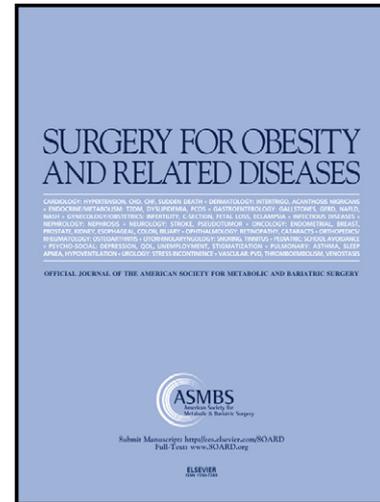


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American Society for Metabolic and Bariatric  
Surgery Position Statement on Intra-Gastric Balloon  
Therapy

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Kim MD, Shanu N. Kothari MD, FACS, on behalf of  
the American Society for Metabolic and Bariatric  
Surgery Clinical Issues Committee



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**AMERICAN SOCIETY FOR METABOLIC AND BARIATRIC SURGERY POSITION  
STATEMENT ON INTRA-GASTRIC BALLOON THERAPY**

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Running head: ASMBS statement on intra-gastric balloon therapy

The American Society for Metabolic and Bariatric Surgery (ASMBS) has issued the following position statement in response to numerous inquiries made to the Society by patients, physicians, society members, hospitals, health insurance payers, the media, and others regarding the role of intra-gastric balloons in the treatment of obesity. The intent of issuing such a statement is to provide an overview of the available evidence regarding the impact of endoscopically placed intra-gastric balloon technology in the current management of obesity and related diseases. The statement is not intended as, and should not be construed as, stating or establishing a local, regional, or national standard of care.

### **The Issue**

The continuing rise of obesity rates worldwide and the lack of effective medical treatments for this disease have propelled interventional weight loss therapies to the forefront of the battle against this epidemic. A large body of high quality clinical evidence identifies bariatric and metabolic surgery as the most effective method to achieve and maintain substantial weight loss for individuals with clinically severe obesity. There are, however, those individuals who, despite meeting medical necessity for bariatric surgery, may choose not to have surgery or may not qualify as surgical candidates based on existing criteria or surgeon assessment. Examples of the latter include individuals with obesity-related comorbidities whose body mass index (BMI) falls below presently established eligibility criteria that qualify patients for bariatric surgery and/or patients who are deemed to be at high surgical risk, whether that is due to severe obesity with excessively high BMI or poor general health status. Other patients, such as those belonging to specific age groups or those seeking to optimize health as a bridge to a non-obesity therapy

(organ transplant, knee or hip replacement, e.g.) may wish to lose weight using options other than surgery. Effective options for these patient groups are limited. To date, pharmacotherapy and medically supervised diet programs have variable and modest efficacy for weight loss, and they are generally ineffective for long-term weight loss maintenance and co-morbidity reduction.<sup>1-3</sup> Thus, there is a need for effective bariatric and metabolic interventions that can selectively serve specific groups of obese patients by offering alternatives to surgery or providing adjunctive therapy.

One management strategy that has been proposed to fill this treatment gap is intra-gastric balloon therapy. With three decades of innovation in this field, clinical experience with intra-gastric balloons has emerged. The U.S. Food and Drug Administration (FDA) mandated trials have helped to address intra-gastric balloon outcomes in rigorous clinical investigation. Furthermore, the physiologic mechanisms by which intra-gastric balloons achieve weight loss are not completely understood. The prevailing notion is that weight loss results from increased satiety and a delay in gastric emptying.<sup>4,5</sup> Currently, there are two balloon therapy systems that are FDA approved: The *ReShape*<sup>TM</sup> Integrated Dual Balloon System (ReShape Medical, Inc., San Clemente, CA) and the *ORBERA*<sup>TM</sup> Intra-gastric Balloon System (Apollo Endosurgery, Inc., Austin, TX).<sup>6,7</sup>

### **Description of the Technology and its Application**

The use of intra-gastric balloons to treat obesity is not recent. The original description of intra-gastric balloon therapy for weight loss has been credited to Nieben in 1982.<sup>8</sup> Over the next

decade, a few randomized controlled trials were performed to evaluate the clinical applicability, safety, and efficacy of this technology.<sup>9-11</sup> Recent innovation in balloon materials and methods for delivery and extraction, combined with clinical need has renewed interest in the intra-gastric balloon as a weight loss treatment.

Intra-gastric balloons are generally placed endoscopically. Procedures have been performed under conscious sedation or general anesthesia with success.<sup>12,13</sup> A number of papers, which cite technical data, indicate that procedure time for insertion and filling of the balloon is usually about 15 minutes.<sup>13,14</sup> Balloon insertion and extraction are associated with relatively few operative complications.<sup>12-14</sup> These will be addressed separately in the adverse events section of this document.

Available clinical data and manufacturer recommendations indicate six months to be the current standard duration of therapy from insertion to removal. However, balloon extraction is often followed by weight regain, and studies investigated the weight loss effect of long-term single<sup>15</sup> or multiple sequential balloon insertions.<sup>16</sup> Other balloons have been designed to remain implanted for 12 months and allow adjustment in fluid volume to address patient symptoms (deflation) and weight loss plateaus (inflation).<sup>17</sup>

Regardless of the type of balloon and duration of use, there is often a need for aggressive symptom control in the early period after balloon insertion with anti-nausea medications and proton pump inhibitors. While many patients can experience early nausea and epigastric pain, these symptoms seem to persist beyond the first week only in a minority.<sup>13,14,18</sup>

**Safety (adverse events including voluntary removals)**

Initial balloons in the early 1980s were filled with air, but complications quickly arose including insufficient weight loss, and were most commonly related to patient intolerance due to nausea, as well as difficulties with deflation and inflation of the balloon. Occasionally, spontaneous deflation and passage of the balloon into the small bowel would occur, causing bowel obstruction. Aside from unplanned deflations and obstructions, gastric ulcers with gastrointestinal hemorrhage and gastric perforation have been reported.<sup>19</sup> Consequently, an “expert” panel convened and proposed ideal characteristics for an intra-gastric balloon to enhance safety.<sup>20</sup> Panel recommendations included that the balloon be liquid filled and enhanced with a methylene blue indicator that can be absorbed and excreted by the patient in the event of balloon leakage, prompting timely detection and endoscopic intervention for removal. Since then, many new fluid-filled and modified air-filled balloons have been developed and employed worldwide.<sup>14,21,22</sup>

Despite modifications to the technology, adverse events, including non-efficacy, occasionally occur. This warrants consideration and discussion with patients who are considering the intra-gastric balloon as a stand-alone weight loss intervention or, in select situations, as adjunctive therapy to optimize readiness for bariatric surgery despite the lack of clear evidence to support such practice at this time. First, some historic sham-controlled studies failed to demonstrate superiority of intra-gastric balloon interventions when compared to lifestyle modification with diet, exercise and follow-up.<sup>9,23-26</sup> Second, early complications of clinical

significance to patients include epigastric pain, nausea, and vomiting. While these symptoms are generally transient, they may be difficult to control even with pharmacotherapy and place some patients at risk of dehydration, resulting in the voluntary removal of the balloon in up to 7% of cases.<sup>18,26</sup>

A review of 3443 patients documented early removal of the Bioenterics Intra-gastric Balloon (BIB) to occur at a rate of 4.2%, primarily for abdominal pain, obstruction in the gastrointestinal tract, nausea and vomiting, gastric ulceration, gastric perforation, dehydration, voluntary removal, and deflation of the balloon with or without displacement.<sup>18</sup> Spontaneous balloon deflation has been reported to occur at variable frequencies (3-23%).<sup>26</sup> These can be detected early to minimize complications either by ultrasonography at regular intervals or by green discoloration of the urine in balloons (such as the BIB) with the methylene blue indicator, which is absorbed upon leakage and excreted into the urine. Most deflated balloons are passed spontaneously, but obstructions have been reported, particularly in patients with previous abdominal surgery. Rarely, gastroduodenal ulcers, Mallory-Weiss tears, and esophagitis have also been reported after balloon placement despite aggressive proton pump inhibitor therapy.<sup>26,27</sup> It is generally recommended that if used for weight loss, intra-gastric balloons should be removed within 6 months to reduce the risk of deflation and complications.<sup>27</sup> Although severe complications reported in the literature were infrequent, they did include bowel obstructions requiring surgery, gastric perforations, and death.<sup>18</sup> In a review of BIB, Dumonceau et al reported a treatment-related mortality rate of 0.07% due to post-insertion broncho-aspiration and gastric perforation in patients with previous fundoplication, highlighting the importance of patient selection.<sup>26</sup> Generally cited absolute contraindications for intra-gastric balloon use

include previous gastric surgery, hiatal hernia  $\geq 5$  cm, a coagulation disorder, a potential bleeding lesion of the upper gastrointestinal tract, pregnancy or desire to become pregnant, breast-feeding, alcoholism or drug addiction, severe liver disease, or any contra-indication to endoscopy.<sup>13,14,26,28</sup>

Relative contraindications include previous abdominal surgery, hiatal hernia, esophagitis, Crohn's disease, non-steroidal anti-inflammatory drug use, or uncontrolled psychiatric disorders.<sup>13,14,26,28</sup>

One final point regarding the adverse event profile of intra-gastric balloon technology requires separate and special mention. Because all balloons require removal, adverse events can result from patients getting lost to follow-up. Loss to follow-up increases the likelihood of balloon leakage and passage into the intestine, where obstruction may occur. The risk of premature passage into the intestine increases if a balloon is left in the stomach longer than six months.<sup>19</sup> Thus, selection of patients committed to follow-up, prompt removal by six months from the time of insertion of most balloons are recommended to enhance the safety profile and utilization of available intra-gastric balloon technologies.

## **Efficacy**

The efficacy of an intra-gastric balloon intervention has at least two components: the behavioral (diet and lifestyle) effect and the balloon effect. To isolate the balloon effect it is important to look at controlled studies. Historically, some evidence exists to suggest that weight loss observed in patients receiving balloon therapy is comparable to weight loss that can be achieved by dietary manipulation alone.<sup>9,23-25</sup> In recent approval of two intra-gastric balloon

systems, the FDA cited pivotal trial evidence that greater weight loss can be accomplished with device use than with diet alone and that this difference reached statistical significance.<sup>6,7</sup>

A review in 2008 showed only one of three sham-controlled trials found a significantly higher weight loss with the BIB compared to the sham procedure plus exhaustive follow-up.<sup>26</sup> Mathus-Vliegen et al randomized 43 patients with morbid obesity a mean baseline BMI of 43.3 kg/m<sup>2</sup> into a sham group and a balloon-treated group for three months.<sup>24</sup> Based on an intention to treat, weight loss was not statistically different between groups at 3 months. After the first 3 months, the sham group underwent balloon insertion, and both groups were followed for one year. Although an independent benefit of balloon treatment beyond that of diet, exercise, and behavioral therapy could not be demonstrated at 3 months, the observed mean percentage of total body weight loss (%TBWL) at one year was approximately 17%, and 75% of patients were able to achieve >10% TBWL.<sup>24</sup>

Genco et al, on the other hand, reported an effect of the balloon in inducing weight loss beyond that obtained with sham treatment.<sup>28</sup> In a randomized controlled study of 32 patients with a baseline BMI of 43.3 kg/m<sup>2</sup>, a 34% excess weight loss (EWL) was observed in the treatment group when compared to sham ( $p < 0.001$ ).<sup>28</sup> In 2008, the same group also published results of a case matched series where a cohort of 130 patients receiving intra-gastric balloon therapy was compared to a historical cohort of 130 matched patients that received diet therapy alone.<sup>29</sup> Again, they demonstrated that the %EWL of 33.9% in the balloon group was statistically better than the 24.3% EWL observed in the historical, non-randomized control group at six months of treatment time.

A smaller randomized trial primarily focused on assessing the efficacy of BIB in improving liver histology in patients with nonalcoholic steatohepatitis (NASH) showed improvement in NASH with the balloon. The study did not report TBWL or EWL in a sample of patients with  $\text{BMI} \geq 27 \text{ kg/m}^2$  randomized to balloon plus step 1 American Heart Association diet versus diet alone.<sup>25</sup> They did not note a significant difference in mean BMI decrease between the groups indicating a weight-independent improvement for NASH patients.

Ponce et al conducted a randomized controlled trial utilizing the ReShape Duo Integrated Dual Balloon System (DUO) + diet and exercise in comparison to sham endoscopy + diet and exercise.<sup>14</sup> Patients with a mean BMI of  $35 \text{ kg/m}^2$  were enrolled and followed for 24 weeks. After randomization, the study included a large sample of 187 treatment subjects and 139 control subjects. At six months, %EWL was significantly higher at 25.1% in the treatment group when compared to the 11.3% EWL observed in the control group. For the 167 patients (out of 187) who completed DUO balloon therapy, %EWL was even higher at 27.9%. This was more than double that observed in the diet and exercise group. Reported mean TBWL was 7.2 kg or 7.6% TBWL (i.e. <10%).<sup>14</sup>

The estimate of intra-gastric balloon effectiveness at removal (6 months post-insertion) comes from a number of additional retrospective and prospective case series.<sup>30-33</sup> The reviewed studies varied in reporting of outcomes, and the most commonly reported anthropometric measurement was %EWL. On average, %EWL was approximately 34.5% (range 7% to 56%).

Overall, the data suggest that the intra-gastric balloon is an effective tool for weight loss. Most of its effect has been observed in the first three months after insertion, during which patients usually lose more than 12 kg. At removal, or 6 months post-insertion, studies, including randomized controlled trials, suggest that the expected %EWL is about 24%. Lopez-Nava et al reported that TBWL is higher in patients with higher starting weight but that %EWL is greater in women and in the less obese.<sup>34</sup> On the other hand, Peker et al observed that weight loss plateaued at three months and that BIB therapy was more effective in those with a BMI > 40 kg/m<sup>2</sup> than in those with BMI between 30 – 39 kg/m<sup>2</sup>.<sup>30</sup>

Some studies examined the sustainability of weight loss beyond the time of balloon removal. In a randomized sham-controlled study with crossover at three months, Genco et al showed that the group that had the balloon inserted for three months continued to lose weight at a greater rate in the three months following balloon removal compared to the group that started out without a balloon for three months and observed for weight loss.<sup>28</sup> The authors hypothesized the persistence of a device effect on alimentary behavior even after the balloon was removed. In another publication, the same group followed patients for six months after balloon removal and found that, while weight regain was observed, %EWL was still >25% at 12 months.<sup>35</sup> In addition, when a second balloon treatment was offered after a one month break following removal of the first balloon, patients achieved 52% EWL at one year, which was higher than that observed when only one balloon treatment period was offered. In a review, Gaur et al similarly reported that 52% of the weight lost during balloon therapy was sustained 12 months after balloon removal.<sup>19</sup>

Kotzampassi et al, who described five-year outcomes in a retrospective series of 500 patients, reported longer post-balloon treatment follow-up.<sup>36</sup> Only 395 patients were included in the analysis; however, as 17% of patients who did not attain >20% EWL after BIB treatment were excluded. At two years of follow-up, 17.1% EWL was noted in 352 patients. This was down from 27.7% EWL observed at one year after balloon removal in the same patient cohort. This study reported that 68% of the weight lost during balloon therapy was sustained 12 months after removal in responders (patients who lost >20% EWL) who were not lost to follow-up.<sup>36</sup> At five years, 12.97% EWL was maintained in patients available for follow-up.

The most contemporary evidence for efficacy comes from two different FDA trials on intra-gastric balloon technology. Both balloon systems have been recently approved for clinical use in the United States: ORBERA™ and *ReShape*™. The pivotal study of ORBERA™, known as IB-005, was a multicenter, prospective, randomized, non-blinded comparative study of 448 patients. The pivotal trial for *ReShape*™, known as REDUCE, was a prospective, sham-controlled, double-blinded, randomized multicenter clinical study of 330 patients. Both balloon technologies demonstrated greater weight loss that reached statistical significance when compared to diet interventions in their study population, as detailed in the FDA documents.<sup>6,7</sup>

## **Summary and Recommendations**

1. Level 1 data regarding the clinical utility, efficacy, and safety of intra-gastric balloon therapy for obesity are derived from randomized clinical studies.

2. Implantation of intra-gastric balloons can result in notable weight loss during treatment. A few studies, representing lower level evidence, have suggested that the weight loss effect can be maintained after balloon retrieval for some finite time into the future.
3. While utilization of intra-gastric balloons results in notable weight loss, separating the effect of the balloon alone from those of supervised diet and lifestyle changes may be challenging. Of note, the recent FDA pivotal trials demonstrate a benefit to balloon use compared to diet alone in their study populations. In general, any obesity treatment, including intra-gastric balloon therapy, would benefit from a multi-disciplinary team skilled and experienced in providing in-person medical, nutritional, psychological and exercise counseling.
4. The safety profiles for intra-gastric balloons indicate a safe intervention with rare serious complications. Early postoperative tolerance challenges can be significant but can be controlled with pharmacotherapy in the majority of patients, thereby minimizing voluntary balloon removals. These early symptoms should be discussed with the patient prior to the procedure.
5. Although prolonged duration of balloon therapy and sequential treatments with multiple balloons has been studied, awareness and adherence to absolute and relative contraindications of use and timely removal optimize device safety. Based on current evidence, balloon therapy is FDA approved as an endoscopic, temporary (maximum 6 months) tool for the management of obesity. Further review will evaluate the impact that diet, lifestyle changes and pharmacotherapy have during and after balloon removal.

6. The ability to perform appropriate follow-up is essential when intra-gastric balloons are used for weight loss to enhance their safety and avoid complications related to spontaneous deflation and bowel obstruction.

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#### **Disclosures**

No conflicts of interest to disclose.