**Comparison between a rotatable sphincterotome and a conventional sphincterotome for selective bile duct cannulation**

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**Submitted** 16.3.2018  
**Accepted after revision** 22.12.2018

**Bibliography**
DOI https://doi.org/10.1055/a-0835-5900  
Published online: 13.2.2019 | Endoscopy 2019; 51: 852–857  
© Georg Thieme Verlag KG Stuttgart · New York  
ISSN 0013-726X

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**Online content viewable at:**  
https://doi.org/10.1055/a-0835-5900

**Fig. s1**

**ABSTRACT**

**Background** Selective biliary cannulation (SBC) is the first challenge of endoscopic retrograde cholangiopancreatography (ERCP), especially for trainees, and a rotatable sphincterotome may be useful to guide the directional axis of the scope and SBC.

**Methods** We performed a prospective randomized single-center trial, enrolling 200 patients with a native papilla who required therapeutic biliary ERCP. Patients were randomly assigned to the rotatable sphincterotome group (n=100) or the conventional sphincterotome group (n=100). The primary endpoint was successful SBC by the trainees within 10 minutes.

**Results** The early and late cannulation success rates did not differ significantly between the groups (P=0.46 and P>0.99, respectively). For the patients in whom trainees failed to achieve SBC, the rotatable sphincterotome was used as a rescue cannulation technique in four patients from the conventional group; in no patients in the rotatable group was the conventional sphincterotome used for SBC. Post-ERCP pancreatitis (PEP) occurred in 11 patients (5.5%; 6 mild, 5 moderate); the incidence did not differ significantly between the two groups (rotatable group 3%, conventional group 8%; P=0.21). The two groups were thus combined for evaluation of the factors relating to cannulation difficulty for trainees, which revealed that orientation of the papilla was a significant factor (P<0.001).

**Conclusions** The type of sphincterotome used did not affect the success of SBC by trainees. However, orientation of the papilla was revealed to be a significant factor relating to cannulation difficulty for trainees overall.

University Hospital Medical Network Clinical Trials Registry UMIN000018032  
TRIAL REGISTRATION: Single-center, randomized, prospective study UMIN000018032 at http://www.umin.ac.jp

**Introduction**
Endoscopic retrograde cholangiopancreatography (ERCP) is an indispensable procedure for pancreaticobiliary disorders, not only for therapeutic aims but also as a diagnostic tool. ERCP is however a technically challenging procedure, with a high adverse event rate (up to 10%); it is difficult to educate trainees in its performance because there is little time to spare during the procedure [1–4]. The first challenge for trainees is selective biliary cannulation (SBC). To improve their SBC rate, trainees...
need experience with many cases, but at the same time, involving trainees should be avoided to reduce the risk of adverse events, which thereby creates a dilemma.

Some studies have reported the efficacy of an ERCP mechanical simulator (EMS) to overcome this problem [5, 6]. The availability of an EMS is not widespread however, even among educational institutions in Japan. In hospitals in which there is no EMS, novice trainees must sometimes depend on verbal cues from the expert to more quickly determine the appropriate directional aim toward the bile duct.

Novice trainees often have difficulty positioning the scope against the papilla of Vater and appreciating the alignment of the catheter with the bile duct axis. These conditions make SBC difficult. A rotating sphincterotome with the ability to change the orientation of the tip in relation to the papilla, which is often used in patients with altered anatomy such as a prior Billroth II anastomosis, may help to guide the directional axis of the scope and has been used to perform wire-guided cannulation [7, 8]. Although the rotating tip may help the novice endoscopist to cannulate the desired duct, its usefulness has not been evaluated. Therefore, in this study, we evaluated the efficacy of a rotatable sphincterotome compared with a conventional sphincterotome for SBC performed by beginners.

Methods

Study design

Between May 2016 and December 2017, a single-center prospective randomized controlled trial was carried out at Kitano Hospital. A total of 13 endoscopy trainees were involved in the study. The definition of an ERCP trainee was someone with experience of fewer than 200 ERCP cases, in accordance with the American Society for Gastrointestinal Endoscopy (ASGE) recommendation [9]. This study was approved by the Kitano Hospital ethics review board and registered in the UMIN clinical trials registry (UMIN000018032).

Patients with a native papilla requiring therapeutic biliary ERCP were candidates for the study. Informed consent was obtained from all participants before the procedure. Exclusion criteria were as follows: age < 20 years, Billroth II or Roux-en-Y anatomy, ERCP for pancreatic intervention, suspected anomalous pancreaticobiliary channel, inaccessible papilla (e.g., due to duodenal stenosis), ampullary neoplasm, acute pancreatitis, bilioduodenal fistula opening around the papilla, poor general condition with severe cardiopulmonary disease or altered consciousness.

Enrolled patients were randomly assigned to one of two groups (rotatable group or conventional group) when a native papilla appeared during ERCP. Randomization was performed centrally, stratified according to the presence of acute cholangitis, using a computer program. Patients were randomly assigned to the use of either sphincterotome.

Endoscopic procedures

ERCP was performed with a side-viewing duodenoscope (TJF-260V; Olympus Medical Systems Co. Ltd., Tokyo, Japan) in the standard manner, with the patient under conscious sedation using diazepam and pethidine hydrochloride, and with continuous pulse oximetry monitoring of their oxygen saturation.

SBC was performed by wire-guided cannulation using a sphincterotome preloaded with a 0.025-inch guidewire (VisiGlide2; Olympus Medical Systems Co. Ltd., Tokyo, Japan). The CannulaTome is a rotatable sphincterotome with a rounded tip (6 Fr, 7-mm nose, cutting wire 20 mm, double-lumen type; Cook Medical, Bloomington, Indiana, USA; Video 1). The CleverCut 3V is a conventional sphincterotome that is used widely throughout the world (4.5 Fr, 7-mm nose, cutting wire 20 mm, triple-lumen; Olympus Medical Systems Co. Ltd.).

All procedures were first performed by the 13 trainees with the assistance of one of two trainers (A. K. or Y. K.), each having more than 10 years ERCP experience, who controlled the guide-wire. The trainees performed the cannulation using the randomly assigned sphincterotome for the first 10 minutes. If biliary access was not achieved within 10 minutes, the endoscopist was changed to the trainer to access the bile duct without changing strategies for a further 10 minutes, before alternative...
techniques, such as double-guidewire cannulation, were adopted to access the biliary tree.

In patients where SBC failed, other methods were considered, including salvage techniques such as precut sphincterotomy and endoscopic ultrasound (EUS)-related procedures, including EUS-guided choledochoduodenostomy (EUS-CDS) and EUS-guided rendezvous procedure (EUS-RV).

During the trainee’s attempt to cannulate, the trainer provided unlimited verbal instructions without hands-on assistance. The trainer was able to modulate the angle of the sphincterotome, the rotation (only in rotatable group), as well as directly control the guidewire during cannulation.

During the ERCP procedure, another trainer recorded the appearance (a/b/c) and orientation in the endoscopic view (d/e/f) of the papilla, number of cannulation attempts, number of pancreatic duct entries with the guidewire, cannulation time by trainees, and total cannulation time, and total procedure time (Video 1: see online-only supplementary material). The position of the papilla recorded in the data collection sheet was the position where the papilla was for the majority of time after rectification of the scope during attempts at biliary cannulation.

Definition of events

Early SBC success was defined as biliary cannulation within 10 minutes by the trainee using either of the two sphincterotomes. There was no consensus regarding the optimal time allocated for trainees to attempt the cannulation. European guidelines define a difficult biliary cannulation as more than five contacts with the papilla while attempting to cannulate and/or >5 minutes spent attempting to cannulate following visualization of the papilla [10]. For novice trainees, achieving SBC within these limitations is difficult; however, in one randomized controlled trial 10 minutes was considered to be an appropriate amount of time for trainees to attempt cannulation [11]. Late SBC success was defined as the sum of primary SBCs without precut sphincterotomy or EUS-related procedures. Final biliary access success was defined as the sum of the times when biliary access was achieved, even using precut sphincterotomy or EUS-related methods.

The time needed for early biliary cannulation was defined as the time period from the initial attempt at biliary cannulation to successful selective insertion of the guidewire into the bile duct. Consensus guidelines were used for definitions, grading, and therapy for ERCP adverse events, such as post-ERCP pancreatitis (PEP) [12].

Outcome measurements

The primary endpoint was successful SBC by the trainees within 10 minutes. The secondary endpoints were successful SBC by trainers after 10 minutes, final biliary access rate, incidence of adverse events (PEP, bleeding, perforation, and mortality), number of attempts at biliary cannulation, cannulation time period, and number of unintended pancreatic duct cannulations.

Statistical analysis

The SBC success rate by the trainees using a conventional sphincterotome was 50% in a previous report [6]. We hypothesized that a rotatable sphincterotome would improve the SBC rate to 70%. To detect this difference with a power of 0.8 and an alpha of 0.05, complete data from at least 93 patients per group were required. Therefore, assuming a dropout rate of 7% of enrolled patients, a sample size of 100 patients was needed for each group.

All continuous variables are expressed as the median (range), and categorical values are described with counts and percentages. Categorical variables were compared using either the chi-squared test or the Fisher’s exact test and a logistic regression model; quantitative variables were compared using either Student’s t test or the Mann-Whitney U test. A P value of <0.05 was considered statistically significant (for the Student’s t test and Mann-Whitney U test, P values were always two-sided). All statistical analyses were performed using JMP version 13.0 (SAS Institute, Cary, North Carolina, USA).

Results

During the study period, 966 patients underwent ERCP. Among them, 246 patients met the initial inclusion criteria, of whom 46 were excluded (Fig. 2). The remaining 200 patients were enrolled in the study and their data were analyzed. The demographic data are shown in Table 1. The two groups did not differ significantly in age, American Society of Anesthesiologists (ASA) classification, or indications for ERCP, but there were significant differences between the groups in terms of sex and the rate of periampullary diverticula.

Study outcomes are shown in Table 2. There was no statistically significant difference between the two groups in any of the outcomes, including the rate of early cannulation success. Early SBC was achieved in 65% of the patients, with a total median cannulation time of 3 minutes, whereas overall SBC rates reached 96%. For the patients in whom the trainees failed to...
To achieve SBC, the rotatable sphincterotome was used as a rescue cannulation technique in four patients in the conventional group; in contrast, the conventional sphincterotome was not used for any patients in the rotatable group. SBC was not achieved by either trainee or trainer in eight patients, with the rescue methods used to gain biliary access being precut sphincterotomy (n = 6), EUS-CDS (n = 1), and EUS-RV (n = 1).

The rates of overall procedure-related adverse events did not differ significantly between the two groups (P = 0.16), and no patients died in either group. Mild post-ERCP bleeding occurred in one patient in the conventional group following sphincterotomy. Perforation occurred in two patients in relation to the sphincterotomy—one in the rotatable group and one in the conventional group. In both patients, conservative treatment was effective without the need for surgery. PEP occurred in 11 patients (5.5%; 6 mild, 5 moderate), and there were no significant differences between the two groups (rotatable group 3%, conventional group 8%; P = 0.21). In the rotatable group, for all three patients PEP occurred after the failure of early cannulation. In the conventional group, PEP occurred in four patients after early cannulation (all mild), and in another four patients after the failure of the early cannulation.

Because there was no difference between the two groups, we combined them into one to evaluate factors relating to cannulation difficulty for trainees. These results revealed that the
orientation of the papilla was a significant factor ($P<0.001$; Table 3). On the other hand, the presence of a periampullary diverticulum and appearance of the papilla were not important factors in the trainee’s ability to cannulate.

### Discussion

Here we report a randomized controlled study comparing the safety and efficacy of a rotatable sphincterotome vs. a conventional sphincterotome for trainees performing SBC using the wire-guided cannulation technique. Our findings revealed no significant differences in SBC when trainees used the rotatable sphincterotome compared with the conventional sphincterotome. In the present study, however, trainees achieved better SBC rates (65%) compared with previous reports (~50%), regardless of the type of sphincterotome used [6, 11, 13]. Therefore, the successful results of SBC with the conventional sphincterotome were better than we had assumed beforehand. On the other hand, our findings revealed that orientation of the papilla was a significant factor relating to cannulation difficulty for trainees.

There are limited data on SBC rates for a native papilla among trainees. A greater than 80% SBC rate is considered to be the bare minimum for credentialing to perform ERCP for trainees [9, 14]. These data included patients whose papilla had previously undergone sphincterotomy and actual data limited to a native papilla were lacking, but would be presumed to...

### Table 2 Study outcomes for the two groups of patients undergoing selective biliary cannulation by trainees.

<table>
<thead>
<tr>
<th></th>
<th>Rotatable (n = 100)</th>
<th>Conventional (n = 100)</th>
<th>Odds ratio (95% confidence interval)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early cannulation success, n (%)</td>
<td>68 (68)</td>
<td>62 (62)</td>
<td>1.30 (0.73 – 2.33)</td>
<td>0.46</td>
</tr>
<tr>
<td>Early cannulation time, median (range), minutes</td>
<td>3 (1 – 10)</td>
<td>3.5 (1 – 10)</td>
<td></td>
<td>0.56</td>
</tr>
<tr>
<td>Number of attempts at early cannulation, median (range), n</td>
<td>7 (1 – 16)</td>
<td>8 (1 – 24)</td>
<td></td>
<td>0.76</td>
</tr>
<tr>
<td>Pancreatic duct entry during early cannulation, n (%)</td>
<td>24 (35.3)</td>
<td>19 (30.6)</td>
<td>1.35 (0.68 – 2.65)</td>
<td>0.58</td>
</tr>
<tr>
<td>Late selective bile duct cannulation success, n (%)</td>
<td>96 (96)</td>
<td>96 (96)</td>
<td>1.00 (0.24 – 4.11)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>Late cannulation time, median (range), minutes</td>
<td>15.5 (10 – 58)</td>
<td>16 (10 – 66)</td>
<td></td>
<td>0.95</td>
</tr>
<tr>
<td>Secondary cannulation method used by trainer, n</td>
<td>Rotatable 24</td>
<td>Conventional 27</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final method of biliary access, n</td>
<td>Precutting 3</td>
<td>Precutting 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final technical success for bile duct access, n (%)</td>
<td>100 (100)</td>
<td>100 (100)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall adverse events, n</td>
<td>4</td>
<td>10</td>
<td>0.38 (0.11 – 1.24)</td>
<td>0.16</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>3</td>
<td>8</td>
<td>0.36 (0.09 – 1.38)</td>
<td>0.21</td>
</tr>
<tr>
<td>– Mild</td>
<td>–</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Moderate</td>
<td>3</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>–</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perforation</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>–</td>
<td>–</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GW, guidewire; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-RV, EUS-guided rendezvous procedure.

### Table 3 Risk factors affecting the cannulation success of the trainees.

<table>
<thead>
<tr>
<th></th>
<th>Trainee success (n = 130)</th>
<th>Trainee failure (n = 70)</th>
<th>Odds ratio (95% confidence interval)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periampullary diverticulum, yes/no, n</td>
<td>53/77</td>
<td>22/48</td>
<td>1.50 (0.81 – 2.78)</td>
<td>0.22</td>
</tr>
<tr>
<td>Appearance of papilla of Vater, a/b/c*, n</td>
<td>7/72/51</td>
<td>8/29/33</td>
<td>1.76 (0.97 – 3.16)</td>
<td>0.10</td>
</tr>
<tr>
<td>Orientation of papilla of Vater, d/e/f*, n</td>
<td>22/103/5</td>
<td>27/35/8</td>
<td>3.81 (2.03 – 7.18)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* See Fig. 1

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be lower. Taking this into consideration, our trainees’ SBC rate of 65% is not so bad.

The most important factor for trainees to improve their ERCP technique is the ability to image the direction of the intrapapillary and suprapapillary bile duct from the orifice of the papilla. Verbal cues from the expert trainer are helpful to achieve this imaging and, especially when using a rotatable sphincterotome, may be theoretically helpful to guide adjustments of the direction of the catheter toward the papilla. In our study, the trainers were allowed to provide unlimited verbal instructions to both groups, which may have facilitated the trainees obtaining a better orientation in front of the papilla. The trainer’s instructions might therefore have reduced the benefits of the rotatable sphincterotome.

Although our data do not demonstrate the efficacy of a rotatable sphincterotome over a conventional sphincterotome, exchanging the conventional sphincterotome with a rotatable sphincterotome was necessary to gain SBC in four patients with an intradiverticular papilla (detailed data not provided). On the other hand, there were no patients in whom the rotatable sphincterotome was exchanged for a conventional sphincterotome to achieve SBC. This suggests that a rotatable sphincterotome may manifest benefits in special situations, such as an intradiverticular papilla, because of the ability to rotate the head to adjust to the papillary orifice and bile duct. Further studies are needed to demonstrate the usefulness of a rotating device by evaluating its use in patients with anatomic limitations.

Another reason for this study, apart from comparing the efficacy of the two devices, was to evaluate whether the use of a rotatable sphincterotome reduces adverse events, especially PEP, because of its rounded-tip, which may cause less mechanical trauma. Our results revealed no significant difference between the two groups with regard to the overall adverse event rate and PEP rate (rotatable group, 4% and 3%, respectively; conventional group, 10% and 8%, respectively), although no PEP was observed in patients with SBC successfully achieved by the trainees with the rotatable sphincterotome. The number of women in the conventional group was significantly higher than in the rotatable group. Female sex is considered to be an independent risk factor for PEP; however, our results showed the rate of PEP was similar between male and female patients (data not provided). Taken together, the rounded tip of the rotatable sphincterotome should work effectively to protect the papilla, thereby reducing the stress to prevent PEP.

This study has some limitations. First, the study was performed at a single center and the sample size was relatively small. To obtain more robust data regarding the potential superiority of the rotatable sphincterotome, a larger number of patients is required. Second, enrolled patients in this study all had a native papilla and SBC was achieved in more than half of the patients within 5 minutes; therefore, it appears many easy cases were included and patients would need to be carefully selected to demonstrate the efficacy of the rotatable sphincterotome where SBC is more difficult. Our data also showed that orientation of the papilla was a significant factor relating to cannulation difficulty for trainees, so patients with a particular orientation of the papilla might be chosen as cases of difficult SBC.

In conclusion, our findings suggest that the type of sphincterotome used is not the most important point for trainees to achieve SBC. Appropriate verbal cues from the trainers may be more important. Orientation of the papilla was revealed to be a significant factor relating to cannulation difficulty for trainees overall.

Competing interests

None

References