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Can 0.025-inch Guidewire VisiGlide™ become a Standard in the ERCP-related Procedures? VIP Study

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Authors' contributions

Authors YS, TT, MM and YO were responsible for study design, data analysis and manuscript preparation. Author YS wrote the paper. Authors YS, TT, KS, TF, YY, TN, TN and HS performed the endoscopic treatment. Authors DS and MN were responsible for data collection. All authors read and approved the final manuscript.

Original Research Article

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ABSTRACT

Aims: With the progress of development of 0.025-inch guidewire (GW), various treatments with 0.025-inch GW have become possible. To date, however, there has been no multicenter cooperative prospective study using 0.025-inch GW VisiGlide™ as the versatile GW. This time, we decided to examine the result of the use of 0.025-inch GW VisiGlide™ as the first choice in the endoscopic retrograde cholangiopancreatography (ERCP)-related procedure without selecting the patient in a multicenter cooperative prospective study.
Study Design: Multi-center single arm prospective study.
Methodology: The 0.025-inch GW VisiGlide™ was used in the patients with

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biliopancreatic diseases requiring ERCP as the first choice to examine the accomplishment rate of procedure and the incidence of accidental symptom.
Results: The accomplishment rate of procedure was 92.8% (180/194). The accidental symptoms of ERCP-related procedures were observed at 4.6% (9/194) and GW perforation was observed as a GW-related accidental symptom at 2.1% (4/194) but all the accidental symptoms resolved conservatively.
Conclusion: The 0.025-inch GW VisiGlide™ has a high accomplishment rate of procedure and a low incidence of accidental symptom in its use in the ERCP-related procedure, and it was suggested that it may be available as a versatile GW. Clinical Trial Registry (UMIN000008180).

Keywords: 0.025-inch guidewire; endoscopic sphincterotomy; endoscopic retrograde cholangiopancreatography.

1. INTRODUCTION

It is needless to say that the endoscopic retrograde cholangiopancreatography (ERCP)-related procedures are important ones in diagnosis and treatment of biliopancreatic diseases. In the ERCP-related procedures, guidewires (GW) are essential to conduct the procedures safely and to increase the success rate. GW is indispensable in the cannulation procedures conducted using GW, such as wire-guided cannulation and double guidewire technique[1-3], papillary procedures such as endoscopic sphincterotomy (EST), endoscopic papillary balloon dilation (EPBD) and endoscopic papillary large balloon dilation (EPLBD) [4-6], diagnosis of biliopancreatic lesions by scraping cytology, etc., as well as treatment such as biliary drainage etc. [7-12]. 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. It has only 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 cholangioscopy (POCS) and placement of expandable metallic stent (EMS) have generally been conducted with 0.035-inch GW because of the problem of rigidity [8-12]. Along with endoscope, GWs have also been improved and even 0.025-inch VisiGlide™ having good visibility and sufficient rigidity has become clinically available Fig. 1. In this GW, the visibility of GW under radioscopy was improved by employing two radiopaque tips and the GW as thin as 0.025 inches (0.63 mm) ensured the rigidity and rotational performance similar to those of 0.035 inches (0.89 mm) by special processing methods Fig. 2 [13]. This time, we decided to examine the accomplishment rate of procedure and the incidence of accidental symptoms in the use of 0.025-inch GW VisiGlide™ as the first-choice versatile GW in the ERCP-related procedure without selecting patients in a multicenter cooperative prospective study.

Fig. 1. 0.025 inch guide wire VisiGlide™

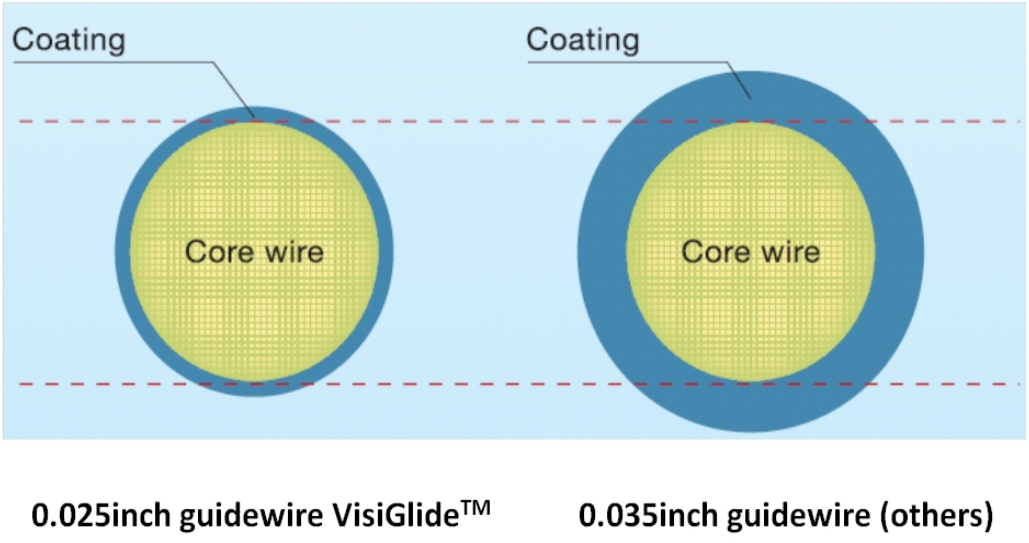

Fig. 2. Comparison between 0.035-inch guidewire and 0.025-inch guidewire VisiGlide™

2. MATERIALS AND METHODS

All the patients with biliopancreatic diseases, who were decided to undergo ERCP in 4 institutions participating in this clinical study in a month of October 2012, were included. The patient's background and disease background are shown in Table 1. There were 194 patients including 113 males and 81 females, and the age was 70.9 (38 to 95) years old on average. There were 104 patients with bile duct stone, 26 with bile duct cancer, 18 with chronic pancreatitis, 16 with pancreatic cancer, 6 with gallbladder cancer, 5 with intrahepatic gallstone, 5 with metastatic biliary obstruction, 4 with intraductal papillary mucinous neoplasm (IPMN), 3 with benign biliary stricture, 2 with acute cholecystitis, 2 with primary sclerosing cholangitis (PSC), 1 with postoperative bile leakage, 1 with pancreaticobiliary maljunction and 1 with duodenal papillary cancer. The ERCP was conducted aiming at bile duct in 180 patients and pancreatic duct in 14 patients. There were 77 patients with bile duct/pancreatic duct stricture and 117 with no stricture. ERCP was conducted for diagnosis in 14 patients, for diagnosis and treatment in 9 patients and for treatment in 171 patients. There were 4 patients having postoperatively reconstructed intestinal tract, 3 patients after Rou-X-en Y anastomosis, 1 after Billroth-I method and the others of usual stomach. There were 81 patients undergoing ERCP for the first time and 113 patients on whom papillary treatment has already been implemented. As the papillary treatment, EST was conducted on 101 patients and endoscopic pancreatic sphincterotomy (EPST) was conducted on 12 patients. The case in which 0.025-inch guidewire VisiGlide™ was used as a versatile GW and the scheduled procedure could be accomplished only with VisiGlide™ at the ERCP was considered as the success of procedure, and the success rate and the incidence of accidental symptom were examined. Prior performing ERCP, midazolam or diazepam was administered intravenously as a premedication depending on the patients' age and previous history. Scopolamine butylbromide or glucagon was used for duodenal relaxation. During ERCP, arterial oxygen saturation was continuously monitored by a pulse oximeter. Patients were kept fasting after the procedure for at least 24 h with drip infusion and stayed in the hospital for at least 72 h. They received 8-h infusion of protease inhibitor (nafamostat mesilate, 20-30mg/d Torii pharmaceutical Co., LTD. Japan) and antibiotics (SBT/CPZ, 2 g/d) for 2 d. Protease inhibitor was used at the investigator's direction. For cannulation, catheters PR-104Q, PR110Q-1, PR-233Q and Clever-Cut3V (Olympus Corp. JAPAN) were used. A 0.025-inch GW (VisiGlide: Olympus Corp. JAPAN straight type or angle type) was used. The endoscopes used were JF200, JF240, JF260V, TJF260V (Olympus Corp. JAPAN), backward side-viewing endoscope and bile ducts were observed using a standard cholangioscope CHF-B260 (Olympus Corp. JAPAN). In the patients after Rou-X-en Y anastomosis, a double balloon endoscope, EC-450B1-5 (FUJINON, Japan), was used. After cholangiography, a GW was placed in the bile duct to conduct EST. Clever-Cut3V (Olympus Corp. JAPAN) or Autotome RX Sphincterotome (Boston Scientific Corp. Natick, MA) was used as the knife for EST. A generator with an automatically controlled cut-out system (Endocutmode, ICC200, ERbe Electromedizin GmbH, Tubingen, Germany) or a single electrosurgical current generator (PSD-20, Olympus Corp. JAPAN) at a power of 25 watts was used for EST. An incision method, which is a mild-moderate incision from the papillary opening to papillary ridges, was selected during EST. In the EPST, the GW was inserted into the pancreatic duct to conduct incision to the direction to pancreatic duct using the equipment as in EST. In the EPBD, the GW was placed after succeeding in insertion into the bile duct, a balloon (QUANTUM. COOK JAPAN) was selected according to the diameter of bile duct, the balloon was dilated until disappearance of balloon notch, and the balloon was deflated soon after disappearance of notch. Patients with difficulty in selective biliary cannulation were defined as patients who are considered by an investigator to be difficult cases for 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 (NKPP), transpancreatic precut papillotomy (TPPP) and pancreatic duct guidewire indwelling method (P-GW). NKPP was performed to obtain repeated shallow incisions from the papilla opening to the bile duct to expose the opening of bile duct with KD10Q-1 or KD11Q-1 (Olympus Corp. JAPAN). TPPP was performed using Clever-Cut3V (Olympus Corp. JAPAN) to insert Papillotome by using a guidewire placed in the bile duct in over the wire method, to make an incision to the bile duct and to expose the opening of bile duct. P-GW was performed to insert a guidewire to the tail of pancreatic duct, to hold the papilla and to make cannulation by directing a catheter to the bile duct and expanding the papilla opening with the guidewire loaded in the bile duct. A spontaneous dislodgement-type pancreatic duct stent was used depending on patient's condition at the investigator's direction to prevent pancreatitis. Used as pancreatic duct dislodgement stent was 5 Fr. 3-cm straight unilateral-flapped stent (GEENEN PANCREATIC STENT: COOK Medical Corp. North Carolina USA), or 5 Fr. 4-cm stent with a single duodenal pigtail (ZIMMON PANCREATIC STENT: COOK Medical Corp. North Carolina USA). The endoscopic nasobiliary drainage (ENBD) or endoscopic nasopancreatic drainage (ENPD) tubes of 7 Fr. was used FLEXIMA: (Boston Scientific Corp., Natick, MA), TC-50-1800-SHO: (HANACO Medical. JAPAN) or SD5: (SILUX. JAPAN). The tube stents of 7 Fr., 8.5 Fr. and 10Fr. were used FLEXIMA, (Boston Scientific Corp. Natick, MA), QuickPlace (Olympus Corp. JAPAN), Double-layer (Olympus Corp. JAPAN), or Zimmon (COOK Medical Corp. North Carolina USA). EMS was conducted using WallFlex (Boston Scientific Corp., Natick, MA) or Bile Rush (PIOLAX, Japan). A basket catheter used collecting stones was FG-22Q or FG-V416Q (Olympus Corp. JAPAN). A basket catheter used for endoscopic mechanical lithotripsy (EML) was LBGT-7245S (ZEON Medical, JAPAN) or BML-V237QR-30 (Olympus Corp. JAPAN). A balloon catheter used was B-V232P (Olympus Corp. JAPAN), EXP718200 (ZEON Medical, JAPAN) or FS-QEB-XL-B (COOK Medical Corp., North Carolina USA). As for small stones, lithotomy was performed using a basket or a balloon catheter after papilla treatment. For those in which an incision has been already made, a guidewire was placed in the bile duct after cholangiography to perform EPLBD. In performing EPLBD, CRE 12-20mm (Wire-guided type 5.5cm: Boston Scientific Corp. Natick, MA) was used depending on diameter of the bile duct. Bioptome used was Radial Jaw 3 or 4 (Boston Scientific Corp., Natick, MA) and biliary brush cytology used was RX Cytology Brushes (Boston Scientific Corp., Natick, MA). SSD-560 (Aloka Co., JAPAN) was used in intraductal ultrasonography (IDUS). For patients with moderate or severe cholangitis, urgent ERCP was performed according to the Tokyo Guideline [14]. The scheduled ERCP was conducted on 155 patients, and emergency ERCP was conducted on 39 patients.

Iatrogenic morbidity was assessed according to the criteria of Cotton et al. [15]. The observation period was 30 days 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. This study was performed based on approval of ethical committee of each institution, and registered at UMIN Clinical Trial Registry (UMIN000008180 -VIP study-).

Table 1. Patients' background and disease background

Patients' background and disease background		
Sex	113 males	81 females
Age	70.9(38-95)	
Disease	Bile duct stone	103
	Cholangiocarcinoma	26
	Chronic pancreatitis	18
	Pancreatic cancer	16
	Gallbladder cancer	6
	Intrahepatic stone	5
	Metastatic biliary obstruction	5
	IPMN	4
	Benign biliary stenosis	3
	Acute cholecystitis	3
	PSC	2
	Postoperative bile leakage	1
	Pancreaticobiliary maljunction	1
	Duodenal papillary cancer	1
Target region	Bile duct	180
	Pancreatic duct	14
Stenosed lesion	Present	77
	Absent	117
Purpose	Diagnosis	14
	Diagnosis + treatment	9
	Treatment	171
Papillary treatment	None	81
	post EST	101
	post EPST	12

IPMN: intraductal papillary mucinous neoplasm, PSC: primary sclerosing cholangitis, EST: endoscopic sphincterotomy, EPST: endoscopic pancreatic sphincterotomy

3. RESULTS

The accomplishment rate of procedure only with VisiGlide™ was 92.8% (180/194). The straight type was used in 134 patients and the angle type in 60 patients. Wire-guided cannulation was not performed in this study. Among the unsuccessful patients, GW was changed in 8 patients. Among these 8 patients, Radifocus (RF-GS25263 TERUMO, Japan) was used in 7 patients, among whom the procedure was successful in 5 patients and unsuccessful in 2 patients. One of these 2 patients was a patient with acute cholecystitis, who underwent insertion of percutaneous transhepatic gallbladder drainage (PTGBD) and showed internal fistula, and when endoscopic gallbladder stenting (EGBS) was attempted, the GW could not be induced into the cystic duct, so this patient was followed up. In another patient, the second ERCP was attempted, and the procedure was successful. In the remaining one patient who changed GW, the procedure was successful by using METRO DIRECT (MET II-35-480, COOK, Japan). There were 2 patients in whom the procedure was discontinued in the initial ERCP, who induced GW perforation, so percutaneous transhepatic biliary drainage (PTBD) was conducted. The remaining 4 unsuccessful patients had difficulty in insertion into bile duct. In these patients, precut was conducted, but the GW could not be inserted into the bile duct, so the procedure was terminated. The second ERCP was conducted on 5 patients. Among them, the procedure was successful in 4 patients and 1 patient was suspected of spontaneous stone drainage, who was followed up without conducting ERCP again Fig. 3. The final success rate of ERCP was 97.9% (190/194). Among the patients succeeded in insertion into the bile duct and not undergoing papillary

treatment, 79 patients underwent papillary treatment. Among them, EST was conducted on 67 patients, EST+EPLBD on 5 patients, EPST on 3 patients and EPBD on 4 patients. There were 15 patients with difficulty in insertion into the bile duct, among whom P-GW was conducted on 7 patients, NKPP on 2 patients, TPPP on 2 patients and P-GW+TPPP on 4 patients. Insertion into the bile duct was achieved within the time of procedure on the day in 11 patients. The papillary treatment was successful in all the 79 patients conducted, the success rate of 100% (79/79) Table 2. As the treatment after success of insertion into the bile duct after papillary treatment, ENBD was attempted on 51 patients, ENPD on 3 patients, endoscopic nasogallbladder drainage (ENGBD) on 1 patient, EGBS on 1 patient, endoscopic biliary stenting (EBS) on 78 patients, endoscopic pancreatic stenting (EPS) on 22 patients, EML on 2 patients, EMS on 8 patients, lithotomy on 69 patients, bile duct biopsy on 9 patients, pancreatic duct biopsy on 1 patient, peroral cholangioscopy on 1 patient, IDUS on 6 patients, bile duct scraping cytology on 9 patients and pancreatic duct scraping cytology on 2 patients, and the procedure was successful in all the patients other than those attempted EGBS. The success rate was 99.6% (262/263) Table 3. The trouble of GW such as GW dislocation during a maneuver trial did not exist. Accidental symptoms were observed at 4.6% (9/194). GW perforation, bleeding and pancreatitis were observed at 2.1% (4/194: type of GW; 2 straight type, 2 angle type), 2.1% (4/194: type of GW; 2 straight type, 2 angle type) and 1.0% (1/194 type of GW; straight type), respectively. GW perforation and bleeding were mild and resolved conservatively in all the patients. Pancreatitis was severe but resolved conservatively. The procedural time was 31.2 (4 to 117) minutes.

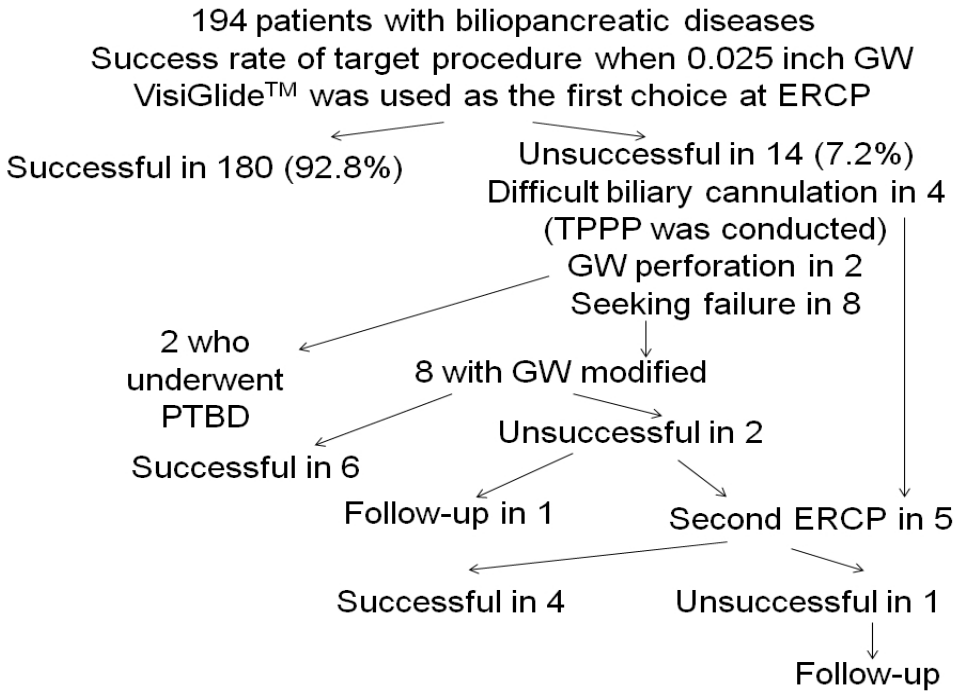

Fig. 3. Result of use of 0.025-inch GW VisiGlideTM in the ERCP as the first choice. ERCP: endoscopic retrograde cholangiopancreatography, TPPP: transpancreatic precut papillotomy, PTBD: percutaneous transhepatic biliary drainage

Table 2. Papillary treatment

Papillary treatment	N	Success rate of procedure
EST	67	100(67/67)%
EST+EPLBD	5	100(5/5)%
EPST	3	100(3/3)%
EPBD	4	100(4/4)%
Total	79	100(79/79)%

EST: endoscopic sphincterotomy, EPLBD: endoscopic papillary large balloon dilation, EPST: endoscopic pancreatic sphincterotomy, EPBD: endoscopic papillary balloon dilation

Table 3. Procedure conducted after insertion into the bile duct or pancreatic duct

Procedure conducted	N	
ENBD	51	100(51/51)%
ENPD	3	100(3/3)%
ENGBD	1	100(1/1)%
EGBS	1	0(0/1)%
EBS	78	100(78/78)%
EPS	22	100(22/22)%
EML	2	100(2/2)%
EMS	8	100(8/8)%
Lithotomy	69	100(69/69)%
Bile duct biopsy	9	100(9/9)%
Pancreatic duct biopsy	1	100(1/1)%
Peroral cholangioscopy	1	100(1/1)%
IDUS	6	100(6/6)%
Bile duct scraping cytology	9	100(9/9)%
Pancreatic duct scraping cytology	2	100(2/2)%
Total	**263**	**99.6(262/263)%**

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, EMS: expandable metallic stent, IDUS: intraductal ultrasonography

4. DISCUSSION

In the ERCP-related procedures, GW is essential. The roles of GW are accession to the target site, breakthrough of stenosis and insertion of treatment tool. The functions required for the roles are visibility, insertion performance, operability, rigidity and sliding potential. There are the types of 0.018, 0.021, 0.025 and 0.035 inches in diameter, the hardness of standard type and stiff type and the tip shape of angle, straight and loop types[16,17]. It is the present status that the method of use of GW so far was different according to disease or purpose of use. This time, we examined whether or not the procedure can be accomplished with one 0.025-inch GW VisiGlide^{TM} without using GWs differently for each patient. The success rate of procedure was very high. In the past, the 0.035-inch GW has been used as the first choice, but other GWs have been used for breakthrough of stenosis or difficulty in selective insertion into branches in a lot of patients. VisiGlide^{TM} has a merit of thinness as 0,025 inches as well as good rigidity and visibility because of technical progress Figs 4A and B, which could be used for implementation of POCS which was difficult in the past Fig. 5 and placement of metallic stent Fig. 6 with no problem. As just described, if the procedure can be

accomplished with one GW without using GWs differently for each patient, it is suggested that the procedural time and the time of radiography can be shortened and that the medical cost may be reduced. The technical points in procedure is that, if the procedure can be conducted using a 0.025-inch GW, it is possible to obtain a merit of increase in free space in forceps. Accordingly, we may obtain the merits that various devices are available and that the degree of freedom in operation may increase. In the two-devices in one channel method [18] and the double guidewire technique [2,3], it may be possible to shorten the procedural time and to increase the success rate of procedure because of improvement of operability. The same goes for not only ERCP but also the procedure using endoscopic ultrasonography. In pancreatic cyst drainage under EUS, for example, two GWs may have to be inserted into a forceps hole in ensuring 2 drainage routes in some cases [19]. In such cases, the use of this GW may increase the operability compared with insertion of two 0.035-inch GWs.

As described previously, no inconvenience was felt in the procedure with 0.025-inch GW so far because 0.025-inch GW VisiGlide™ has adequate rigidity for placement of metallic stent which has not been conducted so frequently. Because the patients undergoing placement of metallic stent often have strong stenosis, it is advantageous to use 0.025-inch GW, and since 0.025-inch GW VisiGlide™ has adequate rigidity, metallic stent can be placed without changing the GW as it is after breaking through the stenosis. Since GW was changed to more rigid one in a lot of cases when other 0.025-inch GW was used, the use of 0.025-inch GW VisiGlide™ is considered useful from the aspects of shortening of procedural time and reduction of medical cost. In the partial stent in stent with a metallic stent, the procedure used in unresectable malignant hepatic-portal biliary obstruction, particularly, examination by accumulation of cases is required but it is possibly useful. 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 metallic stent. 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 metallic stent 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. The incidence of accidental symptoms was 4.6% (9/194). As concerns accidental symptoms, there is no large difference in the overall incidence from that in the use of conventional GW but GW perforation was observed at 2.1% (4/194). This GW has strong rigidity, so there is the possibility of GW perforation because it is advantage in breaking through stenosis. It is considered less possible that GW perforation may result in serious accidental symptoms [20] but actually in the report about GW perforation in the use of this GW, penetration into the portal vein has been reported, so it is considered necessary to pay attention [21]. The frequency of the accidental occurrence symptom did not change in type of GW. The rigidity of the GW base might participate in perforation than the shape of the tip. Although not examined this time, in seeking the cystic duct in ENGBD, etc., the relatively soft GWs of high seeking capacity, such as Radifocus, have been used according to the reports so far [22]. This GW may induce cystic duct perforation in seeking the cystic duct because of strong rigidity, it is necessary to pay attention. In the case in which stones are incarcerated in the cystic duct, however, the thinness and rigidity of this GW may work advantageously. It is considered necessary to be examined this in a lot of patients in the future. It was suggested in the present study that the 0.025-inch GW VisiGlide™ can be used

as a versatile GW. However, it is problematic that this study is a multicenter prospective study but conducted in a short period as 1 month and has no comparative control group. In order to examine the utility and safety of 0.025-inch GW VisiGlide™, the RCT with 0.035-inch GW may be required in the future.

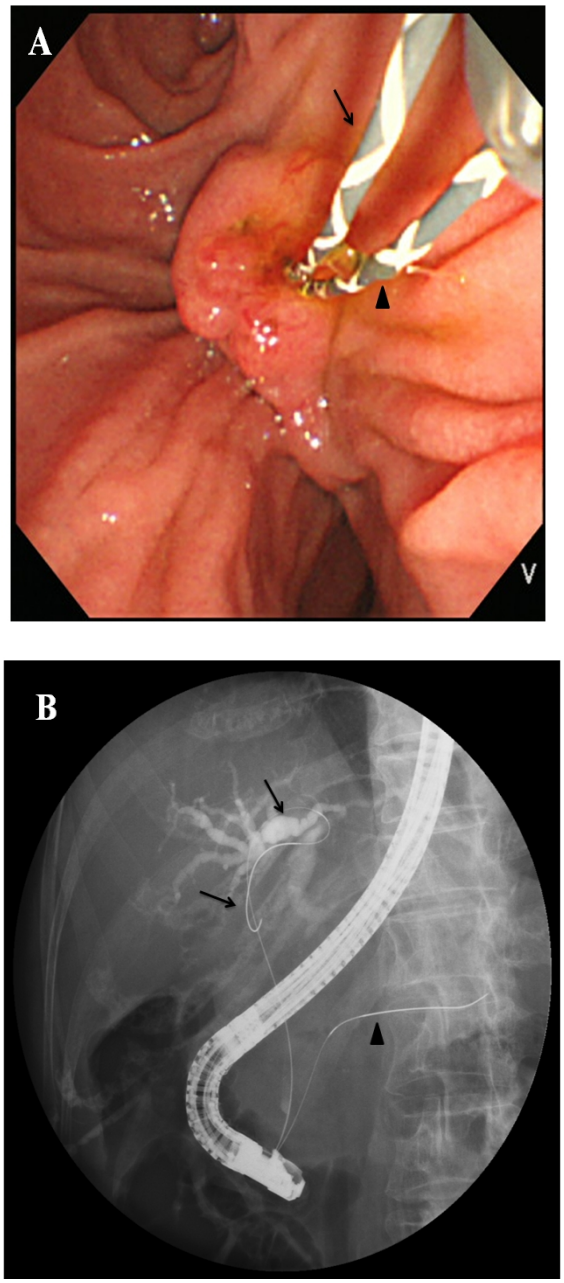

Fig. 4. 0.025-inch GW VisiGlide™ placed in the bile duct/pancreatic duct. The visibility is good both under endoscopy (A) and radiography (B)

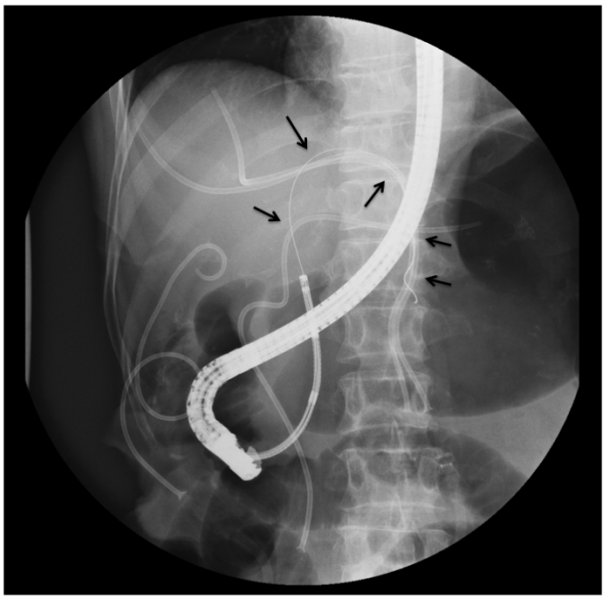

Fig. 5. Condition in which multiple drainage tubes are placed in the bile duct. The tip of GW overlaps with the drainage tube, but the visibility is good, so the position of GW can be identified (→). In the peroral cholangioscopy conducted for diagnosis of progress level, the procedure could be accomplished because of adequate rigidity of GW

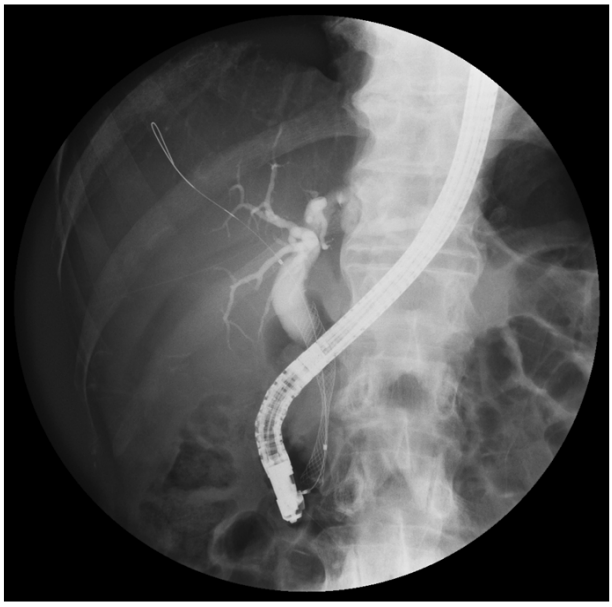

Fig. 6. Placement of metallic stent using 0.025-inch GW VisiGlide™. It was possible to break through the stenosis, to induce delivery and to place stents only with this GW

5. CONCLUSION

The 0.025-inch GW VisiGlide™ has a high accomplishment rate of procedure and a low incidence of accidental symptom in its use in the ERCP-related procedure and it was suggested that it may be available as a versatile GW.

CONSENT

Not applicable.

ETHICAL APPROVAL

Not applicable.

ACKNOWLEDGEMENTS

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COMPETING INTERESTS

The authors report no competing of interest exists.

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