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MINI REVIEW

Management of difficult or failed biliary access in initial ERCP: A review of current literature

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KEYWORDS
Difficult cannulation;
Surgically altered anatomy;
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Pre-cut;
Needle-knife;
Balloon-assisted endoscopy;
Cap-assisted endoscopy;
Laparoendoscopic rendezvous;
ERCP;
PTCD

Summary Selective bile duct cannulation is the prerequisite for all endoscopic biliary therapeutic interventions, but this cannot always be achieved easily. Despite advances and new developments in endoscopic accessories, selective biliary access fails in 5%—15% of cases, even in expert high volume centers. Various techniques — such as double-guidewire induced cannulation, pre-cut papillotomy or transpancreatic sphincterotomy with or without placement of a pancreatic stent — have been used to improve cannulation success rates. Repeated and prolonged attempts at cannulation increase the risk of pancreatitis. Repeating the ERCP within a few days after initial failed pre-cut is a successful strategy and should be tried before contemplating more invasive, alternative interventions such as percutaneous-endoscopic or endoscopic ultrasound guided rendezvous procedure, percutaneous transhepatic or surgical intervention. However, standard guidelines or sequential protocol has not been existed up to now. In certain circumstances, there are unique clinical indications for which invasive, alternative interventions should be preferred. We present and discuss the methods that can be used in difficult or failed initial ERCP, therefore to provide practical advice for endoscopists, especially those who are inexperienced.

Introduction

Successful biliary therapy during endoscopic retrograde cholangiopancreatography (ERCP) requires selective access of the bile duct. Despite advances and new developments in

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endoscopic accessories such as catheters, guidewire, stents and sphincterotomes, selective biliary cannulation fails in 5%—15% of cases, even in expert high volume centers [1].

The definition of difficult biliary cannulation is highly variable among different studies. According to the ESGE guidelines, the criteria for a difficult biliary cannulation are more than 5 minutes of cannulation time, more than five instances of meaningful papillary contact, or more than one instance of unintentional pancreatic duct (PD) cannulation [2]. When selective biliary access is difficult, despite frequent meaningful contact with the papilla or prolonged cannulation times without unintentional PD cannulation, an early pre-cut fistulotomy may be preferable. In cases of frequent unintentional PD cannulation, double-guidewire induced cannulation, transpancreatic pre-cut with the guidance of a guidewire as well as a prophylactic pancreatic stent (PS) may be useful. Based on the current literatures, the application of a stepwise algorithm rather than a single technique is needed to facilitate biliary access during ERCP without increasing complications [3].

Several studies have demonstrated that repeating the ERCP within a few days after initial failed pre-cut is a successful strategy and should be tried before contemplating more invasive, alternative interventions [4,5]. Percutaneous transhepatic biliary drainage (PTBD) is the conventionally alternative method in patients who fail ERCP. However, PTBD is associated with high morbidity and can lower patients' quality of life. It may also be difficult to carry out when the intrahepatic bile ducts are not dilated. ERCP occasionally fails because of surgically altered anatomy, gastric outlet obstruction, periampullary diverticulum, indwelling duodenal stent and large tumors. In cases of failed cannulation in surgically altered anatomies, balloon enteroscopy-assisted ERCP is as an alternative that has shown high technical and clinical success in specialized centers [6]. Since first described in 2001, endoscopic ultrasound guided biliary drainage (EUS-BD) has been increasingly used as an alternative in patients with biliary obstruction who fail standard ERCP [7]. However, in certain circumstances, there are unique clinical indications for which percutaneous-endoscopic rendezvous (PE-RV) should be preferred [8]. This review aims to presents and discusses the possible techniques that can be used for achieving difficult biliary cannulation and alternative strategies for failed initial ERCP, therefore to provide practical advice for endoscopists, especially those who are inexperienced to deal with such difficult situations.

Methods

For a literature review, a Medline search (keywords for search: difficult cannulation, surgically altered anatomy, ERCP complication, post-ERCP pancreatitis, pre-cut, needle-knife, balloon-assisted endoscopy, cap-assisted endoscopy, laparoendoscopic rendezvous, ERCP and PTCD) for the years 1990—2018 was performed. The reference list of this review is by no means comprehensive and 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 of difficult biliary cannulation

Definitions of difficult cannulation vary in reports. Most studies have defined a difficult biliary cannulation according to a minimum number of cannulation attempts (typically 5 to 15) or the time taken to cannulate (greater than 5 to 30 minutes). In addition to time and/or number of cannulation attempts at the papilla, the number of unintentional passages or contrast injections into the pancreatic duct must also be considered, as when either of these things occurs more than once this is associated with an increased risk of PEP. The strictest limits within the arbitrarily set time have been one 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. Based on literatures, ESGE guidelines suggest the criteria for a difficult biliary cannulation are more than 5 minutes of cannulation time, more than five instances of meaningful papillary contact, or more than one instance of unintentional PD cannulation [2]. A recent guideline defined difficult cannulation as the inability to achieve selective biliary cannulation within 10 minutes or up to five cannulation attempts using standard ERCP techniques [9].

Factors associated with difficult biliary cannulation

The likelihood of successful cannulation is influenced by operator factors (experience) and patient factors (anatomy). Expert endoscopists are expected to be successful at biliary access in 95% to 100% of attempts, a goal that is supported by the literature. Community success rates should exceed 90% [10].Trainees are deemed competent to perform endoscopic procedures independently when a success rate of 80% to 90% is achieved [11,12]. A direct association between the case volume, local expertise, endoscopic training, and practice setting has been demonstrated in multiple studies [13,14]. Both the anatomy of the papilla and anatomical variants could also cause a difficult cannulation. In some cases, the papilla may be flat and small. For example, the sphincter is often stenotic because of Oddi dysfunction. The papilla can be difficult to locate in the setting of tumor infiltration of the papilla or the duodenum, or pancreatitis that causes duodenal edema and distortion. Intradivertiucular or peridiverticular papillas are other well-known causes for difficult cannulation [15,16]. Patients with surgically altered anatomy, such as post-Billroth-II or post-Roux-en-Y, present particular challenges, because the papilla is approached either from the opposite direction or using a forward-viewing endoscope that lacks the advantage of an elevator [6].

Contrast or guidewire cannulation technique

Deep cannulation of the biliary duct may be achieved by either injecting contrast medium or using a guidewire inserted into the ERCP cannula or sphincterotome. Compared with the contrast technique, guidewire-assisted biliary cannulation is associated with a higher incidence of successful cannulation [17—19]. Two different techniques have been described for guidewire cannulation, the touch (T) technique (engaging the papilla with a sphincterotome

and then advancing the guidewire) and the no-touch (NT) technique (engaging the papilla only with the guidewire). The guidewire was advanced through a sphincterotome to approximately 1 to 3 mm beyond its tip and was then directly pushed into the papillary orifice in the axis of the common bile duct under fluoroscopic control. Recently, a multicenter RCT study clearly indicated that the T technique is superior to the NT technique for biliary cannulation [20]. However, it is recognised that expertise of the operator and assistant need also to be considered when deciding on the preferred technique for biliary cannulation.

Pre-cut or persistent attempts with the standard approach

Gaining access to the biliary duct is the first and most important step for a successful ERCP. However, access to the common bile duct fails in about 5%—15% of cases, even in experienced hands. In cases where biliary cannulation is not achieved for any duct, the most widely practiced techniques are pre-cuts, including needle-knife papillotomy (started cutting from the papillary orifice) and needle-knife fistulotomy (started cutting from at least 5 mm above the orifice). Pre-cut sphincterotomy seems to be associated with a higher procedure related complication rate in many studies, such as haemorrhage, perforation and especially acute post-ERCP pancreatitis, but this is probably due to an increased number of cannulation attempts in patients undergoing pre-cut sphincterotomy. In the end, while the complication rate is lower if pre-cut sphincterotomy is carried out early (< 10 attempts) [1,21,22]. A systematic review and meta-analysis shows overall cannulation rates were comparable between both pre-cut techniques [14]. In an RCT of 153 patients, the rate of PEP was significantly lower after fistulotomy (0%) compared with conventional pre-cut (7.59%) [23]. However, in a retrospective study, a non-significant trend to a lower rate of PEP was observed after fistulotomy compared with the conventional pre-cut [24]. The issue of the best timing for pre-cut procedure implementation has been widely debated. Several authors have suggested that the early use of pre-cut should be preferred to persistent attempts with the standard approach, in order to reduce all the well-known risk factors. However, RCTs that investigated the issue of timing of the pre-cut procedure were limited. Current evidence suggests that in experienced hands the early implementation of pre-cut does not result in a higher rate of primary cannulation or lower rate of post-ERCP complications; however, it can reduce the risk of post-ERCP pancreatitis when compared with conventional techniques [1,22,25].

The performance of pre-cutting over a pancreatic duct stent (PPDS) is the facilitation of biliary access by using the stent as a guide for pre-cutting whilst reducing the incidence of PEP (Fig. 1). A retrospective study revealed that biliary cannulation success rates were significantly better for PPDS compared with the conventional needle-knife technique [95/98 (96.9%) vs. 31/36 (86.1%); $P = 0.0189$]. In terms of overall adverse events, PPDS were significantly lower than conventional needle-knife [7/98 (7.1%) vs. 12/36 (33%); $P < 0.001$] [26]. Prophylactic PD stents have been shown to be useful for preventing PEP when applying rescue techniques. Randomised controlled trials showed that prophylactic PD stents reduced the incidence of PEP by up to 70% [27]. A meta-analysis showed that patients who had prophylactic PD stenting had a significantly lower incidence of PEP than groups without PD stents (OR = 0.35, 95% CI 0.25—0.49) [28]. However, the type, size or location of the PD stents that should be used is unclear. Most authors reported using short 3—6-Fr devices with external pigtails or flanges. Stents without the internal flange tend to migrate spontaneously after the procedure [29—31]. One study found PEP rates were significantly lower in the group where the pancreatic duct stent was left in situ [32]. The stent should be left in the pancreatic duct for at least 12—24 hours to reduce the risk for PEP. Another study revealed PD stents for the prevention of PEP should be inserted up to the pancreatic body or tail [33]. However, if PD stenting is attempted, but fails, the rate of PEP increases significantly to 35—66% in high-risk patients [28]. Therefore, the 2016 ESGE guideline on papillary cannulation and sphincterotomy state that prophylactic PD stenting should only be performed by experienced endoscopists [2]. Recently a retrospective study also suggested that pancreatic duct stenting may be less important, even in high-risk patients, with the widespread use of rectal non-steroidal anti-inflammatory drugs [34].

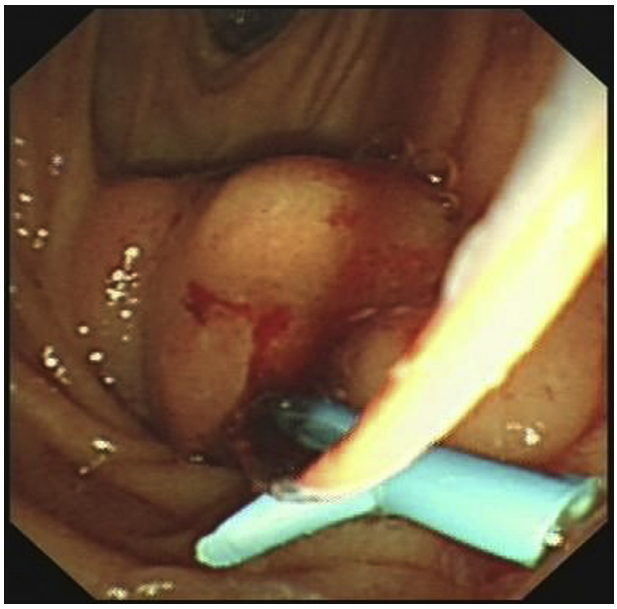

Figure 1 Needle-knife papillotomy over a pancreatic duct stent.

Transpancreatic pre-cut sphincterotomy or double guidewire technique

If unintended pancreatic cannulations are repeated without biliary access, there are two ways to assist bile duct cannulation with pancreatic guidewire placement. One is the double-guidewire technique (DGT), which requires the use of a guidewire to physically occupy the pancreatic duct and another guidewire for bile duct cannulation [35—37]. Since its first description, this method has been used with promising results in cases of complex biliary cannulation,

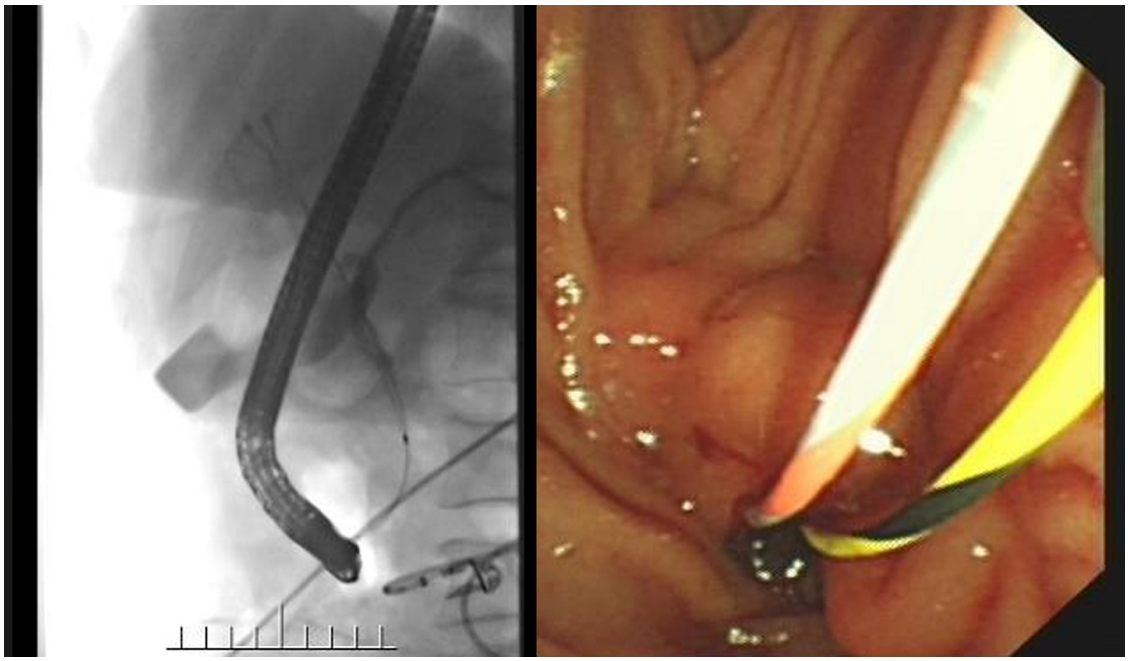

Figure 2 The double-guidewire technique (DGT).

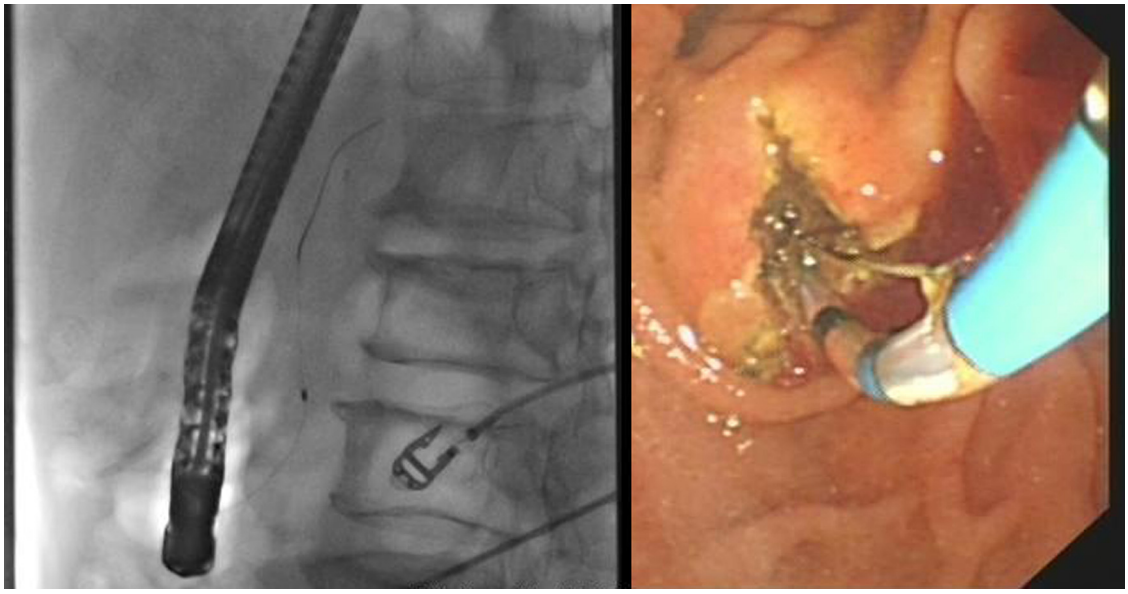

Figure 3 Transpancreatic pre-cut sphincterotomy (TPS).

especially in patients with a distorted bile duct anatomy caused by neoplasia or atypical morphology of the ampulla. With a guidewire in the pancreatic duct, the biliary axis gets straightened and the guidewire may serve as a fluoroscopic roadmap (Fig. 2) [36]. The other is transpancreatic pre-cut sphincterotomy (TPS) [38,39]. A sphincterotomy over the guidewire in the pancreatic duct helps to cannulate the biliary orifice because the cut either opens the bile duct or runs along the side of the duct, thus exposing the duct's anatomy (Fig. 3). One prospective, randomized study compared DGT with TPS showed similar success rates. However, post-procedure pancreatitis was significantly higher in the DGT group [40]. Another prospective, randomized study showed TPS had a significantly higher success rate (94.1%) than DGT (58.8%). The rate of PEP was 2.9% in both groups. There was no significant difference between the two groups in the overall rate of complications related to cannulation [41]. The four available alternatives (persistence with standard cannulation technique, pancreatic guidewire-assisted cannulation techniques, pre-cut techniques, pancreatic duct stent insertion) for achieving successful cannulation in cases of difficult biliary cannulation have yielded similar results in RCTs. However, the endoscopists should also understand sometimes termination of the procedure because of limited

operator experience (if not urgent) may be a better option than rescue access techniques.

Periampullary diverticulum and cannulation

Periampullary diverticulum (PAD) was first reported by Chomel et al. in 1710. In 2006 Boix et al. proposed a classification of PAD, differentiating three types: type I, papilla located inside of the diverticulum (50%); type II, papilla located in the margin of the diverticulum (30%); and type III, papilla located close to the diverticulum (20 %) [42]. The overall incidence of PAD varies widely from 6% to 31.7% based on different diagnostic approaches [15,42]. Incidence of acquired diverticula increases with age, being rarely seen before 40. PAD do not significantly increase the difficulty of deep cannulation [42]. Selective biliary cannulation with a side-viewing endoscope is sometimes difficult in patients with a periampullary diverticulum due to the tangential approach or a hidden papilla. The fundamental principle of several reported techniques is to expose the papillary orifice and align the ducts in preparation for cannulation. This can be accomplished by cap-fitted forward-viewing endoscope, double-endoscope method, double-catheter method, everting the diverticulum using biopsy forceps, saline injection to lift the papilla, endoscopic endoclip-assisted cannulation, or intubation of distal tip of duodenoscope into diverticulum [15,16].

Surgically altered anatomy

ERCP is difficult after intestinal reconstruction, particularly in patients who have undergone Billroth-II (B-II) reconstruction, Rouxen-Y (R-Y) reconstruction or pancreaticoduodenectomy. Success of ERCP in the presence of surgically altered anatomy requires complete knowledge of the reconstructed anatomy, availability of specialty instruments and devices, and expertise with the techniques of deep endoscopic intubation. Various techniques have been proposed to facilitate scope insertion, cannulation, and treatment. In 2005, double-balloon enteroscope-assisted ERCP (DBE-assited ERCP) was first successfully used in a patient who undergone biliary reconstruction by R-Y choledochojejunostomy. DBE-assited ERCP is reported the safest and most effective procedure [6,43]. A summary of recommended endoscopes and cannulation methods based on type of surgical reconstruction is provided in a recent review [44]. The risks, benefits, and alternatives to device-assisted ERCP should be thoroughly reviewed with the patient and endoscopy team, so as to improve the success rate and reduce operation-related complication risk.

Second ERCP after failure of initial biliary cannulation following pre-cut sphincterotomy

In cases where cannulation is difficult, pre-cut sphincterotomy can provide access into the distal bile duct. However, pre-cut sphincterotomy does not always achieve primary biliary cannulation success. Prolonged or repeated attempts of cannulation of the papilla and the diathermy effect of the pre-cut sphincterotomy can result in papillary oedema with distortion of the papillary anatomy and narrowing of the distal common bile duct which renders insertion into the bile duct even more difficult. Furthermore, the view can become restricted by bleeding. Asking for assistance from a more experienced colleague or referral to an expert center may increase cannulation rates, although the cannulation still may fail. Expert tertiary centers have reported successful cannulation at ERCP in more than 95% of cases in which bile duct access failed elsewhere. Repeating ERCP a few days after the initial pre-cut failure often reveals an open and easily accessible papilla, although sometimes a second pre-cut is required. Furthermore, this second ERCP within days also seems safe. Previous studies have found that delaying bile duct drainage rarely increases other adverse events such as cholangitis [5,45—48]. One study revealed a second ERCP after failure of initial biliary cannulation following a pre-cut sphincterotomy appears to be safe and particularly effective if it can be delayed at least 4 days [4]. Another study showed the high success rate of biliary cannulation in a second attempt ERCP justifies repeating ERCP within 2—7 d after unsuccessful pre-cut sphincterotomy before more invasive approaches should be considered [5].

Feasible alternative strateges

What to do when cannunlation fails? If the procedure is urgent, or multiple attempts by different endoscopists or even expert at tertiary centers fail, several alternative techniques, such as percutaneous transhepatic biliary drainage (PTBD), surgery, and endoscopic ultrasound guided biliary drainage (EUS-BD) can be performed. PTCD is commonly used as an alternative. However, it can lead to external bile acid loss, as well as significant long-term costs, and frequent adverse events. It may be extremely difficult to carry out when the intrahepatic bile ducts are not dilated. Overall PTBD adverse events range between 9 and 13% and severe adverse events range between 4 and 8%. EUS-BD is increasingly used in patients who fail standard ERCP. The two major endoscopic approach routes for EUS-BD are the transgastric intrahepatic and the transduodenal extrahepatic approaches. Biliary drainage can be achieved by major procedures, transpapillary rendezvous technique, transluminal or antegrade biliary stenting [49]. A systematic review and meta-analysis reported that there is no difference in technical success rates between EUS-BD and PTBD, but EUS-BD was associated with higher success rates and lower adverse event and re-intervention rates when compared with PTBD [50]. These findings suggest that EUS-BD is a safe and good alternative to PTBD after failed ERCP if adequate expertise in advanced endoscopy is available.

However, in certain circumstances, there are unique clinical indications for which percutaneous-endoscopic rendezvous (PE-RV) should be preferred and endoscopic ultrasound guided rendezvous (EUS-RV) is difficult to perform. A recent review suggested the potential indications for PE-RV over EUS-RV and described diverse PE cannulation techniques [8]. For patients with symptomatic cholecystocholedocholithiasis in whom ERCP as part of a two-stage approach has either failed or is considered unsuitable, the

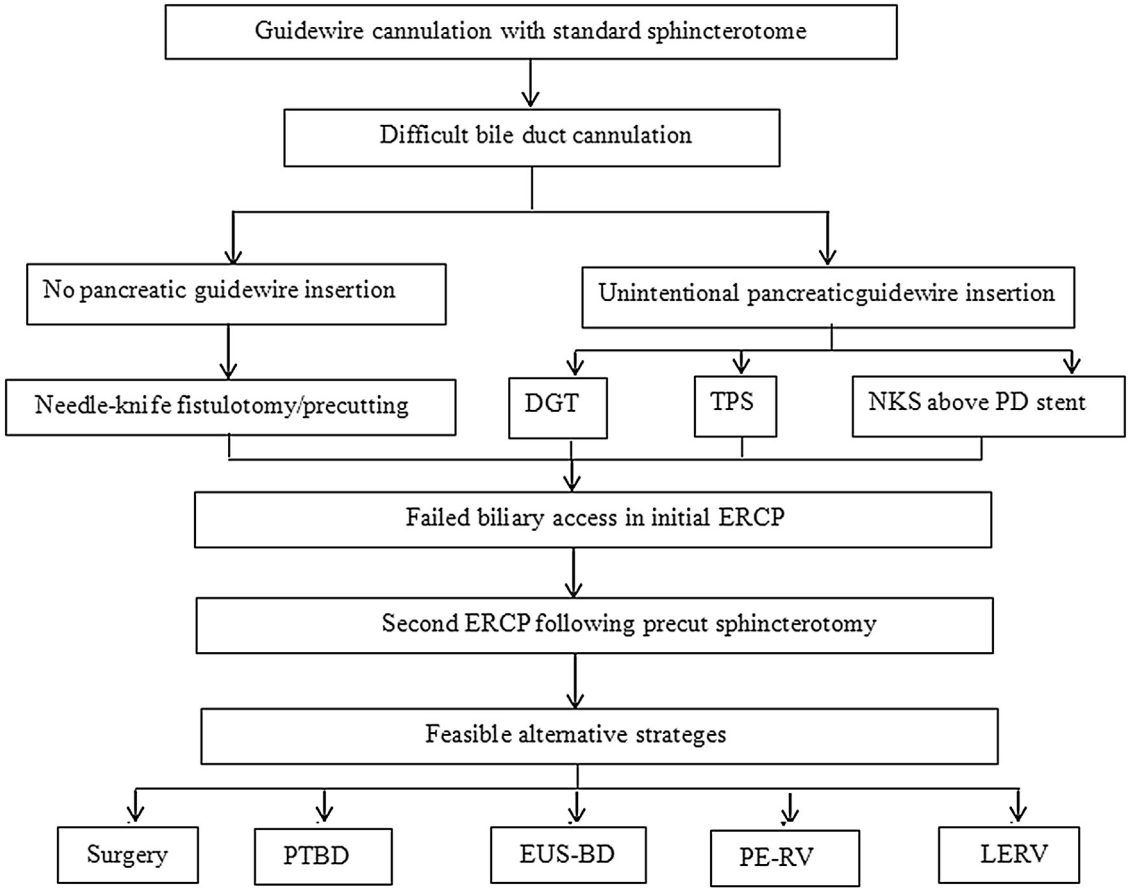

Figure 4 Algorithm for difficult or failed biliary access in initial endoscopic retrograde cholangiopancreatography (ERCP). NKS: needle-knife sphincterotomy; DGT: double-guidewire technique; TPS: transpancreatic pre-cut sphincterotomy; PD: pancreatic duct; PTBD: percutaneous transhepatic biliary drainage; EUS-BD: endoscopic ultrasound guided biliary drainage; PE-RV: percutaneous-endoscopic rendezvous; LERV: laparoendoscopic rendezvous. The preferred technique should depend on patient risk and operator experience.

so-called laparoendoscopic rendezvous (LERV), during which the gallbladder is removed laparoscopically and the CBD is cleared endoscopically, while selective cannulation is simultaneously applied could be an alternative procedure [51,52].

Conclusions

Despite advances and new developments in endoscopic accessories and techniques, selective biliary cannulation cannot always be achieved easily. The definition of difficult biliary cannulation is highly variable among different studies. A standard guidelines or sequential protocol has not been existed up to now. Repeating the ERCP within a few days after initial failed pre-cut is a successful strategy and should be tried before contemplating more invasive, alternative interventions. However, in certain circumstances, there are unique clinical indications for which invasive, alternative interventions should be preferred. The risks, benefits, and alternatives to ERCP should be thoroughly reviewed with the patient and endoscopy team accordingly, so as to improve the success rate and reduce operation-related complication risk.

An algorithm is suggested in Fig. 4.

Disclosure of interest

The authors declare that they have no competing interest.

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