Methods

Intragastric Balloon Intolerance: A Retrospective Review of 100 Patients Treated with Two Different Devices
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Results

Baseline Characteristics

- 88% female with mean baseline age 48.9 (range 24-76), weight 231 lbs (range 155-329) and BMI 37.4 (range 28.8-56.2).
- No significant difference in baseline characteristics between two IGB groups.

Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>Orbera n=50</th>
<th>ReShape n=50</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>49.5 ± 12.1</td>
<td>48.4 ± 9.1</td>
<td>0.59</td>
</tr>
<tr>
<td>Height (inches)</td>
<td>66.8 ± 3.7</td>
<td>64.6 ± 3.1</td>
<td>0.52</td>
</tr>
<tr>
<td>Baseline weight (lbs)</td>
<td>227.7 ± 42.1</td>
<td>236 ± 46.8</td>
<td>0.80</td>
</tr>
<tr>
<td>Baseline BMI</td>
<td>37.3 ± 6.2</td>
<td>37.8 ± 6.1</td>
<td>0.86</td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td>73.4 ± 32.4</td>
<td>79.3 ± 36.8</td>
<td>0.46</td>
</tr>
<tr>
<td>% female</td>
<td>84%</td>
<td>88%</td>
<td>0.77</td>
</tr>
</tbody>
</table>

1 kind of IGB only (n=98)

IGB + weight loss RX (n=34)
Not analyzed for weight loss

The difference in duration across the measures of severity is also significant:
- ReShape balloons were associated with significantly shorter durations of nausea for all 3 severities (p=0.0077).
- ReShape balloons were associated with shorter durations of vomiting for all 3 severities that approached statistical significance (p=0.066).

Background

The ReShape® Dual Balloon and Orbera® intragastric balloons (IGBs) are safe and effective nonsurgical treatments for obesity introduced in 2015 in the United States. Accommodative symptoms post-implantation may occur, reducing patient satisfaction and leading in some cases to early removal. We report on the tolerability of IGBs in 100 patients (the first 50 Orbera and the first 50 ReShape) from our bariatric practice.

Methods

Single-center, retrospective data collection
HIPAA compliant data collection form
Trained research staff used practice EMR
Variables included:
- Baseline characteristics
- Occurrence, severity and duration of symptoms
- Early retrievals secondary to GI intolerance
- Weight loss

Treatment intervals:
- Orbera: August 2015 to Feb 2016
- ReShape: December 2015 to March 2016

Orbera
- Single balloon 400-700cc
- Dual balloon 750-900cc
- Anti-migration design

ReShape
- Dual balloon 750-900cc
- Anti-migration design

Results

Table 2. Weight Loss, IGB only Subjects

<table>
<thead>
<tr>
<th>Implanted Patients (n=100)</th>
<th>Orbera n=33</th>
<th>ReShape n=31</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pounds</td>
<td>21.9 ± 13.7</td>
<td>23.4 ± 13.1</td>
<td>0.67</td>
</tr>
<tr>
<td>%TBWL</td>
<td>10.2 ± 6.6</td>
<td>10.0 ± 5.0</td>
<td>0.88</td>
</tr>
<tr>
<td>%EWL</td>
<td>39.4 ± 32.1</td>
<td>35.8 ± 21.8</td>
<td>0.60</td>
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</tbody>
</table>

Conclusions

- Both IGBs are effective for weight loss in patients with obesity.
- ReShape patients had much shorter symptom durations for nausea and vomiting.
- Early retrievals due to intolerance were required twice as often in Orbera patients compared with ReShape patients.

Figure 1. Duration of Accommodation
Figure 2a and 2b. Comparison of Accommodation Duration by Severity
Figure 3. Early Retrievals for Intolerance
Figure 4. Weight Loss Analysis Consort Diagram
Table 2. Weight Loss, IGB only Subjects