Douglas G. Adler MD, FACG, AGAF, FASGE, Series Editor

Transluminal ERCP using a Lumen Apposing Metal Stent in a Patient with Roux-En-Y Gastric Bypass Anatomy: The EDGE Procedure

A Case Report and Review of the Literature

Jay Dubroff

Douglas G. Adler

Case Report

A 57 year old man with a history of a Roux-en-Y gastric bypass developed symptomatic cholelithiasis. The patient underwent laparoscopic cholecystectomy with an intraoperative cholangiogram. The cholangiogram showed filling defects in the distal CBD. A common bile duct exploration was not performed and the patient was referred for endoscopic treatment. Given his anatomy, a transluminal approach was selected for access to his biliary tree.

Using a linear EUS scope, when viewing from the gastric pouch the remnant stomach was identified. A 19g EUS FNA needle was used to access the gastric remnant and fill it with saline mixed with water. (Figure 1) A 0.035" guidewire was passed through the needle and coiled in the gastric remenant. (Figure 2). A 20mm Hot Axios lumen apposing metal stent (LAMS) (Boston Scientific, Natick MA) was passed over the wire

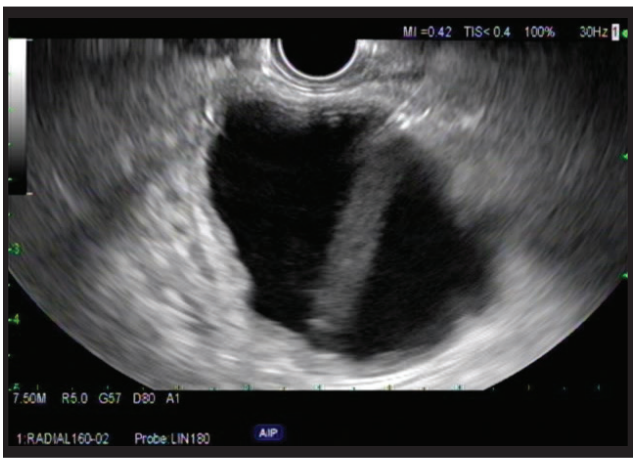

Figure 1. EUS image of needle access to gastric remnant through the pouch.

and, using an electrocautery enhanced catheter, deployed transluminally between the pouch and the gastric remnant (Figure 3). Several days later, the patient returned to the endoscopy suite and the LAMS was widely patent. (Figure 4) The duodenoscope was passed through the LAMS and ERCP was performed in a standard manner

(continued on page 36)

Jay Dubroff MD, Douglas G. Adler MD, FACG, AGAF, FASGE University of Utah School of Medicine, Gastroenterology and Hepatology, Salt Lake City, UT

(continued from page 34)

with biliary sphincterotomy and stone extraction. (Figure 5). Afterwards, the LAMS was removed with a rat-tooth forcep. The gastro-gastro fistula was mature appearing. The fistula was closed using an over the scope clip, with contrast injection into the pouch confirming closure. The patient tolerated all endoscopic procedures well.

ERCP in patients with Roux-en-Y Gastric Bypass

Patients who have undergone Roux-en-Y gastric bypass surgery (RYGB) present a distinctive challenge for the endoscopist seeking to perform endoscopic retrograde cholangiopancreatography (ERCP). Patients with RYBG anatomy are often at greater risk of requiring ERCP as both rapid weight loss,[1] obesity,[2] increased abdominal and visceral adipose[3] predispose patients to augmented risk of gallstone formation. The altered anatomy resulting from RYGB precludes a standard duodenoscope from accessing the second portion of the duodenum through the stomach given the creation of the gastric pouch and a distal jejunal limb.

Endoscopic Options

For ERCP to be performed via oral endoscopy insertion in this setting would require the endoscope to pass through the gastric pouch, Roux limb, jejunojejunostomy and finally up the pancreatobiliary limb to access to the ampulla in a retrograde approach as is typically encountered in patients with Billroth II anatomy.

Generally, oral approaches utilize single balloon enteroscopy (SBE), spiral balloon enteroscopy (SE) or double balloon enteroscopy (DBE), which all rely upon an overtube to provide anchoring to facilitate deeper advancement of the enteroscope.[4,5] All of these endoscopes have limited maneuverability, lack an elevator and have limited accessories, making ERCP difficult even if the ampulla is reached.[4,5] Indeed, balloon enteroscopy guided ERCP have less than optimal reported success rates with one multicenter study indicating 60% success rate for SBE, 63% for DBE and 65% for SE.[4] A more recent large, international study found a similar success rate for SBE and DBE, 63% and 37%, respectively.[6] Despite the technical disadvantages of balloon enteroscopy guided ERCP, this approach is common given the alternatives.[6,7]

Surgical Options

Laparoscopic-assisted ERCP (LA-ERCP) provides another means of performing ERCP in RYGB altered anatomy by creating access via a surgically placed trocar into the remnant stomach, allowing access to the pylorus and the duodenum via the normal route, through which ERCP can be easily performed. Compared to balloon enteroscopy ERCP, LA-ERCP is a superior technique with nearly 100% of cases achieving successful papilla cannulation, or approximately 28% higher than either SBE or DBE.[7,8]

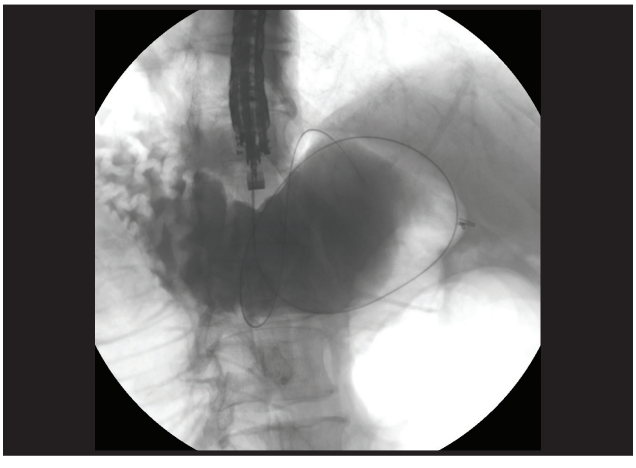

Figure 2. Wire looped in gastric remnant, with gastric remnant containing contrast.

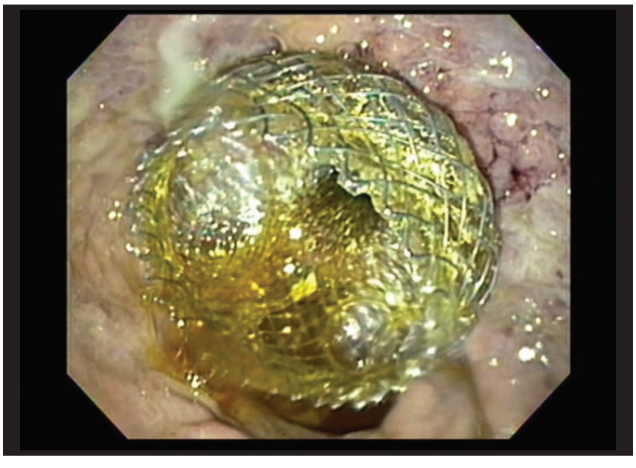

Figure 3. LAMS immediately after deployment spanning the pouch to the gastric remnant. Note the gastrojejunostomy at the most inferior aspect of the pouch.

However, this technique is markedly resource intensive and carries higher associated costs, hospital stays and rates of adverse events.[8,9,10] Relative to balloon enteroscopy, LA-ERCP has been noted to carry an 11% increased risk of adverse events.[8] One study found that even in cases of failed balloon enteroscopy ERCP with subsequent rescue LA-ERCP procedures still incurred a total cost savings of $1015 compared to LA-ERCP alone.[7] This cost savings was diminished if the jejunojejunal limb length was greater than 150cm as this resulted in increased time undergoing balloon enteroscopy ERCP.[7] Additionally, LA-ERCP requires the coordination of endoscopic, anesthesia and surgical teams, which raises potential institution specific challenges for both resource allocation and creates difficulties with arranging physician availability.

EDGE Procedure

The endoscopic ultrasound-directed transgastric ERCP (EDGE) procedure provides an innovative solution to this technically challenging anatomy by deploying a lumen apposing metal stent (LAMS) between the remnant stomach and either the gastric pouch or the proximal jejunal Roux limb.[11,12] The LAMS, placed under EUS guidance, effectively creates a connection to the remnant stomach through which a standard duodenoscope can be passed, allowing ERCP to be performed in the standard direction and manner, and without the need for any special accessories once the remnant stomach has been reached.

First described in 2014,[13] the EDGE procedure is typically performed in two stages; after EUS guided placement of the LAMS to create temporary access via the remnant stomach the stent is typically allowed to mature for several days or even weeks before the second stage and transluminal ERCP are performed.[12] While the initial feasibility study excluded patients with indications for acute biliary intervention,[12] more recently, EDGE procedures have been successfully performed in a single stage for acute indications, such as acute cholangitis.[14] This approach is usually reserved for acute cases in need of urgent biliary intervention. After ERCP is performed, and ampullary access is no longer indicated the LAMS is usually removed with a snare or grasping forceps. The remaining fistula can be closed with endoscopic clips (usually over the scope clips), endoscopic suturing, or a combination thereof. Argon plasma coagulation (APC) has also been proposed as a potential means to support fistula closure by promoting granulation tissue formation, as has been used to close fistulas in other contexts.[15] In some patients, the fistula can be left to close secondarily.

Weight Gain Following EDGE

Weight gain following EDGE procedures has been a concern as creation of a temporary fistula could potentially work against RYGB anatomy and its original indication. Most studies have found that patients undergoing EDGE procedures

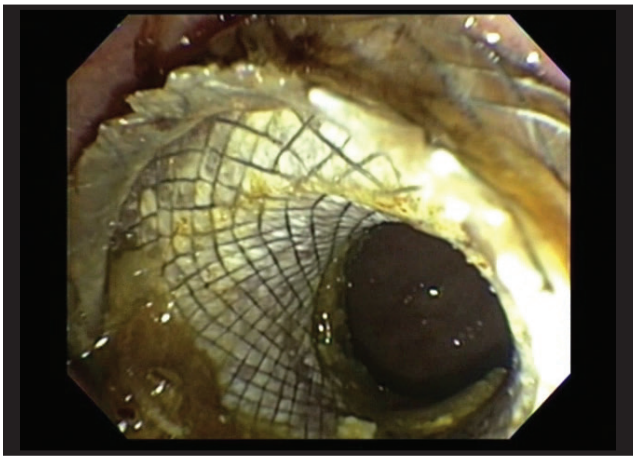

Figure 4. LAMS appearance at 2nd procedure, fully effaced.

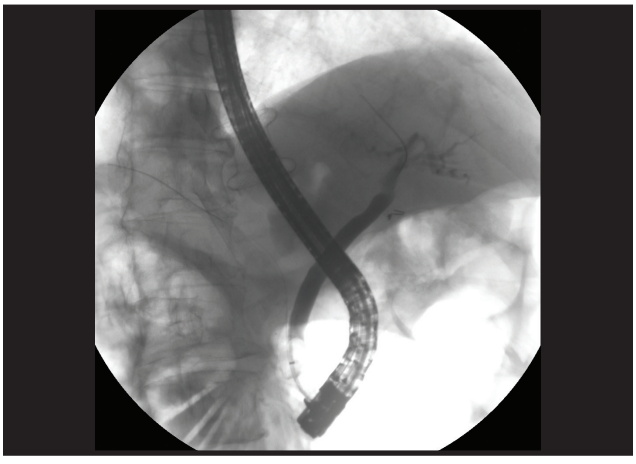

Figure 5. Fluoroscopic image of ERCP performed through LAMS. The duct has been cleared of stones at this point.

experience, on average, a net negative weight loss of approximately 1 to 3 kg.[6,16,17] However, one small retrospective study including nineteen patients showed a mean weight gain of 1.7 kg.[15] The weight loss may be due to the biliary issues needing attention in the first place.

Similar to LA-ERCP, the EDGE procedure carries a high technical success rate that approaches 100%, which is 40% greater compared to enteroscopy guided ERCP.[14] Unlike LA-ERCP, the EDGE procedure has fewer reported adverse events, which have been described as similar to enteroscopy guided approaches; 6.7% versus 10%, respectively.[14] This low adverse event rate may be secondary to the nature of the procedure itself or may be underrepresented given the novelty of the procedure.

Previously described adverse events associated with EDGE approaches include localized PEG site infections,[12] intraprocedure bleeding, fistula persistence and previously described adverse events associated with conventional ERCP.[14] Reports in the literature of fistula persistence following stent removal are rare, and are usually managed endoscopically without surgical intervention.[6,16]

Compared to previously employed modalities for achieving ERCP in RYGB anatomy, the EDGE procedure has emerged as a promising, new technique. Although the EDGE procedure is novel, it seemingly combines the high technical success rate of LA-ERCP with the safety profile of oral balloon enteroscopy approaches. EDGE procedures also result in significantly shorter procedure times as well as length of hospital stays when compared to LA-ERCP.[17] Accordingly, there is a small amount of initial evidence that EDGE, as an initial approach, may be less costly than either LA-ERCP or balloon enteroscopy guided ERCP.[18] While preliminary published evidence of the EDGE procedure is encouraging, future longitudinal studies are needed to further validate the technique's success rate, safety, effect on weight and cost over time.

CONCLUSION

The EDGE procedure provides the endoscopist another potential modality for accomplishing ERCP in the technically challenging RYGB anatomy. No single technique will accommodate all patients and the choice of technique in this context, should be carefully weighed against multiple considerations including clinical circumstances, urgency, need for future repeat ERCP as well as institutional resources and expertise. ■

References

1. Melmer A, Sturm W, Kuhnert B, Engl-Prosch J, Ress C, Tschoner A, Laimer M, Laimer E, Biebl M, Pratschke J, Tilg H, Ebenbichler C.Obes Surg. 2015 Jul;25(7):1171-6. doi: 10.1007/s11695-014-1529-y.
2. Bonfrate L, Wang DQ, Garruti G, Portincasa P. Best Pract Res Clin Gastroenterol. 2014 Aug;28(4):623-35. doi: 10.1016/j.bpg.2014.07.013. Epub 2014 Jul 22. Review.
3. Radmard AR, Merat S, Kooraki S, Ashraf M, Keshtkar A, Sharafkhah M, Jafari E, Malekzadeh R, Poustchi H. Ann Hepatol. 2015 Sep-Oct;14(5):702-9.
4. Shah RJ, Smolkin M, Yen R, Ross A, Kozarek RA, Howell DA, Bakis G, Jonnalagadda SS, Al-Lehibi AA, Hardy A, Morgan DR, Sethi A, Stevens PD, Akerman PA, Thakkar SJ, Brauer BC. Gastrointest Endosc. 2013 Apr;77(4):593-600. doi: 10.1016/j.gie.2012.10.015. Epub 2013 Jan 3.
5. Skinner M, Popa D, Neumann H, Wilcox CM, Mönkemüller K.Endoscopy. 2014 Jul;46(7):560-72. doi: 10.1055/s-0034-1365698. Epub 2014 May 16. Review
6. Bukhari M, Kowalski T, Nieto J, Kunda R, Ahuja NK, Irani S, Shah A, Loren D, Brewer O, Sanaei O, Chen YI, Ngamruengphong S, Kumbhari V, Singh V, Aridi HD, Khashab MA.Gastrointest Endosc. 2018 Sep;88(3):486-494. doi: 10.1016/j.gie.2018.04.2356. Epub 2018 May 3.
7. Schreiner MA, Chang L, Gluck M, Irani S, Gan SI, Brandabur JJ, Thirlby R, Moonka R, Kozarek RA, Ross AS. Gastrointest Endosc. 2012 Apr;75(4):748-56. doi: 10.1016/j.gie.2011.11.019. Epub 2012 Jan 31.
8. da Ponte-Neto AM, Bernardo WM, de A Coutinho LM, Josino IR, Brunaldi VO, Moura DTH, Sakai P, Kuga R, de Moura EGH. Obes Surg. 2018 Dec;28(12):4064-4076. doi: 10.1007/s11695-018-3507-2. Review.
9. Abbas AM, Strong AT, Diehl DL, Brauer BC, Lee IH, Burbridge R, Zivny J, Higa JT, Falcão M, El Hajj II, Tarnasky P, Enestvedt BK, Ende AR, Thaker AM, Pawa R, Jamidar P, Sampath K, de Moura EGH, Kwon RS, Suarez AL, Aburajab M, Wang AY, Shakhatreh MH, Kaul V, Kang L, Kowalski TE, Pannala R, Tokar J, Aadam AA, Tzimas D, Wagh MS, Draganov PV; LA-ERCP Research Group. Gastrointest Endosc. 2018 Apr;87(4):1031-1039. doi: 10.1016/j.gie.2017.10.044. Epub 2017 Nov 10.
10. Banerjee N, Parepally M, Byrne TK, Pullatt RC, Coté GA, Elmunzer BJ. Surg Obes Relat Dis. 2017 Jul;13(7):1236-1242. doi: 10.1016/j.soard.2017.02.005. Epub 2017 Feb 10.
11. Kedia P, Sharaiha RZ, Kumta NA, Kahaleh M. Gastroenterology. 2014 Sep;147(3):566-8. doi: 10.1053/j.gastro.2014.05.045.
12. Kedia P, Kumta NA, Widmer J, Sundararajan S, Cerefice M, Gaidhane M, Sharaiha R, Kahaleh M. Endoscopy. 2015 Feb;47(2):159-63. doi: 10.1055/s-0034-1390771.
13. Kedia P, Sharaiha RZ, Kumta NA, Kahaleh M. Gastroenterology. 2014 Sep;147(3):566-8. doi: 10.1053/j.gastro.2014.05.045. Epub 2014 Jun 26.
14. Bukhari M, Kowalski T, Nieto J, Kunda R, Ahuja NK, Irani S, Shah A, Loren D, Brewer O, Sanaei O, Chen YI, Ngamruengphong S, Kumbhari V, Singh V, Aridi HD, Khashab MA. Gastrointest Endosc. 2018 Sep;88(3):486-494. doi: 10.1016/j.gie.2018.04.2356. Epub 2018 May 3.
15. James TW, Baron TH. Obes Surg. 2018 Oct 10. doi: 10.1007/s11695-018-3531-2.
16. Tyberg A, Nieto J, Salgado S, Weaver K, Kedia P, Sharaiha RZ, Gaidhane M, Kahaleh M.Clin Endosc. 2017 Mar;50(2):185-190. doi: 10.5946/ce.2016.030. Epub 2016 Sep 19.
17. Kedia P, Tarnasky PR, Nieto J, Steele SL, Siddiqui A, Xu MM, Tyberg A, Gaidhane M, Kahaleh M. J Clin Gastroenterol. 2018 Apr 17. doi: 10.1097/MCG.0000000000001037.
18. Wang TJ, Ryou M. Curr Opin Gastroenterol. 2018 Nov;34(6):444-450. doi: 10.1097/MOG.0000000000000474.