ORIGINAL ARTICLE

A Randomized Controlled Trial Comparing Different Interventional Techniques for Difficult Common Bile Duct Cannulation in Endoscopic Retrograde Cholangiopancreatography

Ahmed E. Sallam [a,*], Omkolsoum E. Alhaddad [b], Maha M. Elsabaawy [b], Eman A. Mahmoud [b], Ahmed K. Khamis [b], Ahmed M. Edrees [b]

[a] Department of Hepatology and Gastroenterology Mahalla Hepatology Teaching Hospital, General Organization of Teaching Hospitals, Mahalla, AL Gharbia, Egypt
[b] Department of Hepatology and Gastroenterology, National Liver Institute, Menoufia University, Menoufia, Egypt

Abstract

Background: ***The gold standard for diagnosing and treating pancreatic-biliary disorders is endoscopic retrograde cholangiopancreatography (ERCP).***

Aim: ***To evaluate the effectiveness of precut and fistulotomy procedures, trans-pancreatic sphincterotomy (TPS), and the double guidewire technique (DGT) in patients with challenging biliary cannulation (DBC).***

Patients and Procedures: ***150 ERCP candidates with DBC participated in this prospective randomised research. Three groups of patients were randomly assigned: Group I (DGT), Group II (TPS), and Group III (fistulotomy method or needle knife precut).***

Results: ***Out of the 812 patients who were initially enrolled, 622 were able to successfully undergo selective cannulation. The remaining 150 patients were randomized. The success rates of initial and final cannulation were comparable among the three groups (P=0.882), periampullary diverticulum type (P=0.354), successful cannulation both initial and final endoscopic sphincterotomy (P=0.957), first and second cannulation time, hospital stay (P=0.328), cholangitis (P=0.485), bleeding (P=0.107), and post-ERCP (PEP) problems (P=0.151). The only significant difference was less contrast injection in the fistulotomy and precut group (P < 0.005).***

Conclusions: ***With similar success rates, trans-pancreatic sphincterotomy (TPS), precut and fistulotomy, or the double guidewire approach can all be effectively used to handle difficult ERCP cannulation***

Keywords: Interventional Techniques; Bile Duct; Difficult Cannulation; Endoscopic Retrograde Cholangiopancreatography

1. Introduction

ERCP is the standard procedure used for both diagnostic and therapeutic interventions in patients with pancreaticobiliary diseases .[1] Bile duct cannulation is a critical procedure for both diagnostic and therapeutic biliary procedures. The standard biliary cannulation procedure is unsuccessful in about 5-20% of instances .[2]

Several endoscopic methods for selective bile duct cannulation have been documented, such as biliary wire-guided cannulation, the pancreatic guidewire technique (specifically the double guidewire technique), precut sphincterotomy, endoscopic papillotomy, the endoscopic ultrasound-guided rendezvous procedure, and the percutaneous transhepatic biliary drainage-guided procedure .[3]

BD cannulation can be challenging due to normal anatomical variations, inflammatory conditions, neoplastic processes, and the presence of adenomas on the papilla or periampullary diverticulum. Complications related to ERCP are independently associated with the difficulty of cannulation, as noted in references .[4-6]

Accepted 01 February 2025.
Available online 28 February 2025

* Corresponding author at: Hepatology and Gastroenterology Mahalla Hepatology Teaching Hospital, General Organization of Teaching Hospitals, Mahalla, AL Gharbia, Egypt. E-mail address: Dr_ahmed_sallam@hotmail.com (A. E. Sallam).

https://doi.10.21608/aimj.2025.446424

Several additional procedures improve access to the common bile duct in situations where biliary cannulation is challenging, substantially increasing the success rate of selective biliary cannulation and reducing the incidence of complications .[7]

The pre-cutting technique, comprising needle-knife papillotomy, suprapapillary fistulotomy, and trans-pancreatic sphincterotomy (TPS), has been shown to be effective in reducing the difficulty associated with biliary cannulation. The TPS technique is particularly effective for difficult biliary cannulation, particularly as it allows for the cannulation of the pancreatic duct without avoidance .[8]

The double-guidewire technique employs a guidewire to fill the PD, yielding encouraging results in intricate biliary cannulation procedures, particularly for patients with abnormal BD anatomy resulting from neoplasia or unusual ampulla morphology .[9, 10]

This research seeks to evaluate and compare the effectiveness and results of the double guidewire technique, trans-pancreatic sphincterotomy, and precut and fistulotomy techniques in individuals with challenging biliary cannulation.

2. Patients and methods

One hundred fifty patients over the age of 18 who were prepped for ERCP because of various biliary issues with challenging common bile duct (CBD) cannulation were the subjects of this prospective randomised research. Following permission by the National Liver Institute's Ethical Committee at Menoufia University in Egypt (approval code: 00537/2024) and clinicaltrials.gov registration (ID: NCT06315647), the study was carried out between March 2019 and March 2022. The patients gave their signed, informed permission.

Patients under the age of 18, severe coagulopathy (INR>2), chronic kidney disease, severe heart disease, dilatation or stenting of either duct, complicated acute pancreatitis, moderate to severe acute pancreatitis as defined by the 2012 revised ATLANTA criteria, and intrauterine pregnancy were all excluded .[11]

Difficult biliary cannulation is defined according to ESGE guidelines, including prolonged cannulation time (>10 minutes), multiple cannulation attempts (>10), and the need for advanced techniques .[12]

Randomization

Group I (double guidewire method), Group II (trans-pancreatic sphincterotomy), and Group III (needle knife precut or fistulotomy technique) were randomly assigned to three equal groups using a specialised computer system.

Every patient had a clinical examination, history taking, and laboratory testing (liver function tests: ALT, AST, albumin, bilirubin, alkaline phosphatase, INR; Kidney function tests: creatinine; complete blood picture; pancreatic enzymes: amylase, lipase; tumor markers: CEA, CA19-9, AFP). Radiological examinations included Abdominal Ultrasound, MRCP, and selected cases underwent Triphasic CT Abdomen and pelvis.

ERCP Procedure

For sedation, midazolam (3–5 mg) and propofol were infused, and antispasmodic medications were given as required. A typical iodinated contrast agent and a side-viewing therapeutic duodenoscope were used for ERCP. Under C-arm supervision, biliary cannulation was first tried using a cannula or sphincterotome. Ineffective cannulation after ten or more tries or failure after ten minutes was considered difficult biliary cannulation.

The Double-Guidewire Method

The PD was fitted with a guidewire. A second wire was put at the ampullary orifice above the first wire, and a sphincterotome catheter was reintroduced alongside the guidewire in the PD. After that, biliary cannulation was tried (Figure 1).

Trans-Pancreatic Sphincterotomy Technique

A conventional traction sphincterotome was pushed into the pancreatic orifice, and a guidewire was introduced deeply into the PD. To reveal the BD orifice, a sphincterotomy was performed along the biliary route. After TPS, biliary cannulation was attempted (Figure 2).

Needle Knife Precut and Fistulotomy

Over the protruding part of the main papilla, a downward incision was created. A wire-preloaded sphincterotome knife was used to probe the BD once the submucosa had been exposed (Figure 3). The success rate of biliary cannulation was the main result. Hospitalisation duration, operation duration, and post-ERCP problems such cholangitis, haemorrhage, and pancreatitis were secondary outcomes.

Calculating the sample size:

Based on prior research and statistical power analysis, a sample size of 150 patients was chosen in order to identify a substantial variation in the success rates of biliary cannulation procedures. To assess the effect of liver cirrhosis on the results of various biliary cannulation procedures, a subgroup study was conducted to compare patients with and without the condition.

Statistical analysis:

SPSS v27 was used for statistical analysis (IBM©, Chicago, IL, USA). Histograms and the

Shapiro-Wilks test were employed to assess the data distribution's normality. ANOVA (F) test with post hoc test (Tukey) was used to evaluate quantitative parametric data, which were shown as mean and standard deviation (SD). The median and interquartile range (IQR) of quantitative non-parametric data were displayed, and each group was compared using the Kruskal-Wallis test in conjunction with the Mann-Whitney test. The Chi-square test was used to assess the qualitative variables, which were shown as frequency and percentage (%). Statistical significance was defined as a two-tailed P value < 0.05.

3. Results

There were 812 cases in all in this study, 622 of whom had successful cannulation, and 150 of whom had challenging cannulation. These patients were randomly assigned to one of three groups: DGW, TPS, and precut or fistulotomy groups and 40 patients failed cannulation referred for another technique. After randomization into three groups DGW, TPS, and precut or fistulotomy techniques, they had initial success in 104 (69%) patients and failed in 46 (31%) patients. Failed patients (46 patients) in difficult cannulation DCW, TPS, precut, or fistulotomy technique had a 2nd trial that had final success in all patients (46 patients) with no failure (Figures 1-4).

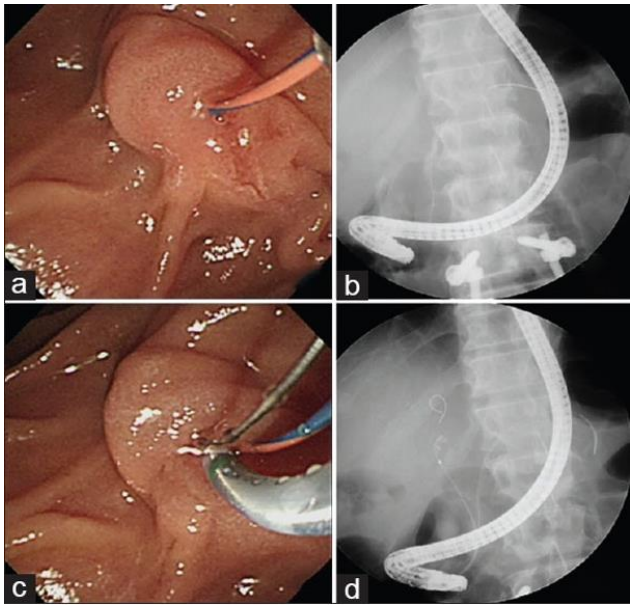

Figure 1. Double-guidewire technique. Endoscopy (a) and fluoroscopy (b) showed that the guidewire had been placed in the pancreatic duct. (c) A sphincterotome with another preloaded guidewire was introduced at the papilla to cannulate the bile duct, while the first guidewire remained in the pancreatic duct. (d) Cannulation into the bile duct was successfully performed

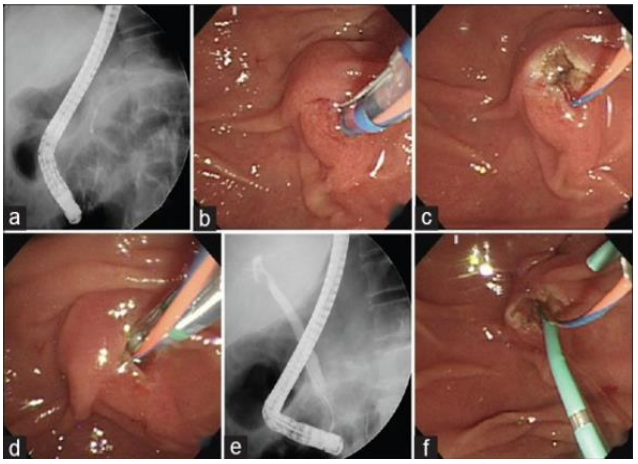

Figure 2. Trans pancreatic precut sphincterotomy. (a) Fluoroscopy image showed opacification of the pancreatic duct. (b) The endoscopic trans pancreatic precut sphincterotomy was performed with a sphincterotome. (c) A small cut of approximately 5 mm was created with a guidewire in the pancreatic duct. (d) A sphincterotome that was preloaded with another guidewire was introduced at the small cut, while the first guidewire remained in the pancreatic duct. (e) Biliary cannulation was successfully performed. (f) A stent was placed in the pancreatic duct

Figure 3. Endoscopic findings in precut fistulotomy. Needle-knife precut fistulotomy is initiated over the maximally bulging portion of the papilla (left) and extended downwards, stopping short of the orifice of the ampulla of Vater (middle). Finally, the guidewire-preloaded papillotome inserts into the common bile duct (right)

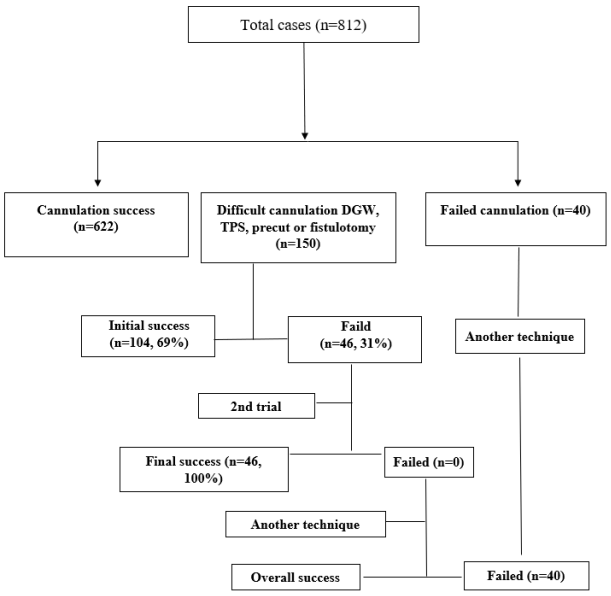

Figure 4. CONSORT flow chart of the studied group

There was an insignificant difference between the studied groups regarding demographic data, laboratory parameters, and clinical data in difficult CBD cannulation cases (Table 1).

There was an insignificant difference between the studied groups regarding PAD type, EST, EPBD, stone extraction, stenting, successful cannulation, 1st cannulation time, 2nd cannulation time, hospital stay, PEP, bleeding, cholangitis, perforation, and in-hospital mortality. Contrast dye was significantly different between the studied groups (Table 2).

There was an insignificant difference between the studied groups regarding age, sex, ERCP indication, HCV treatment, liver cirrhosis, CHILD score and classes, ascites, splenomegaly, HCC, liver metastasis, DM and HTN in patients with and without liver cirrhosis (Table 3& 4). There was an insignificant difference between the studied groups on etiological classification regarding sex, HCV treatment, liver cirrhosis, CHILD score, CHILD classes, ascites, splenomegaly, DM, and HTN between the studied groups (Table 5).

In table 6 a difference between techniques was illustrated.

Table 1. Characters, and indications of the three cannulation techniques patient groups.

		CANNULATION TECHNIQUES			P
		DGW (n= 50)	TPS (n= 50)	Precut or fistulotomy. (n= 50)	
AGE (YEAR)		57.0(20.0)	56.0(15.25)	56.0(14.25)	0.777
SEX	Male	29 (58.0%)	24 (48.0%)	26 (52.0%)	0.602
	Female	21 (42.0%)	26 (52.0%)	24 (48.0%)	
LABORATORY PARAMETERS					
HB (G/DL)		12.00 (2.15)	12.10 (2.22)	12.90 (3.0)	0.748
PLT (10^3 CELL/ML)		252.0(169.00)	285.50(128.25)	255.0(178.50)	0.465
WBCS (10^3 CELL/ML)		3.40 (1.10)	3.48(1.33)	3.60 (1.05)	0.598
ALT (U/L)		51.50(32.50)	45.0(79.25)	55.0(31.25)	0.553
AST (U/L)		55.0(35.50)	52.50(112.50)	55.0(49.25)	0.893
ALP (U/L)		283.50(184.50)	266.50(149.50)	287.50(130.25)	0.672
TOTAL BILIRUBIN (MG/DL)		17.34±6.84	15.36±8.10	15.67±7.86	0.378
DIRECT BILIRUBIN (MG/DL)		13.95 (8.00)	11.05(10.17)	11.0(11.0)	0.071
ALBUMIN (G/DL)		4.0(0.90)	3.90(0.95)	3.98(1.09)	0.906
CREATININE (MG/DL)		1.25(0.50)	1.10(0.60)	1.20(0.53)	0.371
INR		1.20(0.15)	1.20(0.12)	1.20(0.12)	0.764
CRP (MG/DL)		38.0(32.25)	42.50(32.75)	42.0(40.50)	0.761
AMYLASE (U/L)		51.50(48.50)	62.0(49.50)	62.0(35.50)	0.396
LIPASE (U/L)		50.0(51.00	60.50(49.25)	64.50(41.25)	0.624
CEA (NG/ML) *		4.05(2.25)	5.0(7.75)	6.0(6.0)	0.551
CA19-9 (NG/ML) *		70.50(61.50)	97.50(69.50)	100.0(108.0)	0.712
AFP (NG/ML) **		8.50(21.75)	9.50(38.25)	16.0(56.75)	0.736
CLINICAL DATA					
ERCP INDICATIONS	Calcular obstruction	22(44.0%)	17(34.0%)	22(44.0%)	0.679
	Ampullary mass	1(2.0%)	1(2.0)	0(0.0%)	
	Cholangiocarcinoma	11(22.0%)	8 (16.0%)	11 (22.0%)	
	Malignant LNs obstruction	2(4.0%)	4(8.0%)	0(0.0%)	
	Pancreatic cancer	9 (18.0%)	8 (16.0%)	9 (18.0%)	
	CBD stricture	2 (4.0%)	4 (8.0%)	3 (6.0%)	
	Cyst in pancreas	1 (2.0%)	5 (10.0%)	4 (8.0%)	
	Portal biliopathy	2 (4.0%)	3 (6.0%)	1 (2.0%)	
HCV TREATMENT		4(8.0%)	2(4.0%)	6(12.0%)	0.394
LIVER CIRRHOSIS		7(14.0%)	6(12.0)	7(14.0%)	0.944
CHILD SCORE *		8.0 (3.0)	9.0(2.25)	8.0(1.0)	0.828
CHILD CLASSES	B	5 (71.4%)	4 (66.7%)	6(85.7%)	0.829
	C	2(28.6%)	2(33.3%)	1(14.3%)	
ASCITES	Mild	1(2.0%)	3 (6.0%)	3(6.0%)	0.622
	Moderate	2(4.0%)	1(2.0%)	0(0.0%)	
SPLENOMEGALY		6(12.0%)	6 (12.0%)	5(10.0%)	0.936
HCC		6(12.0%)	6(12.0%)	7(14.0%)	0.942
LIVER METASTASIS		4(8.0%)	5(10.0%)	4(8.0%)	1.000
DM		38(76.0%)	37(74.05)	44(88.0%)	0.174
HTN		27(54.0%)	16(32.0%)	24(48.0%)	0.073

Data are presented as median (IQR) or frequency (%). DGW: double guidewire; TPS: trans pancreatic sphincterotomy, Hb: Hemoglobin, PLT: Platelets, WBCs: white blood cell, ALT: Alanine aminotransferase, AST: aspartate aminotransferase, ALP: Alkaline phosphatase, INR: international normalized ratio, CRP: C- reactive protein, CEA: carcinoembryonic antigen, CA19-9: Cancer antigen 19-9, AFP: alpha-fetoprotein test, ERCP: Endoscopic retrograde cholangiopancreatography, LNs: lymph node, CBD: Corticobasal degeneration, HCV: Hepatitis C virus, HCC: hepatocellular carcinoma, DM: diabetes mellitus, HTN: hypertension.

Table 2. Comparisons between the three BD cannulation techniques regarding Procedure and complications:

		CANNULATION TECHNIQUES			P
		DGW (n= 50)	TPS (n= 50)	Precut or fistulotomy (n= 50)	
PAD TYPE	None	45(90%)	44(88%)	44(88%)	0.354
	Type I	2(4%)	4(8%)	0(0%)	
	Type II	2(4%)	1(2%)	4(8%)	
	Type III	1(2%)	1(2%)	2(4%)	
EST		41(82%)	41(82%)	40(80%)	0.957
EPBD		12(24%)	8(16%)	12(24%)	0.530
STONE EXTRACTION		12(54.5%)	10(58.8%)	13(59.1%)	0.945
STENTING	No	14(28%)	10(20%)	14(28%)	0.425
	Metallic	9(18%)	6(12%)	11(22%)	
	Plastic	27(54%)	34(68%)	25(50%)	
SUCCESSFUL CANNULATION	Initial success	36(72%)	34(68%)	34(68%)	0.882
	Final success	14 (28%)	16 (32%)	16 (32)	
1ST CANNULATION TIME (MINUTE)		21(10.25)	17.50(11)	18(11.25)	0.145
2ND CANNULATION TIME (MINUTE)		12.50(6)	10.0(5.50)	9.50(2.75)	0.104
CONTRAST DYE (CC)		30(15)	25(15)	25(10)	0.048*
HOSPITAL STAYS (DAY)		5 (4)	5.0(3)	5(3)	0.328
POST-ERCP COMPLICATIONS					
PEP		5(10%)	11(22%)	12(24%)	0.151
BLEEDING		0(0%)	0(0%)	3(6%)	0.107
CHOLANGITIS		9(18%)	14(28%)	11(22%)	0.485
PERFORATION		0(0%)	0(0%)	0(0%)	--
IN HOSPITAL MORTALITY		0(0%)	0(0%)	0(0%)	--

Data are presented as median (IQR) or frequency (%). * Significant p value <0.05. DGW: double guidewire; TPS: trans pancreatic sphincterotomy, PC: precut, PAD: Periampullary diverticulum, EST: Endoscopic sphincterotomy, EPBD: Endoscopic papillary balloon dilatation, PEP: Post-Exposure Prophylaxis.

Table 3. Comparison between cannulation techniques, Indications, and complications in difficult CBD cannulation in patients with and without liver cirrhosis

PARAMETERS	LIVER CIRRHOSIS		SIGNIFICANCE TEST	P-VALUE
	No (n=130)	Yes (n=20)		
CANNULATION TECHNIQUES [N (%)]			x^2=0.12 [a]	0.944 NS
DGW	43 (33.1)	7 (35.0)		
TPS	44 (33.8)	6 (30.0)		
PC OR FISTULOTOMY	43 (33.1)	7 (35.0)		
ERCP INDICATIONS [N (%)]			x^2=2.89 [a]	0.236 NS
CALCULAR OBSTRUCTION	55 (42.3)	6 (30.0)		
MALIGNANCIES	52 (40.0)	12 (60.0)		
OTHERS	23 (17.7)	2 (10.0)		
PEP [N (%)]			x^2=0.20, [b]	0.768 NS
NO	105 (80.8)	17 (85.0)		
YES	25 (19.2)	3 (15.0)		
BLEEDING [N (%)]			x^2=0.47 [b]	1.000 NS
NO	127 (97.7)	20 (100.0)		
YES	3 (2.3)	0 (0.0)		
CHOLANGITIS [N (%)]			x^2=0.09 [b]	1.000 NS
NO	100 (76.9)	16 (80.0)		
YES	30 (23.1)	4 (20.0)		

%: percent within non-cirrhotic and cirrhotic difficult CBD cannulation cases, a: Pearson Chi-square test, b: Fisher's Exact test, NS: Non-significant at P-value ≥0.05.

Table 4. Comparisons between BD cannulation techniques in difficult CBD cannulation in patients with liver cirrhosis

		CANNULATION TECHNIQUES			P
		DGW (n= 7)	TPS (n= 6)	Precut or fistulotomy (n= 7)	
ERCP INDICATION	Calcular obstruction	3(42.9%)	0(0.0%)	3(42.9%)	0.147
	Malignancies	4(57.1%)	4(66.7%)	4(57.1%)	
	Others	0(0.0%)	2(33.3%)	0(0.0%)	
CHILD SCORE		8.0(3.0)	9.0(2.25)	8.00(1.0)	0.590
CHILD CLASSES	B	5 (71.4%)	4 (66.7%)	6(85.7%)	0.829
	C	2(28.6%)	2(33.3%)	1(14.3%)	
ASCITES	Mild	1(14.3%)	3(50.0%)	3(42.9%)	0.475
	Moderate	2(28.6%)	1(16.7%)	0(0.0%)	
PAD TYPE	None	7(100.0%)	6(100.0%)	6(85.7%)	--

	Type I	0(0.0%)	0(0.0%)	0(0.0%)	
	Type II	0(0.0%)	0(0.0%)	0(0.0%)	
	Type III	0(0.0%)	0(0.0%)	1(14.3%)	
EST		6(85.7%)	4(66.7%)	4(57.1%)	0.602
EPBD		1(14.3%)	2(33.3%)	3(42.9%)	0.602
STONE EXTRACTION		3(42.9%)	0(0.0%)	2(28.6%)	0.292
STENTING	No	3(42.9%)	0(0.0%)	2(28.6%)	0.283
	Metallic	2(28.6%)	1(16.7%)	3(42.9%)	
	Plastic	2(28.6%)	5(83.3%)	2(28.6%)	
SUCCESSFUL CANNULATION	Initial success	6(85.7%)	4(66.7%)	6(85.7%)	0.636
	Final success	1(14.3%)	2(33.3%)	1(14.3%)	
1ST CANNULATION TIME (MINUTE)		21.0(10.0)	15.50(11.0)	20.0(9.0)	0.607
2ND CANNULATION TIME (MINUTE)		-	8.50	-	--
CONTRAST DYE (CC)		25.0(10.0)	20.0(8.75)	25.0(25.0)	0.434
HOSPITAL STAYS (DAY)		6.0(4.0)	6.0(4.75)	5.0(3.0)	0.229
POST-ERCP COMPLICATIONS					
PEP		1(14.3%)	1(16.7%)	1(14.3%)	1.000
BLEEDING		7(100.0%)	6(100.0%)	7(100.0%)	--
CHOLANGITIS		1(14.3%)	0(0.0%)	3(42.9%)	0.263

Data are presented as median (IQR) or frequency (%). DGW: double guidewire; TPS: trans pancreatic sphincterotomy, ERCP: Endoscopic retrograde cholangiopancreatography, LNs: lymph node, CBD: Corticobasal degeneration, HCV: Hepatitis C virus, HCC: hepatocellular carcinoma, DM: diabetes mellitus, HTN: hypertension. DGW: double guidewire; TPS: trans pancreatic sphincterotomy, PC: precut, PAD: Periampullary diverticulum, EST: Endoscopic sphincterotomy, EPBD: Endoscopic papillary balloon dilatation, PEP: Post-Exposure Prophylaxis.

Table 5. Comparative study of difficult CBD cannulation cases according to ERCP indication

		ERCP INDICATIONS			P
		Calcular obstruction (n=61)	Malignancies (n=64)	Others (n=25)	
AGE (YEAR)		54.0(18.0)	59.0(16.0)	55.0(10.0)	0.016*
SEX	Male	30(49.2%)	40(62.5%)	9(36.0%)	0.062
	Female	31(50.8%)	24(37.5%)	16(64.0%)	
CLINICAL DATA					
HCV TREATMENT		5(8.2%)	6(9.4%)	1(4.0%)	0.853
LIVER CIRRHOSIS		6(9.8%)	12(18.8%)	2(8.0%)	0.236
CHILD SCORE		8.0(1.25)	8.50(2.0)	9.50	0.590
CHILD CLASSES	B	6(100.0%)	8(66.7%)	1(50.0%)	0.212
	C	0(0.0%)	4(33.3%)	1(50.0%)	
ASCITES	Mild	2(3.3%)	4(6.3%)	1(4.0%)	0.560
	Moderate	0(0.0%)	2(3.1%)	1(4.0%)	
SPLENOMEGALY		5(8.2%)	10(15.6%)	2(8.0%)	0.359
HCC		5(8.2%)	13(20.3%)	1(4.0%)	0.045*
LIVER METASTASIS		1(1.6%)	11(17.2%)	2(8.0%)	0.011*
DM		47(77.0%)	51(79.7%)	21(84.0%)	0.767
HTN		23(37.7%)	32(50.0%)	12(48.0%)	0.360
CANNULATION TECHNIQUES	DGW	22(36.1%)	23(35.9%)	5(20.0%)	0.406
	TPS	17(27.9%)	21(32.8%)	12(48.0%)	
	PC/ Fistulotomy	22(36.1%)	20(31.3%)	8 (32.0%)	

Data are presented as median (IQR) or frequency (%). * significant p-value <0.05, HCV: Hepatitis C virus, HCC: hepatocellular carcinoma, DM: diabetes mellitus, HTN: hypertension. DGW: double guidewire; TPS: trans pancreatic sphincterotomy, PC: precut, PAD: Periampullary diverticulum, EST: Endoscopic sphincterotomy, EPBD: Endoscopic papillary balloon dilatation, PEP: Post-Exposure Prophylaxis.

Table 6. Comparisons between BD cannulation techniques regarding cost and operator skills

	CANNULATION TECHNIQUES		
	DGW	TPS	PC/ Fistulotomy
ACCESSORIES	Sphincterotome	Sphincterotome	Sphincterotome + Needle knife
	Guidewire (2)	Guidewire (1)	Guidewire (1)
	Contrast (50 cc bottle)	Contrast (50 cc bottle)	Contrast (50 cc bottle)
COST	Approx 15000 EGP	Approx. 10000 EGP	Approx. 16000 EGP
OPERATOR SKILLS	+	++	+++

DGW: double guidewire; TPS: trans pancreatic sphincterotomy, PC: precut, EGP; Egyptian pound.

4. Discussion

For therapeutic ERCP, selective biliary cannulation is an essential step. Over 90% of biliary cannulations are effective when performed by skilled endoscopists .[13] Since it was first reported, this approach has been used in cases of complex biliary cannulation with positive outcomes, particularly in individuals with an abnormal ampulla morphology or a deformed BD architecture due to neoplasia .[14] Because the incision either exposes the BD or runs along the side of the duct, exposing the duct architecture, a sphincterotomy can be performed over the guidewire in the PD to cannulate the biliary

orifice. DGT and TPS may facilitate biliary cannulation .[14] The effectiveness and safety of three cutting-edge interventional techniques—DGT, TPS, and Needle-Knife Precut or Fistulotomy—in accomplishing successful biliary cannulation in patients who presented with challenging CBD anatomy during ERCP were assessed and compared in this study. Our findings indicate that all three techniques are effective, with comparable success rates and similar complication profiles, consistent with the existing body of literature.

The success rates were high across all three techniques, with no statistically significant differences. This suggests that each technique can be effectively utilized to overcome the challenges of difficult cannulation. Previous studies have reported similar findings .[15]

For instance, Dumonceau et al.[16] found high success rates with DGT, TPS, and Needle-Knife Precut in patients where standard cannulation methods failed, reinforcing our results.

Moreover, Akshintala et al.[17] emphasized the importance of having multiple techniques at an endoscopist's disposal, noting that flexibility in approach is critical for managing complex cases. Studies by Berry et al.[18] and Yoo et al.[19] have demonstrated similar success rates and complication profiles when using advanced cannulation techniques like DGW and precut sphincterotomy in patients with difficult biliary access, further supporting the findings of this study.

The complication rates, encompassing post-ERCP pancreatitis, bleeding, and cholangitis, showed no significant difference between the two groups. Research by Williams et al.[20] and Wu et al.[21] found that advanced cannulation techniques yielded no notable disparities in complication rates. The decrease in the use of contrast dye in the precut and fistulotomy group implies a lower risk of post-ERCP pancreatitis, given that overuse of contrast dye has been linked to a heightened pancreatitis risk.

In patients with liver cirrhosis, the use of therapeutic ERCP is linked to a heightened likelihood of complications, including pancreatitis and post-procedure bleeding .[22] The diagnostic ERCP also increases the risk of post-ERCP pancreatitis (PEP) and cholecystitis in this group of individuals .[23] The presence of multiple health conditions in patients with cirrhosis significantly increases the risk of complications and death following ERCP procedures .[24]

Consequently, the utilization of ERCP in this vulnerable population necessitates meticulous consideration.

The difficulties and results of ERCP operations in individuals with and without liver cirrhosis are highlighted in this study. The study's findings revealed that there were no appreciable differences between the groups with and without cirrhosis in terms of clinical outcomes, laboratory markers, or demographic traits.

Unlike what is settled, this study found that even though patients without cirrhosis had a smoother procedural experience, the success rates of cannulation techniques were comparable across both groups, indicating that the techniques are robust enough to handle varying degrees of complexity in liver conditions. These results are indeed unexpected, especially when compared to what is typically reported in the literature. One possible explanation could be that the patients with liver cirrhosis in this study were carefully selected and managed, potentially reducing their overall risk during the ERCP procedure. Additionally, advancements in medical technology and techniques may have improved the success and complication rates for all patients undergoing ERCP, regardless of underlying conditions. It's also important to consider the sample size and specific characteristics of the patient population in your study. If the number of patients with liver cirrhosis was small, it may not accurately represent the overall risk for this population. Additionally, the severity of liver cirrhosis and other comorbidities among the patients could have influenced the outcomes. Further research is imperative to enhance our understanding and management of this critical cohort.

Regarding cost analysis, the current study did not explicitly address any differences between the three techniques. However, considering the procedural aspects, the following points can be inferred. The DGW Technique may incur higher initial costs due to the use of additional guidewires and the potential for extended procedural time. The TPS Technique is generally cost-effective, as it involves fewer additional tools and materials. However, the need for expertise in this technique could lead to higher indirect costs associated with specialist time. Precut/Fistulotomy Technique: While cost-effective in terms of tools, this technique can be time-consuming and may require additional hospital stays if complications arise. A cost-effectiveness analysis by García-Cano J et al.[25] demonstrated that while the upfront costs of techniques like DGW might be higher, the overall costs could be balanced by reduced complication rates and shorter hospital stays, aligning with the cost implications observed in this study.

Accordingly, all three techniques (DGW, TPS, and precut/fistulotomy) can be effective in difficult cannulation cases. However, the choice of technique might be influenced by specific patient

conditions. Because a guidewire is used to stabilise and guide the cannulation process, the DGW Technique has a high success rate and is especially helpful for patients with changed biliary architecture. Because it addresses the bile duct directly, the TPS Technique works well for individuals with challenging biliary architecture without running the risk of damaging the pancreatic duct.

While the recut/Fistulotomy Technique is beneficial when initial cannulation attempts fail, it offers an alternative route with high success rates. In patients with cirrhosis, the TPS and precut techniques might be preferable due to the potential for less manipulation of the ductal structures and lower contrast use, reducing the risk of procedure-induced pancreatitis and other complications. The clinical implications of these findings are significant. The high success rates and comparable safety profiles of DGT, TPS, and Needle-Knife Precut offer endoscopists the flexibility to choose the technique they are most comfortable with, based on patient-specific anatomical considerations and their expertise. Borrelli et al.[26] advocate for such tailored approaches in ERCP, emphasizing the necessity of adaptability in technique selection to optimize patient outcomes. This study reinforces this perspective, suggesting that proficiency in various advanced techniques is essential for effectively and safely managing difficult biliary cannulation cases.

It also underscores the importance of comprehensive training for endoscopists in all three advanced cannulation techniques. The ability to perform DGT, TPS, and Needle-Knife Precut proficiently can significantly enhance procedural success rates and patient safety. Similar studies, such as those by Williams et al.[20] and Maurice et al.[27], have emphasized the necessity for endoscopists to be well-versed in multiple methods to effectively handle complex cases.

Multi-technique proficiency can lead to reduced procedure times and improved overall patient outcomes, highlighting the value of rigorous and diverse training programs in endoscopic education. The study by Gad et al.[28] suggested that larger, more diverse populations can provide more comprehensive data on the efficacy and safety of these techniques.

This study has a number of shortcomings in spite of its advantages. The findings may not be as broadly applicable as they may be due to the single-center methodology and the rather small sample size. Additionally, the randomization process, while rigorous, could not account for all potential confounding variables. Future research should focus on larger, multicentre trials to validate these findings and explore the potential differences in outcomes based on patient demographics and anatomical variations.

Furthermore, it would be beneficial to investigate the long-term outcomes and potential complications associated with each technique. Understanding the impact of these techniques on long-term patient health and quality of life is crucial for developing best practice guidelines. Additionally, exploring the cost-effectiveness of these techniques could provide valuable insights for healthcare providers and policymakers.

4. Conclusion

For patients with challenging CBD anatomy during ERCP, DGT, TPS, and Needle-Knife Precut or Fistulotomy are all practical and efficient methods for accomplishing successful biliary cannulation.

The choice of technique should be individualized, considering the patient's specific anatomy and the endoscopist's expertise and underscoring the importance of personalized treatment approaches in ERCP procedures. Additionally, this study refuted the claim that ERCP in patients with liver cirrhosis is always associated with a high rate of complications. The cost analysis suggests that while some techniques may have higher initial costs, their efficacy in reducing complications can lead to overall cost savings.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

Funding

No Funds : Yes

Conflicts of interest

There are no conflicts of interest.

References

1. McCune WS, Shorb PE, Moscovitz H. Endoscopic cannulation of the ampulla of vater: a preliminary report. Ann Surg. 1968; 167(5): 752-6.
2. Wang P, Zhang W, Liu F, Li ZS, Ren X, et al. Success and complication rates of two precut techniques, transpancreatic sphincterotomy and needle-knife sphincterotomy for bile duct cannulation. J Gastrointest Surg. 2010; 14(4): 697-704.
3. Freeman ML, Guda NM. ERCP cannulation: a review of reported techniques. Gastrointest Endosc. 2005; 61(1): 112-25.
4. Freeman ML, Nelson DB, Sherman S, Haber GB, Herman ME, et al. Complications of endoscopic biliary sphincterotomy. N Engl J Med. 1996; 335(13): 909-18.

5. Vandervoort J, Soetikno RM, Tham TC, Wong RC, Ferrari AP, Jr., et al. Risk factors for complications after performance of ERCP. Gastrointest Endosc. 2002; 56(5): 652-6.
6. Masci E, Mariani A, Curioni S, Testoni PA. Risk factors for pancreatitis following endoscopic retrograde cholangiopancreatography: a meta-analysis. Endoscopy. 2003; 35(10): 830-4.
7. Laohavichitra K, Akaraviputh T, Methasate A, Leelakusolvong S, Kachintorn U. Comparison of early pre-cutting vs standard technique for biliary cannulation in endoscopic retrograde cholangiopancreatography: a personal experience. World J Gastroenterol. 2007; 13(27): 3734-7.
8. Katsinelos P, Gkagkalis S, Chatzimavroudis G, Beltsis A, Terzoudis S, et al. Comparison of three types of precut technique to achieve common bile duct cannulation: a retrospective analysis of 274 cases. Dig Dis Sci. 2012; 57(12): 3286-92.
9. Dumonceau JM, Devière J, Cremer M. A new method of achieving deep cannulation of the common bile duct during endoscopic retrograde cholangiopancreatography. Endoscopy. 1998; 30(7): S80.
10. Herreros de Tejada A, Calleja JL, Díaz G, Pertejo V, Espinel J, et al. Double-guidewire technique for difficult bile duct cannulation: a multicenter randomized, controlled trial. Gastrointest Endosc. 2009; 70(4): 700-9.
11. Sarr MG, Banks PA, Bollen TL, Dervenis C, Gooszen HG, et al. The new revised classification of acute pancreatitis 2012. Surg Clin North Am. 2013; 93(3): 549-62.
12. Testoni PA, Mariani A, Aabakken L, Arvanitakis M, Bories E, et al. Papillary cannulation and sphincterotomy techniques at ERCP: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. Endoscopy. 2016; 48(7): 657-83.
13. Facciorusso A, Ramai D, Gkolfakis P, Khan SR, Papanikolaou IS, et al. Comparative efficacy of different methods for difficult biliary cannulation in ERCP: systematic review and network meta-analysis. Gastrointest Endosc. 2022; 95(1): 60-71.e12.
14. Wang HP. Transpancreatic biliary sphincterotomy for difficult biliary cannulation: can it be better than other methods? Endoscopy. 2021; 53(10): 1020-2.
15. Eminler AT, Parlak E, Koksal AS, Toka B, Uslan MI. Wire-guided cannulation over a pancreatic stent method increases the need for needle-knife precutting ın patients with difficult biliary cannulations. Gastrointest Endosc. 2019; 89(2): 301-8.
16. Dumonceau JM, Kapral C, Aabakken L, Papanikolaou IS, Tringali A, et al. ERCP-related adverse events: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy. 2020; 52(2): 127-49.
17. Akshintala VS, Kalloo AN. Comparing the efficacy and safety of transpancreatic sphincterotomy, double-guidewire, and precut techniques: Which one makes the cut? Dig Dis Sci. 2019; 64(9): 2373-5.
18. Berry R, Han JY, Tabibian JH. Difficult biliary cannulation: Historical perspective, practical updates, and guide for the endoscopist. World J Gastrointest Endosc. 2019; 11(1): 5-21.
19. Yoo YW, Cha SW, Lee WC, Kim SH, Kim A, et al. Double guidewire technique vs transpancreatic precut sphincterotomy in difficult biliary cannulation. World J Gastroenterol. 2013; 19(1): 108-14.
20. Williams EJ, Krishnan B, Lau SY. Difficult Biliary Cannulation and Sphincterotomy: What to Do. Gastrointestinal and Pancreatico-Biliary Diseases: Advanced Diagnostic and Therapeutic Endoscopy. 2021; 101-34.
21. Wu CCH, Lim SJM, Khor CJL. Endoscopic retrograde cholangiopancreatography-related complications: risk stratification, prevention, and management. Clin Endosc. 2023; 56(4): 433-45.
22. Solanki S, Kichloo A, Dahiya DS, Solanki D, Singh J, et al. Endoscopic retrograde cholangiopancreatography (ERCP) in patients with liver cirrhosis: Analysis of trends and outcomes from the national inpatient sample database. J Clin Gastroenterol. 2022; 56(7): 618-26.
23. Cahyadi O, Tehami N, de-Madaria E, Siau K. Post-ERCP pancreatitis: Prevention, diagnosis and management. Medicina (Kaunas). 2022; 58(9).
24. Kim JY, Lee HS, Chung MJ, Park JY, Park SW, et al. Bleeding complications and clinical safety of endoscopic retrograde cholangiopancreatography in patients with liver cirrhosis. Yonsei Med J. 2019; 60(5): 440-5.
25. García-Cano J. What is the most cost-effective method for a difficult biliary cannulation in ERCP? REED. 2017; 109(3): 171-3.
26. Borrelli de Andreis F, Mascagni P, Schepis T, Attili F, Tringali A, et al. Prevention of post-ERCP pancreatitis: current strategies and novel perspectives. Therapeutic Advances in Gastroenterology. 2023; 1617562848231155984.
27. Maurice JB, Rochford A, Marshall S, Sebastian S, Dhar A, et al. Green endoscopy: using quality improvement to develop sustainable practice. Frontline Gastroenterol. 2022; 13(4): 342-5.
28. Gad EH, Zakaria H, Kamel Y, Alsebaey A, Zakareya T, et al. Surgical (Open and laparoscopic) management of large difficult CBD stones after different sessions of endoscopic failure: A retrospective cohort study. Ann Med Surg (Lond). 2019; 4352-63.