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What is This?

Intragastric Balloon Therapy in the Management of Obesity: Why the Bad Wrap?

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For the first time in the history of the United States, in the 21st century, there may be a decline in life expectancy, as a result of the increasing rate of obesity. It is known that even the modest reduction of 10% of excess body weight significantly reduces obesity-associated comorbidities. Conservative measures such as diet and exercise seldom give durable results in the long term. Bariatric surgery has been shown to achieve durable weight loss but is not without significant risks and complications. As a result, greater focus has turned toward minimally invasive endoscopic therapies for the management of obesity. There have been multiple reports of creative endoscopic devices and techniques in the literature, but most have only demonstrated early pilot data. By far, the most widely studied of the minimally invasive endoscopic therapies for obesity is the gastric balloon. Now obsolete, the Garren-Edwards gastric bubble was removed from the market in the United States after several sham-controlled studies showed that diet and behavior modification were equally efficacious and that the device was associated with a prohibitive number of complications. However, the concept and technique of intragastric balloon placement has evolved considerably since that time, and we now have data on nearly 3,000 patients who have undergone placement of the BioEnterics Intragastric Balloon (Carpenteria, CA) worldwide. The balloon is approved as part of a multifaceted approach to obesity in many countries and has been shown to result in at least a 10% excess weight loss durable over 1 year. However, the device is not yet approved for use in the United States. In this article, the authors review the efficacy, indications, complications, and potential uses for the intragastric balloon. The intragastric balloon might be the best start as gastroenterologists in the United States begin to play an increasing role in the treatment of the obesity pandemic. (*JPEN J Parenter Enteral Nutr*. 2011;35:25-31)

Clinical Relevancy

Although bariatric surgery has been shown to achieve durable weight loss, it is not without significant morbidity. Greater focus has turned toward minimally invasive endoscopic therapies in the management of obesity. Most of these therapies are cumbersome and unlikely to be practical in an outpatient endoscopy setting. The most widely studied endoscopic treatment for obesity is the gastric balloon. Although the Garren-Edwards gastric bubble (GEGB) is now obsolete, significant modifications to its design have resulted in a safer and

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more effective intragastric balloon that is being used extensively in other countries but has not been approved for use in the United States. The current article reviews the endoscopic therapies for obesity and focuses on the intragastic balloon as an adjunctive therapy in the treatment of obesity, as practicing gastroenterologists begin to play an increasing role in the treatment of the obesity pandemic.

For the first time in the history of the United States, in the 21st century, there may be a decline in life expectancy, as a result of the increasing rate of obesity.[1] Now a true pandemic, it is estimated that more than 300 million people worldwide are obese and that 1 in every 3 American adults is obese.[2,3] The comorbidities associated with obesity have been well described, including diabetes, hypertension, hyperlipidemia, gastroesophageal reflux disease (GERD), sleep apnea, osteoarthritis, coronary heart disease, stroke, nonalcoholic fatty liver disease (NAFLD), and various malignancies. While the direct effect of obesity on mortality was once unclear, a curvilinear relationship between body mass index (BMI) and mortality has recently been documented.[4] A recent large-population study showed that patients with a BMI

≥35 kg/m² or a waist circumference in the highest quintiles have nearly twice the mortality as matched controls.[5] Second only to smoking, obesity is a leading preventable cause of death in the United States.

In the gastroenterologist's practice, obese and overweight patients are seen commonly. This may be because of the high incidence of associated diseases such as GERD, NAFLD, hepatocellular carcinoma, colon cancer, and cholelithiasis within this patient population. First-line treatment options for obese and overweight patients include dietary and exercise therapy, behavior modification, and pharmacotherapy. These therapies are all effective in the short term but seldom lead to durable, long-term weight loss and maintenance in obese patients. By contrast, bariatric surgery has been shown to achieve durable weight loss that is sustainable for more than 10 years, with improvements in nearly all obesity-associated comorbidities. In the short term, bariatric surgery can result in an approximate 60% excess weight loss (EWL). Importantly, a more modest weight loss of 5% to 10% of initial weight significantly decreases obesity-associated comorbidities.[6] As for the long-term results, one of the largest studies to evaluate the efficacy of bariatric surgery showed that obese patients weighed 16.1% less 10 years following surgery, compared with a 1.6% weight gain in matched controls.[7]

Of special interest, bariatric surgery is capable of curing diabetes independent of weight loss. In fact, insulin resistance decreases within 1 week following Roux-en-Y gastric bypass (RYGB) surgery.[8] A recent randomized controlled trial (RCT) showed that laparoscopic adjustable gastric banding (LAGB) was more effective at curing type 2 diabetes than medical therapy.[9]

In fact, the 2009 American Diabetes Association guidelines[10] stated for the first time that bariatric surgery should be considered for adults with a BMI ≥35 kg/m² and type 2 diabetes, especially if the diabetes is difficult to control with lifestyle and pharmacologic therapy. In fact, 77% of patients with preoperative diabetes no longer required medication following bariatric surgery, with similar rates of improvement in hypertension, hyperlipidemia, and sleep apnea.[11] As the benefits of bariatric surgery have become clearer, the number of surgeries performed has grown exponentially, from 12,775 in 1998 to more than 140,000 in 2005.[12]

However, bariatric surgery is not without significant risks and complications. Depending on the type of surgery (eg, LAGB, sleeve gastrectomy, RYGB, biliopancreatic diversion with duodenal switch), the mortality rates are estimated at between 0.1% and 2.0%.[13] While the mortality rate is relatively low, the postoperative morbidity can be substantial. Complications such as anastomotic leak, small bowel obstruction, anastomotic strictures, and anastamotic ulcers are common.[14] Other complications, including dumping syndrome, vitamin deficiencies (thiamine, iron, cobalamin, and folate, in particular), diarrhea (from malabsorption, vagal nerve injury, or small intestinal bacterial overgrowth), and metabolic bone disease, are not uncommon.

RYGB can present a significant challenge for the endoscopist, as the excluded portion of the stomach, duodenum, and biliopancreatic limb of the jejunum are not readily accessible with standard upper endoscopy. Enteroscopy of the Roux limb to reach the ampulla or excluded stomach is not always possible. This becomes particularly problematic when there is biliopancreatic pathology or bleeding in the excluded portion of the stomach.

In addition, failure to lose weight or weight gain after initial weight loss is not an uncommon indication for upper endoscopy in patients with a history of bariatric surgery. Gastrogastric fistulas or dilation of the gastrojejunostomy anastamosis may be encountered. Endoscopic treatment with sodium morrhuate injection has been used to restore integrity of the anastamosis, but gastrogastric fistulas often require surgical repair.[15]

An Endoscopic Approach Is Needed

Because of the complications and cost of bariatric surgery, greater focus has turned toward minimally invasive endoscopic therapies in the management of obesity. There have been multiple reports of creative endoscopic devices and techniques in the literature. Most of the studies on endoscopic therapies for obesity, as well as bariatric surgery, report percentage of EWL, defined as the difference between the preprocedure weight and the end weight, divided by baseline excess weight (ie, the percentage of the weight above the ideal weight that is lost).

Ideally, a safe, short, and reproducible endoscopic procedure with the potential to be performed under moderate sedation would advance the gastroenterologist's role in the treatment of obesity considerably. Endoluminal therapy has the potential to extend therapy to those with multiple comorbidities, older age, and those with mild obesity (ie, BMI 30–35 kg/m²). Reversible strategies that avoid commitment to permanent surgical modification of the gastrointestinal (GI) tract are particularly attractive for some patients. Currently, several such transoral endoluminal procedures are under investigation in the United States.[16]

The primary endoscopic treatment modalities for obesity are restrictive interventions, including intragastric balloons, transoral gastroplasty, and endoluminal vertical gastroplasty. The duodenojejunal bypass sleeve is the only malabsorptive endoluminal device that has been

studied in humans. Electrical stimulation to delay gastric emptying is also under investigation, with some early experience in humans.[17]

Transoral endoluminal vertical gastroplasty with the Bard EndoCinch Suturing System (C.R. Bard Inc, Murray Hill, NJ) has been recently described, and the results of 64 patients were reported.[18] The preliminary data are encouraging, but the procedure requires general anesthesia and is fairly aggressive, involving endoluminal suturing of the anterior and posterior walls of the stomach. The TOGA System (Satiety Inc, Palo Alto, CA) is the first endoscopic stapling device that creates a full-thickness plication in the proximal stomach, and encouraging early data in humans have been reported.[19,20] Although technically feasible, the number of active therapeutic endoscopists who are willing to perform these procedures in a practice setting remains to be seen and may be limited.

The duodenal-jejunal bypass sleeve (DJBS) has recently been introduced, and preliminary data are available. In their study, Tarnoff et al[21] compared the DJBS with a low-calorie diet to achieve short-term weight loss before bariatric surgery. At 12 weeks, the mean EWL was 22% for the device and 5% for the control group (*P* < .001), which was similar to another small pilot study.[21,22] However, the procedure required the use of general anesthesia and fluoroscopy, with an average procedure time of 38.9 ± 27 minutes (range, 14–111 minutes). In addition, 5 of the 25 patients in their study did not tolerate the procedure and required the removal of the device.[21]

By far, the most widely studied of the minimally invasive endoscopic therapies for obesity is the gastric balloon. The physiologic concept of intragastric balloons and their effect on satiety has been explored far beyond the original concept of the artificial gastric bezoar described by Nieben[23] in 1982. Placement of an intragastric balloon results in a complex interplay of neurohormonal factors and changes in gastric motility, in addition to the obvious space-occupying effect.

Basis for Gastric Distention as a Target for Endoscopic Therapy

Cholecystokinin (CCK) is an important regulatory hormone involved in satiety that plays an important role in the physiologic effect of intragastric balloon placement. CCK is produced in the duodenum and is stimulated by the presence of digestion products in the stomach, mainly fats and proteins. In addition to its actions on pancreatic enzyme secretion, gallbladder contraction, and increased gastric vagal afferent activity, CCK delays gastric emptying and causes pyloric constriction. CCK is also stimulated by gastric distention. In addition, it has been shown that infusion of CCK, in combination with gastric distention, significantly reduces food intake in humans, and this effect is thought to be due to a CCK-mediated delay in gastric emptying.[24,25]

Short-term satiety is principally affected by gastric distention and gastric volume. In both animals and humans, short-term food intake is affected by the weight and volume of food more than its energy content (calories).[26-28] As an example, Rolls et al[28] showed that gastric infusion of high-volume, low-calorie feedings decreased subsequent caloric intake of a buffet meal to a similar degree as a high-volume, high-calorie meal. This volume-regulated satiety is thought to result primarily from gastric distention. Mechanical gastric balloon distention to a volume greater than 400 cc during meals significantly reduces oral intake, and even lesser volumes may have an effect.[29] However, physiologic data for intragastric balloons are sparse, and other supportive studies would be helpful to investigate the effect of balloons on levels of hormones such as CCK.

History of Intragastric Balloon Therapy

In 1985, the first widely used intragastric balloon, the GEGB, was approved for use in the United States. Approved as an adjunctive modality to a multifaceted approach to obesity, the GEGB was a polyurethane cylindrical device with a self-sealing valve through which a removable air-insufflation catheter was inserted. The bubble was insufflated with 220 mL of air and detached. It is unclear how the volume of 220 mL was decided on, as this was a lesser volume than had been determined in the medical literature to be effective.[29] The bubble was then left to float freely in the stomach and could be removed endoscopically after being punctured with a forceps. In the late 1980s, several sham-controlled studies were published showing that diet and behavior modification were equally as efficacious as the GEGB in producing weight loss.[30-34] These studies reported on less than 200 patients collectively, and while they did not show a statistically significant decrease in weight loss over any of the follow-up periods, initially, the GEGB did show a significant advantage in weight loss over the sham procedure.[33]

Complications of the GEGB were significant and included gastric erosions, gastric ulcers, small bowel obstruction, Mallory-Weiss tears, and esophageal lacerations due to the use of a cumbersome overtube during balloon placement.[35,36] As a result of the sham-controlled trials and their high complication rates, the GEGB is no longer used or available in the United States, but more than 25,000 were placed before its withdrawal from the market.

Several hypotheses for the demise of the GEGB in the United States have been proposed. A significant

proportion of obese patients overeat in a pattern of compulsive eating rather than in response to physiologic hunger. Binge eating behavior is very prevalent within obese populations, and studies have shown that binge eating is associated with unsatisfactory weight loss even following aggressive bariatric surgery.[37-39] Previous studies have shown that binge eaters have a large gastric capacity, less negative gastric feedback, and that they lose less weight with intragastric balloons.[29] There were no attempts to exclude binge eaters from receiving the GEGB.

The initial weight loss following placement of the GEGB was thought to be negated by overeating. This may be explained in part by the fact that the balloon was clearly too small. As mentioned, studies have shown that an effect on satiety and subsequent caloric intake is only seen after distention of balloons to at least 400 mL.[29] Importantly, there is a marked variation in stomach size and shape from patient to patient, and therefore, the degree of distention produced by a fixed volume may differ significantly between patients.

Acknowledging that the concept of gastric distention seemed rational in the management of obesity, but noting the lack of efficacy and poor safety profile of the GEGB, 75 international experts met in 1987 and defined the fundamental attributes for an effective and safe intragastric balloon. These attributes included a smooth surface to avoid gastric ulcerations, a small and flexible deflated structure so that it could be inserted and removed under direct endoscopic visualization, construction with a soft and highly elastic material, and that the device be filled with fluid rather than air.[40]

Its irregular surface, free-floating nature, and the awkward use of an overtube led to several renditions of the GEGB. The Taylor intragastric balloon (a pear-shaped, smooth silicone balloon filled with 550 mL of saline) and the Ballobes intragastric balloon (inflated to 475 mL of room air) were among those tried. However, several trials again showed no benefit in these devices compared with conventional therapy with diet and behavior modification.[41,42] In addition, several polyurethane balloons (kept in place by a nasogastric catheter taped to the nose) were tried, with similar results.[43,44] None of these renditions were widely used in clinical practice. Other balloons used in the 1980s are now obsolete and had little controlled data, including devices produced by Wilson-Cook (Winston Salem, NC), Tremco (Cleveland, OH), and Dow-Corning (Midland, MI).

The BioEnterics Intragastric Balloon

After much research and focus on the requirements set forth by the expert guidelines, the BioEnterics intragastric balloon (BIB; Allergan, Irvine, CA) was introduced in 1999. The BIB is a spherical balloon made of transparent silicone elastomer that is filled with 400 to 700 mL of saline. The device is constructed of an inert, nontoxic silicone elastomer that is resistant to corrosion by gastric acid. The BIB has a self-sealing radio-opaque valve to which a silicone catheter is attached to fill the balloon. It is inserted under direct endoscopic visualization and without the use of fluoroscopy. After filling is complete, the insertion catheter is detached and withdrawn with the endoscope. One of the appeals of the BIB is the ability to vary balloon volume depending on stomach size and clinical response. Balloon deflation is accomplished by puncturing the balloon with a needle and simply removing it with a foreign-body graspers. The device can generally be placed with moderate sedation, though it is generally recommended that balloon removal be performed under general anesthesia.[45] The BIB is designed to be kept in the stomach for up to 6 months, after which time there is an increased risk of spontaneous deflation and resultant bowel obstruction.

Complications of the BIB are similar, but less frequent, than with earlier-generation balloons and include intolerance to the balloon (resulting in early removal), gastric ulcers, gastric erosions, esophagitis, spontaneous deflation, persistent vomiting, gastroesophageal reflux, and abdominal pain. There have been reports of several gastric perforations, small bowel obstructions, and significant gastric dilatation. To potentially minimize the risk of small bowel obstruction, methylene blue can be used with saline during balloon instillation. If methylene blue is systemically absorbed, it will turn the patient's urine green, thus alerting the patient and clinician to potential early balloon deflation. However, propofol is also known to turn the urine green, and the clinician must be aware of the potential for this "false positive" marker of balloon deflation.[46]

Over the past decade, there has been considerable international experience and a growing amount of data with the BIB, but the device is not approved for use in the United States. The BIB has been widely used since 1995 in well over 20 countries worldwide, particularly in Europe, South America, and Asia. Several large retrospective and prospective studies have reported significant efficacy in short-term weight loss when the balloon is used in conjunction with a low-calorie diet. In addition, there is a growing amount of sham data available. A Brazilian multicenter, prospective trial of 483 overweight and obese patients showed an EWL of 48.3% at 6 months.[47] Only 85 of the patients were followed up to 12 months, but all of these patients maintained more than 90% of the initial weight loss observed at their 6-month follow-up, and many continued to lose weight. At a 2-year follow-up, only 17 patients remained in the study program, but they maintained 89% of their initial EWL. All patients in that study were treated in conjunction with a multidisciplinary program involving clinical, psychiatric, exercise, and dietary therapy.[47] The most significant side

effects in the study were nausea and vomiting (39.9%) for the first 3 days after balloon placement, and all of the patients were admitted to the hospital and treated with proton pump inhibitors. Other minor complications included abdominal pain (20.1%) and dehydration (4.6%), but intolerance leading to early removal of the balloon was relatively rare, occurring in only 3.4% of the study population. Major complications were infrequent and included balloon impaction in the antrum with gastric hyperdistention requiring removal of device under general anesthesia (0.6%) and spontaneous deflation leading to small bowel obstruction (0.3%). There was no mortality in their study. Separately, an Italian study of 2,515 patients showed that the BIB was effective in decreasing obesity-related comorbidities, including diabetes.[48] Neither of these studies were controlled.

A recent meta-analysis provided the most comprehensive review of the available data on BIB.[49] The study evaluated 15 studies to estimate the effectiveness of the BIB and included 3,608 patients. The results were heterogeneous. The estimates for weight loss at the time of balloon removal (usually at 6 months) were 14.7 kg (12.2%) of initial weight loss, 32.1% EWL, and a decrease in BMI of 5.7 kg/m². Only 2 studies included in the meta-analysis provided longer follow-up had regarding weight loss maintenance, for a total of 143 patients.[50,51] These patients had regained 39.6% of their initial weight loss at the time their balloons were removed.

Two RCTs that included a total of 75 patients (sham-designed studies similar to those which led to the demise of the GEGB) were included in the meta-analysis and were used to gauge efficacy.[50,52] These studies showed that patients who received the BIB lost 6.7 kg (1.5%) of their initial weight, 17.6% EWL, with a decrease in BMI of 3.2 kg/m² more than those patients receiving sham balloons. While these data fall far short of the established weight loss of gastric bypass surgery, they also suggest greater efficacy than the pharmacologic therapies for weight loss currently approved by the US Food and Drug Administration, such as sibutamine and ordistat, and conventional therapy.[52]

In the meta-analysis conducted by Imaz et al[49] 4.2% of patients underwent early removal of the balloons. Similar to other studies, nausea and vomiting were the most frequent complications, and serious complications such as bowel obstruction and gastric perforation were uncommon, occurring in 0.8% and 0.1% of patients, respectively.[49]

Preoperative Use of the Balloon

Preoperative placement of the BIB results in a decreased risk of bariatric surgery and other elective surgeries in obese patients.[54,55] In super-obese patients (BMI ≥50 kg/m²), even a partial weight loss improves the risk of complications from bariatric surgery. This is thought to result from a reduction of visceral fat, which makes laparoscopic approaches easier and decreases the rate of conversion to open procedures and the need for 2-stage surgeries.[55,56] In addition, the weight loss produced by the BIB results in improved metabolic indices such as plasma antioxidant capacity in morbidly obese patients.[57] Such antioxidants are known to reduce the inflammatory process associated with obesity.

The BIB may serve as a segue to reconsideration of bariatric surgery in patients who initially considered surgery but refused. Melissas et al[58] commented that such patients had a greater understanding of the potential benefits of weight loss interventions after having an intragastric balloon placed. As a result, many such patients reconsidered bariatric surgery.[58]

Another reasonable approach is to use the device as a "balloon test," so to speak. In patients who had good results with a multidisciplinary weight loss program in combination with balloon therapy, surgeons often proceed with restrictive surgeries such as LAGB, whereas in patients who responded suboptimally to BIB placement, it may be reasonable to proceed with malabsorptive procedures such as RYGB or biliopancreatic diversion.[59]

Conclusion

Intragastric balloon therapy may be the best option left for patients unresponsive to conventional therapy who are either not candidates for surgery or who do not wish to undergo surgery immediately. On the other hand, a significant number of patients may not respond to the device. Patients who do not comply with conventional therapy and binge eaters are unlikely to respond to balloon placement. In addition, the risks of intolerance and complications of the procedure must be explained in detail to patients.

According to a recent meta-analysis, the BIB produced removal and a 32.1% EWL. A weight loss of 10% is associated with a decrease in the majority of obesity-associated comorbidities.[60]

The BIB is an effective and safe component of a comprehensive weight loss management program. Large prospective, sham-controlled trials with longer follow-up periods are needed to clarify its ability to maintain weight loss over time. However, delaying the introduction of the balloon into the US market while we await such data might not be prudent. The device is as safe as current surgical interventions and could be used now in the United States as it is in other countries. Either as a bridge to restrictive bariatric surgery, as part of a preoperative evaluation to determine which bariatric procedure might benefit patients most, or as a component of a multifaceted

weight loss program, the device is being used successfully in several different capacities.

Recently, the Centers for Medicare and Medicaid Services issued guidelines stating that Medicare will not cover bariatric surgery for beneficiaries with BMI <35 kg/m² with type 2 diabetes.[61] This is a large patient population who will not be offered gastric bypass surgery. These patients should be offered adjunctive therapies to diet and lifestyle changes. To be sure, all of these patients cannot be treated with evolving experimental endoscopic approaches as part of clinical trials at major academic medical centers. A need clearly exists for an endoscopic approach that is reasonably quick, safe, effective, and able to be performed with moderate sedation by practicing gastroenterologists in the community. Introduction of the balloon into the US market would allow practicing gastroenterologists to play an integral role in the primary treatment of obesity.

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