Intragastric Balloon

Presented by:
Ronnie Keith, DO

Offices:
Lawton, Ok
OKC, Ok
Tulsa, Ok

Disclosures
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Apollo EndoSurgery
✓ Proctor
✓ Consultant

Ethicon EndoSurgery
✓ Proctor
✓ Consultant

Scope of Practice
Locations
1) General-Trauma Surgery
2) Weight Loss Surgery
3) Medical Weight Loss

Lawton  Oklahoma City  Tulsa
INRAGASTRIC BALLOON

1) Temporary
   - 6 months

2) Can be repeated

3) Ambulatory procedure

Balloon History

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>Old Balloons Complications</th>
<th></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>

What’s needed?
**Tarpon Springs criteria**

- **1987 Obesity Congress “Tarpon Springs” (Florida, USA):**
  - Scientific conference held with 75 international experts from the fields of gastroenterology, surgery, obesity, nutrition and behavior medicine to develop a general consensus on this technology/treatment option.


- **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


**Intragastric balloon**

**Liquid Filled**

Submitted to FDA
Intragastric balloon
Double

Comparison with bariatric surgery

- Surgery outcomes
  - Long term efficacy
  - Higher probability of complications and mortality
  - Needs for a multidisciplinary team support

- Balloon outcomes
  - Short term efficacy
    - Real possibility of weight regain after removal
  - Lesser probability of complications and mortality
  - Needs for a multidisciplinary team support

Which Balloon to choose?
Comparison with bariatric surgery

- Mortality
  - Balloon
    - Close to zero
    - Very low risk
  - Surgery
    - Mortality depends upon
      - Patient clinical conditions
      - Medical care environment
      - Surgical team expertise

Comparison with clinical treatment

- Clinical treatment
  - Short term efficacy
    - Lesser than the balloon
  - Improve results when more therapy’s are added
    - Diet + Weight loss meds + Exercise
  - ↑ levels of patients quitting before the end of treatment

- Balloon
  - Short term therapy
  - Works solo
  - ↓ levels of patients quitting before the end of treatment

Intragastric balloon

“Mechanism of action”
Intragastric balloon  
“Mechanism of action”  
A pure space occupying device

Effects of intragastric balloon on gastric emptying and plasma ghrelin levels in non-morbidly obese patients.

Background: Intragastric balloons have been proposed to induce weight loss in obese subjects. The consequent of the balloon on gastric emptying and plasma ghrelin secretion in non-morbidly obese patients has not been described.

Patients and methods: 17 patients were included in the study, with mean BMI of 34.4 (range 31.0-38.3). The balloon was implanted under general anesthesia and endoscopic control, inflated with 800 ml saline, and removed 6 months later. Body weight and gastric emptying (12C) were measured before and 1 month after removal. Ghrelin levels were measured just before balloon insertion and removal.

Result: Linear weight loss was 8.7 kg (range 5.0-15.0). Gastric emptying times were significantly decreased with the balloon in place, and returned to preimplantation values after balloon removal. Plasma ghrelin levels were significantly decreased (mean -12.5 ± 30.7 ng/ml) despite concomitant weight loss. Weight reduction was not correlated to the effect of the balloon on gastric emptying, but was significantly correlated to the ghrelin variations (r=-0.65, p<0.05; r=0.51-0.85).

Conclusion: Gastric emptying rates and plasma ghrelin levels are decreased in the presence of intragastric balloon. Weight loss induced by the intragastric balloon is related to ghrelin variations, but not to gastric emptying. Ghrelin inhibition may explain part of the effect of the balloon on weight.

ACN: 109445221 [Position: Internal for UCI-UC]

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Intragastric balloon  
“Mechanism of action”  
A pure space occupying device

Intragastric balloon-induced satiety is not mediated by modification in fasting or postprandial plasma ghrelin levels in morbid obesity.

Method: 21 out of 22 enrolled patients completed the study (17 women, 4 men). 1.8 ± 8.9 years; BMI 36.4 ± 7.4 kg/m²). Pre-intervention weight decreased from 140.6 ± 27.0 kg to 136.4 ± 26.2 kg in Group Ballon (P < 0.001) and from 18.6 ± 2.4 kg to 18.1 ± 2.0 kg in Group Sham (P = 0.01) at the end of the study. Weight loss was not significantly different in Group Ballon and Group Sham at any timepoint of the follow-up. Only patients from Group Ballon showed a temporary increase in pre- and postprandial ghrelin, which was maximal at 4 weeks after the intervention. Table area under the curve, fasting and postprandial plasma ghrelin were not significantly different between groups at inclusion or 4 weeks after follow-up. No correlation was found between any of the ghrelin levels at any timepoint with body mass index levels.

Conclusion: BSIs reduces a temporarily sense of satiety in morbidly obese patients which is not mediated by modification of fasting or postprandial levels of plasma ghrelin.

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Intragastric balloon  
“Mechanism of action”  
A pure space occupying device

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Intragastric balloon “indications”

- Morbid obesity treatment
- BMI > 35 with comorbidities
- BMI > 40 with surgical limitation or who refuse surgical treatment

Intragastric balloon “Traditional indications”

- Super obese (BMI >50)
- Pre-op to risk reduction
- Brazilian Society of Bariatric Surgery

<table>
<thead>
<tr>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI</td>
<td>80</td>
</tr>
<tr>
<td>Weight</td>
<td>276</td>
</tr>
<tr>
<td>Fasting glucose</td>
<td>282</td>
</tr>
<tr>
<td>HbA1c</td>
<td>10.4</td>
</tr>
<tr>
<td>US GIII steatosis</td>
<td>1.0</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>287</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>268</td>
</tr>
</tbody>
</table>
Intragastric balloon “Alternative indications”

- Repositioning the indications
  - Hard to control co-morbidities in lower BMI
  - Diabetes / Hypertension
    - ↓ weight = control

- Weight loss to improve surgical condition in non bariatric operations
  - Orthopedic surgery
    - Joints
    - Column

- Infertility
  - An effective weight loss
  - Improves women fertility
Repositioning the indications

- Weight loss post "pregnancy obesity"
  - Woman should lose all the weight gain on the pregnancy with breast feeding
  - But...
    - It is not what we see in consecutive pregnancies

- Teenagers
  - > 12 years

- Child
  - < 12 years

- Esthetics
  - "Preparing for special happenings"
  - "Psychological well being"
  - "Same or less riskier than liposuction"
Intragastric balloon
Results

Brazilian Multicenter Study of the Intragastric Balloon. Obesity Surgery 2004,14,:991-998

Intragastric balloon
Weight loss

<table>
<thead>
<tr>
<th>Reference</th>
<th>N</th>
<th>Method</th>
<th>%EWL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galloro</td>
<td>13p</td>
<td>BIB</td>
<td>18.3</td>
</tr>
<tr>
<td>Weiner</td>
<td>14p</td>
<td>BIB</td>
<td>16</td>
</tr>
<tr>
<td>Hodson</td>
<td>10p</td>
<td>BIB+diet</td>
<td>40</td>
</tr>
<tr>
<td>Lofredo</td>
<td>64p</td>
<td>BIB</td>
<td>23.5</td>
</tr>
<tr>
<td>Tolte</td>
<td>126p</td>
<td>BIB+diet</td>
<td>37.7</td>
</tr>
<tr>
<td>Evans</td>
<td>63p</td>
<td>BIB</td>
<td>46.3</td>
</tr>
<tr>
<td>Salet</td>
<td>323p</td>
<td>BIB+diet</td>
<td>38.2±9.4</td>
</tr>
</tbody>
</table>

Mean of studies 613        --------- 40.9

Intragastric balloon
Comorbidities Improvement

BioEnterics Intragastric Balloon: The Italian Experience with 2,515 Patients

A. Genco; T. Bruni; S. B. Doldi; P. Forestieri; M. Marino; L. Busetto; C. Giardiello; L. Angrisani; L. Pecchioli; P. Stornelli; F. Puglisi; M. Alkilani; A. Nigrì; N. Di Lorenzo; F. Furbetta; A. Cascardo; M. Cipriano; M. Lorenzo; N. Basso

Italian Group for Lap-Band®, Fondazione IDIS - Città della Scienza, Naples, Italy
Intragastric balloon
Comorbidities Improvement

Table 2. Co-morbidities at time of BIB removal (8 months)

<table>
<thead>
<tr>
<th>Co-morbidity</th>
<th>Resolution</th>
<th>Improvement</th>
<th>No Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>10/19 (52.6%)</td>
<td>20/42 (47.6%)</td>
<td>12/24 (50%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>17/35 (48.6%)</td>
<td>27/54 (50%)</td>
<td>18/36 (50%)</td>
</tr>
<tr>
<td>Respiratory disorders</td>
<td>12/25 (48%)</td>
<td>23/47 (49%)</td>
<td>13/28 (46.4%)</td>
</tr>
<tr>
<td>Osteoarthropathy</td>
<td>22/45 (48.9%)</td>
<td>32/64 (50%)</td>
<td>21/42 (50%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>12/24 (50%)</td>
<td>22/45 (48.9%)</td>
<td>12/24 (50%)</td>
</tr>
<tr>
<td>Others</td>
<td>25/50 (50%)</td>
<td>42/84 (50%)</td>
<td>28/56 (50%)</td>
</tr>
</tbody>
</table>

* = lower drug dosage or shift to other therapy.
† = sleep apnea disappeared, but remained obstructive after physical activity.
§ = patients without radiological evidence of aortic modification.
¶ = patients with hyperglycemia.
* = the improvement was predominantly linked to normalization of triglycerides while cholesterol has been less influenced by the weight loss after 6 months.

Intragastric balloon
Compared with diet

Intragastric Balloon or Diet Alone?
A Retrospective Evaluation

Received: 28 September 2007 / Accepted: 22 November 2007 / Published online: 16 May 2008

Intragastric balloon
Compared with diet

Table 1 Demographic data at baseline in 130 morbidly obese patients who underwent dietetic regimen and 130 sex-, age-, and BMI-matched historical controls treated with BioEnterics Intragastric Balloon (BIB)

<table>
<thead>
<tr>
<th></th>
<th>Diet (n=130)</th>
<th>BIB (n=130)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>37.7±11.0 (30–55)</td>
<td>38.0±10.9 (30–55)</td>
</tr>
<tr>
<td>Sex</td>
<td>30M/100F</td>
<td>30M/100F</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>115.9±21.9 (91–155)</td>
<td>117.1±22.6 (90–160)</td>
</tr>
<tr>
<td>BMI</td>
<td>41.9±6.8 (35.1–50.0)</td>
<td>42.1±6.5 (35.1–50.2)</td>
</tr>
</tbody>
</table>

Data are expressed as mean±standard deviation (range)
p=NS between the two groups for all parameters
Intragastric balloon Compared with diet

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BIB</td>
<td>Diet</td>
<td>BIB</td>
</tr>
<tr>
<td>kg</td>
<td>117.3±22.8</td>
<td>125.6±21.9</td>
<td>101.5±18.7</td>
</tr>
<tr>
<td>kg lost</td>
<td>-</td>
<td>-</td>
<td>36.7±6.7</td>
</tr>
<tr>
<td>BMI</td>
<td>42.1±6.3</td>
<td>41.9±6.8</td>
<td>35.1±11.2</td>
</tr>
<tr>
<td>BMI lost</td>
<td>-</td>
<td>-</td>
<td>6.1±4.5</td>
</tr>
<tr>
<td>%BMI lost (%)</td>
<td>-</td>
<td>-</td>
<td>11.8±4.7</td>
</tr>
<tr>
<td>%BMI lost (%)</td>
<td>-</td>
<td>-</td>
<td>13.9±5.8</td>
</tr>
</tbody>
</table>

*Data of BIB removal
*4 months from BIB removal
*For body mass index live

Intragastric balloon Compared with diet – Level I evidence

**ORIGINAL ARTICLE**

BioEnterics® Intragastric Balloon (BIB®): a short-term, double-blind, randomised, controlled, crossover study on weight reduction in morbidly obese patients

A Genni, A Cipriano, V Becchi, M Guadagno, A Marzetta, L Rapetti, C Dottino, M Lorenzini and N Bano

Department of Surgery, University “Sapienza”, Medical School, Rome, Italy; Italian Group for Laparoscopic Bariatric Surgery (IGLBS) – GILC, Città della Scienza, Napoli, Italy and T大酒店, Data elaboration and analysis, Napoli, Italy

**Figure:**

Inability to lose weight (40-45 BMI patients)
**Intragastric Balloon**

*Allergan® - BIB®*

- Gastro Obeso Center own casuistic
- 6m(%EWL)
  - BMI 35-40 Kg/M2
  - BMI 40-50 Kg/M2
  - BMI > 50 Kg/M2
- Adverse Events
  - Nauseas and vomiting 65%
  - Abdominal pain 30%
  - Dehydration 09%

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**Brazilian Society of Digestive Endoscopy - SOBED**

National BIB training program 2011

- > 300 Doctors trained
- SOBED – training centers
- Attendees implants under proctorship supervision
  - SOBED – Specialists (board certified
  - Under Regional Consil of Medicine scrutiny
- Training workshops –2011 - 2014
  - Over 200 implanted patients
  - All under multidisciplinary team follow-up
  - No complications at implant and explants

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**Figure 2** BMI trend during different times of the study.
Intragastric balloon
Big clinical series

- Efficiency of intragastric balloon as an auxiliary method to weight loss: Analysis of 2002 Patients (DDW2013)

  Authors:
  - Sander, Bruno Q.; Fittipaldi-Fernandez, Ricardo J.;
  - Scarparo, Jimi I.B.; Galvão Neto, Manoel P.; Nunes, Gabriel C

Intragastric balloon
Big clinical series

- N = 2002 patients initially

  - 107 excluded
    - 70 (3.49%) due to early IGB removal
    - 13 (0.65%) due to absence of weight loss
    - 14 (0.70%) due to weight gain
    - 10 (0.50%) due to incomplete data.
Intragastric balloon
Big clinical series

- N 1895
  - 1422 women / 473 men.
  - Mean age 37.32 years
- Initial BMI - 36.47±5.61 kg/m²
  - Range: 27.74
- BMI at removal - 28.93±4.71 kg/m²
  - Range: 18.98-57.38 (p<0.0001)

Efficiency of intragastric balloon as an auxiliary method to weight loss: Analysis of 2002 Patients
Sander, Bruno Q.; Fittipaldi Fernandez, Ricardo J.; Scarparo, Jimi I.B.; Galvão Neto, Manoel P.; Nunes, Gabriel C
Presented at DDW 2013, sent to IFSO 2014

- BMI reduction 7.55±3.49 kg/m²
  - Range: 0.36-29.79
- %TBWL 20.43±7.82%
- (%EWL) 73.48±36.71%
  - Range: 2.22-431.1
- %EWL was higher in the overweight group, followed by obesity grades I, II and III sequentially (p<0.0001)

- %EWL was higher in the overweight group, followed by obesity grades I, II and III sequentially (p<0.0001)
- Presence of high number of overweight patients explains the high %EWL
Intragastric balloon
Big clinical series
• N = 2002 patients
  - Complications leading to removal
    » Fungus 0.2% (n=4)
    » Ballon leakage was 0.25% (n=5)
    » Pregnancy 0.1% (n=2)
    » Wernick Korsakoff 0.05% (n=1)
    » Gastric perforation 0.05% (n=1).
    » Digestive bleeding 0.05% (n=1).

Intragastric balloon
Mortality
• Not many papers...
  • But it exists..
    1-2 for brochial aspiration on removal
    1 for esophageal perforation
    1 for “gastric explosion”
    Urban legend?

Intragastric balloon
CONCLUSION
• Intragastric balloon
  • Obesity treatment
    • Works better than clinical treatment
    • Wide spectrum
    • Indication is being “repositioned”
THANKS!