ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

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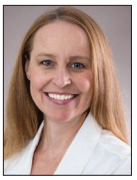
Riding the Wave of Rapid Innovation in Endobariatric Care



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G&H Where do endoscopists stand on securing fair reimbursement for endobariatric services?

SS As of August 15, 2025, Cigna is now covering endoscopic sleeve gastroplasty (ESG) in patients with obesity meeting certain criteria and in metabolic and bariatric programs that meet specific criteria. Although coverage is still somewhat limited, it is the first step, and it is a huge first step for endoscopists and other multidisciplinary physicians (gastroenterologists and surgeons) providing endoscopic bariatric and metabolic therapies (EBMTs), having an entire insurance plan nationally include ESG as part of their covered procedures. One of the drivers for this change in policy is why I moved to Dartmouth. Health institutions like Dartmouth have decided to invest in building metabolic and bariatric programs to be able to offer endoscopic procedures and then cover these procedures for their employees. It makes sense for Dartmouth and other institutions to cover EBMTs for their employees because there is significant cost savings with these procedures in comparison to weight loss medications.

G&H As the field matures, which EBMTs have been shown to be useful?

SS According to a joint guideline from the American Society for Gastrointestinal Endoscopy and the European Society for Gastrointestinal Endoscopy (ASGE/ESGE) published in 2024, EBMTs are given conditional recommendations based on the way grading is done. Although the intragastric balloons (IGBs), endoscopic gastric remodeling procedures, and duodenojejunal bypass liners met safety and efficacy criteria, grading includes patient preferences, costs, access, etc. The conditional recommendation is based on these additional grading questions, not on safety, efficacy, or cost-effectiveness. The endoscopic gastric remodeling procedures included in the analysis were the Apollo ESG System using the OverStitch device (Boston Scientific), the primary obesity surgery endoluminal incisionless operating platform (USGI Medical), and the Endomina device (EndoTools Therapeutics) for ESG. We used the term *endoscopic gastric remodeling* because this term includes different devices for both suturing and plication procedures. There will be a new Current Procedural Terminology (CPT) code available for use on January 1, 2026, for ESG. The Relative Value Unit of the CPT code for this procedure is currently being evaluated by the Centers for Medicare & Medicaid Services. The final determination is due to be released in November 2025.

G&H Which technologic innovations can be expected to further simplify and facilitate endobariatric interventions?

SS Devices in the pipeline include the automated suturing device EndoZip (Nitinotes Surgical), which has been studied in humans and is undergoing a randomized controlled trial in the United States, and the SimpleStitch suturing device (EnVision Endoscopy). There are currently no published data in humans on weight loss using the SimpleStitch device for an endoscopic gastric remodeling procedure, or ESG, but it has the same US Food and Drug Administration (FDA) 510(k) clearance for tissue apposition in the gastrointestinal (GI) tract. SimpleStitch is a pretty simple device to use and could be used for endoscopic gastric remodeling in the future. The advantage to EndoZip is that it is an automated suturing device, which can potentially make the procedure more uniform, decreasing the variability between different physicians performing the procedure. EndoZip utilizes a pediatric

upper endoscope, which is fed through the device itself. This enables the endoscopist to see the endoscope location and, once in position, remove the pediatric endoscope and apply suction to pull the opposing stomach walls together. The rest of the procedure is automated: a helical needle winds through the approximated tissue creating the suture, and then tightens the suture to a specific tension and cuts. Multiple sutures can be added by repeating this process. There are also multiple small bowel devices that are currently under evaluation, including the duodenaljejunal bypass liner (RESET, Morphic Medical) and the ablation therapies such as duodenal mucosal resurfacing (Revita, Fractyl Health), electroporation (RECET, Endogenex), and radiofrequency vapor ablation (Aqua Medical). The small bowel procedures have a whole other host of effects that are both weight loss dependent and weight loss independent. What this means is that sometimes, even in the absence of significant weight loss, profound improvements in glycemia and in liver fat content are still observed. Patients with metabolic dysfunction-associated steatotic liver disease can benefit from a small bowel procedure, even without significant weight loss.

An important consideration and something that insurers and patients are really asking for is whether EBMTs will be able to provide an off-ramp for weight loss medications. The REMAIN-1 trial (NCT06484114) is an ongoing study looking at the effects of duodenal mucosal resurfacing (DMR) with the Revita device in patients with obesity who lost weight on a glucagon-like peptide-1 receptor agonist (GLP-1 RA) to see whether the Revita procedure can maintain weight loss after GLP-1 therapy is discontinued. Early data from the open-label REVEAL-1 cohort of the trial are positive. The early data were available for only 13 patients enrolled in the study who had clinically lost at least 15% total body weight on GLP-1 therapy, which they discontinued at least 1 week prior to the DMR procedure. At 3 months post-procedure, this group of patients had a total body weight change of 0.46% (~1 lb), compared with the 5% to 6% of total body weight gain (10-15 lb) that was expected, as seen in prior clinical studies. Essentially, 12 of 13 patients maintained their weight loss, and some of them continued to lose weight. One patient regained the weight that all of them were expected to regain with coming off the medication. These early results demonstrate that patients can indeed come off GLP-1 therapy and maintain their weight loss. Weight regain is a big issue once patients discontinue GLP-1 therapy. In our practice, patients are told from the inception of obesity medicine that for any weight loss attained, in order to maintain that weight loss, they must continue taking the medication and to consider the medication to be long term, if not lifelong.

There is also the Allurion Balloon that has been approved for use in multiple countries, although not yet in the United States. This is considered a procedureless balloon because the patient swallows the balloon in a capsule and is awake for its deployment. Once the physician verifies that the balloon is in the stomach in the right position with either fluoroscopy or digital x-ray, the balloon is inflated with 550 mL of saline. The catheter is then detached, leaving the self-sealing balloon in place. At 4 months, the balloon self-deflates and passes naturally out of the GI tract. The Allurion Balloon is currently being evaluated in the AUDACITY trial (NCT05368259) in the United States and would be approved as a multi-balloon or sequential balloon therapy, as 2 balloons would be used in a year.

G&H Where does endoscopic management fit in the overall algorithm of obesity management?

SS Endoscopic procedures are for patients who meet body mass index criteria and are not able to lose or maintain weight loss through lifestyle therapy alone. Shared medical decision-making should be used with the patient to understand their goals, and the clinician can then guide the patient to the best therapy that meets those goals. The first consideration is whether or not a patient wants a removable device such as an IGB or a more permanent procedure like ESG. It is also important to know the goal weight loss for the patient. If a patient tells me they want to lose over 100 lb, I tell them they also need to see the bariatric surgery team for an information session before making a final treatment decision because an endoscopic procedure alone is less likely to achieve that level of weight loss. Next, it is important to know what other obesity therapies are being used by the patient. The gut and the brain are the most important body systems when it comes to managing obesity. The most effective medications currently available are gut hormones that have both central effects and peripheral effects in the GI tract. Endoscopic bariatric procedures not only have significant effects on the gut and gut physiology but also may have some effects on gut hormones. In particular, some data suggest that endoscopic gastric procedures have an effect on ghrelin and on gastric emptying. If a patient is already on a GLP-1 RA or GLP-1/glucose-dependent insulinotropic polypeptide RA, that can also cause delayed gastric emptying. The medication may have to be held for the period around the endoscopic procedure.

An algorithm of EBMTs can be divided into 2 categories, gastric devices and small bowel devices, but only gastric devices are currently available in the United States outside of study protocols. The gastric devices that are available are the endoscopic gastric remodeling procedures and IGBs. The excitement currently is Cigna's approval for coverage of ESG. It is assumed that Cigna

would cover the other endoscopic gastric remodeling procedures as well, but that remains to be seen. Patients who prefer a procedure that has more durable weight loss and are comfortable with permanent changes to the GI tract may want to consider ESG or other endoscopic gastric remodeling procedures. Patients who prefer a completely removable device may want to consider an IGB. IGB procedures are not covered by most insurance plans, but they are still performed at a high rate worldwide. Right now, only endoscopically placed and endoscopically removed balloons are available commercially. There is the FDA-approved swallowable Obalon Balloon, although its production has been halted owing to a change in company ownership that occurred during the COVID-19 pandemic, which hurt a lot of the EBMT companies.

G&H How do the various EBMTs compare on weight loss?

SS In general, weight loss with IGBs in the United States is between 10% to 15% depending on the balloon. Weight regain occurs with time, but unlike with medications where weight regain starts to occur right away, most patients are maintaining their weight loss 6 months after the balloon removal. In the Obalon Balloon study, 90% of the weight loss was maintained at 12 months. These patients could repeat the balloon therapy. This is especially helpful for patients who do not want to be on medications or want any changes to their GI tract. Some patients highly value not having any changes to their anatomy. There is, in general, less weight loss with IGB therapy than there is with endoscopic gastric remodeling procedures. In our ASGE/ESGE guideline document, meta-analysis of studies found 17.3% total weight loss at 1 year after an endoscopic remodeling procedure. Once any sutures or staples have been placed in the stomach from an endoscopic remodeling or surgical procedure, the patient cannot go backwards to a balloon. Other patients value greater weight loss and more durability very highly, so the type of procedure depends on what patients value. There are some patients who, even if they qualify for bariatric surgery, do not want bariatric surgery for a variety of reasons. It could be because of the time off work, the potential complications, or the restrictions that they go through. Although endoscopic procedures may not result in as much weight loss as bariatric surgery does, some people would still value the lower risk and the faster recovery with the endoscopic procedures over the surgical procedures. If somebody would have coverage for bariatric surgery, more often than not I refer them to bariatric surgery, so they can at least go to an information session. They can still come back to me for a procedure. First, it is important for patients to understand their options and the risks and benefits from each procedure.

G&H What are reasons for weight regain after an endoscopic technique, and how is it managed?

SS It is important to note that obesity is a chronic disease that is relapsing and remitting, and patients have certain triggers that may cause weight gain some of which are unrelated to patient behaviors. The same is true for patients who have had bariatric surgery or ESG. It is common to ask what caused treatment failure; however, this needs to be reframed as, how should recurrent weight gain after treatment be managed? There can be many reasons why weight regain happens.

The American Gastroenterological Association IGB guidelines have recommended several options for managing recurrent weight gain after IGB therapy. One option is to add medications. Multiple studies demonstrate that medications in combination with IGB prolong weight loss, maintain weight loss for a longer amount of time, and ultimately, the amount of weight loss achieved is actually higher than that attained with either the balloon or the medication alone. Studies have looked at adding weight loss medications in retrospective analyses for patients after endoscopic remodeling procedures. The weight loss medication is added either after waiting until the patient starts regaining weight or at 3 to 6 months after a procedure as part of a protocol, regardless of whether the patient has regained weight, to increase overall weight loss and maintain that weight loss for a longer period. Having these options reflects real-world practice. Again, some patients want to be off of medication—that is why they opt for these procedures—and some people highly value the most weight loss that they can get, so it depends on what each patient values.

Another option is to repeat ESG or balloon therapy. This is partially why the Allurion Balloon study is important because it is looking at getting FDA approval for repeated balloon therapy to manage weight long term. Any of the endoscopic gastric remodeling procedures can be redone. Studies looking at that have demonstrated significant weight loss. One retrospective analysis reported 16% total body weight loss after repeated ESG. Endoscopic revision of ESG can be performed to tighten up the stomach because the gut naturally stretches and remodels over time. After any endoscopic bariatric or surgical procedure, there is the potential for the affected area to become dilated. I tell patients that it is not their fault or the surgeon's fault; it is the normal process of intestinal remodeling. With any therapeutic strategy for obesity, even the best surgical procedures, there is a risk of recurrent weight gain that must be managed.

G&H What are rescue strategies in the event of insufficient or no weight loss?

SS After an endoscopic procedure, endoscopic gastric remodeling procedures can be repeated, but sometimes patients may decide to go straight to a surgical procedure such as a sleeve gastrectomy or Roux-en-Y gastric bypass. They could also start a weight loss medication, which has been shown to increase weight loss after a procedure. For an IGB, if the first balloon was not associated with weight loss, it is unlikely that a second balloon will result in weight loss, and another therapy should be considered.

G&H How does the advent of new weight loss drugs affect use of endoscopic treatments?

SS All of the weight loss medications have helped endoscopists in promoting treatment of obesity. Even though there is some competition between medications and endoscopic procedures, the media coverage of obesity medications has helped educate patients that there are effective treatments for obesity beyond bariatric surgery—although I am a supporter of bariatric surgery as well. The reality is that only 1% to 2% of patients who qualify for bariatric surgery actually get bariatric surgery on a year-to-year basis. Of patients who have coverage for it, many do not want to have surgery.

Medications have broadened the options, and what is important is that they have incentivized patients to learn about endoscopic therapies. Access to weight loss medications has made it easier to talk about obesity and obesity treatment options. As the topic of obesity has become more mainstream, the public is now aware of the need to have excess weight treated, and the stigma of obesity as a moral failing is being removed. It is socially acceptable to refer to obesity as a disease that needs to be treated. From an educational standpoint, this helps endoscopists because many patients do not know that endoscopic therapies for obesity exist. The lack of awareness compounded by the lack of widespread insurance coverage for the procedures makes it challenging for endoscopists who provide obesity care. However, EBMT may ultimately have an advantage over medications owing to their high cost. Cost-benefit analyses demonstrate that endoscopic therapies are more cost-effective than the weight loss medications, which is probably one of the reasons why Cigna has decided to cover the procedures, along with the fact that they provide a good outcome, which helps patients.

Overall, medications can help endoscopists with managing patients and help improve everyone's comfortability with treating obesity as a disease, like it should be.

G&H Should there be a broader comprehensive training in weight management beyond acquiring endoscopic skills?

SS The consensus is that there should be broader comprehensive training. Currently, endoscopists can take the ASGE STAR Bariatric Suturing Course that tests a physician's cognitive understanding of ESG as well as their skills. However, more intensive training that includes how to manage patients with obesity in the clinic (ie, how to use weight loss medications in combination, treat complications, and address patient diet and expectations) and many other aspects of obesity management such as lifestyle therapy, which is known to enhance these procedures, is needed. As insurance coverage improves and more programs have higher volumes, training centers will likely be transitioning into this format with more formal training in obesity medicine in conjunction with procedural training. The inclusion of EBMTs within the GIQuIC registry also will allow ease of data collection to capture outcomes and perform quality assurance and quality improvement that could assist in identifying benchmarks for training.

G&H What will drive further innovation in this field?

SS The most important factor for EBMTs that will push innovation is having a CPT code with a fair reasonable and customary charge. Once that is in place, having insurance plans cover endobariatric procedures will encourage more institutions and EBMT providers to offer and perform endobariatric procedures. The increased number of EBMT providers performing these procedures on patients who have coverage for them will allow industry to be able to develop more tools for endobariatric specialists to use because device manufacturers know there is a pathway to reimbursement.

Disclosures

Dr Sullivan has received research grants from Fractyl Health and Allurion Technologies and consulting fees from Allurion Technologies, Biolinq, Fractyl Health, Olympus, and Pentax.

Suggested Reading

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