Double balloon enteroscopy-assisted endoscopic retrograde cholangiopancreatography in Roux-en-Y gastric bypass anatomy: expert vs. novice experience

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ABSTRACT
Background and study aims Double-balloon enteroscopy-assisted endoscopic retrograde cholangiopancreatography (DBE-ERCP) in post-Roux-en-Y gastric bypass (RYGB) patients is a technically challenging procedure. We aimed to determine the success rate of DBE-ERCP performed by a novice to the procedure in post-RYGB after training with an expert.

Patients and methods Medical records for 103 consecutive post-RYGB patients who underwent DBE-ERCP in a tertiary center were retrospectively reviewed. The procedures were performed by Operator A (18 years of high-volume ERCP practice before acquiring DBE skill in 2004), and operator B (<2 years’ experience in DBE and ERCP). ERCP success rate and time in patients with an intact papilla were compared between Operator A’s first and last sets of cases in equal number to the cases performed by Operator B.

Results A total of 129 DBE-ERCPs were performed (Operator A: 109; Operator B: 20) over an 80-month time span. Among patients with an intact papilla, DBE-ERCP success rates for Operator A’s first (87.5 %) and last (92.9 %) 20 cases were similar to that of Operator B (92.9 %) (P=1.00 for both). Mean of DBE-ERCP time for the last 20 cases of Operator A was (100 minutes; 95% confidence interval: 81,123) less than that for operator B (176 minutes; 95% confidence interval: 138,224) (P=0.01). Overall adverse events rates were 11 % and 5 % for Operators A and B, respectively (P=0.69): pancreatitis (n = 10), cholangitis (n = 1), and perforation (n = 2); all were mild and treated conservatively.

Conclusions Despite the intrinsic technical difficulty, DBE-ERCP can be successfully and safely performed in post-RYGB patients by an endoscopist proficient in both conventional DBE and ERCP. Ideally, this endoscopist should observe several cases of DBE-ERCP performed by an expert to learn the techniques.

Introduction
It is rather difficult to perform endoscopic retrograde cholangiopancreatography (ERCP) in patients with surgically altered gastrointestinal anatomy [1]. Among the diverse types of reconfigured gastrointestinal tracts, Roux-en-Y gastric bypass (RYGB) poses the greatest challenge to endoscopists [2]. With the increasing numbers of RYGB operations and higher risks of pancreaticobiliary disorders amongst post-RYGB patients, endoscopists are expected to evaluate pancreaticobiliary complaints in many of these patients [3,4]. Due to the complexity of ERCP in this setting, most patients are being referred for more invasive and costly surgical modalities [5]. An alternative is to pass a double-balloon enteroscope (DBE) through the afferent limb to perform ERCP [6]. However, the reported low success rate of DBE-ERCP in RYGB patients [5,7,8], may be discouraging to gastroenterologists. A learning curve associated with the procedure time in a few small case series on DBE-
Table 1  Parameters reflecting the endoscopist’s performance of DBE-ERCP.

**DBE performance parameters**
- Afferent limb intubation success rate: afferent limb was successfully found and intubated (previously tattooed afferent limb was excluded in this step).
- Afferent limb intubation success rate (first attempt): successful intubation of the afferent limb on first attempt. (When time spent examining the efferent limb then this was considered as an unsuccessful on the first attempt; if this was not described by the endoscopist, then it was excluded in this step).
- Reaching the papilla success rate: after successful intubation of the afferent limb if papilla was successfully reached.

**ERCP performance parameters**
- Intact papilla cannulation success rate: successful cannulation of the intact papilla if it was reached.
- Overall ERCP time: time spent to perform a successful ERCP including cannulation of the papilla.
- ERCP time (intact papilla): time spent to perform a successful ERCP including cannulation of the intact papilla.

**DBE-ERCP performance parameters**
- Overall DBE-ERCP success rate: performing a successful ERCP including all procedures.
- DBE-ERCP success rate (intact papilla): performing a successful ERCP if an intact papilla was reached.
- Overall DBE-ERCP time: time from insertion of the enteroscope until the enteroscope is out, in procedures with a successful ERCP.
- DBE-ERCP time (intact papilla): time from insertion of the enteroscope in until the enteroscope is out, in procedures with a successful ERCP on intact papilla.

ERCP in post-RYGB patients has been reported [9,10]. Outcomes for overall performance by novice endoscopists however, is not well known. In this report, we aim to assess how the level of experience with conventional DBE and ERCP and appropriate training in DBE-ERCP by an expert may impact a novice’s performance. Also, in this large case series, the success rate of DBE-ERCP in post-RYGB patients is evaluated.

**Patients and methods**

**Study design**

Medical records for 103 consecutive patients with a history of RYGB who underwent DBE-ERCP in a tertiary care center between December 2005 and July 2012 were retrospectively reviewed. Retrievable data from the procedure report were: total procedure time, ERCP time, intubation of afferent limb on first attempt versus spent time on examining the wrong limb (afferent limb) first before eventual successful intubation, and status of the papilla (intact papilla vs. prior sphincterotomy). Because DBE-ERCP is generally considered a time-intensive procedure with a relatively low success rate, we defined various DBE and ERCP parameters reflecting endoscopist performance in regard to procedure time and success rate (Table 1). In this cohort, procedures were performed by two endoscopists with different levels of experience with conventional DBE and ERCP prior to the first DBE-ERCP: Operator A (SKL), the senior interventional gastroenterologist with more than 20 years’ experience in conventional ERCP and DBE (available in the United States since August 2004), and Operator B (LHJ) with less than 2 years of experience (300 ERCPs and 120 DBEs). To assess the effect of experience level with conventional DBE and ERCP on DBE-ERCP performance, we compared the DBE-ERCP performance parameters between Operator B and Operator A’s first set of cases with an equal number of procedures performed by Operator B. Also, to evaluate the performance of a novice and an expert in DBE-ERCP, those parameters were compared between Operator B and Operator A’s last set of cases with an equal number of procedures performed by Operator B. To demonstrate the learning curve associated with the procedure, the operators’ performance with time was evaluated separately. Procedure-related adverse events including pancreatitis, cholangitis, perforation, and bleeding were reported. The study protocol was approved by the Institutional Review Board. All authors had access to the study data and have reviewed and approved the final manuscript.

**Procedures**

As part of the learning process, Operator B initially observed Operator A performing approximately 10 DBE-ERCPs, focusing on cannulation and sphincterotomy techniques. He then performed the procedure independently, with occasional supervision by Operator A. This included verbal guidance on how to perform the procedure during approximately 5 of the first 10 procedures.

Enteroscopy was performed using a DBE system (EN-450T5, Fujifilm Endoscopy, Wayne, New Jersey, United States). ERCP accessories were commercially available long-length devices; however, a 320-cm sphincterotome (Cotton Cannulatome, Cook Medical, Winston-Salem, North Carolina, United States) was modified into a needle knife to perform sphincterotomy in most instances. The DBE was advanced to the jejunum-jejunal anastomosis. If there were three limbs, the convenient lumen...
across the staple line was randomly chosen to intubate first. If the duodenum was not reached, the alternate limb beyond the staple line was then attempted. When the enteroscope and overtube reached the excluded stomach, the overtube balloon was inflated to straighten the enteroscope to facilitate subsequent maneuvering. With gradual withdrawal and careful inspection, the minor and then major papillae were identified. The enteroscope was ideally rotated such that the major papilla was situating at the 6 o’clock position. Cannulation was attempted using a 320-cm ERCP catheter (Glo-Tip ERCP catheter, Cook Medical, Winston-Salem, North Carolina, United States), or the modified sphincterotome. Most often, the sphincterotome or cannulating catheter was pre-loaded with a hydrophilic guidewire (Tracer Metro Direct Wire Guide, Cook Medical, Winston-Salem, North Carolina, United States) to facilitate ductal access. Access or standard sphincterotomy were both done with the modified needle-knife sphincterotomy. All procedures were performed under monitored anesthesia care, with occasional general anesthesia when clinically indicated.

Statistical analysis

To compare DBE-ERCP performance parameters between the operators, an independent two-sample t-test was used for continuous variables (time-containing variables); chi square or Fisher’s exact tests were applied for nominal variables (success rate variables) as appropriate. Where the time-containing variables were not normally distributed, a logarithmic transformation of data was first performed; the analysis was conducted on the transformed data accordingly. Then, the results were back-transformed and reported as the geometric mean and the confidence interval (CI) of mean (standard deviation is not calculable with this method). If the logarithmic transformation of the data did not satisfy the assumption of normality, then the nonparametric Wilcoxon two-sample test was applied; reports were median and interquartile ranges (IQR). A P value less than 0.05 was considered significant for all results. Statistical Analysis Systems (SAS) software v9.4 (SAS Institute Inc., Cary, North Carolina, United States) was used for the statistical analysis.

Results

A total of 129 DBE-ERCPs were performed in 103 post-RYGB patients with different pancreaticobiliary disorders. Indications for DBE-ERCP were abdominal pain suggestive of sphincter of Oddi dysfunction (n=66); common bile duct stone (n=26); pancreatitis (n=9); biliary stricture/obstruction (n=8); bile leak (n=8); cholangitis (n=6); abnormal liver tests (n=5); and recurrent liver abscess (n=1). Patients’ baseline characteristics are shown in Table 2.

**DBE performance parameters**

The afferent limb intubation success rate for Operator A was 99.1 % (106/107); it was 100 % for the first and last 20 cases performed by the same operator; both sets of cases no different from Operator B (94.1 %) (P=0.46). However, the success rate for afferent limb intubation on the first attempt for Operator A’s first (63.2%) and last (80 %) 20 cases was higher than for Operator B (50 %); with a trend toward significance between the last 20 cases of Operator A and Operator B (P=0.057). After successful intubation of the afferent limb, Operator A had six failed attempts to pass the enteroscope through the afferent limb due to adhesions and looping; Operator B successfully reached the papilla in all cases. Rates of success in reaching the papilla for Operator A’s first (90%) and last (100 %) 20 cases were no different from those for Operator B (100 %) (P= 1.00). Stepwise comparison of DBE performance parameters between the two operators is shown in Table 3.

**ERCP performance parameters**

The success rate for intact papilla cannulation in the last 20 cases for Operator A (100 %; 73/78) was no different from that for Operator B (100 %; 14/14). Time was missing for the first seven cases of DBE-ERCP performed by Operator A, so we were unable to calculate the procedural time in the first 20 cases of Operator A. Among patients with an intact papilla, median ERCP time for the last 20 cases performed by Operator A was 43 minutes (IQR: 38, 54); this was significantly less than for Operator B (72 minutes; IQR: 64, 115) (P<0.01). Stepwise com-

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**Table 2** Patient baseline characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Cumulative</th>
<th>Operator A</th>
<th>Operator B</th>
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<tbody>
<tr>
<td>Number of procedures</td>
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<td>109</td>
<td>20</td>
</tr>
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<td>Procedures per patient</td>
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<td>1 – 3</td>
<td>1 – 3</td>
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<tr>
<td>Number of patients</td>
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<td>88</td>
<td>15</td>
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<td>Gender (M/F)</td>
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<td>12/76</td>
<td>1/14</td>
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<td>Age (year)¹</td>
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<td>52 (22 – 82)</td>
<td>48 (34 – 67)</td>
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<tr>
<td>BMI (kg/m²)¹</td>
<td>27.5 (16 – 45)</td>
<td>28 (16 – 44)</td>
<td>27 (18 – 45)</td>
</tr>
</tbody>
</table>

M, male; F, female; BMI, body mass index

¹ Value presented as median (range)
Comparison of ERCP performance parameters for both operators is shown in ►Table 4.

### DBE-ERCP performance parameters

For 109 procedures performed by Operator A, the overall DBE-ERCP success rate was 88.1% (96/109); reasons for unsuccessful attempts were: failure to intubate the afferent limb (n=1), failure to pass the enteroscope through the afferent limb (n=6), inability to cannulate the papilla (n=5), ERCP failure after successful cannulation of the papilla (n=1; and inability to advance catheter across after successful contrast injection of the bile duct). Operator B had an overall DBE-ERCP success rate of 90% (18/20); one procedure failed due to unsuccessful intubation of the afferent limb and the second one was an ERCP failure after successful cannulation of bile duct. In the latter, the wire dislodged from the bile duct and the bile duct could not be re-cannulated. Among patients with an intact papilla, DBE-ERCP success rate in the first and last 20 cases performed by Operator A was no different from that for Operator B (87.5% and 92.9% vs. 92.9% respectively; P = 1.00). The mean overall DBE-ERCP time for Operator A was 101 minutes (CI: 93, 109) and for Operator B was 150 minutes (CI: 117, 194). In patients with an intact papilla, mean DBE-ERCP time for the last 20 cases for Operator A (100 minutes; CI: 81, 123) was less than that for operator B (176 minutes; CI: 138, 224) (P = 0.01). ►Table 5 shows the comparison of total procedure time between the two operators at different states.

### Learning curve

To demonstrate the learning curve associated with the procedure, we evaluated the performance of both operators at different steps individually. As mentioned before, due to missing data, we were unable to calculate the procedural time for Operator A’s first set of cases. This operator showed an improvement in afferent limb intubation on first attempt in the first set of cases compared with the last set, although this was not statistically significant (63.2% vs. 80%; P = 0.21). For Operator B, there was a decline in mean DBE-ERCP time when comparing the first 10 cases (183 minutes (CI: 139, 242), to the second 10 cases (123 minutes; CI: 79, 192). Because of the to low sample size, this difference did not reach statistical significance (P = 0.1). There was no difference in afferent limb intubation or ERCP success rates between the first and last 10 cases for Operator B (data not shown).

### Adverse events

Overall adverse events rates were 11% (12/109) and 5% (1/20) for Operators A and B, respectively (P = 0.69) (►Table 6). For Operator A, 9 of 10 procedures complicated by mild pancreatitis were performed in patients with suspected sphincter of Oddi...
dysfunction. Severity of all cases of pancreatitis and cholangitis were described as mild and they were treated conservatively with complete recovery. Two procedures were complicated by a perforation; one for each operator. The first patient had a history of chronic pancreatitis and suspected sphincter of Oddi dysfunction, and had the fourth DBE-ERCP performed by Operator A. After cannulating the bile duct and placing a plastic stent, biliary needle knife sphincterotomy was performed. However, a redundant fold overlying the major papilla was accidentally cut and was closed with an endoclip. Post-procedure imaging studies revealed pneumoperitoneum. The patient remained clinically stable on parenteral antibiotic and was discharged on Day 7 post-procedure. The second patient underwent DBE-ERCP for cholangitis and choledocholithiasis and had the second DBE-ERCP procedure performed by Operator B. After successful cannulation of the common bile duct, needle-knife sphincterotomy over a wire was performed, followed by sphincteroplasty and stone extraction. Under fluoroscopy, intrabdominal free air was noted. Therefore, a 7-Fr double pigtail stent was placed into the bile duct and the procedure was aborted. Post-procedure imaging studies revealed pneumoretroperitoneum and pneumomediastinum. Parenteral antibiotic therapy was continued. The patient remained intubated and was extubated on Day 2 and discharged home on Day 6 post-procedure. This patient was electively brought back for two more sessions of DBE-ERCP with extraction of the remaining stones, with no further complications.

### Discussion

In the current report, we demonstrate how the different steps in successful performance of DBE-ERCP are affected by the endoscopist’s level of experience with conventional DBE and ERCP. Afferent limb intubation, passing the enteroscope to reach the papilla, cannulation of the papilla, and ERCP success rate are the main steps assessed in our study. Our results revealed a high success rate for afferent limb intubation for Operator B, readily comparable to that in Operator A’s first set of cases (94% vs. 100%, respectively). However, Operator A showed a better success rate with intubation on the first attempt (63.2% vs 80%), compared to Operator B (50%). Although Operator A’s procedure time was significantly less than for Operator B, the latter’s success rate was 90%, which was comparable to that for Operator A (80% to 95%). The fact that Operator B had a relatively better success rate than Operator A with his first 20 cases is in line with our hypothesis about impact of appropriate training. Operator A had more experience with conventional ERCP and DBE, but he had challenges in learning the combined procedure. However, Operator B had the advantage of learning the techniques from an expert, which resulted in a 90% success rate, compared to 80% for Operator A’s first 20 cases.

Performing ERCP in patients with RYGB anatomy is challenging for a variety of reasons, including lengthy travel to reach the papilla [7, 9], identification of the afferent limb [10, 11], intubation of the afferent limb with an acute angle at the jejuno-jejunostomy anastomosis [2, 7, 9], wavering small bowel while looping the enteroscope leading to limited maneuverability [10], misconfigured papilla requiring retrograde cannulation because forward-viewing enteroscopes lack an elevator [1, 5, 9], cannulation of the intact papilla while hard to position the enteroscope [10, 11], limited instruments specifically designed for ERCP in these patients [1], and finally it is time-consuming, staff-intensive, and rather costly [7]. In this report, we aimed to...
elaborate on the impact of endoscopist’s experience with conventional DBE and ERCP on these challenging steps.

Prior studies showed that identification and intubation of the afferent limb are considered important steps for performing DBE-ERCP in Roux-en-Y anatomy. Abaken et al. showed a 50% success rate in afferent limb intubation on first attempt [10]. In our study, the rate ranged from 50% to 80%, depending on our endoscopists’ expertise. It appears that much of DBE time is spent on identifying and intubating the afferent limb. A median intubation time of 40 minutes and a learning curve associated with this step have been reported [10]. Our results supported this idea by showing an increase in the number of procedures in which the operators intubated the afferent limb on first attempt correlated with the endoscopist’s level of experience. Following successful intubation of the afferent limb, the next challenge is reaching the papilla, which in our experience can be secondary to adhesions or looping. Another hurdle is cannulation of an intact papilla, which can be time-consuming (>30 minutes) [9]. In our study, among patients with an intact papilla, there was no difference in ERCP time for the first 20 and last 20 cases performed by Operator A, but it was significantly less than the time taken by Operator B (almost 30 min). Among patients with an intact papilla, ERCP time varied by the endoscopists’ level of experience, but the ERCP success rates for Operator A (87.5% to 92.9%) and B (92.9%) were the same. Most ERCP failures were secondary to inability to reach the papilla (7 cases for Operator A vs 1 case for Operator B) rather than inability to cannulate the papilla (5 cases for Operator A vs. 0 for Operator B). Another drawback to performing DBE-ERCP is that it is time-intensive [7]. Emmett et al. showed a learning curve associated with the total procedure time on evaluation of 20 cases (122 vs. 71 minutes for the first and last 10 cases, respectively) [9]. We observed an almost 50-minute difference in total procedure time between Operator A (both first and last 20 cases) and Operator B, but we did not see a change in total procedure time for Operator A by time. We hypothesized that while an endoscopist with adequate experience in conventional DBE and ERCP performed the DBE-ERCP in a timely manner, the endoscopist with less experience might improve in the amount of time spent. This was supported by a 60-minute decline in total procedure time when comparing the first and second 10 cases performed by Operator B.

Performing ERCP in post-RYGB patients requires a high dexterity level, thus it has been limited to certain tertiary care centers. The reported success rate associated with balloon enteroscopy-assisted ERCP in RYGB anatomy ranges between 56% and 100% [5, 7–17]. Although most studies with a high success rate are small case series [13, 17]. Recently, Ishii et al. reported their experience with the balloon enteroscopy-assisted ERCP in a large cohort of RYGB patients (n = 98) with a success rate of 88% [14].

Alternatively, surgery-assisted ERCP which requires the skill of conventional ERCP has been advocated [5, 7, 8]. The success rate for surgery-assisted ERCP (89% to 97%) has been shown to be higher than for enteroscopy-assisted ERCP [5, 7]. The need for an experienced surgeon to access the excluded stomach [1], higher rate of adverse events [7], and higher costs [5] are considered drawbacks for the surgical approaches. In our report, endoscopists with experience in conventional DBE and ERCP, when beginning to perform DBE-ERCP, showed a success rate of 80% to 90%. Accordingly, these numbers improved over time to a success rate of 95%, which is readily comparable with the surgical approaches. Also, the mean total procedure time for an experienced endoscopist in our report (97.5 to 105 min) was comparable to what was reported for surgical alternatives (75 to 101.2 min) [5, 7]. Among different reports, the DBE-ERCP-related adverse event rate ranges between 0% and 15.8% [9, 18]; that for surgical approaches was 4.2% to 14.5% [5, 7, 8]. Adverse events related to DBE-ERCP were mainly mild pancreatitis while for surgical approaches they were associated with the surgical component of the procedure. Choi showed that DBE-ERCP had a better safety profile than surgery-assisted ERCP (adverse events rate: 3.1% vs. 14.5% respectively; P = 0.02) [7]. In our report, regardless of the endoscopist’s level of experience with this procedure, DBE-ERCP had a good safety profile with a low adverse events rate. For Operator A, of 10 procedures complicated by mild pancreatitis, 9 procedures had been performed in patients with suspected sphincter of Oddi dysfunction, who generally have a higher risk of pancreatitis [19]. All the adverse events including the two perforation cases were treated conservatively with complete recovery. Both procedures complicated by perforation were performed at the beginning of both operators’ DBE-ERCP experience.

The current study has a few limitations. It was retrospective with missing value for some variables. Also, the number of procedures performed by Operator B was low, leading to inadequate power in measuring the performance of this operator in some steps. Another limitation of the current study is that we were assessing the performance of one novice endoscopist, which may limit the generalizability of our results. Nevertheless, to our knowledge, this report has the highest number of post-RYGB patients undergoing DBE-ERCP.

**Conclusion**

In conclusion, DBE-ERCP can be safely accomplished in post-RYGB patients with a high rate of success, requiring an endoscopist skilled at conventional DBE and ERCP independently. This endoscopist should first observe several DBE-ERCPs cases performed by an expert. There is a learning curve associated with the success rate for afferent limb intubation on the first attempt, and total procedure time that results in performing DBE-ERCP in a timely manner.

**Competing interests**

None

**References**


