

AGA Clinical Practice Guidelines on Intra-gastric Balloons in the Management of Obesity

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Definition

Intra-gastric balloons (IGB) are endoscopically placed silicone balloons filled with saline or air mixture, left in the gastric lumen for 6-12 months to reduce apparent gastric capacity and facilitate weight loss. Only 1.1% of eligible patients with obesity receive bariatric surgery, and <5% patients are aware of endoscopic options.

Appropriate Candidates

- BMI 30-40
- Participation of balloon deployment at least 6 months, implementation of concomitant lifestyle changes

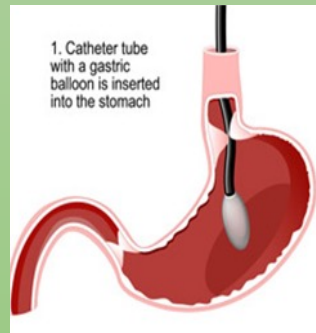
Absolute Contraindications

- Prior history of esophageal and stomach surgery
- Coagulopathy
- Upper GI Bleeding Lesions
- Child-Pugh B/C or decompensated cirrhosis
- Pregnancy

-Hiatal hernia >5cm

Relative Contraindications

- Hiatal hernia 3cm-5cm
- IBD: Crohn's, UC
- Chronic NSAID Use
- History of Esophagitis



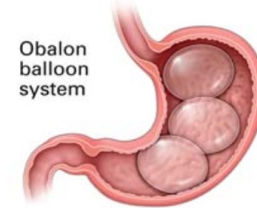
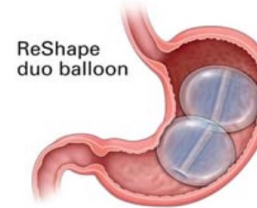
Efficacy

- Average weight loss of 9-15 pounds over course of insertion within 12 months with as much as 20% by 9 months
- 4.1cm average waistline reduction
- Improvement in lab markers: A1c, fasting blood glucose, liver function tests
- Higher remission rates of type 2 diabetes, hypertension, hyperlipidemia




Adverse Events

- Gastric Perforation: 0.1%
 - Balloon Migration: 1.4%
 - Mortality: 0.08%
- Side Effects**
- Nausea/Vomiting
 - Abdominal pain
 - Diarrhea

FDA Approved Devices



Balloon	1 Balloon	2 Balloons	3 Balloons	1 Balloon
Volume	400-700ml Saline	450ml saline x2	250ml Nitrogen Gas x3	300-900ml saline Adjustable
Duration	6-12 month	6 month	6 month	12 month
Advantages	Longest in market and studied	High gastric volume occupancy	No endoscopy for insertion	Volume capacity adjustment

	Recommendation	Strength of Recommendation	Quality of Evidence
<u>Implementation:</u>	<p>Among patients failing conventional weight loss intervention and pursuing IGB, lifestyle modifications should be used in conjunction.</p> <p><i>Fluid-filled balloons may be associated with more weight loss, however less favorable safety profile than gas-filled. Shared decision making is warranted.</i></p>	Conditional	Moderate
	<p>Among patient pursuing IGB, moderate-high intensity lifestyle modification should be used in conjunction.</p> <p><i>High intensity lifestyle interventions are multi-faceted including counseling sessions with trained interventionists, low calorie diet 1200-1500 kcal/day, and 200-300 min/week of aerobic exercise.</i></p> <p><i>Patients with ongoing lifestyle modifications post-balloon removal continue to have ongoing weight loss.</i></p>	Strong	Moderate
<u>Tissue Injury Prevention:</u>	 <p>PPI prophylaxis recommended among patient having IGB inserted.</p> <p><i>Lowest dose and frequency suggested: Once a day dosing</i></p>	Strong	Moderate
<u>Side Effect Prevention:</u>	 <p>Scheduled anti-emetic regimen for 2 weeks post IGB placement is recommended.</p> <p><i>Choice of agent per clinical practice, evidence used compared ondansetron and midazolam, with better performance using both.</i></p>	Conditional	Low
<u>Nutrition:</u>	 <p>Pre-IGB laboratory screening of nutritional deficiencies is not recommended. Daily supplementation with 1-2 adult dose multivitamins is recommended.</p> <p><i>Low quality evidence for presence of thiamine or folate deficiency with 0-29% prevalence.</i> <i>Low quality evidence of thiamine or folate deficiency being prevented with supplementation.</i></p>	Conditional	Low Very Low