Gastric Balloon for Weight Loss

Karol A Gutowski, MD, FACS

Hot Topics
Disclosures

None related to this topic

Will use brand names due to lack of distinguishing generic names
Levels of Evidence and Qualifying Studies (Therapeutic Studies):

I High-quality, multi-centered or single-centered, randomized controlled trial with adequate power (N ≥ 100); or a systematic review of these studies

II Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies

III Retrospective comparative study; case-control study; or a systematic review of these studies

IV Case series

V Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles"
Gastric Balloon FDA Approvals

- ReShape Dual Balloon 2015
- Orbera Balloon System 2015
- Obalon Balloon System 2016

Non-Balloon Devices

- Lap-Band Adjustable Gastric Band 2001
- Maestro Electrical Stimulation System 2015
- AspireAssist Gastric Emptying System 2016
Status of Product

Obalon Balloon System

- Obalon Therapeutics
- FDA approved September 2016
- Cost for 3 balloons: $2600
- Cost to patient: $6,000 to $10,000
- > 10,000 patients treated worldwide

Indications

- Temporary weight loss for up to 6 months
- BMI 30 to 40 kg/m²
- Used with moderate intensity diet & exercise program
Liquid vs Gas Filler Gastric Balloons

Liquid-Filled Balloons

Orbera® Liquid Filled Balloon
1989 Patent Filed
2015 FDA-approved

ReShape Duo® Liquid Filled Balloon
2007 Patent Filed
2015 FDA-approved

Gas-Filled 3-Balloon System

Obalon® Gas Filled 3-Balloon System
2011 Patent Filed
2016 FDA-approved
### Liquid-Filled vs Gas-Filled Balloons

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Liquid Filled Balloon Systems</th>
<th>Gas-Filled 3- Balloon System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Placement</td>
<td>Endoscopy under general anesthesia</td>
<td>Swallowable, no anesthesia or sedation</td>
</tr>
<tr>
<td>Material and Filling Agent</td>
<td>Silicone rubber, Saline and methylene blue dye</td>
<td>Multi-layer, non-porous, nylon polyethylene polymer filled with a proprietary nitrogen gas mix</td>
</tr>
<tr>
<td>Balloon Volume</td>
<td>Range 400-900 cc</td>
<td>750 cc total volume 250 cc per balloon</td>
</tr>
<tr>
<td>Progressive Volume Over Time</td>
<td>No, total volume added during the initial placement</td>
<td>Yes, three balloons added gradually during the first 3 months of the 6-month treatment</td>
</tr>
<tr>
<td>Total Weight (g)</td>
<td>Weight &gt;400-900 g</td>
<td>Weight &lt;10 g, (~3g per balloon)</td>
</tr>
<tr>
<td>Balloon residence location in the stomach</td>
<td>Antrum (bottom)</td>
<td>Fundus (top)</td>
</tr>
<tr>
<td>Removal</td>
<td>Endoscopy under general anesthesia</td>
<td>Endoscopy under light, conscious sedation (intubation not required)</td>
</tr>
</tbody>
</table>
Approval Study

• 419 subjects
• 387 able to swallow device
  – 198 balloon device vs 189 sham control device
  – All had diet & exercise counseling
• Results
  – Balloon 14 lbs 6.6% of body weight
  – Control 7 lbs 3.4% of body weight
• Common adverse events
  – Abdominal pain & nausea x 1-2 weeks
  – 0.9% gastric ulcers
  – 3.0% early removal due to non-serious adverse events
Balloon Placement Process

• 1\textsuperscript{st} balloon, then at least 2 weeks apart
  – 2\textsuperscript{nd} Balloon 3 to 4 weeks later
  – 3\textsuperscript{rd} balloon 9 to 12 weeks later

• Supervised diet & exercise program
  – Monthly meetings

• Endoscopic removal at 6 months
Gas-Filled Balloon Placement

Swallowable Balloon Capsule

Inflation System

Flouroscopic Confirmation
Behavior Modification Program

• Balloons are a tool to facilitate weight loss

• Patients follow supervised program
  • Nutrition & exercise
  • Managing goals and barriers
  • Customized by the practice
    • In-house registered dietitian, contract out, virtual platforms

• Weight loss maintenance is dependent on patients continuing learned habits after balloons are removed
Endoscopic Balloon Removal
Balloon vs Control Results

% Total Body Loss

1st

2nd

3rd

Mean Difference 3.3%

Control  Treatment  Represents Balloon Placement
Balloon Group Stratified Weight Loss

<table>
<thead>
<tr>
<th>≥ %Total Body Loss</th>
<th>Number of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>120 / 185 (64.9%)</td>
</tr>
<tr>
<td>6%</td>
<td>98 / 185 (53.0%)</td>
</tr>
<tr>
<td>7%</td>
<td>81 / 185 (43.8%)</td>
</tr>
<tr>
<td>8%</td>
<td>68 / 185 (36.8%)</td>
</tr>
<tr>
<td>9%</td>
<td>55 / 185 (29.7%)</td>
</tr>
<tr>
<td>10%</td>
<td>49 / 185 (26.5%)</td>
</tr>
</tbody>
</table>

2/3 lost at least 5% body weight
Average 89% of weight loss maintained 6 months after balloon removal
Why Market to Plastic Surgeons?

- Need fluoroscopy & table *(Used about $10-20K)*
  - Radiology regulations, hospital privileges, etc
- Need dietician support
- Need gastroenterologist to remove balloons
  - Included in patient package price
Plastic Surgeons & Self Pay Patients

- Self financed patients have better weight loss outcomes with compared to insured patients
- Plastic surgeons charge on the higher end
- Additional service for aesthetic patients
- Bundle with other body contouring treatments
• 5 reported deaths since 2016
  – All deaths within 1 month of placement
  – NO root cause available

• 2 additional deaths associated with fluid filled balloons
  – Gastric perforation
  – Esophageal perforation
Summary

- Role of Plastic Surgeons in weight loss
  - Are we qualified?
- Medical liability issues
- Cost for 20 lb weight loss
- Long term efficacy?
  - FDA mandated post-approval trial soon
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Hot Topics

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