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Randomized Controlled Trial
Randomized study of 0.025-inch vs 0.035-inch guide wires with wire-guided cannulation

Kitamura K et al. Guide wires with wire-guided cannulation

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Author contributions: Kitamura K designed this study, collected and analyzed the data; Kitamura K drafted the manuscript and gave final approval of the version to be published; Kitamura K, Yamamiya A, Ishii Y, Sato Y, Iwata T, Nomoto T, Ikegami A and Yoshida H took part in this study as endoscopic operators or assistants.

Supported by
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Abstract

BACKGROUND

AIM
To compare the clinical outcomes between 0.025-inch and 0.035-inch guide wires (GWs) when used in wire-guided cannulation (WGC).

METHODS
A single center, randomized study was conducted between April 2011 and March 2013. This study was approved by the Medical Ethics Committee at our hospital. Informed, written consent was obtained from each patient prior to study enrollment. Three hundred and twenty-two patients with a naïve papilla of Vater who underwent endoscopic retrograde cholangiopancreatography (ERCP) for the purpose of selective bile duct cannulation with WGC were enrolled in this study. Fifty-three patients were excluded by the exclusion criteria, and 269 patients were randomly allocated to two groups by a computer and analyzed: a 0.025-inch GW group \((n = 109)\) and a 0.035-inch GW group \((n = 160)\). The primary point measurement was the success rate of selective bile duct cannulation with WGC. Secondary point measurements were the success rates of the pancreatic GW technique and precutting, selective bile duct cannulation time, ERCP procedure time, the rate of pancreatic duct stent placement, the final success rate of selective bile duct cannulation, and the incidence of post ERCP pancreatitis (PEP).

RESULTS
The primary success rates of selective bile duct cannulation with WGC were 80.7\% \((88/109)\) and 86.3\% \((138/160)\) for the 0.025-inch and the 0.035-inch groups, respectively \((P = 0.226)\). There were no statistically significant differences in the success rates of selective bile duct cannulation using the
pancreatic duct GW technique (46.7% vs 52.4% for the 0.025-inch and 0.035-inch groups, respectively; \( P = 0.884 \)) or in the success rates of selective bile duct cannulation using precutting (66.7% vs 63.6% for the 0.025-inch and 0.035-inch groups, respectively; \( P = 0.893 \)). The final success rates for selective bile duct cannulation using these procedures were 92.7% (101/109) and 97.5% (156/160) for the 0.025-inch and 0.035-inch groups, respectively (\( P = 0.113 \)). There were no significant differences in selective bile duct cannulation time (median ± interquartile range: 3.7 ± 13.9 min vs 4.0 ± 11.2 min for the 0.025-inch and 0.035-inch groups, respectively; \( P = 0.851 \)), ERCP procedure time (median ± interquartile range: 32 ± 29 min vs 30 ± 25 min for the 0.025-inch and 0.035-inch groups, respectively; \( P = 0.184 \)) or in the rate of pancreatic duct stent placement (14.7% vs 15.6% for the 0.025-inch and 0.035-inch groups, respectively; \( P = 0.832 \)). The incidences of PEP were 2.8% (3/109) and 2.5% (4/160) for the 0.025-inch and 0.035-inch groups, respectively (\( P = 0.793 \)).

CONCLUSION
The thickness of the GW with WGC does not appear to affect either the success rate of selective bile duct cannulation or the incidence of PEP.

Key words: Endoscopic retrograde cholangiopancreatography; Guide wire; Post-endoscopic retrograde cholangiopancreatography pancreatitis; Selective bile duct cannulation; Wire-guided cannulation

Core tip: The thickness of the guide wire with wire-guided cannulation appears not to affect either the success rate of selective bile duct cannulation or the incidence of post endoscopic retrograde cholangiopancreatography pancreatitis.
INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is important for diagnosing and performing procedures that are related to the biliary tract and pancreatic disease. Selective bile duct cannulation is a basic biliary tract procedure of ERCP. Cannulation using contrast medium has been performed as a conventional cannulation; however, it has been suggested that pancreatic contrast injection might be associated with the mechanism of post-ERCP pancreatitis (PEP)\[1\]. According to several reports, the incidence of PEP following this procedure is 1%-15\%\[2-5\]. In a meta-analysis of randomized, controlled trials (RCTs), it has been suggested that selective bile duct cannulation using wire-guided cannulation (WGC) might improve the primary bile duct cannulation rate and reduce the risk of PEP\[6\].

A sphincterotome or catheter and a guide wire (GW) are necessary for the WGC procedure. Various GWs are used, such as a straight or an angled type of tip with different outer diameters. One report suggested that there were no significant differences in the success rate of primary cannulation or in the risk of adverse events between 0.025-inch and 0.035-inch GWs\[7\]; however, no consensus exists regarding the type of GW that is most appropriate for the WGC procedure.

The aim of this study was to investigate whether clinical differences exist in the success rate of selective bile duct cannulation and the incidence of PEP with WGC using 0.025-inch or 0.035-inch GWs.

MATERIALS AND METHODS

This study was conducted as an exploratory randomized study at Showa University Hospital. The study protocol was approved by the Medical Ethics Committee at our hospital and was registered at UMIN Clinical Trial Registry (UMIN000010082). Informed, written consent was obtained from each patient. Endoscopists performed ERCP either as an operator or as an assistant.
**Patients**

The success rate of selective bile duct cannulation with WGC using a sphincterotome is reportedly $69.1\%-98.5\%$.[8-13] The sample size was calculated based on the assumption of a 90% success rate of selective bile duct cannulation using WGC. Non-inferiority was demonstrated within a margin of 10% at a one-sided significance level of 0.025 and a power of 80%, with a sample size of 142 patients in each group.

Between April 2011 and March 2013, 322 patients with a naïve papilla of Vater who underwent ERCP for the purpose of selective bile duct cannulation with WGC were enrolled in this study. Exclusion criteria were as follows: age under 15 years, postoperative intestinal reconstruction (Billroth II or Roux-en-Y), acute biliary pancreatitis, or inability to obtain informed consent. Fifty-three patients were excluded based on the exclusion criteria; the remaining 269 patients were randomly allocated to two groups using a computer and analyzed: the 0.025-inch GW group ($n = 109$) and the 0.035-inch GW group ($n = 160$) (Figure 1).

**Devices**

ERCP was performed using a duodenoscope (JF-260V; Olympus Medical Systems Corp, Tokyo, Japan). As a GW, a 0.025-inch, 450-cm-long GW with an outer diameter of 0.65 mm or a 0.035-inch, 450-cm-long GW with an outer diameter of 0.91 mm with a straight tip (Jagwire; Boston Scientific, Natick, MA, USA) was used. Jagwire contains a nitinol core covered with polytetrafluoroethylene, and the tip is coated with a hydrophilic polymer. A sphincterotome with a tip length of 7 mm and a cutting wire length of 20 mm (Autotome RX39 or RX44; Boston Scientific) was used.

**Selective bile duct cannulation with WGC**

Physician-controlled WGC using a sphincterotome and a GW was performed
for bile duct cannulation. When we could not perform bile duct cannulation within approximately ten minutes after seeing the papilla of Vater, bile duct cannulation using the pancreatic duct GW technique (double-wire technique) was attempted. If bile duct cannulation using the pancreatic duct GW technique was not successful within approximately five minutes, pancreatic sphincter precutting was performed. If the cannulation of GW to the pancreatic duct was difficult, precutting from the papilla of Vater without use of the pancreatic duct GW technique was performed. To prevent pancreatitis, all patients received intravenous infusions of protease inhibitor (gabexate mesilate, 600 mg) for approximately 12 h, beginning immediately after the ERCP procedures. A 5-Fr straight, 3-cm-long pancreatic duct stent, which was unflanged on the pancreatic ductal side and had 2 flanges on the duodenal side (GPDS-5-3, COOK Endoscopy Inc., Winston-Salem, NC, United States), was retained after performing the pancreatic GW technique and precutting. Stent dislodgments were confirmed using abdominal X-rays, which were recorded the day after the ERCP.

Outcome measurements
The primary point was the success rate of selective bile duct cannulation using WGC. The secondary end points were the success rates of the pancreatic GW technique and precutting, selective bile duct cannulation time, ERCP procedure time, the rate of pancreatic duct stent placement, the final success rate of selective bile duct cannulation, and the incidence of PEP.

PEP was defined as abdominal pain and serum amylase level more than three times the upper limit of normal within 24 h after the procedure[14]. The severity of PEP was graded according to widely accepted criteria: mild, requiring hospitalization for 2-3 d; moderate, requiring hospitalization for 4-10 d; and severe, requiring hospitalization for more than 10 d, requiring intervention (percutaneous drainage or surgery), the development of necrosis, or the
development of pseudocyst\textsuperscript{[14]}. Other adverse events, such as bleeding, perforation, and cholangitis, were defined according to the same criteria\textsuperscript{[14]}. 

**Statistical analysis**

Continuous variables are expressed as medians with interquartile ranges (IQRs). Statistical analyses were performed using StatMate III (ATMS Co. Ltd., Tokyo, Japan). Data were analyzed using the Mann-Whitney \textit{U}-test and the Chi-squared test, and differences of \( P < 0.05 \) were considered significant.

**RESULTS**

**Patient characteristics**

Patient characteristics are shown in Table 1. There were no statistically significant differences in age and sex between the groups. There was significantly more cholangiocarcinoma in the 0.025-inch group than in the 0.035-inch group (\( P = 0.019 \)), but other diseases were not significantly different between the groups. There were no significant differences in the biliary and pancreatic procedures between the groups.

**Selective bile duct cannulation**

The primary success rates of bile duct cannulation using WGC were 80.7\% and 86.3\% for the 0.025-inch and in 0.035-inch groups, respectively (\( P = 0.226 \)). Rates of use of the pancreatic duct GW technique were 13.8\% and 13.1\% for the 0.025-inch and 0.035-inch groups, respectively (\( P = 0.880 \)), and the success rates of selective bile duct cannulation using the pancreatic duct GW technique were 46.7\% and 52.4\% for the 0.025-inch and the 0.035-inch groups, respectively (\( P = 0.884 \)). Precutting rates were 8.3\% and 6.9\% for the 0.025-inch and 0.035-inch groups, respectively (\( P = 0.672 \)), and selective success rates of bile duct cannulation with precutting were 66.7\% and 63.6\% for the 0.025-inch and 0.035-inch groups, respectively (\( P = 0.893 \)). The final success rates of selective
bile duct cannulation using these procedures were 92.7% and 97.5% for the 0.025-inch and 0.035-inch groups, respectively \((P = 0.113)\). There were no statistically significant differences regarding these procedures between the groups (Table 2).

**Pancreatic duct stent placement**

The pancreatic duct stent placement rate was 14.7% (16/109) in the 0.025-inch group and 15.6% (25/160) in the 0.035-inch group. There was no statistically significant difference in pancreatic duct stent placement between the groups \((P = 0.832)\).

**Selective bile duct cannulation time and ERCP procedure time**

Median selective bile duct cannulation time was 3.7 min (IQR: 13.9) in the 0.025-inch group and 4.0 min (IQR: 11.2) in the 0.035-inch group. The median ERCP procedure times were 32 min (IQR: 29) and 30 min (IQR: 25) for the 0.025-inch and 0.035-inch groups, respectively. There were no statistically significant differences in selective bile duct cannulation time \((P = 0.851)\) and ERCP procedure time \((P = 0.184)\) between the groups.

**Adverse events**

PEP occurred in 2.8% of the 0.025-inch group and in 2.5% of the 0.035-inch group. There was no statistically significant difference in the incidence of PEP between the groups \((P = 0.793)\). With respect to the severity of PEP, in the 0.025-inch group, 2 patients had moderate pancreatitis and 1 patient had severe pancreatitis, whereas in the 0.035-inch group, 1 patient had mild pancreatitis, 2 patients had moderate pancreatitis, and 1 patient had severe pancreatitis. Adverse events of bleeding, perforation, and cholangitis were not significantly different between the groups (Table 3).
DISCUSSION

Several reports have noted that PEP occurred in 1%-15% of cases\textsuperscript{[2-5]}. Risk factors for PEP in multivariate analyses were patient and procedure-related factors, such as young age, female sex, suspected sphincter of Oddi dysfunction, prior PEP, recurrent pancreatitis, chronic pancreatitis absent, pancreatic duct injection, pancreatic sphincterotomy, balloon dilation of intact biliary sphincter, difficult or failed cannulation, and pre-cut sphincterotomy\textsuperscript{[1]}. Lella et al\textsuperscript{[8]} reported that WGC using a sphincterotome reduced the incidence of PEP compared with the standard method with contrast injection. In a meta-analysis of RCTs without a cross-over design, it was reported that WGC increased the primary bile duct cannulation rate [odds ratio (OR) = 2.05, 95\% confidence interval (CI): 1.27-3.31] and decreased the incidence of PEP (OR = 0.23, 95\%CI: 0.13-0.41) compared with the standard contrast injection method\textsuperscript{[6]}. However, a meta-analysis of RCTs with a cross-over design by Shao et al\textsuperscript{[15]} showed a non-significant reduction in the rate of PEP with the use of WGC. Based on these reports, the use of WGC for the prevention of PEP remains controversial.

The WGC technique includes physician-controlled (single-operator) or assistant-controlled cannulation. One report showed that the single-operator WGC technique was feasible, safe, and efficient without requiring an experienced assistant and precise coordination between the operator and assistant\textsuperscript{[16]}. A sphincterotome or a catheter is used as the device for WGC. Kawakami et al\textsuperscript{[13]} reported that WGC appears to significantly shorten cannulation and fluoroscopy times compared with the contrast injection method; however, there was no significant difference in either the success rate of bile duct cannulation or the PEP rate, regardless of the type of sphincterotome and catheter, based on a multicenter, prospective, randomized study. A GW with a straight or angled tip is used for WGC. Several articles on WGC
using GW with a straight or angled tip type have been reported\textsuperscript{[11-13,17]}. Normal and thin types of GW are used. It is not yet known which GW is more suitable for WGC. A prospective, randomized study reported that GW thickness did not appear to affect either the success rate of primary cannulation or the risk of adverse events\textsuperscript{[7]}. In the present study of WGC using a 0.025-inch or a 0.035-inch GW of the straight type with a sphincterotome, the primary success rates of selective bile duct cannulation using WGC were 80.7% in the 0.025-inch group and 86.3% in the 0.035-inch group. No statistically significant difference was seen in the primary success rate of selective bile duct cannulation between the groups.

A case of difficult biliary cannulation was treated using the pancreatic duct GW technique, the double-wire technique, pancreatic duct stenting, needle knife precutting, and transpancreatic sphincterotomy as the next step\textsuperscript{[18-25]}. In the present study, cannulation was performed using the pancreatic duct GW technique (double-wire technique) for a difficult bile duct cannulation using WGC; then, cannulation with precutting was performed for difficult bile duct cannulation using the pancreatic duct GW technique. The pancreatic duct GW procedure was performed in 36 patients (13.3%) for primary difficult bile duct cannulation using WGC; however, it was difficult to perform selective bile duct cannulation using the pancreatic duct GW technique in approximately half of the cases. No statistically significant differences were observed in the success rates of bile duct cannulation using the pancreatic duct GW technique between the groups (46.7% vs 52.4% for the 0.025-inch and 0.035-inch groups, respectively). Precutting was performed for difficult bile duct cannulation in 20 patients (12.5%). No statistically significant differences were observed in the success rates of bile duct cannulation with precutting between the groups (66.7% vs 63.6% for the 0.025-inch and 0.035-inch groups, respectively). The final success rates of selective bile duct cannulation using these techniques showed no statistically significant difference between the two groups (92.7% vs 97.5%...
for the 0.025-inch and 0.035-inch groups, respectively). Based on these results, it is suggested that successful bile duct cannulation appears equivalent for either GW with WGC.

The mechanism of PEP is suggested to involve a defect of pancreatic duct drainage that is caused by papillary edema, pancreatic duct injury, or spasm of the sphincter of Oddi after the ERCP procedure\cite{1,14}. Several studies have reported the usefulness of endoscopic pancreatic duct drainage using a pancreatic duct stent for preventing PEP in patients at high risk\cite{26-30}. In the present study, a pancreatic duct stent was used to treat 41 patients (15.2%) after using the pancreatic GW technique and precutting, which have been suggested as risk factors for PEP. There were no statistically significant differences in the rates of placement of pancreatic duct stents and the incidence of PEP between the two groups.

In this study, there were no statistically significant differences in the bile duct cannulation time and the ERCP procedure time between the groups. Halttunen et al\cite{7} also reported that there were no significant differences in the bile duct cannulation time and the ERCP procedure time between the 0.025-inch and 0.035-inch GWs with WGC.

A difference in the incidence of PEP caused by the mechanical stimulation of the papilla of Vater and pancreatic duct cannulation due to the use of 0.025-inch or 0.035-inch GW with WGC was expected; however, no statistically significant difference was observed in the incidence of PEP between the groups (2.8% vs 2.5% for the 0.025-inch and 0.035-inch groups, respectively). Other adverse events of bleeding, perforation, and cholangitis were not significantly different between the groups. A previous study also reported that the thickness of the hydrophilic GW used in that study did not appear to affect the risk of adverse events\cite{7}.

A limitation of this study was the use of a small number of patients in a single center, with a consequent lack of power. Furthermore, a protease
inhibitor was used to prevent PEP during the ERCP procedure in all cases.

CONCLUSION
In conclusion, the thickness of the GW with WGC appears not to affect either the success rate of selective bile duct cannulation or the incidence of PEP. However, multi-center RCTs are needed to confirm these findings.

ARTICLE HIGHLIGHTS
At present, researchers often read a scientific paper in the order of title, abstract, keywords, introduction, materials and methods, results, discussion, conclusions, and references. However, this reading order is associated with many deficiencies, because most researchers are very busy and cannot read the entire paper carefully. In contrast, authors hope that readers will read their papers as carefully as possible at the earliest time after publication, and that this reading will give a meaningful understanding of the paper’s topic so that the reader will repeat or cite their work.

In order to help more readers to find what they want to read in the shortest possible time, we have added a section known as ‘Article Highlights’ to every paper published by BPG journals; this section will appear before the References section. This new section will consists of summarized information on the research background, motivation, objectives, methods, results, conclusions, and perspectives; the subsections will be titled accordingly (e.g., Research background, Research motivation, etc.; see below). Each of these subsections should be a clear and concise but sufficiently detailed summary of the information provided in the guidelines below (1-4 sentences for each subsection should suffice). This section should not be a verbatim (copy-paste) repeat of the full text in the manuscript’s main text sections (i.e. Methods, Results, or Conclusion).

The content of Article Highlights will also be released through media
including WeChat message forwarding, WeChat public number, Quick Response code, E-mail, Facebook, Twitter, and Google. The guidelines for writing and formatting Article Highlights are as follows:

**Research background**
The background, present status, and significance of the study should be described in detail.

**Research motivation**
The main topics, the key problems to be solved, and the significance of solving these problems for future research in this field should be described in detail.

**Research objectives**
The main objectives, the objectives that were realized, and the significance of realizing these objectives for future research in this field should be described in detail.

**Research methods**
The research methods (e.g., experiments, data analysis, surveys, and clinical trials) that were adopted to realize the objectives, as well as the characteristics and novelty of these research methods, should be described in detail.

**Research results**
The research findings, their contributions to the research in this field, and the problems that remain to be solved should be described in detail.

**Research conclusions**
The most relevant of the following questions should be briefly answered:
What are the new theories that this study proposes?
What are the new methods that this study proposed?

Research perspectives
The most relevant of the following questions should be briefly answered:
What is the direction of the future research?

ACKNOWLEDGEMENTS

REFERENCES


Footnotes

Institutional review board statement: The study was reviewed and approved by the Medical Ethics Committee of Showa University Hospital.

Clinical trial registration statement: This study is registered at UMIN Clinical Trial Registry. The registration identification number is UMIN000010082.

Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Conflict-of-interest statement:

Data sharing statement: No additional data are available.

CONSORT 2010 statement:
Figure Legends

Naïve papillae used for the purpose of selective bile duct cannulation
\( n = 322 \)

Exclusion:
- Acute biliary pancreatitis \( n = 34 \)
- Postoperative intestinal reconstruction \( n = 4 \)

Randomization
\( n = 269 \)

Allocated 0.025-inch group
\( n = 109 \)

Allocated 0.035-inch group
\( n = 160 \)

Analyzed 0.025-inch group
\( n = 109 \)

Analyzed 0.035-inch group
\( n = 160 \)

Figure 1 Flow diagram representing the study.
<table>
<thead>
<tr>
<th></th>
<th>0.025-inch group (n = 109)</th>
<th>0.035-inch group (n = 160)</th>
<th>P value</th>
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<tr>
<td>Age, median ± IQR, year (range)</td>
<td>73 ± 12 (31-90)</td>
<td>72 ± 16 (20-97)</td>
<td>0.869¹</td>
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<td>Sex, male/female</td>
<td>68/41</td>
<td>83/77</td>
<td>0.088²</td>
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<td>Benign disease</td>
<td>69 (63.3)</td>
<td>114 (71.3)</td>
<td>0.170²</td>
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<td>Choledocholithiasis</td>
<td>54 (49.5)</td>
<td>78 (48.8)</td>
<td>0.899²</td>
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<td>Gallbladder stones</td>
<td>8 (7.3)</td>
<td>15 (9.4)</td>
<td>0.558²</td>
</tr>
<tr>
<td>Benign biliary stricture</td>
<td>5 (4.6)</td>
<td>7 (4.4)</td>
<td>0.827²</td>
</tr>
<tr>
<td>Cholangitis</td>
<td>1 (0.9)</td>
<td>7 (4.4)</td>
<td>0.203²</td>
</tr>
<tr>
<td>Others</td>
<td>1 (0.9)</td>
<td>7 (4.4)</td>
<td>0.203²</td>
</tr>
<tr>
<td>Malignant disease</td>
<td>40 (36.7)</td>
<td>46 (28.8)</td>
<td>0.170²</td>
</tr>
<tr>
<td>Pancreatic cancer</td>
<td>13 (11.9)</td>
<td>26 (16.3)</td>
<td>0.323²</td>
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<td>Cholangiocarcinoma</td>
<td>12 (11.0)</td>
<td>6 (3.8)</td>
<td>0.019²</td>
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<td>Gallbladder cancer</td>
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<td>3 (1.9)</td>
<td>0.358²</td>
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<td>Ampullary cancer</td>
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<td>0.954²</td>
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<td>Cholangiocellular carcinoma</td>
<td>1 (0.9)</td>
<td>1 (0.6)</td>
<td>0.654²</td>
</tr>
<tr>
<td>Others</td>
<td>6 (5.5)</td>
<td>7 (4.4)</td>
<td>0.893²</td>
</tr>
</tbody>
</table>

¹Mann-Whitney U-test; ²χ² test. IQR: Interquartile range.
<table>
<thead>
<tr>
<th></th>
<th>0.025-inch group (n = 109)</th>
<th>0.035-inch group (n = 160)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success rate of selective bile duct</td>
<td>80.7% (88/109)</td>
<td>86.3% (138/160)</td>
<td>0.226¹</td>
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<td>cannulation with WGC</td>
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<td></td>
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<tr>
<td>Pancreatic duct GW</td>
<td>13.8% (15/109)</td>
<td>13.1% (21/160)</td>
<td>0.880¹</td>
</tr>
<tr>
<td>Success rate of selective bile duct</td>
<td>46.7% (7/15)</td>
<td>52.4% (11/21)</td>
<td>0.884¹</td>
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<tr>
<td>cannulation with pancreatic duct GW</td>
<td></td>
<td></td>
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<tr>
<td>Precutting</td>
<td>8.3% (9/109)</td>
<td>6.9% (11/160)</td>
<td>0.672¹</td>
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<tr>
<td>Success rate of selective bile duct</td>
<td>66.7% (6/9)</td>
<td>63.6% (7/11)</td>
<td>0.893¹</td>
</tr>
<tr>
<td>cannulation with precutting</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Final success rate of selective bile</td>
<td>92.7% (101/109)</td>
<td>97.5% (156/160)</td>
<td>0.113¹</td>
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<tr>
<td>duct cannulation</td>
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</tbody>
</table>

¹χ² test. WGC: Wire-guided cannulation; GW: Guide wire.
Table 3 Results of adverse events following endoscopic retrograde cholangiopancreatography procedures

<table>
<thead>
<tr>
<th></th>
<th>0.025-inch group (n = 109)</th>
<th>0.035-inch group (n = 160)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatitis</td>
<td>2.8% (3/109)</td>
<td>2.5% (4/160)</td>
<td>0.793$^\text{1}$</td>
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<td>Mild/moderate/severe, n</td>
<td>0/2/1</td>
<td>1/2/1</td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>1.8% (2/109)</td>
<td>0.6 (1/160)</td>
<td>0.737$^\text{1}$</td>
</tr>
<tr>
<td>Perforation</td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Cholangitis</td>
<td>0</td>
<td>1.3 (2/160)</td>
<td>0.654$^\text{1}$</td>
</tr>
</tbody>
</table>

$^\text{1}$χ$^2$ test.