

Controversies in ERCP: Technical aspects

Christoph F. Dietrich^{1,13,14}, Noor L. Bekkali², Sean Burmeister³, Yi Dong⁴, Simon M. Everett⁵, Michael Hocke⁶, Andre Ignee⁷, Wei On⁵, Srisha Hebbar⁸, Kofi Oppong⁹, Siyu Sun¹⁰, Christian Jenssen^{11,12}, Barbara Braden^{2,13}

¹Department of Ultrasound, The First Affiliated Hospital of Zhengzhou University, China; ²Translational Gastroenterology Unit, Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom; ³Surgical Gastroenterology Unit, Groote Schuur Hospital, Cape Town, South Africa; ⁴Department of Ultrasound, Zhongshan Hospital, Fudan University, Shanghai, China; ⁵Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom; ⁶Medical Department, Helios Klinikum Meiningen, Germany; ⁷Medical Department 2, Caritas-Krankenhaus, Uhlandstr 7, D-97980 Bad Mergentheim, Germany; ⁸University Hospitals of North Midlands, United Kingdom; ⁹HPB Unit, Freeman Hospital, Newcastle upon Tyne, United Kingdom; ¹⁰Endoscopy Center, ShengJing Hospital of China Medical University, Shenyang, Liaoning, China; ¹¹Krankenhaus Märkisch-Oderland, Department of Internal Medicine, Strausberg, Germany; ¹²Brandenburg Institute for Clinical Ultrasound (BICUS) at Medical University Brandenburg, Neuruppin, Germany; ¹³Johann Wolfgang Goethe University, Frankfurt/Main, Germany; ¹⁴Department of Allgemeine Innere Medizin, Kliniken Hirslanden Beau Site, Salem und Permanence, Bern, Switzerland

ABSTRACT

The aim of the series of papers on controversies of biliopancreatic drainage procedures is to discuss pros and cons of the varying clinical practices and techniques in ERCP and EUS for drainage of biliary and pancreatic ducts. While the first part focuses on indications, clinical and imaging prerequisites prior to ERCP, sedation options, post-ERCP pancreatitis prophylaxis, and other related technical topics, the second part discusses specific procedural ERCP techniques including precut techniques and their timing as well as management algorithms. In addition, reviews on controversies in EUS-guided bile duct and pancreatic drainage procedures are under preparation.

Key words: magnetic resonance cholangio pancreaticography, EUS, bile stones, tumor, endoscopic sphincterotomy, papillotomy

INTRODUCTION

Indications, clinical pathways, training, sedation practice, and techniques used for ERCP may vary in different cultural contexts, countries, and endoscopic centers.^[1-3] In this paper, important practical issues regarding performance and controversies of ERCP are discussed from multiple perspectives. Practicing endoscopists from various regions across the world contributed to

this review and discussed their standard practices in the context of currently available evidence and according personal preferences.

The aim of this paper is to discuss pros and cons of the varying clinical practices and techniques in ERCP. The first part focused on indications, clinical

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Address for correspondence

Prof. Christoph F. Dietrich, Department Allgemeine Innere Medizin (DAIM), Kliniken Beau Site, Salem und Permanence, Hirslanden, Bern CH-3036 Bern, Switzerland.

E-mail: c.f.dietrich@googlemail.com

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and imaging prerequisites prior to ERCP, sedation options, post-ERCP pancreatitis (PEP) prophylaxis, and other related technical topics. In this second part, we review and discuss specific procedural techniques including precut techniques and their timing as well as management algorithms.

The authors declare that this paper is not intended as a guideline, but rather as an opportunity to document and reflect on current practice, allowing readers to evaluate their own procedures and to encourage further discussion.

WHAT IS THE BEST CANNULATION TECHNIQUE (NO TOUCH AND THINK BEFOREHAND STRATEGY)

Introduction and review of the literature with respect to biliary cannulation

Successful biliary cannulation requires a thorough knowledge of the appropriate landmarks. The bile duct enters the papilla in the 11 o'clock position while the pancreatic duct orientates in the 1–2 o'clock position.^[4-6] Guidewire cannulation is more successful than the contrast technique where contrast is injected into the papillary orifice through a sphincterotome or a catheter to guide deeper cannulation with the catheter, sphincterotome, or guidewire. With guidewire-assisted biliary cannulation, the guidewire is passed prior to instillation of contrast.^[7] Several meta-analyses have shown the superiority of the guidewire technique in terms of successful biliary cannulation and prevention of PEP,^[8-12] but the studies included in those meta-analyses had significant limitations including failure to assess the cannulation time. Some trials included in the meta-analyses allowed a crossover to alternative techniques, some included trainees, the devices for cannulation differed, and precut was used as a rescue technique.^[6]

The majority of US endoscopists (76%) prefer the guidewire-assisted technique.^[13] The guidewire can be advanced through a sphincterotome or a standard ERCP cannula. Whether it is preferable to first insert the catheter (touch technique) or to instead pass the guidewire into the orifice without touching the papilla with the catheter (no-touch technique) is still under debate.^[14] The touch technique describes inserting a catheter or sphincterotome in the 11-12 o'clock position, bending it to ensure correct alignment with

the axis of the bile duct then gently pushing the catheter forward until it is seen in the common bile duct (CBD). With the no-touch technique, 1–2 mm of guidewire is extended beyond the front tip of the catheter and inserted in the direction mentioned above. A RCT showed superiority of the touch technique in terms of primary biliary cannulation success (88% *vs.* 54%) with no difference of adverse events.^[15] The reason for this could be that the lumen of the ampulla of Vater is filled with mucosal folds, which cannot be easily overcome using the guidewire alone. Short-wire techniques, where the endoscopist controls the guidewire, are superior to assistant-controlled guidewire manipulation with respect to PEP.^[16] A double-guidewire technique (pancreatic guidewire-assisted biliary cannulation) was recommended in case of difficult biliary cannulation and repeat unintentional access to the pancreatic duct,^[6] but results of RCTs were controversial, and a recent meta-analysis did not show any advantage in terms of success rates but a higher PEP risk.^[17]

There is no consensus on defining a difficult ERCP. ESGE guidelines suggest more than 5 attempts to cannulate the papilla, more than 5 min following papilla visualization, and more than one unintended pancreas cannulation or opacification.^[6] These numbers are on the lower level used in the referenced studies, which range from 5 to 15 attempts and up to 20 min. In addition, operator and patient factors can predict and contribute to difficult cannulation, e.g., presence of a diverticulum.

Minor papilla interventions

A study using ERCP and magnetic resonance cholangio pancreaticography (MRCP) data determined a prevalence of 8% for pancreas divisum in the general population and of 8% for patients with pancreatitis.^[18] The authors draw the conclusion that there seems to be no causative link between pancreas divisum and pancreatitis.^[18] Nevertheless, in cases of recurrent pancreatitis and pancreas divisum, papillotomy of the minor papilla can be considered.^[19,20] The first step is to identify the minor papilla 20 mm above the major papilla in the 1–2 o'clock direction.^[6] Secretin injection has been shown to improve the cannulation rate;^[21] however, the drug is expensive and not always readily available. Other techniques to aid identification of the minor ampulla (in incomplete pancreas divisum) include methylene blue and contrast injection in the major papilla. After injection of 45 ml of 0.1 mol/L hydrochloric acid

into the duodenum,^[22,23] the minor papilla becomes more prominent. The morphology of the minor papilla (enlargement or open orifice) has an about 90% negative predictive value for pancreas divisum,^[24] but this finding has not found its way into clinical practice. The cannulation itself can be challenging. Needle-knife techniques and standard sphincterotomes can be used, as shown by a retrospective study.^[25] We also recommend PD stenting and aggressive hydration given the high-risk nature for PEP.

ENDOSCOPIC SPHINCTEROTOMY AND CONFIRMATION OF COMMON BILE DUCT CLEARANCE IN CHOLEDOCHOLITHIASIS – DEFINITIONS, TECHNIQUES, AND RECOMMENDATIONS

Background

Analyses of nationwide ERCP registries have demonstrated CBD stones to be the most common reason to perform ERCP.^[26,27] Standard techniques to clear ductal stones include biliary endoscopic sphincterotomy (EST), followed by trawls with an extraction balloon or Dormia basket. EST was first described in 1974^[28] and refers to cutting the biliary sphincter muscle and intraduodenal portion of the distal CBD to facilitate therapeutic interventions. EST is associated with a substantial risk of complications and outcomes improve with operator experience.^[29] Following EST and balloon/basket trawls for CBD stones, it is important to confirm that the duct has been fully cleared of stones to prevent recurrence of biliary obstruction. Usually, this is achieved by performing a balloon occlusion cholangiogram, yet this is not 100% sensitive in diagnosing residual stones.^[30,31] Despite significant risks related to ERCP, there are limited data or guidelines that allow standardized descriptions or best practice in these frequently performed procedures. In the below paragraph, we discuss the available evidence and make recommendations for standardization of terminology and the need for consensus guidelines for EST and confirmation of duct clearance for CBD stones.

Biliary EST techniques

The direction of EST should be orientated toward 11 o'clock and it is generally accepted that the maximal extent of EST should not exceed the superior margin of the papillary bulge, which is the intramural portion of the CBD, to prevent iatrogenic perforation.^[32]

This superior margin may not be easily appreciated endoscopically but may be demonstrable by inflation of a balloon catheter in the distal CBD and pulling down to the papilla.^[33,34] Despite the long history of EST, there has not been a universally accepted method of describing the appropriate extent of an EST. In general, the distance cut is described in relation to the superior margin of the papillary bulge, but there is significant variation in the terms used both in clinical trials and in clinical practice. Various studies have described an EST which extends to the superior margin of the papillary bulge as “adequate,”^[35,36] “major”^[37] “large,”^[38] or “full” (defined as a cut more than two-thirds the length of the ampulla).^[39] Smaller sphincterotomies have been described as “limited” (less than half the length of the papillary mound);^[40-42] “small” (one-third of the distance to the papillary roof without extending beyond the transverse fold of the papilla);^[43-45] “standard” (proximal to the transverse fold);^[46] or “minor” (one-third the distance of the papillary bulge).^[47] Despite the use of such terms, many studies do not provide a definition for the size of the EST in describing their methods.^[41,42,44] Instead of descriptor terms, the distance of tissue cut has been used to provide an illustrative definition of the size of an EST,^[48] yet the use of measurements may not be generalizable to all patients as it is well recognized that papillae differ in their phenotypes and “one size does not fit all”^[49] Society guidelines in the Western world have not provided definitions on the sizing of EST.^[50-53] The Japanese Gastroenterological Endoscopy Society guidelines classify the size of EST into three categories [Figure 1]: small (does not exceed the transverse fold), large (reaching the superior margin of the papillary bulge), and medium (anywhere in between).^[54] The guidelines are based on the “standard” papillary phenotype with a clear first transverse fold and infundibulum and one that has not been distorted by a duodenal diverticulum. Different EST techniques are shown in Figure 2.

In patients with post-surgical altered anatomy of the upper gastrointestinal tract, biliary access techniques have to be modified according to the respective anatomy.^[6,55] In patients with a history of Billroth-II gastrectomy, a standard sphincterotome should not be used. In particular, two techniques are established: needle-knife sphincterotomy following bile duct cannulation and placement of a biliary 7 FR-plastic endoprosthesis or wire-guided sphincterotomy using a dedicated sphincterotome for Billroth II

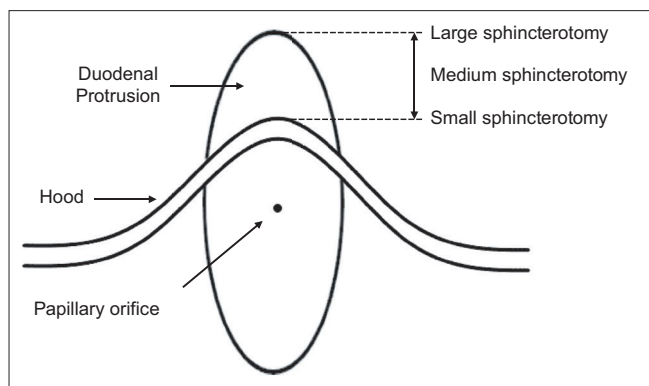


Figure 1. Classification of size of biliary endoscopic sphincterotomy as defined by the Japanese Gastroenterological Endoscopic Society

anatomy such as an inverted sphincterotome or an S-shaped sphincterotome [Figure 3]. In a simulator model, needle-knife sphincterotomy guided by a plastic endoprosthesis was more time-consuming, but technically more successful compared to sphincterotomy using a Billroth-II sphincterotome.^[56] High success rates are also reported with a rotatable sphincterotome.^[57] In some cases, use of a forward-viewing endoscope instead of a side-viewing duodenoscope may be preferential.^[58-60] Prospective studies comparing the different techniques are lacking.

The adequacy of an EST has not been formally defined. The optimal size of EST permits the intended therapeutic intervention for a specific patient without taking an additional risk by cutting wider than needed.^[39] Size of EST will be influenced by indication and will vary between extraction of CBD stones and those that require stricture management or stent placement. In the context of choledocholithiasis, the adequacy of an EST will be determined by the minimum extent, which facilitates successful stone extraction while the maximal safe extent will be determined by the ampullary anatomy in the duodenal wall and CBD diameter. The former can often be determined by initial extraction of a balloon inflated to the approximate size of stone(s) to be extracted. Further considerations may include whether the patient will be proceeding to or has had a cholecystectomy or if this is to be considered definitive therapy in those either unfit or unwilling to undergo a cholecystectomy. However, objective means to determine the adequacy of an EST in any of these contexts are not well defined as there is substantial heterogeneity in currently available studies in terms of size of EST performed, size of the stone(s) involved, and whether endoscopic balloon sphincteroplasty was performed.^[50]

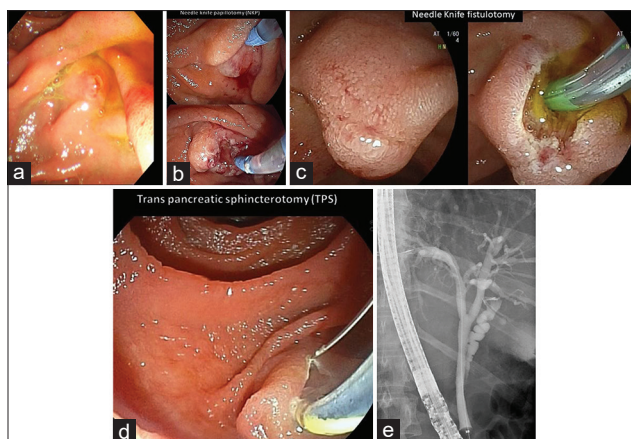


Figure 2. Normal papilla (a) and different endoscopic sphincterotomy techniques (b-d). Needle knife papillotomy (b), needle knife fistulotomy (c) and NKF and transpancreatic sphincterotomy (d). A normal cholangiogram is shown in (e)

Standardized reporting of sphincterotomy

The need to standardize endoscopic reporting using Minimal Standard Terminology has been stressed by the World Endoscopy Organization.^[61] It has been possible to standardize descriptors of ampullary anatomy using consensus techniques with substantial inter- and intraobserver agreement^[62] and such descriptors can positively influence clinical outcomes.^[49] We believe that it is essential that terms for describing sphincterotomy size and adequacy be standardized using similar rigorous research processes to facilitate subsequent integration into clinical practice, research terminology, and international guidelines. Such terminology would improve the quality and reproducibility of research in ERCP and allow standardization of audited outcomes for clinical practice.

In the absence of universally agreed terminology, the use of single word adjectives should be discouraged. Instead, we recommend the following descriptive approaches be utilized for ERCP reporting in both clinical practice and trials:

- Stating the rationale for choice of sphincterotomy size
- Describing the proportion of tissue cut compared to the superior margin of the ampullary bulge
- Stating the size of the inflated extraction balloon that emerges without resistance.

Confirmation of duct clearance at ERCP

The goal of an ERCP in patients with choledocholithiasis is to ensure complete stone extraction. A balloon occlusion cholangiogram is the most common technique used to demonstrate complete duct clearance; despite widespread practice, there has not been consensus on the optimal

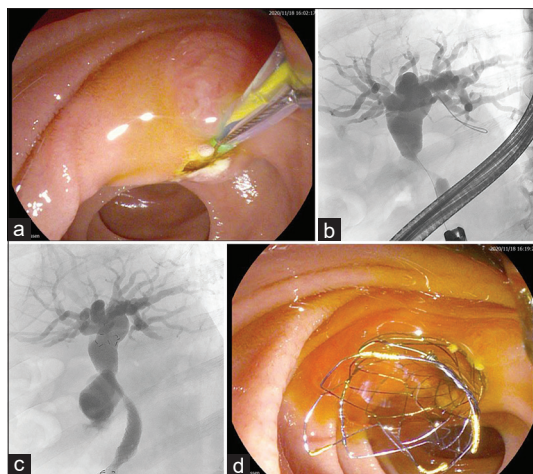


Figure 3. Patient with obstructive jaundice due to advanced gallbladder cancer and a history of Billroth-II-gastrectomy. Biliary sphincterotomy was performed using a wire-guided inverted sphincterotome (a). Retrograde cholangiography revealed a 2 cm stricture of the common bile duct (b). A partially covered self-expanding metal stent was inserted for drainage of the dilated hepatic and intrahepatic ducts (c and d)

technique.^[63,64] Failure to demonstrate complete duct clearance results in residual biliary stones, which may cause recurrent biliary obstruction, pain, cholangitis, and pancreatitis as well as related legal ramifications for the endoscopist.^[5] Studies have demonstrated the sensitivity of cholangiogram in detecting intraductal stones during ERCP to be 89%–93% despite careful attention to technique.^[30,31] Similarly, a meta-analysis of intraoperative cholangiogram demonstrated a sensitivity of 87% in detecting CBD stones.^[65] Although the aforementioned modalities are used in different settings, they share common ground in the pitfalls of cholangiography, which can lead to a false negative cholangiogram.

The pitfalls of cholangiography can be categorized into technical, interpretative, and operative factors.^[66,67] In most institutions, the onus is on the endoscopist to acquire and interpret images during the procedure. It is important to optimize the position of the image intensifier to obtain an image of adequate exposure as well as utilize techniques such as oblique rotation of a C-arm or changing the patient or endoscope position to obtain complete views.^[68] Accurate knowledge of anatomy and interpretation of cholangiographic findings is crucial to ensure appropriate therapy; yet, several studies have demonstrated discordance in postprocedure interpretation of ERCP images between radiologists and endoscopists.^[69-71] Finally, there are steps to performing a good-quality cholangiogram that may help improve outcomes, which are described in detail elsewhere.^[64,66] The rates of residual bile duct stones after intended

complete duct clearance have been reported to be between 4.8%–37%.^[72-80] The risk is increased in the setting of a dilated CBD, presence of pneumobilia, following lithotripsy (mechanical, electrohydraulic or laser) and pancreatic guidewire placement. In these studies, the subsequent methods used to reveal residual bile duct stones included intraductal ultrasound (IDUS),^[72] EUS,^[73] cholangioscopy,^[74-79] and computed tomography or magnetic resonance imaging.^[80] The use of balloon occlusion cholangiogram was described in these studies, but its technique was not expanded upon. The size of residual stones in these studies ranged from 2 to ≥ 8 mm in diameter. The clinical impact of small residual stones is of uncertain significance, though they may act as a nidus for further stone formation. Larger residual stones may lead to further biliary events such as obstruction, pain, cholangitis, and pancreatitis. Consequently, complete duct clearance at index ERCP will result in fewer repeat procedures in the future.^[74]

How to ensure stone clearance and perform a high-quality occlusion cholangiogram

Several reviews have described techniques for achieving optimal cholangiographic imaging.^[64,66-68] However, given the long-standing history of ERCP, it is perhaps surprising that there are no published standards stipulating the minimum set and quality of images that need to be acquired and captured. The American Society of Gastrointestinal Endoscopy task force alluded to the importance of capturing endoscopic and fluoroscopic images as an objective way of demonstrating what has been carried out during an ERCP, but the recommended dataset of image documentation was not defined.^[81] In contrast, there are numerous national and international guidelines that mandate acquisition of images as a standard for diagnostic endoscopies. The justification for such stored images, despite a lack of evidence, is the perceived notion that such practice encourages a complete examination and acts as a legal record of an adequate and/or complete procedure.^[82,83] Similar justifications can be made for ERCP and we recommend that standard radiological image acquisition should be listed in international guidelines to reflect the same principles as those outlined for diagnostic endoscopies. With respect to defining and performing a high-quality occlusion cholangiogram, this too should be the subject of rigorous consensus research, similar to that performed for descriptors of ampullary anatomy.^[62] In the absence of such an approach, our opinion is that a high-quality

occlusion cholangiogram should be defined as adequate contrast filling and visualization of the entire biliary tree without any artefactual disturbances. Techniques to achieve this will vary but should follow simple principles:

- The initial cholangiogram should commence with contrast injection at the liver hilum to prevent flushing debris and fragments from the extrahepatic bile duct into the intrahepatic ducts
- Contrast should initially be instilled with the balloon collapsed, allowing air bubbles or debris within the intrahepatic system to hopefully be flushed into the extrahepatic system before inflation of the balloon
- The size of the balloon should match the size of the duct to ensure appropriate occlusion and retention of contrast above the balloon
- Inflate balloon at the hilum after initial contrast injection and continue contrast injection while simultaneously withdrawing balloon
- Obtain multiple acquisition images with the inflated balloon at the liver hilum, midduct, and just above the papilla
- The midduct, which tends to be obscured by the duodenoscope, should be visualized by either pushing the duodenoscope into a long position with anticlockwise torque or rotating the fluoroscopy arm and then saving the image.

Should additional techniques to confirm duct clearance be a standard?

Although the use of adjunctive methods to detect residual stones after occlusion cholangiogram has demonstrated significant pickup rates, this is not appropriate in every instance where ERCP has been performed due to the need for specialized equipment, availability of expertise to perform such procedures, and additional financial costing's incurred. A balloon occlusion cholangiogram is still reasonably sensitive, and where residual stones are missed, the majority of these should pass given that a sphincterotomy has been performed that allows passage of a suitably sized balloon. Adjunctive procedures may themselves have associated inherent risks. Finally, for patients still requiring cholecystectomy, intraoperative cholangiography will provide an additional opportunity to obtain a repeat cholangiogram if needed.

There may be situations when the use of adjunctive techniques is justifiable; for example, the tandem use of cholangioscopy in a patient who has had cholangioscopy-guided intraductal therapy of stones.

The majority of patients, however, only require standard techniques of stone extraction, and thus, it is of utmost importance that careful attention is paid to ensure complete duct clearance and to demonstrate this with a good-quality occlusion cholangiogram before scope withdrawal at the end of the ERCP.

Arguments in favor of terminology standardization

Efforts have been made to standardize the use of terminology in other forms of endoscopy,^[84,85] and this should apply to ERCP as well. Standard terminology in describing anatomical landmarks or therapeutic interventions has various advantages. From a clinical perspective, it serves as a marker of quality control and performance measures by providing a benchmark that can be audited. From a research perspective, standard terminology will lead to a reduction in heterogeneity in the methodology and reporting of clinical trials. With specific regards to EST and occlusion cholangiogram, these could be considered the “bread and butter” of ERCP; therefore, it is imperative that a unifying consensus exists to formally define and describe these techniques.

Arguments against terminology standardization

The practice of ERCP has spanned decades and is carried out worldwide. In competent hands, ERCP has proven to have high technical and clinical success rates. The intention to develop standardized terminology may be met with resistance and a reluctance to disrupt the current status quo. Therefore, it begs the question; do we need further rigorous standardization for a procedure that is already well established?

Summary and conclusions

Treatment of choledocholithiasis is the most common indication for performing ERCP of which EST and occlusion cholangiogram play integral roles in ensuring successful duct clearance. Despite their longstanding and widespread utilization, there remains clear variability in how they are performed. We postulate that the lack of standardized terminologies and techniques has contributed to this. This impacts on everyday clinical practice and has led to heterogeneity in the reporting of clinical trials. Above, we have summarized the evidence in the literature and highlighted the shortcomings of current practice. There should be an impetus to standardize the definitions, descriptors, and techniques of these commonly performed practices via further research, expert consensus, and societal

guidelines. We believe that standardization will lead to improved quality in clinical research and everyday practice ultimately leading to better patient outcomes.

WHAT KIND OF PRECUT EST TECHNIQUE (KIT) SHOULD BE USED?

Introduction and review of the literature

Precut sphincterotomy is the technique defined by performing a cut/incision prior to cannulation of the CBD to gain access. This is usually required when standard techniques fail to achieve selective biliary cannulation. The principle of the precut sphincterotomy for difficult biliary cannulation has been introduced by Huibregtse in 1986.^[86] Various precut techniques have been developed, including needle-knife papillotomy (NKP), needle-knife fistulotomy (NKF), and transpancreatic sphincterotomy (TPS). In the NKP, the incision starts at the papillary orifice and is extended cranially toward the 11 o'clock position to expose the bile duct. In NKF, the incision is begun from the top/middle of the roof of the papilla and extended downward toward the papilla. After the initial exposure, a white bulge of the bile duct with superficial capillaries is seen. Further incision is performed until the pink mucosa of the bile duct is exposed. Through this incision, the bile duct is cannulated with the wire. In TPS, after inadvertent wire insertion into the pancreatic duct, the sphincterotome is used to cut the septum between the pancreatic and bile duct, along the direction of 11 o'clock position, the expected direction of the bile duct, while the guidewire remains in the pancreatic duct.

Both NKF and NKP are effective techniques in cannulating the bile ducts. NKF is more favorable as the incision creates a choledochoduodenal fistula distant to the papillary orifice and pancreatic duct. In a study comparing NKF and NKP,^[87] the rate of pancreatitis was higher in the NKP group. In a meta-analysis comparing TPS with NKP,^[88] TPS had a higher success rate and less bleeding than NKP. There was no difference in pancreatitis, perforation, and total complication rates between the two techniques. In another retrospective study,^[89] which compared the three types of precut techniques, there was no difference overall in CBD cannulation rates, bleeding, and perforation, but in the NKF group, there was reduced PEP risk. Another study aimed to evaluate the efficacy and safety of TPS, NKF, or both based on the presence of unintentional pancreatic access and pancreatic morphology.^[90] The overall success

rate of biliary cannulation was similar with TPS, NKF, and NKF over pancreatic stent (PS). No severe adverse event was noted. A recent randomized study demonstrated reduced PEP rate after direct needle-knife precut compared to precut after two failed attempts of wire-guided sphincterotome cannulations^[91] though this study was not reflective of normal ERCP practice in a number of ways. Similarly, another randomized study documented avoidance (9.2% *vs.* 0%) of pancreatitis risk by direct NKF compared to the conventional cannulation method in a cohort with high risk for post-ERCP-pancreatitis.^[92]

Arguments in favor of “precut”

If the wire is in the pancreatic duct, and the papilla is small, then TPS has an advantage over NKF. After TPS has been performed, preventive pancreatic duct stenting is suggested.^[6] If the intraduodenal segment of the bile duct is bulged, NKF is a favorable technique due to the low pancreatitis rate.

Arguments against “precut”

In NKP, the incision starts at the papillary orifice, and so there is a slightly higher risk of pancreatitis compared to NKF. For the TPS technique, the PD has to be cannulated, so this technique is not favorable if the wire is not in the PD. In a small papilla, the depth and direction of the incision cannot be very well controlled with either the NKF/NKP technique.

Conclusion

The choice of precut technique depends on 3 factors: the experience of the endoscopists in different techniques, the papillary morphology, and whether there has been an unintended pancreatic duct cannulation.

PRECUT EST AFTER ZERO, ONE, TWO OR THREE FAILED CANNULATION ATTEMPTS

Introduction and review of the literature

Early timing of precut is mostly defined as within 10 min or after <5 cannulation attempts. A meta-analysis of 7 randomized trials with 999 patients comparing early precut sphincterotomy with persistent cannulation attempts concluded that early precut results in lower PEP rate.^[93] Furthermore, another meta-analysis with subgroup analysis of trainee involvement found that the risk of PEP is reduced for early precut compared to conventional therapy when performed by experienced endoscopists.^[94] A randomized controlled trial including 303 patients

compared primary precut access using direct needle-knife precut against precut after 2 failed attempts of wire-guided sphincterotome cannulation. The PEP rate was significantly lower (0.67%) in the primary precut group than in the early precut group (5.2%; $P = 0.04$), while the overall cannulation success rate was similar.^[95]

Arguments in favor of early precut EST

When performed by experts, early precut reduces the risk of PEP and increases the chances of successful biliary cannulation compared to precut after multiple cannulation attempts when papillary oedema has already started.^[94] A very recent RCT showed superiority of primary precut EST compared to very early precut EST (after two failed wire-guided cannulation attempts) performed by one single experienced endoscopist in terms of both, bile duct cannulation time, and incidence of PEP, whereas success rate was equally high (>98%) with both techniques.^[91]

Arguments against early precut EST

CBD cannulation rate is high with conventional techniques and precutting requires a high level of skill. Therefore, most practitioners consider it only after protracted cannulation attempts.^[29,96,97]

Conclusion

Early precut by an experienced ERCP-ist is a safe procedure and can reduce PEP caused by swelling of the papilla due to prolonged cannulation attempts

DOES TRAINING INFLUENCE OUTCOME AND COMPLICATION RATE? MINIMUM TRAINING REQUIREMENTS, HOW TO MEASURE SKILLS?

Introduction and review of the literature

ERCP is one of the most advanced and technically challenging interventional endoscopic procedures and carries the risk of significant complications. Performing high-quality ERCP requires highly trained physical and manual skills as well as good clinical judgment and interpretation of findings. Acquiring these skills has a long learning curve and requires life-long learning with the ambition to constantly optimize one's techniques and maintain expertise.^[98,99]

Direct observation of procedural skills provides an assessment tool for trainees with direct feedback in

various domains of the procedure. In a prospective study including 109 trainees, a selective biliary cannulation rate of 89% was achieved after 300 hands-on ERCP procedures.^[98] Similar case numbers are suggested by a multicenter US study that found that the "average" trainees reached technical competency for level 2 complex ERCP at approximately 305 ERCPs.^[100] The ASGE recommends a minimum caseload of 200 ERCPs followed by a competence assessment before independent practice is considered.^[101] Cannulation rate of the native papilla >80%–90% is accepted as surrogate marker for competency but often (unsurprisingly) not achieved by trainees at the end of their program.

Arguments in favor of case-based requirements for ERCP training

Trainees need direct supervised hands-on exposure in a multitude of clinical scenarios. Minimal procedure volumes within the ERCP training curriculum would ensure that most trainees have the opportunity to achieve competence in complex interventional procedures.

Arguments against

Learning curves vary individually and sheer caseload does not ensure competency. Instead of time-or volume/case number-based accreditation models, competency-based approaches with regular assessments during supervised training reflect the individual progress and ability. The UK will agree on a dedicated training curriculum and the document is now open for expert consultation nationwide before completion end 2021 (<https://www.thejag.org.uk/news/new-training-pathways-in-ercp-and-device-assisted-enteroscopy—consultation-open>).^[101]

Conclusion

There are no globally agreed curricula for ERCP training programs; quality assessment tools and key performance parameter for ERCP such as the cannulation rate of the native papilla are under evaluation.

WHY DO WE NEED PROCEDURES BEYOND ERCP?

ERCP was introduced in the late 1960s^[102] and served initially as a diagnostic tool for the biliary and pancreatic system. Since then, however, less invasive imaging techniques such as CT, MRCP and EUS have largely replaced its diagnostic role. The development of EST facilitated access to the bile duct and interventional techniques such as stone extraction and stenting

were applied, thereby shifting the role of ERCP to the therapeutic arena. Until recently, ERCP had been considered first line in the management of biliary obstruction caused by either benign or malignant pathology. Endoscopic transpapillary stenting via ERCP enables biliary drainage with a high success rate (90%–95%) but is associated with considerable adverse event rates. Acute PEP, perforation, bleeding, cholangitis, or stent dysfunction that may require re-intervention which could occur in one out of 15–20 patients.^[103] Selective bile duct cannulation from the papilla for therapeutic biliary intervention cannot be achieved in approximately 10% of patients despite using modern accessories and techniques,^[12,103] though rates of biliary access are higher in expert hands. Furthermore, in patients with a complex duodenal diverticulum, surgically altered anatomy or duodenal obstruction, endoscopic access to the papilla may be technically impossible. Double guidewire cannulation, pre-cut papillotomy, fistulotomy, and TPS are techniques to improve the biliary cannulation rate. Reattempting ERCP after a few days is an alternative approach and may also be successful.^[104] When using all available techniques in patients with normal anatomy and a native papilla, bile duct cannulation should be achievable substantially in more than 90% of cases.^[105] The cannulation rate of a native papilla is suggested as quality indicator for ERCP by the UEG. The ASGE/ACG task force suggests that operators who persistently achieve < 80% in terms of cannulation rate should undergo retraining or discontinue ERCP.^[81] As the endoscopic transpapillary approach for biliary stenting in patients with malignant biliary obstruction is unsuccessful in 5%–10% of cases and is associated with a significant adverse event rate of about 5%, alternative techniques for biliary drainage are needed that provide a high success rate and a good safety profile.

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Conflicts of interest

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