Communication from the ASGE Technology Committee

STATUS EVALUATION REPORT

Endoscopic bariatric therapies

The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, performing a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. This Technology Status Evaluation Report is drafted by 1 comember of the ASGE Technology Committee and the Bariatric Endoscopy Task Force (B.K.A.D.). It was reviewed and edited by the entire ASGE Bariatric Endoscopy Task Force and the Chair of the ASGE Technology Committee and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided.

For this review, the MEDLINE database was searched through December 2014 for relevant articles by using the key words "bariatric," "endoscopic," "intragastric balloon," "bypass sleeve," "gastroplasty," and "aspiration therapy."

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BACKGROUND

More than one-third of U.S. adults are obese.[1] The increasing prevalence of obesity in the United States has been accompanied by an increasing prevalence in its associated comorbid conditions including hypertension, diabetes, dyslipidemia, coronary heart disease, stroke, sleep apnea, osteoarthritis, gallbladder disease, GERD, nonalcoholic fatty liver disease (NAFLD), and cancer. Obesity is associated with an increased risk of all-cause and cardiovascular mortality and accounts for about 2.5 million preventable deaths annually.[2] The economic consequences of obesity are enormous, and projected increases may threaten the integrity of our health care system. Recent analyses estimate that 147 to 210 billion dollars are spent annually to treat obesity-attributable medical problems in the United States, accounting for about 21% of health care expenditures.[3,4]

Current approaches to therapeutic weight loss include lifestyle modification, pharmacotherapy, and bariatric surgery. Intensive lifestyle modification is associated with only modest weight loss.[5-7] The available pharmacological approaches for the treatment of obesity increase weight loss by 3% to 9% compared with lifestyle therapy alone, but are associated with unfavorable side effects.[8] Weight loss achieved by lifestyle modification or pharmacological approaches is rarely maintained as both interventions are subject to significant weight recidivism.[9] Bariatric surgery remains the most effective and durable treatment option for obese patients. Available procedures include laparoscopic and open Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy, adjustable gastric band, vertical banded gastroplasty, duodenal switch, and biliopancreatic diversion. Despite its proven efficacy, it is estimated that less than 1% of obese subjects who qualify for bariatric surgery will undergo this intervention.[10] The explanation for this is likely multifactorial, including high surgical costs, patient preference, access to care, and the morbidity and mortality associated with surgical interventions. Although mortality rates associated with bariatric surgery have decreased significantly and are now comparable to those of cholecystectomy or appendectomy in bariatric centers with high surgical volumes, early and late rates of adverse events associated with bariatric surgery remain problematically high at 17%.[11]

There is consequently a need for less-invasive weight loss interventions to bridge the current gap in our management approach to obesity and also to improve access. Our understanding of the mechanisms by which bariatric surgery works has evolved from the initially narrow view that weight loss was largely related to mechanical restriction and malabsorption. It is now evident that anatomic surgical manipulations of the GI tract also result

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in physiological alterations in gut neuroendocrine signaling, GI motility, autonomic nervous system signaling, bile acid production and absorption, and gut microbiota, all of which contribute to weight loss and to improvement in diabetes.[12,13] Emerging endoscopic technologies can reproduce some of the anatomic alterations created during bariatric surgery and are proving to be effective treatments for obesity in selected patients. They additionally offer the potential advantages of reduced invasiveness, reversibility, repeatability, and cost-effectiveness. These advantages may allow endoscopic procedures to be applied to a larger segment of the population with moderate obesity.

This review focuses on endoscopic bariatric therapies (EBTs) that are in clinical practice or in advanced stages of development and regulatory approval. Of note, however, at the time of this review, none of the EBTs discussed are as yet approved for use in the United States for bariatric indications. In discussing EBTs, it is helpful to separate them into gastric and small-bowel endoscopic interventions.

TECHNOLOGY UNDER REVIEW

Gastric interventions

Gastric restriction is an important component of surgical weight loss procedures (Table 1). This is accomplished through the creation of a small gastric pouch in RYGB surgery, through placement of an adjustable gastric band, or through the creation of a sleeve in sleeve gastrectomy surgery. In addition to inducing early satiety, it is thought that reducing the gastric reservoir capacity increases the stimulation of gastric mechanical and chemical receptors, alters gastric emptying, and modulates the level of gastric orexigenic hormones, which further contribute to weight loss.[14-16] Several EBTs attempt to mimic these mechanisms by decreasing effective gastric capacity. These technologies include space-occupying devices and those that alter gastric anatomy. Space-occupying devices most commonly take the form of temporarily placed prostheses such as balloons. EBTs that alter gastric anatomy use endoscopic suturing or plication devices.

Intragastric balloons. Endoscopically placed intragastric balloons (IGBs) for the treatment of obesity were first introduced to the U.S. market in 1985 with the Garren-Edwards Gastric Bubble (GEGB). The GEGB was associated with multiple adverse events including gastric mucosal damage and small-bowel obstruction related to spontaneous balloon deflation with migration into the small bowel. This necessitated endoscopic or, more commonly, surgical retrieval of the migrated balloons. In addition, the GEGB failed to demonstrate efficacy in a prospective, double-blind, sham-controlled, randomized trial of 59 obese patients with a 9-month follow-up period.[17] These issues resulted in its withdrawal from the U.S. market. In the early 1990s, the BioEnterics Intragastric Balloon (BIB) (Allergan, Irvine, Calif), currently known as the Orbera Intragastric Balloon (Apollo Endosurgery, Austin, Tex), was developed. The Orbera is an elastic spherical balloon made of silicone, filled with 450 to 700 mL of saline solution. The deflated balloon comes preloaded on a catheter, which is blindly advanced transorally into the stomach. An endoscope is then advanced alongside it to ensure accurate placement of the balloon in the fundus. Under direct visualization, the balloon is then inflated by injecting saline solution mixed with methylene blue through the external portion of the catheter. If inadvertent balloon rupture occurs, the methylene blue is systemically absorbed, causing a change in urine color, which serves as an alert that the balloon has deflated. The Orbera balloon is currently used in many countries outside the United States and is typically implanted for 6 months and then retrieved endoscopically.

Newer IGBs with different migration-hindering and deployment/retrieval mechanisms and some that allow for endoscopic balloon volume adjustments are now available. The ReShape Duo (ReShape Medical, San Clemente, Calif) is an endoscopically inserted and retrieved, saline-solution filled, dual intragastric balloon system with 2 balloons attached to each other by a flexible tube. Each balloon has independent channels so that unintentional leaks or deflation in 1 balloon does not affect the other balloon. The ReShape Duo is filled with 900 mL of saline solution with methylene blue by a power pump delivering 450 mL to each balloon. The manufacturer recommends that the balloon be removed endoscopically after 6 months.

Other IGBs with unique design features have been developed. The Spatz Adjustable Balloon System (Spatz Medical, Great Neck, NY) is an endoscopically placed IGB that is filled with saline solution. It has an extractable inflation tube that allows for volume adjustment while the IGB remains in the stomach. The balloon volume may be decreased to improve patient tolerance or increased to enhance efficacy. Outside the United States, the Spatz balloon is approved for 12-month implantation.

The Obalon Gastric Balloon (Obalon Therapeutics Inc, Carlsbad, Calif) is packaged within a large gelatin capsule. The balloon contains a self-sealing valve connected to a thin catheter. The capsule with the balloon is ingested, while the catheter extends from the stomach through the esophagus and the mouth. Fluoroscopy is used to verify that the capsule has entered the stomach. The gelatin dissolves, freeing the balloon. The catheter is then used to inflate the balloon by using a gas-filled canister. After balloon inflation, the catheter is detached and removed. Up to 3 balloons can be swallowed during the same or sequential sessions, and balloons are removed endoscopically after 12 to 26 weeks.

The Elipse balloon (Allurion Technologies, Wellesley, Mass) is enclosed inside a capsule and is attached to a thin, flexible catheter long enough to remain outside the