Gastric Balloons for Obesity: Past, Present and Future

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Disclosures and Credits

• Allurion Technologies: Senior medical advisor, Equity position
• Boston Scientific: Consultant
• Olympus: Consultant

Credits:
Dr. Alfredo Genco
Dr. Eduardo Moura
Dr. Evzen Machytka
Dr. Yannis Rafthapoulos
Early Intragastric Balloons had a Suboptimal Benefit/Risk balance

Garren Edwards Balloon (1987)

Premature deflation resulted in small bowel obstruction in ~2% of patients

250 cc, air-filled cylinder
1987 Tarpon Springs Conference was held to define the ideal IGB

Ideal Gastric Balloon Design Criteria:

- Constructed of a high quality elastomer resistant to gastric acidity and sharp pieces of food
- Liquid-filled, 500 cc volume
- Smooth surface to reduce erosion/obstruction risk
- Radiopaque Marker
**Intragastric Balloons**

- **Orbera™**: Air, 6 M
- **ReShape Duo™**: Liquid, 6 M
- **Heliosphere™**: Air, 6 M
- **Spatz™**: Non-crushable anchor, Highly visible blue extraction clasp, Highly visible white inflation tube valve, Adjustable, saline filled silicone balloon, 12 M

*Not FDA approved*
VIDEO: Orbera
Question 1: Do intragastric balloons work?
Weight loss in gastric balloon patients is superior to sham in a larger sample size of US patients.

\[ N = 326; \text{multi-center, randomized, sham controlled trial}\]
Meta-analysis of 15 studies including 3,608 BIB® patients demonstrates efficacy and safety\(^1\)

<table>
<thead>
<tr>
<th>Metric</th>
<th>Mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Loss (kg)</td>
<td>14.7 (12.4-17)</td>
</tr>
<tr>
<td>% Total Body Weight Loss (TBL)</td>
<td>12.2 (10-14.3)</td>
</tr>
<tr>
<td>BMI Loss (kg/m(^2))</td>
<td>5.7 (4.4-6.9)</td>
</tr>
<tr>
<td>% Excess Weight Loss (EWL)</td>
<td>32.1 (26.9-37.4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptom</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea and vomiting after first week</td>
<td>295</td>
<td>8.6</td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>171</td>
<td>5.0</td>
</tr>
<tr>
<td>Deflation and migration of balloon*</td>
<td>87</td>
<td>2.5</td>
</tr>
</tbody>
</table>

* typically seen in patients who are lost to follow-up\(^2\)

Question 2: How do intragastric balloons work?
Multiple hypotheses of action exist, but none have been tested thoroughly.

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Studies</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes in leptin/ghrelin</td>
<td>Mion et al.</td>
<td>↓ ghrelin, ↓ leptin</td>
</tr>
<tr>
<td></td>
<td>Mathus-Vliegen et al.</td>
<td>No change in ghrelin</td>
</tr>
<tr>
<td>Delayed gastric emptying</td>
<td>Bonazzi et al.</td>
<td>Rapid decrease in gastric emptying time, returning to normal over 6 mos.</td>
</tr>
<tr>
<td></td>
<td>Mion et al.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Su et al.</td>
<td></td>
</tr>
</tbody>
</table>

Slowed gastric emptying may also contribute to mechanism of action.

1Bonazzi et al, ERMCS, 2005. 2Su et al, Clinical Nuclear Medicine, 2013. Note: different methods were used to measure GET resulting in substantially different absolute measures.
Question 3: How well do intragastric balloons work?
The right answer depends on the context in which gastric balloons are studied

### US sham controlled, pre-market study
- \( N \approx 218 \)
- Starting BMI = 35.4
- 7.6\% TBL at 24 weeks\(^1\)

- **Free** devices
- **Uncustomized** follow-up
- **Less intense** diet/exercise recs

### EU single-arm, post-market study
- \( N = 60 \)
- Starting BMI = 38.8
- 15.5\% TBL at 24 weeks\(^2\)

- **Patients pay** for devices
- **Customized** follow-up
- **More intense** diet/exercise recs

Serial IGB Placement vs. Diet Control

“[30 days] allows the stomach to restore the pre-BIB placement conditions.”
- Genco et al., 2010
RESULTS

BIB treatment vs Sleeve Gastrectomy

Kg

0 120 125 130 135 140 145 150 155 160

6 months

p = n.s.
RESULTS: BMI after 18 months

BMI

baseline 6 m. 8 m. 12 m. 18 m.
BIB
SLEEVE

p = n.s.  

p < 0.01
Question 4: Does intragastric balloon size matter?
Yes, but only beyond a certain threshold.

\( N = 4 \) lean and 4 obese subjects\(^1\)

<table>
<thead>
<tr>
<th>Balloon</th>
<th>( N )</th>
<th>Design</th>
<th>Starting BMI</th>
<th>Fill (mL)</th>
<th>Weight Loss (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIB(^2)</td>
<td>126</td>
<td>Single-arm, post-market</td>
<td>37.7</td>
<td>500</td>
<td>15.7</td>
</tr>
<tr>
<td>Duo(^3)</td>
<td>60</td>
<td>38.8</td>
<td>900</td>
<td>16.6</td>
<td></td>
</tr>
</tbody>
</table>

Question 5: What happens after the end of intragastric balloon therapy?
Key Questions:

• Is weight loss that results from Orbera® therapy time-limited?

• How long is weight loss sustained after Orbera® removal?
Study Design

All Studies Screened
n = 436

Excluded
Reviews, Case Studies, Editorials, No Report on Orbera Balloon Efficacy
n = 281

Studies Retrieved for Detailed Evaluation
n = 155

Studies Reporting Weight Loss at 3 and 6 Months
n = 7

Studies Reporting Timing of Adverse Events
n = 2

Studies Reporting Weight or BMI at 6 and/or 12 Months After Balloon Removal
n = 11

Gaur et al. 2015, *GI Endoscopy*,

Beth Israel Deaconess Medical Center

Harvard Medical School
## Results: Time-defined Weight Loss

80% of weight occurs in the first 3 months of Orbera® therapy.

<table>
<thead>
<tr>
<th>Reference</th>
<th>No.</th>
<th>Starting BMI, kg/m²</th>
<th>Fill volume, mL</th>
<th>Weight loss at 3 mo, kg</th>
<th>Weight loss at 6 mo, kg</th>
<th>% of weight loss at 3 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonazzi et al, 22 2005</td>
<td>12</td>
<td>38.5</td>
<td>700</td>
<td>12.4</td>
<td>14.4</td>
<td>86</td>
</tr>
<tr>
<td>Fuller et al, 36 2013</td>
<td>31</td>
<td>36.0</td>
<td>450-750</td>
<td>10.5</td>
<td>14.4</td>
<td>73</td>
</tr>
<tr>
<td>Mathus-Vliegen and Tytgat, 37 2005</td>
<td>19</td>
<td>43.3</td>
<td>500</td>
<td>12.9</td>
<td>16.7</td>
<td>77</td>
</tr>
<tr>
<td>Mathus-Vliegen et al, 25 2014</td>
<td>19</td>
<td>43.0</td>
<td>500</td>
<td>13.1</td>
<td>16.4</td>
<td>80</td>
</tr>
<tr>
<td>Peker et al, 38 2010</td>
<td>31</td>
<td>41.8</td>
<td>600</td>
<td>12.17</td>
<td>15.04</td>
<td>81</td>
</tr>
<tr>
<td>Stimaq et al, 39 2011</td>
<td>171</td>
<td>41.9</td>
<td>600</td>
<td>12.8</td>
<td>16.9</td>
<td>76</td>
</tr>
<tr>
<td>Totte et al, 40 2001</td>
<td>126</td>
<td>37.7</td>
<td>500</td>
<td>13.7</td>
<td>15.4</td>
<td>89</td>
</tr>
<tr>
<td>Total</td>
<td>409</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weighted mean ± weighted SD</td>
<td></td>
<td></td>
<td></td>
<td>12.9 ± 0.8</td>
<td>16.0 ± 0.9</td>
<td>80 ± 6</td>
</tr>
</tbody>
</table>

Gaur et al. 2015, *GI Endoscopy*, in press
Results: Time-defined Weight Loss

Gaur et al. 2015, *GI Endoscopy*, in press
<table>
<thead>
<tr>
<th>Ref.</th>
<th>No.</th>
<th>Patient seen regularly after Orbera balloon removal?</th>
<th>Fill volume, mL</th>
<th>Baseline weight, kg</th>
<th>Weight, kg</th>
<th>Difference from baseline, kg</th>
<th>Weight, kg</th>
<th>Net loss</th>
<th>Weight, kg</th>
<th>Net loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dastis et al, 2009</td>
<td>100</td>
<td>No</td>
<td>500-650</td>
<td>96.5</td>
<td>83.9</td>
<td>12.6</td>
<td>N/A</td>
<td>N/A</td>
<td>88.6</td>
<td>7.9</td>
</tr>
<tr>
<td>Dogan et al, 2013</td>
<td>50</td>
<td>Yes</td>
<td>600</td>
<td>127.6</td>
<td>114.9</td>
<td>12.7</td>
<td>118.1</td>
<td>9.5</td>
<td>120</td>
<td>7.6</td>
</tr>
<tr>
<td>Fuller et al, 2013</td>
<td>31</td>
<td>Yes</td>
<td>450-700</td>
<td>104.6</td>
<td>90.2</td>
<td>14.4</td>
<td>95.2</td>
<td>9.4</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Genco et al, 2009</td>
<td>80</td>
<td>N/A</td>
<td>500</td>
<td>156.1</td>
<td>134.9</td>
<td>21.2</td>
<td>137.8</td>
<td>18.3</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Genco et al, 2010*</td>
<td>50</td>
<td>Yes</td>
<td>500</td>
<td>127.5</td>
<td>102.4</td>
<td>25.1</td>
<td>107.4</td>
<td>20.1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Herve et al, 2005</td>
<td>100</td>
<td>Yes</td>
<td>500</td>
<td>95.9</td>
<td>83.9</td>
<td>12.0</td>
<td>N/A</td>
<td>N/A</td>
<td>87.3</td>
<td>8.6</td>
</tr>
<tr>
<td>Mathus-Vliegen and Tytgat, 2005</td>
<td>43</td>
<td>Yes</td>
<td>400-800</td>
<td>125.1</td>
<td>103.8</td>
<td>21.3</td>
<td>N/A</td>
<td>N/A</td>
<td>112.4</td>
<td>12.7</td>
</tr>
<tr>
<td>Ohta et al, 2009</td>
<td>8</td>
<td>Yes</td>
<td>448</td>
<td>97</td>
<td>85</td>
<td>12.0</td>
<td>N/A</td>
<td>N/A</td>
<td>90.6</td>
<td>6.4</td>
</tr>
<tr>
<td>Sallet et al, 2004*</td>
<td>85</td>
<td>No</td>
<td>400-700</td>
<td>114.0</td>
<td>94.9</td>
<td>19.2</td>
<td>96.7</td>
<td>17.4</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Total</td>
<td>547</td>
<td>Weighted mean</td>
<td>116.2</td>
<td>99.5</td>
<td>16.7</td>
<td>113.1</td>
<td>15.9</td>
<td>96.8</td>
<td>8.7</td>
<td></td>
</tr>
</tbody>
</table>

% Sustained

Gaur et al. 2015, *GI Endoscopy*

*Over 50% of weight lost is sustained 1 year after Orbera® removal*
In patients followed for 5 years, ~30% of weight loss is sustained

Serious Complications Are Rare

Meta-analysis\(^1\) of 3,429 patients with the BIB balloon\(^1\)

<table>
<thead>
<tr>
<th>Condition</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea and vomiting after first week</td>
<td>295</td>
<td>8.6</td>
</tr>
<tr>
<td>Abdominal pain and other mild digestive disorders(^c)</td>
<td>171</td>
<td>5.0</td>
</tr>
<tr>
<td>Deflation and displacement of the balloon(^d)</td>
<td>87</td>
<td>2.5</td>
</tr>
<tr>
<td>Inflammation or lesions in digestive lining(^e)</td>
<td>73</td>
<td>2.1</td>
</tr>
<tr>
<td>Gastro-esophageal reflux</td>
<td>63</td>
<td>1.8</td>
</tr>
<tr>
<td>Dehydration</td>
<td>54</td>
<td>1.6</td>
</tr>
<tr>
<td>Deflation without displacement of the balloon(^d)</td>
<td>29</td>
<td>0.9</td>
</tr>
<tr>
<td>Obstruction in the digestive tract</td>
<td>26</td>
<td>0.8</td>
</tr>
<tr>
<td>Diarrhea and/or constipation</td>
<td>23</td>
<td>0.7</td>
</tr>
<tr>
<td>Gastric ulcer</td>
<td>12</td>
<td>0.4</td>
</tr>
<tr>
<td>Gastric perforation</td>
<td>4</td>
<td>0.1</td>
</tr>
<tr>
<td>Mortality related with balloon (gastric perforation)</td>
<td>2</td>
<td>0.1</td>
</tr>
</tbody>
</table>

\(^a\) Absolute number of patients experienced each type of complication. A patient could suffer several types of complication.

\(^b\) Percentage of patients experienced each type of complication

\(^c\) Dyspepsia, heartburn, flatulence, and digestive subocclusion

\(^d\) Deflation more than 50% of the volume

\(^e\) Esophagitis, gastritis, erosions, and Mallory–Weiss tears are included.

\(^1\)Imaz I et al, 2007
Innovative IGBs: Obalon

- Up to three are swallowed
- 250 cc, gas-filled design
- **Must be endoscopically removed at 3 months**
World’s First Procedureless Gastric Balloon

Final Results From A Multi-Center, Prospective Study Evaluating Safety, Efficacy, Metabolic Parameters, Quality Of Life, and 6-month Follow-Up

Ram Chuttani, Evzen Machytka, Ioannis Raftopoulos, Martina Bojkova, Tomas Kupka, Marek Buzga, Andreas Giannakou, Kandilitis Ioannis, Kathryn Stecco, Samuel Levy, and Shantanu Gaur
The Team
Then and Now
Elipse™: the first procedureless gastric balloon for weight loss
VIDEO: Elipse
Novel Patented Filling and Emptying Technologies

1. Balloon Film
   - 85% thinner than silicone balloons
   - Flexible enough to fold into capsule and safely pass GI tract
   - Durable enough to spend months in stomach

2. Swallowing
   - Balloon is rolled into a capsule and swallowed along with a thin Delivery Catheter for filling

3. Fill Valve
   - Made from thin film
   - Seals shut after Delivery Catheter is pulled out

4. Release Valve
   - Made from thin film
   - Only exposed to inside of device
   - Weakens over time, then opens catastrophically, allowing balloon to empty
## Multi-Center Trial Design

<table>
<thead>
<tr>
<th>n</th>
<th>Up to 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric Residence</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Fill Volume (mL)</td>
<td>550</td>
</tr>
<tr>
<td>Follow-Up</td>
<td>Basic nutritional counseling</td>
</tr>
<tr>
<td>Starting BMI (kg/m²)</td>
<td>27.0 – 40.0</td>
</tr>
</tbody>
</table>
| **Endpoints** | • Safety-related  
|               | • Efficacy-related  
|               |   o Change in weight  
|               |   o Change in metabolic parameters  
|               |   o Change in QOL |
Imaging: Pre-Filling

Left hemi-diaphragm

Radiopaque Marker

Delivery Catheter
Imaging: Post-Filling

Ultrasound

X-ray

Elipse™

Radiopaque Marker

Bra Wire
## Patient Characteristics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n</strong></td>
<td>34</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td>23 female / 11 male</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>42 (range: 18-59)</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td>34.8 (range: 27.0 – 40.0)</td>
</tr>
</tbody>
</table>

### Key Exclusion Criteria
- Dysphagia
- Prior open abdominal surgery
- Multiple laparoscopic abdominal surgeries
- Inflammatory bowel disease
- Prior intestinal obstruction

### Sites
- University Hospital Ostrava, Czech Republic
- Iatrikio Medical Center, Athens, Greece
Results: Safety

- No serious adverse events
- No serious adverse device effects
- Adverse events (AEs):

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of AEs</th>
<th>Participants with AE (N)</th>
<th>Participants with AE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal distension</td>
<td>1</td>
<td>1</td>
<td>3.6</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>7</td>
<td>7</td>
<td>25.0</td>
</tr>
<tr>
<td>Constipation</td>
<td>5</td>
<td>5</td>
<td>17.9</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4</td>
<td>4</td>
<td>14.3</td>
</tr>
<tr>
<td>GERD</td>
<td>3</td>
<td>3</td>
<td>10.7</td>
</tr>
<tr>
<td>Nausea</td>
<td>19</td>
<td>15</td>
<td>53.6</td>
</tr>
<tr>
<td>Vomiting</td>
<td>21</td>
<td>18</td>
<td>64.3</td>
</tr>
</tbody>
</table>
Results: Performance

**Elipse™ Placement**

• All devices swallowed without endoscopy or sedation

• Mean visit time: 22min +/- 8 min

• Mean device fill time: 6 min

• 34/34 (100%) catheters successfully detached
Results: Performance (cont’d)

**Elipse™ Excretion**

- 13 (39.4%) balloons were recovered by the patient
- All recovered balloons were analyzed and had emptied exactly as designed
- Mean residence time = 117 days +/- 14 days
- Remaining balloons were not recovered, and these patients were also asymptomatic
Results: Weight Loss

Elipse™ led to weight loss and waist circumference reduction

<table>
<thead>
<tr>
<th></th>
<th>Mean reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>-10.0</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>-3.9</td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>-8.4</td>
</tr>
<tr>
<td>% Excess Weight Loss (EWL)</td>
<td>39%</td>
</tr>
<tr>
<td>% Total Body Weight Loss (TBL)</td>
<td>10.0%</td>
</tr>
</tbody>
</table>
Results: Metabolic Parameters and Vitals

Elipse™ led to reduction in metabolic parameters & blood pressure

<table>
<thead>
<tr>
<th>Metabolite</th>
<th>Mean Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>-0.16%</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>-16.4</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>-9.7</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>-9.6</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>-5.8</td>
</tr>
</tbody>
</table>
Results: Quality of Life

Elipse™ led to significant improvement in QOL across all domains

Change in IWQoL Score from Baseline to Trial Exit

- Overall: Baseline +12.2, Trial Exit +12.9
- Physical Function: Baseline +18.8, Trial Exit +7.7
- Self-Esteem: Baseline +7.7, Trial Exit +8.2
- Sexual Life: Baseline +8.2, Trial Exit +7.7
- Public Distress: Baseline +7.7, Trial Exit +8.2
- Work: Baseline +7.7, Trial Exit +8.2

Baseline (n=27) vs Trial Exit (n=26)
Results: Participant Preference

Most Elipse™ participants would repeat therapy & recommend it to a friend

- Would you recommend Elipse to a friend?
  - Yes: 90%
  - No: 10%

- If you regained weight, would you repeat Elipse?
  - Yes: 90%
  - No: 10%
Post-Excretion Follow-Up

- After excretion, patients (Greek cohort $n=11$) were asked to return approximately every month to be weighed.
- No dietary or nutritional follow-up was provided.
- **At 6-month follow-up:** 92% of weight loss was sustained.
- Follow-up is on-going.
Elipse™ Weight Loss: on par with Orbera®

Weeks of Therapy

Mean Pounds Lost (lbs)

Elipse™ Weight Loss: on par with Orbera®

*Elipse™ (Athens Cohort; n=11); Totte et al. Obes Surg. 2001. Orbera 16-week weight loss interpolated
Post-Excretion Follow-Up*

Results: Incidence of Vomiting

- Three different anti-emetic regimens were tested

  1. Zofran (ondansetron) alone
     - 8mg PO TID x 3-5 days
  2. Emend (aprepitant) alone
     - 125mg PO night before or day of
     - 80mg PO daily x 2 days
  3. Zofran + Emend
     - Zofran + Emend led to significantly less nausea and vomiting
     - No voluntary withdrawals in all patients treated with Zofran + Emend
Thank you!
Setting Up a Successful Gastric Balloon Program

Sheryl Smith RN, BSN, M.Ed

Clinical Nurse Coordinator
Bariatric Endoscopy
Beth Israel Deaconess Medical Center

No Disclosures
Obesity

- Frequently subdivided into categories
  - Class 1: BMI of 30 to < 35
  - Class 2: BMI of 35-40
  - Class 3: BMI of 40 or higher

• cdc.gov
Obesity Statistics in the US

- Overweight and Obesity among Adults Age 20 and Older, United States, 2009–2010* Estimated Percentage by BMI

  - Normal weight or underweight (BMI under 24.9)
  - Overweight (BMI of 25 to 29.9)
  - Obesity (BMI of 30+)
  - Extreme obesity (BMI of 40+)

*Source: Harvard Medical School
https://www.niddk.nih.gov/health-information/health-statistics/Pages/overweight-obesity-statistics.aspx
Weight Loss Options

- Diet & Exercise
- Pharmaceuticals
- Gastric Balloon
- Surgery
Gastric Balloons offer an option for patients who:

- Have not had long term success with their weight loss attempts
- Do not qualify for bariatric surgical options
- Do not want surgery to achieve weight loss.
- Want to “jump start” their long term weight loss
Who Can Receive Gastric Balloon (IGB)?

- Adults
- BMI 30-40
- Must be willing to commit to a year long program
- Failed other weight loss programs
Who Should Not Receive IGB?

- Previous bariatric/gastric Surgery
- Structural abnormality of the esophagus
- Under 21
- On blood thinners
- Pregnant or planning to become pregnant
- Liver disease*
The Team

- Gastroenterologists
- Registered Dietitian
- Registered Nurse/Clinical Coordinator
- Program Coordinator
- Personal Trainer
- Psychologist
- Nutritionist
Things Prospective Patients Need to Know

- Self-pay
- Side effects of balloon
- No magic bullet
- Average weight loss ~10.7% at 6 months
- Requires a one year commitment

One or more of these things may be a deal breaker
Side Effects of Balloon Placement

- Nausea
- Vomiting
- Abdominal pain
- Cramping
- Acid reflux
- Anxiety

Symptoms typically last a few days, but can last up to several weeks. Patients receive prescription medications to help manage symptoms.
Medication Protocol

- Begin taking a multi-vitamin and calcium with vitamin D
- PPIs starting 2 weeks before balloon placement until 1 week after balloon removal
- Emend and Zofran qd x 3 days
- Hycosamine (Levsin) bid prn
- Ativan q 4-6 hours prn
Balloon Placement

• NPO for 12 hours pre-procedure
• Patient pre-medicates with anti-emetics and PPI
• Given IV hydration pre/post procedure
• EGD with MAC
• Patient typically discharged with little discomfort
Patient Education on Discharge

• You are not going to feel well later
• Take all Medications as prescribed
• Clear liquids only today. Will have to experiment with either sips or 4oz at a time...temperature of fluids
• A member of your team will be checking in with you later today
Patient Education on Discharge-contd

- Rest with head elevated on extra pillows
- Some people feel more comfortable resting on their left side
- No restrictions on activity after today, but only advance when symptoms have subsided
- Keep the card identifying you as someone with an IGB with you whenever you are not at home
Nutrition

- Clear liquids until symptoms subside, typically about 48 hours
- Advanced to full liquids (protein shakes, drinkable yogurt…) typically several days
- Advanced to soft solids (cottage cheese, eggs, yogurt…) can be up to 2 weeks
- Reintroduction of solid food, one at a time
- Goal is for ~60-80 gms protein/day, ~1200-1800 cal/day
Tips for Success

- Protein first
- Eat slowly
- Chew and then chew some more
- Put your fork down between bites
- Don’t eat and drink at the same time*
- Stop eating when you start to feel full
- Use a smaller plate
Physical Activity

• The CDC recommends at least 150 minutes of moderate-intensity aerobic activity every week

  AND

• Muscle strengthening activities on 2 or more days per week

• In addition, adding lifestyle activities can increase energy expenditure
A 12 Month Program

- Balloon placement
- Daily phone contact with RN until feeling well
- Phone contact with RD ~day 3
- Phone contact with RN Week 1
- Office visit with MD/RD week 2
- Bi-monthly contact with RD/RN months 2-6
- Balloon removal
- Office visit with MD 2-4 weeks after
- Continued bi-monthly contact with RD/RN months 6-12

*Contact with Team Can Be in the Office or Over the Phone
Our Experience

• Out of approximately 200 Inquiries:

  • ~73% No…because of cost
  • ~10% Did not follow through
  • ~5% Did not qualify
  • ~12% Came for RN/RD consultation

(All but one has gone on to have IGB placed)
Results

Since February 2016:
• 21 Balloons placed to date
• 11 Balloons removed to Date (2 not our patients)

At 6 Months:
• Average TWL: 10.7%
• Maximum total weight loss: 23.6%
• 2 Patients with no weight loss- both lost weight initially, then regained.
• One patient who lost 13.9% with first balloon and wanted a second one…lost an additional 4.3% for a total weight loss of 18.2%
What We Have Learned

• The majority of our patients verbalize improving health as the number one reason for the procedure
• The greatest success stories have come through hard work
• Sometimes there is more to weight-loss than "calories out must be more than calories in" (This is a whole separate lecture!)
• We are committed to helping our patients attain and maintain weight-loss, but we can’t do it for them
• We are still learning and adapting our program to help our patients achieve success
Thank You for Your Kind Attention,
Namaste!