

Original Article

Living on the EDGE: Canadian Experience With EUS-directed Transgastric ERCP (EDGE) in Patients With Roux-en-Y Gastric Bypass Anatomy

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Abstract

Introduction: Roux-en-Y gastric bypass (RYGB) surgery imposes anatomic barriers to endoscopic retrograde cholangiopancreatography (ERCP). Potential options for biliary access in these patients include laparoscopic-assisted ERCP or balloon enteroscopy. However, these approaches require specialized equipment and/or operating room personnel and are associated with high rates of failure and adverse events compared to conventional ERCP. A recently described technique, EDGE, is an endoscopic approach which involves accessing the excluded stomach to facilitate ERCP.

Objective: The objective of this study is to describe the results of EDGE procedures performed in Canada.

Methods: Data were collected from patient cases who had undergone an EDGE procedure across centers in Canada. All patients had a history of RYGB bariatric surgery. In each procedure, a 20-mm diameter lumen-apposing metal stent (LAMS) was deployed under EUS guidance to allow access from the gastric remnant/proximal jejunum to the excluded stomach. Subsequently, during a separate procedure, a duodenoscope was passed through the LAMS to perform ERCP. Following ERCP, the LAMS was replaced with a pigtail stent or APC was used to facilitate closure of the gastro-jejunal/gastro-gastric fistula.

Results: The indication for EDGE in the seven included cases was for the treatment of choledocholithiasis (six) or gallstone pancreatitis (one). The technical success rate of the EDGE procedure in these cases was 100%. Clinical success, defined by normalization of bilirubin and symptomatic relief, was observed in all cases. There were no adverse events reported.

Conclusion: The results of this series support EDGE as a safe and minimally invasive approach to biliary access and therapy in patients with previous RYGB surgery.

Keywords: *Bariatric surgery; EDGE; ERCP; Roux-en-Y gastric bypass*

Introduction

Obesity is a public health crisis that has arisen in recent decades (1). In 2017, 64% of adults in Canada over age 18 were

overweight or obese (2). Although lifestyle and behavioural modifications are the first-line option for managing obesity, low long-term success rates have prompted a shift toward surgical

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management options. Over the past decade, bariatric surgery rates have increased from an estimated 4400 surgeries in 2011 to over 8000 surgeries in 2017 (3,4). One consequence of rapid weight loss following bariatric surgery is an increased risk of cholelithiasis and subsequently choledocholithiasis (5). However, current surgical guidelines do not recommend routine prophylactic cholecystectomy at the time of bariatric surgery (6). These factors contribute to an increased prevalence of biliary calculous disease in patients who have undergone bariatric surgery.

The most common bariatric surgeries performed in Canada are Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (7). Sleeve gastrectomy surgically excludes a large part of the stomach while preserving duodenal continuity, whereas RYGB involves creation of a small gastric pouch which is attached to the jejunum, bypassing the duodenum and often the proximal jejunum. Thus, RYGB surgery imposes anatomic barriers to transoral ERCP, thereby limiting the use of standard equipment and techniques. Techniques that have been used previously for biliary access in post-bariatric surgery patients include laparoscopy-assisted ERCP and enteroscopy-assisted ERCP (Figure 1). However, these approaches require specialized equipment and/or operating room personnel and are associated with higher rates of failure (8) compared to conventional ERCP.

A recently described technique, EUS-directed transgastric ERCP (EDGE) using a lumen-apposing metal stent (LAMS), is an entirely endoscopic approach which involves accessing the excluded stomach to facilitate conventional ERCP (Figure 2). Although bariatric surgery rates are rising in Canada, performance of the EDGE procedure for management of pancreaticobiliary disease has not yet been described in Canada's post-bariatric surgery patient population. We aimed to assess the practice patterns and clinical outcomes of EDGE among Canadian institutions.

METHODS

Practicing endosonographers at University affiliated tertiary care centers across Canada were solicited via email in February 2021 asking whether any EDGE procedures had been performed at their centers. Endoscopists e-mailed were affiliated with the following universities: University of British Columbia, University of Alberta, University of Calgary, University of Saskatchewan, University of Manitoba, University of Toronto, University of Western Ontario, McMaster University, Queen's University, University of Ottawa, McGill University and University of Dalhousie. An e-mail reminder was sent 2 weeks later.

Upon identification of the EDGE procedure cases, consent was obtained from each of the cases and the data were anonymously extracted from the operative reports into a password-protected Excel file. Extracted data included patient

demographics and surgical history including age, sex and type of prior bariatric surgery. Further data related to the EDGE procedure were collected including any previous attempts at ERCP or device-assisted ERCP, location of LAMS placement, ancillary maneuvers during LAMS deployment, time from LAMS to ERCP, time from ERCP to LAMS removal, method of fistula closure if applicable, technical and clinical success and any complications. Technical success was defined as ability to perform a conventional ERCP with deep biliary cannulation following placement of the LAMS. Clinical success was defined as normalization of bilirubin and/or resolution of patient's symptoms.

RESULTS

Of the 12 centers that were e-mailed, we received responses from gastroenterologists from 9 of these institutions. Apart from two hospitals affiliated with the University of British Columbia (Victoria General Hospital and Vancouver General Hospital) and McGill University (McGill University Health Center), responses from the remainder of the centers indicated that they were not performing this procedure. Feedback from these centers identified that laparoscopy-assisted ERCP was the most common modality of obtaining biliary access in these patients with RYGB anatomy. Data were ultimately collected from seven patient cases who had undergone an EDGE procedure at Victoria General Hospital (5), Vancouver General Hospital (1) in British Columbia and McGill University Health Center (1) in Quebec from 2019 to 2021.

Demographics

The median age of patients was 67 (range 40 to 72). Four patients were female and three were male. All patients had a remote history of Roux-en-Y gastric bypass surgery. Among the seven cases in the series, six had choledocholithiasis and one had gallstone pancreatitis as the indication for ERCP.

Procedure

In each of the procedures, a 20-mm-diameter lumen-apposing metal stent (LAMS) was deployed under EUS guidance to allow access from the gastric remnant or proximal jejunum to the excluded stomach. The excluded stomach lumen is typically collapsed and is identified endosonographically by the so-called 'sand dollar sign' (9). Standard FNA needle puncture access is followed by injection of saline-contrast solution with or without methylene blue to expand the target for access with the electrocautery enhanced delivery device and placement of LAMS.

Zero patients underwent an ERCP in the same session as LAMS placement. The median time between LAMS insertion and ERCP was 9 days (interquartile range [IQR] 15, range 4 to 28 days). Following ERCP, the LAMS was removed at a median

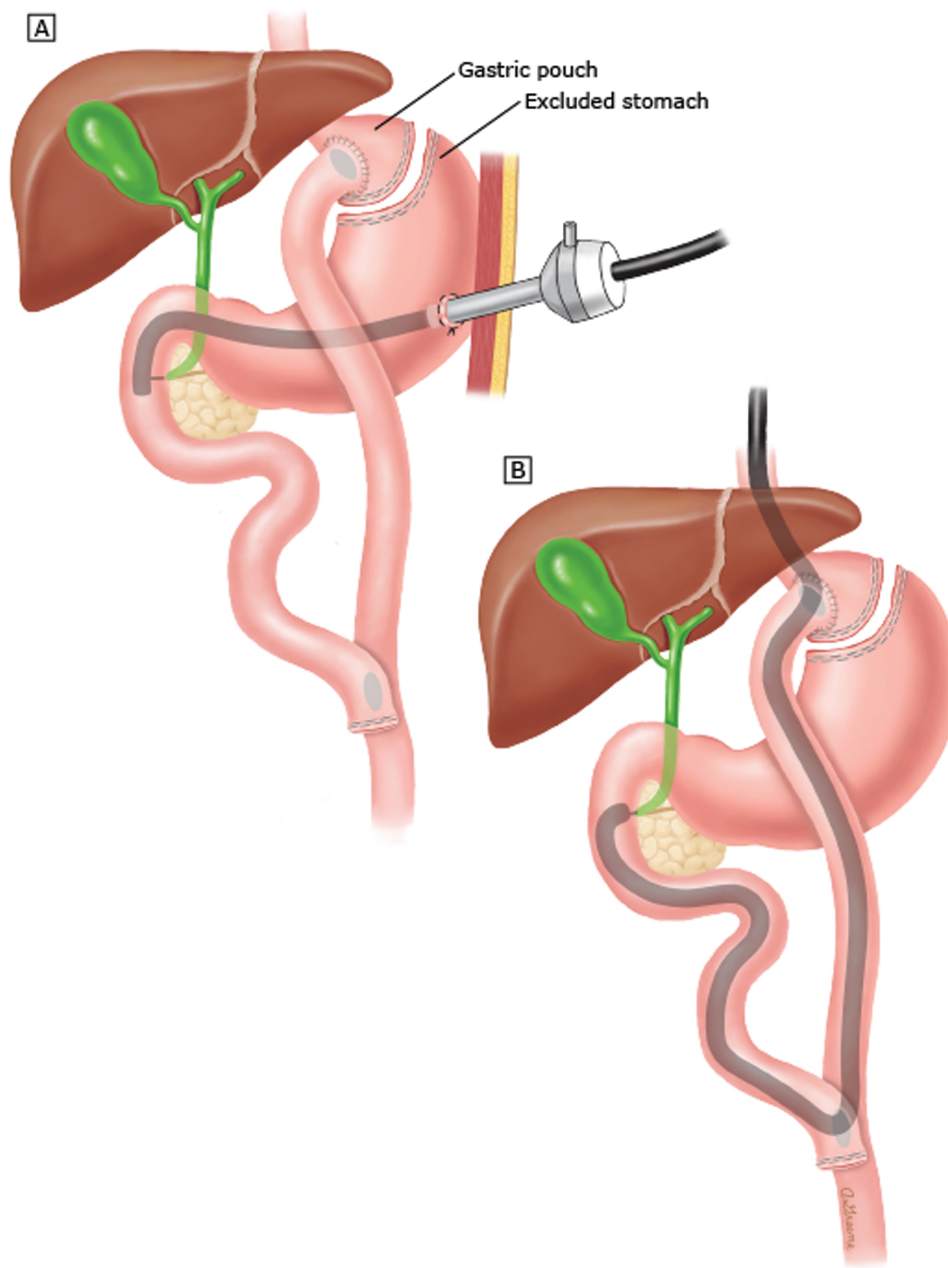


Figure 1. (A) Laparoscopy-assisted ERCP. (B) Enteroscopy-assisted ERCP. Huang CS. ERCP in patients with Roux-en-Y anatomy. *UptoDate*. 2020. Available from URL: <https://www.uptodate.com/lookup/contents/ercp-in-patients-with-roux-en-y-anatomy>.

time of 17 days (range 0 to 38) later. In five of the cases, the LAMS was replaced with a double pigtail biliary stent to facilitate controlled closure of the gastro-jejunal or gastro-gastric fistula. The double pigtail stent was removed at a subsequent procedure. In one case, argon plasma coagulation (APC) was administered following LAMS removal to promote closure of the fistula. One patient was awaiting cholecystectomy and therefore the LAMS had not yet been removed.

Technical and Clinical Success

The technical success rate of the EDGE procedure in the seven cases was 100%. In one case, the excluded stomach could not

be identified during the initial EUS procedure. After radiologic review, it was determined that the patient had a hiatal hernia, with the gastric remnant positioned above the diaphragm. A second EUS procedure was able to identify the distal portion of the excluded stomach and a LAMS was successfully deployed via jejunal limb access. Clinical success, defined by normalization of bilirubin and symptomatic relief, was observed in all cases. There were no immediate or delayed adverse events related to the EDGE procedure in these seven cases.

Seventy-one per cent of the EDGE cases comprised a total of four procedures: (1) initial EUS-directed LAMS placement,

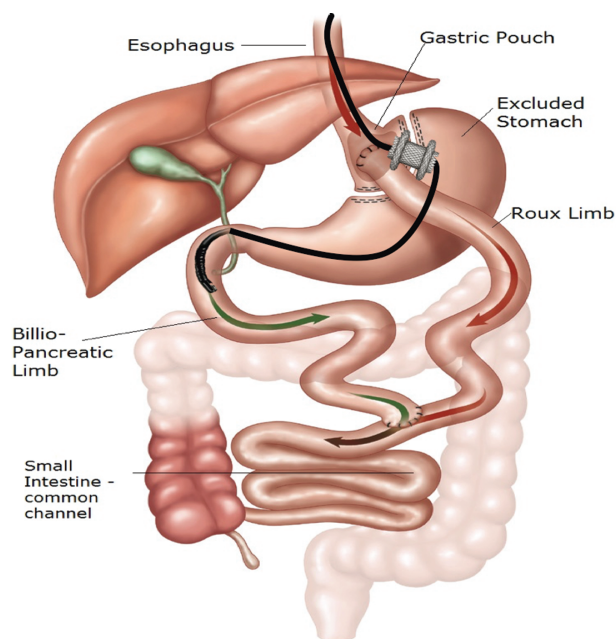


Figure 2. (A) EUS-direct transgastric ERCP. Kedia, P. Internal EDGE (EUS-directed transgastric ERCP. *Kedia MD*. 2020. Available from URL: <https://www.kediamd.com/internal-edge-eus-directed-transgastric-ercp-procedure/>.

(2) ERCP through LAMS, (3) LAMS removal and pigtail stent placement and (4) pigtail stent removal. Two of the cases comprised three procedures; in one, the LAMS removal and pigtail stent placement was performed during the same procedure as ERCP, and in another, the fistula was treated with APC.

Discussion

The altered anatomy of RYGB surgery imposes unique challenges to endoscopic management of biliary stone disease. The result of this series supports EDGE as a safe, minimally invasive and reproducible approach to biliary access and therapy in patients with previous RYGB surgery. Interestingly, we found that there has been minimal uptake of this procedure among Canadian centers, and that previously developed methods such as laparoscopy-assisted or enteroscopy-assisted ERCP remain the modality of choice. Our survey identified performance of EDGE in only 25% of Canadian centers with advanced EUS services. While it is possible that the procedure may be performed by a small number of survey nonresponders or at nontertiary centers, we believe that we received responses from majority of the advanced EUS services who are the most likely to have performed EDGE. Further, our finding that EDGE has been adopted in only a small number of Canadian centers was corroborated by data from the supplier of the LAMS device (M. Stemerink, Boston Scientific, personal communication, May 26, 2021).

Most Canadian centers manage post RYGB patients who require ERCP via non-EUS approaches. Enteroscopy-assisted ERCP involves passage of a balloon enteroscope via the jejunal limb to reach the papilla in retrograde fashion. Although it is a safe procedure with low risk of adverse events (0 to 12.5%), reported technical success rates are as low as 68% in multicentered trials (8,10–12) (Table 1). This may be due to the small working channel in the enteroscope in comparison to a therapeutic endoscope, the lack of an elevator and the length of the balloon enteroscope (11,13). Laparoscopy-assisted ERCP has comparatively higher rates of technical success (73 to 100%) but with higher rates of serious adverse events such as perforation (5 to 19%). It involves accessing the excluded stomach via a laparoscopically placed access port to facilitate transgastric intra-operative ERCP. Additional drawbacks of laparoscopy-assisted ERCP include longer hospital stays and increased costs. Logistic challenges with this procedure include lack of easy access to operating rooms and the need for coordination with multiple teams including anesthesia and general surgery (12).

The EDGE procedure was first reported in 2014 by endoscopists at Weill Cornell Medical College (15). A recent U.S. retrospective, multicenter study compared EDGE to laparoscopy-assisted ERCP (16). The study suggested that both techniques had similar technical success and adverse event rates; however, patients who underwent EDGE had significantly shorter procedure time and length hospital stay. Furthermore, a recent cost-analysis of laparoscopy-assisted ERCP, enteroscopy-assisted ERCP and EDGE among post-RYGB patients showed that EDGE was the most cost-effective modality and was associated with the highest total quality-adjusted life-years (14) (Table 1). As a purely endoscopic approach, EDGE avoids the costs and delays that accrue from coordinating operating room time and anesthesia and surgical personnel. Indeed, a major impetus toward implementing EDGE at Victoria General Hospital was to obviate these additional services.

Potential barriers to the EDGE procedure include operator training and experience, need for multiple procedures and preferential management of these patients by surgeons. There may also be concern regarding potential non-healing fistulas and undesired weight gain following LAMS removal. However, the incidence of persistent gastro-gastric fistula post-EDGE is low (17). In our series, approaches used to minimize the risk of persistent fistula included placement of a temporizing double pigtail stent or application of APC following LAMS removal. It has previously been shown that placement of a double pigtail stent facilitates access tract closures following endoscopic necrosectomy or postoperative anastomotic leak (18,19). The postulated mechanism by which a plastic stent aids in fistula closure is by providing friction at the fistula site, causing irritation and facilitating formation of granulation tissue to close the tract

Table 1. Comparison of EDGE, laparoscopy-assisted ERCP and enteroscopy-assisted ERCP

Procedure	Endoscopic success (%) (13)	Adverse event rate (%)	Number of procedures required	Cost per QALY (\$USD) (14)
EDGE	89–100	11–19	3–4	8,356
Laparoscopy-assisted ERCP	73–100	5–19	1–2	34,483
Enteroscopy-assisted ERCP	68–100	0–12.5	1–2	12,620

(18,19). Fistula patency was not formally assessed during follow up in this series. While some authors report routinely closing the fistula defect with sutures or clips at the time of LAMS removal (20), in the absence of randomized comparisons of the effectiveness of these or other approaches, operators are guided by their personal experience and judgement.

In summary, this nation-wide survey of Canadian interventional endosonographers found that EDGE appears to be a safe and reliable method of managing choledocholithiasis in RYGB patients, though it is performed at a minority of centers. Given the favorable outcomes similar to previous studies, and additional advantages of reduced costs and hospital length of stay compared to alternative techniques, EDGE should be considered a viable first-line option in RYGB patients who require ERCP. However, due to the relative novelty of the procedure and lack of Canadian experience, the consideration should only be made in centers where there is appropriate level of EUS expertise and existing surgical support.

AUTHOR CONTRIBUTIONS

R.L.B. was the primary author of the manuscript. A.J., B.F., Y.I.C. and F.D. were all contributing authors and have reviewed and agreed with the final manuscript submission.

CONFLICT OF INTEREST

Y.I.C. is a consultant for Boston Scientific.

References

- World Health Organization. Obesity and overweight. 2020. <<https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight>> (Accessed May 10, 2021).
- Government of Canada. Tackling Obesity in Canada: Obesity and excess weight rates in Canadian adults. 2018. <<https://www.canada.ca/en/public-health/services/publications/healthy-living/obesity-excess-weight-rates-canadian-adults.html>> (Accessed May 10, 2021).
- Tchernof A, Weisnagel SJ. The rapidly evolving landscape of bariatric surgery. *Can J Diabetes* 2017;41(4):339–40.
- Biertho L, Hong D, Gagner M. Canadian adult obesity clinical practice guidelines: Bariatric surgery: Surgical options and outcomes. 2020. <<https://obesitycanada.ca/guidelines/surgeryoptions/>> (Accessed May 10, 2021).
- Oliveria CI, Chaim EA, Borges de Silva B. Impact of rapid weight reduction on risk of cholelithiasis after bariatric surgery. *Obes Surg*. 2003;13(4):625–8.
- Leyva-Alvizo A, Arredondo-Saldaña G, Leal-Isla-Flores V, et al.; ASMBS Foregut Committee. Systematic review of management of gallbladder disease in patients undergoing minimally invasive bariatric surgery. *Surg Obes Relat Dis* 2020;16(1):158–64.
- Rohaila S, Jackson TD, Fralick M. Bariatric surgery. *CMAJ* 2017;189(31):E1017.
- Inamdar S, Slattery E, Sejjal DV, et al. Systematic review and meta-analysis of single-balloon enteroscopy-assisted ERCP in patients with surgically altered GI anatomy. *Gastrointest Endosc* 2015;82(1):9–19.
- Siddiki H, Baron TH. The sand dollar sign: A reliable EUS image to identify the excluded stomach during EUS-guided gastrogastrostomy. *Gastrointest Endosc* 2018;88(2):398–9.
- Shah RJ, Smolkin M, Yen R, et al. A multicenter, U.S. experience of single-balloon, double-balloon, and rotational overtube-assisted enteroscopy ERCP in patients with surgically altered pancreaticobiliary anatomy (with video). *Gastrointest Endosc* 2010;71:AB134–135.
- Ma Y, Li F, Zhou X, et al. Four reconstruction methods after laparoscopic distal gastrectomy: A systematic review and network meta-analysis. *Medicine (Baltimore)* 2019;98(51):e18381.
- Abbas AM, Strong AT, Diehl DL, et al.; LA-ERCP Research Group. Multicenter evaluation of the clinical utility of laparoscopy-assisted ERCP in patients with Roux-en-Y gastric bypass. *Gastrointest Endosc* 2018;87(4):1031–9.
- Wang TJ, Ryou M. Evolving techniques for endoscopic retrograde cholangiopancreatography in gastric bypass patients. *Curr Opin Gastroenterol* 2018;34(6):444–50.
- James HJ, James TW, Wheeler SB, et al. Cost-effectiveness of endoscopic ultrasound-directed transgastric ERCP compared with device-assisted and laparoscopic-assisted ERCP in patients with Roux-en-Y anatomy. *Endoscopy* 2019;51(11):1051–8.
- Kedia P, Shariha RZ, Kumta NA, et al. Internal EUS-directed transgastric ERCP (EDGE): Game over. *Gastroenterology* 2014;147(3):566–8.
- Kedia P, Tarnasky PR, Nieto J, et al. EUS-directed transgastric ERCP (EDGE) versus laparoscopy-assisted ERCP (LA-ERCP) for Roux-en-Y Gastric Bypass (RYGB) anatomy: A multicenter early comparative experience of clinical outcomes. *J Clin Gastroenterol* 2019;53(4):304–8.
- Runge TM, Chiang AL, Kowalski TE, et al. Endoscopic ultrasound-directed transgastric ERCP (EDGE): A retrospective multicenter study. *Endoscopy* 2021;53(6):611–8.
- Eisendrath P, Cremer M, Himpens J, et al. Endotherapy including temporary stenting of fistulas of the upper gastrointestinal tract after laparoscopic bariatric surgery. *Endoscopy* 2007;39(7):625–30.
- Saeed ZA, Ramirez FC, Hepps KS. Endoscopic stent placement for internal and external pancreatic fistulas. *Gastroenterology* 1993;105(4):1213–7.
- James TW, Baron TH. Endoscopic ultrasound-directed transgastric ERCP (EDGE): A single-center US experience with follow-up data on fistula closure. *Obes Surg* 2019;29(2):451–6.