

Bile duct cannulation for ERCP therapy : success rates for techniques and devices at a single institution

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Abstract

Background and study aims : Deep bile duct cannulation is the first step in carrying out ERCP biliary interventions. Although many special techniques have been described, there is a lack of reports that describe all methods employed to cannulate in a single series. This is a prospective study about the way in which cannulation was achieved in an ordinary ERCP workload.

Patients and methods : From January 2002 to June 2004, all patients who underwent ERCP with accessible and intact papilla and no gastroduodenal surgical alterations were included. Cannulation either with a 5.5 french tapered, triple lumen sphincterotome (5.5 Fr-S), loaded with a 0.035 inch hydrophilic tip guidewire, or with a 3 french tapered, double lumen sphincterotome (3 Fr-S), plus a 0.025 inch guidewire, was considered standard cannulation (SC). Other methods and devices were considered to be alternative methods.

Results : Of the 199 patients, SC succeeded in 150 (75.4%). Initial cannulation was achieved in 78/100 with the 3 Fr-S, and in 59/96 (61.4%) with the 5.5 Fr-S, ($p = 0.01$). Alternative methods used to reach a final 98% success rate were any type of precut (23 patients, 11.5%), cannulation above a pancreatic placed guidewire (11, 5.5%), above a pancreatic stent (7, 3.5%), utilization of two devices at the same time (3, 1.5%), and papillectomy (1, 0.5%). In 4 (2%) patients, cannulation failed.

Conclusions : In almost a quarter of the patients (45, 22.6%) in this series, cannulation had to be performed by alternative methods. A 3 Fr-S is a very useful tool for gaining access to the bile duct. (*Acta gastroenterol. belg.*, 2006, 69, 261-267).

Key words : ERCP, bile duct cannulation, ERCP complications, ERCP success, sphincterotome.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has become, in many cases, the method of choice to treat bile duct obstruction (1) and other biliary diseases. From its first diagnostic description (2), ERCP has evolved into a mainly therapeutic procedure, initially by means of endoscopic sphincterotomy (3,4) and stenting (5). Currently, despite its sophisticated instruments, materials and therapeutic possibilities (6), deep bile duct cannulation continues to be the *sine qua non* condition to carry out ERCP biliary interventions, and this still constitutes a challenge, even for the experienced endoscopist (7).

When standard cannulation fails, many alternative methods of gaining access to the bile duct have been described (see Table 1). Nevertheless, there is limited data on how cannulation is performed in large series using both standard and more advanced techniques, without focusing on special ones. Although catheters,

sphincterotomes, and guidewires seem to be the devices commonly used for standard cannulation, the way in which they are usually arranged is not well reported. Therefore, our aim was to investigate the manner in which cannulation was achieved in an ordinary ERCP workload.

Patients and methods

A prospective study was undertaken to examine the techniques used in our centre for bile duct cannulation during ERCP. All the procedures with intact papillae and no major surgical alterations of the gastroduodenal anatomy, performed from January 2002 to June 2004, were considered for the study. Consequently, cannulation into papillae with previous sphincterotomy or sphincteroplasty and surgical operations such as Billroth II were excluded. Situations in which the papillary area could not be reached were also excluded. Cannulation had to be made through the papillary orifice and not, for instance, using a spontaneous fistula in the area.

All the procedures were performed by the two authors, who have more than 10 years experience in ERCP. Patients were sedated by these endoscopists with meperidine and midazolam. Buscopan was given to achieve duodenal relaxation. In general, patients were laid in the prone position at the beginning of the intervention. Oxygen supply was administered by means of a nasal cannula. Blood oxygen saturation and heart rate were monitored using an automated device during all procedures. All patients underwent ERCP on in-patient basis, and remained in the hospital for at least one night after the intervention. The same team of nurses and gastrointestinal endoscopy assistants attended the majority of the procedures. A therapeutic duodenoscope with a 4.2 mm channel, ED-3440TK (Pentax Corporation, Tokyo, Japan) was used. As procedures were performed in an accepted and established mode, patients did not give written informed consent other than for the ERCP itself.

Although manufacturers are cited, there is no conflict of interest.

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Table 1. — Several techniques described to achieve deep bile duct cannulation when standard methods fail. Standard methods are considered to be those using a cannula, with or without a flexible tip and sphincterotomes, with both devices loaded, or not, with guidewires

<i>Cutting techniques</i>	<i>Author/description (reference)</i>
Needle-knife precut (including infundibulotomy)	Huibregtse (17)
Needle-knife precut over a pancreatic stent	Fogel (16)
Precut with an Erlangen-type pre-cut	Binmoeller (18)
Precut with standard sphincterotome within the pancreas	Goff (28) / Akashi (29)
Precut with standard sphincterotome	*
Precut with "Iso-Tome"	Park (30)
Pancreatic sphincterotomy as a precut	Kahaleh (31)
Intramural incision technique	Burdick (32)
Scissors to cut the papilla	Heiss (33)
Blunt dissection of the suprapapillary distal common bile duct	Hashiba (34)
Papillectomy	Farrell (10)
<i>Non cutting techniques</i>	
Guidewire within the pancreas	Gyökeres (12), Maeda (11), Gotoh (13)
Stent within the pancreas	Fry (14), Titus (15)
Two-devices in the same channel	Fujita (9)
Clip fixation of the papilla	Scotiosis (35)
Balloon dilatation of the neck of a diverticulum	Tóth (36)

* Technique of precut similar to that of Binmoeller, but with a standard sphincterotome having a leading tip (nose) of 5 mm.

Sphincter of Oddi dysfunction was diagnosed on clinical, laboratory and radiological grounds. Manometry was not performed.

Patients' demographics, ERCP diagnosis, therapy, types of devices and manoeuvres made to cannulate were recorded. To facilitate proper documentation and reporting, only the first method used to achieve cannulation and the last one (if others were unsuccessful) was recorded. Easy cannulation was defined as that requiring fewer than six (from one to five) attempts to gain the bile duct. Complications were diagnosed according to previously established criteria (8).

Cannulation methods

Figure 1 shows the steps that are usually followed in our centre to achieve deep bile duct cannulation, although they are not accomplished in a rigid manner.

Standard cannulation was considered to be that achieved by means of a sphincterotome loaded with a hydrophilic-tipped guide wire. Two types of sphincterotomes were used at the endoscopists' discretion: a 5.5 french tapered, triple lumen sphincterotome (Ultratome XL, Microvasive Endoscopy, Boston Scientific Corp., Natick, Massachusetts, USA), plus a 0.035 inch guidewire (Jagwire), and a 3 french tapered, double lumen sphincterotome (Tapertome), together with a 0.025 inch Jagwire (all three from Microvasive). To cannulate, the sphincterotome was usually bent to achieve a proper angle for attempted insertion into the papilla in the 11 o'clock position. Minor movements (i.e. towards the right) were then made to avoid impaction within the ampulla. Afterwards, the guidewire was gently pushed and its progression was monitored fluoroscopically. If the guidewire passed deeply in the direction of the bile duct, the sphincterotome was also

passed over it and cholangiography was carried out. With the 5.5 french triple lumen sphincterotome (5.5 Fr-S); contrast medium can be injected while the guidewire is in place. However, using the 3 french double lumen sphincterotome (3 Fr-S), the guidewire has to be removed or a side-arm device attached to inject contrast medium.

Alternative cannulation included all the manoeuvres and devices other than use of the sphincterotome-guidewire assembly alone.

Cannulation of a hidden papilla within a duodenal diverticulum was usually attempted by manoeuvring two devices (a paediatric biopsy forceps and a Glo-tipII catheter (Cook Medical Inc., Winston-Salem, North Carolina, USA) together, in the same duodenoscope channel (9).

Cannulation in the setting of polypoid ampullary tumours was attempted, at first, in a standard manner, although papillectomy (10) was soon considered.

The time to persist at attempting cannulation with standard methods varied. Attempts to gain the bile duct with the same device depended on the endoscopist's judgment that there was a possibility of success, and varied according to the patient having the ERCP performed (e.g. early insertion of a pancreatic guidewire in suspected sphincter of Oddi dysfunction).

If a guidewire passed repeatedly into the pancreatic duct, it could be left there. The sphincterotome was then removed and the guidewire was secured in place, outside the duodenoscope. Another guidewire was loaded into the sphincterotome and this was reinserted to attempt bile duct cannulation above the guidewire previously placed in the pancreas (11,12,13). If this was not successful, a pancreatic stent could be inserted (usually a 5 french, 5-cm-long stent without inside flaps: GPDS-

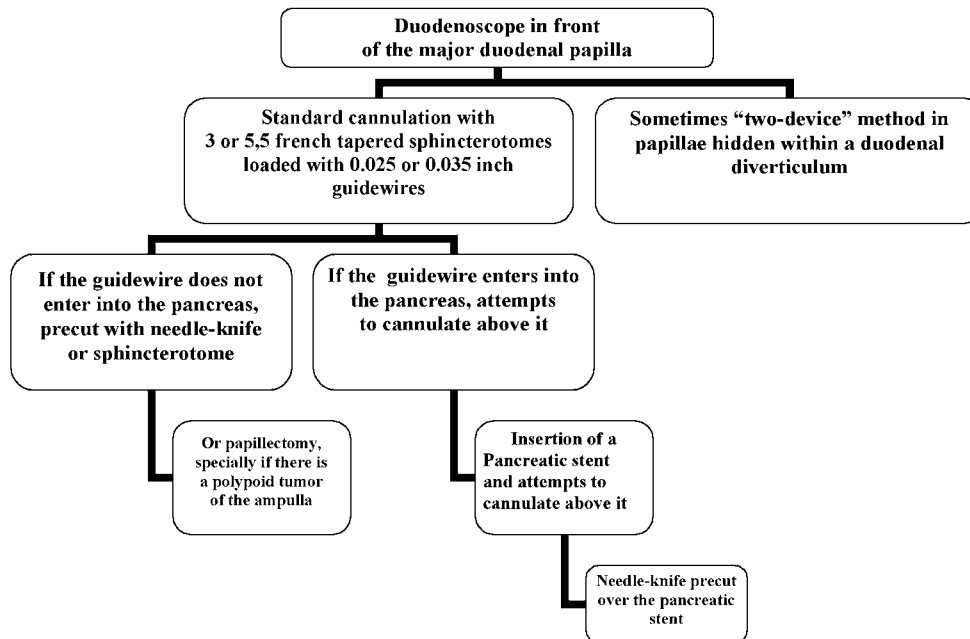


Fig. 1. — Steps to achieve deep cannulation of the bile duct during ERCP. They are not followed in a rigid manner. For instance, although the guidewire enters the pancreas, it can be removed in order to try standard cannulation again, instead of attempting cannulation above it.

5-5, Cook). Attempts to cannulate with the sphincterotome above the stent were then made (14,15). If these were unsuccessful, a needle-knife precut over the pancreatic stent could be carried out (16).

When cannulation failed and the guidewire did not enter the pancreas, two types of precut could be made by use either the needle-knife (17) or the standard sphincterotome. In this case, the device had to be within the papillary orifice but not in the bile duct or pancreas, and consequently an upward cut through the papilla could be made. This is a modification of the technique described by Binmoeller *et al.* (18), although they used a sphincterotome with a 1-mm leading tip (nose). The leading-tip length of the standard sphincterotomes used in this study was 5 mm.

Comparisons between categorical variables were made by using either the chi-square test or Fisher's exact test when appropriate. Two-tailed *p* values were measured and a *p* < 0.05 was considered significant.

Results

One hundred ninety-nine patients met the criteria and took part in the study. The patients' characteristics, final diagnoses, and endoscopic therapies are shown in Table 2.

In the entire series, deep bile duct cannulation was achieved in 188 patients (94%) at first ERCP and in 195 (98%) at a second session. In four patients (2%) the procedure definitively failed.

Standard cannulation

Selective bile duct cannulation was achieved by standard methods in 150 patients (75.4%), including one hundred forty-nine patients during the first procedure, and another patient, in whom the papilla could not be found in the initial session, during a second ERCP.

When the two types of sphincterotomes employed were compared (Table 3), the 3 Fr-S was superior to the 5.5 Fr-S in terms of cannulation rate. As the first device used, the 3 Fr-S achieved cannulation in 78 of 100 (78%) procedures, while the 5.5 Fr-S worked in 59 of 96 (61.4%, *p* = 0.01). Nevertheless, the rates of easy cannulation, acute pancreatitis, and the use of any type of precut to finally gain the bile duct did not differ significantly.

Cannulation was obtained by changing from the 5.5 Fr-S to the 3 Fr-S on nine (4.5%) occasions during the first ERCP (Table 4). Conversely, switching from the 3 Fr-S to the 5.5 Fr-S resulted in success three (1.5%) times in the first procedure. There was no significant difference in the number of successful alternative methods used after cannulation had failed with the first chosen sphincterotome (26/96 in the group of the 5.5 Fr-S vs. 16/100 with the 3 Fr-S, *p* = 0.08).

Alternative cannulation

In 45 patients (22.6%), seven other methods apart from sphincterotomes and guidewires alone had to be used to gain access to the bile duct (Table 4).

Table 2. — Patients' characteristics, diagnosis, and ERCP therapy

n patients	199
Men	107 (53.8%)
Women	92 (46.2%)
Age yr mean (SD)	73 (SD 13)
Range yr	24-92
n ERCP	208
Success (deep bile duct cannulation) at first ERCP	188 (94%)
Success at a second ERCP	195 (98%)
Complications (per patient, not per number of ERCP)	25 (12.5%)
Acute pancreatitis	12 (6%)
Haemorrhage after sphincterotomy	7 (3.5%)
Cholangitis	4 (2%)
Papillary area perforation after sphincterotomy	1 (0.5%)
Pulmonary oedema	1 (0.5%)
Mortality (1 out of 7 patients with haemorrhage)	1 (0.5%)
<i>Diagnosis</i>	
Cholelithiasis	96(48.2%)
Tumour	46 (23.1%)
Bile duct dilatation	20 (10%)
Normal	18 (9%)
Sphincter of Oddi dysfunction	9 (4.5%)
Benign stricture	6 (3%)
Biliary leak	4 (2%)
<i>Therapy</i>	
Sphincterotomy alone	44 (22.1%)
Sphincterotomy + stone extraction	69 (34.7%)
Sphincterotomy + stent	68 (34.2%)
Stenting alone	5 (2.5%)
Papillectomy + stent	1 (0.5%)
No therapy	12 (6%)

Three (1.5%) patients had a papilla hidden within a duodenal diverticulum; for these, the two-device method was successfully used as the initial procedure.

After leaving a guidewire into the pancreas, in eleven (5.5%) patients, the choledochus was gained using the sphincterotome-guidewire assembly to cannulate above the previously placed pancreatic guidewire. The same method was used in seven (3.5%) patients, but with the use of a pancreatic stent instead of a guidewire.

In total, precut procedures were used in 24 (12%) patients. A needle-knife precut over a pancreatic stent was used on two (1%) occasions. In another 17 (8.5%) patients, the needle-knife was employed as a free-hand

technique without a pancreatic stent. Thus, the success rate of the needle-knife precut during the first ERCP was 11 of 17 (64.7%), and this increased to 16/17 (94%) at the second attempt.

In five (2.5%) patients, a precut was made by using the standard sphincterotome, which entered into the papilla but not into the pancreas or bile duct.

In one patient with a polypoid tumour of the ampulla, a papillectomy was performed, although cannulation was not possible until a second ERCP was done.

Cannulation according to diagnostic groups (Table 5)

In choledocholithiasis, standard cannulation was successfully used in 82 out of 96 patients (85.4%). This constitutes the diagnostic group in which standard methods were more fruitfully employed ($p = 0.004$ compared to the rest of the diagnostic groups). However, access to the bile duct was gained by the standard technique in 4/9 (44.4%) patients suffering from sphincter of Oddi dysfunction ($p = 0.03$). Thus, this is the group in which alternative methods of cannulation had to be used more frequently.

The use of the standard technique of cannulation in patients with tumours, bile duct dilatation, normal findings, benign strictures, or biliary leak did not differ significantly from its use in the rest of the series.

Complications

The rate of acute pancreatitis was almost the same (6%) for the 150 patients in whom standard cannulation was achieved (9/150) as for the 45 patients with alternative cannulation (3/45, 6.6%; $p = 0.2$).

Haemorrhage was observed in 2 of 24 (8.3%) patients in whom any type of precut was used, and in 5 of the 175 remaining patients (2.8%, $p = 0.2$). This difference is not significant and, besides, many patients in both groups underwent a biliary sphincterotomy during the procedure. In the standard cannulation group, a 74-year-old woman suffering from cholangitis due to choledocholithiasis had a brisk bleeding 24 hours after a sphincterotomy in order to extract the stones, and died.

Table 3. — Comparison between the two types of sphincterotomes employed. Three intradiverticular papillae were excluded because the two-device technique was immediately used

	5.5 Fr sphincterotome + 0.035 inch guidewire	3 Fr sphincterotome + 0.025 inch guidewire	p value
Success as first device during the first ERCP	59/96 (61.4%)	78/100 (78%)	0.01*
Any type of precut as alternative method during the first ERCP	14/96 (14.6%)	10/100 (10%)	0.4
Easy cannulation (< 6 attempts)	33/59 (55.9%)	52/78 (66.6%)	0.2
Acute pancreatitis (in the whole cohort of patients according to the first device used to cannulate)	4/96 (4%)	8/100 (8%)	0.4

* $p < 0.05$.

Table 4. — Devices and methods employed to achieve deep bile duct cannulation in the whole series

	Device/manoeuvre	Success/attempted	successful cannulation in the whole series (percentage)
First attempt during the first ERCP	5,5 Fr. sphincterotome+0.035 guidewire 3 Fr. sphincterotome + 0.025 guidewire Two-devices	59/96 78/100 3/3	59 (29.6%) 78 (39.2%) 3 (1.5%)
Last successful attempt during the first ERCP*	Switch from 5.5 Fr to 3 Fr sphincterotome Switch from 3 Fr to 5,5 Fr sphincterotome Cannulation above a pancreatic guidewire Cannulation above a pancreatic stent Needle-knife precut over a pancreatic stent Needle-knife precut without a pancreatic stent Precut with standard sphincterotome		9 (4.5%) 3 (1.5%) 11(5.5%) 7 (3.5%) 2 (1%) 11(5.5%) 5 (2.5%)
Cannulation at a second ERCP	Previous papillectomy Previous needle-knife precut 3 Fr sphincterotome (papilla not found at first ERCP)	1/1 5/6 1/1	1(0.5%) 5 (2.5%) 1(0.5%)
Failed ERCP			4 (2%)

* Intermediate devices and manoeuvres were not registered. Therefore, this number refers to each time the device was successfully employed.

Table 5. — Utilization of standard and alternative methods of cannulation according to diagnostic groups. The p value refers to the comparison of each group with the rest of the series

Diagnosis	Total	Standard cannulation	Alternative cannulation	Failed	p value
Cholelithiasis	96	82 (85,4%)	13	1	0.004*
Tumor	46	30 (65,2%)	15	1	0.09
Bile duct dilatation	20	13 (65%)	5	2	0.056
Normal	18	11 (61,1%)	7		0.1
Sphincter of Oddi dysfunction	9	4 (44%)	5		0.03*
Benign stricture	6	6 (100%)	0		0.3
Biliary leak	4	4 (100%)	0		0.5
	199	150 (75,4%)	45 (22,6%)	4 (2%)	

* p < 0.05.

Cholangitis and cardiorespiratory events were not considered to be cannulation-related complications. One perforation after sphincterotomy occurred. Cannulation in this patient was done by standard methods, and it also was therefore not considered to be a cannulation-related complication.

Discussion

Our aim in this study has been to investigate the way in which bile duct cannulation is achieved in the ordinary ERCP workload. We think it is interesting to share this information with many other centres. Not only the difficult cases, but also for the whole series of patients with intact papillae undergoing ERCP.

Deep cannulation of the bile duct is one of the most difficult aspects of therapeutic biliary endoscopy (19). Therefore, it is not surprising that being able to achieve an acceptable cannulation rate is considered to be a key issue in ERCP training and competency (20,21).

Previous studies have demonstrated that bending cannula (22,23) and sphincterotomes (24,25) are superior to

the traditional standard straight cannula for deep bile cannulation. We have considered standard cannulation as a cannulation achieved by means of sphincterotomes loaded with guidewires. In our series, we had a 75.4% success rate with this method.

Some authorities base the cannulation technique on fine movements made with the sphincterotome, and do not like, for this purpose, the routine use of guidewires. However, we think that guidewires are very useful, especially to avoid pushing and poking the papilla with the sphincterotome, as well as in keeping the pancreas away from the injected contrast medium. Moreover, a reduction in the pancreatitis rate has been reported by the use of sphincterotomes and guidewires, instead of only sphincterotomes, to achieve cannulation (26).

We have found the 3 Fr-S plus 0.025 guidewire to be superior to the 5.5 Fr-S plus 0.035 guidewire, in terms of cannulation rate. Abraham (27) did not find any significant difference comparing 4 Fr vs. 5 Fr sphincterotomes. Nevertheless, in our study both devices were used without restriction, at the endoscopists' preference. This was not intended to be a randomized, controlled trial. We

have found the 3 Fr-S to be a very useful tool for gaining access to the bile duct, but further studies are needed to support this finding.

We have also observed that patients with choledocholithiasis form the diagnostic group with the highest rate of standard cannulation, while those with sphincter of Oddi dysfunction had the lowest. Assuming that standard cannulation is the easiest way to gain access to the bile duct, a previously known diagnosis (e.g., by magnetic resonance cholangiopancreatography) can have consequences, in terms of the skill the endoscopist needs to deal with the procedure.

In our series, in almost a quarter of ERCPs, standard cannulation did not succeed and alternative methods had to be used to gain access to the bile duct. Our aim was not to compare them, but to assess the way in which several of the many previously described alternative techniques (Table 1) are used in our centre.

Apart from the two-device method (9), which is employed when the papilla is hidden within a diverticulum, we have found the entrance of a guidewire into the pancreas to be the single most useful manoeuvre for alternative cannulation. However, the number of procedures in our series is too small to draw conclusions. The guidewire within the main pancreatic duct can be used as a step to gain access to the choledochus (11,12,13). In addition, it also allows a pancreatic stent to be inserted and to be used again as a step for bile cannulation (14,15). If unsuccessful, a needle-knife papillotomy can be carried out over the stent (16).

As for cutting techniques, we have found it helpful to make use of the standard sphincterotome for the precut. An upward cut can be made when it enters the papilla, but not in the pancreas or bile duct. As mentioned before, this is a modification of the papillary roof incision previously reported by Binmoeller (18), using an ultra-short leading tip papillotome.

In some alternative cutting procedures (needle-knife precut and papillectomy), a second procedure became very useful after the first failed. Perhaps oedema from the cutting had subsided and the bile duct was more clearly exposed. As a result, cannulation succeeded in the majority on the second attempt, through the cut made in the previous procedure.

In summary, when there is normal anatomy and the papillary area is reached, deep bile duct cannulation by means of ERCP is successful in the majority of patients (98% in this series). Standard methods, defined as the use of sphincterotomes loaded with guidewires, achieved a cannulation rate of 75.4%. To arrive at the final success rate, seven alternative cannulation techniques were used.

It has been more than 30 years since the first ERCP biliary interventions were reported (3,4), but methods of entering the bile duct continue to be a matter of concern. Many special techniques have been reported. We believe it will be very useful for the bilio-pancreatic endoscopist to learn from other studies the way in which standard

and alternative techniques are arranged and combined in consecutive, non-selected series of patients.

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