SUPRAPAPILLARY PUNCTURE OF THE COMMON BILE DUCT FOR SELECTIVE BILIARY ACCESS IN ERCP

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ABSTRACT

Background and Rationale : Getting directly into the common bile duct (CBD) is the most important step for successful therapeutic endoscopic retrograde cholangiopancreatography (ERCP). In 5% - 10% of cases, the CBD remains inaccessible, necessitating suprapapillary puncture or fistulotomy with a needle-knife. The aim of this study was to evaluate and compare the safety and efficacy of the suprapapillary puncture technique using the needle-knife with other methods used for biliary access after failure of these methods as regard immediate and long term outcomes.

Methods : From December 2008 to December 2009, out of 112 patients who were candidates for ERCP, 70 patients were selected satisfying the inclusion criteria, they were exposed to clinical assessment, laboratory and radiological investigations, they were divided according to the technique used during ERCPinto four groups ; group A (15 patients underwent a suprapapillary puncture or fistulotomy using the needle-knife), group B (15 patients underwent a precut using the standard pull sphincterotome), group C (20 patients who underwent a conventional transpapillary wire-guided cannulation without sphincterotomy), group D (20 patients underwent a conventional transpapillary wire-guided cannulation with standard sphincterotomy). The cannulation times, success rates and post-ERCP complications were evaluated and compared among the studied groups.

Results : Seventy patients (33 males and 37 females with a mean ± SD age of 56.3 ± 11.5 years) underwent ERCP during this period of time. The overall success rate in group A was 93.3%, while in group B was 86.6%, 85% in group C and 70% in group D. There were no cases of post-ERCP pancreatitis in group A, while there were one case in group B and C and two cases in group D. The total incidence of pancreatitis was 5.7%. There were 3 cases of bleeding in group A, while two cases in group B and C and 4 cases in group D. There was one case of cholangitis in group D. One case of mortality in group C. Perforation was not occurred in any of the groups.

Conclusion : Suprapapillary needle-knife fistulotomy is an effective method for accessing the biliary system in expert hands after failed standard cannulation. Despite a higher rate of bleeding, fistulotomy was not associated with an increased risk of serious complications.

Keywords : Suprapapillary puncture, Common bile duct, Endoscopic retrograde cholangiopancreatography, Fistulotomy, Needle-knife, Cannulation, Complications.

INTRODUCTION

ERCPis the standard approach for the diagnosis and treatment of many of hepatopancreaticobiliarydiseases. Since its development, it has gained widespread use and has become a therapeutic tool in that field. The first endoscopic cannulation of the papilla of Vater was described in 1968 by McCune et al and from then on the clinical application for ERCP have increased markedly. ERCP is an advanced endoscopic procedure that requires considerable training and experience to be performed effectively and safely [(1)].Therapeutic ERCP, especially the endoscopic management of biliary stones and tumors has attracted a lot of interest. It is more preferable to surgery in terms of a lower risk of morbidity and mortality; it costs much less and is the first therapeutic approach in stone disease[(2)]. Both the accessories available for gaining access to the bile duct and the techniques used have evolved during the last 3 decades [(3)]. These include standard transpapillary biliary cannulation techniques, such as those using catheters and papillotome[(4)]with or without the use of a guide wire[(5)];placement of a pancreatic guide wire (or stent) to assist biliary cannulation[(6)]; precut "access" papillotomy, by using a needle knife or a traction

papillotome[7];novel devices, such as endoscopic scissors[8]and endoscopic dissection by using a cotton swab[9]and papillectomy[10].

The four typical complications of ERCP are : acute pancreatitis, post-sphincterotomy bleeding, sepsis of biliary origin (cholangitis and cholecystitis) and perforation, either of the papillary area for sphincterotomy or duodenal (far from the papillary area) for endoscopy or biliary stents. Other less frequent complications are Zenker's diverticulum perforation, cardio–respiratory arrest, pulmonary edema and intrapancreatic stent fracture[11]. The procedure itself carries a risk of 5%-10% [12].

The suprapapillary needle puncture technique or fistulotomy is another technique that could be used in case of failure of other standard cannulation[13].

The aim of this prospective randomized controlled clinical trial was to evaluate and compare the safety and efficacy of the suprapapillary puncture or fistulotomy technique using the free hand needle knife with other techniques used for biliary access after failure of the standard transpapillary biliary cannulation as regard immediate and long term outcomes.

PATIENTS AND METHODS

The ethical committee of our institution approved this study to be conducted at the Gastrointestinal Endoscopy Unit of the Internal Medicine Department, Zagazig University Hospitals in the period from December 2008 to December 2009. Written informed consent was obtained according the guidelines of the institute. Out of 112 patients who underwent therapeutic ERCP, 70 of them have been selected satisfying the following inclusion and exclusion criteria :

Inclusion criteria :

(1) History: Jaundice, biliary colic, discoloration of urine and stool, itching, weight loss and previous cholecystectomy.
(2) Laboratory: Direct hyperbilirubinemia, elevated gamma–glutamyl transferase and alkaline phosphatase at least two times above normal levels.
(3) Radiological: Bile duct dilatation on abdominal ultrasound (≥ 8 mm in patients with a gallbladder in situ and >10 mm in patients who underwent cholecystectomy) with or without intrahepatic biliary radicals dilatation.

Exclusion criteria :

(1) The patients had a failed prior ERCP *(14 cases).*
(2) Severe hemorrhagic diathesis *(11 cases).*
(3) Prior gastric surgery (Total gastrectomy or Billroth II gastrectomy).
(4) Unreached papilla due to stenosis or anatomical deformities (partial or complete obstructive lesions of the foregut expected to impede access to 2nd part of the duodenum).
(5) The patient did not consent for all or part of the expected procedures.
(6) Recent (≤8 weeks) cerebrovascular stroke or acute myocardial infarction.
(7) Pregnancy (In first trimester).
(8) A known hypersensitivity to contrast agents.
(9) Severely–ill patients (Class IV and V according to American Society of Anesthesiology (ASA) physical status classification) [14] *(9 cases).*
(10) Child–Pugh class C liver disease patients *(8 cases).*

Patients :

The patients then were divided into four groups according to the method used to gain access into the biliary system :

Group A:15 patients who underwent a suprapapillary puncture or fistulotomy using the needle–knife as an access to the

bile duct after failure of trans-papillary wire-guided cannulation.

Group B:15 patients who underwent a precut using the standard pull sphincterotome as an access to the bile duct after failure of trans-papillary wire-guided cannulation.

Group C: 20 patients who underwent a conventional trans-papillary wire-guided cannulation without sphincterotomy.

Group D: 20 patients who underwent a conventional trans-papillary wire-guided cannulation with standard sphincterotomy.

Cannulation failure was defined as up to three unintended cannulations of the pancreatic duct or failure of biliary cannulation attempts within a time limit of 20 minutes[15]or 10 minutes[16]. In this study, we adopted the 10 minutes to avoid prolonged attempts on the papilla or multiple pancreatic cannulations.

All the patients were subjected to full history taking, thorough clinical evaluation, laboratory and radiological investigations.

All the procedures were performed by a single experienced endoscopist*(M.A.G.)* with or without the assistance of a trainee.ERCP was performed under unconscious sedation with titrated intravenous 1 % propofol with or without endotracheal intubation in the presence of an anesthesiologist in 64 patients. The remaining 6 patients were deeply sedated with intravenous *Pethidine* (50 mg) and *Midazolam* (10 mg) due to their poor general condition (Class III ASA classification system) that interfered with general anesthesia[17]. The patients were in the left – lateral or prone position. Supplementary oxygen was given to all patients with monitoring of pulse rate and oxygen saturation. All the procedures were performed by standard videoduodenoscopes*(Olympus EXERA – CLV160*and *Pentax ED-344OT)*. 10 – 20 mg of hyoscinebutylbromide*(Buscopan)* was given intravenously on demand to reduce duodenal peristalsis. A standard diluted contrast medium sodium and meglumineioxitalamate*(Telebrix)* at a 35 % concentration was used for cholangiography. A radiological screening unit, model *TCA 4R* plus (supply 115/230 volt) was used with an image intensifier and two television screens, placed behind the patient's head so that both screens are comfortably visible to the endoscopist and to the radiology technician. Electrosurgical unit *CONMEDsabre 2400* was used during the procedures for cutting purposes and suprapapillary punctures. Accessory instruments used such as : Diagnostic biliary cannulae (catheters) of different sizes, Guide wires, Needle-knife for the suprapapillary puncture : HUIBREGTSE triple lumen needle knife® (Wilson Cook, USA) with cutting wire of 4mm and a sheath of 7fr tapered to 5fr/200 cm. A sphincterotome for the precut : TRI-TOME PC triple lumen sphincterotome® (Cook Medical, USA) with braided cutting wire of 10mm and a sheath of 7fr/200cm.Sphincterotomes for conventional transpapillarycannulation with standard sphincterotomy, Dormia extraction basket, Extraction balloon, Biliary dilatation balloon, Stent introducers,Pushing catheters and Biliary stents ; either plastic or metallic.

ERCP was done, with the duodenoscope positioned and rectified at the second duodenal portion, the four procedures were applied :

A.Suprapapillary puncture or fistulotomy :by using a needle knife in the direction of the CBD at a point corresponding to the proximal third of the line between the transversal fold and the papillary ostium, at least five millimeters above the orifice, perpendicular to the papilla at 11–12 O'clock position, and

three millimeters deep to the surface (over the most bulging point of the pregnant papilla ; on the bulged intraduodenal segment of the CBD extending upward or downward over the papillary mound).

B. Precut by using a pull sphincterotome :It is an incision of the papillary roof which is carried out from the papillary orifice along the midline of the papilla.

C. Transpapillarycannulation without sphincterotomy.

D. Transpapillarycannulation with sphincterotomy.

Cannulation was viewed from four perspectives, namely :duration, number of trials(each targeting was considered as an individual trial), use of aiding instruments and methods andsuccess rate.

Recording complications during ERCP like hemorrhage and perforation. A diagnostic failure was considered when the CBD could not be cannulated. Therapeutic failure was defined as the lack of adequate duct drainage when necessary.

Follow up videoduodenoscope of the suprapapillary puncture site after 30 days after the procedure to evaluate the status of thesuprapapillary biliary fistula [13].

According to Vandervoort et al[18] and Ong et al[19], post-ERCP complications were defined as any adverse event clearly related to the ERCP that required hospitalization or readmission of a previously discharged patient, and these include :pancreatitis, cholangitis, perforation, bleeding, contrast-induced nephropathy and duodenal tear.

Complications were graded according to a 1991 consensus [20]. Complications were classified as mild if the length of hospital stay was less than or equal to 3 nights ; moderate if the length of hospital stay was between 4 and 9 nights ; and severe if the patient was hospitalized for 10 or more nights, was admitted to an intensive care unit, or required surgery[12]. As regards timing, complications were considered *"immediate"* if they occurred during or shortly after the procedure within one hour ; complications were considered *"early"* if they occurred within 1 – 48 hours ; and complications were considered *"delayed"* if they occurred after 2 days[12].

STATISTICAL ANALYSIS

Data were checked, entered and analyzed using SPSS version 13 for data processing and statistics. The *P* value of less than 0.05 was considered statistically significant.

RESULTS

Seventy patients fulfilling the inclusion criteria underwent ERCPs for therapeutic purposes, while, 42 patients were excluded not fulfilling the criteria in the period from December 2008 to December 2009.Baseline characteristic of the patients, indication for ERCP and radiological findings are shown in Table 1. This table showed that there were 33 males and 37 females with a mean ± SD age of 56.3 ± 11.5 years.

The most frequent indication was choledocholithiasis (48.5%), followed by CBD stricture and pancreatic masses. Most of patients had a dilated CBD. Jaundice was the most frequent presentation of our patients. The most frequent co-morbidity enrolled was chronic liver disease (11.4%). Significant hyperamylasemia noticed post-ERCP that was lower in group A than other groups, however, no other significant laboratory results changes.

Table 1. Baseline demographics, indication and radiological findings of the patients.

Demographics		Group A (n = 15)	Group B (n = 15)	Group C (n = 20)	Group D (n = 20)	F	P value.	Sig.
Age (years)	Mean	54.3	53.7	57.5	59.7	1.079	0.36	NS
	± S.D.	13.7	12.7	9.4	10.3			
	Range	31 - 75	28 - 71	39 - 73	36 - 78			
		Group A n (%)	Group B n (%)	Group C n (%)	Group D n (%)	X^2	P value.	Sig.
Sex	Male	8 (53.3%)	6 (40%)	10 (50%)	9 (45%)	0.64	0.88	NS
	Female	7 (46.7%)	9 (60%)	10 (50%)	11 (55%)			

Indication	Group A (n = 15)		Group B (n = 15)		Group C (n = 20)		Group D (n = 20)		X^2	P value.	Sig.
	n	%	n	%	n	%	n	%			
CBD stone.	7	46.7	6	40	8	40	9	45	5.18	0.99	NS
Passed stone.	1	6.7	1	6.7	1	5	1	5			
Distal CBD stricture.	2	13.3	2	13.3	4	20	4	20			
Proximal CBD stricture.	0	0	1	6.7	1	5	2	10			
Pancreatic mass.	3	20	4	26.7	5	25	4	20			
Intra-operative biliary trauma.	2	13.3	1	6.7	1	5	0	0			

Radiological findings		Group A (n = 15)		Group B (n = 15)		Group C (n = 20)		Group D (n = 20)		X^2	P value.	Sig.
		n	%	n	%	n	%	n	%			
CBD	Dilated	15	100	14	93.3	19	95	18	90	1.64	0.65	NS
	Normal	0	0	1	6.7	1	5	2	10			
	Range	8 - 12		6 - 11		6 - 10		6 - 10				

The mean trials number for transpapillarycannulation among the studied groups was lower in groups A and B because of shifting to the suprapapillary puncture technique and the precut technique respectively after 10 minutes, whereas, the mean trials number was 4.3 ± 2.0 in group C and 4.8 ± 1.9 in group D with the range of trials from 2 to 9 times, with the mean time 21.5 ± 18 minutes in group C and 18.4 ± 9 minutes in group D with statistically significant difference among the studied groups.

The cannulation of the CBD was successful in group A in 93.3% of cases with fair drainage of the dye in 73.3% of them, 86.7% of cases in group B with fair drainage of dye in 80% of them, 85% of cases in group C with fair drainage of dye in 70% of them and lastly 85% of cases in group D with fair drainage of dye in 80% of them, with no statistically significant difference among the studied groups regarding the cannulation success rate or the fair drainage of the biliary tree.

Table 2. The incidence of complications among the studied groups.

Complication		Group A (n = 15)		Group B (n = 15)		Group C (n = 20)		Group D (n = 20)		Total (n = 70)		P value	Sig.
		n	%	n	%	n	%	n	%	n	%		
Pancreatitis (n = 4)		0	0	1	6.7	1	5	2	10	4	5.7%	0.65	NS
Bleeding (n = 11)	During procedure "immediate"	2	13.3	1	6.7	1	5	2	10	6	8.5%	0.82	NS
	After procedure "delayed"	1	6.7	1	6.7	1	5	2	10	5	7.1%	0.39	NS
Cholangitis (n = 1)		0	0	0	0	0	0	1	5	1	1.4%	0.46	NS
Contrast-induced nephropathy (n = 2)		0	0	0	0	1	5	1	5	2	2.8%	0.67	NS
Hepatic encephalopathy (n = 1)		0	0	0	0	1	5	0	0	1	1.4%	0.65	NS
Prolonged hospital stay (n = 18)		3	20	3	20	5	25	7	35	18	25%	0.7	NS
Mortality (n = 1)		0	0	0	0	1	5	0	0	1	1.4%	0.65	NS

Table 2 shows thatthere was no incidence of pancreatitis with group A , while the incidence was 6.7% with group B, 5% with group C and 10% with group D and the difference was statistically non significant. Regarding the severity of pancreatitis according to Cotton et al[20],one case in group B and another one in group C presented by mild form, while in group D the two cases presented by moderate degree. They are treated conservatively in the hospital then discharged within 8 – 10 days. There were no cases presented by severe degree and there was no mortality related to pancreatitis. This table showed also that 2 cases in group A developed bleeding during the procedure, one case in group B, one case in group C and 2 cases in group D, which stopped either spontaneously or after diluted adrenaline flushing, while after the procedure there was one case in each group of A, B and C and 2 cases in group D, treated conservatively and with blood transfusion, neither surgery nor therapeutic angiography were needed with no statistically significant difference among the studied groups. Regarding the bleeding after the procedure "delayed" according to Cotton et al [20]either hematemesis and/or melena within 48 hours after the procedure or post procedure anemia (drop of HB % > 2 grams within 48 hours). There was one case of cholangitis in group D which evolved satisfactorily with medical treatment, while there were no cases in the other groups with no statistically significant difference. Renal impairment post ERCP occurred in 2 cases ; one in group C and another in group D with no statistically significant difference. Hepatic encephalopathy developed in one case of Child's class B chronic liver disease in group C with no statistically significant difference. Prolonged hospital stay (more than 3 days) occurred in 3 cases in group A, 3 cases in group B, 5 cases in group C and 7 cases in group D with no statistically significant difference among the studied groups. The

only case of mortality among the groups was recorded in group C of the same patient with Child's class B chronic liver disease.There was a significant relation of post-ERCP pancreatitis with the number of trials and the duration taken for cannulation, while there are no other significant factors have been found. Also, a significant relation has been found between post-ERCP bleeding with the chronic liver disease Child's class A and B and prothrombin time. A significant relation of post-ERCP mortality with the duration of cannulation, the chronic liver disease "Child's class B" and with the developmentofencephalopathy has been found.

The total number of cases reached the overall success were 58 cases (82.85%). Group A showed a better overall success which was achieved in 14 cases (93.3%), group B showed an overall success in 13 cases (86.6%), , group C showed an overall success in 17 cases (85%) and group D showed an overall success in 14 cases (70%) with no statistically significant difference among the studied groups (Table 3).

Parameters of overall success:

(1)Successful CBD cannulation.
(2)Absence of post-ERCP pancreatitis.
(3)Absence of post-ERCP bleeding.
(4)Absence of post-ERCP cholangitis.
(5)Absence of post-ERCP renal impairment.
(6)Absence of post-ERCP hepatic encephalopathy.
(7)Survival.

Table 3. The overall success rates among the studied groups.

	Group A (n = 15)		Group B (n = 15)		Group C (n = 20)		Group D (n = 20)		Total cases (n = 70)		X^2	P value	Sig.
	n	%	n	%	n	%	n	%	n	%			
The overall success	14	93.3	13	86.6	17	85	14	70	58	82.85	3.7	0.29	NS

DISCUSSION

Cannulation of the CBD remains the most important and challenging aspect of the diagnostic and therapeutic ERCPs. Even in experienced hands the rate of cannulation via the papillary orifice reaches 10%[21]. Several techniques have therefore been developed to facilitate cannulation of the papilla during ERCP[22]. In 1980, Siegel first introduced the concept of precutting to improve success at ERCP. Since that date the precut techniques have been used. They emerged as a valuable method that allow a high success rate for cannulation with a low complications rate[23]. Subsequently, the invention of two kinds of specialized accessories have become available for precut, namely, the short–nosed Erlangen–type sphincterotome designed by Soehendra[24]and the needle – knife papillotome designed by Huibregtse[25]greatly promoted the clinical use of precut papillotomy or fistulotomy, facilitating biliary cannulation in difficult ERCPs[26].

In this study, we look to use the suprapapillary puncture technique previously used by Everson et al in 2007 [13] who accomplished this technique by a specially designed needlewhich was introduced by Artifon et al in 2005[27], hence the name "puncture".Because of unavailability of this needle in our work, needle-knife of Huibregtse was used for a fistulotomy technique as accomplished previously by Mavrogiannis et al in 1999[28],Zhou et al in 2006[21],Khatibian et al in2008[29]andDonnellan et al in 2009[30].

In order to reach this aim, 70 cases fulfilling the inclusion criteria, 37 females

(53%) and 33 males (47%) with mean age 56.3 years (range 28 – 78 years) who have undergone ERCP with therapeutic intention at the Gastrointestinal Endoscopy Unit, Internal Medicine Department, Zagazig University Hospitals in the period from December 2008 to December 2009.They were divided into 4 groups according to the used technique ;suprapapillary puncture technique, other precut techniques especially by using the pull-type sphincterotome , standard transpapillarycannulation without cannulation and standard transpapillarycannulation with standard sphincterotomy. The mean age of our patients 56.3 ± 9.4 years (range 28 – 78 years). Biliary diseases can affect any age groups, from neonatal period up to the elderly and each age has its inclined diseases, so ERCP can be used in children (with special precautions specially for the genitalia) and in the elderly even 90 years and older. Therapeutic ERCP is safe and effective for the treatment of pancreato-biliary diseases in extremely elderly patients and advanced age per se should not impinge on decisions relating to its use[31].

Of the 70 cases, 37 females (52.8%) and 33 males (47.2%).Some liver diseases occur only in women and others are more frequent in women than men. Specific to women are the liver diseases of pregnancy such as acute fatty liver of pregnancy, cholestasis of pregnancy and liver disease associated with preeclampsia, hepatic infarction and rupture. Liver and biliary diseases that affect both sexes but are more frequent in women include hepatic adenomas, gallstones, primary biliary cirrhosis, autoimmune liver diseases and non-alcoholic steatohepatitis (NASH)[32].

In our study, the most frequent indication for ERCP was CBD stones (48.6%) which agree with the majority of studies of biliary diseases[19].

Irrespective of the technique used, successful cannulation of the common bile duct was achieved in 87% (61/70) of cases, 85% (53/61) of the successfully cannulated cases achieved fair drainage of the biliary tree. These results are comparable to those by Deng et al., 2007[33]who reported the success rate was 80%. These results also lies centrally within the range of initial cannulation success rates reported by different authors varying from 80% to 95% such asZinsser et al., 1999[34],Cotton, 2002[35], Lehman, 2002[36], Kowalski et al., 2003[37], Ragunath et al., 2003 [38], Sherman and Lehman, 2003[39]and De Weerth et al., 2006[15].

Deng et al in 2007[33]supposed that selective CBD cannulation failure was due to anatomical and physiological factors such as short common cholangiopancreatic duct, duodenal diverticulum or small ampullary orifice. Pathological conditions such as Oddi's sphincter stenosis, duodenal inflammation, ampullary and papillary neoplasms and impacted calculi may result in cannulation failure. The selective CBD cannulation failure rate is 5% - 10%.

In the present study, suprapapillary needle – knife fistulotomy appeared to be more superior than other methods, as successful cannulation of the CBD was achieved in 93.3% of cases, while other precut techniques using the sphincterotome were 86.6% and 85% success rate for the remaining two groups.

The high success rate with the suprapapillary puncture technique 93.3% (14/15) in our results is comparable with Mavrogianniset al., 1999[28]who reported success rate 90.5% (67/74), Everson et al., 2007[13]who reported 90% (25/28),Khatibian et al., 2008[29]who reported 86% (188/218) and Donnellan et al., 2009[30]who reported 90% (317/352).

Precut techniques success rates 86.6% (13/14) in the present study is comparable with Vandervoort et al., 2002[18]who reported 86% (120/140) and Deng et al., 2007[33]who reported 89% (247/277). These results are slightly far from those of Uchida et al., 2005[40]who reported a success rate of 73%.

In another study by De Weerth et al in 2006[15], a precutsphincterotomy was done using the Erlangen – type precutsphincterotome with success rate of 100%. The higher success rate which was achieved in their study in comparison to our study can be contributed to (i) the type of the sphincterotome with its short nose (< 1mm length) that may facilitate cannulation and (ii) the early precutting decision before the papilla becomes oedematous or bleeds gave better chance for visualization.

Regarding the complication risk following the ERCP can occur approximately in 10% of cases and mortality in about 1%[41]. This is the range within which figures from a great number of published series lay and also our study lays [42].

The four typical complications of ERCP are : acute pancreatitis, post-procedural bleeding, sepsis of biliary origin (cholangitis and cholecystitis) and perforation, either of the papillary area for the precut and sphincterotomy or duodenal (far from the papillary area) for endoscopy or biliary stents[42]. Regarding the complication risk following precut techniques, the relationship has varied, with complication rates ranging from just less than 10%[43]to as great as 66%[44].

Regarding the post-ERCP pancreatitis that has been developed after the procedure, the overall incidence in our study was 5.7% with no statistically significant difference among the studied groups, which is in line with the reported data of Garcia-Cano et al., 2004[42]that was 5.5%, Katsinelos et al, 2004[45]thatwas 4% and Donnellan et al., 2009[30]thatwasalso 4%, while Bruins et al., 1996[46]reportedlower rates of post-ERCP pancreatitis 0.5%.

There were no reported cases of pancreatitis after the suprapapillary puncture technique in our study 0% which is in line with Everson et al., 2007[13]whileDonnellan et al., 2009[30]reported only 1% incidence of post – ERCP pancreatitis.Where avoidance of the potential mechanisms that precipitates pancreatitis associated with conventional transpapillary biliary cannulation and endoscopic sphincterotomy.

Direct mechanical injury to the pancreatic duct orifice from repeated probing of the ampulla is avoided by aiming the entry in the suprapapillary portion of the bile duct[41].Asymptomatic hyperamylasemia was reported in this study, that occurred more frequently after the precut and standard sphincterotomy techniques than the needle-knife fistulotomy technique and the difference was statistically significant ($p < 0.01$)which reinforces the view that thermal injury to the pancreatic duct should be avoided and that the needle-knife fistulotomy should be considered a safer alternative precutting technique.

Zhou et al in 2006[21]concluded that suprapapillary needle-knife fistulotomy should be considered first in certain situations including :(1) Stone impacting the papillary orifice. When the papilla is cut by the needle-knife, the stone may be flushed into the intestinal tract by the bile (2) Significant eminence of ampulla or dilation in the end of the CBD (3) Acute obstructive suppurative cholangitis and pancreatitis due to biliary disorders. In these situations, the bile duct and pancreatic tube are dilated, so cutting the papilla rapidly with the needle-knife may reduce the pressure within the bile duct and pancreatic tube, with a success rate of drainage reaching 100% (4) Billroth IIgastrectomy. But for a small flat papilla, peri-ampullary diverticulum and malignant changes of the papilla, the needle-knife technique is contraindicated because it can potentially make the cannulation approach either more difficult or unsafe to perform.

As regard the overall bleeding risk in the present study it was 8.5% during the procedure "immediate bleeding" and 7.1% reported for the post-ERCP "delayed" bleeding with no statistically significant difference among the studied groups. As

regard the bleeding risk in the needle-knife fistulotomy group (group A) it was 13.3% during procedure and 6.7% post procedural that agreed with Donnellan et al., 2009[30], in the other precut technique with pull-type sphincterotome (group B) the risk was 6.7% for during and after procedural bleeding while for the standard sphincterotomy (group D) it was 10% for both immediate and delayed bleeding.Low rates of bleeding have been reported by several investigators such asDe Weerth et al., 2006[15] that was 4% and 0.8% in the study of Laohavichitra et al., 2007[47].

However, higher rates have been reported by others including,Bruins et al., 1996[46] who reported 5.5% and Mavrogiannis et al., 1999[28]reported5.9%. The relatively high rate of bleeding in our study might be related to the use of pure cutting current for fistulotomy and other precutting techniques, in addition to the relatively high number of chronic disease patients enrolled in our study with abnormal bleeding profile (8 cases, 11.4%).

Regarding to the post-procedural biliary tree infection "cholangitis" the incidence was 1.4% in our study with no statistically significant difference among the studied groups which reported in one female patient in the group who underwent standard sphincterotomy for CBD stones, that is in line with Freeman et al., 1996[41]who reported 1%, Garcia-Cano et al., 2004[42]who reported 1.6%.

Regarding contrast – induced renal impairment the incidence was 2.8% with no statistically significant difference among the studied groups. These lower rates were comparable with those ofBruins et al., 1996[46], Katsinelos et al., 2004[45]andDe Weerth et al., 2006[15].

No reported cases of perforation in our study, these results were compatible to recent series of studies by Zhou et al., 2006[21],Khatibian et al., 2008[29] and Donnellan et al., 2009[30]who showed that a perforation risk was less than 0.5%.The careful handling of the instruments during fistulotomy or precutting, the position, direction and depth of incision controlled by combined movements of lowering the bridge and the outward movement of the large wheel of the endoscope, all help avoidance of perforation[21].

In the present study, hepatic encephalopathy after ERCP has occurred in one patient (1.4%). The only significant risk factor for its development was advanced chronic liver disease (Child's class B). The enhanced effect of sedation with the relatively long procedure time could explain the development of hepatic encephalopathy.

ERCP could be done as an outpatient procedure with same day discharge after 6 hours or as inpatient procedure with admission and observation just overnight unless post-ERCP complications are suspected[48]. In our study, prolonged hospital stay (more than three days) occurred in 25% of cases (range 1 – 10 days). This could may be explained by high rate of co-morbidity (30 cases, 45%).

In our study, mortality rate has been 1.4%, as only one patient died 7 days after the procedure from hepatic encephalopathy.Mortality rate in our study lies close to the range of post-ERCP mortality rates in most ERCP studies ; 1% mortality in the study of Zinsser et al., 1999[34], 0.16% mortality in the study of Vandervoort et al., 2002[18] and 1% mortality in the study of Garcia-Cano et al., 2004[42]. In this study, significant risk factors for death of this only patientwere development of hepatic encephalopathy and long procedure time (40 minutes). This proofs that hepatic encephalopathy has been the cause of death in this patient, that in its turn resulted from enhanced effect of the sedation due to long procedure time.

Other rarer and less typical adverse effects of ERCP, there was a Zenker's diverticulum perforation,intrapancreatic fracture of a plastic stent, cardio – respiratory arrest

(probably related to sedation) and pulmonary edema a few hours after ERCP; this complication considered to be related to the endoscopic intervention since myocardial blood flow reduction has been described during ERCP[49].

In conclusion, Suprapapillary needle-knife fistulotomy can be used when standard biliary cannulation proves to be difficult, it is associated with a high success rate and a low complication risk in experienced hands, it can be used as an alternative method, at least in difficult patients[30].

To experienced endoscopists, once a difficult biliary cannulation is encountered, the needle-knife technique must be performed at once as repeated papillary cannulation for a long time may result in cholangitis and pancreatitis[21].

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