pump inhibitor (PPI) daily dose consumption were significantly improved from baseline...” |
Evidence of Improvement in Health Outcomes:
13 Years of Clinical Studies Safe, Effective + Durable

- > 20,000 patients treated to date
  - >2400 patients involved in Clinical Study

- 10 Year outcome study published in *Surgical Endoscopy* February 2014

- 33+ published peer-reviewed studies
  - Consistency of reported results (US, EU, Japan, China)
  - Uniform protocols and inter-trial consistency
  - Use of validated clinical surveys

- **Level I Evidence**
  - 3 Randomized Sham Control trials
    - 158 total patients followed 3-12 months
    - Significant improvement in symptom scores or quality of life compared to Sham group
  - 1 Randomized vs. PPI
SAGES Clinical Spotlight Review Recommends Stretta

Clinical Spotlight Review – Endoluminal Treatments for Gastroesophageal Reflux Disease (GERD)

Clinical Spotlight Review published on: 02/2013 by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

Conclusion

More than 30 peer reviewed studies, including 4 adequately powered randomized, controlled studies, a comprehensive meta-analysis and multiple prospective clinical trials have documented the safety and efficacy of the Stretta procedure. Durable treatment outcomes to at least 48 months also have been demonstrated in multiple studies, with significant reduction or elimination of medications used to treat the symptoms of GERD, as well as improvement in GERD QOL and symptom scores. Stretta may be recommended as an appropriate therapeutic option for patients with GERD who meet current indications and patient selection criteria and choose endoluminal therapy over laparoscopic fundoplication. Those criteria include:

Adult patients (age >= 18) with symptoms of heartburn, regurgitation, or both for >= 6 months who have been partially or completely responsive to antisecretory pharmacologic therapy.

The procedure has not been studied and should not be applied in treating patients with severe esophagitis, hiatus hernias > 2 cm, long segment Barrett esophagus, dysphagia, or those with a history of autoimmune disease, collagen vascular disease, and/or coagulation disorders. Further studies are needed to evaluate the role of Stretta in children if it is to be considered a therapeutic option.

Recommendation:

Stretta is considered appropriate therapy for patients being treated for GERD who are 18 years of age or older, who have had symptoms of heartburn, regurgitation, or both for 6 months or more, who have been partially or completely responsive to anti-secretory pharmacologic therapy, and who have declined laparoscopic fundoplication.

Quality of Evidence: (+++). GRADE Recommendation: Strong
Stretta used for GERD post-RYGB

Original articles

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

S. G. Mattar, F. Qureshi, D. Taylor, P. R. Schauer

Department of Surgery, Indiana University, Emerson Hall, 545 Barnhill Drive, Suite 242, Indianapolis, IN 46202, USA
Seven patients received post-LRYGB Stretta for refractory GERD.

Changes in patient’s pH Data

DeMeester Scores

Percent of time with pH<4 (24-h)

Duke University Experience with Stretta for refractory GERD post Sleeve

- 5 patients treated with Stretta to date
  - 4 with full remission of symptoms
  - 1 with symptom’s improvement

- Duke University
  - One of the US Center participants in an upcoming multicentric study aimed to study efficacy of Stretta in post Sleeve Gastrectomy GERD
Summary

- Sleeve Gastrectomy can increase reflux symptoms in patients with preexisting GERD
- Sleeve Gastrectomy can result in de novo GERD
- Sleeve Gastrectomy can decrease LESP and length of the LES
- In refractory GERD post Sleeve Gastrectomy: Stretta can be used after medical treatment optimization and before conversion to RYGB
- Previous data in RYGB patients with GERD and Sleeve (personal data) are promising and warrants future studies
Thanks

Any chance you can loosen the band a little? I plan to have lots of milk and cookies!

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