

[ ORIGINAL ARTICLE ]

# A Prospective Multicenter Randomized Feasibility Trial of Double-guidewire Techniques for Difficult Biliary Cannulation Comparing a New Double-guidewire-supported Sphincterotome (MagicTome) to a Conventional Device

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## Abstract:

**Objective** To evaluate the effectiveness and safety of the double-guidewire technique (DGT) using a new double-guidewire-supported sphincterotome (MagicTome) for patients who required endoscopic retrograde cholangiopancreatography (ERCP) for biliary cannulation.

**Methods** This prospective multicenter randomized feasibility trial involved patients with difficult biliary cannulation at any of the three study sites from June 2017 to October 2018. Patients were assigned to the DGT with MagicTome (MDGT) initially performed group and the conventional DGT (CDGT) initially performed group. The success rates of biliary cannulation by MDGT and CDGT and the ERCP-related complications were evaluated.

**Results** Twenty-eight patients were included in this study. No significant difference was observed in the success rates of first attempts and crossover attempts between the groups ( $p=0.69$  and  $p=1.00$ ). Furthermore, no significant difference was observed in the success rate of biliary cannulation between MDGT and CDGT (62.5% and 75.0%, respectively;  $p=0.48$ ). CDGT was successful in two of four patients with malignant biliary obstruction. MDGT was successful in all four patients with malignant biliary obstruction, including the two for whom CDGT was unsuccessful. Post-ERCP pancreatitis occurred in only one MDGT case.

**Conclusion** MDGT is safe for biliary cannulation and can be used in cases where biliary cannulation by CDGT is difficult.

**Key words:** endoscopic retrograde cholangiopancreatography, biliary cannulation, double-guidewire technique, new type of double-guidewire-supported sphincterotome, pancreatitis

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## Introduction

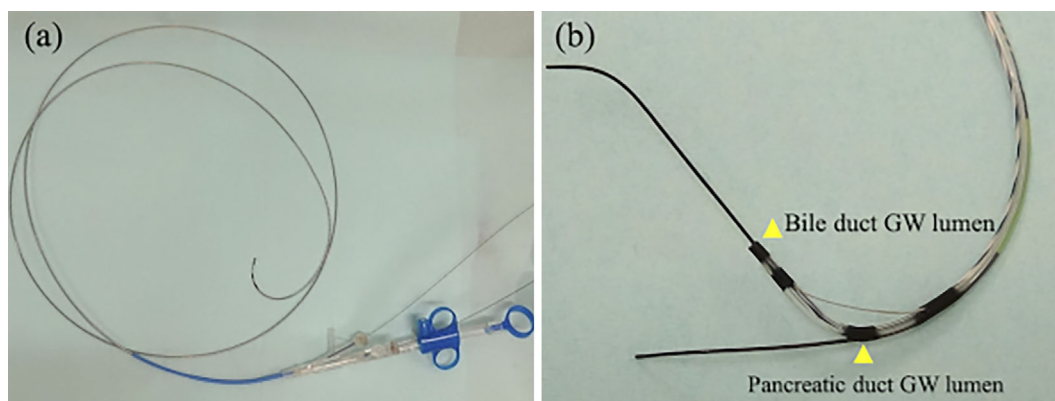
Endoscopic retrograde cholangiopancreatography (ERCP)

is a technique that was first reported in 1968 (1). Currently, selective biliary cannulation with high reliability is needed because ERCP procedures are indispensable in the endoscopic diagnosis and treatment of biliary tract diseases.

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**Figure 1.** Photographs of the MagicTome: (a) overall view; (b) the device has a lumen for the bile duct GW and for the pancreatic duct GW. It can also be swung upward.

However, selective bile duct cannulation can occasionally be difficult owing to anatomical issues and the shape of the papilla.

Previous studies have reported that 1.7-16% of selective cannulations into the bile duct by ERCP are unsuccessful (2-6). Therefore, to increase the success rate of selective biliary cannulation, various methods have been used. The double-guidewire technique (DGT) is used when biliary cannulation is difficult. The DGT was first reported by Dumonceau et al. in 1998 (7). Since then, its effectiveness has been well demonstrated. However, difficulty in performing selective biliary cannulation can still occur even when the DGT is used. In such cases, biliary cannulation should be performed with other methods, including the precut method. Given that the precut method is likely to cause procedural complications (8), the further development of the DGT, which is more effective and safer than the precut method, is required.

To improve the ease of use and safety of the biliary cannulation technique in the DGT, we developed a new type of double-guidewire-supported sphincterotome (MagicTome, Piolax Medical Devices, Yokohama, Japan). The MagicTome has a basic structure that allows the tip to swing upward in the same way as that of conventional sphincterotomes. In addition, it has a multi-lumen structure that includes an additional lumen for a pancreatic duct guidewire (GW). Since the MagicTome is inserted via the pancreatic duct GW, it can easily access the papilla. This enables the bile duct to be approached while looking at the papilla of Vater from the front view. Biliary cannulation is performed from the other lumen (Fig. 1). Performing the DGT with the MagicTome is expected to lead to a higher biliary cannulation success rate and improved safety (9).

The present study therefore validated the effectiveness and safety of the DGT with the MagicTome.

## Materials and Methods

### Study design and ethics statement

This study is a prospective multicenter randomized feasibility study involving three institutions in Japan. The data obtained from the institutions were collected in another facility.

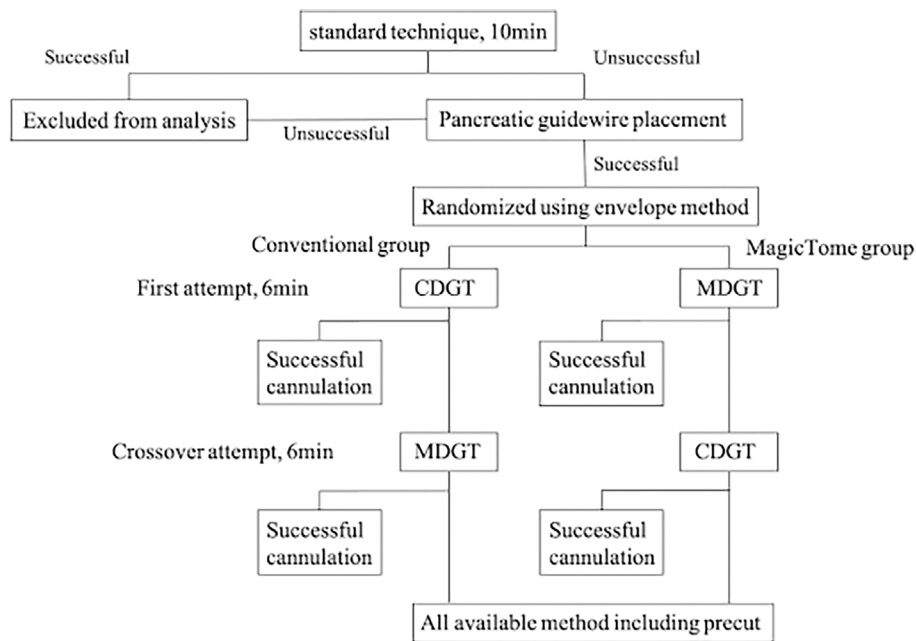
This study was approved by the Institutional Review Board at Saitama Medical University International Medical Center (16-289). Approval was obtained from the institutional review board of each study site. The study was registered in the University Hospital Medical Information Network with number UMIN000026232. All patients received detailed information and provided their informed consent prior to undergoing the procedure. Patients were registered for this clinical study after consent was obtained from them.

### Patients

Subjects were patients who underwent ERCP for the purpose of biliary cannulation for their native papilla at any of the three study sites from June 2017 to October 2018. The following patients were excluded: those with a performance status (PS) of 4, those whose papilla were treated, those who had undergone gastric surgery previously (including the Billroth I method), those with serious complications in other organs, those who did not give their informed consent, those  $\leq 19$  years old, and those determined to be ineligible by a principal investigator.

### Procedures

When performing ERCP, one of the investigators of this study was assigned the role of the operator. Changing operators during the study was not permitted. The algorithm of this study is shown in Fig. 2. Following the full observation of the duodenal papilla, chronological measurement began when the preparation for biliary cannulation was completed. Cases for which the cannula could not reach the deep part of the bile duct after 10 minutes were defined as cases of



**Figure 2.** The algorithm of this study. CDGT: double-guidewire technique with a conventional device, MDGT: double-guidewire technique with the MagicTome

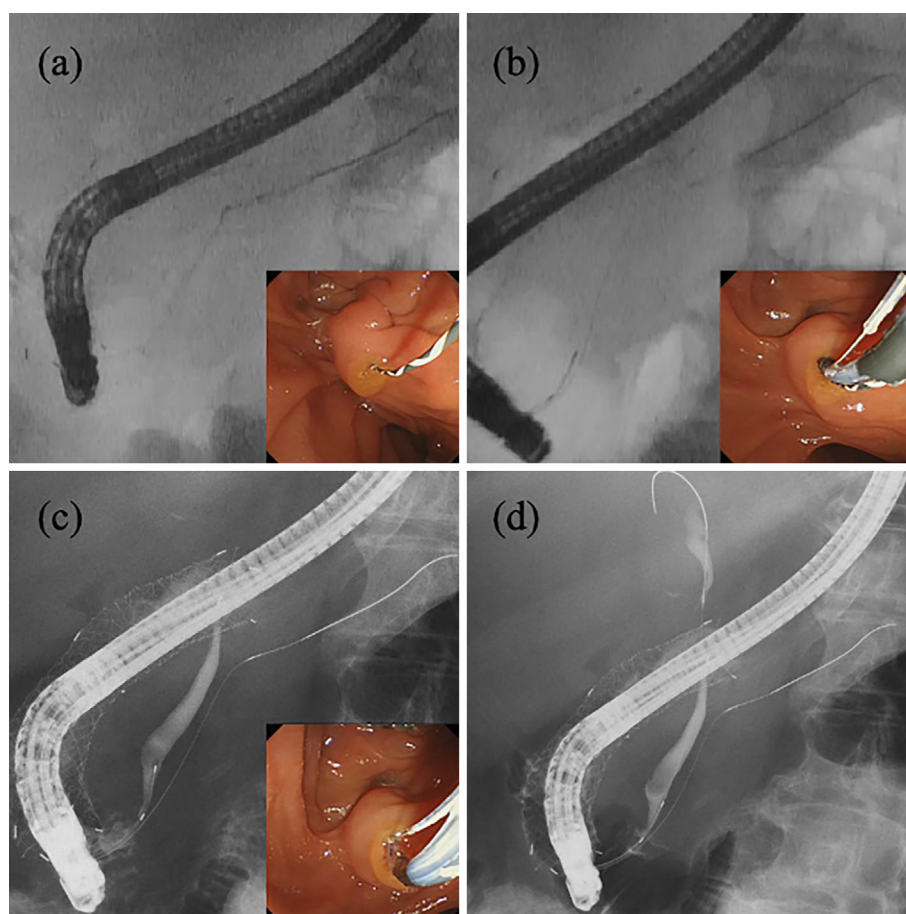
difficult biliary cannulation. No particular cannula types or cannulation methods (contrast-guided cannulation and wire-guided cannulation) were specified for the 10-minute procedure. While the technique differed at each study site, the use of the DGT or precut technique was not permitted. For cases of difficult biliary cannulation, an attempt to place a GW in the pancreatic duct was made 10 minutes later. Patients for whom the GW could be left indwelling were included in this study. No particular time restrictions were applied when placing a GW in the pancreatic duct.

Patients with difficult biliary cannulations for whom a GW could be placed in the pancreatic duct (subjects eligible for this study) underwent cannulation using two different DGTs: the DGT with the MagicTome (MDGT) and the DGT with a conventional device (CDGT). For the patients that underwent the MDGT, a GW was placed in the pancreatic duct. Thereafter, the MagicTome was inserted through the GW in the pancreatic duct via the GW lumen for the pancreatic duct. An attempt was made to insert the device into the bile duct while swinging its tip upward in the direction of the bile duct axis (Fig. 3). For patients that underwent the CDGT, a GW inserted into the pancreatic duct was left indwelling. Thereafter, an attempt was made to insert the device into the bile duct while moving a conventional cannula or sphincterotome along the pancreatic duct GW. Using either contrast-guided cannulation or wire-guided cannulation for biliary cannulation was permitted.

In this study, patients were further allocated to either of the following groups: those initially undergoing the MDGT (the MagicTome group) and those initially undergoing the CDGT (the conventional group). For randomized allocation, we used sequentially numbered opaque envelopes. Randomization was done through the computer-generated stratified

block randomization according to study institution (block size 4). The assistant who did not performed the ERCP opened the envelope. Crossover attempts were also made in this study. For patients in the MagicTome group, the procedure was switched to the CDGT if biliary cannulation by the MDGT was unsuccessful, and for patients in the conventional group, the procedure was switched to the MDGT if biliary cannulation by the CDGT was unsuccessful. For both groups, the initial procedure was performed for 6 minutes. If biliary cannulation with the initial procedure was unsuccessful, the procedure was switched to the other option. The alternative procedure was then performed for a subsequent 6 minutes. If biliary cannulation could not be achieved within the second 6-minute crossover attempt using either the MDGT or CDGT, further biliary cannulation was performed using all available methods, including the precut technique. In such cases, changing operators was permitted. A case was considered a drop-out if any of the following applied: operators were changed during the MDGT or CDGT, the examination was performed by a method other than the allocated one, and the pancreatic duct GW became dislocated during the procedure. Following successful biliary cannulation, ERCP procedures appropriate for each case were implemented.

At baseline and 24 hours after ERCP, serum amylase levels and white blood cell (WBC) count were obtained in all patients. All patients received an infusion of antibiotics (cefoperazone-sulbactam sodium, 2,000 mg/day) and a protease inhibitor (nafamostat mesylate, 20 mg/day) for 2 days. The total infusion volume was 2,000 mL/day for 2 days if there were no setbacks related to the cardiac or renal function. Insertion of a pancreatic duct stent and the use of rectal nonsteroidal anti-inflammatory drugs (NSAIDs) were de-



**Figure 3.** Biliary cannulation using the double-guidewire technique with the MagicTome (MDGT). (a) A guidewire (GW) is placed in the pancreatic duct. (b) The MagicTome is inserted through the GW in the pancreatic duct via the proximal lumen. The distal lumen is easily positioned in the direction of the bile duct axis. (c) The MagicTome is swung upward, which helps select the bile duct. Thereafter, we inject the contrast medium. (d) After the injection of contrast medium, the GW is inserted carefully into the bile duct. Selective biliary cannulation by the MDGT is successful.

terminated at each institution in consideration of the risk of developing post-ERCP pancreatitis.

### Definitions and outcome measurements

The primary endpoint was the success rate of biliary cannulation, and the secondary endpoints were the biliary cannulation time with the MDGT and CDGT, success rate of the DGT in the crossover attempt in cases where biliary cannulation with the initial DGT was unsuccessful, and the incidence of procedural accidents.

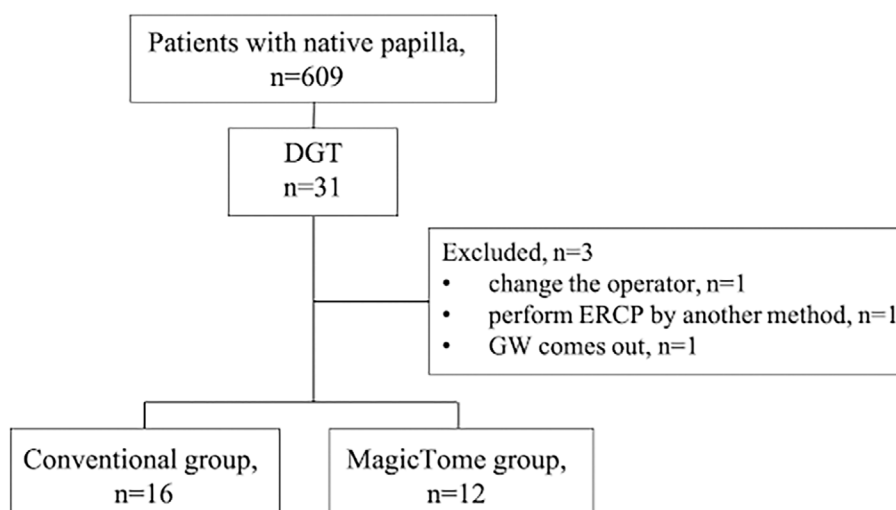
Successful biliary cannulation was defined when a cannula was selectively inserted into the deep part of the bile duct; obtaining a contrast image of the bile duct did not fall under the definition of a successful biliary cannulation. The biliary cannulation time in the MDGT and CDGT was defined as the time from the beginning of insertion into the bile duct using each DGT to successful biliary cannulation.

Complications of ERCP such as post-ERCP pancreatitis, bleeding, and perforation were classified and graded according to the consensus guidelines proposed by Cotton et al. (10). The severity of post-ERCP pancreatitis and perfora-

tion was classified according to the length of hospitalization for treatment as follows: mild, <4 days; moderate, 4-10 days; and severe, >10 days or interventional treatment, such as surgery. The severity of bleeding was classified as follows: mild, hemoglobin drop <3 g/dL and no need for transfusion; moderate, transfusion ( $\leq 4$  units); severe, transfusion ( $\geq 5$  units) or interventional treatment (angiographic or surgical).

### Statistical analyses

For statistical analyses, Fisher's exact probability test was used for categorical variables, and the Mann-Whitney U-test was used for continuous variables. The SAS JMP (version 14.1.0) and SAS (version 9.4; SAS Institute, Cary, USA) software programs were used for all statistical analyses. Statistically significant differences were defined as those with  $p < 0.05$ .



**Figure 4.** Flow chart of patient selection through this study. DGT: double-guidewire technique, ERCP: endoscopic retrograde cholangiopancreatography, GW: guidewire

**Table 1.** Comparison of Patient Characteristics between the Two Groups.

	MagicTome group (n=12)	Conventional group (n=16)	p value
Age (years), median	74 (67-83)	73 (56-94)	
Sex (male/Female), n	7/5	8/8	0.72
Post-cholecystectomy, n (%)	1 (8.3)	0 (0)	0.43
Pancreatitis history, n (%)	1 (8.3)	0 (0)	0.43
Cholangitis, n (%)	2 (16.7)	3 (18.8)	1.00
Normal bilirubin level, n (%)	8 (66.7)	7 (43.8)	0.28
Presence of diverticulum, n (%)	2 (16.7)	4 (25.0)	0.67
<b>Indications for ERCP</b>			
Bile duct stone, n (%)	9 (75.0)	11 (68.8)	1.00
Benign biliary stricture, n (%)	1 (8.3)	1 (6.3)	1.00
Distal cholangiocarcinoma, n (%)	1 (8.3)	1 (6.3)	1.00
Perihilar cholangiocarcinoma, n (%)	0 (0)	1 (6.3)	1.00
Intrahepatic cholangiocarcinoma, n (%)	0 (0)	1 (6.3)	1.00
Gallbladder cancer, n (%)	1 (8.3)	0 (0)	0.43
Biliary stricture due to metastatic lymph node, n (%)	0 (0)	1 (6.3)	1.00

ERCP: endoscopic retrograde cholangiopancreatography

## Results

### Patients

From June 2017 to October 2018, a total of 609 patients who underwent ERCP and met the criteria for this clinical study were identified at all study sites. Of these 609 for whom a GW could be placed in the pancreatic duct, difficulty in biliary cannulation was observed in 31, with the following 3 excluded from the study: 1 patient for whom operators were changed, 1 for whom the examination was performed by a method other than the allocated one, and 1 for whom the pancreatic duct GW became dislocated during the examination. The remaining 28 patients were registered for

this clinical study. Of these 28 patients, 12 were in the MagicTome group, and 16 were in the conventional group (Fig. 4). The characteristics of the two groups are shown in Table 1. No significant differences were observed in the age, gender, or medical history, nor in the disease that led to the indication for ERCP. A breakdown of diseases indicated that the most common condition leading to ERCP was choledocholithiasis, which accounted for 71.4% of total cases.

### Cannulation

The number of successful cannulation cases for both groups is shown in Table 2. In Table 2, "First Attempt" indicates the initial biliary cannulation method used in each group. In the first attempt, biliary cannulation was successful in 8 out of 12 patients (66.7%) in the MagicTome group



**Table 2. Rates of Successful Cannulation in the Two Groups.**

	MagicTome group (n=12)	Conventional group (n=16)	p value
<b>First attempt</b>	(MDGT)	(CDGT)	
Successful, n (%), (95% CI)	8 (66.7) (40.0-93.4)	12 (75.0) (53.8-96.2)	0.69
Unsuccessful, n (%)	4 (33.3)	4 (25.0)	
<b>Crossover attempt</b>	(CDGT)	(MDGT)	
Successful, n (%)	3 (25.0)	2 (12.5)	1.00
Unsuccessful, n (%)	1 (8.3)	2 (12.5)	

CI: confidence interval, MDGT: double-guidewire technique with MagicTome; CDGT: double-guidewire technique with a conventional device

**Table 3. Rates of Successful Cannulation and Median Procedure Time according to Cannulation Techniques.**

	MDGT (n=16)	CDGT (n=20)	p value
Successful cannulation, n (%), (95% CI)	10 (62.5) (38.8-86.2)	15 (75.0) (56.0-94.0)	0.48
Median procedure time, s (IQR)	176 (34-342)	212 (24-338)	0.24

CI: confidence interval, IQR: interquartile range, MDGT: double-guidewire technique with MagicTome; CDGT: double-guidewire technique with a conventional device

**Table 4. Comparison of Adverse Events between the Two Groups.**

	MagicTome group (n=12)	Conventional group (n=16)	p value
<b>Median laboratory data</b>			
WBC, / $\mu$ L (IQR)	7,497 (2,020-14,500)	8,073 (4,290-15,800)	0.73
Amylase, U/L (IQR)	398 (31-1,522)	225 (54-628)	0.29
<b>Adverse events</b>			
Post-ERCP pancreatitis, n (%)	1 (8.3)	0 (0)	0.43
Perforation, n (%)	0 (0)	0 (0)	-
Bleeding, n (%)	0 (0)	0 (0)	-
Mortality, n (%)	0 (0)	0 (0)	-

ERCP: endoscopic retrograde cholangiopancreatography, IQR: interquartile range

and in 12 out of 16 (75.0%) patients in the conventional group. No significant difference was observed in the success rate of biliary cannulation in the first attempt between the 2 groups ( $p=0.69$ ). A crossover attempt was made for four patients in each group. In the MagicTome group, biliary cannulation in the crossover attempt was successful in three out of four patients. In the conventional group, biliary cannulation in the crossover attempt was successful in two out of four patients. No significant difference was observed in the number of cases of successful biliary cannulation in the crossover attempt between the two groups ( $p=1.00$ ).

Biliary cannulation was not successful in either the first or crossover attempts for one patient in the MagicTome group and two patients in the conventional group. However, successful biliary cannulation was subsequently achieved for all of these patients using other methods, such as the precut method.

The number of successful cases of biliary cannulation and the biliary cannulation time in the first and crossover at-

tempts are shown in Table 3. Successful biliary cannulation by the MDGT was achieved in 10 out of 16 patients (62.5%), and successful biliary cannulation by the CDGT was achieved in 15 of 20 patients (75.0%). No significant difference was observed between these methods ( $p=0.48$ ). For the MDGT and CDGT, successful biliary cannulation by the DGT was achieved in 25 out of 28 patients (89.3%). The median biliary cannulation times were 176 seconds [interquartile range (IQR): 34-342 seconds] for the MDGT and 212 seconds (IQR: 24-338 seconds) for the CDGT. No significant difference was observed in the biliary cannulation time ( $p=0.25$ ). The total procedure times were 41.7 minutes (IQR: 28-62 minutes) in the MagicTome group and 53.1 minutes (IQR: 30-132 minutes) in the conventional group. No significant difference was observed in the total procedure time between the 2 groups ( $p=0.20$ ).

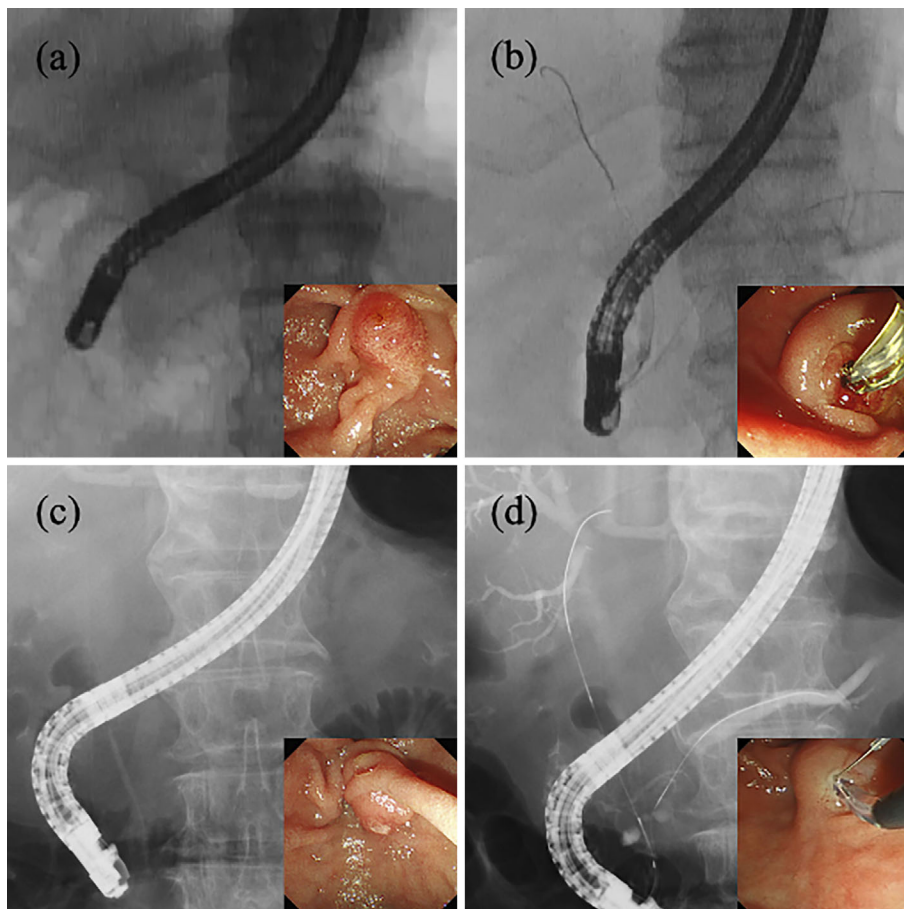
### Adverse events

The results of postoperative blood testing and procedural

**Table 5. Advantages and Disadvantages of MDGT and CDGT.**

	MDGT	CDGT
Advantages	<ul style="list-style-type: none"> <li>•Easy to direct the distal tip of MagicTome to the bile duct axis by fixing the positional relationship between the pancreatic duct guidewire and device.</li> <li>•The tip of MagicTome can be swung upward.</li> </ul>	<ul style="list-style-type: none"> <li>•Useful in the case of misalignment between the axis of the bile duct and pancreatic duct because pancreatic duct guidewire and cannulation devices are maneuvered independently.</li> </ul>
Disadvantages	<ul style="list-style-type: none"> <li>•Not suitable for cases in which the axis of the bile duct and pancreatic duct are misaligned.</li> <li>•Requires replacement of the MagicTome with another cannula or removal of the pancreatic duct guidewire when inserting a cannula into the deep portion of the bile duct.</li> </ul>	<ul style="list-style-type: none"> <li>•Maneuvering can be restricted if the cannulation device interferes with the guidewire while the device is being moved toward the bile duct.</li> </ul>

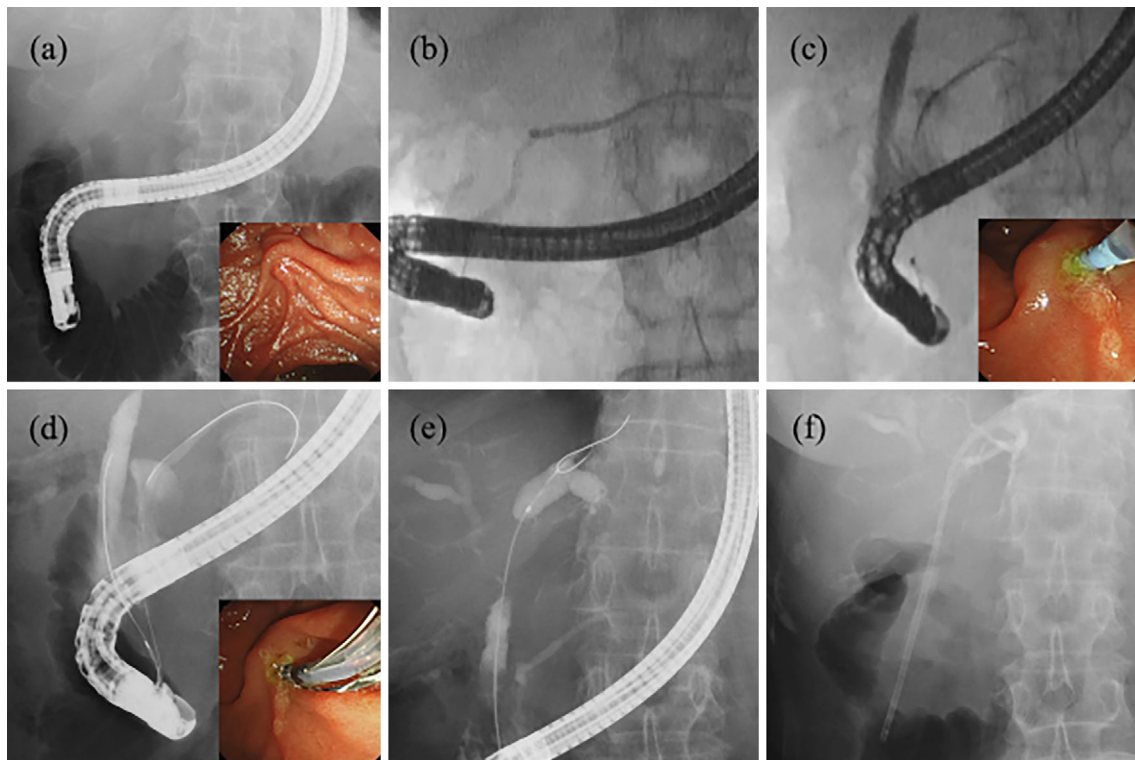
MDGT: double-guidewire technique with MagicTome, CDGT: double-guidewire technique with a conventional device



**Figure 5.** Two cases of successful biliary cannulation using the double-guidewire technique with the MagicTome (MDGT). (a) Malignant hilar biliary stricture due to gallbladder cancer. It was difficult to position the duodenoscope properly against the papilla due to adhesions. (b) It was difficult to attach the catheter to the bile duct axis, but biliary cannulation was facilitated by the MDGT. (c) Distal cholangiocarcinoma. The papilla hangs down with the orifice oriented caudally. (d) Selective biliary cannulation was successful using the MDGT by swinging the catheter tip up to align with the biliary axis.

accidents are shown in Table 4. To prevent post-ERCP pancreatitis, pancreatic duct stents were inserted in three patients, and NSAIDs were used in one. No significant difference was observed in the white blood cell count or amylase levels. Post-ERCP pancreatitis was observed in one patient in the MagicTome group; however, it was mild. In the case of post-ERCP pancreatitis, pancreatic duct stents were not

inserted, but NSAIDs were used. The total procedure time was 34 minutes, which was shorter than that in other cases. No other procedural complications were observed in either group.



**Figure 6.** Case of malignant hilar biliary stricture due to metastatic lymph nodes. (a) Frontal-view image of the duodenal papilla. The papilla is small with a long oral protrusion. (b) Pancreatography is only performed using a standard technique. (c) Contrast image showing the bile duct managed using a double-guidewire technique with a conventional device, but selective biliary cannulation is not successful. (d) Selective biliary cannulation using a double-guidewire technique with the MagicTome is successful. (e) Cholangiography shows hilar biliary obstruction. (f) A 7-Fr plastic stent is deployed.

## Discussion

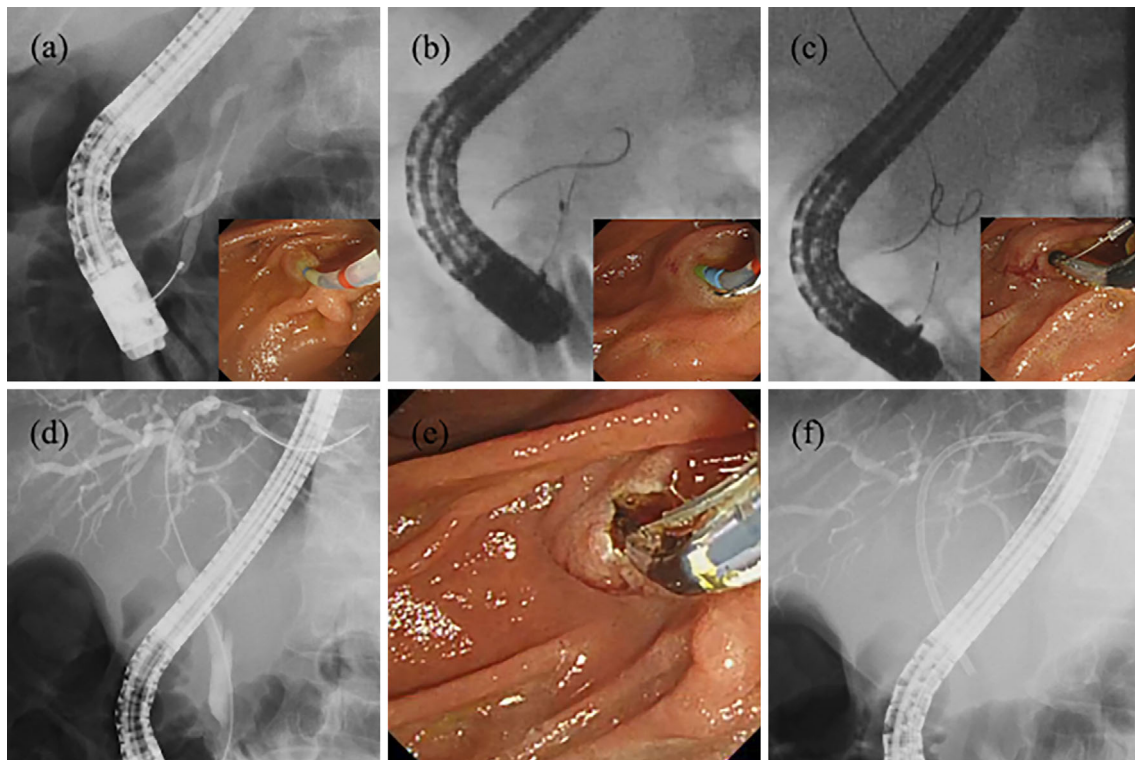
In the CDGT, a GW is placed in the pancreatic duct. Thereafter, a cannulation device is inserted again via the working channel. Selective biliary cannulation is then performed along the GW in the pancreatic duct. In this method, the GW left indwelling in the pancreatic duct and the cannulation device are maneuvered independently. Maneuvering can be restricted if the cannulation device interferes with the GW while the device is moved toward the bile duct. In such cases, it can be difficult to apply the device to the papilla. Furthermore, great care is required during biliary cannulation not only in maneuvering the cannulation device but also with regard to ensuring that the GW in the pancreatic duct does not become dislocated. In contrast, in the MDGT, the cannulation device and the pancreatic duct GW are integrated with each other because a MagicTome is inserted into the lumen for the pancreatic duct GW through the GW in the pancreatic duct. Therefore, unlike with the CDGT, the positional relationship between the pancreatic duct GW and device is fixed. This enables the easy application of the procedural device to the papilla. In addition, the tip of the MagicTome can be swung upward in a similar fashion to conventional sphincterotomes, making it easy to direct the tip toward the bile duct axis. Owing to MagicTome's design,

the device can likely increase the success rate of biliary cannulation by the DGT. Furthermore, the MagicTome can help reduce post-ERCP pancreatitis because the device is expected to reduce accidents during insertion into the pancreatic duct.

The advantages and disadvantages of the MDGT and CDGT are shown in Table 5. One advantage of the MDGT is that the distal tip of the MagicTome is easy to direct to the bile duct axis by fixing the positional relationship between the pancreatic duct GW and the device. In cases where it is difficult to attach a catheter at the bile duct orifice because of adhesion or other factors, the MDGT can be an effective tool. Another advantage of the MDGT is that the tip of the MagicTome can be swung upward, which facilitates difficult biliary cannulation, even in cases where the papilla hangs down with the orifice oriented caudally. However, one disadvantage of the MDGT is that it may not be suitable for cases in which the axis of the bile duct and pancreatic duct are misaligned, as pancreatic duct GW and cannulation devices are not maneuvered independently. Another disadvantage of the MDGT is that it requires replacement of the MagicTome with another cannula or removal of the pancreatic duct GW when inserting a cannula into the deep portion of the bile duct.

We will now describe several cases in which the MagicTome was useful for biliary cannulation and one case in



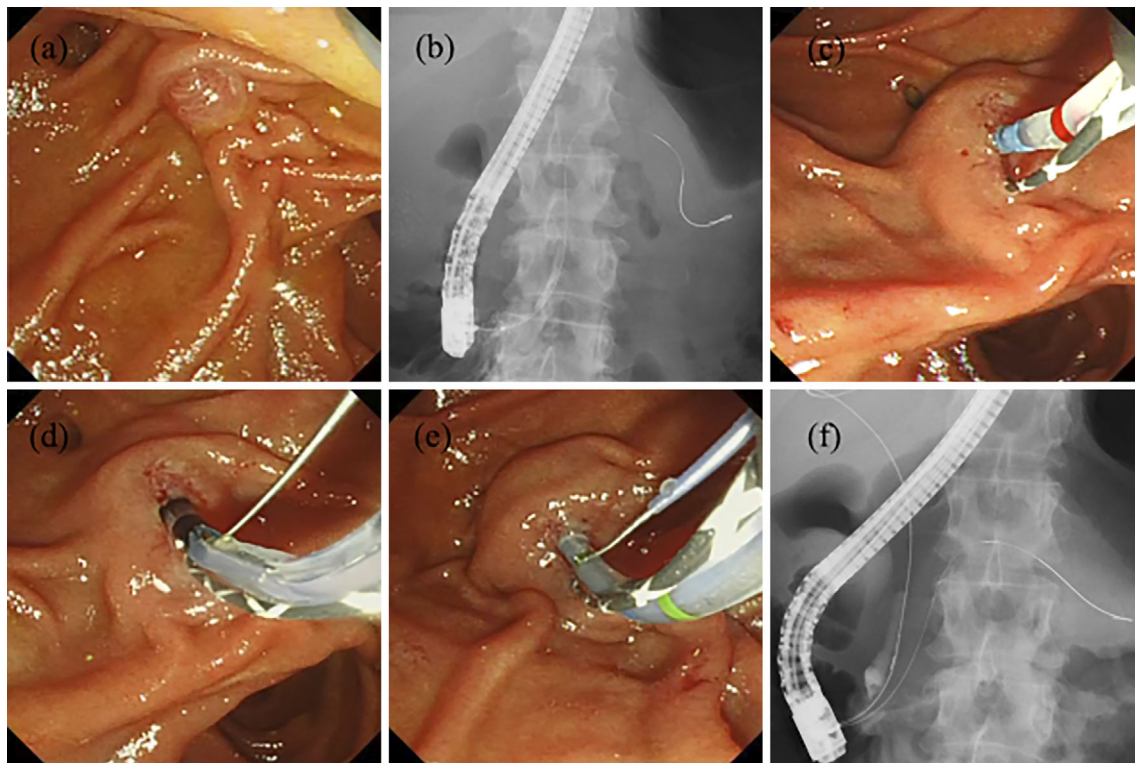


**Figure 7.** Case of hilar cholangiocarcinoma. (a) Pancreatography is only performed using a standard technique. (b) After placing the guidewire into Santorini's duct, we attempt selective biliary cannulation using a double-guidewire technique with a conventional device, but it is unsuccessful. (c) Selective biliary cannulation is successful using a double-guidewire technique with the MagicTome by swinging the catheter tip up to align with the biliary axis. (d) Cholangiography shows hilar biliary obstruction. (e) Sphincterotomy is performed using the MagicTome. (f) A 7-Fr plastic stent is deployed above the papilla in the left hepatic bile duct.

which biliary cannulation using a MagicTome was unsuccessful in the present study. Two cases of successful biliary cannulation using the MDGT in the MagicTome group are shown in Fig. 5. In one of the cases, it was difficult to attach the catheter to the bile duct axis due to adhesion, but the MDGT facilitated attachment. In the other case, the papilla hung down with the orifice oriented caudally. Selective biliary cannulation was successful using the MDGT by swinging the catheter tip up to align with the biliary axis. In both cases, the use of the MDGT was considered effective for ensuring safe and reliable biliary cannulation. Two cases of successful biliary cannulation in the conventional group are shown in Fig. 6 and 7. In both cases, biliary cannulation was successfully achieved by changing the technique from the CDGT to the MDGT. In contrast, three cases of successful biliary cannulation by changing the cannulation method from the MDGT to the CDGT were observed. In some of these cases, the axes of the bile duct and pancreatic duct were misaligned, and the efficacy of the MDGT was not fully demonstrated. Three cases of unsuccessful biliary cannulation in either the first or crossover attempt were also observed. One case in which biliary cannulation was unsuccessful for both the first and crossover attempts in the conventional group is shown in Fig. 8.

In the present study, the success rate of biliary cannula-

tion by the MDGT for patients with difficult biliary cannulation was 62.5%. There was no marked difference between this finding and the success rates of biliary cannulation by the DGT reported in earlier studies. The success rate of biliary cannulation by the MDGT was expected to be higher than that by the CDGT, but there was no significant difference between these techniques. There are two reasons for this. First, the number of patients included was small. Second, the MagicTome was a new device that was not regularly used for biliary cannulation. Thus, the rate of biliary cannulation by the MDGT may improve with experience. Furthermore, this study found that using the MDGT for patients in the conventional group for whom successful biliary cannulation could not be achieved using the CDGT led to successful biliary cannulation. In addition, the overall success rate of biliary cannulation with the DGT, which combined data for the CDGT and MDGT, was 89.3%. The success rate of biliary cannulation using the DGT was 43.8-92.6% in previous reports (11-18). The result of this study was favorable compared to previous reports. Since this study examined only a small number of patients, future studies should examine a larger number of patients, including not only those with malignant biliary obstruction, but also those with certain conditions, such as periampullary diverticulum, which can make it difficult to approach the duodenal papilla.



**Figure 8.** Case of a bile duct stone. (a) Frontal-view image of the duodenal papillae. (b) The guidewire is placed into the pancreatic duct. (c) Biliary cannulation by the CDGT is unsuccessful because the catheter is unable to align with the bile duct axis. (d) Biliary cannulation by the MDGT is also unsuccessful. (e) Successful biliary cannulation is achieved using a conventional sphincterotome by swinging the catheter tip up to align with the biliary axis. (f) The guidewire is inserted into the bile duct.

The main limitation associated with the present study is that it involved a small number of patients. This was due to the fact that very few cases required the DGT during the study period. Since there were many cases of successful bile duct cannulation within the first 10 minutes, it was considered difficult to secure a sufficient number of cases even if the duration of this study was extended. Future studies should secure a larger number of patients in order to validate the effectiveness of the MDGT.

In conclusion, the MDGT is an effective and safe biliary cannulation technique for patients in whom biliary cannulation is difficult.

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

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