American Journal of Biology and Natural Sciences
https://biojournals.us/index.php/AJBNS
ISSN: 2997-7185

Needle-Knife Fistulotomy Vs. Standard Biliary Canulation Cannulation: Comparative Study

Dr. Ibrahim Rahim Abed (M.B.Ch.B, F.I.B.M.S) (Int. Med.) [1]
Muhannad Ayal Wheeb (M.B.Ch.B, D.M, F.I.B.M.S) [2]
Ali Kamil Abd Ali Ali Al-Jubory (MBCHB, FIBMS, FICMS) (GIT & Hepatology) [3]
Al Muthanna health directorate, Al Hussain teaching hospital. [1, 3]

Imam Hussain teaching hospital [2]

Received: 2024, 15, Apr
Accepted: 2025, 21, May
Published: 2025, 26, Jun

Annotation: Background: the patients with common bile duct (CBD) stones, access to the CBD can be achieved through the papilla orifice followed by standard biliary sphincterotomy (SBS), or through precut fistulotomy (PF) in case of difficult cannulation. The two procedures alter papilla anatomy different ways.

Aims: Is to evaluate complication and clearance rate following CBD stone extraction for both ways.

Patients and Methods: This was prospective study including 100 patients with common bile duct stone. Patients demographics and clinical characteristics were collected. Indication for ERCP are CBD stones All included patients were subjected to laboratory tests before and after procedure. Patients were divided into two groups 50 patients undergone precut fistulotomy and 50 patients subjected to standard biliary cannulation according to the order of the procedure. The outcomes measured were the number of therapeutic procedures required for complete stone

removal and associated complications.

Results: Age of patients ranged from (23-68) years, with a mean age of (48.3 ± 12.7) years. The duration of the procedure was significantlyshorter in the standard biliary cannulation (SBC) group (19.2 ± 4.9 min.) compared to the precut fistulotomy (PF) group (32.0 ± 6.6 min.), P-value < 0.001. There were no significant differences in post-ERCPinvestigations or complications between the two groups. However, incases of post-ERCP pancreatitis, the duration of the procedure wassignificantly longer in the PF group compared to the SBC group. P. value= 0.011.

Conclusions: The SBC group had shorter procedure durations compared to the PF group. There were no significant differences in stone characteristics or post-ERCP investigations. Complication rates were similar between the groups. Among cases of post-ERCP pancreatitis, the PF procedure had a significantly longer duration.

Keywords: fistulotomy, pancreatitis, common bile duct.

Introduction;

The common bile duct is structure that is tube like and consider as a part of biliary system and the main function is responsible, for transporting bile from the liver and gallbladder to the small intestine. Bile, a fluid important for digestion of fat .bile is produced by the liver parenchyma and after that stored in the gallbladder where needed later for digestion. When the food pass to the intestine the bile is released from the gallbladder [1]. Travels through the common bile duct until reach the duodenum, which is the initial site of the small intestine. The common bile duct (CBD) is measuring around eight centimeters in length .the common bile duct forms when both common hepatic duct and cystic duct merge together . The liver secrete bile through the duct while bile from the gallbladder flows through the cystic duct. As it passes through the pancreas this important pathway meet with a duct at a pocket called ampulla of Vater. Within this pocket there is a muscle known as sphincter of Oddi which responsible for regulating the secretion of both bile and pancreatic juice flow into duodenum [2].

Common bile duct stones (CBDS) are occur in about 10–20% of patients with gallstones

symptoms. They can cause different manifestation, these clinical features including pain, jaundice, acute pancreatitis [3].Gallstones or Cholelithiasis are characterized by the accumulation of fatty sediments or mineral deposits in the common bile duct (CBD) or gallbladder. Cholesterol stones are composed mainly of cholesterol, while black pigment stones are mainly made of pigment, and brown pigment stones are composed of a mix of pigment and bile lipids. Cholesterol stones make up approximately 75% of the secondary common bile duct stones in the United States, while black pigment stones comprise the remainder. Primary common bile duct stones are usually brown pigment stones. Bile flow is obstructed by stones within the common bile duct, which leads to obstructive jaundice and possibly hepatitis. The stagnant bile can also lead to bactibilia and ascending cholangitis. Cholangitis and sepsis are more common in patients with choledocholithiasis than other sources of bile duct obstruction because a bacterial biofilm typically covers common bile duct stones.

The risk factors include diet, lifestyle, Family history of CBD stone, female gender. We all know that women are consider more likely to develop choledocholithiasis than male, this is because associated with higher levels of estrogen . The decreased force of contractile of the gallbladder muscles leads to more cholestasis and the precipitation of cholesterol crystals, aging that over 65 years of age is consider as risk factor. Common bile duct (CBD) expansion in diameter, CBD angulations were all consider to be associated with the development of calculi in elderly patient. High-calorie Diet and carbohydrates refined diet, fiber diet and unsaturated-fat diet, total intravenous (i.v.) nutrition and TPN life style with low physical activity, fast food intake, pregnancy, obesity, prolong fasting, rapid weight reduction Other causes include Alcoholic cirrhosis, dyslipidemia, diabetes mellitus, oral contraceptives or estrogen therapy, metabolic syndrome and other metabolic disease are also among the condition and risk factors for Metabolic syndrome and related factors, such as abnormality of lipid metabolism, hyperuricemia, hypercalcemia, insulin resistance, and nonalcoholic fatty liver are risk factors for the development of choledocholithiasis[4]. Choledocholithiasis (stones in common bile duct) is one of the complications of Cholelithiasis (gallstones), so the initial step is to confirm the diagnosis of Cholelithiasis.

Patients and Methods

This was prospective study including 100 patients with CBD stones who were admitted and treated as inpatients at the department of internal medical ward at the Gastroenterology / GIT and Hepatology Teaching Hospital/ Baghdad during the period from 1st march 2023 to 1st march2024.All patient are follow up for one week after ERCP procedure for for post ERCP complications The study was approved by the Iraqi Council of Medical Specializations.

Undergoing ERCP for CBD stones (native papilla) for the first time; 2- Aged ≥18; 3- undergoing ERCP performed by expert endoscopists.

Exclusion Criteria

1-Patients undergoing papillary balloon dilation;

2-Patients undergoing precut fistulotomy and, later on, standard biliary cannulation from the natural orifice to re-gain access to CBD;

3-Pregnancy;

4 -Contrast allergy

5-Lack of requested data or follow-up information in the database

6-Patient undergoing pancreatic canulation

7-Acut and chronic pancreatitis

8- INR more than 1.5 or platelet less than 100

9 -Inability to identify and access the intra-duodenal portion of the bile duct,

10- Altered upper GI tract anatomy

11 - Evidence of malignant infiltration of the ampulla or peri-ampullary area

12-Intahepatic stones 13- Patient with CBD stricture.

Data Collection

Patients demographics (age, gender) and clinical characteristics (CBD diameter, stone size and stone number) were collected. All included patients were subjected to laboratory tests at the beginning of treatment, including complete blood count (CBC), alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (AP), total serum bilirubin TSB), direct bilirubin, prothrombin time (PT), partial thromboplastin time (PTT). Serum lipase and serum amylase were reported before and 6 hour after the procedure.

Study groups

Patients were divided into two groups according to the order of the procedure: 1.we select randomly Fifty patients from patients who underwent precut fistulotomy and 2. Fifty patients from those who underwent standard biliary canulation. And we make comparison between these two groups

Procedure

Local anesthesia of the pharynx was obtained using lidocaine gel or spray. The patients were sedated with an i.v injection of 50 mg of pethidine and diazepam (5 mg) . To halt duodenal peristalsis, 20 mg of hyoscine, n- butyl bromide was administered i.v when reach the pylorus

All patient given indomethacin suppository before ERCP, ERCP was performed by experienced endoscopists at a single center using side-viewing endoscopes (TJF-Q180v; Olympus medical system Corporation, Tokyo, Japan), (TJF – 4.2; pentaxhoya corporation; Tokyo Japan) .

After selective cannulation of the CBD using a triple lumen sphincterotome (Papillotome, Boston scientific microvasive; cork; Ireland) with a guide wire (Hydra Jagwire 0.035 inch, Boston Scientific Microvasive. Cork,13Ireland), a diagnostic cholangiogram was obtained, and the stone size and number were documented.

Access to the CBD will be attempted via either NKF or a standard sphincterotome.. To perform the NKF, the ampulla will be identified and closely examined to accurately delineate the infundibulum.

Aneedle knife (Needlecut 3 V, Olympus Medical Canada, Markham, Ontario) will be used to make a 4-mm incision in the mid to proximal third of the vertical axis in the intra-duodenal segment of the bile duct. The needle will be used to cut through the mucosa with intermittent examination for the muscular ampullary complex and subsequent penetration into the bile duct usually signaled by bile flow. When bile is seen, the fistula will be gently probed with a guidewire until the CBD is cannulated. Cannulation of the CBD will be confirmed with proximal advancement of the guidewire and contrast injection with cholangiography. If the findings on the cholangiogram indicate that further interventions are necessary, then the fistulotomy site will be extended with the use of standard sphincterotome. Further interventions include placement of biliary stents balloon sweeping of the CBD.

The standard cannulation will be performed using a traditional sphincterotome (Clever-cut 3 V, Olympus Medical Canada, Markham, Ontario) with access gained to the biliary system via the native orifice.

Statistical analysis

SPSS® software version 23.0 For Linux® operating system (SPSS Inc.Chicago, IL, USA) was used

to perform statistical analysis for this study. Continuous variables were represented as means ± SD while categorical variables were represented as frequencies and percentages. Student's t-test was used to compare means between two groups, while chi-square test was used to assess the relationship between categorical variables. P-value of ≤ 0.05 was considered statistically significant.

Results

This study included a total of (100) patients, age of patients ranged from 23 to 68 years, with a mean age of (48.3 ± 12.7) years and a median of 50 years. Fifty patients (50%) had underwent precut fistulotomy (PF) procedure, while the other 50 patients underwent standard biliary cannulation (SBC) procedure.

Comparison of age between the two groups had revealed that SBC group were significantly older (53.1 ± 10.9 years) compared (43.4 ± 12.7 years), with a mean difference in age of (9.7) years, Student's t-test = 4.1, P-value < 0.001. Age groups distribution of study patients according to procedure group is illustrated in Figure (3-1).

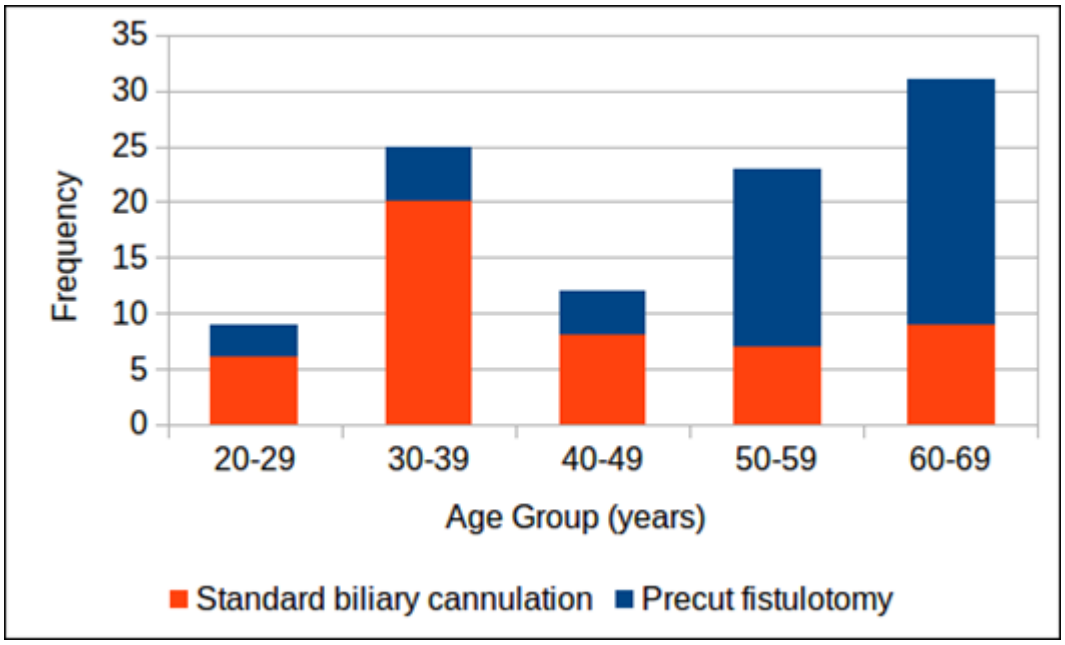

Figure (3-1): Age group distribution of study patients according to procedure group (n=100) **.**

There was significant difference between the two study groups regarding age (P < 0.05), however, no significant difference was observed regarding sex.There was significant difference between the two study groups regarding both CBD diameter and size of ampulla of Vater, P-value = 0.001 and 0.019, respectively. No significant differences were observed between the study groups regarding stone size, or history of cholecystectomy (Table 3-1).

Table (3-1): Demographic characteristics of study patients (n=100)

Demographic Characteristics		**Procedure No. (%)**		**Total No. (%)**	**P. value**
		SBC	**PF**		
Age	**Mean ± SD (years)**	43.4±12.7	53.1±10.9	48.3±12.7	**<0.001***
Sex	**Male**	24 (53.3%)	21 (46.7%)	45 (100%)	0.546
	Female	26 (47.3%)	29 (52.7%)	55 (100%)	
CBD	**Mean ± SD**	13.2 ± 4.4	10.7 ± 2.7	12.0 ± 3.8	**0.001***

Diameter	**(mm)**				
Stone size	**Mean ± SD (mm)**	8.3 ± 3.2	7.9 ± 2.4	8.1 ± 2.8	0.474
Cholecyst-ectomy	**Yes**	5 (29.4%)	12 (70.6%)	17 (100%)	0.062
	No	45 (54.2%)	38 (45.8%)	83 (100%)	
Ampulla of Vater	**Small**	5 (26.3%)	14 (73.7%)	19 (100%)	**0.019***
	Normal	35 (61.4%)	22 (38.6%)	57 (100%)	
	Large	10 (41.7%)	14 (58.3%)	24 (100%)	

No significant differences were observed between the two groups regarding any of the investigations, P. value > 0.05 (Table 3-2).17

Table (3-2): Pre-ERCP values of laboratory investigations

Laboratory Investigations	**Pre-ERCP values Mean ± SD**		**Total Mean ± SD**	**P. value**
	SBC (n=50)	**PF (n=50)**		
PT (sec)	12.9 ± 2.1	13.1 ± 1.8	13.0 ± 2.0	0.610
PTT (sec)	26.9 ± 5.4	28.3 ± 5.0	27.6 ± 5.2	0.182
INR	1.0 ± 0.1	1.0 ± 0.1	1.0 ± 0.1	0.028
TSB (mg/dL)	6.1 ± 7.2	8.2 ± 6.4	7.2 ± 6.9	0.126
DSB (mg/dL)	4.9 ± 6.7	6.7 ± 5.6	5.8 ± 6.2	0.158
ALP (U/L)	377 ± 226	440 ± 319	409 ± 277	0.257
ALT (U/L)	103 ± 103	98 ± 101	100 ± 102	0.841
AST (U/L)	88.4 ± 87.0	80.7 ± 68.1	84.5 ± 77.7	0.626
WBC ($\times 10^3$/mL)	7.1 ± 2.1	8.1 ± 2.9	7.6 ± 2.6	0.064
Platelet ($\times 10^3$/mL)	270 ± 100	242 ± 47	255 ± 79	0.082
S. amylase (U/L)	34.8 ± 18.7	40.4 ± 7.2	37.6 ± 14.3	0.053
S. lipase (U/L)	35.2 ± 12.3	38.9 ± 6.4	37.1 ± 9.9	0.060

Regarding the procedure, duration was significantly shorter in SBC (19.2 ± 4.9 min.) compared to PF (32.0 ± 6.6 min.), Student's t-test = 11.0, d.f.=98, P. value < 0.001 (Table 3-3).

Table (3-3): Comparison of procedures regarding duration of the procedure

Group	**N**	**Procedure duration (minutes)**			**P-value**
		Mean	**SD**	**Range**	
SBC	50	19.2	4.9	13.0 – 32.0	**<0.001***
PF	50	32.0	6.6	15.0 – 45.0	
Total	100	25.6	8.6	13.0 – 45.0	

* Significant at P < 0.05

Discussion

CBD stone are complex disease witch manifested in various forms. It may be associated with gall stone calculi or may be detected after cholecystectomy. Besides causing complication in the CBD they also causing inflammation in the adjacent organs including pancreas[6-8]ERCP is commonly performed procedure for treatment of CBD stones. The conventional technique involves the

cannulation of the bile duct via ampulla of vater,this followed by doing incision using electro cautery[9].If the standard biliary cannulation fails then biliary access achieves through precut fistulotomy, witch theoretically decreases risk of pancreatitis. Despite that ERCP is the main stay of treatment ,both precut fistulotomy and standard biliary cannulation are associated with complication .In our study we compare post ERCP complication between two groups ,standard biliary cannulation and Needle knife precut fistulotomy techniques .

There are different types of precut techniques including needle knife fistulotomy, precut papillotomy and trans pancreatic precut sphincterotomy.of these the most common technique is precut fistulotomy our study we choice precut fistulotomy as precut technique in this procedure we creates choledochoduodenal fistula that avoids the orifice of the papilla so avoid puncturing and trauma to the papilla .In the current study Comparisons between SBC group and PF group regarding demographic characteristics. There was significant difference between the two study groups regarding age ($P < 0.05$). gain biliary access occurs more through SBC than 50 year, but for that more than 50 years gain biliary access occur more with precut fistulotomy with a mean difference in age of (9.7) years but however, no significant difference was observed regarding sex.this in accordance with previous studies .In retrospective single _ cohort study including 85 patients undergoing for the first time ERCP for CBD stones with 85 PF incase of failed cannulation attempts, matched for sex and age[10-13]Livia Archbugi et al.reported that there were no significant differences in gender proportion, average size of stones, number of gallstones, previous cholecystectomy. But in occurrence with this study PF higher in older age. This might related to difference in anatomy of ampulla and associated comorbid .In our study Complications including bleeding, pancreatitis, and perforation were observed higher among PF than SBS but statically No significant difference was observed between the two study groups.This occurs in accordance with Livia Archbugi et al, where there were no significant difference in terms of post procedural complication despite the difference but statically not significance, patients with PF had higher rate of perforation (3.6% vs.1,2%, P= 0.37) and post ERCP pancreatitis (12.9 vs. 7.1, P= 0.3) where 3 /85 of PF develop perforationvs. 1 for 85 among SBC ,post ERCP pancreatitis develop in 11 for 85 of PF vs. 6 for 85 SBC, bleeding was higher in SBS 5/ 85 vs. 2/85 for PF. No case of cholangitis or mortality observe in both groups.

Despite that not statically significant post ERCP pancreatitis was higher among patient with PF, this indeed, when cannulation is difficult ,repeated attempted may cause papillary edema , and delayed PF is usually attempt after repeated cannulation The high rate of post-procedural complications following precut sphincterotomy may arise from an excessively edematous major papilla and extensive injury following multiple or prolonged attempts to cannulation the CBD by standard methods, before precut sphincterotomy is performed. In addition, the greater number of complications could have resulted from a direct thermal injury caused by the needle-knife itself in our study also some limitation is that sample size relatively small and the possible difference between these two groups is difficult to be hypothesize.[14,15]

References

1. WILLIAMS, Earl, et al. Updated guideline on the management of common bile duct stones (CBDS). *Gut*, 2017, 66.5: 765-782.
2. MAPLE, John T., et al. The role of endoscopy in the evaluation of suspected choledocholithiasis. *Gastrointestinal endoscopy*, 2010, 71.1: 1-9.
3. FREEMAN, Martin L., et al. Complications of endoscopic biliary sphincterotomy. *New England Journal of Medicine*, 1996, 335.13: 909-919.
4. ABRAHAM, Sherly, et al. Surgical and nonsurgical management of gallstones. *American family physician*, 2014, 89.10: 795-802.

5. SPATARO, Joseph, et al. Prevalence and risk factors for choledocholithiasis after cholecystectomy: 72. *Official journal of the American College of Gastroenterology| ACG*, 2017, 112: S32-S33.
6. POTTS, Courtney, et al. Reliability of Addenbrooke's Cognitive Examination III in differentiating between dementia, mild cognitive impairment and older adults who have not reported cognitive problems. *European Journal of Ageing*, 2022, 19.3: 495-507.
7. POTTS, Courtney, et al. Reliability of Addenbrooke's Cognitive Examination III in differentiating between dementia, mild cognitive impairment and older adults who have not reported cognitive problems. *European Journal of Ageing*, 2022, 19.3: 495-507.
8. EL NOSHOKATY, Said. Shipping optimization systems (SOS) for tramp: stochastic cargo soft time windows. *Journal of Shipping and Trade*, 2021, 6.1: 17.
9. KOMPANIEZ-DUNIGAN, Elysse, et al. Visual adaptation and the amplitude spectra of radiological images. *Cognitive research: principles and implications*, 2018, 3: 1-12.
10. PIVONKOVA, Helena, et al. The contribution of TRPV4 channels to astrocyte volume regulation and brain edema formation. *Neuroscience*, 2018, 394: 127-143.
11. DAVEE, Tomas; GARCIA, Jairo A.; BARON, Todd H. Precut sphincterotomy for selective biliary duct cannulation during endoscopic retrograde cholangiopancreatography. *Annals of gastroenterology*, 2012, 25.4: 291.
12. KATSINELOS, Panagiotis, et al. Comparison of three types of precut technique to achieve common bile duct cannulation: a retrospective analysis of 274 cases. *Digestive diseases and sciences*, 2012, 57: 3286-3292.
13. COMPTON, Carolyn C., et al. (ed.). *AJCC cancer staging atlas: a companion to the seventh editions of the AJCC cancer staging manual and handbook*. Springer Science & Business Media, 2012.
14. COMPTON, Carolyn C., et al. Exocrine and endocrine pancreas. *AJCC Cancer Staging Atlas: A Companion to the Seventh Editions of the AJCC Cancer Staging Manual and Handbook*, 2012, 297-308.
15. COMPTON, Carolyn C., et al. Gestational Trophoblastic Tumors. *AJCC Cancer Staging Atlas: A Companion to the Seventh Editions of the AJCC Cancer Staging Manual and Handbook*, 2012, 515-520.