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Incidence of Needle Knife Precut Sphincterotomy in a Sample of Patients Attending Gastroenterology and Hepatology Teaching Hospital in Baghdad

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Abstract: Background: Endoscopic retrograde cholangiopancreatography (ERCP) has been a remarkable technological advance has redefined the medical and surgical approach to patients with pancreatic and biliary tract diseases.

Selective deep cannulation of the common bile duct (CBD) or pancreatic duct is the most important step for successful therapeutic endoscopic retrograde cholangiopancreatography (ERCP). Successful cannulation rates of more than 85% are achievable by most practising endoscopists.

despite technical innovations, improved endoscopic imaging, and specialized accessories, deep biliary cannulation still fail in (5% to 15%) of cases, even in experienced centers. In these situations the use of alternative techniques may be necessary.

Needle-knife papillotomy technique used during endoscopic retrograde cholangiopancreatography (ERCP) to facilitate access to the common bile duct or pancreatic duct (PD) when Standard cannulation techniques have failed.

Aim of the Study: Evaluation of patients seeking gastroenterology and hepatology teaching hospital / medical city / Baghdad, about the incidence of needle knife precut sphinctrotomy and whether agreed with the percent of needle knife precut sphinctrotomy of other centers in the world or not.

Patients and Methods: The study was a hospital based cross sectional descriptive analytic study conducted in the gastroenterology and hepatology teaching hospital / Medical City / Baghdad / Iraq during a period from November 2022 to November 2023 ,about (350) patients for endoscopic retrograde pancreatocholangiography(ERCP) examinations for different causes.

When standard biliary duct cannulation was unsuccessful and the bile duct was deemed inaccessible,The endoscopist was then permitted to use the precut method by needle knife .

Results: From 1030 patients were involved in our study , about 111 patients underwent needle knife (precut) Sphincterotomy in a percent (10.7%) , the causes for needle knife sphictrotomy was: Choledocholithiasis in 62 patients (55.8%) ; pancreatic cancer in 24 patients (21.6%) suspected cholangiocarcinoma 16 patients (14.4%) other causes (ampullary tumor (3 patients), bile duct injury (2 patients) and diverticulum effect (1 patients) .

The patient had different age groups ; (about 43.2% were at middle age (46-65 years), followed by the elderly group (40%), while the young age group constitute the minor proportion (only 20.7%)) and in both sexes , our patients were 55 male patients(49.5%) and 56 female patients(50.5%).

Conclusion: The results of our study are comparable to incidence of needle knife precut sphincterotomy reported by high-volume tertiary referral centers and suggest that such a strategy can be safe and effective in trained and experienced hands.

Key words: sphincterotomy, cholangiocarcinoma, Choledocholithiasis.

Introduction:

Endoscopic retrograde cholangiopancreatography (ERCP) has been a remarkable technological advance that has evolved over its nearly 50 years in the field of gastrointestinal endoscopy and has redefined the medical and surgical approach to patients with pancreatic and biliary tract diseases. 1

Selective deep cannulation of the common bile duct (CBD) or pancreatic duct is the most important step for successful therapeutic endoscopic retrograde cholangiopancreatography (ERCP). Deep cannulation allows contrast to be injected into the duct of interest to visualize the anatomy, and to introduce various accessories into the duct in order to perform therapeutic manoeuvers. Successful cannulation rates of more than 85% are achievable by most practising endoscopists, although in the hands of experts success rates are higher than 95%.

Since the initial description of precut sphincterotomy by Siegel in 1980. successful biliary cannulation has improved significantly. However, despite technical innovations, improved endoscopic imaging, and specialized accessories, deep biliary cannulation may still fail in 5% to 15% of cases, even in experiencedcenters. In these situations the use of alternative techniques may be necessary. 2

As opposed to traditional biliary sphincterotomy, precut is usually not a planned intervention, but endoscopists must be prepared for this event in case of unsuccessful cannulation, This technique remains a challenge for man endoscopists and is often reserved for “experts,” as it is often considered to be complex and associated with an escalation in the risk related to ERCP.1

“Precutting” is simply de-roofing the duodenal part of the ampulla to expose the biliary orifice enabling deep cannulation, a concept first introduced by Siegel in 1980 and later popularized by Kees Huibregtse and Nib Soehendra. 2 To better understand the concept and the technique of “precut” sphincterotomy, it is essential to review the anatomy of the ampulla of Vater . The terminal parts of the biliary and the pancreatic ducts taper down to open into the medial duodenal wall, where the flow of secretions of both the ducts are controlled by the presence of a biliary and a pancreatic sphincter, respectively, In addition, an ampullary sphincter envelops these two structures The Vaterian ampulla that is seen endoscopically consists of the ampullo-bilary-pancreatic sphincters covered by the duodenal mucosa and submucosa. There are several variations in how the biliary and pancreatic ducts terminate at the medial duodenal wall. Usually they join each other just before terminating at the duodenum forming a common channel, which is about 5mm long with a single common orifice. This anatomy is often clear on injection of contrast at the orifice and most of the successful effortless cannulations are associated with this category. Whenever the common channel is longer, it is considered abnormal and is incriminated in or considered contributory to the development of pancreatitis. On the other hand, the ducts may each enter the duodenum separately and careful inspection of the ampulla endoscopically demonstrates two separate orifices for ready cannulation. In some cases, although the two orifices are separate, there is a common, lengthy, redundant ampullary mucosa making selective biliary access difficult while contrast injection delineates both the ducts. This is one situation where precut sphincterotomy may be required.8.

Patients and Methods

This study is cross sectional analytical study was done prospectively. A total of 350 patients who attended Gastrointestinal tract center in medical city of Baghdad in the duration From November 2022 to November 2023, for endoscopic retrograde pancreatocholangiography (ERCP) examinations for different causes.

all the patients signed informed consents.All our patients were indicated for endoscopic retrograde pancreatocholangiography (ERCP) examinations due to obstruction of biliary system for different causes (choledocholithiasis, pancreatic carcinoma, suspected cholangiocarcinoma and others). Indications for ERCP were defined by preoperative evaluation with liver enzymes and ancillary

examinations such as abdominal ultrasonography, computed tomography, magnetic resonance and, in some cases, endoscopic ultrasound.

The patient had different age groups ;those whom underwent needle knife sphinctrotomy were(about 43.2% were at middle age(46-65 years), followed by the elderly group (40%), while the young age group constitute the minor proportion (only 20.7%)) and in both sexes , our patients were 55 male patients(49.5%) and 56 female patients(50.5%). Endoscopic retrograde pancreatocholangiography (ERCP) examinations was done by side view dudenoscope of Pentax (11mm). Starting time was determined at the moment the duodenoscope crossed the cricopharyngeus, . Cannulation time was measured after the papilla was first touched by the instrument. The endoscopists applied a minimally traumatic cannulation protocol in all subjects with native papilla, utilizing triple lumen sphincterotomes and 400cm-0.035inch hydrophilic guidewires.

Cannulation was characterized by free and deep instrumentation of the common bile duct (CBD). Trainees started most of the ERCPs, were allotted 10 min for cannulation and, if they failed, the expert endoscopist would take over.

Fistulotomy precut was performed following the attending's failure in cannulation by standard means (i.e. difficult cannulation) in therapeutic ERCPs with intact papillas and common bile duct diameter of at least 10 mm.

When standard biliary duct cannulation was unsuccessful after more than 20 minutes, the bile duct was deemed inaccessible. The endoscopist was then permitted to use the precut method by needle knife either above the papillary orifice or from orifice (Fistulotomy) procedure .

With the supra-papillary needle-knife fistulotomy technique a small incision was made by means of a 4 mm Huibregtse-Wilson Cook needle-knife a few millimeters above the papillary orifice to avoid injuring the pancreatic duct and to minimize the rate of post-ERCP pancreatitis, which is the most serious complication of such procedures.

The starting point of the fistulotomy on the papilla (distal third, midportion or proximal third) and the length of the incision varied depending on the disorder being treated (bile duct stones, strictures, etc.) and on the size of the papilla. The needle knife consists of a O.2-mm diameter straight wire that can be extended 5 mm from the tip of the cannula .The electrosurgical current setting is the same as that employed in routine papillotomy. Before one begins actually cutting with the knife, it is important to make several trial movements of the catheter tip by turning the control knobs or by using the elevator. The wire is then extended 5 mm from the tip of the catheter and inserted into the papillary orifice A 5- to 6-mm incision is made at the 11 o'clock orientation, which is the usual position of the bile duct.

The proper orientation of the cut is achieved by creating pressure with the wire on the roof of the papilla, using either the cannula elevator or control knobs to deflectthe wire.It is essential to move the knife while giving current to avoid excessive focal coagulation. After a small incision is made, the orifice to the biliary tract may be noted by outflow of bile. The precut incision should be gently probed with a smooth metal-tipped cannula.

The actual opening may be anywhere along the site of the incision, but in the majority of cases it is not located in the superior aspect.If biliary tract access is still not achieved, the incision can be extended another 2 to 4 mm or a slightly deeper incision can be made. Once biliary opacification is achieved, the precut incision may be extended via a standard papillotome, which will allow stone extraction or endoprosthesis placement. Of these 1030 patients , about 111 patients underwent needle knife fistulotomy.

The causes for needle knife sphictrotomy was: Choledocholithiasis in 62 patients (55.8%); pancreatic cancer in 18 patients(16.2%) suspected cholangiocarcinoma 16 patients(14.4%) other causes(ampullary (3patients),periampullary tumor (6patients), bile duct injury (2 patients) and diverticulum effect (1 patients) .

Inclusion criteria: patients included in our study those with ineffective common bile duct deep cannulation using a conventional cannulotome after a 10 -20min 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 alterd anatomy of gastrointestinal tract due to surgery e.g.(gastrojejunostomy).

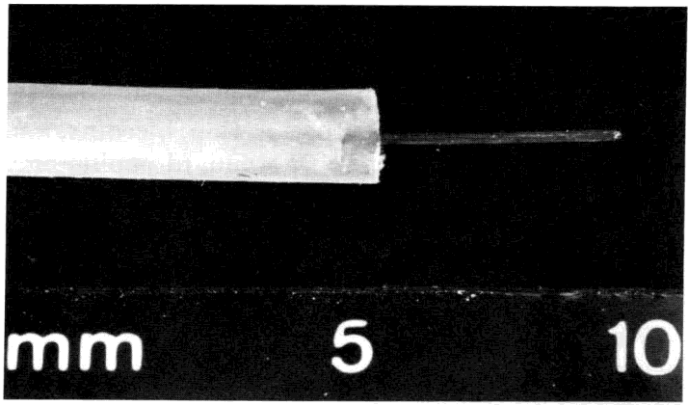

Figure 1. Fine-needle knife papillotome, 5 mm in length and 0.2 mm in diameter (Wilson Cook, Inc., Winston-Salem, N.C.).

Results:

Overall (111) patientsunderwent the precut of total no.(1030)patients were involved in ERCP procedure in this study , the percentage of NKP (precut) sphincterotomy was(10.7%).

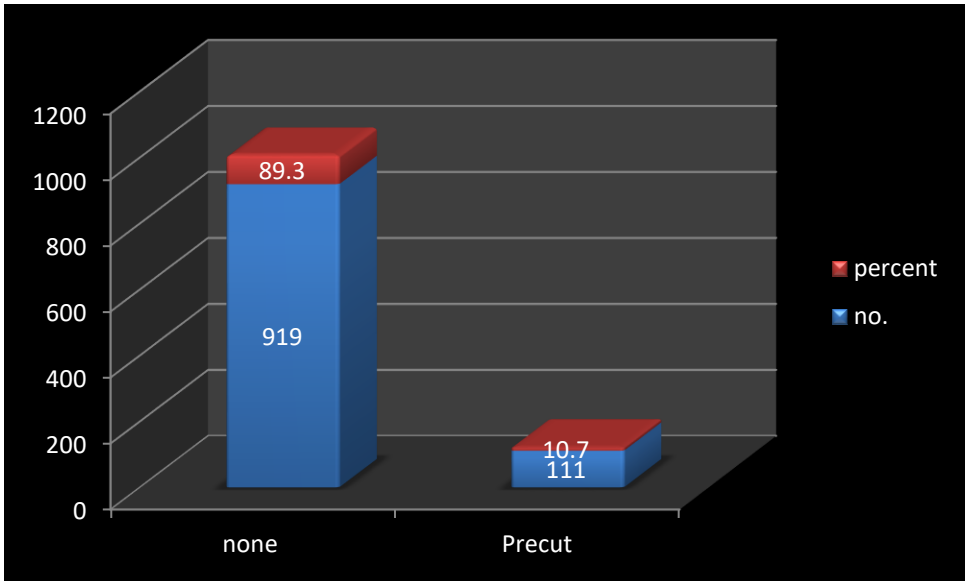

Figure 1: **incidence of NKP sphincterotomy**.

Overall (111) patients underwent the precut; about 43.2% were old middle age(46-65 years), followed by the elderly group (40%), while the young age roup constitute the minor proportion (only 20.7%).

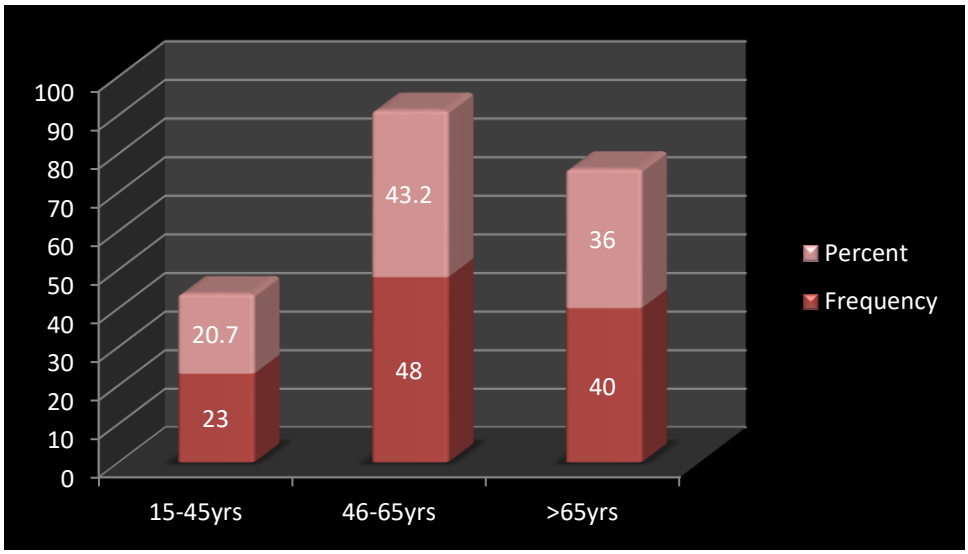

Figure1: Distribution according to the age

Most of the cases underwent the precut were diagnosed to have CBD stone, followed byCa –pnacreas, then cholingiocarcinoma while the other aetiologies, constitute the minimum proportion of the total aetiology.

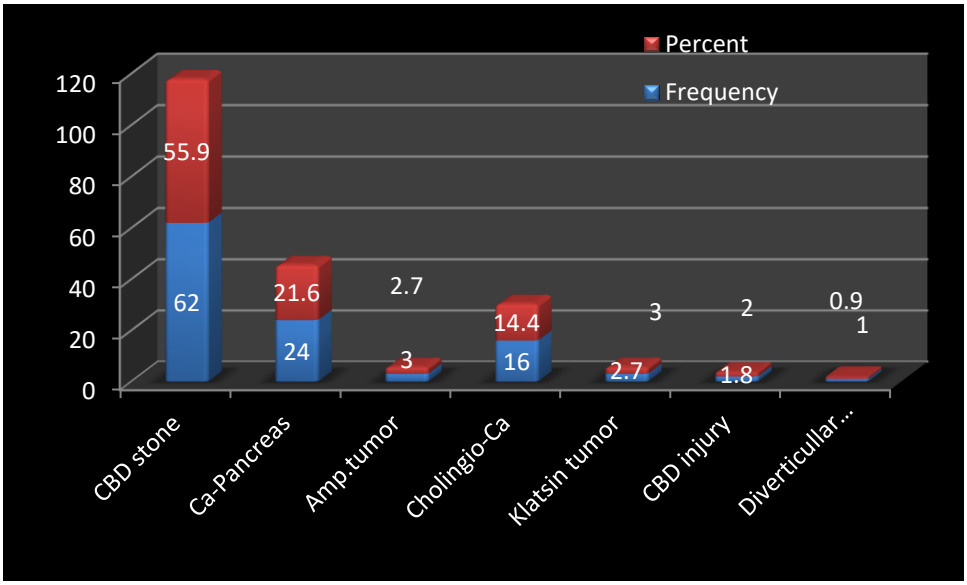

Figure3: Distribution of the precut according to the aetiology

Table 1: Association of the age and different causes of CBD obstruction

	N	Mean	S. D.	Min.	Max.	ANOVA P value
CBD stone	62	54.2903	16.72	16	80	2.737 0.012
Ca-Pancreas	24	60.3889	10.38	40	73	
Ambulatory tumor	3	56.3333	14.02	42	70	
Cholingio-Ca	16	68.8125	14.83	44	101	
Klatsin tumor	3	69.3333	7.51	65	78	
CBD injury	2	70.0000	7.07	65	75	
Diverticular effect	1	65.0000		65	65	
Total	111	59.0721	15.82	16	101	

There was significant statistical association between the age and the causes of obstruction, where the p value was <0.05.

Table 2: distribution of the aetiology according to the Age							
cause			recoded Age			Total	FE
			15-45	46-65	>65		P value
	CBD stone	No.	19	26	17	62	
		%	30.6%	41.9%	27.4%	100.0%	14.694
	Ca-Pancreas	No.	2	9	7	18	0.017
		%	11.1%	50.0%	38.9%	100.0%	
	Amp.tumor	No.	1	1	1	3	
		%	33.3%	33.3%	33.3%	100.0%	
	Cholingio-Ca	No.	1	5	10	16	
		%	6.3%	31.3%	62.5%	100.0%	
	Klatsin tumor	No.	0	2	1	3	
		%	0.0%	66.7%	33.3%	100.0%	
	CBD injury	No.	0	1	1	2	
		%	0.0%	50.0%	50.0%	100.0%	
	Periamp.tumor	No.	0	3	3	6	
		%	0.0%	50.0%	50.0%	100.0%	
	Diverticullar effect	No.	0	1	0	1	
		%	0.0%	100.0%	0.0%	100.0%	
Total		No.	23	48	40	111	
		%	20.7%	43.2%	36.0%	100.0%	

the table 2show: A significant statistical difference, within age groups and distribution regarding the causes**,** where P value <0.05,

Table 3: distribution of the aetiology according to the gender						
			gender		Total	X 2
			Male	Female		P value
cause	CBD stone	No.	25	37	62	8.523
		%	40.3%	59.7%	100.0%	0.226
	Ca-Pancreas	No.	12	6	18	
		%	66.7%	33.3%	100.0%	
	Amp.tumor	No.	1	2	3	
		%	33.3%	66.7%	100.0%	
	Cholingio-Ca	No.	11	5	16	
		%	68.8%	31.3%	100.0%	
	Klatsin tumor	No.	2	1	3	
		%	66.7%	33.3%	100.0%	
	CBD injury	No.	1	1	2	
		%	50.0%	50.0%	100.0%	
	Periamp.tumor	No.	3	3	6	
		%	50.0%	50.0%	100.0%	
	Diverticullar effect	No.	0	1	1	
		%	0.0%	100.0%	100.0%	
Total		No.	55	56	111	
		%	49.5%	50.5%	100.0%	

No significant statistical difference, with gender groups and distribution of the causes**,** where P value >0.05, as shown in the table 3

Discussion:

Endoscopic precut papillotomy is useful in patients with an inaccessible bile duct. If the transpapillary approach fails in patients in whom the bile duct is inaccessible endoscopically, it takes more time and resources to approach the duct using other methods (transhepatic or operative).Recently, the precut method has been regarded as the standard method; it has a high success rate when done by expert endoscopists. However, the needle knife precut technique is by no means easy and safe, as there is a risk of pancreatitis and perforation.18,19. This follows trauma and edema of the papilla due to multiple unsuccessful attempts and inadvertent pancreatic duct cannulations and precutting in such circumstances results in higher morbidity, especially when performedon undilated bile ducts [20,21].

Thus, only expert pancreaticobiliary endoscopists should use this method.22However, despite technical innovations, improved endoscopic imaging, and specialized accessories, deep biliary cannulation may still fail in 5% to 15% of

cases, even in experienced centers. In these situations the use of alternative techniques may be necessary. This study is the first study in our center and in Iraq about the percent of NKP Sphincterotomy of patients counselted GIT hospital for ERCP procedure due to different causes, and the first comparison with the percents of precut procedure of other centers in the world.

In our study , the percentage of needle knife precut sphincterotomy in ERCP cases followed for one year (111 of 1030 patients) GIT center , about (10.7%) and this percent agreed with percent(5-15%) of most experienced centers as in Baron ERCP.1

And also agreed with Alana C B ,et al , their study showed that 211 ERCPs were performed ,the percent of precut (16.6%) of ERCP.23 Our study results agreed with results from Dumonceau JM, et al ,Testoni PA, et al and Lawrence C ,et al in different centers which showed the incidence of needle knife precut sphincterotomy (0-44%).(24,25,26)

Our results also agreed with the results of Tiing Leong ANG, et al hat showed the index ERCP was successful (710 out of 765 times) (92.8%).Precut was performed in (55 out of 765) patients (7.2%). Bruins Slot W,Schoeman MN,Disario JA, et al ,they performed atotal of 1071patients in their study ,precut sphincterotomy was carried out in 180 patients(16.8%). 28

Rollhauser C,Johnson M, et al their study involved about 1205 therapeutic ERCP procedure. sixty-eight patients(5.6%) had undergo NKP after failure of CBD cannulation.29 JF Dowsett ,A A Polydorou, et al they performed 748 parients, in 96 patients(12.8%) NKP was used after failure of conventional biliary access.30 All these studies results are compatable with the results of our study.

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