Early 'shallow' needle-knife papillotomy and guidewire cannulation: an effective and safe approach to difficult papilla

Fausto Fiocca, Gianfranco Fanello, Fabrizio Cereatti, Roberta Maselli, Vincenzo Ceci and Gianfranco Donatelli

Ther Adv Gastroenterol

2015, Vol. 8(3) 114–120

DOI: 10.1177/

1756283X15576466

© The Author(s), 2015.

Reprints and permissions:

[http://www.sagepub.co.uk/](http://www.sagepub.co.uk/journalsPermissions.nav)

[journalsPermissions.nav](http://www.sagepub.co.uk/journalsPermissions.nav)

Abstract

Introduction: Needle-knife sphincterotomy (NKS), known as 'precut', is used worldwide to facilitate access to the common bile duct when standard cannulation has failed. This procedure is considered hazardous because it is burdened with high procedural related complications (bleeding and perforation). Its right timing is still debated. In this study we report our results using a modified precut approach, early shallow needle-knife papillotomy (eSNKP) coupled with guidewire cannulation in case of difficult papilla. We evaluated its safety and effectiveness.

Methods: From 2012 to 2014, 1034 patients underwent therapeutic ERCP. A total of 138 of them presented difficult papilla and were treated with eSNKP performed after 5 failed attempts of standard guidewire cannulation. Deep biliary cannulation rate was recorded, as well as intraoperative and postoperative complication rate.

Results: Successful biliary deep cannulation was achieved in 132/138 patients (95.7%) by means of eSNKP. In 6 patients (4.3%), cannulation failed even after eSNKP. ERCP was newly performed 72 hours later with successful and immediate guidewire biliary cannulation. Overall morbidity was 10.1% (14/138). No perforation occurred. Minor bleeding occurred in 4/138 cases (2.9%) and 10/138 patients (7.2%) developed mild pancreatitis.

Conclusion: In case of difficult papilla, eSNKP followed by guidewire cannulation increases the successful deep biliary cannulation with low rate of complications.

Keywords: early shallow needle-knife papillotomy, endoscopic retrograde cholangiopancreatography, guidewire cannulation, needle-knife papillotomy, precut sphincterotomy

Introduction

Selective cannulation of the common bile duct (CBD) is the 'primum movens' in therapeutic endoscopic retrograde cholangiopancreatography (ERCP). It is well known that the risk of procedure-related complications increases with the number of failed attempts by the standard technique.

In some patients, cannulation could be difficult due to anatomical features of the papilla. In these cases, needle-knife papillotomy (NKP) – the so-called 'precut' – is one of the possible techniques used to achieve deep biliary cannulation. In NKP the incision is started from the upper lip of the

papillary orifice (at the 11 o'clock position) and proceeds upwards, over the papillary mound. The extent of the cut is determined by the intraduodenal bile duct, stopping short of the upper margin of the bulge [Mavrogiannis *et al.* 1999]. However, this technique is often considered hazardous in view of the increased rate of morbidity such as bleeding and perforation [Freeman, 2002]. Furthermore, there is no certain agreement concerning the systematic use of a soft-tipped guide-wire to gain biliary access following NKP.

The primary cannulation time with a standard sphincterotome is generally less than 5 minutes and requires only a couple of attempts [Cortas

Correspondence to:
Gianfranco Donatelli, MD
Unit of Interventional
Endoscopy, Department of
General Surgery 'Paride
Stefanini', Sapienza
University of Rome,
Viale del Policlinico
155, 00161, Rome, Italy
Unité d'Endoscopie
Interventionnelle, Hôpital
Privé des Peupliers, 75013
Paris, France
[donatelligianfranco@
gmail.com](mailto:donatelligianfranco@gmail.com)

Fausto Fiocca, MD
Fabrizio Cereatti, MD
Roberta Maselli, MD
Vincenzo Ceci, MD
Unit of Interventional
Endoscopy, Department of
General Surgery 'Paride
Stefanini', 'Sapienza'
University of Rome, Italy

Gianfranco Fanello, MD
Surgical Sciences
Department, 'Sapienza'
University of Rome, Italy

et al. 1999]. However, many authors have suggested that allowed attempts on the papilla should be between five and 10 [Kapetanios *et al.* 2007; Cotton *et al.* 2009]. In about 5–10% of procedures, even after several attempts, the access to the bile duct fails, also with the aid of the guide-wire technique, and even in experienced hands [Cortas *et al.* 1999; Loperfido *et al.* 1998; Schwacha *et al.* 2000]. Difficult cannulation is defined as a situation where the endoscopist, using a standard cannulation technique, fails within a certain time limit or after a certain number of unsuccessful attempts [Udd *et al.* 2010]. In these cases, several different methods have been described to achieve deep cannulation of the biliary duct.

NKP is normally considered the second option to achieve deep biliary cannulation because it seems to be associated with higher rate of morbidity [Kaffes *et al.* 2005]. However, there are no clear indications in the literature concerning the right timing of this maneuver and the actual risk of procedure-related complications [Larkin and Huibregtse, 2001; Misra, 2009].

Some technical modifications have been proposed to minimize the risk of complications, such as needle-knife fistulotomy with the incision made from above downwards. The needle is positioned at about the junction of the upper third and the lower two-thirds of the ampullary mound, the incision begins to the left of the mid line toward the 11-o'clock position and stops short of the papillary orifice. Moreover, many groups propose early implementation of precut in cases of difficult approach to the papilla [Cennamo *et al.* 2009, 2010].

The aim of this retrospective study is to analyze the success rate of biliary deep cannulation and the related complications using a modified NKP technique named early shallow NKP (eSNKP) coupled with guidewire cannulation in cases of failure of primary biliary cannulation after five attempts. Early implementation and employment of only 3 mm of the knife's length were routinely carried out to minimize risk of complications related to prolonged attempts with standard procedure.

Materials and methods

From January 2012 to June 2014, 1034 elective therapeutic ERCP procedures for benign and malignant biliary diseases were performed at the

Sapienza University of Rome. Data were collected in a prospectively maintained database and were retrospectively analyzed for this study. Informed consent was obtained in all patients. The study was approved by the Institutional Review Boards for Human Research.

All procedures were carried out by experienced therapeutic endoscopists or under their supervision (F.F., G.D.). Each trainee (F.C., G.F.) had experience of at least 150 ERCP procedures. The procedures were continued by an experienced endoscopist after two failed attempts by the trainee. In 138 patients (13.3%), primary cannulation of the papilla failed within five attempts due to different factors such as impacted stones, periampullary diverticula, small orifice and 'floppy' papilla; 27 patients out 138 presented with malignant disease (pancreatic cancer, cholangiocarcinoma). A cannulation attempt was defined as a 5 second contact with the papillary orifice and/or guidewire probing. Difficult papillae in this series were: impacted stones (35.7%); periampullary diverticula (20.4%); small papilla orifice (26.5%); and 'floppy' papilla (17.4%). In all these cases, eSNKP and guidewire cannulation was attempted as first option after failure of a standard cannulation technique. Neither pancreatic stent nor NKP were used to gain access to CBD.

A triple lumen needle-knife sphincterotome (Microknife XL[®], Boston Scientific, Natick, MA, USA) was used. Diathermy was set at Endocut mode (120W, effect 2) (Olympus[®] PSD-60). Considering the anatomy of the papilla (Figure 1), shallow NKP was performed starting from the upper lip of the papillary orifice and proceeding upward for 3–5 mm; the peculiarity of eSNKP is the systematic use of a reduced knife's length. A maximum 3 mm of length (Figure 2) was used to cut the papilla mucosa and submucosa superficially until exposure of muscular fibers and visualization of the biliary orifice. Particular attention was paid to avoid needle deep penetration in the papilla reaching the duodenal wall (Figure 3a–f). After eSNKP, biliary orifice was probed by a 0.035-inch hydrophilic angled soft-tipped guidewire (Radiofocus GuideWire M, TERUMO[®] Medical Corporation, Somerset, NJ, USA) *via* a conventional sphincterotome (Ultratome XL Short Nose, Boston Scientific[®], Natick, MA, USA) and deep biliary cannulation attempted for five consecutive times, followed by contrast injection and complete sphincterotomy if achieved (Figure 3g–i).

Figure 1. Anatomy of the papilla: the thickness of the mucosa and submucosa layers of the papilla ranges from 2.5 to 3.5 mm (focus in the figure). This is exactly the cutting range of eSNKP. CBD, common bile duct; eSNKP, early shallow needle-knife papillotomy; GB, gall bladder; PD, pancreatic duct.

As mentioned above, the main difference in eSNKP compared with standard NKP is that it relies on the systematic use of only a small part (3 mm) of the knife in order to maintain the cut as superficial and thus reducing risk of complications.

Results

Successful deep biliary cannulation was obtained in 132 patients (95.7%) within five attempts after eSNKP; however, the pancreatic duct was also cannulated in 13 patients before selective biliary cannulation. In the remaining six patients (4.3%) after five failed attempts to achieve deep biliary cannulation, the procedure was interrupted to minimize the risk of complications. A new ERCP was performed after 72 hours with successful and immediate guidewire biliary cannulation. A completely therapeutic procedure was carried out in all 138 cases.

Pancreatic stents were not used to prevent post-ERCP pancreatitis because, due to guidewire probing, the pancreatic duct was never opacified; moreover eSNKP reduced papillary edema. Nor were indomethacin suppositories used as a preventive measure due to their controversial role in preventing post-ERCP pancreatitis [Amara *et al.* 2014; Döbrönte *et al.* 2014].

Figure 2. Triple lumen needle-knife sphincterotome (Microknife XL, Boston Scientific, Natick®, MA, USA) used with a maximum needle length of 3 mm.

No perforations occurred during and after the procedure. Minor bleeding occurred during the papillary incision in four patients (2.9%). They were all successfully treated with intraoperative submucosal adrenaline injection (1:10000). A total of 10 patients (7.2%) developed a mild pancreatitis (as indicated by the Cotton Classification [Cotton *et al.* 1991]) treated with fasting and intravenous (i.v.) gabexate 900 mg/day for 3 days; in all cases clinical recovery and blood tests normalization were obtained within 5 days. Overall morbidity was 10.1% (14/138 patients).

Overall, the morbidity rate for the 896/1034 patients who underwent ERCP without implementation of eSNKP was 5% (45/896), while the mortality rate was 0.1% (1/896).

Bleeding occurred in 10/896 patients (1.1%); 7/10 cases presented a minor intraprocedural bleeding treated with submucosal injection or direct flushing of diluted adrenaline; and 3/10 patients presented delayed bleeding requiring blood transfusion in two cases and radiological embolization in one.

Post-ERCP pancreatitis was developed by 25/896 patients: 20/25 presented a mild pancreatitis and 5/25 a moderate one. All patients were treated with fasting and i.v. gabexate 900 mg/day.

Cholangitis was observed in 9/896 patients (1%) and perforation occurred in one case (0.1%) due to sphincterotomy in a patient with large periam-pullary diverticula.

One mortality case was recorded: a patient presented with jaundice due to advanced neoplastic

Figure 3. eSNKP procedure. A–C: a triple lumen needle-knife sphincterotome (Microknife XL, Boston Scientific, Natick, MA, USA) is used for a papillary incision (from the upper lip of the papillary orifice) and proceeding upwards for 3–5 mm. D–F: maximum 3 mm of length of the knife is used to cut the duodenal mucosa and submucosa superficially until exposure of muscular fibers and visualization of the biliary orifice. G–I: after eSNKP, the biliary orifice is cannulated by a 0.035 inch hydrophilic angled soft-tipped guidewire (Radiofocus GuideWire M, TERUMO Medical Corporation, Somerset, NJ, USA) *via* a conventional sphincterotome (Ultratome XL Short Nose, Boston Scientific, Natick, MA, USA). eSNKP, early shallow needle-knife papillotomy.

disease and died from hepatic encephalopathy 12 hours after the procedure.

Discussion

Selective biliary deep cannulation during therapeutic ERCP may fail in up to 5–10% of cases, even in

experienced hands [Testoni *et al.* 2011]. Regardless of the endoscopist's skills, failure to achieve deep biliary cannulation depends on anatomical peculiarities. In the literature, the major anatomical features leading to difficult cannulation are periampullary diverticula, lack of space and bulky papilla [Horiuchi *et al.* 2007; Farrell *et al.* 1996].

In our study, small papillary orifice and floppy papilla were considered difficult papillae as these two conditions can cause ampullary trauma.

Biliary cannulation with a standard technique should always be attempted first, even in the presence of difficult papilla. We usually use a standard guidewire sphincterotome for cannulation to minimize papillary manipulation and contrast medium injection into the pancreatic duct. This option has been shown to reduce the papillary trauma, mechanical damage, edema and impairment of pancreatic juice [Cheung *et al.* 2009]. The main advantage of the guidewire technique is that successful biliary cannulation can be confirmed fluoroscopically, eliminating pancreatic duct opacification [Bourke *et al.* 2009].

It seems that a difficult papilla alone could be considered a risk factor for post-ERCP complications and, in particular, that each failed attempt on the papilla increases the risk of post-ERCP pancreatitis [Bailey *et al.* 2008; Cheon *et al.* 2007]. However, there is no agreement in the literature on how many attempts or how much long the endoscopist should try before choosing other options in order to avoid procedure-related complications. Bailey and colleagues analyzed the number of attempts as a continuous variable, finding that between five and nine attempts of papilla cannulation, the incidence of post-ERCP pancreatitis was 4.3% and not significantly different from the <5 attempts group at 3.3%. However, in their series, there was a clear transition point at 10 or more attempts, with a more than doubled incidence of post-ERCP pancreatitis to 11.5%, peaking at 15% when >15 attempts were recorded [Bailey *et al.* 2010].

Some authors reported a time limit for the standard technique varying from 10 to 0.5 hours [Udd *et al.* 2010; Kaffes *et al.* 2005; Zhou *et al.* 2006]. However, the majority of studies conclude that the number of attempts is a more reliable method to assess the increased risk of complications. We support this statement and, to minimize the prolonged manipulation of the papilla, a maximum limit of five attempts was used as a cutoff in our study to define a difficult cannulation and to proceed to an eSNKP. We agree with the statement by Tham and Vandervoort who suggested that the resulting greater number of cannulation attempts at the papilla and multiple inadvertent pancreatic injections may be the dominant causative factor

in the association between precut papillotomy and post-ERCP pancreatitis, rather than the precut papillotomy 'per se' [Tham and Vandervoort, 2010], as showed in our study. We believe that, in case of failure of deep biliary cannulation for difficult papilla, it is better to adopt the precut technique at an early stage. Even if the possibility of resorting to NKP in the past was considered somehow dangerous, recently many authors do not identify it as an independent risk factor [Cheng *et al.* 2006; Laohavichitra *et al.* 2007].

An increasing number of studies demonstrate that early institution of NKP is safe and effective to obtain deep biliary cannulation in difficult papilla. There is evidence that earlier use of NKP for cases of difficult cannulation may ameliorate the occurrence of post-ERCP pancreatitis in the difficult cannulation subgroup [Kaffes *et al.* 2005; Laohavichitra *et al.* 2007].

Concerning the procedure-related complications, this technique seems to reduce only the incidence of post-ERCP pancreatitis but not the overall complication [Cennamo *et al.* 2010]. With regard to bleeding and perforation, our study shows that our modified technique of eSNKP, with reduced depth of incision (maximum 3 mm), allows us to pass with the guidewire through the roof of the biliary duct thus reducing the risk of damage to the duodenal wall. However, eSNKP, being a free-hand technique that requires a well-established learning curve, should be performed only in high-volume endoscopic centers and by experienced operators.

In conclusion, our results suggest that in cases of difficult papilla and after five failed attempts of standard guidewired cannulation, performing eSNKP is safe and associated with a high success rate of deep biliary cannulation with a low incidence of post-ERCP pancreatitis and other procedure-related complications such as bleeding and perforation.

Conflict of interest statement

The authors declare that there is no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

References

- Amara, J., Cellier, C., Samaha, E., Rahmi, G., Barret, M., Canard, J. *et al.* (2014) The effect of rectal ketoprofen in the prevention of post ERCP acute pancreatitis. *United European Gastroenterology Week 2014*: P0763.
- Artifon, E., Sakai, P., Cunha, J., Halwan, B., Ishioka, S. and Kumar, A. (2007) Guidewire cannulation reduces risk of post-ERCP pancreatitis and facilitates bile duct cannulation. *Am J Gastroenterol* 102: 2154–2156.
- Bailey, A., Bourke, M., Kaffes, A., Byth, K., Lee, E. and Williams, S. (2010) Needle-knife sphincterotomy: factors predicting its use and the relationship with post-ERCP pancreatitis (with video). *Gastrointest Endosc* 71: 266–271.
- Bailey, A., Bourke, M., Williams, S., Walsh, P., Murray, M., Lee, E. *et al.* (2008) A prospective randomized trial of cannulation technique in ERCP: effects on technical success and post-ERCP pancreatitis. *Endoscopy* 40: 296–301.
- Bourke, M., Costamagna, G. and Freeman, M. (2009) Biliary cannulation during endoscopic retrograde cholangiopancreatography: core technique and recent innovations. *Endoscopy* 41: 612–617.
- Cheng, C., Sherman, S., Watkins, J., Barnett, J., Freeman, M., Geenen, J. *et al.* (2006) Risk factors for post ERCP pancreatitis: a prospective multicenter study. *Am J Gastroenterol* 101: 139–147.
- Cennamo, V., Fuccio, L., Repici, A., Fabbri, C., Grilli, D., Conio, M. *et al.* (2009) Timing of precut procedure does not influence success rate and complications of ERCP procedure: a prospective randomized comparative study. *Gastrointest Endosc* 69: 473–479.
- Cennamo, V., Fuccio, L., Zagari, R., Eusebi, L., Ceroni, L., Laterza, L. *et al.* (2010) Can early precut implementation reduce endoscopic retrograde cholangiopancreatography-related complication risk? Meta-analysis of randomized controlled trials. *Endoscopy* 42: 381–388.
- Cheon, Y., Cho, K., Watkins, J., McHenry, L., Fogel, E., Sherman, S. *et al.* (2007) Frequency and severity of post-ERCP pancreatitis correlated with extent of pancreatic ductal opacification. *Gastrointest Endosc* 65: 385–393.
- Cheung, J., Tsoi, K., Quan, W., Lau, J. and Sung, J. (2009) Guidewire *versus* conventional contrast cannulation of the common bile duct for the prevention of post-ERCP pancreatitis: a systematic review and meta-analysis. *Gastrointest Endosc* 70: 1211–1219.
- Cortas, G., Mehta, S., Abraham, N. and Barkun, A. (1999) Selective cannulation of the common bile duct: a prospective randomized trial comparing standard catheters with sphincterotome. *Gastrointest Endosc* 50: 775–779.
- Cotton, P., Garrow, D., Gallagher, J. and Romagnuolo, J. (2009) Risk factors for complications after ERCP: a multivariate analysis of 11,497 procedures over 12 years. *Gastrointest Endosc* 70: 80–88.
- Cotton, P., Lehman, G., Vennes, J., Geenen, J., Russel, R., Meyers, W. *et al.* (1991) Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc* 37: 383–393.
- Döbrönte, Z., Szepes, Z., Izbéki, F., Gervain, J., Lakatos, L., Pécsi, G. *et al.* (2014) Is rectal indomethacin effective in preventing of post-endoscopic retrograde cholangiopancreatography pancreatitis? *World J Gastroenterol* 20: 10151–10157.
- Farrell, R., Khan, M., Noonan, N., O’Byrne, K. and Keeling, P. (1996) Endoscopic papillectomy: a novel approach to difficult cannulation. *Gut* 39: 36–38.
- Freeman, M. (2002) Adverse outcomes of endoscopic retrograde cholangiopancreatography. *Rev Gastroenterol Disord* 2: 147–168.
- Horiuchi, A., Nakayama, Y., Kajiyama, M. and Tanaka, N. (2007) Effect of pre-cut sphincterotomy on biliary cannulation based of the characteristics of the major duodenal papilla. *Clin Gastroenterol Hepatol* 5: 1113–1118.
- Kaffes, A., Sriram, P., Rao, G., Santosh, D. and Reddy, D. (2005) Early institution of pre-cutting for difficult biliary cannulation: a prospective study comparing conventional *versus* a modified technique. *Gastrointest Endosc* 62: 669–674.
- Kapetanios, D., Kokozidis, G., Christodoulou, D., Mistakidis, K., Dimakopoulos, K., Katodritou, E. *et al.* (2007) Case series of transpancreatic septotomy as precutting technique for difficult bile duct cannulation. *Endoscopy* 39: 802–806.
- Larkin, C. and Huibregtse, K. (2001) Precut sphincterotomy: indications, pitfalls, and complications. *Curr Gastroenterol Rep* 3: 147–153.
- Laohavichitra, K., Akaraviputh, T., Methasate, A., Leelakusolvong, S. and Kachintorn, U. (2007) Comparison of early pre-cutting *versus* standard technique for biliary cannulation in endoscopic retrograde cholangiopancreatography: a personal experience. *World J Gastroenterol* 13: 3734–3737.
- Loperfido, S., Angelini, G., Benedetti, G., Chilovi, F., Costan, F., De Berardinis, F. *et al.* (1998) Major early complications from diagnostic and therapeutic ERCP: a prospective multicenter study. *Gastrointest Endosc* 48: 1–10.

Mavrogiannis, C., Liatsos, C., Romanos, A., Petoumeno, C., Nakos, A. and Karvountzis, G. (1999) Needle-knife fistulotomy *versus* needle-knife precut papillotomy for the treatment of common bile duct stones. *Gastrointest Endosc* 50: 334–339.

Misra, S. (2009) Pre-cut sphincterotomy: does the timing matter? *Gastrointest Endosc* 69: 480–483.

Schwacha, H., Allgaier, H., Deibert, P., Olschewski, M., Allgaier, U. and Blum, H. (2000) A sphincterotome-based technique for selective transpapillary common bile duct cannulation. *Gastrointest Endosc* 52: 387–391.

Testoni, P., Testoni, S. and Giussani, A. (2011) Difficult biliary cannulation during ERCP: How to

facilitate biliary access and minimize the risk of post-ERCP pancreatitis digestive and liver disease. 43: 596–603.

Tham, T. and Vandervoort, J. (2010) Needle-knife sphincterotomy and post-ERCP pancreatitis: time to lower the threshold for the needle? *Gastrointest Endosc* 71: 272–274.

Udd, M., Kylänpää, L. and Halttunen, J. (2010) Management of difficult bile duct cannulation in ERCP. *World J Gastrointest Endosc* 2: 97–103.

Zhou, P., Yao, L., Xu, M., Zhong, Y., Gao, W., He, G. *et al.* (2006) Application of needle-knife in difficult biliary cannulation for endoscopic retrograde cholangiopancreatography. *Hepatobil Pancreat Dis Int* 5: 590–594.