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## A prospective cross-over study using a sphincterotome and a guidewire to increase the success rate of common bile duct cannulation

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### Abstract

**AIM:** During endoscopic retrograde cholangiopancreatography (ERCP), selective cannulation of the common bile duct (CBD) is required in most of the cases.

**METHODS:** From June 2001 till December 2002, all patients referred to our unit for ERCP were considered for entry into the study. Selective CBD cannulation was first attempted with a standard catheter with or without the use of a guidewire. In cases, where CBD cannulation was considered unsuccessful, patients were crossed over to a double-lumen sphincterotome and a guidewire. All patients were hospitalized for 24 h after the procedure in order to assess the incidence of post-ERCP complications.

**RESULTS:** The study sample consisted of 158 patients. Selective CBD cannulation using a standard ERCP catheter with or without the assistance of a guidewire, was accomplished in 129 patients (success rate: 81.65%). From the 29 patients who were crossed over to a sphincterotome and a guidewire, selective CBD cannulation was achieved in 24; the overall success rate rising to 96.8%. Meanwhile, the use of this technique did not increase the incidence of post-ERCP complications.

**CONCLUSION:** The use of a sphincterotome and a guidewire increases the success rate of selective bile duct cannulation in cases that this has not been accomplished with a standard catheter.

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**Key words:** Common bile duct; Cannulation; Sphincterotome; Guidewire

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### INTRODUCTION

Selective cannulation of the common bile duct (CBD) is required, in the majority of cases when performing endoscopic retrograde cholangiopancreatography (ERCP). Experienced endoscopists, using a standard catheter, can achieve selective common bile duct cannulation, in most but not in all cases, with a success rate of approximately 65%<sup>[1-3]</sup>. Repeated unsuccessful attempts to cannulate, may result in trauma to the papilla; intramural injection and inadvertent pancreatic duct injections, increasing the risk of post-ERCP pancreatitis<sup>[2]</sup>.

To increase the success rate of selective CBD cannulation several techniques have been described: additional use of guidewire precutting techniques and the use of sphincterotomes<sup>[1-3,6-11]</sup>.

The aim of this prospective study was to determine whether the use of a sphincterotome with a guidewire increases the success rate of selective CBD cannulation and is a safe alternative in cases where cannulation has not been achieved with a standard catheter.

### MATERIALS AND METHODS

From June 2001 to December 2002 all patients referred to our unit for ERCP were considered for entry into the study. We excluded patients who had a history of previous sphincterotomy or Billroth II gastrectomy, as well as patients who were found, during ERCP, to have an ampullary neoplasm.

All procedures were performed by the same experienced endoscopist using a side-viewing video endoscope (Fujinon ED-200XT; Tokyo, Japan). All patients received topical pharyngeal anesthesia (Xylocaine spray; Astra), as well as intravenous sedation with 3.0 to 6.0 mg of midazolam (Dormicum; Roche) and 150-500 mcg of fentanyl (Fentanyl; Janssen-Cilag). During ERCP, arterial oxygen saturation was continuously monitored by a pulse oximeter. In cases with an overactive duodenum, we also administered 20-40 mg

of hyoscine N-butylbromide (Buscopan; Boehringer Ingelheim).

In order to achieve CBD cannulation we first used a standard ERCP catheter (GLO-Tip, GT-1-T, Wilson Cook Medical Inc., Winston-Salem, NC, USA). Contrast medium was injected only once selective deep cannulation, in a direction strongly suggestive of the CBD, has been achieved. In cases that this was not accomplished, we used a straight tip Tracer-Hybrid (Wilson Cook Medical Inc., Winston Salem, NC, USA) guidewire to aid cannulation. To prevent excessive injury of the papilla, selective common bile duct cannulation was considered unsuccessful when five attempts using a standard catheter and ten more attempts using a guidewire through the catheter failed.

In those cases, where selective CBD cannulation was considered unsuccessful, patients were crossed over to a double-lumen 5 mm tip sphincterotome, with a 2.5 cm cutting-wire (CCPT-25-MONO Cotton cannulotome, Wilson-Cook Medical Inc., Winston Salem, NC, USA) and a guidewire (straight tip Tracer-Hybrid). No contrast medium was injected if we had not previously advanced the guidewire in a route strongly suggestive of the CBD. Once again, selective CBD cannulation was considered unsuccessful if 10 attempts to advance the guidewire failed.

Our technique consisted of the following steps:

(1) We brought the papilla as usual en face and inserted the tip of the sphincterotome, which has been preloaded with the guidewire, at the upper part of its orifice with or without slight flexion of the sphincterotome; (2) After complete flexion of the sphincterotome, we tried to push, very gently, the guidewire forward. We advanced the guidewire in several directions during slow progressive relaxation of the sphincterotome bow, under fluoroscopic control; (3) Whenever we managed to advance the guidewire in a direction strongly suggestive of the CBD, we pushed the sphincterotome over the guidewire a few centimeters further. After pulling back the guidewire, we injected contrast medium in order to ensure cannulation of the CBD; (4) In cases where we had difficulty in inserting the guidewire, we pulled the scope back with simultaneous step-by-step unflexing of the sphincterotome. This maneuver helped us to insert the tip of the sphincterotome slightly deeper into the papilla, onto the upper wall of the tortuous and folded ampullary channel. We then flexed the sphincterotome once again completely, trying to advance the guidewire during slow progressive relaxation of the sphincterotome.

Once selective CBD cannulation has been achieved, sphincterotomy, whenever needed, was performed using the same sphincterotome and applying 34 W of pure-cutting current from a commercially available electrosurgical generator (Plus II, Medical Systems, Teterboro, NJ, USA).

All patients were hospitalized for at least 24 h after the procedure in order to assess the incidence of post-ERCP complications. Pancreatitis was defined as serum amylase and lipase levels greater than two times the upper limit of normal, accompanied with abdominal pain. Serum amylase and lipase levels were determined 24 h after the procedure. Bleeding was defined as a drop in the hematocrit level greater than 5% or clinical signs of hemorrhage (e.g., melena)<sup>[12]</sup>.

The study protocol accorded to the principles of the

Declaration of Helsinki and was approved by the Ethics Committee of our Hospital. All patients gave a written informed consent at the time of enrollment.

### Statistical analysis

Values are expressed as mean±SD. A  $\chi^2$  test was used. A *P* value less than 0.05 was the accepted level of significance.

## RESULTS

During the study period 202 patients were referred to our Unit for ERCP. Thirty-three of these patients have been subjected to sphincterotomy in the past, six had a history of Billroth II gastrectomy; 2 patients had evidence of an ampullary neoplasm; while in 3 patients ERCP was technically impossible due to inadequate sedation. Therefore, our study sample consisted of 158 patients. The characteristics of the study population as well as the reason they were referred for ERCP are presented in Table 1.

**Table 1** Demographic characteristics of the study population and indications for ERCP

Mean age ± SD (yr)	63±11.9
Male / female	76/82
Indications for ERCP (number of patients, %)	
Documented or possible stones in CBD	132 (83.5)
Malignant obstruction	6 (3.8)
Miscellaneous	20 (12.7)

Selective common bile duct cannulation using a standard ERCP catheter, with or without the assistance of a guidewire, was accomplished in 129 patients (success rate: 81.65%). From the 29 patients who were crossed over to a sphincterotome and a guidewire, selective CBD cannulation was achieved in 24 (success rate: 82.75%). Therefore, with this technique, the overall success rate increased to 96.8%.

The endoscopic characteristics of the papilla in those 29 patients in whom cannulation with the use of a standard catheter, with or without the aid of a guidewire, was considered unsuccessful are presented in Table 2. A fleshy papilla was defined as a big, folded, oversized (>2 cm) papilla, protruding into the duodenum. A papilla was characterized as a floppy, if it was slippery when cannulation was attempted, due to loose tissue falling or protruding at the orifice site. Stenotic papilla was the one with a stenosis in the intraampullary distal CBD, evidenced before or after ERCP. An intra-diverticular papilla was the one lying inside the rims of a diverticulum. The success rate of selective CBD cannulation, among these patients, is also presented in Table 2.

**Table 2** Endoscopic characteristics of the papilla in the 29 patients crossed over to a sphincterotome and a guidewire and success rate of selective CBD cannulation

Endoscopic characteristics of the papilla	Number of patients ( <i>n</i> = 29)	Number of patients and success rate of CBD cannulation ( <i>n</i> = 24, %)
Oversized fleshy papilla	19	18 (94.7)
Floppy papilla	5	4 (80.0)
Stenotic papilla	3	1 (33.3)
Intra-diverticular papilla	2	1 (50.0)

From those 5 patients, in whom selective CBD cannulation was unsuccessful even with the use of a sphincterotome and a guidewire, this was finally achieved with a precutting papillotomy, in 3. The remaining 2 patients were referred for percutaneous transhepatic cholangiography.

Post-ERCP pancreatitis developed in 8 out of 129 patients (6.2%) in whom cannulation was achieved with the use of a standard catheter with or without a guidewire and in 2 out of the 29 patients (6.9%) in whom CBD cannulation was achieved with the use of a sphincterotome and a guidewire. This difference was not statistically significant ( $P>0.05$ ). None of our patients developed post-sphincterotomy bleeding and there was no incidence of perforation or evidence of a submucosal tract.

## DISCUSSION

When performing ERCP, selective deep cannulation of the CBD is necessary in order to maximize the diagnostic and therapeutic benefits of the test, while diminishing the risk of post-procedure complications. The standard approach to selective CBD cannulation is the use of an ERCP catheter with or without the aid of a guidewire. According to the literature, even in experienced hands, this approach fails in approximately 10% of the cases<sup>[1-3,13]</sup>.

Precutting may increase cannulation rates, however, it is said to carry a significant risk of complications. Therefore, it should be reserved for cases that all other methods have failed, while it should be performed only by experienced endoscopists<sup>[6-8]</sup>.

Another alternative is the use of a sphincterotome<sup>[9]</sup>. Since a more acute angle is required in order to intubate the common bile duct, the bowed sphincterotome can lift the roof of the papilla facilitating entry into the bile duct. Indeed, studies performed in referral centers have demonstrated the superiority of sphincterotomes over standard catheters and have actually suggested that cannulation should be initially attempted with a sphincterotome<sup>[2,3]</sup>.

The use of guidewires has, also, been described, since they have a hydrophilic coating, which when wet becomes slippery, facilitating cannulation<sup>[14]</sup>.

When all endoscopic methods fail, the percutaneous or the combined approach could be an option, although this method is extremely difficult in the setting of a non-dilated biliary tree<sup>[14,15]</sup>.

According to the results of our study, selective CBD cannulation, with the use of a standard catheter, with or without the aid of a guidewire, was accomplished in 81.65% of our patients. The relatively high failure rate could be attributed to the fact that we did not inject contrast material unless deep CBD cannulation has been achieved. When patients, in whom cannulation was unsuccessful, were crossed over to a sphincterotome and a guidewire, the overall success rate increased to 96.8%. As shown in Table 2 the success rate was particularly high in patients with an oversized, fleshy papilla and this can be attributed to the increased manoeuvrability of the wire tip into the long and tortuous intraampullary portion of the bile duct offered by the sphincterotome's flexing or unflexing.

Our study has been performed in a general hospital with an annual volume of no more than 150 ERCPs. All procedures were performed by a single endoscopist, since the aim of our study was to show if the technique described could enhance the cannulation rates of an endoscopist with certain abilities and skills. Although the endoscopist is experienced, he is not exposed to the number of ERCPs performed in a tertiary referral center. Therefore, we believe our study reflects the every day practice of a regular endoscopist, who works in a community Hospital, with an average load of cases. In such a setting, the use of a sphincterotome and a guidewire is helpful in increasing the success rate of selective CBD cannulation before employing more aggressive techniques.

We preferred a double-lumen sphincterotome instead of using a triple-lumen one although the latter permits injection of contrast medium through the additional channel without removing the guidewire. Our choice was based on the fact that double-lumen catheters, which are characterized by a wide wire channel that permits contrast injection without fierce push, which might result in submucosal injection.

We, also, chose to use a guidewire, to aid CBD cannulation, since modern wires are soft and not traumatic, while with their flexible tip they can enhance the ability to cannulate a CBD with a tortuous intrapapillary ending. Being aware that the use of a guidewire may lead to increased risk of perforation or to bile duct injury, we tried to advance it forward very gently and such an incidence was not encountered in our study. We chose to avoid contrast injection before deep cannulation, since it could potentially cause submucosal injection. In this way we also diminished the inadvertent pancreatic duct injections.

The results of our study show that the use of a sphincterotome and a guidewire is a safe alternative for CBD cannulation since this technique did not seem to be associated with a higher complication rate.

In conclusion, the use of a sphincterotome and a guidewire increases the success rate of selective bile duct cannulation in cases that this has not been accomplished with a standard catheter with or without the aid of a guidewire. This technique is non-invasive, safe and can be easily performed in routine practice.

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