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REVIEW

Management of difficult bile duct cannulation in ERCP

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Abstract

In Encoscopic Retrograde Cholangiopancreatography (ERCP), the main concern is to gain access into the bile duct while avoiding the pancreatic duct because of the risk of post-ERCP pancreatitis. Difficult cannulation is defined as a situation where the endoscopist, using his/her regularly used cannulation technique, fails within a certain time limit or after a certain number of unsuccessful attempts. Different methods have been developed to manage difficult cannulation. The most common solution is to perform a precut papillotomy either with a needle knife or with a sphincterotome with or without a guide wire. This review describes different methods to overcome cases of difficult cannulation. We will discuss the success rate and complication rates associated with different methods of reaching the biliary tract.

Key words: Endoscopic retrograde cholangiopancreatography; Difficult cannulation; Sphincterotomy; Precut; Complication

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INTRODUCTION

This review intends to describe the current situation of so-called difficult cannulation, in endoscopic retrograde cholangiopancreatography (ERCP). Definitions of difficult cannulation vary in reports. There is no established time limit or limits to unsuccessful attempts before the cannulation is termed difficult. The type of primary tool used for cannulation is associated with different success rates and varies according to the preferences of a particular endoscopist (Table 1).

Solutions for overcoming difficult cannulation vary depending on the practices of the endoscopist. Various methods have been developed to manage difficult cannulation and, in addition, to try to avoid the ever-present threat of post-ERCP pancreatitis. The main tools used range from standard catheters to guide-wire-assisted rotatable papillotomes. The most commonly used solution in a difficult situation is to perform a precut (access) papillotomy either with a needle knife or a sphincterotome with or without a guide wire.

For a literature review, a Medline search (keywords for search: difficult cannulation, ERCP complication, precut, needle-knife, post-ERCP pancreatitis) for the years 1990-2009 was performed. The reference list of this review is by no means comprehensive and several good reports are not mentioned. An attempt has been made to include those representative references that contain a typical example of one type of definition, tool or solution to the problem.

DEFINITION

Difficult cannulation is defined as a situation where the endoscopist, using his/her regularly used cannulation

Table 1 Tools and methods for cannulation

Standard techniques
Catheters:
Standard
Steerable
With or without guide wire
Sphincterotomes:
Single or multi-lumen
Rotatable
With or without guide wire
Guidewires:
Nitinol
Hydrophilic
Advanced techniques without precut
Double wire technique
Over pancreatic stent
Precut access with
Needle knife:
Starting at orifice
Fistulotomy above orifice
Over pancreatic stent
Sphincterotome:
Erlangen sphincterotome
Transpancreatic with guide wire
Papillectomy for duct access
EndoUS-guided biliary access

technique, fails within a certain time limit or after a certain number of unsuccessful attempts and hence resorts to precutting in order to achieve deep cannulation of the biliary duct.

In ERCP, because of the risk of post-ERCP pancreatitis the main concern is to gain access into the bile duct while avoiding the pancreatic duct. The difference between success in cannulation and the point where the situation is considered difficult depends on the tools used and on the arbitrarily set time limit. Cannulation of the pancreatic duct may be more difficult than gaining access into the bile duct. However, difficult cannulation specifically refers to the situation where bile duct entry is challenging.

The reported time limits within which the regularly used cannulation technique is abandoned vary between 10 and 30 min[1-6]. The 15- to 30-min limits are used less consistently[7-12].

In addition to time, when defining difficulty the number of passages or contrast injections into the pancreatic duct must also be considered. The strictest limits within the arbitrarily set time have been three to five passages or injections into the pancreatic duct. Even if those entries have occurred before the set time limit has expired, the procedure is recognized as being difficult cannulation[1,2,6,12,13]. Few reports have accepted multiple entries into the pancreatic duct within the time limit[7,10]. In several reports where the time was not specified, the only limiting factor was the number of allowed attempts on the papilla, between five and ten[14,15].

COMPLICATIONS AND RISK OF DIFFICULT CANNULATION IN ERCP

The rate of severe or fatal complications associated with ERCP is low where experienced personnel at high-volume centres are involved. In Charleston, South Carolina, over a 12-year period 11497 ERCPs were performed; 42 (0.36%) patients experienced severe and 7 (0.006%) fatal complications[16]. The frequency of severe and fatal complications associated with ERCP at another single specialized surgical high-volume referral centre where 2555 patients had undergone the procedure revealed 17 severe complications (0.7%) and a procedure-related mortality rate of 0.08% in 9 years[17].

A difficult cannulation alone has been shown to carry an inherent risk for a post-ERCP complication[18-20]. Freeman et al. prospectively studied 1963 consecutive patients at 11 centres in the United States[19]. The risk of pancreatitis after a difficult cannulation compared with a standard cannulation increased from 4.3% to 11.3%. In a single-centre study involving 1223 patients, the risk of pancreatitis after a difficult cannulation was 14.9%, compared with a rate of 3.3% for a standard cannulation[20]. Possible reasons for the increased risk of pancreatitis may be excessive manipulation, resulting in mechanical trauma and oedema of the pancreatic sphincter, or repeated contrast medium injections into the pancreatic duct[19]. In one study, two or more pancreatic duct injections with contrast material were shown to be a significant risk factor for post-ERCP pancreatitis[21]. On the other hand, in the Halttunen *et al*[22] study, the number of contrast injections was not confirmed to be a risk factor for post-ERCP pancreatitis.

In a Chinese multi-centre study[23], a cannulation time exceeding 10 min, one or more pancreatic duct wire passes, and needle-knife precutting were risk factors for ERCP-related complications. Similarly, in an Italian multicentre study of 2769 patients in 9 centres, a small centre size and precutting were independent risk factors for complications after therapeutic ERCP. In this study, small centres exhibited increased technical failures, ERCPs had to be repeated more often and precutting techniques were used more frequently[24]. When the learning curve of a single endoscopist was studied, the need for precut sphincterotomy decreased with increasing ERCP experience. The complication rate of precutting remained at 12%-14% throughout the study period[25].

Using the guide-wire technique for bile duct cannulation may lower the likelihood of post-ERCP pancreatitis by facilitating cannulation and reducing the need for a precut sphincterotomy. As reported by Lella *et al*[26], there was no pancreatitis in the guide-wire group of 200 patients in contrast to eight cases of post-ERCP pancreatitis ($P < 0.01$) in the conventional group. The study of Lee *et al*[1] also supports the use of a guide wire. When conventional cannulation with a contrast injection was compared with wire-guided cannulation, the rate of post-ERCP pancreatitis was higher in the conventional group, 11.3%, than in the wire-guided group ($P = 0.001$)[1]. It is thought that the guide-wire approach is gentler than using a catheter alone and also lessens the risk of accidental injection of the contrast medium into the main pancreatic duct or the papilla itself, thereby reducing pancreatic injury caused by chemicals or pressure.

Table 2 Success and pancreatitis rates with cannulation techniques

	%	Ref.
Primary success in cannulation		
Standard catheter	54 to 67	[3,30]
Standard catheter with guide wire	81	[3]
Sphincterotome	78 to 84	[4,29]
Sphincterotome with guide wire	97 to 99	[26,30]
Success in difficult cannulation after primary failure with standard method		
Persistence	73 to 75	[2,49]
Needle knife	67 to 91	[2,6,9,34,37]
Erlangen knife	78 to 100	[32,50]
Pancreatic sphincterotomy	91 to 100	[10,12,13,22,40,41]
Pancreatic stent	97 to 100	[28,47]
Pancreatic guide wire	73 to 93	[5,8]
Pancreatitis rate after difficult cannulation		
Persistence	2-4	[2,49]
Needle knife	1-11	[2,6,9,34,37]
Erlangen knife	3-7	[32,50]
Pancreatic sphincterotomy	0-12	[10,12,13,22,40,41]
Pancreatic stent	5-7	[28,47]
Pancreatic guide wire	0-2	[5,8]

Randomized controlled trials were used in literature 2, 3, 5, 10, 26, 28, 29, 30 and 49.

Pancreatic duct stents have been used to prevent post-ERCP pancreatitis in several studies[27]. In a prospective study in Milwaukee, only patients at a high risk of pancreatitis were recruited into the study. Patients who were considered to be at high risk were those who had sphincter of Oddi manometry, endoscopic sphincterotomy or difficult cannulation. Difficult cannulation was defined as needing more than 30 min manipulation time. A group of 76 patients was randomised into two groups: one group received a pancreatic stent (n = 36) and the other did not (n = 38). The results favoured pancreatic stenting, as 28% of the patients without a stent developed pancreatitis versus only 5% in the stented group ($P < 0.05$)[11]. Inserting a pancreatic stent after biliary sphincterotomy in patients with sphincter of Oddi dysfunction (SOD) had a similar protective effect. In a randomised study of 80 patients, the risk of pancreatitis decreased from 26% to 7% ($P = 0.03$)[28].

PRIMARY CANNULATION RESULTS

Standard catheters as primary tools only have success rates from 54% to 67%[3,4,29,30]. This translates into failures or difficult cannulations in 46% to 33% of cases. Bendable catheters have been shown to perform only slightly better[4]. When the standard catheter is used with a guide wire, cannulation failures drop to less than 19%[14,31].

As an example, in a study in Greece a standard catheter and a catheter combined with a hydrophilic guide wire were compared when trying to get access into the common bile duct. If the cannulation did not succeed in 10 min, a further 10-min attempt was tried using the guide wire. The primary success rate with the standard catheter was 54% versus 81% with the hydrophilic guide wire ($P < 0.001$). After crossover, the cannulation rates were equal (84%) for the two groups[3].

The use of a sphincterotome as the initial device is nearly as effective as using a catheter with a guide wire. The reported primary failures for sphincterotomes have been between 24% and 16%[1,4,29]. When the sphincterotome is used with a guide wire, primary cannulation failures tend to be less than 10%[2] an one study reported a failure rate of just 3%. This report of Cortas *et al*[30] of a small prospective trial provides a good example of the use and efficacy of a standard catheter versus a wire-guided sphincterotome. Failure was defined as an inability to achieve opacification or deep cannulation after 15 attempts with the initial catheter. Eighteen patients were randomised to the standard catheter group and 29 patients to the standard/wire-guided sphincterotome group. Initial common bile duct cannulation was successful in 67% and 97%, respectively. The mean number of attempts was 12 and 3 ($P = 0.0001$) and the mean time 14 min and 3 min ($P = 0.0001$), respectively.

An similarly positive result with a sphincterotome and guide wire was reported by Karamanolis *et al*. In their study, the primary tool was a standard ERCP catheter with or without a guide wire, with a primary success rate of 82%. The cannulation was tried until there were five unsuccessful attempts with the standard catheter and 10 more attempts with the catheter and guide wire[14]. Obviously the primary result represents wire-guided cannulation and is well in line with other reports[3,31]. When the patients with difficult cannulation were crossed over to the sphincterotome and guide-wire procedure, deep bile duct cannulation was achieved in 83%, amounting to an overall success rate of 97% before precuts. In this study, 10 attempts were allowed for the sphincterotome and guide wire combination. There was no significant difference in post-ERCP pancreatitis in the groups (6% and 7%, respectively) (Table 2).

SOLUTIONS FOR OVERCOMING DIFFICULT CANNULATION

With an effective primary cannulation technique, the rate of difficult cannulations remains around 10% of intact papillae, depending on how the operator defines difficult cannulation. Following identification of a difficult canulation comes the choice of how to proceed. Possibilities include changing the catheter or the operator, or to apply more aggressive methods, keeping in mind the increasing risk of complications. Among possible further steps, needle-knife precut sphincterotomy, papillary roof excision, transpancreatic sphincterotomy, transpancreatic stenting, double wire technique, persistence, papillectomy and special knifes can be used. Of course, if endoscopic methods fail, the transhepatic route can be used directly without an endoscopist or the rendezvous technique can be applied, depending on the problem.

Until now, the most commonly used solution in a difficult situation has been the use of a needle knife to perform an access papillotomy. More recently, however, transpancreatic sphincterotomy is beginning to gain ground, too.

NEEDLE-KNIFE PRECUT

The precut rate varies from zero to as much as 38%-50% of all biliary cannulation attempts[32,33]. Precut sphincterotomy with a needle knife is performed either by avoiding the papillary orifice and opening the mucosa above it[34], usually called fistulotomy, or by a technique where the incision starts from the papillary orifice. In a retrospective study by Abu-Hamda et al., these methods did not differ in success (90%-96%) or complication (2%-13%) rates[35]. Although the precut papillotomy may improve the cannulation success rate, prospective studies have suggested that it is an independent risk factor for post-ERCP complications[18,36]. In one study, however, the needle-knife precut did not increase the risk of complications[19]. In general, precut sphincterotomy has a cannulation rate of 92%-93% and a complication rate of 10%-11%[34,37] although a complication rate of as much as 30% has been reported[38].

If the biliary cannulation attempt was unsuccessful after 20 min, it was defined as being difficult by Fukatsu et al. Standard cannulae failed in 16% of cases. Thereafter a needle-knife papillotomy was performed. The needle-knife sphincterotomy was successful in 88% of cases during the first session[9]. In a study by Laasch et al. involving 312 patients, a needle-knife precut was performed in 23 (7.4%) patients when cannulation by other means had failed. Deep access into the bile duct during the first ERCP session was achieved in 20 patients (87%) with an overall success rate of 97%[4].

In another study, early precutting with a needle knife in 70 out of 346 patients (20%) had an initial success rate of 83%, amounting to a total initial success rate of 97%, and 99% after two sessions. Two different precutting techniques were used, with no difference in complications between the groups[6].

PANCREATIC SPHINCTEROTOMY

Instead of performing a precut with a needle knife after a failed attempt to reach the biliary duct, one alternative is to perform a pancreatic sphincterotomy, which was first described in 1985 for pancreatic procedures[39]. Ten years later the method was reported as a means to access the common bile duct[40]. A sphincterotomy over the guide wire in the pancreatic duct helps to cannulate the biliary orifice as the cut either opens the biliary duct or runs along the side of the duct, thus exposing the duct's anatomy. In over half of cases, the lumen of the common bile duct becomes visible and can be cannulated with either a catheter or a sphincterotome with or without a guide wire. If not, an oblique cut with the needle knife exposes the common bile duct[22]. The advantage of this transpancreatic sphincterotomy is that the depth and location of the incision in relation to the bile duct is more controlled than with the needle-knife precut.

The rate of pancreatic sphincterotomy tends to differ considerably. While Goff reported an incidence of pancreatic sphincterotomy as high as 36%, Kahaleh *et al* had a rate of 5% for pancreatic sphincterotomy in difficult biliary cannulation[13,41]. In the prospective study by Kahaleh *et al*, the primary success rate with pancreatic sphincterotomy was 85% and, when combined with the needle-knife technique, it rose to 95%. The complication rate was 12%. There was no difference in the pancreatitis rate between conventional biliary sphincterotomy and pancreatic precut.

When pancreatic sphincterotomy was compared with needle-knife sphincterotomy, the pancreatic sphincterotomy had a 100% success rate for biliary cannulation compared with 77% in needle-knife precutting. Complication rates were 4% versus 18%[10]. Goff reported a complication rate of 2% after standard sphincterotomy and only 2% for the transpancreatic approach. It is remarkable that there were no cases of post-ERCP pancreatitis in the latter group[41].

In a retrospective study, the complication rate associated with the pancreatic sphincterotomy technique was equal to the overall ERCP complication rate[22]. However, in patients with primary sclerosing cholangitis the rate of post-ERCP pancreatitis was 25%, similar to patients with SOD in other studies, when pancreatic sphincterotomy was performed[22,28].

Even where conventional biliary cannulation and needle-knife precutting failed to achieve access to the bile duct, the pancreatic sphincterotomy was successful in 95% of the cases and the complication rate was 11%, indicating that this technique is safe and effective[12].

In an analysis of ERCP-related complications, needle-knife precutting, but not pancreatic sphincterotomy, was identified as a risk factor for overall complications [odds ratio (OR) 2.70] and for post-ERCP pancreatitis (OR 4.34)[40]. These authors suggest that the risk after transpancreatic precut might be lower than after precutting with a needle knife.

The question of inserting a pancreatic stent after pancreatic sphincterotomy has been addressed in two reports. Esber *et al*[42] found no difference between using and not using a stent. In the study of Kahaleh *et al* the use of a prophylactic pancreatic stent had an adverse rather than a protective effect. The rate of pancreatitis was 14% versus 6%, in favour of not using the pancreatic stent[13].

The question of possible long-term sequalae after pancreatic sphincterotomy has been raised but still remains unanswered[43]. There are few, mostly anecdotal, reports of papillary stenosis causing relapsing pancreatitis. These cases, however, have occurred after biliary sphincterotomy[44-46]. Whether or not papillary stenosis is an

important clinical problem after the transpancreatic approach still awaits clarification through substantial follow-up studies on the subject.

OTHER SOLUTIONS

Inserting a pancreatic stent to facilitate biliary cannulation has been used with success either in difficult cannulation or in the case of a diverticulum. Goldberg et al. reported on a series of 39 patients, with an initial success rate of 90% and final success in 38 patients (97%). Only 5% developed mild pancreatitis. A standard sphincterotome was used for cannulation after inserting the pancreatic stent. Fifty-nine per cent of the patients required a precut sphincterotomy to gain access to the biliary duct[47]. The diverticulum problem was dealt with by Fogel *et al* by inserting a pancreatic stent and then gaining access to the bile duct with a needle knife. Across two sessions, the procedure was successful in 88% of the patients although two out of eight patients developed post-ERCP pancreatitis[48].

Persistence may pay off. In a randomised study in Toronto, patients who had difficult cannulation were randomised either to precut sphincterotomy by a needle knife over the roof of the papilla or to persistent cannulation with a non-wire-guided papillotome. In this study, the difficult cannulation was defined as a failed cannulation after 12 min. The difficult cannulation group consisted of 62 patients (11%) out of a total of 642. They were assigned to the precut arm (n = 32) or to the persistence arm (n = 30). After randomisation, primary success was defined as cannulation of the biliary duct within 15 min. Precut and persistence were equally effective with regard to success (75% *vs* 73%) and complication (4% *vs* 9%) rates. The primary success rate after 15 min was 98% and after the full ERCP session the rate rose to 99.5%[49]. A similar result for persistence was obtained by a Shanghai group. If the biliary cannulation failed within 10 min or the guide wire entered the pancreatic duct three times, the patients were randomised either to needle-knife papillotomy or to persistent cannulation with a double-lumen sphincterotome. Out of a total of 948 patients, there were 91 (9.5%) patients with difficult cannulation, of which 43 were randomised to needle-knife sphincterotomy and 48 to persistence. With the needle knife, the success rate was 91% and the mean cannulation time was 5.5 min, with 9% complications. Persistence was successful in 75%, with a mean cannulation time of 10 min and 15% complications. The only statistically significant difference between the groups was the cannulation time in favour of needle-knife sphincterotomy[2].

The Erlangen precut papillotome is an alternative to the needle-knife technique for performing a precut papillotomy. The tip of the instrument enters the papillary lumen and the roof of the papilla is opened. With this method, the final deep biliary cannulation rate in cases with problematic cannulation was 98%, and complications occurred at a similar rate (8.3%) to that in non-precut patients (7.1%)[32,50].

Endoscopic papillectomy has been proposed as an approach to difficult cannulation[51]. In a small study of 10 patients with failed previous cannulation, all had protuberant ampullae. After ampullectomy, successful biliary and pancreatic cannulation was achieved in all 10 cases. There were no cases of pancreatitis although no pancreatic stent was used. One patient, however, had significant bleeding afterwards. The more common indication for papillectomy is removal of an adenoma. In this situation, the risk for pancreatitis is higher if no pancreatic stent is inserted[52]. Obviously, in the majority of cases of difficult cannulation this method is not feasible. Most papillae are small, flat or even endophytic and have to be accessed by different means.

A pancreatic guide wire has been used to help biliary cannulation in difficult cases. The method was used on 113 patients, with a success rate of 73%[8]. The patients represented only 2.9% of the total, and were considered to be the most difficult population. Post-ERCP pancreatitis occurred in 12%. In this study, inserting a pancreatic stent was a protective factor. It has to be noted, however, that no pancreatic sphincterotomy was performed[8]. A randomised study with 53 patients from Japan found that a pancreatic guide wire gave a higher success rate of 93% compared with a conventional catheter (58%)[5].

When conventional ERCP methods fail, EUS guided biliary access may still be an option, although it is rarely used at present[53,54].

CONCLUSION

Cannulation is usually performed with a catheter or a sphincterotome. Only in special cases of difficult cannulation due to anatomy, diverticula, lack of space or bulky papilla are extraordinary measures necessary[7,51].

The use of needle-knife precutting still remains the primary choice of most endoscopists in difficult cannulations. Nevertheless, studies show that there is a slightly higher complication rate connected with the use of a needle knife when compared with the transpancreatic approach. In addition, pancreatic sphincterotomy has a better success rate in randomised studies. When used as the first choice in difficult situations, the difference in favour of pancreatic precutting is even greater.

Cannulation with a guide wire is, in light of published studies, faster and safer than without one, be it with a catheter or a sphincterotome. A papillotome has the advantage, especially in the case of a rotatable sphincterotome, that its tip can be better adjusted to the papilla and it can be used for manipulation in difficult cases. A guide wire definitely improves accuracy and selection of the desired duct without a contrast injection is possible. On the other hand, a tendency towards the use of a sphincterotome with a guide wire is increasing as purely diagnostic ERCPs are rarely needed any more. A sphincterotome is nearly always necessary as a papillotomy

is the next step in paving the way for further procedures. The same applies to the guide wire in securing access. With a wire-guided sphincterotome, the primary cannulation success rises to around 90%. With a rotatable sphincterotome even the most difficult situations, such as problems with diverticula, are easier to handle.However, in many cases the guide wire enters the pancreatic duct. The location is usually clearly distinguishable without contrast injection under fluoroscopy. If this happens several times, an easy solution is to continue to perform a pancreatic sphincterotomy instead of resorting to a needle knife. This method has proven to be a nearly fail-safe procedure in accessing the common bile duct. If necessary, a further precut with a needle knife accomplishes the task. In less than half of pancreatic sphincterotomy cases, an additional needle-knife cut is necessary to access the biliary duct. An extra needle-knife cut does not increase the complication rate[22].

Currently, there is no well-founded reason to use pancreatic stents in connection with pancreatic sphincterotomy. The situation is different when treating patients with sphincter of Oddi dysfunction or papillary adenomas. There, the protective effect of the pancreatic stent has been well proven.

With a proper selection of tools, cannulation is usually a fast procedure. Much more time is spent on the actual treatment. The time necessary for the primary cannulation in a regular case with a wire-guided sphincterotome is less than 5 min, and requires only a couple of attempts[30]. With this in mind, a difficult cannulation could be defined as anything that takes more than 5 min and/or five attempts on the papilla. A more flexible view of the definition would be 10 min and/or 10 attempts, as has been most often used in recent reports. For the time being, the definition in prospective studies has to include the time frame, number of attempts or injections and especially the tools used. The rate of primary failures depends mainly on tool selection. The reported success rates vary from 52% to 97%. However, irrespective of secondary tool selection in difficult cases, the final success rate can be expected to be well over 96% regardless of the primary tool. According to the best reports, a nearly total success rate has been achieved[1,3,49].

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