Needle Knife Sphincterotomy for ERCP: A Review of Techniques and Outcomes

INTRODUCTION

 Successful biliary interventions during endoscopic retrograde cholangiopancreatography (ERCP) rely upon selective and timely access to the biliary tree. Despite advances in ERCP techniques and accessories, common bile duct cannulation may be unsuccessful in up to 5-15% of cases. Several advanced techniques for difficult biliary cannulation exist and are best utilized by experienced endoscopists in instances where standard biliary cannulation has failed. Advanced techniques such as needle-knife sphincterotomy, pre-cut fistulotomy, and transpancreatic pre-cut sphincterotomy have all been utilized for difficult biliary cannulation with varying rates of success. This review aims to present and compare some of the techniques that can be used when difficult biliary cannulation is experienced but will primarily focus on needle-knife sphincterotomy.

DEFINITIONS

Pre-Cut Papillotomy

Pre-cut papillotomy for difficult biliary cannulation was first introduced in 1986 by Huibregtse, Katon, and Tytgat. Since its initial description, pre-cut papillotomy has been referenced by numerous names and now possesses several synonyms which represent the same procedure. Pre-cut papillotomy can be referred to as pre-cut sphincterotomy, needle-knife sphincterotomy or papillotomy, and access sphincterotomy or papillotomy. The term needle-knife sphincterotomy is most commonly employed today. Regardless, the procedure is defined by the method whereby a biliary sphincterotomy is performed prior to achieving deep biliary access with a catheter and/or a guidewire in an effort to obtain said access. (Figure 1) In its first
description, pre-cut papillotomy was performed through the use of a fine-needle sphincterotome. The sphincterotome consisted of a straight wire that extended roughly 5mm from the tip of a cannula passed through the channel of a duodenoscope. The bare wire is placed at the papillary orifice and electrocautery is utilized while moving the wire superiorly to create an incision towards the 11 o’clock position (the expected position of the intra-duodenal portion of the distal common bile duct). After the incision is made and the outflow of bile is visualized attempts at access can then be performed with the needle knife catheter or with a standard catheter or sphincterotome, usually resulting in biliary access.\(^1\) (Figure 2) However, if the outflow of bile is not visualized and cannulation is unsuccessful the initial incision may be extended or deepened and attempts at biliary cannulation can be resumed. In addition, some endoscopists may elect to perform prophylactic pancreatic stent placement prior to performing the procedure in order to use the stent as a guide for the incision and in an attempt to reduce the rate and severity of post-ERCP pancreatitis (PEP). A recent meta-analysis demonstrated that prophylactic pancreatic stent placement significantly reduced the rate of post ERCP pancreatitis however, if stent placement fails pancreatitis rates increased by 35-66% in select high risk patients.\(^2\)

**Pre-Cut Fistulotomy**

Pre-cut fistulotomy is a variant of needle knife sphincterotomy. In this scenario, a sphincterotome is also utilized however, the initial incision begins superior to papillary orifice, often extending inferiorly towards to papillary orifice or, in some cases, superiorly. (Figure 3) The result of this incision is the creation of a choledocho-duodenal fistula that connects the duodenum to the common bile duct while leaving the Sphincter of Oddi intact. In theory, this approach may reduce the risk of PEP as the pancreatic orifice is not being instrumented.

**Transpancreatic Pre-Cut Sphincterotomy**

While not a true pre-cut procedure, transpancreatic pre-cut sphincterotomy has also been utilized for difficult biliary cannulation. Transpancreatic pre-cut sphincterotomy was first described in 1995 as an alternative to needle knife sphincterotomy or fistulotomy. This procedure attempts to utilize the pancreatic duct as guide for sphincterotomy and aid in common bile duct cannulation by cutting through the intra-ampullary septum between the pancreatic duct and the common bile duct. This procedure is performed by inserting a standard sphincterotome in the pancreatic duct under fluoroscopic observation. After the pancreatic duct is cannulated the cutting wire is exposed and
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Comparison of Techniques
Gaining access to the biliary system is the first and most important aspect of the majority of ERCP procedures. In the scenario of difficult biliary cannulation, the experienced endoscopist may elect to utilize one of the aforementioned procedures as a salvage technique for successful cannulation. The particular procedure performed may depend on operator experience and skill although some effort has been made to compare the individual techniques. Both needle-knife sphincterotomy and fistulotomy have largely similar successful biliary cannulation and complication rates although some studies suggest lower rates of post-ERCP pancreatitis following fistulotomy.\(^4,5,6\)

With regards to transpancreatic pre-cut sphincterotomy, some studies suggest higher biliary cannulation rates utilizing this technique compared to needle-knife sphincterotomy. However, reported successful biliary cannulation rates following needle-knife sphincterotomy were lower in these studies than is typically seen elsewhere throughout the literature which likely accounts for the difference seen between techniques.\(^7,8,9\) Given the conflicting findings, the remainder of this article will focus on needle-knife sphincterotomy as it is the most common advanced technique utilized during ERCP.

Indications, Success Rates, and Potential Adverse Events of Needle-Knife Sphincterotomy:

Indications
The use of needle-knife sphincterotomy for difficult biliary cannulation has been heatedly debated throughout the ERCP literature and some experts regard it as a risky technique whose benefit may not always outweigh the associated risks whereas others view it as a more routine maneuver.\(^10\) As with all endoscopic procedures, needle-knife sphincterotomy can potentially result in complications and it is the responsibility of the endoscopist to weigh the potential benefits against any potential harm. Given the potential for severe complications, routine needle-knife sphincterotomy should not be performed for purely diagnostic reasons and should, in general, be utilized following multiple failed attempts via standard cannulation approaches by an experienced endoscopist.\(^11\)

Successful Cannulation Rate
In its initial description, needle-knife sphincterotomy was only performed in patients following multiple failed attempts at standard biliary cannulation and resulted in successful cannulation in 53% of patients. Successful biliary cannulation through the initial needle-knife incision was increased to 91% of patients when a second ERCP was performed 2-3 days after the initial needle-knife procedure. Furthermore, the authors reported similar rates of complications between the patients that underwent needle-knife sphincterotomy compared to standard sphincterotomy.\(^1\) The overall success rate following needle-knife sphincterotomy has largely been reflected in other studies of similar size although successful biliary cannulation on initial ERCP is now much higher in the modern era, with many studies reporting success rates of 88-99%.\(^12,13,14,15\)

However, despite the reported high biliary cannulation rates following needle-knife sphincterotomy, successful cannulation is not guaranteed. It has been postulated that peri-ampullary trauma and the subsequent edema that can develop after multiple failed attempts at standard biliary cannulation may serve as an impediment to cannulation attempts via needle-knife sphincterotomy.\(^16\) In this scenario, the endoscopist is presented with the difficult decision of how to best obtain biliary access. Alternative methods for biliary access including percutaneous-endoscopic rendezvous, percutaneous transhepatic biliary cannulation, endoscopic ultrasound guided biliary duct access, and even surgical intervention do exist but are more invasive and are generally considered in the context of the indication for biliary access as well as patient stability.

On the other hand, if cannulation fails after
a needle-knife procedure is performed, a second ERCP after ampullary edema has resolved may provide some utility. A second ERCP has been associated with improved cannulation success while not leading to an increase in the rate of complications, but does come at higher cost and use of resources.\textsuperscript{16} In one retrospective review of patients with failed biliary cannulation following needle-knife sphincterotomy, a second, delayed ERCP provided successful cannulation at the previous needle-knife incision site in 75\% of patients. However, the success rate was significantly lower at 44\% if the second ERCP was performed less than 4 days of the initial needle-knife procedure. Interestingly, there were no patients who developed complications of delayed biliary drainage, such as cholangitis, due to failed cannulation after needle-knife was performed in this retrospective review suggesting that a delayed second ERCP is safe, efficacious and worth considering.\textsuperscript{17}

**Adverse Events**

Adverse events of needle-knife sphincterotomy can range from clinically insignificant to severe and most commonly include hemorrhage, pancreatitis, and cholangitis although duodenal perforation has also been reported.\textsuperscript{17} Published complication rates vary significantly throughout the literature but range from 5.7-23.4\%.\textsuperscript{14,16,17,18,19,20}

Critically, higher complication rates and lower biliary cannulation success rates with the use of the needle knife have been shown to significantly correlate with lower case volumes and operator experience.\textsuperscript{20} Furthermore, both clinically insignificant hemorrhage and mild pancreatitis comprise the majority of complications and may be partially influenced by the number of failed standard biliary cannulation attempts that occur prior to the employment of the needle-knife procedure. Currently there is no agreement on the number of failed cannulation attempts or procedure time that should lapse prior to the use of needle-knife sphincterotomy, nor is there likely to be agreement on this point in the future.

In one prospective study that evaluated complication rates of early needle-knife sphincterotomy (after 5 failed standard cannulation attempts) it was demonstrated that pancreatitis occurred less frequently than reported elsewhere in the literature, suggesting that perhaps the needle knife should be employed earlier during a difficult ERCP.\textsuperscript{13} Furthermore, Bailey et al. examined cannulation attempts as a continuous variable and found a sharp delineation between post-ERCP pancreatitis rates in patients who underwent 5-9
cannulation attempts (4.3%) and greater than 10 attempts (11.5%) before needle-knife was performed. In addition, needle-knife sphincterotomy was shown to not be an independent risk factor for the development of post-ERCP pancreatitis in a study of two successive, prospective, randomized controlled trials of biliary cannulation following needle-knife sphincterotomy in a previously uncannulated papilla. Moreover, there is some evidence that prophylactic pancreatic stent placement prior to needle-knife sphincterotomy reduces both post-ERCP pancreatitis rates as well as overall complications.

With regard to hemorrhage and duodenal perforation following needle-knife sphincterotomy, two prospective studies have associated needle-knife as a risk factor for the development of these complications. However, a meta-analysis of six randomized controlled trials conducted by Cennamo et al. found that there was no significant difference in rates of hemorrhage or duodenal perforation between patients who underwent needle-knife sphincterotomy versus persistent standard cannulation. Interestingly, the early implementation of needle-knife sphincterotomy was not associated with a higher biliary cannulation success compared to persistent standard cannulation attempts. These findings suggest that needle-knife sphincterotomy might be best reserved for patients deemed to have difficult ERCP although there is currently no universal consensus as to what constitutes difficult ERCP.

**Endoscopy Experience**

Several factors may influence the discrepancy between the reported successful biliary cannulation and complication rates in studies evaluating needle-knife sphincterotomy including: varying experience amongst endoscopists performing the needle-knife procedure and the number of failed standard cannulation attempts prior to performing needle-knife sphincterotomy.

To date, there have been relatively few studies designed to evaluate the required case volume and experience needed to perform needle-knife sphincterotomy safely. Perhaps the most well documented paper is a consecutive prospective observational study of needle-knife sphincterotomy performed in 253 patients by a single endoscopist who recently completed a third-tier biliary training program. In this study, the authors examined indications for needle-knife sphincterotomy, procedural success, and complication rates and found that there was an overall increase in successful cannulation following needle-knife sphincterotomy as experienced increased. However,
post needle-knife sphincterotomy complication rates remained stable as experience with the procedure and ERCP increased suggesting an inherent baseline complication rate that may not be affected by endoscopist experience. Interestingly, the need for needle-knife sphincterotomy decreased as ERCP experience with standard cannulation increased. In contrast, other studies have suggested that complication rates may be higher when needle-knife sphincterotomy is performed by endoscopists who perform <1 sphincterotomy per week (8.4% vs 11.1%). A separate retrospective analysis suggested that successful cannulation following needle-knife sphincterotomy was not associated with endoscopist experience and found a significant decrease in post-procedure complications following the completion of 100 needle-knife sphincterotomies.  

CONCLUSION

Many advanced procedures exist for difficult biliary cannulation and can be employed after attempts at standard biliary cannulation have been unsuccessful. Needle-knife sphincterotomy is one of these and has the potential to increase successful biliary cannulation up to 99% in instances where standard cannulation has failed. There is currently no consensus on when needle-knife sphincterotomy should be performed although some literature does suggest reduced complication rates when performed before 10 failed standard cannulation attempts. Many commonly employ the technique after less aggressive approaches fail. Furthermore, needle-knife sphincterotomy has also been associated with complications that can range from clinically insignificant to severe and life threatening. Needle-knife sphincterotomy should not be routinely utilized. Higher complication rates have been reported and appeared to correlate with endoscopist experience.

References

Needle Knife Sphincterotomy for ERCP: A Review of Techniques and Outcomes

(continued from page 20)


Answers to this month’s crossword puzzle: