Comparison of Guidewires for Successful Cannulation of Biliary Stenosis and Targeting of Biliary Branches in Endoscopic Retrograde Cholangiopancreatography

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Abstract:
Background and Study Aims: Guidewires play a crucial role in endoscopic retrograde cholangiopancreatography. The ability to pass through stenosis, and the ability to seek the desired biliary branch are particularly important. In this study, we aimed to compare these specific abilities in various guidewires by using a bile duct model. Patients and Methods: Seven 0.025-inch angle-type guidewires (VisiGlide2, Fielder 25, EndoSelector, NaviPro, Jagwire Plus, RevoWave DualMaster, and J-WIRE prologue ST) were evaluated. To compare these, a bile duct silicone model was prepared. The time from the entry of the guidewire into the common bile duct with the stenosis to the emergence of the guidewire from the common bile duct after reaching two target intrahepatic bile duct branches was measured. Results: VisiGlide 2 and Fielder 25 were the fastest guidewires, whereas Jagwire Plus was the slowest. Conclusions: In this study, a guidewire with a tip deflection height of approximately 9 mm and a hydrophilic coating length of 7 to 8 cm achieved the fastest completion time for the course. In clinical practice, it is important to consider the performance required in various scenarios and select the most appropriate guidewire. The results of this model test, which focused on the time required to complete the course around the model, can serve as a foundation for guidewire selection. This method holds potential utility in future guidewire development.

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is widely performed for the treatment of common bile duct stones and malignant biliary obstructions. In cases of malignant biliary strictures, especially hilar cholangiocarcinoma, it is crucial to accurately insert a guidewire into the target bile duct branch to be drained. In recent years, ERCP guidewires have undergone improvements in order to ensure further safety and efficiency [1,2]. However, guidewires remain far from perfect, and there is a growing demand for additional functions beyond their ability to pass through stenosis and seek the desired bile duct branch. These functions include softness and tip flexibility in order to prevent hepatic or pancreatic injury, shaft stiffness during stenting, durability during continuous use, and slipperiness when changing devices even when used in combination with a contrast agent. Despite the various characteristics of guidewires sold by different manufacturers, there is a lack of data comparing their performance. As a result, the decision of which guidewire to use remains a dilemma shared by endoscopists worldwide. In this study, we evaluated the
performance of various guidewires by measuring the time for the guidewires to pass through a stenosis and to reach target bile ducts using a bile duct model.

2. Materials and methods

2-1. Bile duct model

A silicone bile duct model was prepared for this study (Figure 1a). The model consisted of two silicone blocks. The upper block featured eight branch-like interstices that mimicked the intrahepatic bile duct branches (Figures 1b and 1c). The end of each interstice was fitted with a cap with an anti-reflux valve (Figure 1a). The lower block imitated the common bile duct, with a flattened fissure in the middle, mimicking common bile duct stenosis (Figure 1d and 1e). Water filled the interstices between the common bile duct and intrahepatic bile duct in the upper and lower blocks (Figure 1f). An MTW ERCP catheter (MTW Endoskopie, Düsseldorf, Germany) was used in this study. Using this model, we measured the time required for the guidewire to reach the end of branches (1) and (2) and return (Figure 1e).

2-2. Guidewires

Seven 0.025-inch angle-type guidewires; VisiGlide2 (Olympus, Tokyo, Japan), Fielder 25 (Asahi Intecc, Aichi, Japan), EndoSelector (Boston Scientific, MA, USA), NaviPro (Boston Scientific, MA, USA), Jagwire Plus (Boston Scientific, MA, USA), RevoWave DualMaster (Piolax Medical Devices, Yokohama, Japan), and J-WIRE prologue ST (J-MIT, Shiga,
Japan), were used in this study. Guidewires were divided into two types: soft hydrophilic guidewires specialized for seeking, and multipurpose guidewires. NaviPro is hydrophilic-coated guidewire designed for seeking. The length of this guidewire has been shortened to increase its seeking ability. However, it is important to note that this type of guidewire alone may not be sufficient for completing procedures such as stent placement. For this reason, various multipurpose guidewires have been developed in recent years that have a stiff shaft and soft hydrophilic tip, allowing completion of the entire procedure with a single guidewire. The shafts of these guidewires are coated with fluororesin, such as polytetrafluoroethylene (PTFE), to resist friction and achieve excellent rotatability. The individual characteristics of the guidewires used in this study are shown in Table 1 and their tips are shown in Figure 2.

For the RevoWave DualMaster which is a dual-tipped guidewire, the tip that is recommended by the manufacturer for seeking, consisting of a tip deflection height of 11 mm and a hydrophilic length of 7 cm, was used for analysis in this study.

2-3. Measurements

Using these guidewires and model, the time from the entry of the tip of the guidewire into the common bile duct to the emergence of the guidewire from the common bile duct, after passing the common bile duct stenosis and reaching the end of two target intrahepatic bile duct branches (1) and (2), was measured. To prevent the interior from drying out and to ensure complete saturation, water was replenished before each measurement throughout the
experiment. The measurement limit was set at 180 seconds, and measurements were rounded to the nearest number. Measurements were taken alternately by two endoscopists with each more than 1,000 cases of ERCP experience. The seven guidewires were analyzed 10 times each. To prevent familiarity during use, the guidewire was not measured continuously, and for each operator, it was alternated and changed every time to ensure that it was not used continuously (Supplementary Table). Each guidewire was replaced with a new guidewire after five uses to avoid deterioration.

2-4. Statistical analysis

Statistical analysis was performed using the Mann–Whitney U test to compare each guidewire to one another. Statistical significance was set at P < 0.05. All statistical analyses were performed using STATA 16.1 (Stata Corp., TX, USA).

3. Results

The video demonstrates the actual cannulation using the model for each guidewire; taken in the first round (Video). The median measurement for VisiGlide2 was the fastest at 17.5 seconds (interquartile range (IQR) 12-40 seconds), followed by Fielder 25 at 23 seconds (IQR 16-32 seconds). This difference was not statistically significant. The measurements for EndoSelector, J-WIRE prologue ST, NaviPro, and RevoWave DualMaster were not
significantly different between each other. Jagwire Plus took significantly longer to complete the course than the other guidewires (Table 2, Figure 3).

4. Discussion

Guidewires have played an important role in cholangiopancreatic endoscopy during the last decades, and have undergone numerous improvements [1–7]. Initially, a simple metal core with Teflon coating was used, but various coatings were gradually added to the metal core. Coiled springs have been replaced with plastic coatings, and fluororesin coatings are now predominant. 0.025-inch guidewires are increasingly preferred over 0.035-inch guidewires, due to their reduced friction and ease of device exchange [8,9]. However, there is still a need for better guidewires to be developed. Even though many guidewires have been developed and are available, comparing the usefulness of different guidewires in clinical practice remains difficult [10,11]. Although some model tests have been carried out, the clinical relevance of their results remains unclear. [12,13] Endoscopists are therefore faced with the problem of which guidewire to use. Nonetheless, our model, despite not being an exact replica of real-life conditions, proved to be a suitable means for effectively assessing the performance of the guidewires. Notably, our study is the first to utilize an anatomically imitated silicone model of the bile duct to simulate the clinical setting where time is a
constraint. We believe that this approach serves as a valid model for comparing the clinical usefulness of different guidewires.

VisiGlide2 and Fielder 25, two guidewires that were able to complete the course in the shortest time, exhibit similar characteristics. Both of them are 0.025-inch guidewires with a tip deflection height of approximately 9 mm, and hydrophilic coating lengths of 7 cm and 8 cm, respectively. The Endoselector also shares similar characteristics, however, its tip deflection height is shorter than that of the two former guidewires. This could be a reason that it took longer to complete the course because of difficulty in seeking the target bile ducts. The J-WIRE prologue ST is a guidewire with a long hydrophilic tip of 12 cm. The J-WIRE prologue with a longer 16 cm hydrophilic coated tip is also available. The J-WIRE prologue “ST”, used in this study, is a “short taper” type with enhanced selectivity for bile duct branches. However, in this study, the long tip was easily inverted to form a loop shape, impairing bile duct branch selectivity and resulting in a longer course completion time. The J-WIRE prologue ST is a unique guidewire and may be effective when used appropriately, such as when providing access to the pancreatic duct. NaviPro, which has a hydrophilic coating along their entire length, is frequently used for seeking. However, they performed rather poorly in the present study. This may be due to the fact that the guidewire was used up to five times repeatedly with intervals in this examination. This guidewire showed reasonable rotatability at first, but resistance increased with each turn. It is possible that the intervals
between uses prevented the full demonstration of its sufficient slipperiness. Despite having the same characteristics as the VisiGlide2, Fielder 25, and Endoselector, the RevoWave DualMaster is the only stiff-type guidewire used in this study and did not demonstrate the anticipated rotatability. Because of the low tip deflection height and poor rotatability of Jagwire Plus, the bile duct branches could not be adequately selected, which often resulted in failure of navigating around the course within the 3-minute time frame. The Jagwire Plus was the oldest guidewire used in this study, and its suboptimal performance may be attributed to the technological advancements in this field.

In this model, a guidewire with a tip deflection height of 7–8 mm was effective; however, in this study, only one model was tested. It is conceivable that, for instance, in the case of a more dilated bile duct, a guidewire with an even taller tip deflection height may be required to ensure optimal navigation. Moreover, in clinical practice, guidewires are used in situations where they are exposed to bile and contrast media, and are also used after passing through the scope and being bent by the elevator. The soft hydrophilic guidewires are often used as single-use only in clinical practice, unlike the methodology in our study where they were used repeatedly. Therefore, it is important to consider these limitations into account when extrapolating these results to real-world clinical settings. Nevertheless, this study can still serve as a foundation for making an informed decision regarding the usage of the guidewires.
5. Conclusion

In conclusion, 0.025-inch guidewires with a tip deflection height of approximately 9 mm and hydrophilic coating lengths of 7–8 cm were most effective at passing through stenosis and seeking the target bile duct in this study. In clinical practice, it is important to consider the performance required in different situations and select the most appropriate guidewire. The results of this model test, which compared seven different guidewires under the same condition, may provide a basis for guidewire selection in clinical practice, as well as showing potential for directing future guidewire development.

Figure legends

Figure 1. Bile duct model.

a) Full view of the model.

b) Front view of the upper block.

c) Top view of the upper block

d) Side view of the lower block

e) Front view of the lower block

f) Map of the course: the time from the entry of the tip of the guidewire into the common bile duct to the emergence of the guidewire from the common bile duct, after passing the common
bile duct stenosis and reaching the end of two target intrahepatic bile duct branches (1) and (2), was measured.

f) Cannula insertion section.

**Figure 2. Guidewire tips and tip deflection height (mm).**

a) VisiGlide2, b) Fielder 25, c) EndoSelector, d) Jagwire Plus, e) J-WIRE prologue ST, f) RevoWave DualMaster (Seeking side), g) NaviPro, h) Tip deflection height measurement image, x = Tip deflection height.

**Figure 3. Time taken for completion of the course for each guidewire.**

**Table 1. Characteristics of each guidewire.**


**Table 2. Time taken for completion of the course and statistical results for each guidewire.**

**Video. Cannulation of the course for each guidewire (first round).**

**Supplementary Table. Sequence of measurement**

**References**


Keywords

endoscopic retrograde cholangiopancreatography; biliary stricture; guidewire; bile duct model; Technical study.
Supplementary Table. Sequence of measurement.

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<th>4</th>
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*changed to new guidewire

Each guidewire was changed to a new guidewire after 5 uses.

A and B show the two endoscopists involved in the study.

The number depicts the sequence in which the guidewire was used.
Table 1. Characteristics of each guidewire.

<table>
<thead>
<tr>
<th>Product name</th>
<th>Manufacturer</th>
<th>Stiffness</th>
<th>Core material</th>
<th>Tip deflection height (mm)</th>
<th>Length (cm)</th>
<th>Outer diameter (inch)</th>
<th>Length of hydrophilic part (cm)</th>
<th>Coating of non-hydrophilic part</th>
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<td>Asahi intecc</td>
<td>standard</td>
<td>Ni-Ti</td>
<td>9.5</td>
<td>450</td>
<td>0.025</td>
<td>7.5</td>
<td>PTFE/PFA</td>
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<td>standard</td>
<td>Ni-Ti</td>
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<td>450</td>
<td>0.025</td>
<td>7</td>
<td>PTFE</td>
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<td>standard</td>
<td>Ni-Ti</td>
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<td>5</td>
<td>PTFE/silicon</td>
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<td>(Seeking side)</td>
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Ni-Ti: Nickel-titanium, Ni-Ti-Co: Nickel-titanium-cobalt, PTFE: polytetrafluoroethylene, PEEK: polyetheretherketone, PFA: Perfluoroalkoxy alkanes
Table 2. Time taken for completion of the course and statistical results for each guidewire.

<table>
<thead>
<tr>
<th></th>
<th>Time (sec)</th>
<th>Median</th>
<th>IQR</th>
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<th>Fielder 25</th>
<th>EndoSelector</th>
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<th>Jagwire Plus</th>
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</table>
This image shows a series of graphs illustrating different measurements:

- **a**: 8.5mm
- **b**: 9.5mm
- **c**: 6mm
- **d**: 5mm
- **e**: 8.75mm
- **f**: 11mm
- **g**: 6.5mm

The graph in the bottom right corner is labeled with:

\[ x = \text{Tip deflection height} \]