

# EN-580T in Clinical Studies

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**EUS-Directed Transgastric ERCP Versus Double Balloon Enteroscopy-Assisted ERCP in Patients with Roux-En-Y Gastric Bypass Anatomy: A Single Center Experience**

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Abstract # Su1427 from DDW® 2020



**Background:** In a time of obesity epidemic, bariatric surgical treatment by Roux-en-Y gastric bypass (RYGB) has become the standard of care. To date, no single universal algorithmic approach for ERCP has been identified as preferential for these patients. Our institutional protocol has been to use the double balloon enteroscopy– assisted ERCP (DBE-ERCP) as first line and to reserve EUS-directed transgastric ERCP (EDGE) for cases in which adjunctive techniques are needed that cannot be performed through an enteroscope.

**Aims:** To compare the indications, techniques and technical outcomes of DBE-ERCP versus EDGE in patients with prior bariatric RYGB anatomy and native papilla.

**Methods:** Retrospective analysis of patients with RYGB anatomy who underwent ERCP between 1/2014 and 1/2019 by a single experienced endoscopist. Data on demographics, indications, procedure success, and adverse events (AE) according to ASGE lexicon were collected. Procedure success was defined when all the following were achieved: reaching the papilla, cannulating the desired duct and providing endoscopic therapy when indicated. Fistula was created using lumen apposing metal stents (LAMS). Wilcoxon Rank Sum was used to compare continuous variables. Z-Test of proportions was used to compare differences in percentages.

**Results:** A total of 41 patients (median age 65, 78% female) underwent a total of 72 ERCP (52% outpatient procedures): 9 (22%) underwent EDGE and 32 (78%) underwent DBE-ERCP. The indications for ERCP in EDGE vs DBE-ERCP were biliary (89% vs 88%), pancreatic (11% vs 3%), and both (0% vs 9%), respectively (Table 1). Baseline characteristics of patients were similar except for average stone size on pre-op imaging which was significantly higher in EDGE (13.25 mm  $\pm$  3.3125) vs DBE-ERCP (8.917 mm  $\pm$  2.556)  $p < 0.001$ . The rate of total therapeutic success was higher in the EDGE vs. DBE-ERCP group (100% vs. 84.4%,  $p = 0.066$ ) (Table 2). Total procedure time (including EUS-GG/JG) was shorter in patients who underwent EDGE vs DBE-ERCP (49.18 min vs. 67.2 min,  $p = 0.045$ ). Although numerically more AE's were observed with EDGE procedure vs DBE-ERCP (11% vs 6%,  $p = 0.53$ ), this failed to reach statistical significance. All patients had spontaneous fistula closure after LAMS removal verified by upper GI series 14 days later.

**Conclusion:** In centers with expertise, DBE-ERCP should remain the preferred initial approach in patients with RYGB anatomy given its high success rate and low risk for adverse events. While EDGE has higher therapeutic success, it carries high risk for complications related to LAMS dislodgement and leads to delays of ERCP in order to allow for fistula maturation. However, patients with large biliary stones  $> 1$ cm are better suited for EDGE as an initial step due to the high likelihood of requiring lithotripsy techniques which are not technically feasible with long DBE.

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	EUS-GG/JG-ERCP (n=9)	DBE-ERCP (n=32)	P-value
<b>Total number of ERCPs performed</b>	20	52	
<b>Type of endoscope used for ERCP</b>			
• Therapeutic duodenoscope	9 (100)	0	
• Long double-balloon enteroscope	0	32 (100)	
<b>Mean total number of ERCP per patient</b>	2.22	1.625	0.12
<b>Demographics</b>			
<b>Age (year, mean ±SD)</b>	69.7 (9.71)	64.5 (10.84)	0.18
<b>Sex (female, %)</b>	8 (88.9)	24 (75.0)	0.37
<b>Weight before ERCP (kg, ±SD)</b>	80.56 (18.58)	79.04 (17.86)	0.81
<b>ASA:</b>			
• II	1 (11.1)	21 (65.6)	0.004
• III	7 (77.8)	11 (34.4)	0.02
• IV	1 (11.1)	0 (0.0)	0.056
<b>Anatomy</b>			
• Roux-en-Y gastric bypass (n, %)	9 (100.0)	32 (100.0)	
• Native papilla (n, %)	8 (88.9)	32 (100.0)	0.056
• Prior cholecystectomy (n, %)	6 (66.7)	21 (65.6)	0.95
• History of abdominal adhesions (n, %)	1 (11.1)	11 (34.4)	0.17
<b>Prior failed pancreatobiliary</b>			
• No prior attempts (n, %)	5 (55.6)	30 (93.8)	0.004
• DBE ERCP (n, %)	4 (44.4)	2 (6.25)	0.004
<b>Main ERCP Indications</b>			
• Biliary (n, %)	8 (88.9)	28 (87.5)	
• Pancreatic (n, %)	1 (11.1)	2 (3.12)	
• Both (n, %)	0 (0.0)	2 (9.38)	
<b>Biliary Indication of ERCP</b>			
• Cholecholelithiasis (n, %)	7 (77.8)	13 (40.63)	
• Suspected papillary stenosis (n, %)	1 (11.1)	11 (34.38)	
• Dilated duct (n, %)	0 (0.0)	3 (9.38)	
• Abnormal LFTs (n, %)	0 (0.0)	2 (6.25)	
<b>Pancreatic Indications</b>			
• Pancreatic Tumor (n, %)	1 (11.1)	1 (3.12)	0.33
• Recurrent Pancreatitis (n, %)	0 (0.0)	1 (3.12)	0.33
• Ampullary Lesion (n, %)	0 (0.0)	1 (3.12)	0.59
<b>Rescue procedure after failed ERCP</b>			
• EUS-GG/JG ERCP (n, %)	0 (0.0)	4 (7.69)	0.2
• Laparoscopy assisted ERCP (n, %)	0 (0.0)	1 (1.92)	0.53
• Repeat DBE-ERCP (n, %)	0 (0.0)	1 (3.12)	0.59
• Cholangitis (n, %)	2 (22.2)	9 (28.1)	>0.99
<b>Average stone size on pre-op imaging (mm ±SD)</b>	13.25 (3.3125)	8.917 (2.556)	<0.001

	EUS-GG/JG-ERCP (n=9)	DBE-ERCP (n=32)	P-value
<b>Overall ERCP therapeutic success, n (%)</b>	9 (100)	27 (84.4)	0.066
• Success at reaching the papilla (all procedures, %)	100.0	96.0	0.36
• Successful cannulation (all procedures, %)	100.0	89.0	0.12
• Contract enhancement of targeted duct (all procedures, %)	100.0	89.0	0.12
• Technical therapeutic success rate (all procedures, %)	20/20 (100.0)	44/52 (85.0)	0.066
<b>Mean Procedure time [EUS-GG/JG + ERCP], (min, ±SD)</b>	49.18 (37.22)	67.2 (32.2)	0.045
<b>Mean LOS, (days, ±SD)</b>	3.37 (3.26)	5.04 (2.54)	0.02
<b>Reason for failed procedure— all procedures</b>			
• Endoscopy failure: Unable to reach JJ anastomosis	0	2	
• Cannulation failure due to acute bowel angulation	0	4	
• Sphincterotomy failure due to angulation	0	1	
• Stone extraction failure due to large stone	0	1	
<b>Fistula creation: EUS-GG/JG</b>			
<b>Technical success (n, %)</b>	9 (100.0)		
<b>Route of fistula creation:</b>			
• EUS-Gastrostomy (GG) (n, %)	8 (72.73)*		
• EUS-Jejunogastrostomy (JG) (n, %)	3 (27.27)*		
<b>Type of LAMS</b>			
• Cautery assisted (hot) (n, %)	11 (100)*		
• Non-cautery assisted (cold) (n, %)	0 (0.0)		
<b>Timing of ERCP relative to fistula creation</b>			
• At time of fistula creation (n, %)	1 (9.09)		
• After fistula creation (n, %)	10 (90.91)		
• Median time of ERCP relative to fistula creation (days)	18.6		
<b>Method of fistula closure: Spontaneous (n, %)</b>	9 (100.0)		
<b>Verification of fistula closure: UGI 2 weeks post removal (n, %)</b>	9 (100.0)		
<b>Mean procedure time of EUS-GG/JG, (min ±SD)</b>	39.54 (10.1)		
<b>Mean weight change (while maintaining fistula) (kg, ±SD)</b>	0.95 (8.65)	-0.33 (4.32)	0.41
<b>Interventions performed (all procedures)</b>			
• Fistula Creation: EUS-GG/JG	11*	0	
• Biliary Sphincterotomy	12	28	
• Biliary Stent Placement	12	31	
• Stone Extraction	9	10	
• Cholangioscopy (SPY)	5	0	
• Electrohydraulic Lithotripsy (EHL)	4	0	
• Stent Removal	5	16	
• Biliary Sphincteroplasty	4	6	
• Pancreatic Stent Placement	6	6	
• EUS-FNA Pancreatic Mass	1	0	
• Pancreatic Sphincterotomy	1	2	
<b>ERCP performed outpatient (all procedures, %)</b>	12/20 (60.0)	25/52 (48.08)	0.63
<b>Mean total number of procedures [EUS-GG/JG + ERCP]</b>	3.44	1.625	0.36
<b>Adverse Events</b>			
<b>Mild: (n, %)</b>	1 (11.11)	2 (6.25)	0.53
• < 3 units prbc transfusion (n, %)	0 (0.0)	2 (6.25)	>0.99
• Post-ERCP pancreatitis (n, %)	1 (11.11)	0 (0.0)	0.24
• Aspiration pneumonia (n, %)	0 (0.0)	0 (0.0)	
• Hemorrhage (n, %)	0 (0.0)	0 (0.0)	
• Urinary tract infection (n, %)	0 (0.0)	0 (0.0)	
• Perforation (n, %)	0 (0.0)	0 (0.0)	
• LAMS migration (n, %)	0 (0.0)	0 (0.0)	
<b>Moderate (n, %)</b>	0 (0.0)	0 (0.0)	
<b>Severe (n, %)</b>	0 (0.0)	0 (0.0)	
<b>Death (n, %)</b>	0 (0.0)	0 (0.0)	

**Table 1. (far left):** Patient demographics and ERCP indications for EUS-GG/JG vs. DBE-ERCP

SD, standard deviation

**Table 2. (at right):** Interventions Performed and Success Rate of DBE-assisted ERCP vs. EUS-GG/JG ERCP (EDGE)

\* Two patients required repeat fistula creation for biliary access after fistula closure

## FUJIFILM SUMMARY

Patients with prior gastric bypass surgery often seek ERCP treatment for the removal of gallstones. This proves challenging to physicians because the anatomical changes to the pathway to the duodenum make passage of a duodenoscope difficult. Physicians need to find alternate ways to perform ERCP on these patients. This study looks at two options, to assess the outcomes of performing ERCP using a Double Balloon endoscope vs. performing an EDGE procedure, which utilizes EUS to access the ducts through the stomach.

### Key Takeaways:

1. This study was conducted using the long Double Balloon Enteroscope (EN-580T). The EI-580BT was not commercially available at the time of the study.
2. Both procedures were found to show equivalence with a high therapeutic success (100% for EDGE vs. 84.4% for DBE, p=0.066).
3. The EDGE procedure time was lower (49.18 min for EDGE vs. 67.2 min for DBE, p=0.045).
4. More adverse events were observed with EDGE procedure vs DBE-ERCP, but it was not statistically significant (11% for EDGE vs 6% for DBE, p=53).

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