INTRAGASTRIC BALLOONS: HISTORY

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<table>
<thead>
<tr>
<th>Company</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethicon Endosurgery</td>
<td>Consultant/Speaker/Advisory</td>
</tr>
<tr>
<td>Covidien</td>
<td>Speaker</td>
</tr>
<tr>
<td>Cine-Med</td>
<td>Speaker</td>
</tr>
<tr>
<td>Olympus</td>
<td>Consultant</td>
</tr>
<tr>
<td>Apollo</td>
<td>Advisory Board</td>
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Gastric Weight Loss Devices: Early Experiences

- 1920s: Observations of effects on weight of naturally occurring large balls of ingested material in the stomach (bezoars)

- Early 1980s: Experiments with polyethylene bottles in dogs and rubber or latex balloons in humans

- 1985: First use of inflatable, air filled polyurethane devices (ballobes)

### Symptoms of gastric bezoars.

<table>
<thead>
<tr>
<th>Category</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most common</td>
<td>Abdominal pain, Intestinal obstruction</td>
</tr>
<tr>
<td>Less common</td>
<td>Weight loss, Poor appetite, Vomiting, Malnutrition, Weight loss</td>
</tr>
<tr>
<td>Rare</td>
<td>Ulcer (with or without bleeding), Perforation, Intussusception, Cholestasis, Protein-losing gastroenteropathy, Pancreatitisa</td>
</tr>
</tbody>
</table>

*a* indicates very rare conditions.
Intragastric Prosthesis for Management of Obesity

Jimmy D. Miller, M.D.

Department of Surgery, University of Mississippi Medical Center, Jackson, Mississippi, U.S.A.

World Journal of Surgery 6, 492-493, 1982
1980: Intragastric Balloons Evaluated in Dogs

- Intragastric prosthesis for management of obesity

- Abstract: During the fall and winter months of 1979–1980, nine dogs were variously studied using an intragastric prosthesis to investigate chronic gastric distention which might lead to reduced food intake and consequent weight loss. The rationale was that large gastric bezoars at times produced weight loss in humans. The prosthesis was a 250-ml polyethylene bottle introduced at laparotomy, with the intent of subsequent peroral-esophageal introduction if the initial studies produced weight loss.
9 Dogs

Laparotomy with small gastrostomy

Insertion of a **250-ml polyethylene bottle (Intragastric Prosthesis)**

N = 6

Sham operation

N = 3

Food and water ad libitum

Follow-up “variously” 5-16 weeks

Conclusion

An intragastric inert space-occupying polyethylene bottle failed to produce significant weight loss in dogs. Further studies are encouraged.
Introduction of Garren-Edwards Bubble

- September 1985: FDA approved Garren-Edwards Bubble
  - Cylindrical 'tin can' shape with sharp edges
  - Elastomer plastic
  - Air Filled, 220ml
  - Recommended placement: 3 months
Withdrawal of Garren-Edwards Bubble

- 20,000 sold in the first year
- 1986-1988: complications presented and increased in frequency
- 1988: FDA restricted the use to 'investigation trials'
- May 15, 1988 the company withdrew the product from the market
Features of Intragastric Balloons used in the 80s

<table>
<thead>
<tr>
<th>Complication</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric Erosion</td>
<td>26%</td>
</tr>
<tr>
<td>Gastric Ulcers</td>
<td>14%</td>
</tr>
<tr>
<td>Small Bowel Obstruction</td>
<td>2%</td>
</tr>
<tr>
<td>Mallory-Weiss Tear</td>
<td>11%</td>
</tr>
<tr>
<td>Oesophageal lacerations</td>
<td>1%</td>
</tr>
</tbody>
</table>
Experts meeting held to guide design of future balloon

- 1987

- Obesity Congress “Tarpon Springs” (Florida, USA):

  75 international experts from the fields of:

  Gastroenterology
  Surgery
  Obesity
  Nutrition
  Behavior medicine

OBJECTIVE: to develop a general consensus on this technology/treatment option

Experts meeting held to guide design of future balloon

• Conference Conclusions with respect to a Gastric Volume Displacing Weight Loss Device:
  ✓ Be effective at promoting weight loss
  ✓ Be filled with liquid (not air)
  ✓ Be capable of adjustment to various sizes
  ✓ Have smooth surface and low potential for causing ulcers and obstructions
  ✓ Contain a radiopaque marker that allows proper follow-up of the device if it deflates
  ✓ Be constructed of durable materials that do not leak

IT SHOULD BE:

- EFFICACIOUS

- LOW ULCEROGENIC AND OBSTRUCTIVE POTENTIAL

- WITH A RADIOPAQUE MARKER

- ADJUSTED TO A VARIETY OF SIZE

- COMPOSED OF MATERIALS THAT WILL LAST FOR LONG PERIOD

- WITHOUT EDGES OR SHARP RIDGES

- LARGE VOLUME

- MADE TO MAXIMIZE WEIGHT LOSS AND LIMIT FOOD INTAKE

- FILLED WITH FLUID (NOT AIR)
Range of Intragastric Balloon Options
INTRAGASTRIC BALLOON (BIB)
## Differences between BIB and olds balloon

<table>
<thead>
<tr>
<th></th>
<th>BIB (USA)</th>
<th>G-E (USA)</th>
<th>BALLOBES (Denmark)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shape</strong></td>
<td>sphere</td>
<td>cylinder</td>
<td>oval</td>
</tr>
<tr>
<td><strong>Volume</strong></td>
<td>500cc (liq.)</td>
<td>220cc (air)</td>
<td>500cc (air)</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Silicone</td>
<td>Polyurethane</td>
<td>Polyurethane</td>
</tr>
<tr>
<td><strong>Shedul. dur.</strong></td>
<td>6 months</td>
<td>2 months</td>
<td>2 months</td>
</tr>
<tr>
<td><strong>Effect. dur.</strong></td>
<td>&gt; 180 days</td>
<td>limited</td>
<td>7-21 days</td>
</tr>
<tr>
<td><strong>Radiopaque</strong></td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>good</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td><strong>Ulcer</strong></td>
<td>0.5 %</td>
<td>13-20 %</td>
<td>9-33 %</td>
</tr>
<tr>
<td><strong>Occlusion</strong></td>
<td>rare</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>
Multiple Roles in Obesity Treatment

- **Bridge to Surgery:**
  - Making surgical procedures safer
  - Hernias, Orthopedics, Transplants

- **Bridge/Test to Surgery:**
  - High Risk patients
  - Restrictive Vs Malapsortive

- **Definitive Weight Loss Procedure**
THANKS