

Clinical Trials Study

Clinical utility of 0.025-inch guidewire VisiGlide2™ in the endoscopic retrograde cholangiopancreatography-related procedures

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Abstract**AIM**

To examine the result of the use of 0.025-inch guidewire (GW) VisiGlide2™ as the first choice in the endoscopic retrograde cholangiopancreatography (ERCP)-related procedures without selecting the patient in a multicenter prospective study.

METHODS

ERCP using 0.025-inch GW VisiGlide2™ as the first choice was conducted in patients who have needed ERCP, and its accomplishment rate of procedure, procedural time, incidence of accidental symptoms were compared with those of ERCP using 0.025-inch GW VisiGlide™.

RESULTS

The accomplishment rate of procedure was 97.5% (197/202), and procedural time was 23.930 ± 16.207 min. The accomplishment rate of procedure using 0.025-inch GW VisiGlide™ was 92.3% (183/195), and procedural time was 31.285 ± 19.122 min, thus the accomplishment rate of procedure was significantly improved and procedural time was significantly shortened ($P < 0.05$). Accidental symptoms by ERCP-related procedures were observed in 3.0% (6/202), and all were conservatively alleviated.

CONCLUSION

When 0.025-inch GW VisiGlide2™ was used for ERCP-related procedure as the first choice, it showed high accomplishment rate of procedure and low incidence of accidental symptoms, suggesting it can be used as the universal GW. Clinical Trial Registry (UMIN0000016042).

Key words: Endoscopic sphincterotomy; Endoscopic retrograde cholangiopancreatography; 0.025-inch guidewire

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Core tip: When 0.025-inch guidewire (GW) VisiGlide2™ was used for endoscopic retrograde cholangiopancreatography-related procedure as the first choice, it showed high accomplishment rate of procedure and low incidence of accidental symptoms, suggesting it can be used as the universal GW.

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP)-related procedures have played a very important role for diagnosis/treatment of biliary and pancreatic disease. In ERCP-related procedures, it is needless to say that the guidewire (GW) is essential in performing the procedure safely, and elevating the accomplishment rate of the procedure. There are the GWs of various diameters, but the GW which has been used as the first choice was of 0.035 inches considering the stability of procedure^[1-12]. The 0.025-inch GW is thin and excellent in breaking through the stenosis and selecting the branch but problematic in visibility and rigidity, which has not been used as the first choice^[1-12]. It has been used in the case in which it was impossible to break through the stenosis even by using 0.035-inch GW, and in particular, peroral



Figure 1 0.025-inch guidewire VisiGlide2™. The tip of hydrophilic coating is flexible.

cholangioscopy (POCS) and placement of metallic stent (MS) have generally been conducted with 0.035-inch GW because of the problem of rigidity^[8-12]. Previously, after 0.025-inch GW was used for breaking through the stenosis, GW was switched to 0.035 inch GW to stabilize the procedure, and the procedure was re-started. However, together with advancement of the endoscope, GW was improved, and it has become possible to use VisiGlide™ with excellent visibility and sufficient rigidity in spite of the external diameter of 0.025-inch in the clinical setting. As a result, we have treated a number of patients in whom ERCP-related procedure can be accomplished using only this GW. However, there remained still problems that GW must be changed due to seeking failure in some patients, and GW perforation comparatively frequently occurs^[13]. After that, it has become possible to use VisiGlide2™ remodeled from VisiGlide™ in the clinical setting (Figure 1)^[14]. VisiGlide2™ has excellent endoscopic visibility (Figure 2), and also has improved fluoroscopic visibility of GW using 2 radiopaque chips similarly to VisiGlide™ (Figure 3). Although it has thinness of 0.025-inch (0.63 mm), its special processing method ensures rigidity equivalent to that of 0.035 inch (0.89 mm) (Figure 4). It is the GW that was devised to reduce GW perforation, the accidental symptom observed in use of VisiGlide™, by making the tip flexible. The torque device for 0.025-inch GW VisiGlide™ was compliant to 0.035 inch previously, whereas that for 0.025-inch GW VisiGlide2™ has become compliant to 0.025-inch, thus torque transmissibility was improved.

We decided to examine the accomplishment rate of procedures and the incidence of accidental symptoms in the use of 0.025-inch GW VisiGlide2™ as the first-choice universal GW in the ERCP-related procedures.

MATERIALS AND METHODS

All the patients with biliary and pancreatic diseases, who were decided to undergo ERCP in 5 institutions participating in this clinical study in a month of December 2014, were included. A 0.025-inch GW (VisiGlide2: Olympus Corp. Japan straight type or angle type) was used. For cannulation, catheters PR-104Q, PR110Q-1,

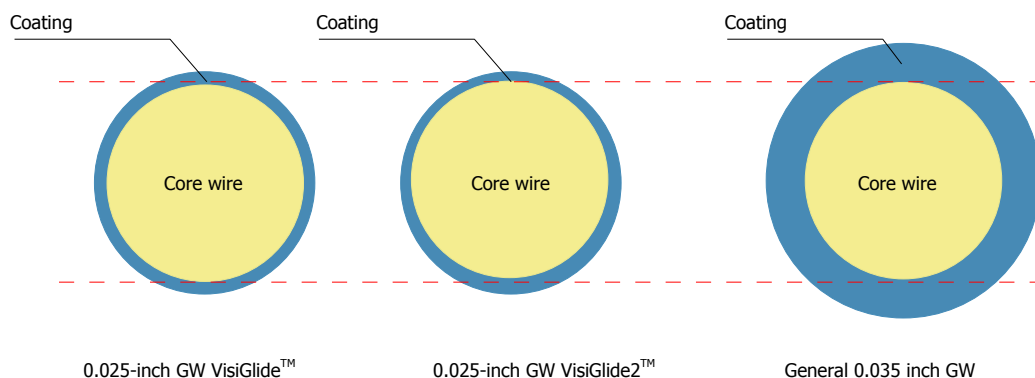


Figure 2 Comparison between 0.025-inch guidewire VisiGlide2™, 0.025-inch guidewire VisiGlide™, and 0.035 inch guidewire. Although it has thinness of 0.025-inch (0.63 mm), its special processing method ensures rigidity equivalent to that of 0.035 inch (0.89 mm). GW: Guidewire.

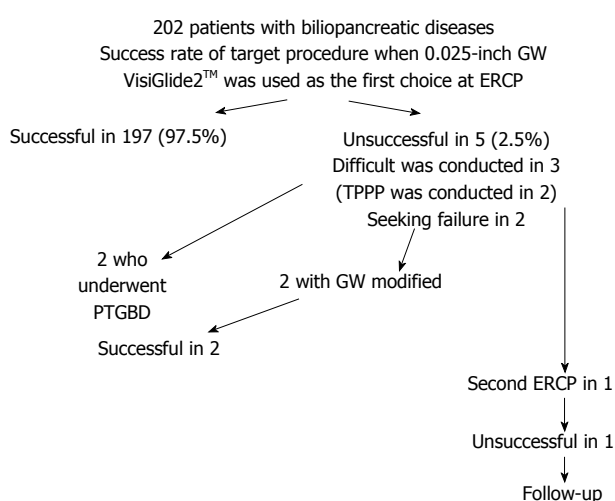


Figure 3 Result of use of 0.025-inch guidewire VisiGlide2™ in the endoscopic retrograde cholangiopancreatography as the first choice. ERCP: Endoscopic retrograde cholangiopancreatography; TPPP: Transpancreatic precut papillotomy; PTGBD: Percutaneous transhepatic gallbladder drainage; GW: Guidewire.

PR-233Q and Clever-Cut3V (Olympus Corp. Japan) were used. The endoscopes used were JF200, JF240, JF260V, and TJF260V (Olympus Corp. Japan). Prospective data collected in multicenter study were compared with those obtained from multicenter prospective study of 0.025-inch GW VisiGlide™ which we have already reported^[13]. Patients treated using VisiGlide2™ are shown. There were 202 patients including 122 males and 80 females, and the age was 72.9 (36 to 98) years old on average. The ERCP was conducted aiming at bile duct in 190 patients and pancreatic duct in 12 patients. There were 80 patients undergoing ERCP for the first time and 122 patients on whom papillary treatment has already been implemented. The case in which 0.025-inch guidewire VisiGlide2™ was used as a versatile GW and the scheduled procedure could be accomplished only with VisiGlide2™ at the ERCP was considered as the success of procedure, and the success rate and the incidence of accidental symptom were examined. Patients with difficulty in selective biliary cannulation were defined as patients who are considered by an investigator to be difficult cases for

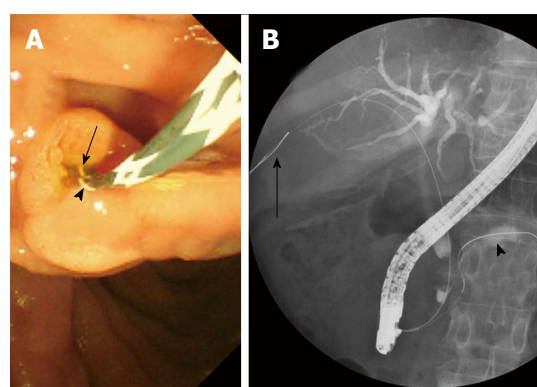


Figure 4 Although it has thinness of 0.025-inch (0.63 mm), its special processing method ensures rigidity equivalent to that of 0.035 inch (0.89 mm). A: 0.025-inch guidewire (GW) VisiGlide2™ placed in the bile duct (arrow)/pancreatic duct (arrow head). The visibility is good under endoscopy; B: 0.025-inch GW VisiGlide2™ placed in the bile duct (arrow)/pancreatic duct (arrow head). The visibility is good under radiography.

biliary cannulation after over 10 min performing papilla cannulation through the frontal view. If such patients were observed, the following procedures were used to achieve biliary cannulation at the investigator's discretion: Needle knife precut papillotomy starting at orifice, transpancreatic precut papillotomy and pancreatic duct guidewire indwelling method. For patients with moderate or severe cholangitis, urgent ERCP was performed according to the Tokyo Guideline^[15]. Iatrogenic morbidity was assessed according to the criteria of Cotton *et al.*^[16]. The observation period was 30 d after the procedure and any coincidental events noted during the period were considered as early coincidental events. All the treatment procedures were performed after obtaining the informed consent in writing from the patients. Assessment of this GW was performed based on approval of ethical committee of each institution, and registered at UMIN Clinical Trial Registry (UMIN0000016042-VIP2 study).

Statistical analysis

Person χ^2 test with Yates correction and Fisher's exact test, when appropriate, were used for statistical analysis of categorical variables. Data were Statistical analyses were performed with SPSS software version 18 (SPSS,

Table 1 Patients' background and disease background

		VisiGlide2™	VisiGlide™	P value
Sex		122 males 80 females	113 males 81 females	NS
Age		72.871 ± 11.403 (36-98)	70.834 ± 11.824 (38-95)	NS
Disease	Bile duct stone	113	103	NS
	Cholangiocarcinoma	31	26	NS
	Chronic pancreatitis	14	18	NS
	Pancreatic cancer	18	16	NS
	Gallbladder cancer	3	6	NS
	Hepatolithiasis	1	5	NS
	Metastatic biliary obstruction	5	5	NS
	IPMN	3	4	NS
	Benign biliary stenosis	4	3	NS
	Acute cholecystitis	5	3	NS
	PSC	2	2	NS
	Postoperative bile leakage	1	1	NS
	Pancreaticobiliary maljunction	1	1	NS
	Duodenal papillary cancer	1	1	NS
Target region	Bile duct	190	180	NS
	Pancreatic duct	12	14	NS
Stenosed lesion	Present	90	77	NS
	Absent	112	117	NS
Procedure	Scheduled ERCP	157	155	NS
	Emergency	45	39	NS
Purpose	Diagnosis	10	14	NS
	Diagnosis + treatment	15	9	NS
	Treatment	177	171	NS
Papillary treatment	None	80	81	NS
	Post EST	110	101	NS
	Post EPST	12	12	NS

IPMN: Intraductal papillary mucinous neoplasm; PSC: Primary sclerosing cholangitis; EST: Endoscopic sphincterotomy; EPST: Endoscopic pancreatic sphincterotomy; ERCP: Endoscopic retrograde cholangiopancreatography; NS: Not significant.

Table 2 Accomplishment rate of procedure and procedural time

	VisiGlide2™	VisiGlide™	P value
Success rate	97.5 (197/202)%	92.3 (180/195)%	0.034
Procedural time (min)	23.930 ± 16.207 (4-65)	31.285 ± 19.122 (4-117)	0.0001

Chicago, IL). A *P* value less than 0.05 was regarded as indicating a statistically significant.

RESULTS

Comparisons of patient background and disease background are shown (Table 1). There was no significant difference between VisiGlide2™ and VisiGlide™ in the patient background. The accomplishment rate of procedure only with VisiGlide2™ was 97.5% (197/202). The procedural time was 23.930 ± 16.207 (4-65) min. Use of VisiGlide2™ enabled significantly to elevate accomplishment rate of procedure and shorten procedural time compared with VisiGlide™ (*P* < 0.05) (Table 2). Of patients who failed accomplishment of the procedure, GW was changed in 2 patients. Of 2 patients, the procedure was successful in 1 patient using Radifocus™ (RF-GS25263 TERUMO Japan), and the procedure was also successful in 1 patient using Navipro™ (Boston Scientific Corp. Natick, MA).

Three patients had difficulty in selective bile duct insertion and 2 were acute cholecystitis patients to whom percutaneous transhepatic gallbladder drainage was inserted. One patient was clinically suspicious spontaneous passage of bile duct stone, and underwent unsuccessfully second ERCP, and followed-up. The final success rate of ERCP was 98.5% (199/202) (Figure 5). Among the patients succeeded in insertion into the bile duct and not undergoing papillary treatment, 74 patients underwent papillary treatment. The papillary treatment was successful in all the 74 patients conducted, the success rate of 100% (74/74) (Table 3). After papillary treatment, we underwent the procedure of purpose. The success rate was 99.4% (331/333) (Table 4). Accidental symptoms were observed at 3.0% (6/202). Bleeding, pancreatitis and perforation were observed at 1.0% (2/202), 1.5% (3/202) and 0.5% (1/202), respectively. Although there was no significant difference in accidental symptoms between VisiGlide2™ and VisiGlide™, GW perforation, which was observed in 2.1% (4/194) when

Table 3 Papillary treatment

Papillary treatment	VisiGlide2™		VisiGlide™		P-value
	n	Success rate of procedure	n	Success rate of procedure	
EST	67	100 (67/67)%	67	100 (67/67)%	NS
EST + EPLBD	3	100 (3/3)%	5	100 (5/5)%	NS
EPST	3	100 (3/3)%	3	100 (3/3)%	NS
EPBD	1	100 (1/1)%	4	100 (4/4)%	NS
Total	74	100 (74/74)%	79	100 (79/79)%	NS

EST: Endoscopic sphincterotomy; EPLBD: Endoscopic papillary large balloon dilation; EPST: Endoscopic pancreatic sphincterotomy; EPBD: Endoscopic papillary balloon dilation; NS: Not significant.

Table 4 Procedure conducted after insertion into the bile duct and pancreatic duct

Procedure conducted	VisiGlide2™		VisiGlide™		P value
	n	Success rate of procedure	n	Success rate of procedure	
ENBD	60	98.3 (59/60)%	51	100 (51/51)%	NS
ENPD	5	100 (5/5)%	3	100 (3/3)%	NS
ENGBD	5	80.0 (4/5)%	1	100 (1/1)%	NS
EGBS	2	100 (2/2)%	1	0 (0/1)%	NS
EBS	95	100 (95/95)%	78	100 (78/78)%	NS
EPS	30	100 (30/30)%	22	100 (22/22)%	NS
EML	2	100 (2/2)%	2	100 (2/2)%	NS
Placement of MS	12	100 (12/12)%	8	100 (8/8)%	NS
Lithotomy	88	100 (88/88)%	69	100 (69/69)%	NS
Bile duct biopsy	8	100 (8/8)%	9	100 (9/9)%	NS
Pancreatic duct biopsy	0	-	1	100 (1/1)%	NS
Peroral cholangioscopy	2	100 (2/2)%	1	100 (1/1)%	NS
IDUS	10	100 (10/10)%	6	100 (6/6)%	NS
Bile duct brushing cytology	12	100 (12/12)%	9	100 (9/9)%	NS
Pancreatic duct brushing cytology	2	100 (2/2)%	2	100 (2/2)%	NS
		Total 333 99.4 (331/333)		Total 263 99.6 (262/263)%	NS
Guidewire type straight angle	127		34		NS
	75		0		NS

ENBD: Endoscopic nasobiliary drainage; ENPD: Endoscopic nasopancreatic drainage; ENGBD: Endoscopic nasogallbladder drainage; EGBS: Endoscopic gallbladder stenting; EBS: Endoscopic biliary stenting; EPS: Endoscopic pancreatic stenting; EML: Endoscopic mechanical lithotripsy; MS: Metallic stent; IDUS: Intraductal ultrasonography; NS: Not significant.

Table 5 Results of incidence of accidental symptoms

	VisiGlide2™ n = 202	VisiGlide™ n = 194	P value
Bleeding	2	4	NS
Pancreatitis	3	1	NS
Perforation	1	0	NS
Guidewire perforation	0	4	NS
Total (%)	6 (3.0%)	9 (4.6%)	NS

NS: Not significant.

VisiGlide™ was used, was not found when VisiGlide2™ was used (Table 5). All the accidental symptoms were mild and conservatively alleviated.

DISCUSSION

GW is essential in conducting ERCP-related procedures to ensure the stable procedure. The functions required for the roles are visibility, insertion performance, rigidity and torqueability. Various types of GWs are available; there are a variety of differences including difference in

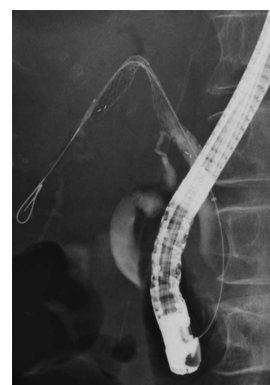


Figure 5 Placement of metallic stent using 0.025-inch guidewire VisiGlide2™. It was possible to break through the stenosis, to induce delivery and to place stents only with this guidewire.

thickness, hardness, or tip shape^[17,18]. As for actual use of GW, at first the procedure was performed with 0.035-inch GW, and for patients whose stenosis cannot be broken through with 0.035-inch GW or patients with difficulty in selecting the branch, GW was switched to accomplish

the procedure. The ideal GW is the universal GW which can accomplish the procedure by itself. Therefore, we evaluated 0.025-inch GW VisiGlide™ (Olympus Corp. Japan) which has visibility and rigidity not inferior to those of 0.035 inch GW, retaining superiority of the conventional 0.025-inch GW in terms of stenosis breakthrough property and branch selectivity as the universal GW^[13]. The success rate of procedure was very high. VisiGlide™ has a merit of thinness as 0.025-inches as well as good rigidity and visibility because of technical progress, which could be used for implementation of POCS which was difficult in the past and placement of MS with no problem. In addition to our reports, there appeared several reports using 0.025-inch GW VisiGlide™ for ordinary ERCP^[19,20], which suggests that it may be one of choices as the first choice in using GW for ERCP. However, GW perforation was comparatively frequently observed, which is the problem to be improved hereafter^[13]. Although it is reported that a few GW perforations are serious accidental symptoms which need operation^[21], there is a report on portobiliary fistula from GW perforation, thus there is a possibility of progressing to a serious accidental symptom, and sufficient attention is required^[20]. The core of 0.025-inch GW VisiGlide2™ is the same as that of 0.025-inch GW VisiGlide™, however, the tip of GW is improved to be flexible, which can reduce the risk of GW perforation, retaining rigidity of GW. Previously the torque device for 0.025-inch GW VisiGlide™ was compliant to 0.035 inch, however, it was improved so that torqueability is elevated, and the torque device for 0.025-inch GW VisiGlide2™ has become compliant to 0.025-inch. The advantage to use 0.025-inch GW as the first choice lies in that the free space within the forceps port is increased when compared with 0.035 inch GW, which provides higher degree of freedom at the time of operation and, in addition, enables the use of various devices, and may elevate accomplishment rate of procedure or shorten the procedural time. Recently a cannulation method to use multiple GWs at the time of performing cannulation as the double GW technique is reported^[2,3]. In such a case, use of 0.025-inch GW may improve operability when compared with insertion of multiple 0.035 inch GWs. Although it is needless to say that GW to fix papillary edge must have rigidity to some degree, the thinner the diameter of GW is, the greater the freedom of the procedure becomes, thus accomplishment rate of cannulation may be elevated. In such a sense, if it has rigidity to some degree, there is sufficient significance in using 0.025-inch GW as the first choice.

This review compared 0.025-inch GW VisiGlide™ and 0.025-inch GW VisiGlide2™. First of all, as for the procedure, the torque device for VisiGlide2™ has become compliant to 0.025-inch GW, thus torqueability was elevated, which led to elevation of seeking ability and enabled to accomplish the procedure using only one piece of GW, and furthermore, accomplishment rate of procedure was improved and procedural time was shortened.

As mentioned above, MS placement was not so frequently performed using 0.025-inch GW because it does not have sufficient rigidity. However, emergence of 0.025-inch GW VisiGlide™ changed the situation drastically. Currently, 0.025-inch GW sufficiently enables placement of MS, though it depends on type of GW. 0.025-inch GW VisiGlide2™ used in this study, has no adverse consequence regarding placement of MS. Since patients who need placement of MS often have severe stenoses, it is advantageous to use 0.025-inch GW in terms of stenosis breakthrough. In addition, since 0.025-inch GW VisiGlide2™ has a sufficient rigidity, it is possible to place MS without changing GW after breaking through the stenosis. Previously, in placement of MS, if it is impossible to break through the stenosis using 0.035 inch GW, it was switched to 0.025-inch GW to continue the procedure, and when stenosis breakthrough succeeded, GW was switched again to 0.035 inch GW to perform MS placement. The procedure is very complicated. In placement of MS, use of 0.025-inch GW VisiGlide2™ may be more useful than use of 0.035 inch GW as the first choice similarly to 0.025-inch GW VisiGlide™ in terms of shortening of procedural time, and reduction in total cost of treatment. In the partial stent in stent with a MS, the procedure used in unresectable malignant hilar biliary obstruction, particularly, examination by accumulation of cases is required, but it is possibly useful. First of all, the tip of this GW has an excellent visibility under fluoroscopic control (Figure 3). Therefore, it has an advantage that the position of GW can be identified easily even if GW is placed within the contrasted intrahepatic bile duct. In conducting this procedure, usually, the procedure has been accomplished by using landmark GW, leading GW or seeking GW differently^[9,10]. In this procedure, when GW is firstly placed, the GW of thin diameter is advantageous in the aspect of breaking through the stenosis. Multiple GWs are placed after breaking through the stenosis. It is considered that a thin GW with good visibility is ideal as a landmark GW. Because the rigidity is adequate, this GW is considered useful as a leading GW because there is no problem in induction of delivery of MS. In placing the next stent after placement of a stent, moreover, the thinner GW is of course more advantageous as a seeking GW in passing through the void of mesh. As described before, the GW has the rigidity possible to place MS as it is after passing through the void of mesh, and this GW is considered an ideal GW in conducting the partial stent in stent. If this GW is used, it will be able to accomplish the procedure without requiring preparation of the GWs of various characteristics. Recently there is a placement method termed side by side as MS placement for unresectable malignant hilar biliary occlusion^[22]. This is the procedure to place MS by placing multiple GWs over hilar bile duct stenosis. In this case, visibility of GW placed in the intrahepatic bile duct is excellent, and in terms of breaking through the stenosis, GW of thin diameter is advantageous, thus this may be an ideal GW even in this procedure. The procedure which we must review in the future is the special procedure such as gallbladder drainage. This is

the procedure to be performed for pathological evaluation in patients with suspected gallbladder cancer or in acute cholecystitis patients with hemorrhagic tendency for whom percutaneous approach is difficult^[23,24]. Therefore, differently from ordinary drainage to the bile duct, chance of implementation is extremely few. According to the report so far, since the cystic duct is spirally-curved, in searching the cystic duct, GW with comparatively soft tip and high seeking ability such as Radifocus™ was comparatively frequently used^[23,24]. This GW has a comparatively soft tip like Radifocus™, and has a high rigidity as a whole. Therefore, in attempting an approach to the cystic duct, flexibility or thinness of the tip of this GW and rigidity of GW itself may make it work for the procedure in patients in whom stones are incarcerated within the cystic duct. This review showed that although sample size is small, accomplishment rate of procedure to approach the cystic duct was as high as 86% (6/7). It may be necessary to review again with a large sample size in the future. Incidence of accidental symptoms was 3.0% (6/202). As for accidental symptoms, there was no significant difference when compared with the results in use of 0.025-inch GW VisiGlide™. Comparison with results using conventional GW showed that results of incidence of accidental symptoms were not so inferior. Although there was no significant difference, GW perforation was not observed in 0.025-inch GW VisiGlide™. 0.025-inch GW VisiGlide™ has high rigidity, however, its tip is flexible, which may have reduced potentiality for occurrence of GW perforation. 0.025-inch GW VisiGlide™ has an advantage enabling the treatment comparatively safely because its tip is flexible, so breaking through of the stenosis is often conducted in the situation forming a loop (Figure 5). As mentioned above, elevation of accomplishment rate of procedure or shortening of procedural time may be caused by discontinuation of the procedure due to GW perforation or no transferring to other procedure. This study suggested that use of 0.025-inch GW VisiGlide™ did not develop GW perforation, and showed a low incidence of accidental symptoms as a whole, thus it may be used as a universal GW. If 0.025-inch GW can be used as a universal GW, it is expected that ERCP related treatment instruments such as the delivery sheath of MS with a thinner diameter will be developed in the future. It suggests a possibility to be more advantageous for stenosis breakthrough or others.

In conclusion, when 0.025-inch GW VisiGlide™ was used for ERCP-related procedure as the first choice, it showed high accomplishment rate of procedure and low incidence of accidental symptoms, suggesting it can be used as the universal GW.

COMMENTS

Background

In endoscopic retrograde cholangiopancreatography (ERCP)-related procedures, it is needless to say that the guidewire (GW) is essential in performing the procedure safely, and elevating the accomplishment rate of the procedure. The

authors decided to examine the accomplishment rate of procedures and the incidence of accidental symptoms in the use of 0.025-inch GW VisiGlide™ as the first-choice universal GW in the ERCP-related procedures without selecting patients in a multicenter prospective study.

Research frontiers

All the patients with biliary and pancreatic diseases, who were decided to undergo ERCP in 5 institutions participating in this clinical study in a month of December 2014, were included. A 0.025-inch GW (VisiGlide2: Olympus Corp. Japan straight type or angle type) was used. Prospective data collected in multicenter study were compared with those obtained from multicenter prospective study of 0.025-inch GW VisiGlide™.

Innovations and breakthroughs

The accomplishment rate of procedure only with VisiGlide™ was 97.5% (197/202). The procedural time was 23.930 ± 16.207 (4 to 65) min. Use of VisiGlide™ enabled significantly to elevate accomplishment rate of procedure and shorten procedural time compared with VisiGlide™ ($P < 0.05$). There was no significant difference in accidental symptoms between VisiGlide™ and VisiGlide™.

Applications

All the patients with biliary and pancreatic diseases, who were decided to undergo ERCP.

Terminology

0.025-inch GW VisiGlide™ showed a high accomplishment rate of procedure and low incidence of accidental symptoms when used in ERCP-related procedures as the first choice.

Peer-review

This is a unique multicenter prospective study with a significant number of patients investigating an important topic, 0.025-inch guidewire VisiGlide™ used for ERCP-related procedures as the first choice. The study results showed high accomplishment rate of procedure and low incidence of accidental symptoms. The results have a clinical impact on selecting the ideal guidewire that can accomplish the procedure by itself. This is a well-written article; the manuscript is concise, clear, comprehensive and convincing.

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