Abstract:

Objectives  We investigated the results of biliary cannulation using a short-type single-balloon enteroscope in patients with a native papilla who had previously undergone Roux-en-Y gastrectomy and analyzed the factors associated with successful cannulation.

Methods  The study subjects consisted of patients with a native papilla who had previously undergone Roux-en-Y gastrectomy and endoscopic retrograde cholangiopancreatography using a short-type single-balloon enteroscope at our institution between September 2011 and July 2019. We carried out a retrospective investigation of the outcomes, including assessing the success rate of biliary cannulation, and analyzed the factors associated with successful cannulation.

Results  In total, 78 patients underwent biliary cannulation of a native papilla. The success rate of biliary cannulation was 80.8% (88.5% when including success on repeated attempts). The success rate of the standard cannulation technique was 60.3%, with the use of advanced cannulation techniques to secure the pancreatic duct providing the same additional effect as a normal anatomy. Adverse events occurred in 9.0% of cases. A multivariate analysis of the Roux-en-Y gastrectomy patients found that cannulation was more likely to be successful in patients in whom the scope could be placed in the retroflex position (odds ratio: 7.88, 95% confidence interval: 2.19-37.77, P<0.001).

Conclusions  Selective biliary cannulation using a short-type single-balloon enteroscope in patients with a native papilla who had undergone Roux-en-Y gastrectomy was effective and safe. The retroflex position provided a good papilla field of view and improved the success rate of biliary cannulation.

Key words: endoscopic retrograde cholangiopancreatography, factors associated with cannulation success, retroflex position, short-type single-balloon enteroscope, surgically altered gastrointestinal anatomy

(Intern Med Advance Publication)
(DOI: 10.2169/internalmedicine.4245-19)
Methods

Ethical considerations

This was a retrospective, single-center study that was approved by the Institutional Review Board of Saitama Medical University International Medical Center (18-278). All patients provided their written informed consent before undergoing the procedure.

Patients

The study subjects consisted of patients with a native papilla who had undergone Roux-en-Y gastrectomy followed by an ERCP-related procedure using a short SBE at our institution between September 2011 and July 2019.

Procedure using a short SBE

All of the procedures in this study were performed using a short SBE. Endoscopic and fluoroscopic videos were recorded whenever possible. Two types of scopes were used [SIF-Y0004 (prototype) and SIF-H290S; Olympus Medical Systems, Tokyo, Japan], both of which had a 152-cm working length and a 3.2-mm working channel. Since March 2016, we have been using the SIF-H290S, which offers passive bending and high force transmission, at our hospital (Fig. 1). All ERCP procedures were conducted under CO2 insufflation with the scope fitted with a distal attachment cap (D-201-10704; Olympus Medical Systems). The patients were basically placed in the prone position, and in cases of difficult insertion, their position was modified or abdominal pressure was applied.

After reaching the target site, we first determined whether or not the scope could be placed in the retroflex position, as that greatly improves the field of view, favoring biliary cannulation (25). Fig. 2 shows the strategy for biliary cannulation used in our cohort of patients with a surgically altered gastrointestinal anatomy. As the “standard cannulation technique”, a standard ERCP cannula (ERCP catheter; MTW Endoskopie, Wesel, Germany) capable of simultaneous contrast and guidewire insertion was used to perform the so-called wire-loaded cannulation, and then deep cannulation was attempted by advancing the guidewire while injecting contrast into the bile duct to confirm its direction. If selective biliary cannulation was difficult to achieve using this “standard cannulation technique”, methods using the pancreatic duct (PD) were employed, such as the double-guidewire technique (5), PD stent-assisted cannulation (9, 27), and the double-lumen cannula method (8, 26). An “advanced cannulation technique” incorporating precutting was also used to achieve selective biliary cannulation. If these methods were still unsuccessful, depending on the patient’s general condition and the procedure to be performed, ERCP was reattempted the next day. In cases of failure to achieve biliary cannulation, the rendezvous technique or direct drainage using an alternative method, such as percutaneous transhepatic biliary drainage (PTBD) or endoscopic ultrasound-guided biliary drainage (EUS-BD), was performed. Depending on the patient’s condition, in some cases, especially those with a poor general condition, a policy of watchful waiting was adopted.

Definitions and outcome measurement

The success rate of biliary cannulation was defined as the rate of successful deep biliary cannulation with obtainment of a cholangiogram. The procedural success rate was defined...
Figure 2. Biliary cannulation strategy in patients with Roux-en-Y gastrectomy. PTBD: percutaneous transhepatic biliary drainage, EUS-BD: EUS-guided biliary drainage

Figure 3. Retroflex position. (a) Retroflex position (−). (b) Retroflex position (+).

as the rate of successful completion from scope insertion to the intended treatment (e.g. stone extraction, stent placement). If we placed a plastic stent before completion of stone extraction, we defined it as procedural success because we were able to control the cholangitis using a plastic stent. The time to successful biliary cannulation was defined as the duration from the start of cannulation to successful deep biliary cannulation. The total procedural time was defined as the duration from scope insertion to removal. Adverse events were assessed using the American Society for Gastrointestinal Endoscopy severity grading system (28).

To assess the factors associated with successful biliary cannulation, we evaluated the success rate of biliary cannulation of all cases as a function of all of the following items, and how each parameter affected the cannulation success was analyzed: age (<75 or ≥75 years old), cholangitis, malignant biliary obstruction, presence of diverticulum, other abdominal surgeries, use of a passive bending scope, and whether the scope could be placed in the retroflex position. To investigate the feasibility of the retroflex position, we reviewed the fluoroscopic images or videos scanned during the ERCP procedure in all subjects, with the retroflex position (+) defined as the ability to observe the papilla with the scope in a J-turn form (Fig. 3).

All procedures included in the present study were carried out by four experienced endoscopists, each having performed >500 ERCP procedures (with a normal anatomy and deep enteroscopy). In each case, the procedure (from scope insertion to intended treatment) was carried out by the same endoscopist.

Statistical analyses

Categorical variables were evaluated using Fisher’s exact probability test, and continuous variables were evaluated us-
ing the Mann-Whitney U-test. Univariate analyses were performed to identify factors associated with cannulation success. Variables with a P-value <0.2 on the univariate analysis were included in the model of the multiple logistic regression analysis. All analyses were carried out using the SAS JMP (version 14.1.0) and SAS (version 9.4; SAS Institute Inc., Cary, NC, USA) software programs. A P-value < 0.05 was considered to indicate statistical significance.

Results

Patients

A total of 85 patients with a native papilla who had previously undergone Roux-en-Y gastrectomy underwent ERCP using a short SBE during the study period. Among these patients, the scope reached the papilla in 78 cases (91.8%) (total gastrectomy with Roux-en-Y in 52 patients and partial gastrectomy with Roux-en-Y in 26 patients). The patient characteristics are shown in Table 1.

Endoscopic procedure

The success rate of biliary cannulation was 80.8% [95% confidence interval (CI) 79.7-88.0%]. The procedural success rate was 80.8% (95% CI: 79.7-88.0%), the median time to successful biliary cannulation was 12 min [interquartile range (IQR): 4.25-24.75 min], and the median total procedure time was 76 min (IQR: 58-98 min). Table 2 shows the results, including those for the different reconstruction methods. With the standard cannulation technique, selective biliary cannulation was achieved in 60.3% of cases, and the use of advanced cannulation techniques, mainly those using the PD (double-guidewire technique in 8 cases, PD stent-assisted cannulation in 6, and double-lumen cannula method in 1), increased this rate by 20.5% (Fig. 4). Among those patients in whom biliary cannulation had failed, reattempted ERCP was successful in 6 cases, increasing the final success rate of transpapillary biliary cannulation to 88.5%.

The therapeutic interventions performed were as follows: endoscopic sphincterotomy (n=5), endoscopic papillary balloon dilation (n=9), endoscopic papillary large balloon dilation (n=29), stone extraction (n=39), plastic stent placement (n=8), and metallic stent placement (n=11).

Adverse events

Adverse events occurred in 9.0% (7/78). The severity of adverse events was moderate in one case of intestinal perforation and mild in the other six events (five cases of pancreatitis and one case of cholangitis). All patients achieved remission with conservative therapy (Table 3). Perforation occurred when extracting the stone from the papilla using a basket catheter. After stone extraction, the muscle layer of the duodenum was torn by the basket catheter. We immediately creased the duodenal mucosa using a clip.

Factors associated with cannulation success

A univariate analysis identified the retroflex position (+) as a factor significantly affecting the success of biliary cannulation (p=0.002). A multivariate analysis also identified the retroflex position (+) as significantly affecting the success of cannulation [odds ratio (OR) 7.88, 95% CI: 2.19-37.77; p=0.001] (Table 4). In this study, the retroflex position was achieved in 60.3% (47/78) of cases. The retroflex position (+) significantly increased both the cannulation success rate and the standard cannulation technique success rate and was also advantageous in the performance of biliary cannulation (Table 5).

Discussion

The development of short SBEs with a 152-cm working length and a 3.2-mm working channel has increased the

| Table 1. Patients’ Characteristics. |
|-----------------------------------|
| Patient characteristics          |
| Patients, n                       | 78 |
| Age, median (range), years        | 71.5 (36-88) |
| Sex (male/female), n              | 61/17 |
| Reconstruction method, n (%)      | Total gastrectomy with Roux-en-Y: 52 (66.7) |
| Reasons for ERCP, n (%)           | Partial gastrectomy with Roux-en-Y: 26 (33.3) |
| Cholelithiasis                    | 53 (67.9) |
| Malignant biliary obstruction      | 25 (32.1) |
| Presence of diverticulum, n (%)   | 23 (29.5) |
| Other abdominal surgeries, n (%)  | 30 (38.5) |
| Passive bending scope, n (%)      | 41 (52.6) |

| Table 2. Summary of Procedure Results. |
|----------------------------------------|
| Biliary cannulation success, % (n) (95% CI) | Procedural success, % (n) (95% CI) | Median time to successful biliary cannulation (IQR), min | Median total procedure time (IQR), min |
|----------------------------------------|
| Total gastrectomy with Roux-en-Y      | 84.6 (44/52) (72.5-92.0) | 84.6 (44/52) (72.5-92.0) | 10 (4-22.5) | 73 (57-96.5) |
| Partial gastrectomy with Roux-en-Y    | 73.1 (19/26) (53.9-86.3) | 73.1 (19/26) (53.9-86.3) | 17.5 (6-31.8) | 81 (55-104.5) |
| Total                                 | 80.8 (63/78) (79.7-88.0) | 80.8 (63/78) (79.7-88.0) | 12 (4.25-24.75) | 76 (58-98) |
range of equipment that can be used and the types of treatment available for ERCP-related procedures in patients with surgically altered gastrointestinal anatomy. These advances have also made it easier to use the double-guidewire technique in selective biliary cannulation.

In the present study, the success rate of biliary cannulation in patients with a native papilla who had undergone Roux-en-Y gastrectomy was 80.8%, and when reattempted ERCP was included, this success rate rose to 88.5%. The incidence of adverse events was 9.0%. The rate was 60.3% with the standard cannulation technique, but the use of advanced cannulation techniques increased this by 20.5%, demonstrating that the use of the PD is just as useful in these patients as in those with a normal anatomy. Reattempted ERCP was successful in six patients in whom the procedure had initially failed, indicating that, depending on the circumstances, it may be worth reattempting ERCP.

However, the success rate of biliary cannulation was still lower than that in patients with a normal anatomy, and there remains room for improvement. As previously reported, the success rate of biliary cannulation in patients with Roux-en-Y gastrectomy ranges from 77% to 95.2%, and the incidence rates of adverse events ranges from 5.9% to 15.7% (14, 18, 20, 24, 25) (Table 6). Although the present findings were similar to those in previous reports, the biliary cannulation success rate of our facility was relatively low. When we were unable to achieve the retroflex position, the biliary cannulation success rate was 64.5%; however, when we were able to achieve the position, the biliary cannulation success rate was 91.5%. The retroflex position (+) can be attributed to the low biliary cannulation success rate.

As no previous study has addressed factors associated with successful cannulation in the selective biliary cannulation of patients with a native papilla, there was a need to investigate such factors to improve the success rate of biliary cannulation. A multivariate analysis of those who had undergone Roux-en-Y reconstruction found that the retroflex position (+) was significantly associated with successful cannulation. Ishii et al. (25) reported that the retroflex position is a useful technique used to obtain a better view of the papilla in Roux-en-Y gastrectomy cases. First, the endoscope is advanced with the up angle at the inferior duodenal angle and adjusted in the retroflex position. This technique provides a J-turn form. When treating patients who had undergone Roux-en-Y reconstruction, we also attempted to place the scope in the retroflex position if at all possible. As the retroflex position provides a better view of the papilla, it is extremely helpful when performing selective biliary cannulation. In this study, the retroflex position was achieved in 60.3% of cases but unfortunately was not feasible in all patients. As this technique carries a risk of intestinal perforation during the J-turn form, it must be used with caution. Therefore, when we can achieve the retroflex position, we do so while reviewing the fluoroscopy image and try not to push the scope too much. Fortunately, we have not experi-

---

**Table 3. Adverse Events.**

| Event                  | n (%) | Severity grade |
|------------------------|-------|----------------|
| Pancreatitis           | 5 (6.4) | Mild: 5       |
| Cholangitis            | 1 (1.3) | Mild: 1       |
| Intestinal perforation | 1 (1.3) | Moderate: 1   |
| Total                  | 7 (9.0) | Mild: 6, Moderate: 1 |
A novel biliary cannulation method for difficult cannulation cases using a unique, uneven, double-lumen cannula (Uneven method). Endoscopy 2018; 50:26-32, 2012.

5. Holt BA, Hawes R, Hasan M, et al. Biliary drainage: role of EUS guidance. Gastrointest Endosc 83: 160-165, 2016.

6. Ito K, Horaguchi J, Fujita N, et al. Clinical usefulness of double-guidewire technique for difficult biliary cannulation in endoscopic retrograde cholangiopancreatography. Dig Endosc 26: 442-449, 2014.

7. Lopes L, Dinis-Ribeiro M, Rolanda C. 634-641, 2014.

8. Takenaka M, Arisaka Y, Sakai A, et al. A novel biliary cannulation method for difficult cannulation cases using a unique, uneven, double-lumen cannula (Uneven method). Endoscopy 50: E229-E230, 2018.

9. Hakata R, Hamada T, Nakai Y, et al. Early pancreatic stent placement in wire-guided biliary cannulation: A multicenter retrospective study. J Gastroenterol Hepatol 34: 1116-1122, 2019.

10. Yamamoto H, Sekine Y, Sato Y, et al. Total enteroscopy with a double-balloon enteroscope in patients with a native papilla who had undergone Roux-en-Y gastrectomy was effective in a range of different cannulation techniques and be placed in the retroflex position, the use of advanced cannulation techniques increases the biliary cannulation success rate by 19.3% (Table 5), and endoscopists must therefore be proficient in a range of different cannulation techniques and be able to use them flexibly as required. As selective biliary cannulation is not always possible, rather than sticking only to the use of short SBE-assisted ERCP, operators must also learn how to use alternative treatment methods, such as PTBD and EUS-BD, in order to complete the intended treatment.

The limitations of this study include its retrospective nature and single-institution setting as well as the involvement of multiple endoscopists. Nevertheless, we were able to evaluate the results of selective biliary cannulation in a large number of patients with a native papilla who had undergone Roux-en-Y gastrectomy and to analyze the factors associated with successful cannulation.

In conclusion, selective biliary cannulation using a short-type single-balloon enteroscope in patients with a native papilla who had undergone Roux-en-Y gastrectomy was effective and safe. Advanced cannulation techniques using the PD increased the success rate of biliary cannulation. Placing the scope in the retroflex position situated the papilla anteriorly, providing a good field of view and improving the biliary cannulation success rate.

The authors state that they have no Conflict of Interest (COI).

References

1. Williams EJ, Ogollah R, Thomas P, et al. What predicts failed cannulation and therapy at ERCP? Results of a large-scale multicenter analysis. Endoscopy 44: 674-683, 2012.

2. Kawakami H, Maguchi H, Mukai T, et al. A multicenter, prospective, randomized study of selective bile duct cannulation performed by multiple endoscopists: the BIDMEN study. Gastrointest Endosc 75: 362-372, 2012.

3. Peng C, Nieretz PJ, Cotton PB, Lackland DT, Romagnoli J. Predicting native papilla biliary cannulation success using a multivariate Endoscopic Retrograde Cholangiopancreatography (ERCP) Quality Network. BMC Gastroenterol 13: 147, 2013.

4. Holt BA, Hawes R, Hasan M, et al. Biliary drainage: role of EUS guidance. Gastrointest Endosc 83: 160-165, 2016.

5. Ito K, Horaguchi J, Fujita N, et al. Clinical usefulness of double-guidewire technique for difficult biliary cannulation in endoscopic retrograde cholangiopancreatography. Dig Endosc 26: 442-449, 2014.

6. Lopes L, Dinis-Ribeiro M, Rolanda C. 634-641, 2014.

7. Yasuda I, Isayama H, Bhatia V. Current situation of endoscopic biliary cannulation and salvage techniques for difficult cases: Current strategies in Japan. Dig Endosc 28 (Suppl 2): 62-69, 2016.
nonsurgical steerable double-balloon method. Gastrointest Endosc 53: 216-220, 2001.
11. Aabakken L, Brethauer M, Line PD. Double-balloon enteroscopy for endoscopic retrograde cholangiography in patients with a Roux-en-Y anastomosis. Endoscopy 39: 1068-1071, 2007.
12. Chu YC, Yang CC, Yeh YH, Chen CH, Yueh SK. Double-balloon enteroscopy application in biliary tract disease: its therapeutic and diagnostic functions. Gastrointest Endosc 68: 585-591, 2008.
13. Iwamoto S, Ryozawa S, Yamamoto H, et al. Double balloon endoscope facilitates endoscopic retrograde cholangiopancreatography in roux-en-y anastomosis patients. Dig Endosc 22: 64-68, 2010.
14. Shimatani M, Hatanaka H, Kogure H, et al. Diagnostic and Therapeutic Endoscopic Retrograde Cholangiography Using a Short-Type Double-Balloon Endoscope in Patients With Altered Gastrointestinal Anatomy: A Multicenter Prospective Study in Japan. Am J Gastroenterol 111: 1750-1758, 2016.
15. Kawamura T, Yasuda K, Tanaka K, et al. Clinical evaluation of a newly developed single-balloon enteroscope. Gastrointest Endosc 68: 1112-1116, 2008.
16. Wang AY, Sauer BG, Behm BW, et al. Single-balloon enteroscopy effectively enables diagnostic and therapeutic retrograde cholangiography in patients with surgically altered anatomy. Gastrointest Endosc 71: 641-649, 2010.
17. Saleem A, Baron TH, Goustout CJ, et al. Endoscopic retrograde cholangiopancreatography using a single-balloon enteroscope in patients with altered Roux-en-Y anatomy. Endoscopy 42: 656-660, 2010.
18. Iwai T, Kida M, Yamauchi H, et al. 26 (Suppl 2): 156-163, 2014.
19. Kawamura T, Uno K, Suzuki A, et al. Clinical usefulness of a short-type, prototype single-balloon enteroscope for endoscopic retrograde cholangiopancreatography in patients with altered gastrointestinal anatomy: preliminary experiences. Dig Endosc 27: 82-86, 2015.
20. Yane K, Katanuma A, Maguchi H, et al. Short-type single-balloon enteroscope-assisted ERCP in postsurgical altered anatomy: potential factors affecting procedural failure. Endoscopy 49: 69-74, 2017.
21. Nakai Y, Kogure H, Yamada A, et al. Endoscopic management of bile duct stones in patients with surgically altered anatomy. Dig Endosc 30 (Suppl 1): 67-74, 2018.
22. Tsuchiya T, Sofuni A, Itoi T. Treatment for difficult bile duct stones: Balloon enteroscopy assisted-endoointrograde cholangiopancreatography. Dig Endosc 30 (Suppl 1): 76-77, 2018.
23. Tanisaka Y, Ryozawa S, Mizuide M, et al. Usefulness of the “newly designed” short-type single-balloon enteroscope for ERCP in patients with Roux-en-Y gastrectomy: a pilot study. Endosc Int Open 6: E1417-1422, 2018.
24. Tanisaka Y, Ryozawa S, Mizuide M, et al. Analysis of the factors involved in procedural failure: Endoscopic retrograde cholangiopancreatography using a short-type single-balloon enteroscope for patients with surgically altered gastrointestinal anatomy. Dig Endosc 31: 682-689, 2019.
25. Ishii K, Itoi T, Tonozuka R, et al. Balloon enteroscopy-assisted ERCP in patients with Roux-en-Y gastrectomy and intact papillae (with videos). Gastrointest Endosc 83: 377-386, 2016.
26. Takenaka M, Yamao K, Kudo M. Novel method of biliary cannulation for patients with Roux-en-Y anastomosis using a unique, uneven, double-lumen cannula (Uneven method). Dig Endosc 30: 808-809, 2018.
27. Tanisaka Y, Ryozawa S, Mizuide M, et al. Novel technique using pancreatic duct stent facilitates difficult biliary cannulation in patients with Roux-en-Y anatomy (with video). JGH Open.
28. Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. Gastrointest Endosc 71: 446-454, 2010.

The Internal Medicine is an Open Access journal distributed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License. To view the details of this license, please visit (https://creativecommons.org/licenses/by-nc-nd/4.0/).