

ROLE OF PRE CUT SPHINCTEROTOMY IN DIFFICULT BILIARY CANNULATION

SAJIDA QURESHI, SHAHRIYAR GHAZANFAR, FAHAD TARIQ, SAAD KHALID NIAZ,
M SAEED QURAI SHY

ABSTRACT

- Objective* To assess the success rate and complications of pre cut sphincterotomy (PBS) in achieving deep common bile duct (CBD) cannulation where standard techniques of biliary cannulation failed.
- Study design* Descriptive study
- Place & Duration of study* Surgical Unit 4, Civil Hospital Karachi from 14 October, 2006 to 18th December, 2007.
- Patients and Methods* Thirty five patients, in whom needle knife was done due to difficulty in achieving cannulation by standard means, in a 14 months period were included in the study. The data was entered into the ERCP database, locally developed at the time of ERCP and follow up was done at 24 hours and 15 days. Data was collected prospectively. No randomization was done. The main outcome measures were success and complications of precut sphincterotomy. Success of the PS was defined as the ability to deeply cannulate the CBD. Statistical data was extracted from the SPSS version 11. Variables were compared using Chi-square or t-tests as appropriate.
- Results* A total of 327 ERCP's were performed during the study period out of which 35 (10.70%) precut sphincterotomies were done. The average age in the PBS group was 44.83 years (range 26-80 years), and 71.4% (n=25) were females. Biliary cannulation was successful in 60% of the patients in the first attempt and 66.66% at a subsequent attempt. The cumulative success rate was 92.5%. Complication rate was 25.9%. Of seven PBS related complications pancreatitis occurred in four (11.4%), infection in two (5.7%) and bleeding in one patient (2.9%).
- Conclusions* Difficulty in PBS should be anticipated in post surgical patients with altered anatomy and collapsed biliary system like CBD leakage and long distal strictures. Complication rate increases with subsequent attempts at cannulation. Overall, in experienced hands, PBS is safe and effective procedure in achieving selective cannulation.
- Key words* Needle knife, Precut papillotomy, Precut up with needle (PUWN), Precut biliary sphincterotomy, Sphincterotomy, Endoscopic retrograde cholangiopancreatography (ERCP).

INTRODUCTION:

Since its introduction in 1974, ERCP has become a common procedure. Majority of ERCPs performed nowadays are therapeutic rather than diagnostic. Success rates depend on the proper training skills and experience of the endoscopist and range from 90 to 95 percent,

even when the technique is performed by experts.¹ Complications cannot always be avoided, with hemorrhage, pancreatitis, perforation of the duodenal wall, and cholangitis being the most frequent. Complications occur in approximately 10 percent of procedures, and about 1 in 100 patient dies.² ERCP is most commonly performed to remove biliary duct stones and is often substituted for surgical exploration of common bile duct in patients undergoing laparoscopic cholecystectomy.^{3,4} Papillotomy

Correspondence
Dr. Sajida Qureshi
Surgical unit 4, Civil Hospital Karachi.

or sphincterotomy is a technically complex endoscopic procedure performed under visual and fluoroscopic guidance. Bile duct cannulation can sometimes be difficult leading to inadvertent repeated cannulation and injection of the pancreatic duct leading to pancreatitis. In cases of cannulation failure by standard techniques, the papilla can be dissected to expose the bile duct using a variety of techniques known collectively as "precut" sphincterotomy^{5,6}.

Precut sphincterotomy enables the experienced endoscopist to increase the chances of successful cannulation in cases where other methods have failed. The conditions leading to difficult or failure of cannulation include papillary stenosis, impacted calculus, anatomical variations and surgery. Precut sphincterotomy is used in 3.8- 19.2% of ERCP procedures with a success rate ranging from 75% to 99% and complication rates from 1.9% to 30%.^{7,8} Many concerns about PBS among the experts however were based on findings from earlier studies.^{9,10} Complications of precut sphincterotomy are same as those encountered with conventional sphincterotomy namely bleeding, perforation, pancreatitis and cholangitis. The crux of the matter is whether these complications occur with increased frequency after precutting as compared to the standard sphincterotomy. There are two schools of thought; one group feels that precutting is inherently more dangerous than standard sphincterotomy while the other group feels it is safe, effective and less risky than repeated attempts to cannulate the bile duct which can result in trauma to the papillae causing edema and sphincter spasm.

Our study sought to evaluate the success and complication of precut sphincterotomy in difficult biliary cannulation and compare the results with national and international studies.

PATIENTS AND METHODS:

A prospective descriptive study was carried out at surgical unit 4, Civil Hospital Karachi, to evaluate the success and complication rate of PBS from October 14, 2006 – Dec, 2007 (14 months). Thirty five patients, in whom needle knife was done due to difficulty in achieving cannulation by standard means, were included in the study. The data was entered into the ERCP database, locally developed at the time of ERCP and follow up was done at 24 hours and 15 days. Informed consent was obtained from all the patients. Endoscopy was performed by a skilled endoscopist who had performed more than 1000 ERCPs. Repeat ERCP was performed after 1 week of failed precut sphincterotomy in some but not all of the patients.

The procedure was performed under sedation using I/V nalbuphine and midazolam titrated according to the patients' requirement. In non compliant patient, the procedure was done under propofol sedation. A standard sphincterotome (Ultratome XL by Boston Scientific) was used to attempt cannulation of the CBD. A guide wire along with the sphincterotome was used if the above method failed. If

cannulation was still unsuccessful then precut sphincterotomy was attempted using a needle knife, made from the standard sphincterotome, using blend setting of diathermy with cutting set to a higher value than coagulation. No prior placement of pancreatic stent was done.

Precut up with the needle (PUWN) method was used for precutting. Success of the PBS was defined as the ability to deeply cannulate the CBD. Approval was taken from the hospital ethical committee. Statistical data was extracted from the SPSS version 11. Variables were compared using Chi-square or t-tests as appropriate. $P < 0.05$ was considered statistically significant.

RESULTS :

A total of 327 ERCP's were performed during the study period in which 35 (10.70%) precut sphincterotomies were done. The average age in the PBS group was 44.83 years (range 26-80 years), and 71.4% (n=25) were females. The indication for PBS, in 35 patients included in the study were lower bile duct strictures (25.7%), common bile duct leak (14.3%), stones and dilated CBD and stricture upper CBD (11.4% each), high stricture (5.7%) and CBD cut off (2.9%).

PBS was successful with the first attempt in 21 out of 35 patients (60%). The causes found in successful PBS are shown in Table 1. Amongst 21 successful PBS, 3 patients had incomplete ERCP; due to equipment failure in one patient and noncompliance in the remaining two patients. The indications of procedure in the fourteen patients with unsuccessful PBS on initial attempt are shown in Table 1.

Fourteen patients, who had initial failure of PBS, repeat procedure was advised after 10 days. Patients were followed up for complications in the intervening period. Eight were lost to follow up and only six patients came back for a repeat procedure. Cannulation after PBS was successful in 4 patients out of these six. Failure of cannulation on second attempt occurred in two patients, both having previous history of biliary tract surgery and anatomical variation ($p=0.03$).

Evaluation of causes of failure in first attempt in 4 patients, who had successful follow up PBS cannulation, revealed that in two patient related factors (uncooperative patient and mentally retarded) were responsible for initial failure. Subsequent PBS and cannulation was successful under propofol, while in the other two no cause of failure could be recognized. The subsequent attempt success rate was 66.66% (4/6 patients). The cumulative PBS success rate was 92.5% (25/ 27 patients). Eight patients who did not come for repeat procedure were excluded from the study.

The complication rate of 35 PBS procedure was 25.9% (7/27 patients). Of seven PBS related complications pancreatitis was seen in four (11.4%), infection seen in two (5.7%) and bleeding in one patient (2.9%). Pancreatitis was classified

as mild in three and severe in one patient. Severe pancreatitis was classified when organ failure, local complications or pancreatic necrosis was present. Two patients had cholangitis, presented with high grade fever with chills, increasing jaundice and pain. All patients were managed successfully with antibiotics and supportive measures. None of the patients had perforation. Six out of seven patient with complications were those who had unsuccessful first time cannulation ($p < 0.011$). Bleeding was seen in one patient who had an impacted stone, which was exsanguinating enough to cumulate in death of the patient. Indications of the procedure in seven patients who had complications are shown in table 2 and table 3

always be inserted into the bile duct successfully, leading to the failure in ERCP. So precut can increase the success rate of ERCP. Needle knife papillotomy was described first by Osnes and Kahrs in 1977¹¹, who used this technique for extraction of impacted stone at ampulla. There are different techniques of precut papillotomy used in different indications¹². Although the success rate for standard sphincterotomy is high at present, the selective bile duct cannulation failure rate is 5-10%.¹² A total of 327 ERCPS were performed in our unit during the study period, precut technique was employed in 35 patients, giving a failure rate of 10.7% of standard sphincterotomy which is in correlation with the results given in various international studies.

The anatomic and physiologic variations such as short common cholangiopancreatic duct, duodenal diverticulum, small ampullary orifice as well as the pathological conditions like Oddi s sphincter stenosis, duodenal inflammation, ampullary/ papillary neoplasm, impacted calculi have been implicated in cannulation failure. Precut plays salvage role in solving such cannulation difficulties. Needle knife is the major tool for precut.⁸ The technique used in our study was precut up with the needle (PUWN). The cumulative success rate of this technique in our study was 92.5 % which is in line with the reported data. One international study published in 2007 has reported a success rate with needle knife of 68.4%.⁸ One national study has cited initial success rate of 84.8% and over all success rate of 14%.¹³

The success of PBS with first attempt was seen in 21/35 patients (60%). According to the clinical context in which the procedure was performed, first attempt PBS failure was seen in 4 patients with post surgical biliary leakage, 3 patients with upper CBD strictures, 3 with lower CBD strictures, 2 with impacted stones and one patient each having lower CBD stricture and dilated CBD only. From these figures we summarize that cannulation failure is seen more in cases where CBD is collapsed like in CBD strictures and post surgical leakage ($p=0.05$). Thus difficulty in precut should be anticipated in long CBD strictures. Similarly cannulation failure was seen more in patients on first attempt who had history of surgical intervention on biliary tract ($p=0.05$). This is again in accordance with the published literature. Patients who had failure on initial PBS were scheduled for repeat attempt after 10 days when local edema of the ampulla of Vater had decreased.

Success rate of second attempt after initial failed precutting was 66.66% (4/6 patients). Two failures on second attempt were those in whom previous surgery i.e cholecystojejunostomy with gastrojejunostomy and cholecystectomy respectively had been done. One patient had floppy abnormally placed ampulla while the other one had large difficult ampulla, proving increased failure rates in cases of altered anatom ($p=0.03$). Although needle knife precut papillotomy has been used for many years and is considered a useful alternative for achieving selective CBD

Cause found	Cannulation		
	Successful	Unsuccessful	Total
Failed ERCP	3	-	-
Dilated CBD only	3	1	4
Stricture upper CBD	1	3	4
Stricture mid CBD	2	1	3
Stricture lower CBD	6	3	9
Stones	2	2	4
High stricture	2	0	2
Cutoff CBD	1	0	1
Leak CBD	1	4	5
Total	24	14	35

	Complications		
	Pancreatitis	Bleeding	Infection
Dilated CBD only	0	1	1
Stricture upper CBD	2	0	0
Stricture mid CBD	1	0	0
Stricture lower CBD	1	0	1
Total	4	1	2

	Patients (n)	Complication	1st attempt success	2nd attempt success
	4	Pancreatitis	0	4
	2	Infection	0	2
	1	Bleeding	1	0
Total	7		1	6

DISCUSSION:

The success rate for different diagnostic and therapeutic ERCP techniques depend on endoscopic sphincterotomy, which is associated with selective and deep cannulation of bile ducts. Due to anatomical, physiological and pathologic variations, the guide wire/ catheter and papillotome cannot

cannulation, there is still controversy regarding its safety.^{14,15,16,17} Precut papillotomy can increase risk of complications compared to standard papillotomy when performed by a less experienced endoscopist.¹⁸ In experienced hands, complication rates are almost the same.¹⁹ Risk factors for complications are young age, inexperienced operator, periampullary carcinoma, diverticulum, sphincter of Oddi dysfunction and non-dilated common bile duct.²⁰ Several studies have shown that both success and complication rates of PBS may improve with increased endoscopist experience. This correlation was not seen in our study as our endoscopist was already experienced in this procedure.

The complication rate in our study was 25.9% (7/27). The complication rates reported in various national and international studies are in the range of 7%-13.3%.^{13, 21, 22} The high rate of complications in our study could be due to more difficult patients and less number of cases. Six out of seven patient with complications were those who had unsuccessful first time cannulation ($p < 0.011$). The probable cause of this significant correlation can be prolonged time of procedure, repeated attempts at cannulation and injection of pancreatic duct and sub mucosal injection of dye. Complications seen commonly were pancreatitis in 11.4%, infection in 5.7% and bleeding in 2.9%.

Pancreatitis is the most common complication of ERCP and sphincterotomy. Risk factors related to this complication include relatively young age, whereas in our study most of the complications were seen in middle age patients. Five out of seven complications were seen in patients above 40 years of age. This could be due to the fact that most of our patients were in that age group ($p = 0.04$). Other risk factors include difficulty in cannulating the bile duct, technique of endoscopist. Pancreatitis was seen in four patients out of seven patients in our study (11.4%) as compared to 7%, 4% and 3.8% in various international and national studies.^{23,11,13} The difference in the rate is not statistically significant. One possible explanation for increased pancreatitis in our study may be due to non placement of pancreatic stent prior to PBS. Placement of pancreatic stent prior to precut is often used to help prevent post ERCP pancreatitis. All four patients with pancreatitis were managed successfully on conservative treatment. Pancreatitis was mild in three cases and severe in one patient who warranted hospital admission and supportive treatment.

Bleeding is a relatively frequent complication. Over all incidence of bleeding in various studies is 2.5% and 5% with a mortality of about 0.3%. Bleeding may occur during this procedure or can be delayed for hours or even several days. It may be mild or severe. Independent risk factors for clinically significant hemorrhage include coagulopathies (which were corrected prior to procedure in our study), low case volume on the part of the endoscopist; which reflects less precise control of incision or less effective endoscopic

control of bleeding once it has occurred (which again was not seen in our study as our endoscopist was highly trained in performing these procedures). Cause related risk factors include papillary tumors and papillary stenosis and variants in vascular anatomy.² In our study, one patient out of seven had severe hemorrhage which resulted in patient death despite all the endoscopic methods to stop bleeding and supportive measures. Surgery was planned as a last resort but the patient died before the procedure. As all the other risk factors were not present, variation in vascular anatomy was considered as a cause for bleeding. Two patients had cholangitis, which was managed conservatively with intravenous antibiotics and supportive measures. Our findings are consistent with other large trials showing PBS as a safe and effective procedure.

CONCLUSIONS:

To summarize, difficulty in PBS should be anticipated in post surgical patients with altered anatomy and collapsed biliary system like CBD leakage and long distal strictures. Complication rate increases with subsequent attempts at cannulation. Overall in experienced hands PBS is safe and effective procedure in achieving selective cannulation.

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