

Safety and Feasibility of Fistulotomy versus Pre-Cut in Achievement of Selective Bile Duct Cannulation in Difficult to Cannulate Papillae: Randomized Controlled Study

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Abstract: Background: The aim of this prospective randomized study was to evaluate and compare the efficacy and safety of two different precutting techniques (fistulotomy and precut) in achievement of biliary cannulation in difficult to cannulate papillae. **Methods:** The patients with suspected distal malignant obstructive jaundice with difficult cannulation were enrolled in this study; they were randomized into two groups. The first group included 42 patients who underwent needle-knife fistulotomy avoiding the papillary orifice, the second group included 47 patients in whom standard pre-cut was done starting from the papillary orifice followed by short standard papillotomy. **Results:** Cannulation was successful in 95.52% of patients in the needle-knife fistulotomy group and 87.23% of patients in the needle-knife precut group. The cannulation time and x-ray dose were significantly shorter in fistulotomy group. The overall complication was significantly less in fistulotomy group, the complications were as follows for the needle-knife fistulotomy and needle-knife precut papillotomy groups, respectively: bleeding 5/42 (4.7%) and 9/47 (19.14%); perforation 0 % and 3/47(6.38%); cholangitis, 0% and one patient (2.12%); pancreatitis, 1/42 (2.38 %) and 7/47 (14.89%) ($p < 0.05$); and death 0 and one patient (2.12%).

Conclusions: Both techniques were effective in getting selective biliary cannulation, the fistulotomy had less complication than pre-cutting technique. But both technique should be reserved for difficult to cannulate papillae and should be done by experienced endoscopists.

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1. Introduction

ERCP is now a widely used technique not only for diagnosis and preoperative evaluation, but also for decompression of the bile duct when there is biliary obstruction, jaundice, and/or cholangitis.¹

Endoscopic trans-papillary biliary stent insertion is effective in decompressing the bile duct in patients with papillary carcinoma. However, endoscopic incision of the tumor with a sphincterotome may result in fatal bleeding, and stent occlusion leading to recurrent jaundice, cholangitis, or both.² For these endoscopic procedures, bile duct cannulation is an absolute prerequisites.

However, in patients with distal malignant biliary obstruction (papillary carcinoma, distal cholangiocarcinoma and cancer head of pancreas) it may be difficult to cannulate the bile duct through the tumor, which is often friable and bleeds readily in response to probing with a catheter. Moreover, the papilla is often distorted and may be displaced distally and not respecting the anatomical position.³

Endoscopic choledochoduodenal fistula formation (endoscopic fistulotomy) has been described in sporadic reports as an alternative procedure when bile duct cannulation with decompression is unsuccessful.⁴

Endoscopic cannulation is changeable for endoscopists, so not all endoscopists can perform ERCP perfectly; cannulation is not always possible especially in papillary lesions and distal CBD strictures. The success rate for the procedure ranges from 80% to 95%, even among highly experienced endoscopists and within highly equipped centers.⁵

In benign or malignant biliary obstruction when selective (deep) common bile duct (CBD) cannulation and consequent biliary drainage are not possible, a precutting technique is used. Among various techniques, precutting with a needle knife is the most popular.⁶

Although needle-knife precut papillotomy (NKPP) has been used many years ago and it is considered a useful assisting technique for achieving selective CBD cannulation, however a lot of controversies regarding its safety.^{4,6}

It carries higher rates of complications as pancreatitis, perforation, and bleeding than cannulation without using this technique.⁷

In an effort to develop safer precutting techniques, a variant of classic NKPP has been described. In this technique, an incision is made with a needle knife on the intra-duodenal part of the CBD (fistulotomy).

The incision is started few millimeters above the papillary orifice to avoid puncture and injury to the pancreatic duct and hence minimizing the post ERCP pancreatitis, which is considered the most serious complication. However, a consequence of the necessarily smaller length of the incision can be increased difficulty in selectively getting an access to the biliary system.^{8,9}

Aim of this study:

The aim of this prospective, randomized study was to evaluate and compare the efficacy and safety of two different needle-knife precutting techniques, needle-knife fistulotomy (NKF) and NKPP, in the selectively cannulate difficult to cannulate papillae.

2. Patients and Methods:

Subjects:

In our referral center (National Liver Institute-Menoufiya University), between January 2011 and December 2011, 809 ERCP examinations were done for patients with biliary obstruction, in home 89 cases had difficult cannulation; most of those patients had distal malignant biliary obstruction, consecutive biliary pre-cut or fistulotomy were done for assessing cannulation. The initial diagnosis of distal malignant obstruction was suggested by clinical, laboratory, and radiologic data, whereas the final diagnosis was documented by ERCP and in some cases intra-ductal biopsies or cholangioscopy were done to clarify the etiology of biliary stricture.

Technique:

Therapeutic duodenoscopes with a working channel diameter of 4.2 mm and an insertion tube diameter of 11.3 to 11.6 mm, accommodated a device up to 11.5 French were used for the examinations in our center. Endoscopic fistulotomy was performed as follows: after insertion of the duodenoscopes to the second part of the duodenum and major papilla was identified short scope is achieved and the intra-duodenal part of the distal CBD was identified by duodenoscopic examination as a bulge in the supra-papillary portion of the papilla. The distal CBD was punctured with needle knife (Wilson-Cook Medical Inc., Winston-Salem, N.C.) by using pure coagulation electrosurgical current. We inserted the whole length of knife(0.5 cm) in tissue depth of papilla at a point lying on the junction of proximal 1/3rd and distal 2/3rd of imaginary line extended between the papillary orifice at 11 o'clock and the duodenal fold and around 5mm width, the papillotome is inserted in this orifice, then a guide wire was introduced through this orifice to biliary system. After cholangiography, the diameter of orifice was considered sufficient if the papillotome is passed smoothly to the bile duct, or the contrast or bile flow is dropped down into the duodenum. If the diameter of the fistula was not sufficient a graduated

dilatator (Soehendra, Cook Endoscopy, Winston-Salem, North Carolina) is introduced to facilitate stenting of CBD, avoidance excessive dilatation should be considered to avoid stent dislocation up to the biliary system or down to the duodenum and losing the drainage way. The pre-cut was done in the standard method using the same needle knife starting from the papillary orifice and extended proximally till the point 2/3 and 1/3 of papillary duodenal line starting 11 o'clock.

Follow-up

All patients were evaluated at day 1, 3 and 7 after the procedure with vital signs, serum bilirubin, pain and signs or symptoms of bleeding or any complication of the procedure.

3. Results:

Between January 2011 and December 2011, 809 cases referred for ERCP to our center. The etiology of biliary obstruction was choledocholithiasis in 530 cases. The rest was due to biliary stricture, the large number of malignant cases in our center may related to that we are a major tertiary referral center for Endoscopy particularly for ERCP, cannulation was difficult in 89 patients and facilitation of cannulation was needed in them, because the time allocated for CBD cannulation expired (In our series the introduction of needle knife either for pre-cut or fistulotomy was introduced after trail of biliary cannulation using .035f guide wire for 10minutes and .025f guide wire for additional 5minutes or because of failure to enter the CBD after 5 pancreatic duct cannulations. Only experienced endoscopist (with more than 1000 ERCP examination by himself did the ERCP procedures).

All 89 patients were randomized to undergo either NKF (n = 42) or NKPP (n= 47). There were no exclusions to randomization for anatomic reasons (e.g., Billroth II or papilla within a diverticulum) or any other reason. Among the 89 patients (cancer head of pancreas in 56, distal cholangiocarcinoma in 13 and ampullay carcinoma in 14 cases the rest of cases had stricture with no evident cause).

All patients who underwent successful ERCP had a dilated bile duct; the diameter was more than 7 mm in patients with a gall bladder and more than 9 mm in patients who had undergone cholecystectomy.

Use of mechanical dilatation was done in 17 cases of NKF group and 36 cases in NKP group. In patients with detectable stones a stent insertions were done for proper biliary drainage and then ERCP was done again in another session and the patients were excluded from the study.

Table (1): the basic characteristics and clinical presentation of studied subjects.

	NKF n=42	NKP n=47
Age	45±5.6	40±4.5
Gender		
Male/female	28/14	34/13
Clinical presentation		
Jaundice	30	35
Pain	15	16
Cholangitis	4	4
Vomiting	3	4
Pancreatitis	2	2
Itching	24	33
Asymptomatic	3	2

Table (2): the operative and post-ERCP management of studied patients.

	NKF n=42	NKP n=47
Initial endoscopic procedure		
Successful in first session	34	37
Successful in second session	6	4
Over all success	40/42=95.23%	41/47=87.23%
Failed	2	6
Dilatation	17	36
Length of incision till cannulation	4±2 mm	11±7
Cannulation time	3.5±3 minutes	7±5 minutes
x-ray time	2±1.5 minutes	4.5±3 minutes
Metal stent	10	13
Plastic stent	30	28
Definitive treatment		
Surgery± Chemotherapy	6	8
Chemotherapy	34	36
No therapy	2	3

Table (3): complication of ERCP in studied groups.

	NKF n=42	NKP n=47	<i>p</i> - value
Complications (over- all)%	5/42	23/47	
Bleeding (total):			< 0.05
Major	2	9	
Required hospitalization and blood transfusion	0	2	
Minor			
Perforation (total):	2	7	
Minor	0	3	
Major	0	2	> 0.05
	0	1	
Pancreatitis (total):	1	7	
Severe (>5 times rise of serum amylase and lipase).	0	2	< 0.05
Mild	1	5	
cholangitis	0	1	
surgical emphysema (total)			> 0.05
Major	0	5	
(ICU admission ± intubation and oxygen).	0	1	
Minor	0	4	< 0.05

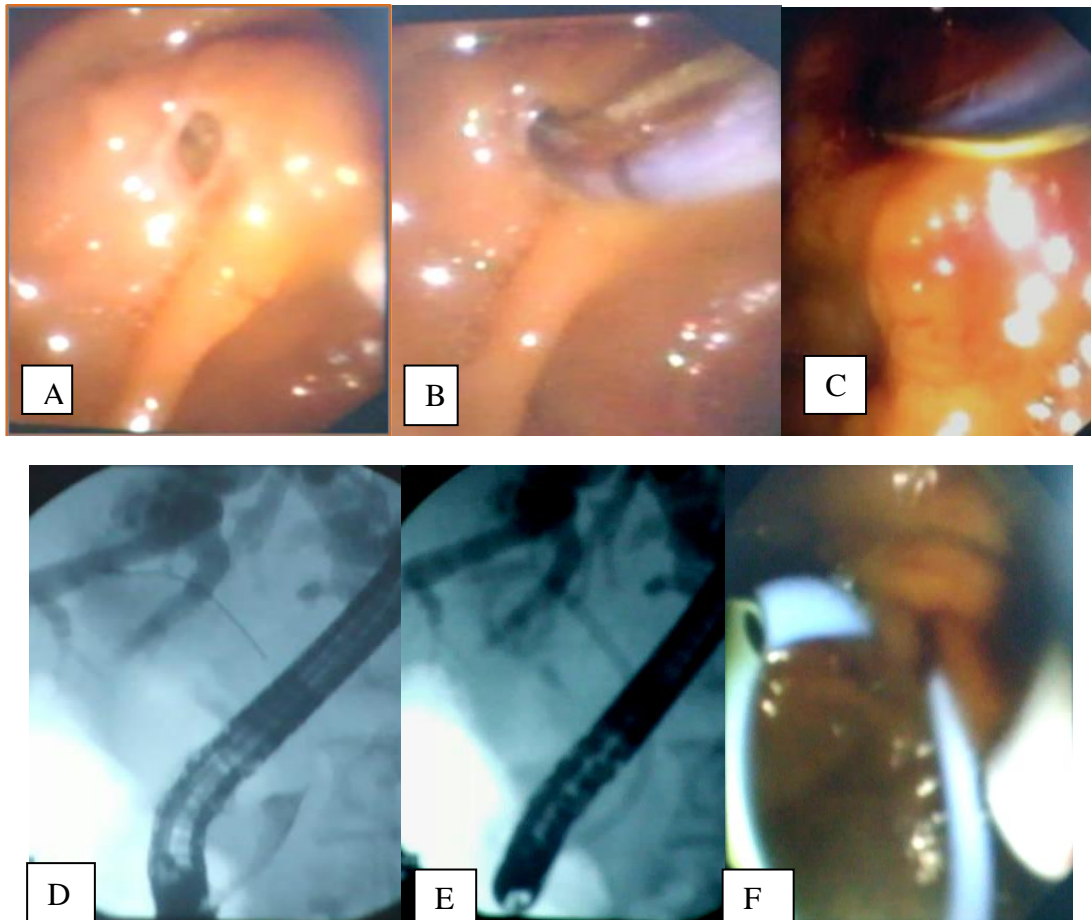


Figure (A): a small whole was done by needle knife in super-papillary portion. **Figure (B):** the papillotome was introduced through the orifice. **Figure (C):** guide wire passed through the papillotome to bile duct. **Figure (D):** the fluoroscopic picture, representing a guide wire inside CBD with distal stricture of CBD. **Figure (E):** the fluoroscopic picture of double pigtail was inserted passing the stricture. **Figure (F):** the duodenoscopic picture of duodenal end of double pigtail with adequate drainage.

Complication:

The overall complication rate was 11.4% in the NKF group (5 complications' in 5 patients out of 42 and 23 complications developed in 15 patients (31.9%) in the NKPP group, some patients developed more than one complication. We excluded non manifested pancreatitis (hyperamylasemia), which was not considered a complication. All complications followed the first ERCP, and non was reported after the second attempt.

Among the 9 cases of bleeding in pre-cut group, 7 were classified as minor and 2 as major (required further intervention by repeated endoscopy and effective injection therapy with 1:10,000 epinephrine; no further treatment was required. In NKF group 2 cases developed minor bleeding and managed conservatively. Only 1 case of perforation (NKPP group) required an operation. A T tube was placed, and the patient recovered

completely after 5 days in the hospital. The other cases of perforation were graded as mild and were managed with naso-gastric suction and antibiotics for 3 to 5 days.

Among the 7 cases of pancreatitis, in the NKPP group alone, 5 were classified as mild, 2 as severe. Surgical emphysema developed only in NKPP in 5 cases; 4 was mild and one case required further ICU and oxygen therapy for one week

4. Discussion:

Biliary drainage is preferred endoscopically, ERCP has a lot of complication even in highly equipped centers and with professional hands, but it has much less complication than Percutaneous drainage.¹⁰

Biliary cannulation is the first step in getting an access to biliary system and achieving biliary drainage. But it is not always easy or successful, so

precutting with a needle knife is mandatory for some cases.³

Pre-cut of the papilla before biliary cannulation was first reported by Siegel in 1980.¹¹

Subsequently, the invention of the needle-knife by Huibregtse greatly solved a great challenge for failed cannulation of biliary system.¹²

However the use of needle knife either in fistulotomy or pre-cut carries a lot of complication but it is not surely known if the complication is related to the use of the technique itself, or just a reflection of the previous repeated unsuccessful cannulation attempts before the use of needle knife. As in prolonged attempts to achieve cannulation may result in trauma and inflammation of the papilla with resultant edema accounting for the increased rate of pancreatitis.⁸

However before the needle-knife was used in difficult biliary cannulation, the risk of complications had already reached 14%¹ and at this point, with the addition of the needle-knife technique, this risk exponentially increased to 29%.⁴

But in a subsequent study, the early institution of the needle knife increased successful biliary access at the first attempt, with reduced rate of complications to 11.8%.⁸

Pre-cut with needle knife has more complication than the use of standard catheter or use of papillotomes in obtaining access to biliary system.¹³ We are in need to cut a lot of tissues for long distance in the papilla to reach the intra-duodenal portion of CBD, this carries a lot of complication as injury of pancreatic duct, bleeding, perforation and surgical emphysema with escape of air under the layers of papilla to the retro-peritoneum.

But in the use of needle knife fistulotomy expected to have less complication as we cut only for shorter distance than the use of standard pre-cut.

In our series we compared the use needle knife in fistulotomy versus standard pre-cut. We found that in the care of 89 of 809 (11%) patients with suspected distal biliary malignant obstruction among whom conventional endoscopic methods of achieving CBD access had failed. The percentage of patients with failed biliary cannulation without the use of needle knife in our study was comparable with that previously reported (16% to 44%) and the use of needle knife has been shown to be highly effective for cannulation of the CBD in these patients.

The success for achieving biliary cannulation between both groups was comparable, however the success was better in fistulotomy group.

This is in agree with experienced endoscopists who are familiar with the use of a needle knife, and success rates range between 85% and 99%.⁹

The possible reason for failure to get deep cannulation for some cases may argued to that malignant biliary obstruction; the tumor tissue does not respect the anatomy of biliary system and may be very hard, especially when performed by less-experienced practitioners.³

From our series we detected that in long papilla: the use of pre-cut methods is more risky as we are in need to cut a longer distance starting from the papillary orifice, in addition in papilla with nipple or misdirected (not in proper access with knife methods) more complication were noted in these cases.

The use of fistulotomy theoretically and practically from our series have less pancreatitis as we cut away from the pancreatic orifice making the injury or edema of pancreatic duct and hence pancreatitis are unlikely than that of standard pre-cut method.

Our prospective, randomized study was, to our knowledge, may not the first to compare the efficacy and safety of NKF and NKPP for the cannulation of CBD but it may the first comparing every variables met during ERCP procedures as complication, operative time till getting the access to bile duct and the exposure to X-ray which showed be minimized to lowest for operative team and patients.

NKF and NKPP were found equally effective in gaining access to the biliary tree after the first attempt (80.9% and 78.23%, respectively) and improved after the second attempt to (95.52% and 87.23%).

The overall success rate for both precutting techniques (93.1%) was comparable with that previously reported.^{2-4, 6-8}

Recchia *et al.*,¹³ reported a success rate of 96%, whereas O'Connor *et al.*,¹⁴ reported a success rate of 89% with the use of the same technique.

The value of a second attempt after initially failed first attempt in both groups improved the success of getting deep cannulation from 79.77% to 93.1%.

This may be explained by that in first attempt edema, inflammation and bleeding may affect the success in the first session.

The overall complication rate for both techniques was 13.07% (10.81% for NKF and 15.18% for NKPP).

Although the reported complication rates of precutting techniques vary and can be as high as 24.3% or 34%, in this study the rates were relatively high, especially among the NKPP group, so we advised that only experienced well skilled endoscopists should do these cases to minimize -as much as possible -the expected higher rate of complications. This was because of the relatively higher rates of bleeding in NKPP group, this may

explained by in pre-cut a longer incision should be done till reaching the access to biliary system, especially we cut through tumor tissue in patients expected to have bleeding tendency due to biliary obstruction and poor liver capacity in reflection to the present malignancy.

Pancreatitis was much less in fistulotomy group and this may explained by that in fistulotomy the incision was anatomically away from the pancreatic orifice and hence avoiding its injury.

Cholangitis, and death were infrequent and were comparable with rates for these complications reported in most studies.^{2-4,6-8}

However, most complications in this study were mild, and all patients, except one with severe pancreatitis and another with perforation who needed further interventions, did well with conservative treatment.

Bleeding as a result of precutting with a needle knife occurred among 12.36% of our patients (4.76% in the NKF and 19.14% in the NKPP group which was significantly high although most of these cases were minimal).

Significantly lower rates of bleeding have been reported by several investigators, such as Kasmin *et al.*,⁴ (4%), O'Connor *et al.*¹⁴ (1.2%), and Huibregtse *et al.*¹² (1.5%). variable explanations can clarify these data as most of our cases were malignant and bleeding tendency is affected with many reasons like prolonged biliary obstruction and the presence of liver disease. However, rates similar to those found in this study or even higher have been reported by others, including Bruins *et al.*¹⁵ (5.5%) and Katsinelos *et al.*¹⁶ who compared the complications in their series; Post-procedure acute pancreatitis was developed in 27 cases (20.9 %) with NKP, compared to two cases (2.6 %) with NKF. No difference was observed between the groups with regard to the occurrence of post-procedure hemorrhage and perforation. however the etiology of biliary obstruction in this study was not discussed

The relatively high rate of bleeding in our study might be related to use of pure cutting current for both precutting techniques. In our study, all 9 cases of bleeding were managed successfully, 3 by means of injection therapy and 6 by means of monitoring and follow-up examinations alone.

Pancreatitis was found only among the NKPP group (14.89%) versus 2.38% in NKF group. The statistically significant difference between the two groups ($p < 0.05$) implies that NKF most probably is a safer technique in terms of avoiding pancreatic injury.

The hypothesis that avoidance of thermal injury to the pancreatic duct by means of cutting above the papillary orifice minimizes risk for pancreatitis seems

to be reinforced by the results of this study, in addition in NKF group minimal trauma was induced due the less operative time consumed till getting our biliary access, although the concept remains controversial.¹

Kasmin *et al.*,⁴ and O'Connor *et al.*,¹⁴ reported low rates of pancreatitis (4% and 2.4%, respectively) after use of a similar technique.

We could not explain the relatively high rate of pancreatitis after NKPP (7.59%) compared with reported rates.

Most investigators have reported a lower rate of post-ERCP pancreatitis, including Rabenstein *et al.*¹⁷ (1.5%), Bruins *et al.*,¹⁵ (0.5%), and Huibregtse *et al.*¹² (1%). However, there are reports of less satisfactory results, including those of Freeman *et al.*,¹⁸ (3.6%, severe pancreatitis) and Buuren *et al.*¹⁹ (6%) and Ayoubi *et al.*²⁰

We are taking much care to minimize risk for post-ERCP pancreatitis (e.g., lack of experience, tapered catheters, repeated pancreatic cannulations, prolonged efforts to cannulate CBD) and attempted to cannulate the CBD in a programmed, step-by-step manner, (only experienced endoscopists did the ERCP for this study), post ERCP prophylaxis was also utilized by us by giving patients expected to have pancreatitis 200mg Diclofenac sodium suppository.

Asymptomatic hyperamylasemia has been reported among as many as 75% of patients after ERCP.¹ In this study, hyperamylasemia occurred more frequently after NKPP (17.72%) than NKF (2.7%), and the difference was statistically significant ($p < 0.01$).

The relatively higher incidence of pancreatitis and hyperamylasemia after NKPP re-enforces the view that thermal and mechanical injury to the pancreatic duct should be avoided and that NKF should be considered a safer alternative precutting technique.

Perforation and surgical emphysema was caused by the escape of air in retro-peritoneum. In our series they happened only in NKPP group and may attributed to the use of longer incision through a tumor tissue

Our results suggest that both NKF and NKPP are effective precutting techniques for treating patients for biliary drainage in the setting of distal biliary strictures attributed to malignancy when cannulation of the CBD by standard methods is not possible.

In our study we compared the cannulation time (the time from start of use needle knife till achieving biliary cannulation) was calculated for this study, it was significantly less in fistulotomy group than pre-cut group as we are not in need to cut this long

distance which was also significantly shorter in fistulotomy group. This minimized the patients risks either procedure or sedation related. We found no enough data in the literature about the comparison between both groups regarding operative time and this study might be the first study compared this item.

The exposure to X-ray during ERCP till now is hazardous to endoscopist and their assistants, unfortunately it is unavoidable, as endoscopists have to map the biliary system under fluoroscopic guidance. So minimizing the exposure to X ray is mandatory. In our study we X-ray dose (calculated from the start of ERCP procedure till getting guide wire in the bile duct). It was significantly shorter in the fistulotomy group. No possible data available

however the use of this technique should be reserved only for therapeutic reasons and must be performed by experienced endoscopists; the position, direction and depth of the needle-knife must be handled perfectly during cutting to avoid the high rate of complication. The needle knife techniques especially fistulotomy should be used to avoid additional risk factors such as prolonged attempts on the papilla or multiple pancreatic cannulations if satisfactory time was exempted.

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comparing the dose of exposure X ray and this study may be the first study comparing this variable between both groups.

Shorter operative time and less X-ray dose further more reinforce the use of biliary NKF versus the NKPP as it looks effective and more safer or at least less has less complication rate.

Conclusions and recommendation:

Needle knife fistulotomy and needle knife pre-cut were effective in assessing selective biliary cannulation in difficult to cannulate papillae, NKF is more safe to patients (had less complication and less operative time) and also for operative team (less exposure to the hazards of X ray) than NKPP, comparing conventional vs. a modified technique. *Gastrointestinal Endoscopy*. 62 (2005) 669–674.

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