# **ORIGINAL ARTICLE: Clinical Endoscopy**

# Multicenter evaluation of the clinical utility of laparoscopy-assisted ERCP in patients with Roux-en-Y gastric bypass



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**Background and Aims:** The obesity epidemic has led to increased use of Roux-en-Y gastric bypass (RYGB). These patients have an increased incidence of pancreaticobiliary diseases, yet standard ERCP is not possible because of surgically altered gastroduodenal anatomy. Laparoscopy-assisted ERCP (LA-ERCP) has been proposed as an option, but supporting data are derived from single-center small case series. Therefore, we conducted a large multicenter study to evaluate the feasibility, safety, and outcomes of LA-ERCP.

**Methods:** This is a retrospective cohort study of adult patients with RYGB who underwent LA-ERCP in 34 centers. Data on demographics, indications, procedure success, and adverse events were collected. Procedure success was defined when all the following were achieved: reaching the papilla, cannulating the desired duct, and providing endoscopic therapy as clinically indicated.

**Results:** A total of 579 patients (median age, 51; 84% women) were included. Indication for LA-ERCP was biliary in 89%, pancreatic in 8%, and both in 3%. Procedure success was achieved in 98%. Median total procedure time was 152 minutes (interquartile range [IQR], 109-210), with a median ERCP time of 40 minutes (IQR, 28-56). Median hospital stay was 2 days (IQR, 1-3). Adverse events were 18% (laparoscopy related, 10%; ERCP related, 7%; both, 1%) with the clear majority (92%) classified as mild/moderate, whereas 8% were severe and 1 death occurred.

**Conclusions:** Our large multicenter study indicates that LA-ERCP in patients with RYGB is feasible with a high procedure success rate comparable with that of standard ERCP in patients with normal anatomy. The ERCP-related adverse events rate is comparable with conventional ERCP, but the overall adverse event rate was higher because of the added laparoscopy-related events. (Gastrointest Endosc 2018;87:1031-9.)

(footnotes appear on last page of article)

The current obesity epidemic has consequently led to an increase in bariatric surgery, with more than 100,000 procedures per year being performed in the United States alone.<sup>1</sup> In recent years the most common bariatric surgery has been and continues to be Roux-en-Y gastric bypass (RYGB).<sup>1,2</sup> This operation excludes most of the stomach (ie, remnant stomach) and all of the duodenum, making conventional duodenoscopy and per-oral ERCP impossible. Importantly, ERCP is commonly indicated in RYGB patients because of an increased risk of choledocholithiasis and gallstone pancreatitis, especially in the setting of rapid weight loss after bariatric surgery.<sup>3,4</sup> Furthermore, several reports have shown increased rate of pancreaticobiliary malignancies in obese patients.<sup>5,6</sup> Various alternative ERCP approaches for patients with RYGB have been described. Per-oral deep enteroscopy techniques, such as single-balloon, double-balloon, and spiral enteroscopy, are minimally invasive, but therapeutic success is far lower compared with standard ERCP. This inferiority is because of the inability to reach the papilla secondary to the surgically altered gastroduodenal anatomy, failure to cannulate the desired duct, or failure to provide therapy because of the change of orientation of the papilla, difficult endoscope position, use of forward optics, lack of elevator, small therapeutic channel, and/or limited availability of devices.<sup>7-13</sup>

Percutaneous access to the gastric remnant by interventional radiology has been described but has not gained wide acceptance because it is impractical for urgent cases due to the requirement of serial dilation and track maturation.<sup>14-16</sup> This is further hindered by the inconvenience of needing a gastrostomy tube (G-tube) and the technical difficulties related to the inability to distend the stomach remnant with air.<sup>6,17</sup> EUS-guided transgastric ERCP is another innovative approach.<sup>18,19</sup> However, this methodology has several cited limitations, most prominently the potential for creating a permanent gastrogastric fistula that compromises the integrity of the RYGB and the need for a 2-stage procedure.<sup>20-22</sup>

Laparoscopy-assisted ERCP (LA-ERCP) is accomplished by placing a trocar in the remnant stomach under laparoscopic guidance followed by insertion of the conventional duodenoscope through the trocar to reach the ampulla of Vater. ERCP is then carried out in a standard fashion. The main appeal of LA-ERCP is that it is a single-stage procedure and affords the use of standard ERCP equipment, including doudenoscope and accessories. This anticipates a very high procedural success, similar to patients with normal upper GI tract anatomy. LA-ERCP was first described in 2002, and since then only a few small singlecenter case series have been published showing high success rates and low adverse events rates.<sup>6,7,23-25</sup> Despite these early encouraging results, the role of LA-ERCP has not been well defined because of a lack of high quality data. Therefore, the aim of this study was to evaluate a large multicenter cohort to assess the feasibility, safety, and outcomes of LA-ERCP in patients with RYGB.

### **METHODS**

This retrospective multicenter cohort study included adult patients with RYGB who underwent LA-ERCP between 2005 and 2016. The study was approved by the institutional review board of each of the participating centers, with the University of Florida serving as the central coordinating center. All authors had access to the study data and reviewed and approved the final manuscript.

### Procedure

Procedure-informed consents for both ERCP and laparoscopy were obtained from all patients. All procedures were performed in the operating room or designated sterile endoscopy room by both a laparoscopy and an endoscopy team with the patient in supine position under general anesthesia. Percutaneous access with a trocar to the remnant stomach was established laparoscopically. Therapeutic duodenoscope was subsequently inserted through the indwelling trocar into the remnant stomach and advanced into the duodenum. ERCP was then carried out in a standard fashion using a conventional duodenoscope and accessories. The gastrostomy and the percutaneous tracts were closed surgically at the end of the procedure or a G-tube left in place in cases where ERCP might be needed again in the future. All patients were inpatients or were admitted for observation postoperatively.

### Data collection

A standardized data entry form was distributed through secured e-mail across all centers to collect information on baseline characteristics and intraprocedural and follow-up data. Baseline characteristics included patient demographics, American Society of Anesthesiologists class, year and type of RYGB surgery (laparoscopic vs open), cholecystectomy status (before LA-ERCP, at the time of LA-ERCP, after the LA-ERCP), prior failed attempts at pancreaticobiliary interventions, and indication and type of LA-ERCP (biliary, pancreatic, or both). Procedure-related data included the use of perioperative antibiotics, total procedure time, ERCP time, the types of ERCP therapeutic interventions (biliary sphincterotomy, dilation of the papilla, dilation of stricture, biliary or pancreatic stent placement or extraction, stone/ sludge removal), need for conversion from laparoscopic to open surgery, G-tube placement, and length of hospital stay.

### Definitions

Procedure success was defined when all the following were accomplished: reaching the ampulla of Vater, cannulation of the desired duct, and performing the desired therapeutic maneuvers as clinically indicated. Total procedure time was measured from the initial surgical incision to final surgical closure. ERCP time was measured from the scope insertion in the trocar to the scope withdrawal.

Adverse events were classified as either ERCP related (pancreatitis, cholangitis, sphincterotomy-related perforation, postsphincterotomy bleeding, stent migration, or others) or laparoscopy related (bleeding, gastric remnant site entry leak, gastric tube site infection, perforation, cardiovascular, other infection, or others). Severity of adverse events was classified using the American Society for Gastrointestinal Endoscopy lexicon as mild, moderate, severe, and death.<sup>26</sup>

### Statistical analysis

Data were analyzed using SPSS version 18.0 software (SSPS Inc, Chicago, Ill). Mean, median, and interquartile ranges (IQRs) were calculated. Categorical data were analyzed using the Fisher exact and  $\chi^2$  tests, and

Center name	City	State	Country	No. of patients
Cirurgia Digestiva e Obesidade	Salvador	Bahia	Brazil	26
Cleveland Clinic	Cleveland	ОН	USA	52
Dartmouth-Hitchcock Medical Center	Lebanon	NH	USA	14
Duke University	Durham	NC	USA	28
Fox Chase Cancer Center	Philadelphia	PA	USA	6
Geisinger Medical Center	Danville	PA	USA	49
Indiana University	Indianapolis	IN	USA	24
Mayo Clinic Scottsdale	Scottsdale	AZ	USA	7
Medical College of Wisconsin	Milwaukee	WI	USA	11
Medical University of South Carolina	Charleston	SC	USA	12
Methodist Dallas Medical Center	Dallas	ТХ	USA	23
Northwestern University	Chicago	IL	USA	6
Oregon Health & Science University	Portland	OR	USA	17
Poudre Valley Hospital	Fort Collins	СО	USA	10
Stony Brook University School of Medicine	Stony Brook	NY	USA	5
The University of Ottawa	Ottawa	ON	CA	3
Thomas Jefferson University	Philadelphia	PA	USA	8
University Hospitals Case Medical Center	Cleveland	ОН	USA	8
University of California Los Angeles (UCLA)	Santa Monica	CA	USA	16
University of Colorado, Denver	Denver	CO	USA	36
University of Florida	Gainesville	nesville FL		20
University of Maryland School of Medicine	Baltimore	MD	USA	30
University of Massachusetts	Worcester	MA	USA	28
University of Michigan	Ann Arbor	MI	USA	14
University of Rochester Medical Center	Rochester	NY	USA	8
University of São Paulo Medical School & Gastro-Obeso-Center Institute	São Paulo	São Paulo	Brazil	14
University of South Alabama	Mobile	AL	USA	2
University of South Florida	Tampa	FL	USA	8
University of Virginia	Charlottesville	VA	USA	10
University of Washington	Seattle	WA	USA	17
Virginia Mason Medical Center	Seattle	WA	USA	28
Virginia Tech Carilion School of Medicine	Roanoke	VA	USA	9
Wake Forest Baptist Medical Center	Winston Salem	NC	USA	16
Yale School of Medicine	New Haven	СТ	USA	14

continuous data were analyzed using the *t* test for normally distributed variables and the Mann-Whitney U test for non-normally distributed variables.

## RESULTS

Thirty-four centers participated in this study (31 from the United States, 2 from Brazil, and 1 from Canada; Table 1). A total of 579 patients with RYGB (84% women) with a median age of 51 years (IQR, 43-61) underwent LA-ERCP during the study period (2005-2016) (Table 2). The number of procedures performed per year increased noticeably after 2011, reflecting the increased adoption of this approach (Fig. 1).

Indications for LA-ERCP are outlined in Table 2. Main indications for procedures were biliary in 89%, pancreatic in 8%, and both biliary and pancreatic in 3% of the cases. Approximately half (47%) of all biliary interventions were because of choledocholithiasis, whereas acute pancreatitis (93%) was the most common indication for pancreatic interventions. The most common therapeutic interventions

# TABLE 2. Demographics and other clinical factors of the included population

	No. of patients	Percent of patients
Age quartile		
<42	144	25
42-51	148	26
52-61	157	27
>61	130	22
Gender		
Female	488	84
Male	91	16
ASA class		
1	4	1
2	242	44
3	291	53
4	14	3
Type bariatric surgery		
Laparoscopic RYGB	340	68
Open RYGB	160	32
Years since RYGB, quartiles		
<3	146	30
3-6	106	22
7-10	125	25
>10	116	24
Cholecystectomy		
Before ERCP	423	78
At the time of ERCP	114	21
After ERCP	6	1
Prior failed attempts of pancreaticobiliary interventions	/	
No prior attempt reported	438	76
Enteroscopy ERCP	109	19
РТС	26	4
Laparoscopic bile duct exploration	5	1
Open bile duct exploration	1	0
Main indication		
Biliary	518	89
Pancreatic	45	8
Both	16	3
Biliary indication		
Biliary stone	254	47
Suspected papillary stenosis	102	19
Dilated duct	75	14
Abnormal liver function tests	46	9
Bile duct stricture	20	4
Post cholecystectomy pain	10	2
Others/abdominal pain	9	2
	(continued on t	the next column)

TABLE 2. Continued

No. of patients	Percent of patients
7	1
7	1
3	1
2	0
56	93
3	5
1	2
89	15
489	85
574	99
5	1
	patients 7 7 3 2 56 3 1 89 489 489

ASA, American Society of Anesthesiologists; RYGB, Roux-en-Y gastric bypass; PTC, percutaneous transhepatic cholangiogram.

were biliary sphincterotomy (96%), stone extraction (44%), and pancreatic stent placement (15%) (Table 3). Eleven patients (26%) among those with pancreatic preoperative indication had stone extraction. Concomitant laparoscopic cholecystectomy was performed in 21% of the cases, and gastric tube was left in place in 17% of the cases for possible subsequent intervention(s).

Overall procedure success was achieved in 98%. The papilla was successful reached in 99% and cannulating the desired duct in 98% of the cases (bile duct cannulation, 99%; pancreatic duct cannulation, 91%). The success rate in performing the desired intervention was 98% (biliary, 99%; pancreatic, 89%). Median total procedure time (laparoscopy + ERCP) was 152 minutes (IQR, 109-210), whereas median ERCP time was 40 minutes (IQR, 28-56). Median total procedure time was significantly longer for patient with a history of open versus laparoscopic RYGB (181 vs 147 minutes, P = .009). Median length of hospital stay was 2 days (IQR, 1-3).

Adverse events were reported in 106 of 579 patients (18%). Laparoscopy-related adverse events were reported in 10%, whereas ERCP-related adverse events were reported in 7% of the patients. One percent of the patients had adverse events related to both laparoscopy and ERCP. The most common laparoscopy-associated adverse event was postoperative infections in 24 of 579 patients (4.1%), whereas the most common ERCP-related adverse event was acute pancreatitis in 42 of 579 patients (7.4%) (Table 4). The rate of pancreatitis varied by the LA-ERCP main indication, and was 7% among those who had the procedure for biliary indications. Among those with pancreatic and both (biliary and pancreatic) indications, the rate of pancreatitis was 11% and 13%, respectively

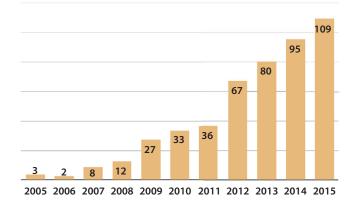


Figure 1. Number of procedures per year.

(P = .3). Regarding the severity of these events, 60% were classified as mild and 31% as moderate, whereas 8% were classified as severe; 1 death was reported. In 5% of the cases ERCP was carried out after conversion to open laparotomy to gain access to the remnant stomach.

We explored the factors associated with laparoscopic versus ERCP-related events by series of univariate analysis as presented in Table 5. Longer duration since RYGB showed a trend toward higher laparoscopy-related events (<3 years had 8%, 3-6 years had 10%, 6-9 years had 10%, and those with >10 years since RYGB had 16%; P = .516). Conversion to open laparotomy was associated with significant increase in the risk of laparoscopy-related events (24% vs 10%, P = .045). Leaving a G-tube in place at the end of the procedure was also significantly associate with increased risk of adverse events (17% vs 9%, P = .036). These factors (years since RYGB, conversion to open, and leaving G-tube) did not affect the ERCP-related adverse events.

Most patients (85%) received perioperative antibiotics. Antibiotic use was associated with a numerically higher overall adverse events rate (19% vs 13%, P = .198), a numerically higher rate of any infectious adverse events (6.2% vs 3.4%, P = .451), and a numerically higher rate of G-tube site infection (1.4% vs 0%, P = .603).

### DISCUSSION

The feasibility of LA-ERCP has been reported from a few single-center case series, with reported success rate ranging from 80% to 100% and adverse events rate ranging from 0% to 30%.<sup>6,7,23-25,27-32</sup> These reports are limited by small sample size and heterogeneous definitions of procedure success and adverse events. In our large multicenter study, LA-ERCP in patients with RYGB was highly successful, with success rates comparable with standard ERCP in patients with normal upper GI tract anatomy.<sup>33</sup> In our study the overall success rates in reaching the papilla, cannulating the desired duct, and performing the indicated

	No. of patients	Percent of patients
Biliary sphincterotomy	550	96
Stone/sludge/cast extraction	253	44
Pancreatic duct stent placement	88	15
Dilation of the papilla	82	14
Dilation of the ampullary orifice with large balloon (≥12 mm)	48	8
Plastic biliary stent placement	32	6
Pancreatic stent extraction	10	2
Biliary stent extraction	20	3
Dilation of a stricture	17	3
Metal biliary stent placement	6	1

therapeutic intervention was 98%. Furthermore, we also demonstrated that LA-ERCP is feasible and efficient. Our total procedure time (laparoscopy + ERCP) was 152 minutes with a median length of hospital stay of 2 days.

In our series ERCP-related adverse events rate appeared to be comparable with conventional ERCP, although the overall rate of adverse events was higher because of the addition of those attributed to laparoscopy.<sup>33</sup> Importantly, the clear majority (92%) of the reported adverse events were classified as mild to moderate. Nevertheless, serious adverse events were seen, including viscus perforation in 5 of 579 patients (.8%). Two patients had sphincterotomy-related duodenal perforations, whereas the rest were laparoscopy related (2 colonic and 1 gastric remnant perforation [trocar perforated the posterior stomach wall]). In 1 of the perforation cases multiorgan failure occurred, and the patient died after a prolonged hospitalization.

Placing an indwelling G-tube and conversion to open laparotomy were factors significantly associated with higher laparoscopy-related adverse events. Patients who had G-tube left had higher overall laparoscopy associated adverse events (17% vs 9%, P = .03). This was attributed to G-tube site infection (6%), gastric entry site leak (4%), and all-cause laparoscopy-associated bleeding (7%). Of note, all patients who had G-tube site infection did receive perioperative antibiotics as part of their care. Based on these data it seems reasonable to avoid G-tube insertion unless a repeat procedure is definitely indicated (Table 5).

Most patients included in our series (85%) received periprocedural antibiotics. There was no statistically significant difference in infection rate between those who received antibiotics versus those who did not. Nevertheless, we cannot exclude any difference based on our findings because of the very low rate of infections and low statistical power to answer this question. Therefore, our data cannot provide definitive guidance for or against the use of perioperative antibiotics.

Adverse event	No. of patients $(n = 579)$	Percent of patients		
Laparoscopy related				
Other postoperative infections	24	4.1		
Laparoscopy-related bleeding	10	1.7		
Gastric site leak	7	1.2		
Gastric tube site infection	7	1.2		
Postoperative respiratory adverse events	6	1.0		
Postoperative cardiovascular adverse events	4	.7		
Laparoscopy-related perforation	3	.5		
Other laparoscopic related	11	1.9		
ERCP related				
Pancreatitis	43	7.4		
Cholangitis	6	1.0		
ERCP-related bleeding	3	.5		
ERCP-related perforation	2	.3		
Stent migration	1	.2		

TABLE 4. Adverse events

Our findings are comparable with the recently published systematic review of 26 studies by Banerjee et  $al^{34}$  that included 509 laparoscopic and open transgastric ERCP cases. The success rate in reaching the papilla, cannulation, and performing therapeutic intervention were 98.9%, 98.5%, and 98.5%, respectively. Adverse events were reported in 14% of cases, with lower G-tube site infection (3.7%) and laparoscopy-associated bleeding (0.9%) and no reported death compared with our findings.

It is noteworthy that EUS-guided transgastric ERCP is currently an evolving and promising approach that involves deploying lumen-apposing metal stents through the newly formed gastrogastric fistula.<sup>18</sup> The intended ERCP could then be performed by passing the endoscope into the remnant stomach through the lumen-apposing metal stent.<sup>18-20</sup> This approach can potentially offer great advantages, including the lack of need for a surgical team, minimal invasiveness, and the higher success rate and shorter operative time compared with enteroscopy-assisted ERCP. However, this methodology has several cited limitations, most prominently the potential for creating a permanent fistula that compromises the integrity of the RYGB,<sup>20-22</sup> high lumen-apposing metal stent dislodgement rate (19%), and the need for multiple sessions in two thirds of patients to allow time for track maturation.<sup>35</sup> Nonetheless, this is a promising approach, and direct comparison with LA-ERCP is warranted in future research.

There are several strengths of our study. The large sample size and diverse patient population from many centers across the United Sates, Brazil, and Canada should improve our findings' external validity by providing more generalizable estimates of success and adverse events rates across many levels of endoscopist and surgeon experiences. These estimates can serve as a reference to physicians when counseling patients. Another strength is the standardization of definitions for the outcomes and adverse events. Also, reporting on all cases done in particular institutions will hopefully decrease the possibility of selection bias. Finally, our findings are congruent with the findings of earlier smaller studies.<sup>6,7,23-25,27-32</sup>

LA-ERCP has the advantage of using a standard sideviewing duodenoscope and the standard ERCP accessories, thus increasing the cannulation and therapeutic intervention success rates. Furthermore, because LA-ERCP is done in conjunction with surgeons in the operating room, concomitant cholecystectomy can be performed if clinically indicated. In our population concomitant cholecystectomy was performed in 20%. Saleem et al<sup>25</sup> reported performing concomitant cholecystectomy in 20% of patients. Additionally, the laparoscopic approach allows the diagnosis and treatment of internal hernias (reported in 20%-40%) and adhesions (in 20%) of the LA-ERCP procedures.<sup>23,25</sup>

Nonetheless, several challenging aspects of LA-ERCP must be addressed before adoption of this procedure by a medical center. The center must have expertise in bariatric surgery as well as advanced endoscopy. Second, maintaining sterility and the layout of the operating room and its equipment are different from what the endoscopy team is accustomed to in usual endoscopy suites.<sup>25</sup> Thus, a special protocol has to be devised and taught to the endoscopy team.<sup>25</sup> In addition, a great deal of schedule coordination is required to ensure that the endoscopist and the surgeon along with their teams are present in the operating room at the same time to avoid delays.<sup>25</sup> At the University of Florida and The Cleveland Clinic, LA-ERCPs are typically scheduled as the first cases of the day to ensure the 2 teams are available and there would be no interference with the rest of the operating room and endoscopy schedules.

Our study has the typical limitations inherent to retrospective design related to potential for patient selection bias and measurement bias, particularly the underreporting of adverse events. We anticipate that underreporting was minimized in our cohort because all our patients were inpatients or were admitted to the hospital after surgery, making detection and reporting of adverse events more likely. In addition, for clarity of reporting we divided adverse events into ERCP- or laparoscopy-related categories. Such a distinction may be straightforward for most adverse events such as post-ERCP pancreatitis but could be arbitrary for others such as cardiovascular compromise. Nevertheless, the reported overall adverse event rate should provide an accurate estimate to use as a guide for physicians and patients.

Our large multicenter study indicates that LA-ERCP in patients with RYGB is highly successful, with success rates comparable with standard ERCP in patients with normal upper GI tract anatomy. ERCP-related adverse

### TABLE 5. Subgroup analyses of adverse events

	Adverse events						
	None		ERCP related		Laparoscopy related		
	n	%	n	%	n	%	P value
Age quartile							.448
<42	121	86	11	8	9	6	
42-51	122	82	13	9	13	9	
52-61	124	81	10	7	19	12	
>61	107	83	6	5	16	12	
Gender							.237
Female	395	82	37	8	50	10	
Male	79	89	3	3	7	8	
ASA class							.225
1	4	100	0	0	0	0	
2	198	83	23	10	18	8	
3	235	82	15	5	37	13	
4	11	79	1	7	2	14	
Type of bariatric surgery							.180
Lap RYGB	285	85	20	6	30	9	
Open RYGB	123	78	14	9	20	13	
Cholecystectomy			· · · · · · · · · · · · · · · · · · ·	·	· · · · · · · · · · · · · · · · · · ·		.135
Before the ERCP	341	82	34	8	41	10	
At the time of ERCP	99	88	2	2	12	11	
After ERCP	6	100	0	0	0	0	
Main indication							.029
Biliary	428	84	34	7	50	10	
Pancreatic	36	84	5	12	2	5	
Both	10	63	1	6	5	31	
Years since RYGB, quartiles							.516
<3	123	85	10	7	11	8	
3-6	86	82	8	8	11	10	
6-10	102	82	9	7	13	10	
>10	85	75	10	9	18	16	
Conversion to open							.045
No	432	83	36	7	50	10	
Yes	20	69	2	7	7	24	
Gastrostomy tube left in place			-				.036
No	384	84	30	7	41	9	
Yes	68	74	8	9	16	17	-

Patients who had both ERCP and laparoscopy-related adverse events were excluded from this analysis (8 patients). P values are derived from comparing the distribution of adverse events across all the groups within the same variable.

ASA, American Society of Anesthesiologists; RYGB, Roux-en-Y gastric bypass.

event rates also appear to be comparable with those expected of conventional ERCP, but the overall adverse events rate was higher because of the addition of laparoscopy-related events. Although most such events were mild to moderate, rare severe adverse events are possible. Given the exceptionally high technical success rate and acceptable safety profile, LA-ERCP can be considered as 1 of the first-line approaches in patients with RYGB who require ERCP. Comparative studies with alternative procedures such as EUS-guided gastrogastrostomy may further refine our approach in this very challenging patient population.

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Abbreviations: G-tube, gastrostomy tube; IQR, interquartile range; IA-ERCP, laparoscopy-assisted ERCP; RYGB, Roux-en-Y gastric bypass.

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