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How to establish an endoscopic bariatric practice

Maselli DB *et al.* Establishing an endobariatric practice

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Abstract

² Obesity is a chronic, progressive, and relapsing disease of excess adiposity that contributes to more than two hundred medical conditions and is projected to affect more than half the adult population of the United States by the year 2030. Given the limited penetrance of traditional bariatric surgery and cost and adherence barriers to anti-obesity medications, there is growing interest in the rapidly evolving field of ¹ endoscopic bariatric therapies (EBTs). EBTs are minimally invasive, same-day, per-oral endoscopic procedures, including endoscopic sleeve gastropasty (ESG), intragastric balloons, and endoscopic bariatric revisional procedures. This field represents an exciting and innovative subspecialty within gastroenterology. However, establishing a successful endoscopic bariatric practice requires thoughtful, disciplined, and methodical effort to overcome the numerous obstacles to entry. Common barriers include technical and cognitive training, practice limitations including the availability of nutrition counseling, facility capabilities, direct-to-consumer marketing, and financial pressures such as facility and anesthesia fees. As the highest-volume center for metabolic and bariatric endoscopy in the United States, we provide insights into successfully establishing an endoscopic bariatric program.

Key Words: Obesity; Endoscopic bariatric therapies; Bariatric endoscopy; Endoscopic sleeve gastropasty; Intra gastric balloon; Practice management

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Core Tip: In this editorial, we review and break-down the key components of an endoscopic bariatric program including endoscopic training, cognitive training and obesity medicine certification, the practice model, equipment considerations, marketing, financial considerations, and program infrastructure.

INTRODUCTION

Obesity is a chronic, progressive, relapsing, and multifactorial disease^[1]. It is characterized by excess adiposity that leads to metabolic and mechanical dysfunction, driving over two hundred weight-related medical conditions^[2]. By 2030, nearly one in two adults in the United States will be affected by obesity, which underscores the pressing need for acceptable treatment options^[3]. Patients with obesity warrant multiple therapeutic options that can be tailored to their specific needs and risk tolerance. The therapeutic landscape is evolving but still faces certain challenges. Metabolic and bariatric surgery reaches 1%-2% of the eligible adult population in the United States, primarily due to concerns about invasiveness and risk^[4-6]. Incretin-based agents has revolutionized anti-obesity pharmacotherapy but has limitations of cost, tolerability, reliable access, and high probability of weight recurrence following discontinuation^[7-10].

Endoscopic bariatric therapies (EBTs) have emerged in the past decade as a viable alternative within the multidisciplinary approach to obesity management, particularly for those seeking a less invasive option than surgery^[11,12]. EBTs are minimally-invasive, same-day, per-oral procedures that facilitate clinically meaningful weight loss in adults with obesity. These include primary obesity therapies, including intragastric balloons (IGBs)^[13,14] and endoscopic sleeve gastroplasty (ESG)^[15,16], as well as revisional therapies for weight return after metabolic and bariatric surgery, such as transoral outlet reduction (TORe)^[17,18] and vertical sleeve gastrectomy revision (VSG-R)^[19] (Table 1). The commercially available EBTs have been thoroughly presented in recent reviews^[20,21]. Existing procedures target gastric restriction, acting through viscerosensitive pathways to enhance satiety and satiation to facilitate weight loss^[22-25]. The future of EBT will very likely additionally involve metabolically-oriented small bowel-targeted therapies^[26,27].

The metabolic and bariatric endoscopy field (or “endobariatrics”) represents an exciting and growing subspecialty of gastroenterology; however, thoughtful, disciplined, and methodical effort is required to build a successful endobariatric program while overcoming the frequent barriers that may arise (Table 2). As the highest-volume center

for metabolic and bariatric endoscopy in the United States, we provide insights into this endeavor.

MAIN BODY

The bariatric endoscopist

Nearly every aspect of the gastrointestinal tract has pathology directly or indirectly impacted by obesity^[28,29] and endobariatrics transforms the gastroenterologist from bystander to facilitator in improving those pathways. An appeal of EBT is the interplay between complex medical management and highly technical advanced endoscopic procedures. The bariatric endoscopist must be facile in both areas.

The endoscopic skillset centers on endoscopic suturing. Presently, this is conducted using the Overstitch Endoscopic Suturing System (Boston Scientific, Marlborough, MA, United States). For many gastroenterologists, endoscopic suturing represents an entirely new and different skill set. Mastering endoscopic suturing will present the first challenge in pursuing a career in EBTs. With a dearth of formalized fellowships in EBT, a reasonable way to achieve these skills is through precepted/proctored cases with experts and dedicated suturing courses. Existing courses run by device manufacturers and professional societies, including the American Society for Gastrointestinal Endoscopy, offer structured didactic and wet-lab training. After learning the fundamentals of endoscopic suturing, proficiency, in our experience, requires between 30 and 50 cases per procedure type (*e.g.*, ESG, TORe, and VSG-R), consistent with existing literature^[30]. In contrast, IGB placement and extraction can be mastered with a significantly more abbreviated training process, given the overlap with fundamental endoscopic skills. Until more formal EBT fellowship programs develop, training and education in EBTs are likely to remain mostly independent and self-driven^[31,32].

The cognitive skillsets of a bariatric endoscopist center around knowledge of obesity, its pathogenesis, pathophysiology, and medical management. Given that obesity affects every organ system, with patients frequently carrying concomitant chronic health conditions, we recommend that the gastroenterologist ⁴ maintain board certification in

internal medicine through the American Board of Internal Medicine. Further, we believe that it is imperative for any gastroenterologist seeking to practice endobariatrics to become board-certified by the American Board of Obesity Medicine (ABOM). This step ensures the acquisition of foundational and specialized knowledge in obesity as a chronic disease state and helps ensure well-rounded, holistic patient care beyond the performance of a procedure. The ABOM curriculum also addresses weight stigma and bias, which is regrettably rampant in medicine and should be well-understood by physicians and proceduralists practicing obesity medicine in any form^[33,34].

It is incumbent on the bariatric endoscopist to rigorously track outcomes longitudinally for patients undergoing EBTs, including both safety and efficacy data. These should ² satisfy the expert consensus thresholds for clinical adoption of EBT: a serious adverse event rate < 5% and an excess weight loss (EWL) exceeding 25%^[12]. While EBTs are safely performed at higher ranges of body mass index (BMI)^[15,17,35], it is more commonly performed in class I and II obesity. At this BMI range, EWL may outpace total body weight loss (TBWL); therefore, we recommend tracking TBWL and targeting > 10% TBWL at one year, as this threshold is associated with substantial improvement in obesity-related comorbidities and mortality^[36,37]. For a high-volume center, this degree of weight loss is readily achievable with ESG^[15,16,38], TORe^[17] and VSG-R^[19].

While increased physician skillset and longitudinal follow-up can augment the likelihood of sustained success, patients undergoing EBT are not immune from non-response, weight loss plateau, and weight recurrence^[39]. The bariatric endoscopist must be comfortable with this reality, the attendant patient dissatisfaction associated with these outcomes in a self-pay model, and the appropriate management steps. ABOM certification can increase one's ability to recognize contributing medical and behavioral factors and discuss and manage anti-obesity medications. Repeat suturing (for ESG)^[40], conversion to ESG (after IGB)^[41], and repeat ablation and/or suturing (for TORe)^[17,42] are all feasible in these circumstances for the bariatric endoscopist comfortable with such techniques; however, this does present challenges with how to select candidates judiciously based on initial success and their willingness to adhere to strict nutritional

follow up^[40,41]. Finally, conversion from restrictive gastric EBTs to metabolic and bariatric surgeries is also an option, underscoring the importance of maintaining strong working relationships with bariatric surgeons as part of the multidisciplinary care model for obesity^[43,44].

The endobariatric patient

Demographically, patients seeking EBTs resemble those who seek traditional metabolic and bariatric surgery. In a survey of 101 consecutive adults seeking ESG or IGB at our center, nearly 9 in 10 ³ were women, the mean age was 43.2 ± 9.7 years, the mean BMI was 38.8 ± 5.6 kg/m², and 76.2% ¹ had at least one obesity-associated medical problem^[11]. The respondents' weight loss history was also instructive: 63.7% had attempted weight loss ten or more times, 66.3% had used ¹ commercial weight loss programs, 66.3% had used over-the-counter weight loss drugs, and 70.3% had used prescription anti-obesity medications. These observations underscore the intractable, chronic, and relapsing nature of obesity, the distressing effects it can have on both health and well-being and the compassion and understanding that bariatric endoscopists must have to meet patients where they are.

This survey also revealed the importance of a thorough consultation with an experienced medical professional to provide patients with realistic expectations of EBT. Patients may overestimate the weight loss outcomes of EBT treatments, with nearly two-thirds believing they are as effective as traditional bariatric surgery, a view that is not supported by the literature^[15,45,46]. Additionally, patients may underestimate risk, with approximately half of respondents failing to recognize that EBTs could induce serious adverse events. Thus, in our practice, about half of the duration of a consult is spent systematically disclosing the technical aspects, benefits, risks, recovery, and alternatives to EBT therapy. These are then provided in detail in a written consent form that patients review and sign before procedure day.

The practice model

Incorporation of EBT into the gastroenterologist's practice may be dictated by the existing practice structure. Reasonable approaches include the mixed practice of general gastroenterology and EBTs (perhaps suited for ambulatory private practices) or interventional endoscopy (common in academic/hospital-affiliated centers). Alternatively, the "all in" approach entirely focuses on EBT at the exclusion of other routine endoscopic procedures. We favor the all-in approach as this facilitates a high-volume clinical practice and allows the physician to focus on the medical management of obesity. However, this approach may be impractical or financially unfeasible until one's practice is well established. Notably, the gastroenterologist should avoid the temptation to "dabble" in EBTs, which may pose diminished efficacy and heightened risk to patients due to inconsistent experience, harming both the patient and the field of EBT. Regardless of practice type, universal features should be consistent across venues (Table 3) and, we suggest, ought to include, at a minimum: (1) ABOM-certified physician(s) to provide a comprehensive approach to obesity management; (2) consistent volume of EBTs to ensure safety and efficacy; and (3) longitudinal support with a nutrition team^[47]. Finally, while safe, EBTs do have rare but serious risks, including gastrointestinal bleeding, which may require emergent endoscopic intervention, as well as interventions that a gastroenterologist cannot typically manage alone—such as a gastric leak, intraabdominal abscess, or perforation—and the need for these services should influence whether EBT can be responsibly offered in the context of any particular call system and practice model^[48,49]. While complications from suture-based EBTs are rare beyond the first two weeks from the procedure, IGBs may present with adverse events (*e.g.*, ulceration, gastrointestinal bleeding, hyperinflation, migration with small bowel obstruction, and viscus perforation) at any point during the dwell time; we therefore recommend that centers offering IGBs have unfettered direct access to an on-call physician who can help triage concerning signs of symptoms^[13,46,50,51].

Equipment

EBT is a dynamic, rapidly evolving field, and equipment needs will evolve. For now, most endoscopic suturing procedures are performed using the OverStitch™ or OverStitch SX™ Endoscopic Suturing Systems (Boston Scientific, Marlborough, MA, United States). The former is compatible with specific dual-channel endoscopes, and the latter is compatible with single-channel endoscopes. For optimal performance of the TORe procedure, argon plasma coagulation is necessary for ablation of the gastrojejunal anastomosis prior to suturing. Additional EBT-specific equipment requirements are listed in Table 4.

While no current Food and Drug Administration-authorized procedure requires fluoroscopy, the migration of EBT to target the metabolically-enriched region of the small intestine suggests that the bariatric endoscopist should reasonably consider fluoroscopic capabilities as an advantage in the coming years^[26,52].

Program infrastructure

In the abovementioned survey study of patients seeking EBTs at our center, the properties of an endobariatric practice that respondents deemed “very important” included physician experience (81.2% of respondents), ease of communication with the facility (74.3%), trust in medical staff (73.3%), quality of nutritional support (67.3%), the online reputation of the facility (67.3%), quality of psychological support (58.4%), self-pay price (52.4%), and wait time to procedure (45.5%)^[11]. Emerging EBT programs can use these priorities as a rubric for successful patient recruitment and retention.

The patient intake model will be distinct from traditional gastroenterology and surgical centers, primarily due to the self-pay nature of EBT and the current lack of medical provider familiarity with the field^[53]. The largely self-referral, self-pay model demands a more tailored level of service from team members who are personable, available, and skilled, as patients often require multiple touchpoints and significant time investment from their initial point of contact to their procedure day, regardless of practice setting. To facilitate the consultation process, this may require additional and intensive medical training of employees without medical background such that patients can be: (a)

appropriately screened for the correct procedure(s); (b) appropriately screened out for absolute contraindications; and (c) provided a basic overview of EBT procedures, as many patients may lack familiarity with the specialty. Beyond managing intake, scheduling, and financing, these team members also facilitate pre-procedural steps, including bloodwork, organization of peri-procedural medications, and subspecialty evaluations/clearances when needed for comorbid disease.

The initial patient consultation can be conducted with the bariatric endoscopist or an advanced practice provider. It should focus on the patient's medical, surgical, and social history, with emphasis on their history of obesity and prior weight loss endeavors, as well as concomitant issues that can impact and potentially contraindicate EBT, which are similar to those of metabolic and bariatric surgery, such as disordered eating, substance use disorders, untreated mood/psychiatric disorders, and significant end-organ dysfunction^[54]. The technical aspects, benefits, risks, recovery, and logistical components of the EBT of interest should be discussed, as well as alternative options (other EBTs, anti-obesity medications, and metabolic and bariatric surgery, when appropriate). The need for behavioral change and longitudinal follow-up should be emphasized, as well as realistic expectations for the degree and trajectory of weight loss. Our published experience showed that patients tend to overestimate weight loss and underestimate risk prior to consultation with an EBT provider^[42].

At a minimum, the procedure-day clinical care team should involve a bariatric endoscopist, registered nurses (pre-procedure intake nurse, circulating nurse, recovery nurse), an anesthesia provider, and an endoscopy technician. Additional staff may be needed to coordinate patient arrivals/departures and to clean endoscopes. After the procedure, medical follow-up can be balanced between the bariatric endoscopist and advanced practice providers to monitor patients' recovery during the early post-procedural course and for non-response, weight loss plateaus, or weight recurrence over the long term.

As emphasized above, we believe registered dietitians are mandatory members of an EBT practice^[55]. Obesity is a chronic, progressive, multifactorial, relapsing condition,

and any intervention aimed at weight loss should be offered and supported in conjunction with longitudinal aftercare focused on behavior change^[1]. While many gastroenterologists have experience with nutrition, dieticians bring an additional, practical skillset that goes beyond understanding physiology to help patients enact meaningful lifestyle changes. In one study we published of 284 patients undergoing TORe at our practice, the strongest predictor of ²weight loss at one year, out of a variety of procedural, patient, and practice components, was ²the number of follow-up visits the patient attended^[17]. Registered dieticians can be integrated into a practice through virtual outsourcing, local outsourcing (*e.g.*, hospital nutrition department), or internal hiring. While these appear in order of increasing difficulty to arrange, their long-term cost decreases, volume permitting. We recommend that all patients considering undergoing an EBT meet with a dietician individually to review expectations of modified diets that follow the procedure to facilitate tissue healing, as well as to provide additional methods of screening for relevant elements of a patient's history that may impact their recovery and weight loss, such as concomitant disordered eating or alcohol use disorder.

Marketing and financial considerations

The self-pay nature of EBT and the existing lack of familiarity with EBT within the medical field^[53] make marketing a critical and challenging aspect of an EBT program. Referrals from other medical professionals tend to be lower yield than in traditional gastroenterology practice, though this may change as provider familiarity increases and insurance coverage for EBT becomes possible. For now, the direct-to-patient approach has proven most fruitful. This should include a dedicated website or program-specific landing page that describes the available procedures and aftercare and heavy investment in social media, Google advertisements, and targeted digital marketing. Traditional marketing with print, signage, or radio may be helpful, but depends on the local market. Marketing may require a significant time and effort commitment from the bariatric endoscopist but is pivotal to building trust and rapport with patients exploring a relatively novel field.

The combination of disposable equipment, marketing, and infrastructure contributes to an EBT program's financial considerations. A significant aspect of cost per procedure is the facility fee and anesthesia costs (general anesthesia capabilities are required for EBT). These must be rigorously negotiated to keep costs low. The sum of these elements for a particular patient—their procedure and aftercare—make the margins in EBT far narrower than one might expect for a self-pay procedure (Figure 1).

CONCLUSION

EBT is an exciting and evolving opportunity for gastroenterologists to care for patients impacted by obesity through both endoscopic and cognitive skills. For the metabolic and bariatric endoscopist, it requires an effortful dedication to specific procedural skills (*e.g.*, full-thickness suturing technique, recognition of anatomy, management of intra-procedural adverse events) to maximize safety and efficacy, as well as a commitment to the cerebral aspects of obesity physiology (*e.g.*, through ABOM certification and continuing obesity education) to ensure patients are receiving comprehensive, longitudinal care. The success of the patient and practice requires the involvement of multiple team members, especially registered dietitians, as well as an engaging, adaptable patient intake team. As the field continues to evolve in reimbursement and toward applications beyond obesity to related comorbidities and novel technologies (*e.g.*, small bowel therapies), the bariatric endoscopist and EBT practice should be prepared to adapt to a rapidly changing landscape.

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SIMILARITY INDEX

PRIMARY SOURCES

1	Daniel B. Maselli, Ashley Kucera, Christopher G. Chapman, Brian Coan, Areebah Waseem, Chase Wooley, Christopher E. McGowan. "The Endoscopic Bariatric Patient: Characteristics, Beliefs, and Fears", iGIE, 2023	92 words — 3%
2	Daniel B Maselli, Vibhu Chittajallu, Chase Wooley, Areebah Waseem et al. "Transoral outlet reduction: Outcomes of endoscopic Roux-en-Y gastric bypass revision in 284 patients at a community practice", World Journal of Gastrointestinal Endoscopy, 2023	39 words — 1%
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