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Living on the EDGE: Preparing for long-term success following EDGE procedure

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Bibliography
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Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard therapeutic procedure for the management of pancreaticobiliary pathology. However, surgically-altered anatomy (SAA) poses a challenge for traditional ERCP, often necessitating the use of additional equipment and techniques to reach the biliary orifice. Roux-en-Y gastric bypass (RYGB) anatomy can be particularly challenging, owing to the length of roux limb that must be traversed in order to reach the major papilla. Several techniques have been developed to help overcome this challenge, including balloon-assisted ERCP (BAE) and laparoscopy-assisted ERCP (LAE); however, the former is associated with suboptimal success rates, and the latter requires significant additional resources and the inherent risks that come with laparoscopic surgery.

Endoscopic ultrasound-directed transgastric ERCP (EDGE), in comparison, is a completely endoscopic procedure that uses a lumen-apposing metal stent (LAMS) to create a gastrogastric (GG) or jejunogastric fistula, bridging the gastric pouch with the excluded stomach and, thus, allowing for more conventional ERCP. Since its first description in 2015, published data on EDGE have demonstrated excellent technical and clinical success rates (91–100%) [1–3]; however, data on long-term outcomes, in particular regarding the incidence and metabolic consequences of persistent GG fistulas, have been limited.

In this issue of Endoscopy International Open, Kedia and colleagues performed an international, multicenter, retrospective review of outcomes following EDGE. A total of 172 patients across 10 institutions were captured between 2015 and 2021, with the most common indication being biliary stricture (82%). Procedural technique varied, with most patients undergoing GG fistula creation (73%), with electrocautery assistance (88%), and with a 20-mm LAMS (81%). Technical (99.4%) and clinical success (95%) were excellent, in line with previous reports. Adverse events (AEs) were not uncommon, with a noteworthy rate of stent migration (16.3%), perhaps in part because of the low rate of stent fixation (19%) in relation to the number of single-session EDGE (44%). During a mean follow-up of 6 months, the LAMS was removed in 83% of patients after a mean dwell time of 69 days, with the fistula closed at the time of stent removal in 69 cases (49%). Among those reassessed, a persistent fistula was identified in 31%, with the sole predictor being LAMS dwell time (86 days in those with persistent fistula vs. 50 days in those without, $P<0.004$). Rates of persistent fistulas were descriptively, but not statistically, lower with fistula closure at time of LAMS removal (25% vs. 37%). Reassuringly, endoscopic closure of all persistent (lasting >8 weeks) GG fistulas was successful.

The authors should be commended for their academic work, which provides further evidence about the role of EDGE in patients with pancreaticobiliary pathology and SAA. Since the first description of EDGE in 2015, several studies have confirmed its excellent procedural success rates. Long-term outcomes, however, have been more heterogenous, with rates of persistent GG fistulas between 0% and 41%% with an uncertain effect on weight regain [4]. Two other groups have reported long-term outcomes in large cohorts of patients undergoing EDGE. In a review of 178 patients undergoing EDGE, Runge and colleagues reported an AE rate of 15.7%, including 19 total cases of LAMS malfunction (10.6%). Of the patients reassessed for a persistent GG fistula, the incidence was nine of 90 (10%) and there

was a trend toward an association with LAMS dwell time (50 days vs. 30 days, $P=0.09$). Of note, no patients with a persistent GG fistula underwent an attempt at fistula closure at the time of LAMS removal. Endoscopic closure of a persistent GG fistula was, however, still successful in all cases [3]. In a more recent case-control study, Ghandour and colleagues matched 25 patients with a persistent GG fistula with 50 patients with no evidence of a fistula. Similarly, no patient or procedural characteristics were predictive of fistula persistence except for LAMS dwell time (127 days in cases vs. 48 days in controls, $P=0.02$), with incidence of a persistent GG fistula increasing by 9.5% for every 7 days the LAMS was left in situ [1]. Patients with persistent GG fistulas gained significantly more weight than those without (>5% total body weight gain; 33.3% v. 10.3%, $P=0.03$). Interestingly, absence of endoscopic closure at the time of LAMS removal was not associated with persistent fistula formation, although the small number of patients who underwent primary closure (26.7%) might be underpowered to detect an effect. Endoscopic closure of persistent fistulas was successful in 73.7% of patients.

EDGE is an attractive alternative to BA-ERCP or LA-ERCP for several reasons. Complete control of the procedure remains with the endoscopist, who, unlike with BA-ERCP, has the full suite of diagnostic and therapeutic accessories available during ERCP. It also avoids the need for laparoscopy, which has been associated with similar rates of AEs, including a 5% to 13% risk of conversion to open laparotomy [2]. With close to a decade of data available on EDGE, several points are worth mentioning. First, despite the optimism about EDGE in published literature, it remains a complex procedure with not infrequent AEs. In the three cohort studies mentioned, the need for additional interventions occurred in 9.3% to 22.3%. Practicing endoscopists should be comfortable with placing bridging stents, in particular, which were needed in 61% of the periprocedural dislodgements in the present study. Given the risks associated with EDGE, it is our practice to first attempt wire-assisted BA-ERCP, in which a percutaneous wire is placed by our interventional radiology colleagues and advanced to the jejunojejunal anastomosis. The guidewire is then grasped with forceps and withdrawn through the enteroscope working channel. This approach facilitates ease of cannulation and additional intervention. At our institution, we tend to use this approach in cases of benign pancreaticobiliary pathology that are likely to be managed with a single endoscopic session (e.g., choledocholithiasis). In cases where the gallbladder remains in situ, strong consideration should still be given to LA-ERCP, given the option of obtaining ductal clearance and removing the gallbladder during a single anesthesia session. Second, if EDGE is pursued, the shorter the LAMS dwell time, the better. LAMS removal must be balanced against the need for repeat interventions, but it has now been demonstrated, in multiple studies, to be a risk factor for GG fistula persistence. Notwithstanding heterogenous data, young patients and those sensitive to weight regain should be counseled about this risk. Finally, if endoscopic closure of the GG fistula is indicated, we would still advocate for early closure using endoscopic suturing or an over-the-scope clip at the time of LAMS removal. Theoretically, attempting endoscopic closure at the time of LAMS removal should maximize the chance of sustained success, because the tract is not yet fully re-epithelized. The current studies are likely underpowered to detect a treatment difference. If successful, primary closure at the time of LAMS removal also obviates the need for routine follow-up, or for repeat endoscopy to attempt or re-attempt closure.

Conclusions

In conclusion, EDGE is an effective option for treatment of pancreaticobiliary pathology in patients with SAA, but it is not without risk, and should be considered one tool among several. Specific factors to consider include the nature of the disease (benign or malignant), the patient's predisposition to weight regain, whether the gallbladder remains in situ, and whether multiple ERCPs will be needed. If pursued, the LAMS should be removed as soon as is feasible and with strong consideration given to concurrent endoscopic closure of the GG fistula.

Competing interests

The authors declare that they have no conflict of interest.

References

[1] Ghandour B, Shinn B, Dawod QM et al. EUS-directed transgastric interventions in Roux-en-Y gastric bypass anatomy: a multicenter experience. Gastrointest Endosc 2022; 96: 630–638

[2] 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: 304–308

[3] Runge TM, Chiang AL, Kowalski TE et al. Endoscopic ultrasound-directed transgastric ERCP (EDGE): a retrospective multicenter study. Endoscopy 2021; 53: 611–618

[4] Krafft MR, Lorenze A, Croglio MP et al. Innocent as a LAMS: Does spontaneous fistula closure (secondary intention), after EUS-directed transgastric ERCP (EDGE) via 20-mm lumen-apposing metal stent, confer an increased risk of persistent fistula and unintentional weight gain? Dig Dis Sci 2022; 67: 2337–2346