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POSITION STATEMENT

ASGE position statement on endoscopic bariatric therapies in clinical practice

Prepared by: ASGE BARIATRIC ENDOSCOPY TASK FORCE

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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 $\geq$30 kg/m^2) in adults in the United States remains high at 35%.[3] Although the total number of U.S. adults with a BMI of $\geq$30 kg/m^2 has remained stable since 2003, the prevalence of adults with a BMI >40 kg/m^2 increased 70% between 2000 and 2010.[4] This is of particular concern due to the positive correlation between increasing BMI above >30 kg/m^2 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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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 Innovations[2] 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 B_{12}, 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