Does endoscopic mean safer? A comparison of the short-term safety of endoscopic versus laparoscopic bariatric therapies

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submitted 25.1.2021
accepted after revision 31.1.2022

Bibliography
Endosc Int Open 2022; 109: E307–E310
DOI 10.1055/a-1783-8573
ISSN 2364-3722

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ABSTRACT

Background and study aims There is minimal research on real-world, large-volume data comparing endoscopic bariatric therapy (EBT) to laparoscopic bariatric therapy (LBT). This study aimed to compare 30-day postoperative morbidity and mortality outcomes of primary EBT vs LBT using the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program.

Patients and methods Patients aged 18 to 80 with body mass index (BMI) 35 to 40 kg/m^2 undergoing primary procedures were included. Propensity score matching 1:50 was performed for EBT versus LBT based on age, sex, and BMI.

Results We matched 211 EBTs with 9,059 LBTs. Operative length (63.9, 95 % confidence interval [CI]: 57.9, 69.8 versus 81.1, 95 % CI: 80.1, 82.1) and length of stay (0.49 days, 95 % CI: 0.29, 0.69 versus 1.43 days, 95 % CI: 1.41, 1.45) were significantly lower in the EBT group than the LBT group. There was no difference between EBT and LBT in the odds of readmission (odds ratio [OR] = 0.31, 95 % CI: 0.08, 1.25), reoperation (OR = 0.39, 95 % CI: 0.05, 2.84), or reintervention (OR = 0.98, 95 % CI: 0.24, 3.99). After controlling for chronic obstructive pulmonary disease, sleep apnea, history of myocardial infarction, hypertension requiring medications, and diabetes, EBT continued to be associated with lower odds of having any adverse event (AE) than LBT, with an OR of 0.34 (95 % CI: 0.16, 0.69). Subgroup analysis comparing EBT to laparoscopic sleeve gastrectomy (LSG) showed that EBT was associated with a lower risk having any AE than LSG, with an OR of 0.39 (95 % CI: 0.19, 0.79).

Conclusions EBT is associated with a lower 30-day AE rate and shorter procedural length and length of stay than LBT, with similar rates of readmission, reintervention, and reoperation.

Introduction

Bariatric procedures are vital to tackling the obesity pandemic and its accompanying metabolic comorbidities. In this space, endoscopic bariatric therapy (EBT) has become increasingly popular as a minimally invasive alternative to well-established surgical bariatric procedures.

EBT includes a wide array of options, such as space-occupying devices (e. g., intragastric balloon [IGB]) [1] and restrictive procedures (e. g., endoscopic sleeve gastroplasty [ESG] and primary obesity surgery, endoluminal procedure) [2]. These procedures are in various stages of development, testing, and adoption, with the IGB having the most long-term data and ESG gaining more recent traction with a randomized clinical trial underway (MERIT trial, NCT03406975). The safety and effi-

cacy of EBT has been explored in multiple retrospective studies and landmark clinical trials with findings thus far suggestive of significant weight loss outcomes with reasonable safety profiles [3–7]. As the popularity of EBT and the data supporting its safety and efficacy grows, it is imperative that clinicians have a data-driven perspective on the outcomes of these procedure compared to laparoscopic bariatric therapy (LBT).

The elective nature of these procedures makes risk assessment of the utmost importance. With the minimally invasive nature of EBT comes the assumption that the procedures are inherently lower risk. Thus far, smaller studies have supported this hypothesis, as reported above. While efficacy and proof of concept can be demonstrated in small retrospective studies, real-world adverse events (AEs) are difficult to extrapolate without large-volume data. It is imperative to perform larger comparative studies to better understand the outcomes and to be able to guide patients in choosing from the menu of options available for these elective bariatric procedures.

Endoscopic and surgical bariatric therapies have traditionally been difficult to compare for many reasons. Patient populations can differ significantly, especially with regard to comorbidities, given the eligibility criteria used for bariatric surgery [8]. In addition, most EBTs are only approved for use in patients with body mass index (BMI) < 40 kg/m^2, limiting overlap. Finally, data on EBTs are limited because of the novelty of the procedures, and long-term data are particularly scarce. Overall, while informative, the available data comparing EBT and LBT is suboptimal because it is retrospective, performed at centers of excellence, and based on small cohorts.

The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) is a unified national accreditation program for bariatric surgery centers that is the result of a combined effort of the American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS). All accredited participating centers report their outcomes to the MBSAQIP database. This study aimed to use the MBSAQIP database to compare 30-day postoperative morbidity and mortality outcomes of primary EBT vs LBT. According to the ASMBS, laparoscopic sleeve gastrectomy (LSG) is currently the most commonly performed bariatric surgery [9]. For this reason, a subgroup analysis was also performed comparing EBT to LSG.

Patients and methods

The MBSAQIP 2019 database contains data from 206,570 cases from 868 centers and our analysis was performed using this dataset. Patients between the ages of 18 and 80 years were included. Patients were included only if their BMI ranged from 35 to 40 kg/m^2, because that is commonly the range of overlap of most endoscopic and surgical procedures. Only endoscopic or laparoscopic primary weight loss procedures were included. Revision or conversion procedures were excluded.

Propensity score matching 1:50 was performed for EBT versus LBT based on age, sex, and BMI. The primary outcome was AEs, which were defined by the occurrence of any one of the 26 recorded AEs in the database. These AEs included: coma > 24 hours, stroke, myocardial infarction (MI), cardiac arrest, unplanned Intensive Care Unit admission, unplanned intubation, pulmonary embolism, deep vein thrombosis, sepsis, septic shock, *Clostridium difficile* infection, urinary tract infection, superficial incisional surgical site infection, deep incisional surgical site infection, organ space surgical site infection, wound disruption, pneumonia, peripheral nerve injury, acute renal failure, incisional hernia, need for transfusion, drain present 30 days post-procedure, need for a ventilator postoperatively, unplanned intubation, treatment for dehydration as outpatient, or Emergency Department outpatient visit.

Secondary outcomes included readmission, reoperation, reintervention, and length of stay. Multivariable logistic regression controlling for baseline comorbidities (obstructive pulmonary disease, history of MI, hypertension, sleep apnea, diabetes) was used to compare the two groups with respect to the occurrence of an AE. $P < 0.05$ was considered significant.

The ACS Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program and the centers participating in the ACS MBSAQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

Results

We matched 211 EBTs with 9,059 LBTs based on age, sex, and BMI. ▶ **Table 1** shows the demographic characteristics and comorbidities of the groups after matching.

Operative length was significantly lower in the EBT group than in the LBT group (63.9, 95 % confidence interval [CI]: 57.9, 69.8 versus 81.1, 95 % CI: 80.1, 82.1). Length of stay post-procedure was also significantly lower in the EBT group than the LBT group (0.49 days, 95 % CI: 0.29, 0.69 versus 1.43 days, 95 % CI: 1.41, 1.45).

There was no difference between EBT and LBT in the odds of readmission (odds ratio [OR] = 0.31, 95 % CI: 0.08, 1.25), reoperation (OR = 0.39, 95 % CI: 0.05, 2.84), and reintervention (OR = 0.98, 95 % CI: 0.24, 3.99).

The odds of having any AE were lower in the EBT group than the LBT group (OR = 0.33, 95 % CI: 0.16, 0.68). After controlling for: chronic obstructive pulmonary disease (COPD), sleep apnea, history of MI, hypertension requiring medications, and diabetes, EBT continued to be associated with lower odds of having any AE than LBT, with an OR of 0.34 (95 % CI: 0.16, 0.69).

Subgroup analysis

A total of 211 patients who underwent EBTs were matched with 8,541 who underwent LSGs based on age, sex, and BMI. ▶ **Table 2** shows the demographic characteristics and comorbidities of the groups after matching.

Operative length was significantly lower in the EBT group (63.9 minutes, 95 % CI: 57.9, 69.8) than the LBT group (69 minutes, 95 % CI: 68.3, 69.8), though the difference of a few minutes may not be of clinical significance. Length of stay post-procedure was also significantly lower in the EBT group than in the

▶ **Table 1** Demographic characteristics and comorbidities of EBT and LBT groups after matching.

	LBT group	EBT group	*P* value
Age (years)	46.6 ± 11.6	46.6 ± 10.9	0.94
Sex (% females)	84.4	84.4	0.92
BMI (kg/m^2)	37.6 ± 1.4	37.5 ± 1.4	0.23
Diabetes (%)	26.7	15.2	0.001
Hypertension requiring medications (%)	47.5	36.5	0.001
Sleep apnea (%)	35.7	25.1	0.001
COPD (%)	0.87	0.47	0.54
History of MI (%)	1.2	0.5	0.34

LBT, laparoscopic bariatric therapy; EBT, endoscopic bariatric therapy; BMI, body mass index; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction.

▶ **Table 2** Demographic characteristics and comorbidities of EBT and LSG groups after matching.

	LSG group	EBT group	*P* value
Age (years)	46.5 ± 11.7	46.6 ± 10.8	0.89
Sex (% females)	85.1	84.3	0.76
BMI (kg/m^2)	37.5 ± 1.38	37.4 ± 1.39	0.38
Diabetes (%)	24.9	15.2	0.005
Hypertension requiring medications (%)	45.9	36.5	0.007
Sleep apnea (%)	34.5	25.1	0.004
COPD (%)	1	0.5	0.43
History of MI (%)	1.3	0.5	0.31

LSG, laparoscopic sleeve gastrectomy; endoscopic bariatric therapy; BMI, body mass index; COPD, chronic obstructive pulmonary disease; myocardial infarction.

LSG group (0.49 days, 95 % CI: 0.29, 0.69 in EBTs versus 1.38 days, 95 % CI: 1.36, 1.39 in LSG).

There was no difference between patients undergoing EBT and LBT in the odds of readmission (OR = 0.41, 95 % CI: 0.11, 1.67), reoperation (OR = 0.47, 95 % CI: 0.06, 3.42), or reintervention (OR = 2.14, 95 % CI: 0.51, 8.93).

The odds of having any AE were lower in the EBT group than in the LBT group (OR = 0.38, 95 % CI: 0.19, 0.78). After controlling for the comorbidities previously listed, EBT continued to be associated with a lower risk of of having any AE than LSG, with an OR of 0.39 (95 % CI: 0.19, 0.79).

Discussion

This is the first study to compare 30-day safety outcomes of EBT versus LBT from a large and validated quality improvement database, the MBSAQIP. Overall, our findings suggest that EBT is associated with a significantly lower rate AEs than LBT in the 30-day post-procedure period. Rates of readmission, reoperation, and reintervention were not significantly different between these two groups.

Only a handful of studies have been performed thus far comparing the outcomes of EBT and LBT. Of them, there has only been one study with large-volume data. This study used the MBSAQIP database to compare an IGB to bariatric surgeries using the MBSAQIP database, which included 145,408 patients undergoing IGB and 144,627 patients undergoing laparoscopic gastric bypass in 2018 [10]. Propensity-matched analysis revealed a higher overall AE rate with IGB when compared to LBT (5.0 % versus 2.6 %, P = 0.024). Other published studies have mostly focused on comparing ESG to LSG in particular and their findings are suggestive of better safety outcomes with ESG, but superior weight loss outcomes with LSG [6, 11]. One retrospective analysis comparing ESG, LSG, and laparoscopic adjustable gastric banding in 279 patients with obesity found that LSG achieved the highest percent total body weight loss (%TBWL) (29.28 vs 13.30 vs 17.57 %, respectively). However, ESG was found to have a significantly lower rate of morbidity and length of stay when compared to the other techniques [11]. A case-matched retrospective analysis performed by our group also compared ESG and LSG outcomes [6]. A total of 54 patients undergoing ESG were matched with 83 patients undergoing LSG. Lower rates of AEs were associated with ESG compared to LSG

(5.2 % vs 16.9 %, P < 0.05). Interestingly, higher rates of de-novo gastroesophageal reflux disease were encountered with LSG compared to ESG (14.5 % vs 1.9 %, *P* < 0.05). Our current study suggests that overall, for any type of EBT, there appears to be better short-term safety outcomes as compared to LBT. When comparing EBT to LSG alone, the short-term safety results were similar.

The strength of this study is that it was based on prospectively collected data from multiple institutions, which allowed them to serve as an accurate representation of real-world outcomes and it adds to the repertoire of information needed to provide patient-centered, personalized care.

In addition, we controlled for differences between the groups in age, sex, BMI, and comorbidities with propensity score matching and multivariable regression. As expected, the LBT group had significantly more comorbidities, namely sleep apnea, diabetes, and hypertension. Interestingly, however, history of MI and COPD were not significantly different between the two groups. Finally, the study provides additional information on operative length and length of stay. Length of stay was significantly lower in the EBT group and was notably < 1 day as compared to LBT, which had a mean length of stay > 1 day, suggesting that overnight observation is required post-procedure.

The authors would like to acknowledge the limitations of this study. One is that the procedure type for EBT had not been recorded in the database, limiting our ability to subcategorize and study different procedures. This is an inherent limitation of the database, which we hope can be amended to allow more informed research and quality improvement for EBT. There is likely a disproportionate representation of IGB over other EBTs in these data, which must be acknowledged. Nevertheless, our results remain a fair representation of the current landscape of EBTs. Another limitation is the absence of long-term safety data, which limits our ability to make broader statements about the overall safety of these procedures. However, with the striking difference between these procedures seen in this analysis, the results remain significant and should be further explored in future prospective studies. When reviewing the results of this study, consideration must be given to the novelty of EBT compared to LBT, which has been well established. It is likely that the safety profile of EBT will further improve with increasing individual and collective experience.

A discussion comparing EBT to LBT is only complete after comparing weight loss, effects on comorbidities, and long-term safety outcomes as well. However, this study focuses only on short-term safety data. Future studies must continue to compare these different facets of treatment and prospective data is much needed. The finding of shorter duration of procedure and length of stay in EBTs vs LBTs may also have strong implications regarding the relative cost of these procedures. Future research is needed to compare the cost-effectiveness of these procedures.

Conclusions

There is currently a menu of bariatric surgical options available for patients to choose from and information about EBT must continue to expand. Shorter duration of procedure, shorter length of stay, and lower rates of post-procedural AEs all contribute to making EBT more palatable for both patients and physicians.

Competing interests

Dr. Kumbhari is a consultant for Medtronic, Pentax Medical, Boston Scientific, FujiFilm, and Apollo Endosurgery. He receives research support from ERBE USA and Apollo Endosurgery.

References

[1] Kotinda A, de Moura D, Ribeiro I et al. Efficacy of intragastric balloons for weight loss in overweight and obese adults: a systematic review and meta-analysis of randomized controlled trials. Obes Surg 2020; 30: 2743–2753

[2] Kumbhari V, Oberbach A, Nimgaonkar A. Primary endoscopic therapies for obesity and metabolic diseases. Curr Opin Gastroenterol 2015; 31: 351–358

[3] Hedjoudje A, Abu Dayyeh B, Cheskin L et al. Efficacy and safety of endoscopic sleeve gastroplasty: a systematic review and meta-analysis. Clin Gastroenterol Hepatol 2019; 18: 1043–1105

[4] Vargas E, Bazerbachi F, Storm A et al. Effectiveness of online aftercare programs following intragastric balloon placement for obesity is similar to traditional follow-up: a large propensity matched us multicenter study. Obes Surg 2019; 29: 4036–4042

[5] Neto A, de Moura D, Ribeiro I et al. Efficacy and safety of endoscopic sleeve gastroplasty at mid term in the management of overweight and obese patients: a systematic review and meta-analysis. Obes Surg 2020; 30: 1971–1987

[6] Fayad L, Adam A, Schweitzer M et al. Endoscopic sleeve gastroplasty versus laparoscopic sleeve gastrectomy: a case-matched study. Gastrointest Endosc 2019; 89: 782–788

[7] Barrichello S, de Moura D, de Moura E et al. Endoscopic sleeve gastroplasty in the management of overweight and obesity: an international multicenter study. Gastrointest Endosc 2019; 90: 770–780

[8] Aminian A, Chang J, Brethauer S et al. ASMBS updated position statement on bariatric surgery in class I obesity (BMI 30–35 kg/m2). Surg Obes Relat Dis 2018; 14: 1071–1087

[9] English W, DeMaria E, Hutter M et al. American Society for Metabolic and Bariatric Surgery 2018 estimate of metabolic and bariatric procedures performed in the United States. Surg Obes Relat Dis 2020; 16: 457–463

[10] Dang J, Switzer N, Sun W et al. Evaluating the safety of intragastric balloon: an analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program. Surg Obes Relat Dis 2018; 14: 1340–1347

[11] Novikov A, Afaneh C, Saumoy M et al. Endoscopic sleeve gastroplasty, laparoscopic sleeve gastrectomy, and laparoscopic band for weight loss: how do they compare? J Gastrointest Surg 2018; 22: 267–273