

Comparative analysis of endoscopic precut conventional and needle knife sphincterotomy

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Abstract

AIM: To compare the efficacy, complications and post-procedural hyperamylasemia in endoscopic pre-cut conventional and needle knife sphincterotomy.

METHODS: We performed a retrospective analysis of two pre-cut sphincterotomy (PS) techniques, pre-cut conventional sphincterotomy (PCS), and pre-cut needle knife (PNK). The study included 143 patients; the classic technique was used in 59 patients (41.3%), and the needle knife technique was used in 84 patients (58.7%). We analyzed the efficacy of bile duct access, the need for a two-step procedure, the rates of complications and hyperamylasemia 4 h after the procedure, "endoscopic bleeding" and the need for bleeding control. Furthermore, to assess whether the anatomy of the Vater's papilla, indications for the procedure or the need for additional procedures could inform the choice of the PS method, we evaluated the additive hyperamylasemia risk 4 h after the procedure with respect to the above mentioned variables.

RESULTS: The bile duct access efficacy with PNK and PCS was 100% and 96.6%, respectively, and the difference between the two groups was not significant ($P = 0.06$). However, the needle knife technique required two-step access significantly more often, in 48.8% vs

8.5% of cases ($P < 0.0001$). The only complication noted was post-ercp pancreatitis (PEP), which was observed in 4/84 (4.8%) and 2/59 (3.4%) patients submitted to PNK and PCS, respectively; the difference between the two procedures was not significant ($P = 0.98$). An analysis of other consequences of the techniques yielded the following results in the PNK and PCS groups: hyperamylasemia 4 h after the procedure > 80 U/L, 41/84 vs 23/59 ($P = 0.32$); hyperamylasemia 4 h after the procedure > 240 U/L, 19/84 vs 11/59 ($P = 0.71$); pancreatic pain, 13/84 vs 7/59 ($P = 0.71$); endoscopic bleeding, 10/84 vs 8/59 ($P = 0.97$); and the need for bleeding control, 10/84 vs 7/59 ($P = 0.79$). In the next part of the study, we analyzed the influence of the method chosen on the risk of hyperamylasemia with respect to an indication for endoscopic retrograde cholangiopancreatography, papillary anatomy and concomitant procedures performed. We determined that the hyperamylasemia risk was increased by more than threefold [odds ratio (OR) = 3.38; $P = 0.027$] after PCS in patients with a flat Vater's papilla and more than fivefold (OR = 5.3; $P = 0.049$) after the PNK procedure in patients who required endoscopic homeostasis.

CONCLUSION: PCS and PNK do not differ in terms of efficacy or complication rates, but PNK is more often associated with the necessity for a two-step procedure.

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Key words: Sphincterotomy; Endoscopic; Endoscopic retrograde cholangiopancreatography; Complications; Hyperamylasemia

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INTRODUCTION

Pre-cut sphincterotomy (PS) may increase the efficacy of the ineffective conventional endoscopic cannulation of biliary ducts by 64%-91%, and some studies have reported increases in efficacy of up to 95%-99%^[1,2]. However, the efficacy and technical details of PS remain controversial, and the reported complication rates range from 3.78% to 19.2%, with an odds ratio (OR) of 0-2.71^[3-7]. Therefore, PS accounts for 0% to 44% of all sphincterotomies at various centers^[3,8-10]. The procedure may be performed by one of two methods, using either a non-needle knife or a needle knife^[3,5,6,11]. The first procedure is performed using a shallowly anchored conventional structure cannulotome [pre-cut conventional sphincterotomy (PCS)]^[11-13]; the second procedure (PNK), relies on a needle knife incision of the intramural part of Vater's papilla^[1,14]. Both methods are performed with various modifications that can independently influence complications^[5]. For example, a variation of PNK proceeds without the distal broadening of the incision to avoid Wirsung's duct orifice damage^[15]. In comparison with the conventional incision, this modification produces different anatomical results with an unknown impact on the complication rate and pancreatic juice efflux. The available literature presents only two studies comparing the PCS and PNK methods. However, in these trials, PCS was performed as a trans pancreatic sphincterotomy, and PNK began at the orifice^[13,16]. Different approaches to PS indication, different indications for the switch from conventional to PS procedures, technical PS variations, the rules of two-step procedure implementation and different definitions of complications at various centers explain the limited value of data reported by different authors^[13]. The lack of interpretable data by different authors prompted retrospective comparison of PCS and PNK (modified, without the distal broadening of the cut). The analysis included the efficacy of access to the common bile duct (CBD), the necessity to initiate a two-step procedure, the frequency of typical complications [post-ercp pancreatitis (PEP), bleeding, and perforation], the frequency of "endoscopic" bleeding, and the need for haemostasis, the influence on impaired pancreatic juice efflux and the need for further hospitalization. Additionally, we assessed the degree to which the effect of the PS method affects on the impaired efflux of pancreatic juice was dependent on papillary anatomy, procedural indications or concomitant procedures. The aim of the study was to answer two questions: (1) is there a difference between the efficacy and safety of the analyzed pre-cut methods; and (2) should Vater's papilla anatomy, procedural indications and concomitant procedures influence the choice of pre-cut method?

MATERIALS AND METHODS

Inclusion criteria

We included patients with ineffective common bile duct deep cannulation using a conventional cannulotome (Ol-

ympus KD 301Q-0729) and guide-wire (MET 35-380 Cook) after a 10 min procedure. Sphincterotomy using a conventional cannulotome was performed if sufficient anchoring in the papilla orifice was possible; the needle knife procedure was used in the remaining patients. Exclusion criteria: Patients with invasive procedures on Vater's papilla in the past, and acute pancreatitis before the endoscopic retrograde cholangiopancreatography (ERCP) procedure were excluded.

Study material

The study included patients submitted to ERCP from one center over 21 mo (February 2010 to November 2011). Papillotomy was performed on 402 patients, during that time frame, of whom 165 qualified for the pre-cut procedure. However, 22 were excluded from analysis because of a previous endoscopic attempt on the papilla or symptoms of acute pancreatitis before ERCP. Finally, 143 (35.6%) patients were admitted to the study. A conventional cannulotome was used in 59 (41.3%) of the patients in this group, the needle knife technique was used in 84 patients (58.7%).

Technique

The conventional pre-cut procedure was performed with a cannulotome (Olympus KD 301Q-0320). A 2 to 3 mm long incision was made after anchoring the cannulotome, and the end of the device was continuously repositioned toward the CBD orifice for deep cannulation. The patient was referred to a two-step procedure, if, a maximum of five trials of cannulation were ineffective. The next ERCP was performed 4-7 d later, after the tissue edema had regressed. The needle knife technique was performed with a KD-441Q Olympus cannulotome at the midway point between the papilla's orifice and the transverse fold. Catheterization was performed when the CBD orifice was exposed, and the sphincterotomy was proximally broadened with a conventional cannulotome with the distal fragment left intact. The procedure was postponed 4-7 d in cases with five ineffective trials of cannulation. For each PS technique, we used prosthesis if a randomly contrasted Wirsung's duct exhibited impaired retrograde contrast efflux. We performed endoscopic hemostasis with an HES solution (hypertonic 5.6% NaCl solution with adrenaline 1:20 000) for cases of bleeding for more than 2 min, which made further cannulation trials impossible. Serum amylase levels were measured in every patient to assess pancreatic juice efflux impairment 4 h after the procedure. Pancreatic pain requiring analgesics was assessed 24 h after the procedure, and pancreatic pain was an indication for subsequent serum amylase level assessment. The analysis: The PCS and PNK techniques were assessed according to the efficacy of CBD access, the necessity of a two-step procedure, pancreatic juice efflux impairment (amylase level > 80 UI after 4 h), hospitalization indications (amylase level > 240 IU after 4 h)^[3,17-19], and PEP, which was defined as an amylase level three times the upper limit with concomitant pancreatic

Table 1 Patient characteristics-risk factor

| | Needle-knife PNK (n = 84) | Conventional PCS (n = 59) | P value |
|-------------------------------|------------------------------|------------------------------|---------|
| Female | 43 | 38 | 0.16 |
| Age < 50 yr | 16 | 7 | 0.36 |
| Bilirubin level (norm) | 8 | 10 | 0.30 |
| Concomitant systemic diseases | 20 | 6 | 0.06 |
| Neoplasms | 26 | 17 | 0.96 |
| Retention cause | | | |
| Choledocholithiasis | 24 | 23 | 0.26 |
| Papillar stenosis | 14 | 10 | 0.85 |
| Distal stenosis | 18 | 13 | 0.70 |
| Middle stenosis | 3 | 5 | 0.37 |
| Hilum stenosis | 5 | 4 | 0.88 |
| Anatomy of the papilla | | | |
| Flat | 28 | 23 | 0.60 |
| Prominent | 32 | 23 | 0.94 |
| In diverticulum | 12 | 10 | 0.84 |
| Tumor | 18 | 5 | 0.06 |
| Biliary duct diameter | | | |
| (mean) | 14.49 | 14.07 | 0.42 |
| (< 9 mm) | 18 | 13 | 0.90 |
| Accessory procedures | | | |
| Prosthesis implantation | | | |
| CBD | 65 | 51 | 0.83 |
| Wirsung | 11 | 2 | 0.08 |
| Prosthesis in CBD | 6.01 | 5.89 | 0.59 |
| diam. (mean) | | | |
| Pathological sampling | 12 | 3 | 0.13 |

CBD: Common bile duct; PCS: Pre-cut conventional sphincterotomy; PNK: Pre-cut needle knife.

pain requiring analgesics 24 h after the procedure^[19-22]. We also analyzed bleeding, which was defined as the presence of clinical symptoms of blood extravasation into the alimentary tract^[20], the frequency of “endoscopic” bleeding (without clinical symptoms), and the necessity of hemostasis (no spontaneous regression 2 min after the incision). We compared perforations, which were defined as contrast extravasation out of the duodenal lumen during ERCP or gas in the retroperitoneal space on imaging^[8,9,22,23]. The PCS and PNK methods were submitted to logistic regression analysis to assess their influence on pancreatic juice efflux and the effect of Vater’s papilla anatomy (flat, prominent, inside diverticulum, or tumor), ERCP indications (choledocholithiasis, distal stenosis, or CBD diameter) and concomitant procedures (prosthesis, hemostasis, or pathological specimen sampling)^[19,23].

Statistical analysis

Frequency tables as well as χ^2 and Mann-Whitney *U* tests were used for the statistical analyses where appropriate. Unifactor and multifactor models of logistic regression were used to assess the probability that the analyzed parameters influenced the presence of hyperamylasemia. The measure of hyperamylasemia risk was expressed as an odds ratio (OR) with 95% confidence intervals. *P* values less than 0.05 were considered to be statistically significant, and the statistical analyses were performed using MedCalc ver. 12.3.

Table 2 Comparison of the efficacy and complication rates of pre-cut conventional sphincterotomy and pre-cut needle knife procedures

| Procedure | PNK (n = 84) | PCS (n = 59) | P value |
|------------------------------|--------------|--------------|----------|
| Two-step access | 41 | 5 | < 0.0001 |
| Efficacy | 84 | 57 | 0.58 |
| Amylase level (after 4 h) | | | |
| > 80 U/L | 41 | 23 | 0.32 |
| > 240 U/L | 19 | 11 | 0.71 |
| Pancreatic pain (after 24 h) | 13 | 7 | 0.71 |
| PEP | 4 | 2 | 0.98 |
| “Endoscopic” bleeding | 10 | 8 | 0.97 |
| Endoscopic homeostasis | 10 | 7 | 0.79 |
| Perforation | 0 | 0 | - |

PEP: Post endoscopic pancreatitis; PCS: Pre-cut conventional sphincterotomy; PNK : Pre-cut needle knife.

RESULTS

The study included 143 patients; the conventional pre-cut technique was used in 59 patients (41.3%), and the needle knife was used in 84 patients (58.7%). The clinical characteristics and risk factors were compared between the PCS and PNK groups, and the parameters are presented in Table 1. There were no significant differences between the groups with respect to the following parameters: sex, age < 50 years, percentage of patients with normal bilirubin levels, concomitant systemic and tumor diseases, cause of icterus (choledocholithiasis, or distal CBD stenosis), Vater’s papilla anatomy (flat, prominent, inside a diverticulum, or tumor) or the diameter of the common biliary duct. The frequency of prosthesis implantation in the CBD and pancreatic duct, the diameter of the prosthesis introduced to the biliary duct and the pathological specimen sampling did not differ between the groups. In the second part of the study, we assessed both techniques according to the necessity of introducing a two-step procedure, the efficacy of the endoscopic approach to the bile ducts and the consequences of the pre-cut procedures (Table 2). A two-step procedure was performed significantly more frequently in the PNK group, than in the PCS group (48.8% *vs* 8.5%, *P* < 0.0001). The two-step procedure allowed for CBD catheterization in all 45 patients in the PNK group, and 2 out of 5 patients in the PCS group. Biliary tree access was achieved in all patients treated with PKN and in 96.6% of patients treated with the PCS technique. Differences in the efficacies of the two methods were not statistically significant; however, in the PNK group, successful access was more frequently associated with a two-step procedure. There were no significant differences in the number of patients with elevated amylase levels exceeding 80 IU and 240 IU 4 h after the procedure. Pancreatic pain was observed 24 h after the procedure in 15.5% and 11.9% of patients in the PNK and PCS groups, respectively, and the differences were not statistically significant. Moreover, there were no notable differences in the rates of PEP. PEP was observed in 4.8% of the patients in the PNK group, and 3.4% in the PCS group. All PEP cases exhibited a mild or mod-

Table 3 Logistic regression-Hyperamylasemia (> 80 U/L) 4 h after the procedure and its association with indication, Vater's papilla anatomy and additional procedures

| Parameter | Conventional (PCS) | | Needle knife (PNK) | |
|--------------------------|--------------------|------|--------------------|------------------|
| | P | OR | P | OR |
| Indications | | | | |
| Lithiasis | 1.4 | 0.73 | 0.19 | 0.52 |
| Distal stenosis | 0.98 | 1.01 | 0.98 | 0.96 |
| Middle stenosis | 0.38 | 0.52 | 0.55 | 0.67 |
| CBD diam. < 9 mm | 0.96 | 0.97 | 0.9 | 1.06 |
| Bilirubin level - N | 0.43 | 1.72 | 0.42 | 1.8 |
| Vater's papilla anatomy | | | | |
| Flat | 0.027 ¹ | 3.38 | 0.22 | 0.56 |
| Prominent | 0.034 | 0.28 | 0.86 | 1.0 |
| In diverticulum | 0.52 | 0.62 | 0.93 | 1.05 |
| Tumor | 0.96 | 1.04 | 0.9 | 1.06 |
| Additional procedures | | | | |
| CBD prosth. diam. < 6 Fr | 0.13 | 5.3 | 0.56 | 0.7 |
| Endoscopic haemostasis | 0.82 | 1.2 | 0.049 | 5.4 ² |
| Specimen sampling | 0.84 | 0.78 | 0.92 | 1.06 |

¹Statistically significant only in unifacto logistic regression; ²Statistically significant only in multifactor logistic regression. CBD: Common bile duct; OR: Odds ratio; PCS: Pre-cut conventional sphincterotomy; PNK: Pre-cut needle knife.

erate course and were not treated surgically. All bleeding events observed in both groups were qualified as "endoscopic". There were no significant differences between the two groups. The pre-cut procedure was not complicated by perforation or bleeding associated with clinical symptoms in any patient in either group. Additionally, the risk of hyperamylasemia 4 h after the procedure was evaluated for any association with procedural indications, papillary anatomy, common bile duct prosthesis, prosthesis diameter, bleeding hemostasis, or the collection of pathological specimens. Logistic regression analysis (Table 3) revealed a three fold increase in the risk of hyperamylasemia after the PCS technique in patients with a flat papilla (OR = 3.38), whereas the hyperamylasemia risk in PNK patients was 5 times higher (OR = 5.38) after endoscopic hemostasis.

DISCUSSION

The pre-cut procedure is used following an unsuccessful conventional cannulation attempt of the biliary tree. The procedure is performed using a variety of techniques that can roughly be divided into two major groups: PNK and PCS^[15]. Some authors believe that the conventional pre-cut procedure is the method of choice, and in case of its failure, needle cannulotome is recommended^[12]. PCS is widely believed to offer better direction and depth for the incision, which should decrease the risk of perforation and bleeding. However, each consecutive unsuccessful cannulation increases the risk of post-endoscopic pancreatitis (OR = 1.39), and can reach OR = 9.4 after more than 15 ineffective cannulations^[4,7]. PNK may be modified in the manner in which the incision is made, halfway between the orifice and the transverse fold with no distal

Table 4 Frequency of pre-cut sphincterotomy with a two-step approach, and efficacy of common bile duct cannulation (pre-cut conventional sphincterotomy and pre-cut needle knife procedures)

| Ref. | PS freq. | PS technique | Two-step | Efficacy |
|--|----------|--------------|----------|----------|
| Slot <i>et al</i> ^[1] | 16.5% | PNK | 12% | 99% |
| Kasmin <i>et al</i> ^[14] | 18.0% | PNK | 32% | 93% |
| Huigbregtse <i>et al</i> ^[21] | 19.2% | PNK | 47% | 91% |
| Dowsett <i>et al</i> ^[25] | 12.8% | PNK | 54% | 96.2% |
| Shakoor <i>et al</i> ^[26] | 3.8% | PNK | 13% | 85% |
| Leung <i>et al</i> ^[27] | 3.9% | PNK | 15% | 95% |
| Own material | 20.9 % | PNK | 48% | 100% |
| | 14.7% | PCS | 8.5% | 94.4% |
| Binmoeller <i>et al</i> ^[11] | 38% | PCS | 9% | 100% |
| Goff <i>et al</i> ^[12] | 44.0% | PCS | 14% | 97% |

PS: Pre-cut sphincterotomy; PCS: Pre-cut conventional sphincterotomy; PNK: Pre-cut needle knife.

elongation. This technique avoids manipulations in the vicinity of Wirsung's duct orifice, which is believed to decrease the risk of PEP. Nevertheless, inferior maneuverability in the direction and depth of the cut may increase the perforation rate^[14,15]. We found only two publications directly comparing the efficacy and safety of needle knife and non-needle knife PS methods^[16,13]. Therefore, we aimed to compare PCS and PNK (modified, without the distal broadening cut) in the present work. The limitations of the present study are the small number of patients and the retrospective format of the study. At least 8422 patients need to be analyzed to assess the lack of difference in PEP frequency between the two groups; however, this would be difficult to accomplish in a single study. The second limitation of the present analysis is the retrospective format of the study, which restrains the exclusion of all of the parameters that indirectly influence the results. This retrospective design explains the difference in the frequency of Vater's papilla tumor in the analyzed groups 18 (PNK) vs 5 (PCS) patients, which may suggest that the needle-knife technique was used more often in patients with Vater's papilla tumor. The difference was not statistically significant ($P = 0.06$); however, the possibility that the difference may become significant in larger sample sizes cannot be excluded. These conditions suggest the necessity of performing larger, prospective, randomized and multi-center studies.

There is a significant discrepancy in the frequencies of PS among various centers. The percentage of patients submitted to PNK in our study was comparable to other reports; however, conventional pre-cut papillotomy is rare. Nevertheless, both PS techniques were employed relatively often, (35.6% of all patients with sphincterotomy) (Table 4). This relatively high frequency was most likely the result of an early switch from the conventional method to the needle knife technique to lower the risk of PEP after multiple ineffective cannulation attempts^[24]. In the present study, the efficacy results demonstrated no significant differences between the PCS and PNK methods, nevertheless, needle knife incision more often

Table 5 Complication rates after pre-cut sphincterotomy

| Ref. | Pts. No. | PS type | Start of cut | All complications | PEP | Bleeding | Perforation |
|---|----------|---------|--------------|-------------------|------|----------|-------------|
| Slot <i>et al</i> ^[1] | - | PNK | Orifice | 12% | 0.5% | 5.5% | 3% |
| Kasmin <i>et al</i> ^[14] | 72/398 | PNK | Centre | 11% | 3.8% | 3.8% | 3.8% |
| Huibregtse <i>et al</i> ^[21] | 190/987 | PNK | Orifice | 2.6% | 1.0% | 1.5% | 0% |
| Dowsett <i>et al</i> ^[25] | 96/748 | PNK | Orifice | 5.20% | 1.0% | 4% | 0% |
| Shakoor <i>et al</i> ^[26] | 53/1367 | PNK | Orifice | 11% | 5.5% | 3.7% | 1.8% |
| Leung <i>et al</i> ^[27] | 20/510 | PNK | Centre | 20% | 0% | 20% | 0% |
| Donnellan <i>et al</i> ^[28] | 352/2603 | PNK | Centre | 4.8% | 1.0% | 4.2% | 0.3% |
| Our data | 84/402 | PNK | Centre | 4.80% | 5.4% | 0% | 0% |
| | 59/402 | PCS | - | 3.4% | 3.4% | 0% | 0% |
| Binmoeller <i>et al</i> ^[11] | 123/327 | PCS | - | 5.3% | 2.7% | 2.4% | 0% |
| Goff <i>et al</i> ^[12] | 32/110 | PCS | - | 12% | 12% | 0% | 0% |

PS: Pre-cut sphincterotomy; PEP: Pos-ercp pancreatitis; PCS: Pre-cut conventional sphincterotomy; PNK : Pre-cut needle knife.

requires a two-step implementation procedure. The overall efficacy of cannulation did not depend on the technique used and was not influenced by the higher frequency of the two-step procedure in PNK, which is similar to data from other centers (Table 4). The aim of the second part of the study was to compare the groups with respect to typical complications (PEP, bleeding, and perforation) and additional parameters, including increased amylase levels 4 h after the procedure, “endoscopic” bleeding confirmed in ERCP and the necessity for endoscopic hemostasis. We did not observe significant differences in any of the above mentioned variables. Similarly, investigators in Helsinki and a multicenter trial performed in China also reported no differences in the complication rates in a direct comparison of needle knife and non-needle knife PS^[16,13]. It should be noted that this study compared two different technical modifications of PCS and PNK. The pre-cut method with conventional sphincterotomy was performed after anchoring the cannulotomy in Wirsung’s duct; meanwhile, the PNK method the cut initiated in the orifice. These technical modifications explain why a direct comparison with the present trial is impossible. The data presented above also demonstrate a unique distribution of complications compared with other available reports (Table 5). We noted one complication, PEP, that fulfilled Cotton’s consensus criteria^[20]. A credible reason for the absence of clinically significant bleeding may stem from frequent endoscopic haemostasis in extravasation observed during the procedure. In contrast, there are various definitions of bleeding after ERCP, which may result in discrepancies in the presented data and make reliable comparisons impossible.

The most probable reason for the lack of perforation in all analyzed patients might be the frequent use of a two-step procedure. This method avoids of further cannulation trials in regions of edematous tissues with altered anatomy. It appears that repeating the procedure after edema regression, 4-7 d after the first procedure, may be safer than repeated cannulation trials, and the visible bile streak may facilitate proper localization of the CBD orifice. This idea is only partially supported by data from different centers. Dowsett *et al*^[25] and Huibregtse *et al*^[21] did not report perforation using a two-step procedure

after PN in almost half their patients; Shakoor *et al*^[26], Donnellan *et al*^[27] and Bruins Slot *et al*^[1], who described the use of a two-step procedure relatively rarely, reported perforation rates in 1.8% and 3% of their patients, respectively. However, Kazimin *et al*^[14] and Leung *et al*^[28] reports, did not report a similar relationship, which may be the result of their relatively low rates of PNK and the technical modifications in their methodology (Tables 4 and 5). One example of such a modification is Doswett’s suggestion^[25] to elevate the upper part of the papilla with the needle knife during PNK cutting, which should lower the risk of duodenal wall penetration. The lack of a standard procedure precludes reliable comparisons of results. Nevertheless, our data seem to validate the statement that the PCS and PNK methods do not differ in terms of complication rates, and that the PNK technique is more often associated with a two-step procedure, justifying the strategy to attempt PCS first and switch to PNK in case of PCS failure. It should be noted that the switch to PNK from PCS was performed relatively early in the presented material, because many ineffective cannulation trials may increase the risk of PEP^[24]. In contrast, the PCS procedure is not feasible in all patients including; for example, in cases of duodenum lumen stenosis in presence of a pancreatic head tumor or obstructed papillary orifice due to the deposit. Other situations that may indicate the use of different types of the pre-cut procedure may depend on papilla anatomy, procedural indications or concomitant actions. In the third part of our study, we attempted to determine which factors should impact the choice of the type of pre-cut procedure. For this reason, we assessed the procedural differences with respect to impaired post-procedural pancreatic juice efflux. The study revealed an additional risk (OR = 3.38) of impaired pancreatic juice efflux 4 h after the procedure in PCS patients with a flat papilla (Table 3). This finding suggests that specific anatomy should prompt special precautions in multiple cannulations, and that specific anatomy indicates an early switch to the needle knife technique, if feasible. However, a flat papilla is a contraindication for the PNK method due to the unsatisfactory depth control during the incision and the higher risk of duodenal wall penetration. We have performed the PNK procedure in 23 patients with flat

papillae without any perforations. It appears that in these patients, the omission of the PCS step and the direct conversion to PNK is reasonable. The second indication of a high risk (OR = 5.4) of hyperamylasemia 4 h after the procedure was hemostasis in patients after analysed PNK pre-cut modification. This result suggests that the necessity for hemostasis requires the distal upper part of the papilla to be incised to ensure proper pancreatic juice efflux in an environment of hemostatic edema. However, the relatively small sample of patients and retrospective character of the present study require further prospective research.

COMMENTS

Background

The pre-cut procedure allows access to the bile ducts in cases of conventional technique failure. However, there are variations in the detailed technique for this procedure, which are generally divided into the non-needle knife procedure using a cannulotome with a conventional structure, and the needle knife using a needle-shaped device. Both techniques have been widely modified, and there are no firm rules defining the indications for the type of technique of choice.

Research frontiers

Author assessed the efficacy and safety profiles of both techniques and estimated their influence on pancreatic juice efflux (on the basis of amylase levels 4 h after the procedure) according to papillary anatomy, indications and the type of concomitant procedures.

Innovations and breakthroughs

In the first part of the study, they compared two modifications of pre-cut sphincterotomy. In contrast to Halttunen's and Wang's studies, the conventional incision was performed without Wirsung's duct cannulation; In addition, another difference was the needle knife incision was initiated from the middle of the intramural portion without a distal incision. The second part of the study concerned the influence of the procedural technique used on pancreatic juice efflux impairment depending on papillary anatomy, indications for the procedure and concomitant procedures. The risk of hyperamylasemia is three times higher after the conventional pre-cut technique in patients with flat papilla. In the group of patients treated with the pre-cut needle knife technique, the risk of hyperamylasemia was five times higher after endoscopic hemostasis.

Applications

The primary part of the study revealed that both analyzed methods may be used interchangeably, as they exhibit no differences in complication rates. Nevertheless, the needle knife technique often requires two endoscopic retrograde cholangiopancreatography (ERCP) procedures and should be the method of choice in cases of conventional pre-cut incision failure. The reason for the increased risk of hyperamylasemia is hemostasis after the needle knife procedure. This finding suggests that leaving the distal papilla intact may impair pancreatic juice efflux. This could be addressed by an incision in the distal part of the papilla, which requires further study.

Terminology

Pre-cut conventional sphincterotomy describes the incision performed with a cannulotome in cases of unfeasible deep cannulation of bile ducts. Pre-cut needle knife procedure is performed with a cannulotome a protruding distal portion responsible for intramural incision of the papilla. The incision may be initiated from the orifice of the papilla (orifice cut) or in the middle segment of the intramural part (middle cut). In the second modification, the distal part may be dissected or intact (as in their data). Two-step procedure-describes the situation after the pre-cut procedure and failure to access bile ducts. The second ERCP is performed 4-7 d after the first one and avoids cannulation in the region of oedematous tissues with altered anatomy.

Peer review

In this retrospective paper, the authors compared safety and efficacy of two different pre-cut technique for biliary access. The authors conclude that the two techniques are basically similar concerning biliary cannulation success and complication rate, except for the need of a second intervention which was more needed in the needle knife group. This is an interesting paper.

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