Needle knife papillotomy: how safe and how effective?

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Abstract
Between January 1986 and July 1988 needle knife papillotomy was attempted in 103 patients after failure of conventional access for endoscopic sphincterotomy (96 cases) or diagnostic cholangiography (seven cases). Access was obtained at the same session in 36 cases and at a subsequent attempt within 2 to 5 days in a further 43, an overall success rate of 77%. The procedure related morbidity and mortality in the therapeutic group were 5.2% and 0.0% respectively. There were no deaths or complications in the diagnostic group. Needle knife papillotomy is a valuable adjunct to conventional techniques of biliary access.

Endoscopic retrograde dye injection into the pancreatic-biliary tree (ERCP) was first described in 1970 and is now successful in over 95% of cases. A wide variety of helpful diagnostic cannulas (including tapered, metal tipped, and guidewires carrying metal are available. It has replaced the percutaneous transhepatic route for diagnostic cholangiography in many centres.

Endoscopic sphincterotomy developed naturally from ERCP in 1973-4 and now has an established, widely repeated success rate of 90-95%. Its success rate is, however, lower after Billroth II gastrectomy (despite the development of specialised sphincterotomes) and in the presence of duodenal diverticulosis. Many new modalities of endoscopic treatment have been developed on the basis of endoscopic sphincterotomy for both benign and malignant biliary tract disease. These include stone extraction and fragmentation, stricture dilatation and stenting, and tumour irradiation.

If conventional diagnostic or therapeutic endoscopic biliary access fails, needle knife papillotomy may secure success. This involves, however, by definition, a less controlled incision and as alternatives are available, including precutting, percutaneous transhepatic catheterisation (including the combined percutaneous-endoscopic technique), and surgery, many endoscopists have not used the technique. It is important therefore to determine in practice how much the use of the needle knife improves the endoscopic success rate and at what cost in terms of added procedural morbidity and mortality.

Patients and methods
Between January 1986 and July 1988, 748 therapeutic biliary procedures (including many as tertiary referrals) were attempted, and in 96 needle knife papillotomy was used after failed conventional biliary access. In addition, seven patients undergoing purely diagnostic cholangiography had needle knife papillotomy performed after failure of conventional access. This was used only if cholangiography was of high clinical importance. Needle knife procedures were performed only by the most experienced endoscopists. (JFD, ARWH, JC, PRS). Many conventional attempts were made in all patients in the diagnostic groups before the needle knife was used, but it was used in patients in the therapeutic group at the time of first ERCP by our group.

There were 65 women and 38 men. The mean age was 71 years. Possible reasons for conventional access failure were evident in 92 patients (malignant duodenal distortion 31, very low common bile duct sticture due to periampullary/pancreatic head tumour 40, duodenal diverticulosis 11, impacted stone seven, Billroth II gastrectomy three). The remaining 11 patients had no apparent reason for failed access. The patients are listed in the Table. The indication for diagnostic cholangiography was possible sclerosing cholangitis in three, possible cholechoolithiasis in three, and possible choleodochal cyst disease in the other. The therapeutic benign disease subgroup included 16 patients with cholechoolithiasis, two with papillary stenosis, and two with benign biliary strictures. All malignant disease treated in this series was primary (ampullary, pancreatic, gall bladder, bile duct).

The outcome of the procedures was prospectively recorded on a computer data base and the complication rate and mortality determined by a review of all inpatient medical and nursing notes. Longer term follow up was obtained from referring consultants, general practitioners, and death registers.

Technique
The needle knife papillotome consists of an outer plastic sheath (5 Fr) and an inner solid stainless steel wire which can be projected from the plastic sheath. It is available commercially or may be homemade from broken bowstring sphincterotomes. There are many possible variations in

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**Table: Needle knife papillotomy**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Success</th>
<th>Failure</th>
<th>Complication</th>
<th>Procedure</th>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic</td>
<td>5</td>
<td>2</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Therapeutic</td>
<td>17</td>
<td>3</td>
<td>(P, B)</td>
<td>(P, B)</td>
<td>None</td>
</tr>
<tr>
<td>Benign</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malignant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>45</td>
<td>18</td>
<td>(B, B, B)</td>
<td>None</td>
<td>3</td>
</tr>
<tr>
<td>Hilar</td>
<td>12</td>
<td>1</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

B = bleeding; P = pancreatitis.
Figure 1: Diagramatic representation of needle knife papillotomy with both en face (a) and side (b) views of the papilla of Vater. In the side view both pancreatic and bile ducts are seen as well as the common pancreaticobiliary channel. Frames (i) to (iii) demonstrate the technique of papillotomy with the needle knife first placed in the common channel and then moved progressively up the papilla by endoscope withdrawal (arrow). Alternatively, if possible the cut may be made entirely by progressive endoscope bridge elevation rather than scope withdrawal. Both techniques direct the cut away from the pancreatic duct and involve only the roof of the bile duct or common channel, or both. After incision the cut is probed with a soft diagnostic cannula (in), the upward bend of which aids access. If this fails, an Erlangen papillotome may be used gently to provide more upward elevation or the needle knife may be used again to lengthen the incision. For endoprosthesis insertion, guide wires may be introduced via the diagnostic cannula or sphincterotome to maintain access.

the technique of its use. The basic technique favoured by the endoscopists in this centre is shown in Figure 1. Because the control of depth and direction is more difficult in this form of papillotomy, it should be used only by experienced practitioners and only after conventional approaches fail. It is our policy to use the needle knife at the time of initial ERCP if better conventional access cannot be envisaged at a later attempt. Further, the needle knife may be preferable to available ‘reverse’ sphincterotomes for at least the initiation of sphincterotomy in post-BII gastrectomy patients. Only papillas with a definite visible intraluminal protrusion signifying a reasonable length of intraduodenal bile duct should be attempted. Flat papillas, particularly those with a small periorificeal ‘face’, are best not treated as complications are probably more common and success is less likely. Moreover, the use of the needle should be particularly careful if neither the pancreatic nor the bile duct has been filled with dye and the endoscopist should make certain in this situation that the major papilla, rather than a more prominent than usual minor papilla, is being addressed.

It is advantageous to start papillotomy at the papillary orifice and cut proximally up the ampulla. Distal to proximal cutting allows better control of depth and direction and means that the direction of cutting is away from the pancreatic duct. Better control is obtained because of the fact that bridge elevation actively pushes the knife up whereas bridge depression does not actively pull the knife down and also because endoscope withdrawal is a smoother and straighter process than endoscope insertion. Another advantage of upward cutting is that the cut may be stopped as soon as bile efflux indicates entry in the bile duct and the blind cutting is thus limited to the distal papilla, with sphincterotomy then being completed using a conventional bowstring sphincterotomy.

Because of the small area of needle knife to tissue contact a high current density is produced and rapid cutting or considerable tissue injury and swelling may ensue. It is therefore best to make short rapid controlled cuts with repeated review of depth and direction rather than a single longer cut which, if incorrect, may be very difficult to salvage. If stenting is desired and wide channelled instruments are used initially (as is always our practice) control of the knife in the spacious channel may be difficult. This may be overcome if needed by the use of an overtube to narrow the channel. It is also important to remember that the length of the exposed wire may vary depending on the amount of bending of the plastic sheath. It is therefore essential to check the length of exposed wire with the plastic sheath uncoiled outside the endoscope and to carefully review the length of exposed wire endoscopically. It is always safer to err on the side of a smaller, more superficial cut than a longer, deeper cut, as the incision can always be deepened and extended. We usually aim to have 3–4 mm of exposed wire and to keep the plastic sheath adjacent to the papilla surface during the cut, thus producing a cut with uniform depth (Fig 2). The proximal cutting should never be extended beyond the junction of the papillary bulge and the flat duodenal wall, nor should it traverse a major transverse fold or papillary hood (the latter should be pushed off the papilla before incision).

Probing after the initial incision should always be done gently with smooth ended diagnostic cannulas rather than with the more blunt ended needle knife sheath. If the duct is identified but is still difficult to access because of angulation problems, gentle use of a conventional sphincterotomy, with tightening of the wire before cannulation providing the necessary upward angulation, may be helpful. Contrast injection should not be tried until the cannula has slipped easily into a duct, as submucosal injection may occur which, although probably harmless, may hinder good radiological visualisation and make further manipulation more difficult due to the swelling produced. Penetration of the soft diagnostic cannula into the retroperitoneal space is undesirable but usually has few sequelae.

If access fails, a repeat at two to five days when oedema has settled is worth while. Access may now be very easy. If it is still difficult the direction and depth of the initial needle knife cut may be reviewed and if not ideal a further incision may be made. It must be stated, however, that a poorly directed needle cut by an inexperienced endoscopist may make later access by a more experienced operator more difficult than if the papilla had been left uncut.

Results
Of the seven procedures in which the needle was
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used to try to obtain diagnostic cholangiography after failed conventional access, five were successful and two failed. In two patients (29%) the access was obtained at the initial session and in three patients (43%) at a subsequent session. No procedural complications or deaths occurred.

Of the 96 attempted needle knife papillotomies for biliary treatment of malignant biliary obstruction, choledocholithiasis, or papillary stenosis, biliary access was gained in 74 patients (74/96, 77%). The bile duct was accessed at the initial session in 34 of these cases and at a second session at two to five days in 40. The overall success rate of sphincterotomy for therapeutic access in the unit was 96.2%, the needle knife contributing an additional 9.6%. There were two fatal (one haemorrhage, one pancreatitis) and three non-fatal (haemorrhage) papillotomy/sphincterotomy related complications, giving an overall complication rate of 5.2%. Both fatal complications developed immediately after the initial needle knife, coincided with failed cholangiography, and occurred in elderly patients with choledocholithiasis without sepsis as the indication for treatment. The bleeding was evident at the time of endoscopy and prevented completion of the procedure. Neither patient was considered fit for surgery. The procedure related mortality was thus 2%. All three patients with non-fatal bleeding had overt melena with an appreciable fall in haemoglobin within 48 hours of papillotomy but no fall in blood pressure. All had failed biliary access even after a repeat attempt and had subsequent combined percutaneous-endoscopic therapy. Fixed extraluminal dye (submucosal or retroperitoneal) was seen after injection in five cases but no clinical sequelae were evident. Three patients died from carcinomatosis within 30 days of successful biliary access for stenting, thus giving an overall 30 day mortality of 5.2% for the reviewed group.

Access failures were further managed as indicated by percutaneous, combined percutaneous-endoscopic, or surgical means.

Discussion

Since the first report of needle knife papillotomy in 1980 it has been used in some centres. Possible indications now include not only impacted intrapapillary stones but also assistance with access to the common bile duct or pancreatic duct after failure of conventional methods of access and transduodenal choledochotomy above small ampullary tumours for the creation of choledochoduodenal fistulas. There has, however, been little discussion of the success and complication rates of the technique or of the relative merits of alternatives.

The use of the needle knife for diagnostic cholangiography was restricted in this series as the authors do not believe the risks involved allow it to be indicated in preference to percutaneous transhepatic cholangiography in most cases. Its use, however, in selected cases was safe (no complications in seven patients) and effective (72%). The success rate of sphincterotomy using the needle knife after failed conventional biliary access was 77%. This improved the overall success rate of sphincterotomy for treatment from 87% to 96.2% and thus allowed non-surgical treatment to be applied more often. The complication rate related directly to the needle knife procedure in patients undergoing attempted therapeutic procedures was 5.2% and the procedure related mortality was 2.0%. The commonest complication by far was haemorrhage. Although pancreatitis was uncommon, the one case was fatal. All haemorrhagic complications were associated with failed treatment. No clinical retroperitoneal perforation occurred. This complication rate, however, may not only be due to the needle but also to the longer than average conventional technique manipulation of the papilla before failure was acknowledged, the completion of sphincterotomy by the bowstring sphincterotome, and the fact that difficult papillas were selected by conventional failure –
for example, in diverticulum, adjacent infiltrating periampullary tumour, associated duodenal distortion, papillary stenosis).

The main alternatives to the use of the needle knife are precutting and the combined percutaneous-endoscopic procedure which was first described in 1982. Precutting involves the use of a bowstring sphincterotome with the cautery wire emerging from the end rather than at a distance of 5–10 mm along the shaft. The cut is made with the sphincterotome inserted only a small distance – that is, presumably in the common pancreaticobiliary channel. This is safe if the common channel is long, but if it is short and the precut knife lies in the pancreatic duct, a considerable amount of pancreatic tissue may be cut by the sphincterotome tip before the bile duct is entered. This may lead to a higher incidence of pancreatitis and haemorrhage than with the needle knife technique which seeks to avoid this pancreatic tissue septum. Combined percutaneous-endoscopic access has recently been shown to have an appreciable complication rate, though not all the complications relate to access alone. The combined procedure should therefore probably be reserved for pure endoscopic failure, which includes attempted needle knife papillotomy at the time of initial failed conventional access.

It is thus clear that needle knife papillotomy is a helpful procedure but probably carries additional, though not prohibitive, risk. It may be used therefore by the most experienced endoscopist available to increase the success rate of common bile duct access after initial conventional method failure, if in the opinion of the operator better access might not be obtained at a repeat attempt. Its use in the diagnostic only investigation of benign biliary disease should probably, however, be strictly limited.

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