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Endoscopic ultrasound-directed transgastric ERCP in patients with Roux-en-Y gastric bypass using lumen-apposing metal stents or duodenal self-expandable metal stents. A European single-center experience

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Conflicts of interest: Manuel Pérez-Miranda is a Boston scientific consultant and speaker and MI Tech consultant. The rest of authors have no conflicts of interest to declare.

ABSTRACT

Introduction: endoscopic ultrasound-directed transgastric ERCP is emerging in Roux-en-Y gastric bypass.

Methods: a review of 14 consecutive patients.

Results: fourteen EUS-directed gastro-gastrostomy/gastro-jejunostomy were performed using lumen-apposing metal stents or duodenal self-expandable metal stents. Single-session ERCP was successful in 9/12 cases and deferred procedures or follow-up in 6/7 cases. Papillary access was obtained in all cases. Dislodgment occurred in 4/19 patients and was handled successfully endoscopically. Transgastric stents were removed after a median of 30 days. No recurrence/fistula were noted after a median

of 256 days post-removal.

Conclusions: duodenal self-expandable and lumen-apposing metal stents can be used for single-deferred endoscopic ultrasound-directed transgastric ERCP in Roux-en-Y gastric bypass.

Keywords: EDGE. Trangastric LAMS. Transgastric SEMS. Bariatric. RYGB.

INTRODUCTION

Roux-en-Y gastric bypass (RYGB) is considered as the gold standard of bariatric surgery (1). Approximately a third of patients who have undergone RYGB develop gallstones related to rapid weight loss following RYGB (2), of whom 5.3% require an ERCP (3).

Two commonly used approaches in RYGB patients for transpapillary biliary interventions are device-assisted enteroscopy (DAE), ERCP and laparoscopically-assisted transgastric ERCP (LA-ERCP) (4). DAE-ERCP is a composite group of procedures that includes different techniques and is limited by forward-viewing optics and limited accessories (5,6). LA-ERCP has impressive technical success rates compared to DAE-ERCP (95% *vs* 63%) but it is associated with higher complication rates (14.5% *vs* 3.1%), higher healthcare costs and logistical difficulties (7-10). Percutaneous approaches for endoscopic access to the excluded stomach were developed in an attempt to overcome these limitations of LA-ERCP (10,11), but never gained widespread acceptance. In contrast, endoscopic ultrasound (EUS)-directed transgastric ERCP (EDGE) was first described in 2014 (11) and has since become increasingly used in the USA as a means of performing ERCP in patients with RYGB. Another advantage over LA-ERCP is that EDGE allows multiple access to the papilla through the stent, for example, to remove previously inserted plastic stents. However, there are no series from outside the USA that have reported on this procedure, which indirectly questions its validity as a first-line approach for this patient population.

The present case series aimed to describe variations in the technique and clinical outcomes of EDGE at a single European center.

PATIENTS AND METHODS

Consecutive patients with RYGB anatomy who underwent EDGE between October 2016 and July 2019 at a Spanish referral unit were identified from prospective database and subsequently reviewed. EUS-directed gastro-gastrostomy (GG) or gastrojejunostomy (GJ) were created with either lumen-apposing metal stents (LAMS) or partially covered duodenal self-expandable metal stents (PC-SEMS) and followed by EDGE, in single or deferred sessions. Clinical outcomes including adverse events (AEs) were recorded, and severity was graded according to the American Society for Gastrointestinal Endoscopy (ASGE) lexicon (12).

Definitions

Complete therapeutic cycle (CTC) was defined as EDGE followed by trangastric stent removal. An index procedure was defined by the creation of EUS-GG/GJ. A single session procedure (SSP) was defined as EUS-GG/GJ and ERCP under the same sedation. Technical success of EUS-GG/GJ was defined as a successful transmural fistula creation using LAMS or PC-SEMS. Technical success of ERCP was defined as the completion of the ERCP procedure, defined as full restoration of bile duct permeability (resolution of the obstruction or leakage) through the endoscopically-created transmural fistula. Clinical success was defined as the resolution of obstructive jaundice.

Procedural description

All procedures were performed under endoscopist directed sedation using midazolam and propofol. A standard therapeutic channel oblique linear echoendoscope (GF-UCT180; Olympus, Europe) was introduced into the gastric pouch, or jejunum (Roux limb) to scan for the gastric remnant. The closest area (puncture point) between the gastric pouch and the gastric remnant was located, excluding vascular structures interposed at the site chosen for puncture with a Doppler. A puncture point between the jejunum and gastric remnant was sought if a gastro-gastric puncture point was not identifiable. An endoscopic ultrasound 19-gauge aspiration needle was passed through the echoendoscope working channel and a EUS directed transmural puncture of the gastric remnant was performed. At least 100 ml of water-soluble contrast medium and sterile water was injected to distend the gastric remnant, under

endosonographic/fluoroscopic visualization (Fig. 1A and B).

In ten cases, electrocautery-enhanced 20 mm LAMS (Hot AXIOS™, Boston Scientific, Marlborough, Massachusetts, United States) or duodenal 20 mm PC-SEMS (Duodenal Hanarostent®, MITech, Seoul, Korea) in four patients were deployed into the gastric remnant across the GI wall under EUS/fluoroscopic guidance (Fig. 1C). An over-the-wire or free-hand insertion technique was used for LAMS according to the endoscopists' preference. Whereas graded over-the-wire dilation with a 6F-cystotome and a 6 mm-balloon was used for PC-SEMS, without stent dilation sutures or anchoring techniques.

Subsequently, a duodenoscope was introduced through the transgastric stent and ERCP was performed, either as SSP or a deferred procedure (Fig. 1D), depending on the endoscopist preference and patient indication. Once access to the papilla was no longer required, transgastric stents (Fig. 2A) were removed using standard polypectomy snares or grasping forceps. Transmural fistula tract closure was facilitated in some patients by over-the-scope clips (OTSC®) (Ovesco, Izasa, Barcelona, Spain) (13) (Fig. 2B). In other cases, 10-Fr plastic double-pigtail stents were placed to induce fistulous hole reduction and were then removed with a polypectomy snare. Surveillance in the case of persistent GG/GJ fistula or recurrence is ongoing in most cases and is therefore not included in this study.

RESULTS

A total of 14 RYGB patients underwent EUS-directed GG or GJ, there were two male cases and the mean (SD) age was 56 (± 9.7) years. An overview of patient and procedure characteristics is summarized in table 1.

EDGE procedure characteristics are summarized in table 2. Papillary access was obtained in all 14 patients (16/19 ERCPs). SSP was only successful in nine of 12 attempted cases (75%), deferred index ERCP were performed in four patients (two failed SSP and two primarily deferred) and the median interval between EUS-GG/GJ and transgastric intervention was 22 days (range = 4-34). Three more patients underwent a second session for hemostasis or biliary stent revision. Eventually, a technical success of ERCP was achieved in 15/16 cases (94%).

Transgastric stents were removed without complications after a median (IQR) of 30 (11-83) days in 13/14 patients (92.8%); all were successfully treated. A closing maneuver was used in six cases, four double pig-tails and two OTSC® in the setting of dislodgement and/or early closure. The 13 CTC patients remained without recurrence or fistula for a median (IQR) of 292 (130-685) days post-removal of transgastric stents. There was one patient with a fistula patency maintained using double pig-tail pending re-ERCP (prior to successful access with incomplete ERCP).

There were four dislodgements (two SSP/two deferred). Three other mild AE were registered, two patients had self-limiting abdominal pain and one post-sphincterotomy bleeding was endoscopically managed.

DISCUSSION

The growing number of patients with surgically altered upper GI anatomy has created new challenges for endoscopists, particularly in the management of pancreaticobiliary disease. EDGE represents an important advancement in patients with RYGB anatomy, as an alternative to surgical and percutaneous approaches. EDGE is technically and clinically successful as it is performed internally by a single team. Furthermore, it is associated with a very high technical success of both EUS-GG/GJ creation and pancreaticobiliary cannulation and its reported AE rate is similar to that of DAE-ERCP (14).

Despite the aforementioned advantages of EDGE, previous studies reported a greater risk of LAMS maldeployment (incorrect placement of the LAMS during EUS-GG) and LAMS dislodgement (slippage of the LAMS during transgastric passage). A retrospective EDGE study (14) reported a rate of stent maldeployment or dislodgement of 25%. Rescue was performed via deployment of a second LAMS placement of a bridging esophageal FC-SEMS and perforation closure with OTSC®. Another USA study (15) reported a LAMS maldeployment rate of 14.3%. Suture for stent anchoring is possible with a new dedicated OTSC®.

In our experience, 20-mm metal stents (FCSEMS or LAMS) allow single-session EDGE without any need for suture-anchoring. There is a definite risk of dislodgement (21%). However, dislodgment seems to depend more on endoscope angulation during

passage rather than on other potential factors. Similar to other studies, we managed this endoscopically, although stent repositioning was used as opposed to a new bridging stent. In our experience, EDGE is an effective option in Roux-en-Y patients, with an acceptable technical success and a low rate of AE.

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Table 1. Patients and procedure characteristics, EUS-directed gastro-gastrostomy or gastro-jejunostomy (GG/GJ) creation (n = 14)

Patient no.	*Age*	*Sex*	*Indication for EDGE*	*Fistula route*	*Type of stent*	*Technical EUS-GG success*	*Incidents*
1	55	Female	Choledocolithiasis	GG	SEMS*	Yes	No
2	62	Female	Bile leakage	GJ	LAMS†	Yes	Duodenal perforation closed by OTSC®
3	63	Male	Cholangitis	GG	SEMS*	Yes	No
4	57	Female	Choledocolithiasis	GG	SEMS*	Yes	No
5	64	Female	Choledocolithiasis	GG	LAMS†	Yes	No
6	45	Female	Other	GG	LAMS†	Yes	No
7	49	Male	Jaundice	GJ	LAMS†	Yes	No
8	51	Female	Acute pancreatitis	GG	LAMS†	Yes	No
9	67	Female	Cholangitis	GG	SEMS*	Yes	No
10	31	Female	Choledocolithiasis	GJ	LAMS†	Yes	No
11	46	Female	Acute pancreatitis	GJ	LAMS†	Yes	No
12	48	Female	Cholangitis	GJ	LAMS†	Yes	No
13	64	Female	Choledocolithiasis	GG	LAMS†	Yes	No
14	62	Female	Choledocolithiasis	GG	LAMS†	Yes	No

SEMS: self-expandable metal stent; LAMS: lumen apposing metal stent; OTSC: over-the-scope clip.

Table 2. Procedure characteristics transgastric ERCP, transgastric stent removal and GG fistula closure

Patient no.	SSP attempted	No. of ERCP required	Technical success of ERCP	Clinical success	Incidents	LAMS removal	Fistula closure method
1	Yes	1	Yes	Yes	No	Yes	OTSC
2	Yes	3	Yes	Yes	No	Yes	OTSC + pigtail
3	No	1	Yes	Yes	Dislodgement OTSC closure	Yes	None
4	Yes	1	Yes	Yes	No	Yes	Pigtail
5	Yes	1	Yes	Yes	No	Yes	None
6	Yes	2	Aborted by friction	No	No	No	
7	Yes	1	Yes	Yes	No	Yes	None
8	Yes	2	Yes	Yes	2 dislodgements Resolved by relocation	Yes	Pigtail
9	No	1	Yes	Yes	No	Yes	Pigtail
10	Yes	1	Yes	Yes	No	Yes	Pigtail
11	Yes	2	Yes	Yes	No	Yes	None
12	Yes	1	Yes	Yes	No	Yes	None
13	Yes	1	Yes	Yes	Dislodgement Resolved by relocation	Yes	Pigtail
14	Yes	1	Yes	Yes	No	Yes	None

OTSC: over-the-scope clip.

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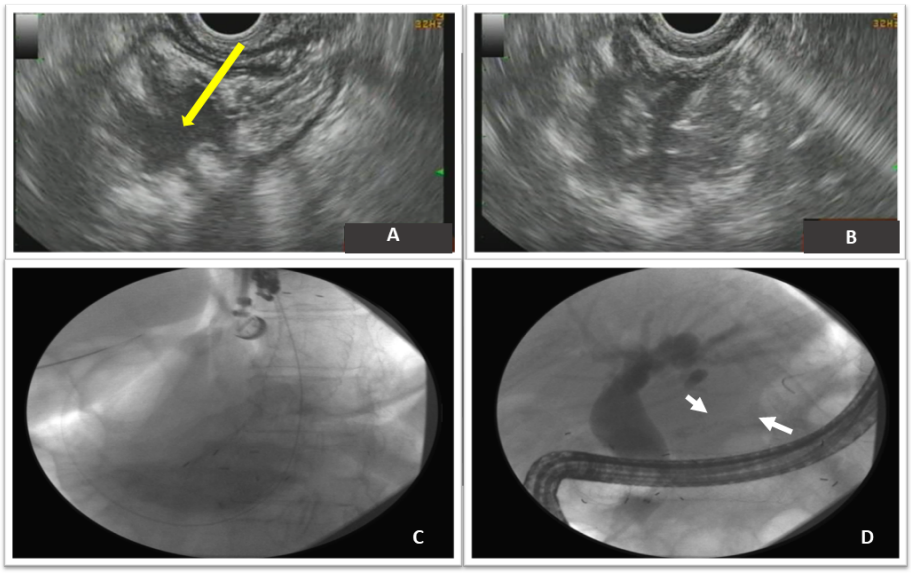

Fig. 1. A. Endoscopic ultrasound (EUS)-guided image showing the gastric remnant (yellow arrow) from the gastric pouch in a RYGB patient. B. EUS-guided image showing a puncture of the excluded stomach remnant with a 19G EUS-fine needle aspiration (FNA). C. Fluoroscopic image of a transgastric 20 mm duodenal PC-SEMS. White arrows indicate a waist in the gastro-gastric anastomosis D. Fluoroscopic image of the ERC through the deployed a transgastric stent.

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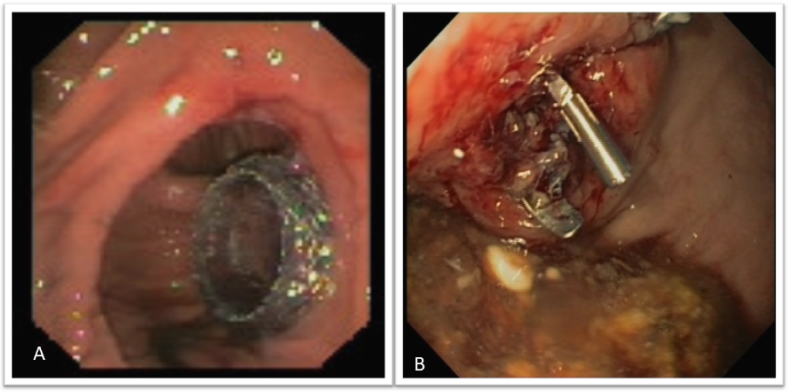

Fig. 2. A. Endoscopic image showing EUS-guided gastro-jejunostomy performed with a 20 mm lumen apposing metal stent. B. Endoscopic image showing the fistula closure with an over-the-scope clip.