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 payors, the media, and others regarding the role of intragastric 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 the technology of endoscopically placed intragastric balloon in the current management of obesity and related diseases. This statement was prepared by the Clinical Issues Committee of the ASMBS with input by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). The final document was approved by the ASMBS Board of Governors November 2016, and co-endorsed by the SAGES Board of Governors January 2016.

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 the epidemic of obesity. 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, some individuals who, despite meeting medical necessity for bariatric surgery, may choose not to have surgery or may not qualify as surgical candidates on the basis of existing criteria or surgeon assessment. Examples of the latter include individuals with obesity-related co-morbidities whose body mass index (BMI) falls below currently established eligibility criteria that qualify patients for bariatric surgery and/or patients who are deemed to be at high surgical risk, as a result of severe obesity with excessively high BMI or poor general health status. Some other patients, such as those belonging to specific age groups or those seeking to optimize health as a bridge to a non-obesity therapy (e.g., organ transplantation, knee or hip replacement), may wish to lose weight by using options other than surgery. Effective options for these patient groups are limited. To date, pharmacotherapy and medically supervised diet programs have shown variable and modest efficacy for weight loss, and they are generally ineffective for long-term weight loss maintenance and co-morbidity reduction [1–3]. Thus, there is a need for effective bariatric and metabolic interventions that can selectively serve specific groups of patients with obesity by offering alternatives to surgery or providing adjunctive therapy.

One management strategy that has been proposed to fill this treatment gap is intragastric balloon therapy. With three decades of innovation in this field, clinical experience with intragastric balloons has been growing. Trials mandated by
the U.S. Food and Drug Administration (FDA) have helped elucidate the outcomes of intragastric balloon therapy in rigorous clinical investigations. However, the physiologic mechanisms through which intragastric balloons lead to weight loss are still not completely understood. The prevailing notion is that weight loss results from increased sense of satiety and a delay in gastric emptying [4,5]. Currently, there are two balloon therapy systems that are FDA approved: The ReShape Integrated Dual Balloon System (ReShape Medical, Inc., San Clemente, CA) and the ORBERA Intragastric Balloon System (Apollo Endosurgery, Inc., Austin, TX) [6,7].

Description of the technology and its application

The use of intragastric balloons to treat obesity is not a recent development. The original description of intragastric balloon therapy for weight loss has been credited to Nieben in 1982 [8]. In the following decade, a few randomized controlled trials were performed to evaluate the clinical applicability, safety, and efficacy of this technology [9–11]. Recent innovations in balloon materials and methods for delivery and extraction, combined with clinical need, have renewed interest in the use of intragastric balloons as a weight loss treatment.

Intragastric balloons are generally placed endoscopically. Procedures have been performed under conscious sedation or general anesthesia with success [12,13]. A number of papers have cited technical data, which indicate that procedure time for insertion and filling of the balloon is usually about 15 minutes [13,14]. Balloon insertion and extraction are associated with relatively few surgical complications [12–14]. These will be addressed separately in the section on adverse events of this article.

Available clinical data and manufacturer recommendations indicate 6 months to be the current standard duration of therapy from insertion to removal. However, balloon extraction is often followed by weight regain, and studies have investigated the weight loss effect of long-term single [15] or multiple sequential balloon insertions [16]. Some balloons have been designed to remain implanted for 12 months and allow adjustment in fluid volume to address symptoms (deflation) and weight loss plateaus (inflation) [17].

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. Although many patients may experience nausea and epigastric pain in the immediate post-insertion period, these symptoms seem to persist beyond the first week only in a minority [13,14,18].

Safety (adverse events, including voluntary removals)

In the initial period of this technology, in the early 1980s, balloons were filled with air, but complications, including insufficient weight loss, quickly arose and were most commonly related to patient intolerance because of nausea, as well as difficulties with deflation and inflation of the balloon. Occasionally, spontaneous deflation and passage of the balloon into the small bowel occurred, causing bowel obstruction. Besides unplanned deflations and obstructions, gastric ulcers with gastrointestinal hemorrhage and gastric perforation have been reported [19]. Consequently, an “expert” panel convened and proposed the ideal characteristics for an intragastric balloon to enhance safety [20]. The panel recommended that the balloon be filled with liquid and enhanced with a methylene blue indicator. In the event of balloon leakage, the indicator would be absorbed and excreted in the patient’s urine, prompting timely detection and endoscopic removal of the balloon. Since then, many new fluid-filled balloons as well as modified air-filled balloons have been developed and employed worldwide [14,21,22].

Despite modifications to the technology, adverse events, including lack of efficacy, do occur. This warrants consideration and discussion with patients contemplating the intragastric balloon as a stand-alone weight loss intervention or, in select situations, as adjunctive therapy to optimize readiness for bariatric surgery despite lack of clear evidence to support such an approach at this time. First, historical sham-controlled studies failed to demonstrate the superiority of intragastric balloon interventions compared with lifestyle modifications with diet, exercise, and follow-up [9,23–26]. Second, early complications that are of clinical significance to patients include epigastric pain, nausea, and vomiting. Although 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 [18,26].

A review of 3443 patients documented the early removal of the bioenterics intragastric balloon (BIB) to occur at a rate of 4.2%, primarily because of 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 [18]. Spontaneous balloon deflation has been reported to occur at variable frequencies (3%–23%) [26]. To minimize complications, deflation can be detected early either by ultrasonography at regular intervals or by green discoloration of the urine in balloons (e.g., BIB) with the methylene blue indicator, which is absorbed upon leakage and excreted into 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 [26,27]. It is generally recommended that, if used for weight loss, intragastric balloons should be removed within 6 months to reduce the risk of deflation and complications [27].
Although severe complications reported in the literature were infrequent, they did include bowel obstructions requiring surgery, gastric perforations, and death [18]. In a review of the BIB, Dumonceau et al. reported a treatment-related mortality rate of 0.07% as a result of post-insertion bronchoaspiration and gastric perforation in patients with previous fundoplication, highlighting the importance of careful patient selection [26]. Generally cited absolute contraindications for the intragastric balloon use include previous gastric surgery, hiatal hernia ≥ 5 cm, a coagulation disorder, a potential bleeding lesion of the upper gastrointestinal tract, pregnancy or desire to become pregnant, breastfeeding, alcoholism or drug addiction, severe liver disease, or any contraindication to endoscopy [13,14,26,28]. Relative contraindications include previous abdominal surgery, hiatal hernia, esophagitis, Crohn’s disease, nonsteroidal anti-inflammatory drug use, or uncontrolled psychiatric disorders [13,14,26,28].

One final point regarding the adverse event profile of intragastric balloon technology requires separate and special mention. Because all balloons require removal, adverse events can result from patients being 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 6 months [19]. Thus, careful selection of patients committed to follow-up and prompt removal by 6 months from the time of insertion of most balloons are recommended to enhance the safety profile and utilization of available intragastric balloon technologies.

Efficacy

The efficacy of an intragastric balloon intervention has at least 2 components: (1) the behavioral (diet and lifestyle) effect and (2) 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 with weight loss that can be achieved by dietary manipulation alone [9,23–25]. In its recent approval of 2 intragastric balloon systems, the FDA cited pivotal trial evidence indicating that greater weight loss can be accomplished with device use than with diet alone and that this difference reached statistical significance [6,7].

A review in 2008 showed that only 1 of 3 sham-controlled trials found significantly higher weight loss with the BIB compared with the sham procedure plus exhaustive follow-up [26]. Mathus-Vliegen et al. randomized 43 patients with morbid obesity and a mean baseline BMI of 43.3 kg/m^2 into a sham group and a balloon-treated group for 3 months [24]. On the basis of an intention to treat, weight loss was not statistically different between the groups at 3 months. After the first 3 months, the sham group underwent balloon insertion, and both groups were followed up for 1 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 weight loss (% TBWL) at 1 year was approximately 17%, and 75% of patients were able to achieve >10% TBWL [24].

Genco et al., however, reported an effect of the balloon in inducing weight loss beyond that obtained with sham treatment [28]. In a randomized controlled study of 32 patients with a baseline BMI of 43.3 kg/m^2, a 34% excess weight loss (EWL) was observed in the treatment group compared with sham (P < .001) [28]. In 2008, the same group also published the results of a case-matched series, where a cohort of 130 patients receiving intragastric balloon therapy was compared with a historical cohort of 130 matched patients who received diet therapy alone [29]. 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, nonrandomized control group at 6 months of treatment time.

A smaller randomized trial focused primarily on assessing the efficacy of the 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 a BMI ≥ 27 kg/m^2 randomized to balloon plus step 1 American Heart Association diet versus diet alone [25]. 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) (ReShape Medical, Inc., San Clemente, CA) plus diet and exercise in comparison with sham endoscopy plus diet and exercise [14]. Patients with a mean BMI of 35 kg/m^2 were enrolled and followed up for 24 weeks. After randomization, the study included a large sample of 187 treatment patients and 139 control patients. At 6 months, % EWL was significantly higher at 25.1% in the treatment group compared with 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%) [14].

The estimate of intragastric balloon effectiveness at removal (6 months after insertion) comes from a number of additional retrospective and prospective case series [30–33]. The reviewed studies varied in their reporting of outcomes, and the most commonly reported anthropometric measurement was %EWL. On average, %EWL was approximately 34.5% (range 7%–56%).

Overall, the data suggest that the intragastric balloon is an effective tool for weight loss. Most of its effect was
observed in the first 3 months after insertion, during which patients usually lost > 12 kg. At removal, or 6 months after insertion, studies, including randomized controlled trials, have suggested 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 less obese persons [34]. In contrast, Peker et al. observed that weight loss plateaued at 3 months and that BIB therapy was more effective in those with a BMI > 40 kg/m² than in those with BMI between 30 and 39 kg/m² [30].

Some studies examined the sustainability of weight loss beyond the time of balloon removal. In a randomized sham-controlled study with crossover at 3 months, Genco et al. showed that the group that had the balloon in place for 3 months continued to lose weight at a greater rate in the 3 months following balloon removal compared with the group that started out without a balloon for 3 months and observed for weight loss [28]. These authors hypothesized the persistence of a device effect on alimentary behavior even after the balloon was removed. In another publication, the same group followed up patients for 6 months after balloon removal and found that although weight regain was observed, %EWL was still > 25% at 12 months [35]. In addition, when a second balloon treatment was offered after a 1-month break following removal of the first balloon, patients achieved 52% EWL at 1 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 [19].

Kotzampassi et al., who described 5-year outcomes in a retrospective series of 500 patients, reported longer post-balloon treatment follow-up [36]. 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 the 2-year follow-up, 17.1% EWL was noted in 352 patients. This was down from 27.7% EWL observed at 1 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 [36]. At 5 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 intragastric 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, nonblinded 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 compared with diet interventions in their study population, as detailed in the FDA documents [6,7].

**Summary and Recommendations**

1. Level 1 data regarding the clinical utility, efficacy, and safety of intragastric balloon therapy for obesity are derived from randomized clinical studies.
2. Implantation of intragastric 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. Although utilization of intragastric 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, recent FDA pivotal trials demonstrated a benefit to balloon use compared with diet alone in their study populations. In general, any obesity treatment, including intragastric balloon therapy, would benefit from a multidisciplinary team that is skilled and experienced in providing in-person medical, nutritional, psychological, and exercise counseling.
4. The safety profiles for intragastric balloons indicate a safe intervention, with serious complications being rare. 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 before the procedure.
5. Although therapy with prolonged balloon in situ time and the use of sequential treatments with multiple balloons have 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 of diet, lifestyle changes, and pharmacotherapy during and after balloon removal.
6. The ability to perform appropriate follow-up is essential when intragastric balloons are used for weight loss to enhance their safety and avoid complications related to spontaneous deflation and bowel obstruction.

**ASMBS disclaimer**

These guidelines are not intended to provide inflexible rules or requirements of practice and are not intended, nor should they be used, to state or establish a local, regional, or national legal standard of care. Ultimately, there are various appropriate treatment modalities for each patient, and the surgeon must use judgment in selecting from among
feasible treatment options. ASMBS cautions against the use of guidelines in litigation in which the clinical decisions of a physician are called into question. The ultimate judgment regarding appropriateness of any specific procedure or course of action must be made by the physician in light of all the circumstances presented. Thus, an approach that differs from this guideline, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious physician may responsibly adopt a course of action different from that set forth in the guideline when, in the reasonable judgment of the physician, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology.

All that should be expected is that the physician will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient, in order to deliver effective and safe medical care. The sole purpose of this guideline is to assist practitioners in achieving this objective.

SAGES disclaimer

Clinical practice guidelines are intended to indicate the best available approach to medical conditions as established by a systematic review of available data and expert opinion. The approach suggested may not necessarily be the only acceptable approach given the complexity of the healthcare environment. These guidelines are intended to be flexible, as the surgeon must always choose the approach best suited to the patient and to the variables at the moment of decision. These guidelines are applicable to all physicians who are appropriately credentialed regardless of specialty and address the clinical situation in question.

These guidelines are developed under the auspices of SAGES, the guidelines committee and approved by the Board of Governors. The recommendations of each guideline undergo multidisciplinary review and are considered valid at the time of production based on the data available. New developments in medical research and practice pertinent to each guideline are reviewed, and guidelines will be periodically updated.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

References

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