

ASGE position statement on endoscopic bariatric therapies in clinical practice

Prepared by: ASGE BARIATRIC ENDOSCOPY TASK FORCE

Shelby Sullivan, MD,¹ Nitin Kumar, MD,² Steven A. Edmundowicz, MD, FASGE,¹ Barham K. Abu Dayyeh,³ Sreenivasa S. Jonnalagadda, MD, FASGE,⁴ Michael Larsen, MD,⁵ Christopher C. Thompson, MD, MSc, FASGE²

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The American Society for Gastrointestinal Endoscopy (ASGE), as well as a number of federal agencies and medical societies, recognizes obesity as a disease requiring primary therapy.¹ In 2011, the ASGE and the American Society for Metabolic and Bariatric Surgery (ASMBS) jointly published a white paper with the intent of providing a pathway for bringing endoscopic bariatric therapy (EBT) to clinical practice and Preservation and Incorporation of Valuable Endoscopic Innovations thresholds for safety and efficacy.² As multiple EBTs are on the verge of being approved for clinical use, this position statement addresses the ASGE position on the role of the endoscopist in the primary treatment and bridge treatment of obesity with EBT.

The prevalence of obesity (body mass index [BMI] of ≥ 30 kg/m²) in adults in the United States remains high at 35%.³ Although the total number of U.S. adults with a BMI of ≥ 30 kg/m² has remained stable since 2003, the prevalence of adults with a BMI >40 kg/m² increased 70% between 2000 and 2010.⁴ This is of particular concern due to the positive correlation between increasing BMI above >30 kg/m² with rates of obesity-related comorbidities and mortality.⁵⁻⁷ The estimated cost associated with treating obesity and directly attributable

diseases ranges from \$147 billion to \$210 billion, which accounts for up to 21% of U.S. health expenditures.^{8,9} However, weight loss can lead to improvements in obesity-related morbidity and mortality, with a positive correlation between the amount of weight loss and improvement in obesity-related disease.¹⁰⁻¹³

Current treatment options for patients with obesity include lifestyle intervention, obesity pharmacotherapy, and bariatric surgery. The components of lifestyle intervention include diet, exercise, and behavior modification and should be considered the cornerstone of any obesity treatment.¹⁴ However, as a stand-alone therapy, even intensive lifestyle intervention is only modestly effective, with 5% to 10% total body weight loss at 1 year.¹⁵⁻¹⁷ Weight regain occurs after 1 year, but some health benefits do persist.^{16,18-20} Medications currently approved for long-term treatment of obesity include orlistat (Xenical/Alli; GlaxoSmithKline, Research Triangle Park, NC), lorcaserin (Belviq; Eisai, Woodcliff Lake, NJ), phentermine/topiramate combination (Qsymia; VIVUS, Mountain View, Calif), naltrexone/bupropion combination (Contrave; Takeda Pharmaceutical, La Jolla, Calif), and liraglutide (Saxenda; Novo Nordisk, Plainsboro Township, NJ). Weight loss medications in combination with moderate intensity lifestyle intervention yields 4.5% to 11% total body weight loss (TBWL).^{10,21,22} Side effects do occur, but weight loss medications are generally well tolerated.^{10,21,22} Guidelines on the pharmacological management of obesity by the Endocrine Society were published in January 2015.²³ With the exception of orlistat, the obesity drugs approved for long-term use have only recently been approved by the U.S. Food and Drug Administration (FDA), and data on weight loss maintenance beyond 2 years of therapy are not yet available. The common bariatric surgeries performed in the United States include Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, and sleeve gastrectomy with 1-year percent excess weight loss (amount of weight loss/[patient's initial weight-ideal body weight] $\times 100$)² of 62% to 74%, 33% to 34%, and 51% to 70%, respectively, as demonstrated in a recent meta-analysis.²⁴ Randomized, controlled trials of

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; ASMBS, American Society for Metabolic and Bariatric Surgery; BMI, body mass index; EBT, endoscopic bariatric therapy; FDA, U.S. Food and Drug Administration; TOS, The Obesity Society.

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Current affiliations: Division of Gastroenterology, Washington University School of Medicine, St. Louis, Missouri (1), Division of Gastroenterology, Brigham and Women's Hospital, Boston, Massachusetts (2); Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, Minnesota (3); Division of Gastroenterology, Saint Luke's Health System, Kansas City, Missouri (4), Division of Gastroenterology and Hepatology, Virginia Mason Medical Center, Seattle, Washington (5), USA.

bariatric surgery consistently demonstrate superiority of bariatric surgery over lifestyle intervention for treatment of obesity and obesity-related comorbidities.²⁵⁻²⁸ Overall, bariatric surgery has low perioperative and postoperative mortality rates (0.08% and 0.31%, respectively); however, the adverse event rate is 10% to 17%, and the reoperation rate is 6% to 7%.²⁴ These rates may contribute to the low use of bariatric surgery for the treatment of obesity.²⁹ Other barriers to bariatric surgery include cost when the procedure is not covered by insurers, access to bariatric surgeons, acceptance of primary care physicians who refer to a bariatric surgeon, and reversibility.

EBT is an adjunctive therapy that fills an important gap in the current obesity treatment options described previously. Multiple devices and procedures are currently being evaluated for clinical use or are currently in clinical use. The recently published ASGE Status Evaluation Report on EBT reviews data that demonstrate the superiority of EBT over lifestyle intervention in randomized, controlled trials and lower observed adverse event rates than reported in the recent meta-analysis cited previously.^{24,30} EBT may also be more effective than obesity medications.³¹ Compared with bariatric surgery, patients and referring physicians may find the reversibility of some EBTs, the larger number of potential providers, and lower BMI threshold indications attractive. The position of the ASGE is that EBTs that have been approved by the FDA and meet thresholds of efficacy and safety as defined in the ASGE/ASMBS Preservation and Incorporation of Valuable Endoscopic Innovations² should be included in the obesity treatment algorithm as adjunctive therapies to a lifestyle intervention program as outlined in the 2013 American Heart Association(AHA)/American College of Cardiology(ACC)/The Obesity Society (TOS) guidelines for the management of overweight and obesity in adults.¹⁴ EBT should be considered for patients with:

- Failed weight loss or weight maintenance with lifestyle intervention alone, unless medical conditions exist that require earlier addition of adjunctive therapy
- BMI criteria for primary EBT (this may vary with individual EBTs)
- Medical conditions that require weight loss for additional therapy but may exceed BMI criteria for primary EBT (bridge therapy)

PROGRAM COMPONENTS

The program components for successful management of obesity by using EBT as an adjunctive tool to enhance weight loss with lifestyle intervention described in the following require a multidisciplinary approach. However, this can be delivered either through a center with all personnel practicing within the center or through referral networks outside of the endoscopist's office.

Preprocedure evaluation

Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of bariatric patients undergoing bariatric surgery were updated in 2013 by the American Association of Clinical Endocrinologists, TOS, and ASMBS.¹¹ Although these guidelines are thorough and appropriate for patients undergoing bariatric surgical procedures, it is not clear whether all EBTs will require all components of the preoperative bariatric surgery assessment. Moreover, patients who may not be operative candidates due to significant comorbidities may still be candidates for a lower-risk EBT. At a minimum, all patients should be evaluated for medical history (including previous weight loss attempts), physical examination, screening for obesity-related diseases, and commitment to lifestyle change. Patients should undergo a nutrition assessment that should include a diet history, assessment of eating patterns, and education for postprocedure diet by a registered dietitian or physician trained in obesity medicine. Obtaining routine laboratory test results including complete blood count, fasting blood glucose, lipid panel, kidney function, liver profile, urinalysis, prothrombin time/international normalized ratio, and nutritional screening including 25-hydroxy vitamin D, iron panel, vitamin B₁₂, and folic acid should be considered with each EBT, as is done before bariatric surgery, until further data are available.¹¹

Many EBT pivotal trials did not include a psychological evaluation by a psychiatric professional, but patients with eating disorders, uncontrolled psychiatric illness, and substance abuse were excluded from these studies based on a review of history and screening tools (questionnaires or interviews by personnel such as dietitians and research coordinators trained to perform the evaluations). The FDA may not require a psychiatric evaluation by a psychiatric professional for these EBTs; however, given the unknown effects of EBT on uncontrolled psychiatric illness, eating disorders, and substance abuse, a psychosocial behavioral evaluation by a psychiatrist, psychologist, or other independently licensed provider with training in the care of patients undergoing obesity treatment may be considered for some patients in whom risk factors for these diseases are identified.^{11,12} Other evaluations including endocrine evaluations, additional cardiopulmonary evaluations, or a sleep study may be considered if risk factors for cardiovascular disease, pulmonary disease, or obstructive sleep apnea are identified in the preprocedure evaluation that may increase the risk of endoscopy.

Postprocedure follow-up

Physician/physician extender (physician assistant or nurse practitioner) follow-up will vary with the EBT as it varies with surgery in the 2013 American Association of Clinical Endocrinologists/TOS/ASMBS bariatric surgery guidelines.¹¹ Follow-up laboratory evaluation and micronutrient supplementation will vary significantly among

procedures as well, given the differences in EBT mechanism of action and effects on micronutrient consumption, absorption, or loss in the GI tract. Further recommendations for postprocedure physician and laboratory follow-up will need to be tailored to the individual therapies.

Lifestyle intervention

Lifestyle intervention comprises diet therapy, exercise therapy, and behavior modification for weight loss and weight maintenance. Use of the AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults for lifestyle intervention in patients who undergo EBT is recommended. Diet therapy to reduce calorie intake can be prescribed by a registered dietitian or physician. Several strategies can be used to reduce calorie intake: reduction of 500 to 750 kcal/day or 30% energy deficit¹⁴ from current intake, prescribing 1200 to 1500 kcal/day for women and 1500 to 1800 kcal/day for men,¹³ or prescribing an evidence-based diet that restricts certain food types. Multiple macronutrient combinations have been shown to be effective for weight loss.³²⁻³⁷ For some EBTs, calorie intake may be reduced further, in a range closer to bariatric surgery patients, due to the mechanism of action of the EBT or to ensure postprocedure healing. Initial calorie intake in the first 3 months after Roux-en-Y gastric bypass ranges from 500 to 970 kcal/day, increasing to 870 to 1420 kcal/day at 1 year,³⁸⁻⁴¹ and caloric intake at 1 year correlates with weight loss.³⁸

Exercise should also be prescribed as part of lifestyle intervention. Exercise improves cardiorespiratory fitness,⁴² enhances weight loss,^{43,44} preserves lean muscle tissue during weight loss,⁴⁵ and is an important tool for weight maintenance.^{46,47} The 2013 AHA/ACC/TOS Guideline recommends ≥ 150 minutes per week of moderate-intensity exercise for weight loss and 200 to 300 minutes per week of moderate-intensity exercise for weight maintenance.¹⁴ This can be prescribed by an exercise professional or a physician or physician extender.

Behavior modification is the third component of lifestyle intervention. It aims to provide a goal-directed, process-oriented therapy that advocates small changes to modify habits that prevent weight loss.⁴⁸ The components of behavior modification include self-monitoring, stimulus control, slowing the rate of eating, social support, cognitive restructuring, problem solving, and relapse prevention.⁴⁹ These topics are covered during lifestyle intervention sessions and can be intermixed with diet and exercise education sessions. The behavior modification sessions can be delivered by a physician or physician extender with specialty obesity medicine training, a registered dietitian, a psychologist, or a trained behavior coach.

Multiple options exist for the delivery of the lifestyle intervention. Most randomized, controlled trials of EBT compared with lifestyle intervention alone have used

moderate-intensity lifestyle intervention,⁵⁰⁻⁵² defined as 6 to 13 sessions in 6 months.¹⁴ Until other regimens are studied, lifestyle intervention for patients undergoing EBT should be performed with at least the same frequency as in the trials used for FDA approval and with therapy continued for a full year. Flexibility exists with delivering these sessions. Face-to-face sessions are the preferred method of follow-up. Telephone follow-up with higher frequency may be as effective as face-to-face sessions,⁵³ but Internet-based therapy has not proved as successful.⁵⁴ Sessions can be conducted with individual patients, with groups of patients, or a combination of both with equivalent efficacy.^{55,56}

The ASGE recognizes the challenges of maintaining weight loss and that obesity management requires long-term treatment of the patient. Therefore, it is advisable that endoscopists performing EBT have a mechanism to enroll patients in long-term follow-up care for weight loss maintenance. Although further research on the components of weight maintenance is needed as outlined by the National Institutes of Health working group on maintenance of weight loss,⁵⁷ programs should use a multidisciplinary approach including lifestyle intervention, pharmacotherapy, EBT, and surgery to help patients successfully maintain weight loss. As with the initial weight loss therapy, this approach can be achieved either with personnel working within a center or through referral networks outside the endoscopist's office.

PHYSICIAN TRAINING AND CERTIFICATION

The ASGE understands that some EBTs are extensions of current endoscopic skills but also may require specific and detailed training to incorporate into a bariatric program and to perform competently. It is the ASGE's intention to offer comprehensive training to endoscopists who seek to perform endoscopic bariatric procedures.

Eligibility

Eligible physicians will have completed an accredited gastroenterology fellowship⁵⁸ or general surgery residency,⁵⁹ will have demonstrated competency in upper endoscopy and endoscopic hemostasis, and have privileges to perform GI endoscopy in a hospital or endoscopy center, as outlined previously by the ASGE.^{60,61} Before initiating a program in EBT, physicians should also obtain obesity treatment education as described in the following.

Obesity treatment education

To perform EBT in practice, physicians should be competent to determine the appropriateness of adjunctive bariatric therapy for the patient and which adjunctive therapy best suits the patient's needs, whether pharmacologic, endoscopic, or surgical, as outlined in the joint ASGE/

ASMBS white paper on EBT.² Physicians should have comprehensive knowledge of the indications, known outcomes, risks, benefits, and contraindications for these therapies.

Procedural education and training

The method and types of education will vary between procedure types, FDA requirements, and industry sponsor requirements. The ASGE previously developed guidance for training and demonstrating competence with new technology.⁶² Using new technology that involves a high level of complexity, interpretative ability, and/or new type of technology (eg, EUS) is defined as a “major skill” and will require a preceptorship or other vehicle of formal instruction to become competent. Using new technology that is a minor extension of an accepted and widely available technique or procedure is defined as a “minor skill” and may only require short courses of didactic and hands-on training to attain competency. The technical complexity of individual EBT and invasiveness of the procedure will determine whether the EBT requires the development of a major or a minor skill.

Credentialing

The principles for credentialing and granting privileges in endoscopic procedures were previously reviewed by the ASGE.⁶⁰ EBT that requires the development of a major skill will likely also require additional credentialing and granting privileges. EBT that requires the development of minor skills may not require additional granting of privileges but may still require a certificate of achievement of competence and training from the manufacturer or an educational program. Maintenance of credentialing and privileges or certification of competence should follow previously published ASGE guidelines on the renewal of and proctoring for endoscopic privileges.⁶³

PROGRAM RECOGNITION

Patients with obesity with or without comorbidities are best managed with a multidisciplinary approach that will address all aspects of the patient’s long-term weight management care and potential adverse events. EBTs need to be recognized as one potential component of a complex treatment program for patients with obesity. This will require endoscopists involved in EBT to be part of a multidisciplinary program able to provide lifestyle therapy, pharmacotherapy, or surgery in addition to EBT or have referral networks to facilitate a multidisciplinary approach for obesity treatment as outlined in the program components section. Each unit performing EBT should employ or coordinate care in a referral network with at least one physician qualified to provide comprehensive care to patients with obesity. Coverage should be available at all times by a

physician capable of emergency care of patients who have undergone endoscopic bariatric procedures.

Endoscopy facility and office requirements

Equipment should be appropriate for patient weight and size, including examination tables, procedure tables, blood pressure cuffs, sequential compression sleeves, gowns, wheelchairs, and walkers. Facility design should be appropriate for patient weight and size, including doorways, chairs, scales, and toilets.

Procedural safety guidelines should account for risks specifically encountered in obese patients. Personnel trained in advanced cardiovascular life support and airway management support should be available during procedures and recovery. Other general safety guidelines should comply with the previously published documents on safety, quality indicators, and competency in endoscopy.⁶⁴⁻⁶⁶ As EBT comes into clinical practice, quality metrics with benchmarks will need to be created and incorporated into quality assurance and improvement programs. The process for creating these metrics and programs will need to be inclusive of all stakeholders, with ASGE maintaining a prominent leadership role.

EBT REGISTRY

The ASGE supports the establishment of registries for EBT either by medical societies with an interest in EBT, industry, or the federal government. Accurate reporting to and regular analysis of a registry is essential to demonstrate the benefit of EBT in the clinical setting. Moreover, registries will allow for a more uniform quality analysis for a recognition program. All data regarding patient demographic characteristics, EBT performed, lifestyle therapy program provided, other adjunctive therapies prescribed, outcomes, and follow-up results should be recorded by trained staff. This staff should have full access to patient records and the ability to contact patients directly as well as the ability to respond to requests regarding incomplete or incorrect data.

CONCLUSION

The development and approval of effective and safe EBTs provide another adjunctive therapy for patients with obesity who are unable to manage the disease with lifestyle intervention alone. Obesity is a complex disorder that should be approached with the proper knowledge of the disease process and management options to improve successful treatment. Therapeutic expertise gained through appropriate training in EBT is important for endoscopists who offer it in their practice; however, the maximum benefit of EBT for obesity is only fully realized in a comprehensive weight management treatment

plan. It is incumbent upon digestive disease specialists who provide EBT in their clinical practice to become educated in the treatment of this complex disease and incorporate a multidisciplinary approach to treatment in their practice.

DISCLOSURE

Dr Edmundowicz, Consultant (consulting fees), Advisory Board Member, Boston Scientific; Consultant (consulting fees), Advisory Board Member, Olympus; Stockholder, Medical Advisory Board Member, SynerZ Medical; Consultant (consulting fees), Research Advisory Committee Member, GI Dynamics; Consultant (consulting fees), Advisory Board Member, Fractyl; Consultant (Stock/Ownership interest), Beacon Endoscopic (now acquired by Medtronic); Contracted Research, site principle investigator or co-investigator; Aspire Bariatrics (Institutional Research Grant), US GI (Institutional Research Grant), ReShape Medical (Institutional Research Grant), Obalon (Institutional Research Grant), Baranova (Institutional Research Grant), GI Dynamics (Institutional Research Grant). Dr Sullivan, Consultant: USGI Medical, EnteroMedics, Obalon; Contracted Research through Institution (Site Principle Investigator or Co-Investigator), Aspire Bariatrics, USGI Medical, ReShape Medical, Obalon, BARONova, and GI Dynamics. Dr Kumar, Contracted Research through Institution (Site Principle Investigator or Co-Investigator), Aspire Bariatrics, Apollo Endosurgery, USGI Medical. Dr Abu Dayyeh, Consultant, Apollo Endosurgery and Metamodix; Contracted Research through Institution (Site Principle Investigator or Co-Investigator), Aspire Bariatrics, Apollo Endosurgery, and GI Dynamics. Dr Larsen, Contracted Research through Institution (Site Principle Investigator or Co-Investigator), Obalon. Dr Thompson, Owner Interest: GI Windows; Consultant: Olympus, Apollo Endosurgery, USGI Medical, Covidien, and GI Windows; Contracted Research through Institution (Site Principle Investigator or Co-Investigator), Olympus, Apollo Endosurgery, Aspire Bariatrics, and USGI Medical. Dr Jonnalagadda, Contracted Research through Institution (Site Principle Investigator or Co-Investigator), USGI Medical and Obalon. All other authors disclosed no financial relationships relevant to this publication.

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