EUS-GUIDED TRANSGASTRIC ERCP (EDGE) UNDER CONSCIOUS SEDATION: AN ASSESSMENT OF SAFETY AND PATIENT TOLERANCE IN A LARGE UK HOSPITAL TRUST

Tom Riley[1], Harry Kaltsidis[2], Venkata Lekharaju[1], Javaid Iqbal[1], Sajjad Mahmood[1]
[1]Manchester Foundation trust, Manchester UK
[2]Northern Care Alliance, Manchester UK

Introduction

Roux-en-Y gastric bypass (RYGB) is the most common surgical treatment for obesity, accounting for around half of all bariatric surgeries. Gallstone formation and its complications are increased in the post-operative period due to rapid weight loss, however, ERCP in patients with RYGB anatomy is technically challenging. Post-surgical options for biliary intervention include laparoscopy-assisted ERCP, balloon enteroscopy-assisted ERCP and EUS-directed trans-gastric ERCP (EDGE). Due to relatively low cost, high success rate and more widespread expertise in interventional EUS, EDGE is becoming an increasingly attractive choice of treatment. The procedure utilises lumen-apposing metal stents to form a fistula between the remnant and excluded stomach formed by a RYGB which then allows passage of a duodenoscope in order to perform (Figure 1). In some cases a jejunogastric fistula, rather than gastrogastric fistula is formed, depending on the post-surgical anatomy.

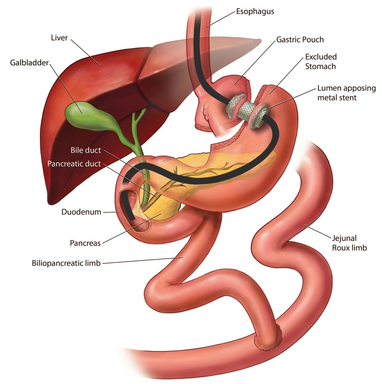

Figure 1. Adapted from Khara et al. Curr Gastroenterol Rep 2021;23:10,

Since the first EDGE in 2014, the most common adverse events include LAMS migration or mis-deployment, persistent fistula (+/- weight gain) and perforation (Table 1). EDGE may be performed in 1 or 2 stages and is most commonly performed under general anaesthesia. Currently, there is little published data regarding EDGE performed under conscious sedation, which if technically successful and safe, may increase its cost-effectiveness and availability. In this case series, we describe the experience of EDGE under conscious sedation within large UK hospital trust, focussing on safety and patient tolerance.

Study name	Type of study	Location	Number of patients	Type of anaesthesia	Most common adverse events		
					Stent migration / mis-deployment	Perforation	Persistent fistula
Bukhari 2018	Multicentre, retrospective	USA, Saudi Arabia	60	General	NR	NR	NR
Kedia 2019	Multicentre, retrospective	USA	29	General	10.3%	3.4%	NR
Kochhar 2020	Multicentre, prospective	USA	26	General	3.8%	0%	30.7%
Runge 2021	Multicentre, retrospective	USA, UK	178	General	7.4%	3.4%	5%
Chiang 2018	Multicentre, retrosecptive	USA	66	General	9%	1.5%	NR
Shin 2020	Multicentre retrospective	USA	128	General	8.6%	NR	NR

NR: not reported

Table 1. Summary of largest EDGE studies

Aim and Methods

The electronic record of all patients in two hospitals within Manchester foundation trust who underwent EDGE were reviewed. The study period was between February 2022 and August 2023. Endoscopists at each hospital had extensive expertise in pancreatobiliary endoscopy and interventional EUS. Patient demographics, indication for ERCP, dose of sedation, procedure time, complication rate, intraprocedural therapy given and repeat ERCP data was collected on review of each patient's record. All patients underwent conscious sedation using fentanyl and midazolam without anaesthetic support. One patient in whom initial EUS was not tolerated and subsequently underwent both stages under general anaesthetic was excluded from this analysis. In terms of procedure technique, a therapeutic linear echoendoscope was used to identify excluded stomach from the remnant stomach. Contrast was injected into the excluded stomach using a 19g FNA needle to confirm position followed by a contrast/saline solution. LAMS insertion was performed using the Hot AXIOS system (Boston scientific). LAMS used were 20mm (n=9) and 15mm (n=1).

Results

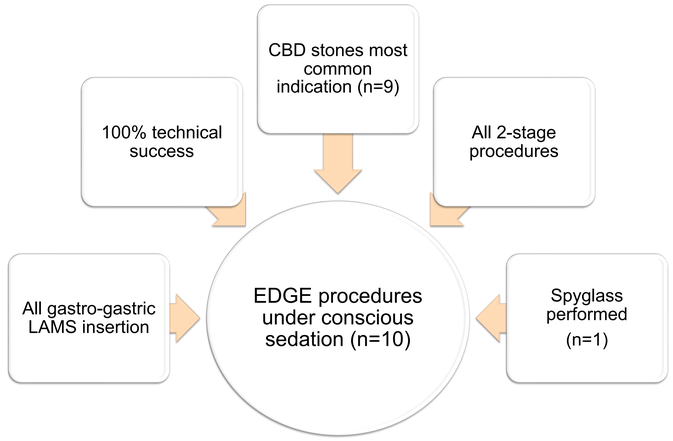

Figure 2. Summary of EDGE procedures performed under conscious sedation

A total of patients underwent EDGE in the study period. All patients tolerated both EUS guided lumen-apposing metal stent (LAMS) insertion and an ERCP under conscious sedation. One patient who required a second ERCP due to incomplete duct clearance underwent a second ERCP under GA due to tolerance and predicted procedure time. All LAMS were placed between the remnant and excluded stomach. In 2 patients LAMS was found to have migrated at ERCP; in both patients the stent was re-inserted through the existing fistula and the patient underwent ERCP at a later date. In total, 7 patients underwent 1 ERCP whilst 3 patients underwent 2 ERCPs due to incomplete ductal clearance at index ERCP. One of these patients underwent cholangioscopy (Spyglass) with electrohydraulic lithotripsy. All procedures were a technical and clinical success. One patient underwent pancreatic biodegradable stent insertion. For the 1st stage (i.e. EUS guided LAMS insertion), mean dose of fentanyl was 67micrograms, whilst mean dose of midazolam was 2.5milligrams. Mean procedure time was 23 minutes. For the 2nd stage (i.e. ERCP), mean dose of fentanyl was 94micrograms, whilst means dose of midazolam was 3.9milligrams. Mean procedure time was 34 minutes. Besides dislodgement of 2 LAMS as described above, there were no adverse events encountered. There were no procedure related readmissions within 30 days for and there were no deaths. There were no significant bleeding events. Mean age of patients was 63 years. There were 9 patients of ASA grade 2 whilst 1 patient was ASA grade 3. A total of 9 patients underwent ERCP for choledocholelithiasis. One patient underwent ERCP for bile leak. Mean time to LAMS removal was 126 days (median 50 days).

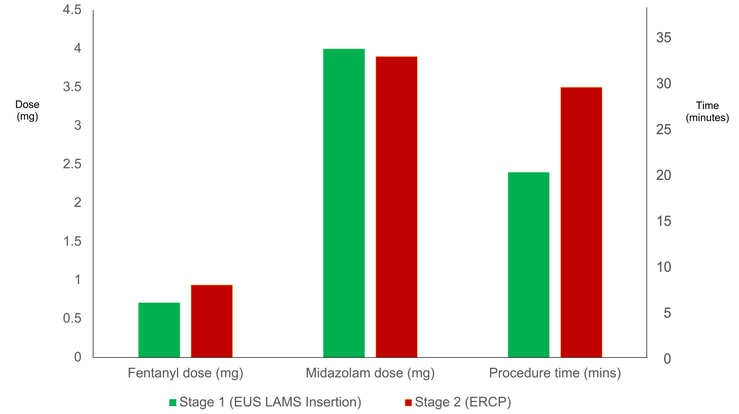

Figure 3. Sedation doses and procedure times in EDGE procedures

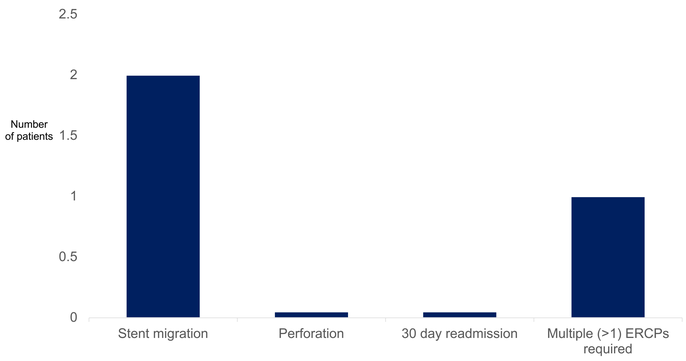

Figure 4. Adverse events in EDGE procedures under conscious sedation

Conclusion

The results from this small study suggest that EDGE is safe and well tolerated under conscious sedation. Furthermore, sedation doses were not excessive and procedure times were acceptable. Technical and clinical success, as well as adverse events, were also comparable to current literature. Cholangioscopy with electrohydraulic lithotripsy (EHL) was well tolerated in 1 patient, suggesting conscious sedation may not prohibit more prolonged biliary intervention. Currently, accepted alternatives to EDGE in patients with RYGB anatomy who require biliary intervention include laparoscopy-assisted ERCP and balloon enteroscopy-assisted ERCP. However, whilst the latter is very challenging, with low technical success rates, the former requires endoscopist and surgical expertise in one session, rendering the procedure logistically difficult. Therefore, if the safety and patient tolerance levels observed in this small case series can be replicated in larger studies, the benefits of EDGE be greatly enhanced when compared to other reasonable alternatives.