Original Article

Endoscopic retrograde cholangiopancreatography in Billroth II gastrectomy patients: Outcomes and potential factors affecting technical failure

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Abstract

Background/Aims: Endoscopic retrograde cholangiopancreatography (ERCP) in Billroth II gastrectomy patients is technically demanding and factors affecting its technical difficulty have not yet been clarified. This study aimed to investigate the outcomes of ERCP in Billroth II gastrectomy patients and identify potential factors affecting its technical failure.

Patients and Methods: A large retrospective study of 308 consecutive patients (391 procedures) with Billroth II gastrectomy—who underwent ERCP from January 2002 to December 2016—was conducted. The outcomes of ERCP and potential factors affecting its technical failure were analyzed.

Results: The success rate of duodenal ampullary access, selective duct cannulation and the accomplishment of expected procedures was 81.3% (318/391), 86.5% (275/318) and 97.3% (256/263), respectively, and the technical success rate was 70.3% (275/391). The overall ERCP-related complication rate was 15.3% (60/391). The multivariate analysis indicated that first-time ERCP attempt [odds ratio (OR) 4.29, 95% confidence interval (CI) 2.34–7.85, $P < 0.001$], Braun anastomosis (OR 3.65, 95% CI 1.38–9.64, $P < 0.009$), and no cap-assisted gastroscope (OR 3.05, 95% CI 1.69–5.51, $P < 0.001$) were significantly associated with technical failure.

Conclusions: ERCP is safe, effective and feasible for Billroth II gastrectomy patients. Previous ERCP history, absence of Braun anastomosis and the use of a cap-assisted gastroscope are the predictive factors for its technical success.

Keywords: Billroth II gastrectomy, endoscopic retrograde cholangiopancreatography, predictive factors, technical failure

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) plays a major role in the management of a variety of

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pancreatic and biliary disorders. However, in patients with surgically-altered gastrointestinal anatomy, such as Billroth II gastrectomy, ERCP remains a challenging procedure with higher than usual risk of post-ERCP complications.[1,2] The endoscopist has to negotiate the endoscope across the gastrointestinal anastomosis, which is usually performed with a sharp angulation, track twisted and long afferent loop, to reach the papilla of Vater, and perform the desired duct cannulation in an inverted position, followed by therapeutic interventions.[3]

With advances in endoscopic devices, such as the balloon-assisted and transparent cap-fitted endoscope,[4] and better operator skills, recent case series have reported that the success rate and incidence of ERCP-related complications in patients with Billroth II gastrectomy and normal anatomy are similar.[5-7] At present, the reported studies on ERCP in Billroth II gastrectomy patients have a small sample size with short-term results. Furthermore, the predictive factors that affect procedural failure have not been studied in detail. Thus, the 15-year experience of ERCP in Billroth II gastrectomy patients at our digestive endoscopy center in China was retrospectively analyzed, along with the predictive factors for its technical failure.

PATIENTS AND METHODS

Patients

From January 2002 to December 2016, consecutive patients with a history of Billroth II gastrectomy—who underwent ERCP at our center—were identified from our medical records and endoscopic information system and included in the retrospective study. All patients were hospitalized before the procedure. Twenty three patients were excluded because of incomplete medical records. Patients using a balloon enteroscope or colonoscope were also excluded because of a relatively small sample size. The present study was approved by the Ethics Committee of Changhai Hospital.

Endoscopic procedures

A written informed consent for the ERCP procedure was obtained from each patient before the procedure. ERCP was performed with a forward-viewing gastroscope (Olympus GIF-Q260/Q240/H260; Olympus Medical, Tokyo, Japan). In addition, a transparent cap or side-viewing duodenoscope (Olympus TJF-260/240) was used as per the preference of the endoscopist. Diazepam (5 mg) and meperidine (25–50 mg) were used for conscious sedation, or propofol (0.5–1.0 mg/kg) for deep sedation. In addition, hyoscine-N-butyl bromide (20 mg) was given to inhibit duodenal peristalsis. For patients at high-risk of complications, such as female gender, young age, history of prior pancreatitis, and suspected sphincter of Oddi dysfunction,[1] rectal indomethacin suppositories (50–100 mg) and intravenous broad-spectrum antibiotics were routinely administered before or after the procedure. The ERCP was started with the patient in the prone position. However, if the endoscope could not be introduced into the afferent loop or reach the papilla of Vater, the patient was turned to the left position to facilitate the ampullary access.

Selective duct cannulation was usually performed using a standard straight Boston catheter (Boston Scientific, Natick, MA, USA) at the 6 o'clock direction of the endoscope, with the guidance of the self-wire or other types of guidewires. From 2012 onwards, in case of failure to achieve selective cannulation, a precut papillotomy or fistulation was performed using a needle-knife (KD-1L-1; Olympus Corp, Tokyo, Japan) or a dual knife, and the stepwise incision of the mucosa started at the upper margin of the papillary orifice in the direction of the bile duct or started directly over the roof of the papilla, followed by upward or downward cut, until the underlying biliary sphincter was visualized.[8] From 2002 to 2006, endoscopic sphincterotomy (EST) in Billroth II anatomy patients was performed using a needle-knife through an 8 Fr plastic stent (Cook). From 2007 onwards, a Billroth II sphincterotome (PTG-20-6-BII-NG, Cook Corp) was used for EST, and the endoscopic papillary (large) balloon dilation (EPBD/EPLBD) with or without sphincterotomy, was performed using a balloon dilator (CRE Balloon Dilator, Boston Scientific). Balloon size was determined according to the diameter of common bile duct (CBD) and the largest stone size.

CBD stones were removed using a retrieval balloon or basket, and a temporary plastic biliary and/or pancreatic stent was inserted to achieve biliary drainage and facilitate delayed stone removal in failed cases, or a pancreatic stent to prevent post-ERCP pancreatitis, when needed. In patients with large CBD stones, mechanical or laser lithotripsy was conducted if needed.

For malignant biliary obstruction patients, an uncovered self-expandable metal stent, biliary brush cytology, or radiofrequency ablation was performed, when needed. In patients with multiple CBD stones or residual stones, an endoscopic nasobiliary drainage (ENBD) was performed, when needed. Repeat attempt at ERCP was performed usually within 1 week after the initial session. Percutaneous, endoscopic ultrasound-guided biliary drainage (EUS-BD), or surgical intervention was recommended for patients with failed ERCP.

Definitions

Duodenal ampullary access was considered to be successful when the endoscope entered the afferent loop and tracked the intestinal tract to reach the papilla of Vater. The cannulation was considered to be successful when the selective duct cannulation was achieved and the cholangiopancreatography could be performed. Technical success was labeled as both successful duodenal ampullary access and selective duct cannulation. Clinical success was defined as completion of the desired therapeutic interventions such as the extraction of CBD stone(s) and/or insertion of biliary stent(s). A senior endoscopist was defined as an endoscopist who has performed >200 sessions of routine ERCP per year, while a junior endoscopist was defined as an endoscopist who did not meet the minimum volume criteria.

ERCP-related complications included intestinal perforation, bleeding, pancreatitis, asymptomatic hyperamylasemia, cholangitis and mortality. The definitions of these complications and the severity of the grading system were according to the Cotton's criteria.[9]

Statistical analysis

Continuous data were presented as mean ± standard deviation (SD), and categorical data were presented as frequency (%). Chi-square test or Fisher's exact test was used for categorical variables. Multivariate logistic regression analysis with a forward likelihood ratio was performed with potential factors that had a univariate P value <0.10 in the preliminary univariate analysis. A P value <0.05 was considered statistically significant. All statistical calculations were performed with the SPSS software, version 21.0 (IBM, Armonk, NY).

RESULTS

Table 1 shows a summary of the baseline characteristics of the study patients. A total of 391 ERCPs were performed in 308 consecutive patients with Billroth II gastrectomy. Among these patients, 250 (81.2%) patients were male, and the mean age of these patients was 66.6 ± 12.3 years old. The first-time attempt of ERCP was conducted in 270 (69.1%) patients, and the mean ERCP attempts per patient were 1.5 (range, 1–10). The indications for ERCPs were bile duct stones or cholangitis in 210 (53.7%) patients, biliary stricture in 151 (38.6%) patients, and chronic pancreatitis with pancreatic duct stones and others in 30 (7.7%) patients. The median duration of hospital stay was nine days (Range: 2–181 days).

Table 2 shows the outcomes of ERCP. A forward-viewing gastroscope was used in 320 (81.8%) procedures, a transparent cap-assisted endoscope was used in 113 (35.3%) patients, and a side-viewing duodenoscope was used in 71 (18.2%) procedures. Access to the papilla was achieved in 318 (81.3%) patients. Thereafter, 275 (86.5%) sessions achieved successful selective duct cannulation. The

Table 1: Baseline characteristics of the study patients

Variable	Total (*n*=308)
Male gender	250 (81.2)
Mean age (years)	66.6±12.3
Mean ERCP attempts per patient	1.5 (1-10)
Gallbladder stones	96
Cholecystectomy history	143
Gastrectomy for benign lesions, such as peptic ulcer	181 (58.8)
Gastrectomy for cancer	127 (41.2)
Braun anastomosis	23 (7.5)
Total ERCP sessions	391
First-time ERCP attempt	270 (69.1)
Indication of ERCP	
Bile duct stones, Cholangitis	210 (53.7)
Biliary stricture	151 (38.6)
Chronic pancreatitis and others	30 (7.7)
Median duration of hospital stay (days)	9 (2-181)

ERCP: Endoscopic retrograde cholangiopancreatography. Values are presented as mean±SDs (range) or as numbers (%)

Table 2: Outcomes of ERCP in Billroth II gastrectomy patients

Variable	Total (*n*=391)
Type of endoscope	
Forward-viewing gastroscope	320 (81.8)
Cap-assisted gastroscope	113/320 (35.3)
Side-viewing duodenoscope	71 (18.2)
Periampullary diverticulum	59
Bile duct-duodenal fistula	14
Total ERCP success	268/391 (68.5)
Successful ampullary access	318/391 (81.3)
Forward-viewing gastroscope	259/320 (80.9)
Side-viewing duodenoscope	59/71 (83.1)
Successful cannulation	275/318 (86.5)
Forward-viewing gastroscope	220/259 (84.9)
Side-viewing duodenoscope	55/59 (93.2)
Technical success	275/391 (70.3)
Diagnostic ERCP	12
Clinical success	256/263 (97.3)
ERCP sessions in CBD stone patients	210
Total duct clearance in CBD stone patients	161/210 (76.7)
Mean CBD diameter, mm	15 (6-35)
Number of stones	
1/≥2/sediment-like	54/84/26
Mean stone size, mm	13 (4-36)
ERCP procedures	
Endoscopic biliary/pancreatic sphincterotomy (EST)	69
Endoscopic papillary (large) balloon dilation (EPBD/EPLBD)	97
Mechanical lithotripsy	12/210 (5.7)
Laser lithotripsy	3
Endoscopic nasobiliary drainage (ENBD)	67
Biliary stenting	145
Including 46 metal biliary stents, 2 radioactive particle scaffolds	
Pancreatic duct stenting	17
Biliary stricture dilation	28
Biliary brush cytology	5
Radiofrequency ablation (RFA)	2

ERCP: Endoscopic retrograde cholangiopancreatography, CBD: Common bile duct. Values are presented as numbers (%)

Table 3: ERCP-related complications

Variable	Value (*n*=391) (%)	Severity grade
Intestinal perforation	4 (1.0)	Moderate: 2, Severe: 2
Bleeding	4 (1.0)	Mild: 4
Post-ERCP pancreatitis	13 (3.3)	Mild: 10, Severe: 3
Asymptomatic hyperamylasemia	31 (7.9)	Mild: 31
Cholangitis	8 (2.0)	Mild: 8
Mortality	3 (0.8)	Severe: 3
Total	60 (15.3)	Mild: 53 (88.3), Moderate: 2, Severe: 5

ERCP: Endoscopic retrograde cholangiopancreatography

technical and clinical success rate were 70.3% (275/391) and 97.3% (256/263), respectively. Twelve ERCPs were diagnostic. Thus, the overall ERCP success rate was 68.5% (268/391).

ERCPs failed in 123 (31.5%) cases. The reasons for ERCP failure were as follows: failure to enter the afferent loop in 7 patients, failure to reach and / or find the papilla in 66 (53.7%) patients, failure to achieve selective duct cannulation in 43 (35.0%) patients, failure of stent placement in 5 patients, and failure of stricture dilation in two patients. In cases of failed ERCPs, 53 patients received repeated ERCPs, and succeeded in 36 (67.9%) patients. 41 patients received percutaneous transhepatic biliary drainage (PTBD) or EUS-BD, and 22 patients underwent surgical CBD exploration. The remaining patients mostly received conservative medical management.

Among patients with CBD stones (n = 210), successful stone removal was performed in 161 patients (76.7%). The mean CBD diameter was 15 mm (range, 6–35 mm) and the mean stone size was 13 mm (range, 4–36 mm). Mechanical lithotripsy was used in 12 (5.7%) patients.

Table 3 shows a summary of the ERCP-related complications. The overall complication rate was 15.3% (60/391), in which 88.3% (53/60) were mild. Asymptomatic hyperamylasemia occurred in 31 (7.9%) patients, and no clinical signs required further intervention among these patients. Intestinal perforation occurred in 4 (1.0%) patients, and all were located in the afferent loop. Among these 4 patients, 2 patients were endoscopically treated using hemoclips and fibrin glue, while the other 2 patients required emergency surgery. Thereafter, one of these patients died after surgery with secondary massive hemorrhage. Bleeding occurred in 4 (1.0%) patients who all presented with melena and improved with conservative medical treatment (proton pump inhibitors, hemocoagulase, somatostatin, or octreotide). Cholangitis occurred in 8 (2.0%) patients, and post-ERCP pancreatitis occurred in 13 patients (3.3%; mild in 10 patients, and severe in 3 patients). Two patients died of sepsis and septic shock as a result of severe post-ERCP pancreatitis, and one of these two patients once received surgical intervention. Thus, ERCP-related mortality was 0.8% (n = 3). Other patients with complications completely recovered with conservative management.

In univariate analysis, history of cholecystectomy ($P < 0.001$), gastrectomy for benign lesions ($P = 0.02$), Braun anastomosis ($P = 0.03$), previous ERCP history ($P < 0.001$), and use of cap-assisted gastroscope ($P < 0.001$) were associated with total ERCP success [Table 4]. In multivariate analysis, first-time ERCP attempt (OR 4.29, 95% CI 2.34–7.85, $P < 0.001$), Braun anastomosis (OR 3.65, 95% CI 1.38–9.64, $P = 0.009$), and no cap-assisted gastroscope (OR 3.05, 95% CI 1.69–5.51, $P < 0.001$) were independent predictors of technical failure [Table 5].

DISCUSSION

ERCP in patients with Billroth II anatomy is a grade 5 endoscopic procedure due to its complexity.[10] To date, there is no consensus on ERCP procedures in patients who have undergone various gastrointestinal reconstructions. Recent case series have suggested promising results with the use of a side-viewing duodenoscope and a cap-fitted forward-viewing endoscope in such patients.[5,6] However, studies on ERCP in Billroth II gastrectomy patients from China are limited, and most of these studies have a

Table 4: Predictive factors affecting technical failure: Univariate analysis

Variable	Technical success (*n*=268)	Technical failure (*n*=123)	*P*
Sex (female/male)	48	24	0.67
Age ≥80 years (yes/no)	36	24	0.11
Gallbladder stones (yes/no)	72	24	0.13
Cholecystectomy history (yes/no)	116	27	<0.001
Gastrectomy for benign lesions (yes/no)	170	61	0.02
Braun anastomosis (yes/no)	12	11	0.03
Previous ERCP history (yes/no)	107	15	<0.001
Forward- *vs*. Side-viewing endoscope	215	106	0.10
Cap-assisted gastroscope (yes/no)	95	18	<0.001
Periampullary diverticulum (yes/no)	45	10	0.25
Senior endoscopist operation (yes/no)	209	102	0.18
Trainee involvement (yes/no)	63	26	0.65

ERCP: Endoscopic retrograde cholangiopancreatography

Table 5: Predictive factors affecting technical failure: Multivariate analysis

Variable	OR (95% CI)	*P*
First-time ERCP attempt	4.29 (2.34-7.85)	<0.001
Braun anastomosis	3.65 (1.38-9.64)	0.009
No cap-assisted gastroscope	3.05 (1.69-5.51)	<0.001

ERCP: Endoscopic retrograde cholangiopancreatography

relatively small number of patients and reported short-term results. Therefore, in the present study, we reported our single center 15-year experience of ERCP (n = 391) in 308 patients with Billroth II gastrectomy.

The most suitable type of endoscope to perform ERCP in patients with Billroth II anatomy remains unclear. In the present study, it was found that the success rate for duodenal ampullary access and desired duct cannulation was 80.9% and 84.9%, respectively, when using a forward-viewing gastroscope, and 83.1% and 93.2%, respectively, when using a side-viewing endoscope. A previous study revealed that in using a cap-fitted forward-viewing endoscope for Billroth II gastrectomy patients (n = 165), the successful ampullary access rate was 91.5%, and the successful selective cannulation rate was 95.4%, with an overall clinical success rate of 85.5%.[6]

Another study reported successful duodenal ampullary access rate of 86.7% (duodenoscope was 84.2%), and the successful cannulation of the desired biliopancreatic duct of 93.8% (duodenoscope was 94.5%).[5] The success rates in the present study were lower when compared to these studies, which was probably due to the referral of difficult and complicated cases from other hospitals, as well as the infrequent use of a side-viewing endoscope (18.2%), considering that the forward-viewing endoscope may be potentially advantageous, especially under the help of a transparent cap, the difficulty of intubation of the side-view endoscope (discussed below) and the preference of endoscopists.

The present study revealed that there was no significant difference in successful duodenal ampullary access (P = 0.49), technical success (P = 0.10), and complication rate (P = 0.73) between a forward-viewing gastroscope and a side-viewing endoscope. However, in the subgroup multivariate analysis, it was found that the use of a transparent cap was an independent predictor of technical success (P < 0.001), while a side-viewing endoscope increased the success rate of selective duct cannulation (P = 0.03) by facilitating the visualization of the papilla. The cap-fitted forward-viewing endoscope can provide good en face visibility, and enables the endoscope to easily and safely enter the afferent loop. The present results are in accordance with the European Society of Gastrointestinal Endoscopy clinical guidelines, which recommend that ERCP in patients with Billroth II gastrectomy should be performed with a side-viewing endoscope as a first option, and a forward-viewing endoscope as a second choice in cases of failure.[8] However, a recent meta-analysis indicated that the forward-viewing endoscope was as safe and effective as conventional side-viewing endoscope for ERCP in patients with Billroth II gastrectomy.[11] Thus, based on the 15-year experience of the investigators, it was considered that a cap-fitted forward-viewing endoscope can increase the probability of successful duodenal ampullary access. It is not inferior to a side-viewing endoscope in selective duct cannulation and may be the preferred choice of endoscope for Billroth II gastrectomy patients, especially for inexperienced endoscopists.

The main reasons for ERCP failure in the present study were failure to reach the papilla (53.7%) and failure of selective duct cannulation (35.0%) as a result of surgically-altered anatomy, which were in line with previous reports.[5] In order to overcome these problems, various new techniques and devices have been developed, including the use of a cap-assisted gastroscope, a spiral enteroscope, and a single- or double-balloon enteroscope.[4] As a result, the success rate of ERCP in Billroth II gastrectomy patients has become comparable to that of patients with normal anatomy. At our center, these advanced techniques and devices (e.g., the balloon enteroscope and a transparent cap) became frequently used from 2012 onwards.

A meta-analysis that compared EPBD and EST for CBD stone removal found that the rate of total stone clearance, incidences of bleeding and acute cholecystitis were lower in the EPBD group than in the EST group, while the incidences of pancreatitis and total long-term complication rate were significantly reduced in the EPBD group.[12] These findings also suggest that in patients with greater risk of bleeding, EPBD can be more suitable. Recent reports on limited EST before EPLBD or EPLBD alone have shown promising results in the removal of CBD stones, especially in large and difficult CBD stones (diameter ≥10 mm, or four or more).[13-15] At our center, limited EST before EPBD/EPLBD was preferred. The present study revealed that limited EST before EPBD/EPLBD did not increase the incidence of overall procedure-related complications (P = 0.71). However, the successful stone removal rate was relatively lower than that of the above reports, which was probably due to the underutilization of EPLBD and mechanical lithotripsy (merely 5.7%), and also the referral of difficult cases from other hospitals.

In patients with Billroth II gastrectomy, the incidences of post-ERCP pancreatitis, perforation and bleeding have been estimated to be 0–9.1%, 0–18.2% (especially when using a side-viewing endoscope), and 0–7.7%, respectively.[6] Furthermore, asymptomatic hyperamylasemia has been reported to occur in 13.3% of the study patients.[6] In the present study, the incidences of post-ERCP pancreatitis, hyperamylasemia, perforation, bleeding and cholangitis were 3.3%, 7.9%, 1.0%, 1.0% and 2.0%, respectively, which were lower than those in previous reports. Merely one ERCP accessory-related adverse event was observed, in which the breakage of the basket steel wire impacted around a large CBD stone, and the broken basket was removed via a salvage lithotripter. In our center, ERCPs in patients with surgically-altered anatomy, including Billroth II gastrectomy, Roux-en-Y anastomosis and pancreaticoduodenectomy, were mostly performed by senior endoscopists who have experience of >200 ERCPs per year, which helps in maintaining the low complication rate.

To date, few studies have investigated the predictive factors that affected the technical failure of ERCP in Billroth II gastrectomy patients. Actually, the Billroth II anatomy itself is a crucial predictive factor for ERCP failure and related complications.[16] A previous study reported that pancreatic indication (OR 4.35), first ERCP attempt (OR 6.03), and no transparent hood/cap (OR 4.61) were potential risk factors for procedural failure in short-type single-balloon enteroscope-assisted ERCP in surgically-altered anatomy patients.[17] In the present study, it was found that patients with first-time ERCP attempt (OR 4.29), who used no cap-assisted gastroscope (OR 3.05), and who had a Braun anastomosis (OR 3.65) would have a lower technical success rate, which were in accordance with the previous study.[17] Patients with a previous history of ERCP appeared to be theoretically easier, when compared with patients with a first-time attempt. This might benefit from previous successful procedure factors, such as prior EST or EPBD/EPLBD, stent placement, and procedure report.[17] Furthermore, Braun anastomosis would increase difficulties in entering the long and angulated afferent loop and decrease the success rate of duodenal ampullary access.[18] However, a transparent cap has advantages in providing good and safe visibility, overcoming the sharp angulation and twisted afferent loop, reducing the risk of perforation, and improving ability of the operator to manipulate the endoscope.[19] Therefore, a transparent cap has been regularly used in our center for all patients with a forward-viewing endoscope since September 2012. These predictive factors would be helpful in identifying high-risk populations before the procedure.

The limitations of the present study include its retrospective nature and the single center experience, which might result in selection bias, and the heterogeneous competency of each endoscopist, which might affect the success rate of ERCP. Future prospective studies are needed to validate the present findings and provide further insight on the predictors of ERCP success in patients with Billroth II and other gastrointestinal reconstructions.

In conclusion, the present study demonstrated that ERCP is challenging, but feasible, in a majority of Billroth II gastrectomy patients, and that the incidence of related complications is low and acceptable. Furthermore, a previous history of ERCP, absence of Braun anastomosis, and the use of a cap-assisted gastroscope are predictive factors for its technical success.

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Conflicts of interest

There are no conflicts of interest.

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