

# A prospective randomized study of thin versus regular-sized guide wire in wire-guided cannulation

Jorma Halttunen · Leena Kylänpää

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## Abstract

**Background** Endoscopic retrograde cholangiopancreatography (ERCP) is a valuable tool in the diagnosis and management of various pancreatobiliary disorders. Our aim was to evaluate whether the combination of a thin guide wire and a thin sphincterotome would facilitate selective cannulation of the bile duct and reduce the incidence of post-ERCP pancreatitis (PEP) by reducing papillary trauma when compared with a regular-sized hydrophilic guide wire.

**Methods** Between June 2011 and February 2012, we performed 100 biliary cannulations for a native papilla in a randomized controlled trial. Having given their written informed consent, patients were randomly assigned to a 0.025-inch guide wire and sphincterotome group ( $n = 50$ ) or to a 0.035-inch guide wire and sphincterotome group ( $n = 50$ ). Number of cannulation attempts, number of accidental guide wire passages into the pancreatic duct, secondary cannulation techniques after failed primary cannulation, time to change the technique, and time for successful cannulation were collected in a database. Patients were followed up after ERCP, and all post-ERCP complications were recorded.

**Results** Primary cannulation was successful in 80 %. With accessory techniques, cannulation of the biliary duct was achieved in every case except one. There was no difference in primary cannulation rate between the 0.025-inch and 0.035-inch wire groups ( $n = 40$  in each group). PEP was diagnosed in two patients (2.0 %), one in each

study group. Postsphincterotomy bleeding occurred in one patient (1.0 %).

**Conclusions** The thickness of the hydrophilic guide wire does not appear to affect either the success rate of primary cannulation or the risk of complications.

**Keywords** Biliary cannulation · ERCP · Guide wire · Post-ERCP complications · Post-ERCP pancreatitis · Technique

Primary cannulation rates using hydrophilic guide wire in endoscopic retrograde cholangiopancreatography (ERCP) are reported within the range of 75–85 %, mainly around 80 % [1–7]. When guide wires have been compared with the standard contrast injection method, using either catheter or sphincterotome, guide wires have on average performed 10 % better. Occasionally success rates of over 90 % are achieved, although this is an exception to the general rule [8]. Working with the short-wire system has been shown to shorten the device exchange time when either the V-system or the hydraulic method is used [9–11].

The reported post-ERCP pancreatitis (PEP) rate for wire-guided cannulation (WGC) ranges from 2 to 11 %, usually being around 6 %, with a tendency toward lower PEP rates in guide wire groups. Compared with the standard contrast injection method, several articles have reported a significantly lower risk of PEP when using the guide wire technique [2, 5, 8, 12]. Some thorough studies find no difference [3, 6, 13].

When accessory methods are used to enter the common bile duct (CBD) after failed primary cannulation, the final success rate is over 94 %, usually around 97 % [1–6, 8]. Few studies report an overall success rate close to or as high as 100 % [2].

J. Halttunen (✉) · L. Kylänpää  
Department of Gastrointestinal and General Surgery,  
Helsinki University Central Hospital, Haartmaninkatu 4,  
PL340, 00029 Helsinki, Finland  
e-mail: jorma.halttunen@hus.fi

It is customary to use a regular 0.035-inch hydrophilic guide wire with catheter or sphincterotome. We tried to find out whether use of a thin 0.025-inch guide wire in combination with a thin-tip sphincterotome would facilitate cannulation and lead to fewer complications compared to regular 0.035-inch hydrophilic wire and sphincterotome.

## Patients and methods

In 2011, a total of 1,068 ERCPs were performed at Helsinki University Central Hospital. Between June 2011 and February 2012, a total of 100 patients with native papilla were randomly assigned to two groups: a 0.025-inch guide wire and sphincterotome group ( $n = 50$ ), or a 0.035-inch guide wire and sphincterotome group ( $n = 50$ ). The indication for ERCP in each case was to gain access to the CBD. After receipt of signed informed consent, a sealed envelope was opened to determine group assignment. Patient characteristics and indications for ERCP are shown in Table 1. Patients with acute pancreatitis with plasma amylase 3 times or more above the upper reference limit and/or pancreatitis diagnosed by computed tomography were excluded from the study. Other exclusion factors were age below 18 years, procedure for chronic pancreatitis, and anatomy after Billroth II gastric reconstruction. The Helsinki University ethical committee approved the study. These procedures were performed by two experienced ERCP operators (JH and LK) who perform around 300 ERCPs a year. JH has over 20 years' experience in ERCP

and LK 10 years. In this study, JH operated in 37 cases and LK in the rest. Forty-eight of the patients were emergency cases. All patients received oral levofloxacin 500 mg as a prophylactic antibiotic within 1 h before ERCP unless they were already receiving antibiotic treatment.

The primary tools for ERCP in the 0.035-inch group were a sphincterotome with a distal tip length of 5 mm, tip diameter of 5.5F, and cutting wire length of 20 mm (Ultra-tome; Boston Scientific, Miami, FL, USA) and a 0.035-inch, 260-cm-long guide wire (Hydrosteer; St. Jude Medical, Minnetonka, MN, USA) to gain access to the CBD.

In the 0.025-inch group, the tools were a sphincterotome with a distal tip length of 7 mm, tip diameter of 4F and cutting wire length of 20 mm (CleverCut3 V; Olympus Medical Systems Corp., Tokyo, Japan) and a 0.025-inch, 270-cm-long guide wire (VisiGlide; Olympus Medical Systems). There was no crossover, and the same guide wire was used with accessory methods when these were necessary.

Hydrosteer guide wire has a nitinol core covered with polymer jacket and hydrophilic coating in the full length. We used a wire with standard stiffness and a straight tip. VisiGlide wire with a thickness of 0.025 inches and with a special metal alloy core provides the same stiffness as a traditional 0.035-inch guide wire. There is a hydrophilic coating in the tip, with a length of 70 mm and a thin fluorine coating on the shaft. We used a wire with standard stiffness and a straight tip.

The endoscope used throughout the study was Olympus TJF-Q180 V (Olympus Medical Systems). The V-system of the endoscope was used for exchange with the VisiGlide wire, and the hydraulic exchange was used with Hydrosteer wire.

After successful cannulation, ERCP continued with various procedures as indicated. Data on ERCP indications, cannulation techniques, possible number of wire passages into the pancreatic duct, contrast injections into the pancreatic duct, number of cannulation attempts, and primary cannulation time were collected in a database. Cannulation time was measured in seconds starting on initial contact with the papilla and ending with deep cannulation and/or with each change of method. An attempt was recorded as a number and defined as continuous contact with the papilla. Losing contact and repositioning counted as a new attempt. Pancreatic passages with a guide wire into the pancreatic duct were counted, as was contrast injection into the pancreatic duct. Success was defined as deep biliary cannulation with the guide wire well inside the CBD. Location of the guide wire in the biliary or pancreatic duct is usually distinguishable without contrast injection under fluoroscopy.

If primary cannulation failed, further techniques required to gain access were recorded. In cases where the guide wire

**Table 1** Patient characteristics

Characteristic	0.025-inch group ( $n = 50$ )	0.035-inch group ( $n = 50$ )	<i>P</i>
Age (years)	65.5 (29–95)	73 (32–92)	0.09
Sex (F/M)	27/23	33/17	0.22
ASA grade			0.84
I	2	3	
II	11	14	
III	27	25	
IV	10	8	
BMI ( $\text{kg}/\text{m}^2$ )	26.2 (12.8–41.4)	26.5 (17.1–39.7)	0.56
Emergency	22	26	0.42
Indication for ERCP			
Stones	22	35	0.01
Stricture	21	12	0.06
After LCC	4	5	0.73
Diverticulum	5	14	0.02

Data are presented as numbers of patients or as median (range)

ASA American Society of Anesthesiology, BMI body mass index, ERCP endoscopic retrograde cholangiopancreatography, LCC laparoscopic cholecystectomy

slipped repeatedly only into the pancreatic duct, most frequently a pancreatic sphincterotomy was performed with the sphincterotome over the guide wire, with the guide wire still in the pancreatic duct. If necessary, a further oblique cut with a needle knife toward 10 o'clock, starting from the upper end of the pancreatic sphincterotomy cut, was performed in order to expose the lumen of the CBD.

Plasma total amylase or pancreatic amylase were measured before and 4–6 h after ERCP. If the patient stayed in the hospital overnight, plasma amylase was checked the next morning. If a complication occurred, the patient remained in the hospital until recovered.

The main focus of the study was to evaluate the rate of successful cannulation and the frequency of complications, i.e., PEP, cholangitis, bleeding, and perforation. PEP was defined as elevated plasma amylase 3 times or more above the upper reference limit and the presence of abdominal pain persisting for 24 h after the procedure. Cholangitis was defined as fever requiring intravenous or intramuscular antibiotics within 2 days of ERCP. Bleeding was defined as a need for repeat endoscopy due to melena or transfusion of blood within 1 week of ERCP. Perforation was diagnosed as an extravasation of contrast during ERCP or retroperitoneal air in computed tomography after the procedure. The severity of the complications was defined according to consensus criteria [14].

Data are presented in the form of median (range) or number of patients and percentages. The data were analyzed by SPSS software, version 15.0 (IBM Corporation, Somers, NY, USA). The Chi-square test was used to test for differences between categorical variables. A nonparametric Wilcoxon-Mann-Whitney test was used to compare differences in continuous and ordinal variables. Probabilities below the 0.05 level were regarded as statistically significant.

## Results

Primary cannulation without a change of tool or method was successful in 80 cases (80 %). The median length of hospital stay was 1 day (range, 0–28 days) after ERCP. In the group with failed primary cannulation, access to the biliary duct was achieved by performing a pancreatic sphincterotomy first in 12 cases, with seven straight successes. A further oblique cut with a needle knife was performed in three cases. In the remaining two, the first was completed with a papillectomy and the second with a pancreatic stent and precutting. Other techniques used after failed primary cannulation were precutting with the sphincterotome in four cases, two of which were completed with a J-tip wire or pancreatic sphincterotomy. Precutting with a needle knife was used twice with success. One

double-wire procedure had to be completed with a pancreatic stent and additional precutting over the stent.

Biliary sphincterotomy was performed in 98 cases and biliary balloon dilatation in eight cases. Bile duct stents were placed in 33 patients. A pancreatic stent for prevention of PEP was introduced in three patients. There was no difference between the 0.025-inch VisiGlide and 0.035-inch Hydrosteer groups in terms of primary cannulation attempts, primary cannulation time, accidental passages of guide wire into the pancreatic duct, or total cannulation time. Primary cannulation success rate was equal, 40 in each group (Table 2). In primary cannulation failure, the technique was changed in a median of 240 (range, 65–920) s. With the use of accessory methods, the final cannulation rate was 99 %, with one failure in the thin wire group. The only failure, a liver transplant recipient, had a pancreatic stent and precutting during the first attempt. The case was successfully completed 3 days later.

There was only one parameter, radiation time, which reached significance between the groups. The 0.035-inch Hydrosteer had a lower value. The total radiation dose was equal in both groups (Table 2).

There was no difference in primary cannulation attempts ( $P = 0.42$ ), primary cannulation success ( $P = 0.41$ ), primary cannulation time ( $P = 0.55$ ), total cannulation time ( $P = 0.18$ ), or the duration of ERCP between the two

**Table 2** Endoscopic intervention

Characteristic	0.025-inch group	0.035-inch group	<i>P</i>
Primary cannulation attempts	2 (1–14)	2 (1–10)	0.87
Successful primary cannulation	40	40	1.00
Primary cannulation time (s)	62 (6–896)	42 (3–223)	0.57
Wire in pancreatic duct	0 (0–22)	0 (0–5)	0.67
Contrast in pancreatic duct	5	3	0.46
Total cannulation time (s)	70 (6–1875)	61 (3–1575)	0.52
Biliary EPT	48	50	0.15
Pancreatic EPT	8	6	0.56
Brush cytology	13	7	0.13
Biliary dilatation	5	3	0.46
Stone extraction	15	29	0.01
Biliary stent placement	19	14	0.29
Duration of ERCP (min)	15 (5–52)	13 (5–65)	0.13
Radiation time (min)	1.4 (0.1–14.9)	0.9 (0.1–7.6)	0.042
Radiation dose (Gy cm <sup>2</sup> )	1.9 (0.11–37.1)	1.95 (0.11–9.5)	0.32

Data are presented as numbers of patients or as median (range) ERCP endoscopic retrograde cholangiopancreatography, EPT endoscopic papillotomy

operators. Primary cannulation was equally as successful in emergency cases as in elective ones ( $P = 0.84$ ). The presence of diverticulum did not affect primary cannulation success either ( $P = 0.44$ ).

PEP was seen in two patients (2.0 %), one in each group. PEP occurred in one patient for each ERCP operator. Both PEPs were cases where primary cannulation was successful, one with two attempts in 55 s and the other with two attempts in 152 s. Both cases were performed without pancreatic passages or injections. Neither of the PEP cases had a protective pancreatic stent. Both PEP cases were treated conservatively. The first PEP patient stayed in the hospital for 5 days, but when recovered from PEP had a laparoscopic cholecystectomy performed during the same hospital stay. The other PEP patient was discharged 2 days after ERCP. As a consequence, both PEP cases can be considered mild. Hyperamylasemia without clinical signs of PEP was present in four patients in the 0.025-inch VisiGlide group and in six in the 0.035-inch Hydrosteer group ( $P = 0.54$ ). Bleeding occurred in one patient (1.0 %) and was related to a sphincterotomy procedure. It was successfully treated with blood transfusion and endoscopic techniques for achieving hemostasis. There were no cases of cholangitis or perforation, nor were there any deaths within 30 days of ERCP.

## Discussion

WGC with sphincterotome has become the most commonly used method of primary cannulation, as it has consistently enjoyed the best and most reliable success compared to other methods. Some authors believe strongly that WGC has a lower PEP rate than the standard injection method, so a recommendation has been expressed that WGC should be the method of choice to be taught to ERCP trainees [15]. In our unit, the WGC method has been in virtually exclusive use for the past 20 years.

With an effective cannulation technique, the rate of primary failures remains at around 20 % of intact papillae, as was the case in our study. After a failed attempt, there is a choice of how to proceed. Needle knife precutting, papillary roof excision, transpancreatic sphincterotomy, pancreatic stenting, double-wire technique, persistence, papillectomy, and special knives can be used as further steps [16–25]. Until now, the most common solution in difficult situations has been use of the needle knife to perform an access papillectomy.

Our preferred choice in a difficult case is to perform a pancreatic sphincterotomy if the guide wire has entered the pancreatic duct several times. A sphincterotomy over the guide wire in the pancreatic duct helps find the orifice of the CBD, as the cut either opens the biliary duct or runs along the side of it, thus exposing the duct's anatomy. In

over half of cases, the lumen of the CBD becomes visible and can be cannulated with the sphincterotome with a guide wire. If not, an oblique cut with the needle knife exposes the CBD [26]. The advantage of this transpancreatic septotomy is that the depth and location of the incision in relation to the bile duct is more controlled than with the needle knife precutting. In this study, the pancreatic sphincterotomy alone or combined with the needle knife was used in 13 of the 20 cases of primary cannulation failure.

When pancreatic sphincterotomy was compared with needle knife sphincterotomy, pancreatic precutting had a 100 % success rate of biliary cannulation, compared to 77 % with needle knife precutting. Complication rates were 4 versus 18 %, respectively [20]. Goff reported a similar low complication rate of 2 % after a standard sphincterotomy and transpancreatic approach. It is noteworthy that there were no cases of PEP in the latter group [17]. In our study, none of the patients in the difficult cannulation group developed PEP, a pancreatic sphincterotomy having been performed in two-thirds of them.

There is no generally accepted definition of difficult cannulation. Definitions in reports differ in terms of time, numbers of attempts, number of pancreatic passages, and number of pancreatic injections before a rescue method is applied. There are further differences between reports in terms of single versus multiple operators, or whether trainees were allowed to participate. Definitions vary still more if a crossover is allowed, and definitions also depend on how the situation of difficult cannulation is handled [2–6]. During this study, median successful primary cannulation was achieved in two attempts and with no pancreatic passages in just 1 min. After a failed attempt, the median time to change to an accessory method was 4 min. Before such a change, there were a median of 4.5 attempts and 2.5 pancreatic passages, even including outliers. We would accordingly consider a cannulation definitely difficult if any of the following criteria were exceeded: 5 min, five attempts, or three pancreatic passages. We usually apply an accessory method no later than these points in order to keep the number of attempts low. In this study, the point of change was within these limits.

The cause of PEP remains as elusive as ever. Both PEP cases were successful primary cannulations, each with only two attempts and with no pancreatic guide wire passages or injections. In larger-scale reports, the number of attempts had a significant effect on the rate of PEP [3, 6]. We had not previously found any clear correlation between PEP and pancreatic injections or passages [26]. In this study, one patient had 22 guide wire passages with no PEP. Pancreatic sphincterotomy caused no adverse effects either. Our explanation is that a wide sphincterotomy toward the pancreas guarantees free drainage of the pancreatic duct

and mitigates the effects of papilla manipulation, as does a pancreatic stent [27]. The practice and results of the study support this theory.

There are only few reports on the use of a thin 0.025-inch wire. With a special scope, the wire we used in the study has been shown to allow accessories to be changed three times faster. This is of course an advantage later in the procedure, but it has no significance for cannulation itself [28]. In fact, in our study, procedure time was slightly lower in the regular wire group. In a relatively large retrospective study using thin guide wire, the overall success rate in 666 native papillae was 98 %. The article does not mention primary cannulation success, as the double-wire technique was used in difficult cases, for example. The PEP rate of native papillae was as low as 1.2 % [29]. The overall result and PEP rate of our prospective study compares well with that report.

Strictly speaking, we were comparing two set of tools and not just wires, as the sphincterotomes were not identical, although very close. The idea before starting the trial was that a thinner wire with a slightly thinner-tip sphincterotome would outperform the standard 0.035-inch set. We could not confirm this assumption. A significant difference was noted only in the radiation time in favor of the 0.035-inch set, but the radiation dose was equal. The recorded median dose was low, 1.9 Gy/cm<sup>2</sup>, corresponding to 10 chest x-rays or to one lumbosacral spine study.

The limitations of this study are the lack of power calculation and a small number of patients. In an unpublished study in our unit, in a group of 250 patients, the frequency of PEP for native papillae was 4.8 %, primary cannulation rate was 78 %, and final success rate was 99.6 %. It would probably take thousands of patients to find a significant difference in these figures using new instruments. We did this prospective pilot study to find out whether there was any tendency toward improved primary cannulation success or a lower PEP rate using thinner instruments. We were unable to find any differences between these tools; both performed satisfactorily.

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