



Primary Closure versus Choledcho-Duodenostomy after Common Bile Duct Exploration for Choledocholithiasis with Failed ERCP, A Single-Centre Expertise

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Abstract: Background: Primary Closure (PC) has been widely favoured as a superior method to T-tube drainage for closure of choledochotomy after CBD exploration. Since no studies have compared PC to Choledochoduodenostomy (CDD), we aim to study the advantages and disadvantages of CDD in comparison with PC. **Methods:** This is a retrospective cohort study of 40 patients, with failed ERCP for CBD stones. They were followed up for 27±6 months, after performing either CDD or PC as a closure method after CBDE. Both groups were compared according to postoperative morbidity and hospital stay. **Findings:** Pre-operative cholangitis was recognised in nine cases (45%) who had CDD technique, and in only 3 patients (15%) in the PC arm; *p* value is 0.038. CBD diameter has been reported as 9.75±1.45 mm and 7.85±1.26 mm in CDD and PC groups respectively, achieving a statistical significance; *P* value 0.002. The five patients (25%), who were diagnosed to have pre-operative biliary stricture by MRCP, were all offered to undergo CDD rather than PC (*P*= 0.047). Operating surgeons took 23.5 ± 2.95 minutes to perform CDD, whereas PC technique consumed only 14.85 ± 2.16 minutes, *p* value was 0.001. There was no significant difference statistically between group one and group two regarding post-operative biliary complications. **Conclusion:** Although Choledochoduodenostomy (CDD) significantly elongates the surgical time, it has closely similar results as Primary Closure (PC) in terms of postoperative biliary complications and hospital stay.

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Keywords: Choledocholithiasis, CBD exploration, Primary closure, Choledochoduodenostomy.

1. Introduction

Common bile duct (CBD) stones are the second most common complication of cholelithiasis; between 10 to 18% of patients undergoing cholecystectomy for cholelithiasis have (CBD) stones⁽¹⁾. While laparoscopic cholecystectomy is considered the main treatment for symptomatic cholelithiasis, the best treatment for CBD stones has yet to be established. Current treatment options include two strategies: a totally laparoscopic treatment, in which laparoscopic cholecystectomy followed by laparoscopic CBD exploration (LCBDE) are done in the same procedure, or another option, which consists of performing endoscopic retrograde Cholangiopancreatography (ERCP) before, during or after laparoscopic cholecystectomy. Both strategies have the same effectiveness and similar complication rates. However, the one-stage approach implies shorter hospital stays and lower costs, making it the more economic strategy^(1,2). The controversy here is how to suture the biliary tract after choledochotomy.

Halstead was the first surgeon who described primary duct closure after open CBD exploration as early as 1917. Since then, the debate between primary closure and Ttube drainage continued even in the era of laparoscopic surgery. In the past decade, a lot of studies comparing primary with T-tube were published and proved the feasibility and safety of primary closure⁽⁴⁾. Many papers recommended the direct closure of the CBD immediately after exploration^(6,7).

There is marked progress has occurred in choledochoduodenostomy (CDD) in the last 25 years⁽⁸⁾. The most frequent cause for a choledochoduodenal anastomosis available in the literature are multiple stones in the CBD, stone impaction, intrahepatic stones, Distal bile duct stricture and recurrent stones⁽⁹⁾. Laparoscopic common bile duct exploration (LCBDE) with choledochoduodenostomy has been proved to be a safe and sufficient method for treating complex CBDS with failed ERCP procedures, with the advantages of early discharge and early return to work⁽¹⁰⁾.

Ample studies have confirmed the efficacy and superiority of primary closure (PC) over T-tube, but, to our best knowledge, no studies have compared it to CDD. The main objective of this work is to evaluate the feasibility of CDD as an alternative to PC after choledochotomy for CBD exploration indicated in choledocholithiasis, and to assess its benefits and harms.

2. Patients and Methods

Study eligibility criteria:

Following are characteristics of this study depicted into the PICOS format:

- **Participants:** This study involved forty adult patients who presented to HBP department at Ain Shams University Hospital (ASUH) with diagnosis of CBD stones in the period between August 2016 and

June 2019. Preoperative workup included, but was not limited to, labs including bilirubin, ALP and GGT plus pelvi-abdominal ultrasound scan and Magnetic resonance cholangio-pancreatography (MRCP) (Figs. 1 a,b). ERCP was offered to all patients as a gold standard technique for choledocholithiasis. Patients with failed ERCP were decided to undergo open CBD exploration and thus included in this study.

According to the method of CBD closure, patients were divided into two groups. Group A underwent Choledochoduodenostomy (CDD), while Group B had primary CBD closure (PC) without T-tube or stenting. All patients were well informed with procedure details and its potential risks and signed informed consent prior to surgery. This study was approved by the IRB of General Surgery Department at Ain Shams Faculty of Medicine.

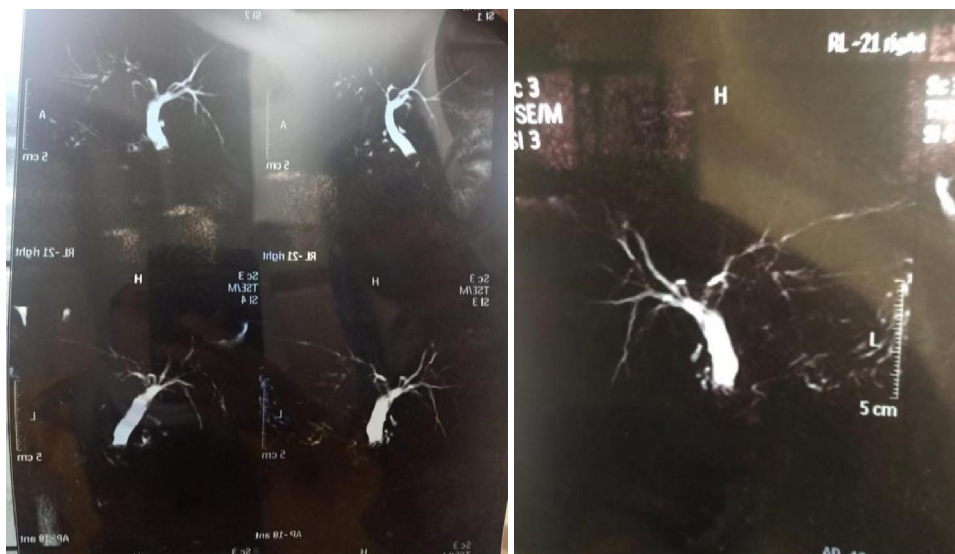


Fig 1a, b: MRCP showing distal CBD stones with proximal biliary dilatation.

- **Intervention:** Group A underwent Choledochoduodenostomy (CDD).

- **Control:** Group B had primary CBD closure (PC) without T-tube or stents.

- **Outcomes:** CDD group is compared against PC group in terms of demographics, blood investigations, MRCP, operative time, length of hospital stay, post-operative complications like bile leak, cholangitis, CBD stricture and re-surgery rates.

- **Study design:** Retrospective cohort study of prospectively collected data.

Operative technique

Diagnostic exploration was performed followed by dissection of adhesions with blunt and sharp tools, which was continued till identification of both duodenum and portal triad. After verifying Calot's anatomy, ligation of cystic artery was done. Cystic

duct is ligated near the Hartman of gall bladder (GB) and divided, followed by dissection of GB from liver, then identification of supra-duodenal portion of CBD. To ensure a tension-free anastomosis, generous Kocher's maneuver was done in most cases. A longitudinal incision was done in CBD with a knife beginning at the point where it transverse the duodenum posteriorly and extending proximally about 2 cm. Stone extraction is performed at first by milking then aided by cold saline irrigation using small tube drain, and sometimes by stone forceps. At this point, the previously placed stent, if any was removed. Both proximal and distal ducts are thoroughly rinsed with cold saline for clearing debris and infected fluid. A longitudinal incision in the duodenum along its superior border was done for a distance of approximately 1.5 cm. A single-layer anastomosis is

performed using 4-0 Vicryl/PDS interrupted sutures (**Fig. 2a, b**). CDD was created as side to side anastomosis as originally described by Glideman and Gold ⁽¹²⁾. Side to side CDD avoids circumferential mobilization and transection, without affecting the blood supply, allows larger anastomosis, and minimizes the chances of anastomotic leak ⁽¹³⁾.

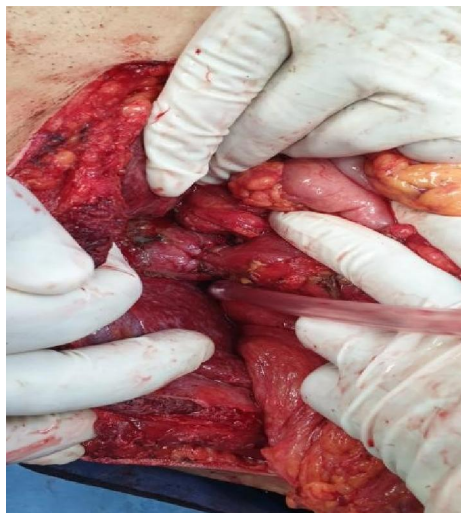
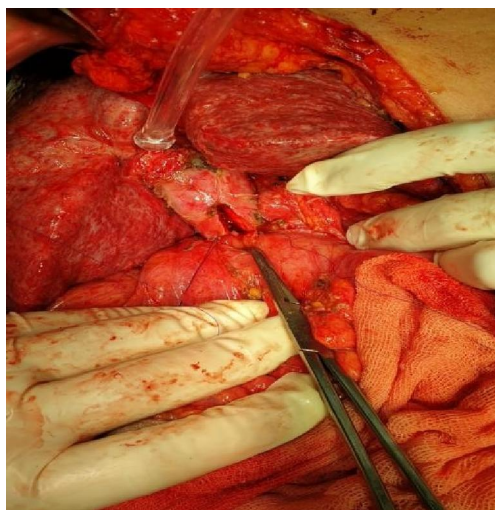


Fig 2a,b: Steps of Choledocho-duodenostomy.

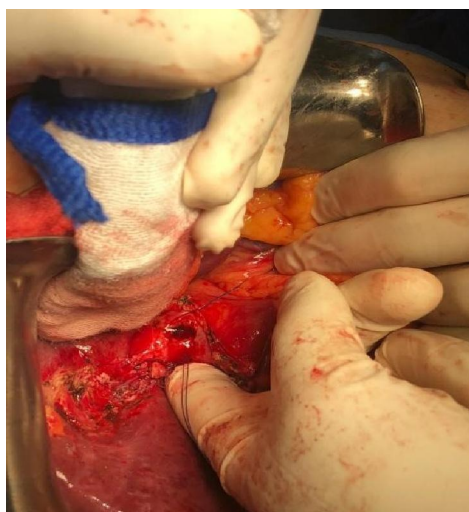


Fig. 3 a, b: Steps of Primary Closure.

Postoperative care and hospital discharge

Early mobilization and restoration of oral intake was carried out a few hours after surgery. Hospital discharge was decided when patient is hemodynamically stable, symptom free, non-significant drain output and near normal blood investigations.

Specifications

Operative time refers to the time consumed to only perform CBD closure with either PC or CDD, excluding other steps in CBD exploration. Hospital stay was defined as the number of days from date of procedure till return home. Postoperative mortality was defined as the number of deaths occurring within the first thirty days after procedure, and post-operative morbidity as the number of complications occurring during the duration of study.

Statistical analysis of data

Continuous variables are expressed as mean and Standard Deviation. Categorical variables are expressed as frequencies and percents. Student t test was used to assess the statistical significance of the difference between two study group mean. Chi square and Fisher's exact test were used to examine the relationship between Categorical variables. A significance level of $p < 0.05$ was used in all tests. All statistical procedures were carried out using SPSS version 18 for Windows (SPSS Inc, Chicago, IL, USA).

3. Results

This study included 40 patients who presented to HBP department and were diagnosed with choledocholithiasis and failed ERCP between August 2016 and August 2019. Because our local institutional protocol recommends ERCP as the first gold standard therapy line for CBD stones, only patients with failed ERCP were included in this study. The reasons for failed ERCP and stone extraction were mainly multiple, large calculi (n=33, 82.5%), CBD strictures (n=5, 12.5%) and impacted stones in lower CBD (n=2, 5%) (**Fig. 4**).

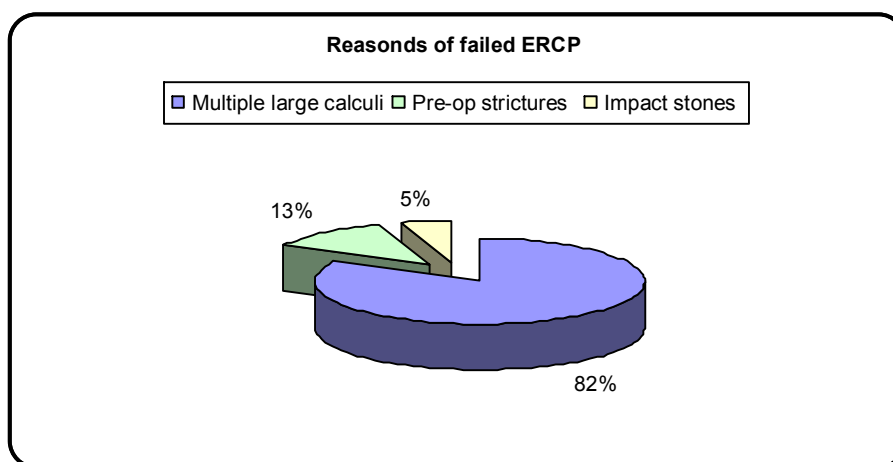


Fig 4: Reasons of failed ERCP.

Table 1: Various presentations of CBD stones

Clinical Presentation	N (%)
Biliary Colic	14 (35%)
Obstructive Jaundice	8 (20%)
Pre-op Cholangitis	12 (30%)
Acute Cholecystitis	4 (10%)
Acute Pancreatitis	2 (5%)

The majority of patients presented with biliary colics (n=14, 35%), while obstructive jaundice, pre-operative cholangitis, acute cholecystitis and acute

pancreatitis have been reported in 8 (20%), 12 (30%), 4 (10%) and 2 (5%) in the rest of the group at time of diagnosis respectively (**Table 1**).

Patients were followed up for a mean time of 27±6 months. The mean age of study population was 38.10±7.36 in CDD group, and 35.25±5.92 in PC group. Twelve females (60%) and eight males (40%) underwent CDD procedure, while 13 ladies and 7 gentlemen were operated upon with PC procedure. Pre-operative cholangitis was recognised in nine cases (45%) who had CDD technique, and in only 3 patients (15%) in the PC arm; p value is 0.038 (**Table 2**).

Table 2: Basic demographic characteristics in study population.

		Choledocho- duodenostomy	Primary Closure	P	Sig
		Mean±SD/ N (%)	Mean±SD/ N (%)		
Age		38.10±7.36	35.25±5.92	0.18 [‡]	NS
Sex	Male	8 (40%)	7 (35%)	0.74*	NS
	Female	12 (60%)	13 (65%)		
Preoperative Cholangitis	No	11 (55%)	17 (85%)	0.038*	S
	Yes	9 (45%)	3 (15%)		

‡Student t test *Chi-Square test

CBD diameter has been reported as 9.75 ± 1.45 mm and 7.85 ± 1.26 mm in CDD and PC groups respectively, achieving a statistical significance; P value 0.002. The mean levels of Total Bilirubin and Direct Bilirubin were 4.37 ± 2.29 mg/dl and 3.18 ± 1.82 in CDD arm, and 3.01 ± 1.23 mg/dl and 1.99 ± 1.02 in PC arm, P value is 0.026 and 0.016 respectively.

Nevertheless, Alkaline Phosphatase (ALP) and Gama GT (GGT) did not show statistical significance among both groups. The five patients (25%), who were diagnosed to have pre-operative biliary stricture by MRCP, were all offered to undergo CDD rather than PC, for fear of predisposition for post-operative bile leakage (P= 0.047) (Table 3, Figs. 5,6).

Table 3: Pre-operative investigations in both groups.

	Group				P	Sig	
	Choledocho-duodenostomy		Primary Closure				
	Mean	±SD	Mean	±SD			
CBD diameter (mm)	9.75	1.45	7.85	1.26	0.002*	HS	
T bilirubin (mg/dl)	4.37	2.29	3.01	1.23	0.026*	S	
D bilirubin (mg/dl)	3.18	1.82	1.99	1.02	0.016*	S	
Alk Phosphatase (U/L)	283.20	91.87	234.85	75.16	0.077*	NS	
GGT (U/L)	297.20	86.84	267.15	90.83	0.292*	NS	
Pre-op MRCP	No stricture	15	75.0%	20	100.0%	0.047**	S
	Stricture	5	25.0%	0	0.0%		

*Student t test **Fisher exact test

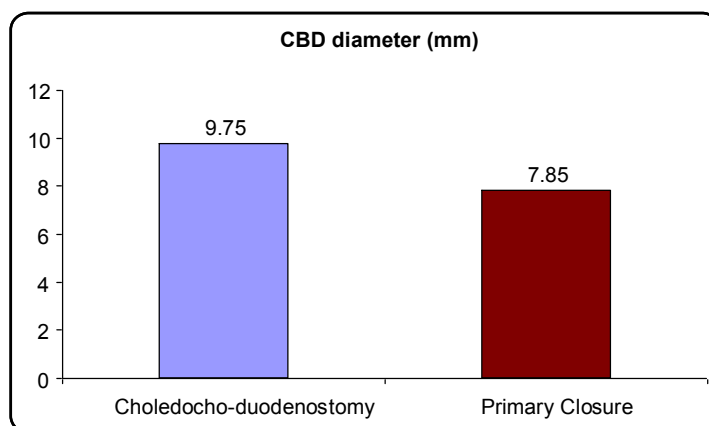


Fig 5: CBD diameter in both groups.

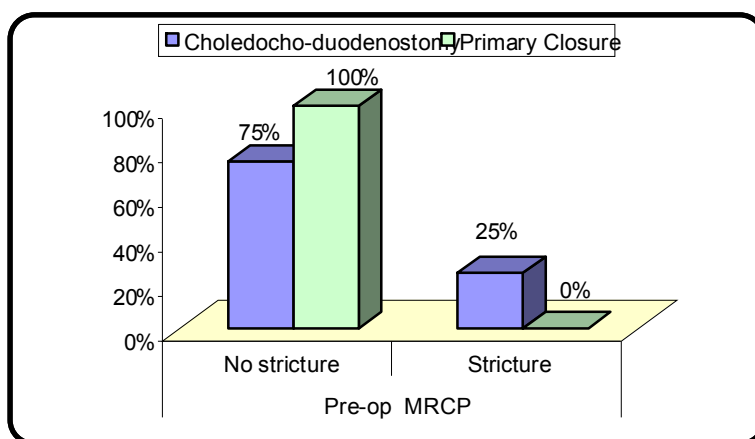


Fig 6: Result of pre-operative MRCP in both groups.

Operating surgeons took 23.5 ± 2.95 minutes to perform CDD, whereas PC technique consumed only 14.85 ± 2.16 minutes, P value was 0.001. Hospital

stay was almost the same in both arms; 5.3 ± 0.8 and 5.2 ± 1.24 in CDD and PC respectively (**Table 4, Fig. 7**).

Table 4: Operative time and hospital stay in both groups.

	Choledocho-duodenostomy	Primary Closure	P	Sig
	Mean \pm SD	Mean \pm SD		
Time of procedure (min)	23.5 \pm 2.95	14.85 \pm 2.16	0.001*	HS
Hospital stay (days)	5.3 \pm 0.8	5.2 \pm 1.24	0.764*	NS

*Student t test

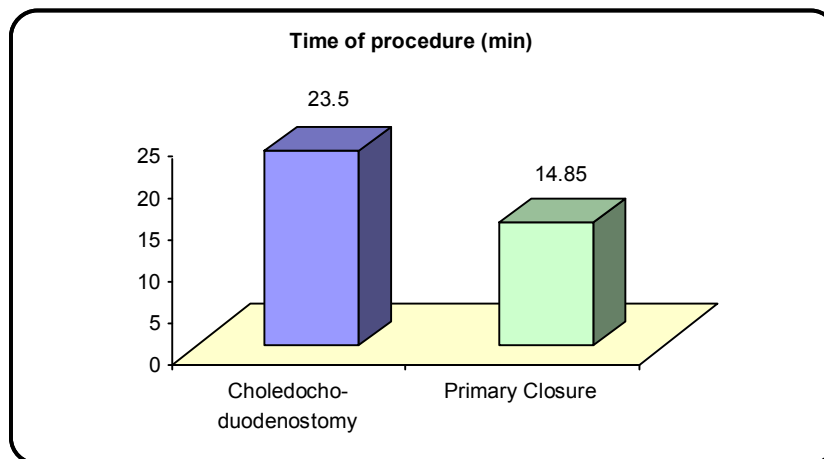


Fig 7: Operative time in both groups.

Bile leak occurred in only one patient (5%) of each group. The patient who had bile leakage after PC was managed successfully with conservative treatment and resolved spontaneously. On the other hand, CDD was converted to Hepatico-jejunostomy to control major bile leak. None of the PC group experienced post-operative cholangitis or the need for a second intervention, however, only one case (5%)

experienced postoperative biliary stricture. In CDD side, only 2 patients (10%) were complicated with post-operative cholangitis, but none of them showed evidence of post-operative biliary stricture during the entire follow up period (**Table 5**). Neither recurrent stones, mortality nor post-operative pancreatitis were encountered during this study.

Table 5: Post-operative complications in both groups

		Choledocho- duodenostomy	Primary Closure	P	Sig
		N (%)	N (%)		
Post-operative Biliary leakage	No	19 (95%)	19 (95%)	1.0*	NS
	Yes	1 (5%)	1 (5%)		
Post-operative Cholangitis	No	18 (90%)	20 (100%)	0.487*	NS
	Yes	2 (10%)	0 (0%)		
Re-intervention	No	19 (95%)	20 (100%)	1.0*	NS
	Yes	1 (5%)	0 (0%)		
Post-op Stricture	No	20 (100%)	19 (95%)	1.0*	NS
	Yes	0 (0%)	1 (5%)		

*Fisher exact test

4. Discussion

Choledocholithiasis is a common cause of hospitalization, which presents in about 10% of the

patients who are referred for laparoscopic cholecystectomy because of symptomatic gallstones⁽¹⁶⁾. Although ERCP has been widely popularized, the

best available evidence reveals that ERCP and LCBDE methods are equally effective in terms of CBD stones clearance and that they share similar morbidity and mortality rates^(17, 18). In recent years, primary choledochorrhaphy has gained favor as the most used technique at many centers⁽¹⁹⁾.

T-tube insertion was avoided in this series because there is enough evidence supporting the conception of no added value, in addition to specific morbidity related to T-tube placement. Pablo and his fellows have stated that primary choledochorrhaphy should be the preferred option for bile duct closure. Although it is believed that adverse effects of T-tube clearly outweigh its privileges, there is a possibility of some bile leak which can be managed conservatively without major clinical consequences⁽²⁰⁾. Our results revealed that sole PC without stenting can be done with low complications rate in patients who were identified to have preoperative episodes of cholangitis. This might ruin the surgical myth that necessitates the usage T-tube in those situations as an extra-precaution to minimize the possibility of bile leak.

The vast majority of literature favour to have a CBD diameter not less 1.2 mm, to be able to safely fashion CDD⁽²¹⁾. In our series, we have managed to create CDD with a mean CBD diameter of 9.75 ± 1.45 mm without increased liability to form CBD stricture along the study duration, as none of the CDD patients had post-operative biliary stricture. This could raise the proposal of doing safe CDD with smaller CBD than described in literature. A plausible explanation of this notion is that after adequate duodenal mobilization, the duodenum can be easily crept over the 2 cm vertical choledochotomy to create at least 2 cm stoma between CBD and duodenum. Larger scale studies are required to focus on this point.

All patients with pre-operative diagnosis of CBD stricture were decided to undergo CDD rather than PC. It is widely perceived that distal stricture is likely to predispose for higher proximal intra-ductal pressure and may end up with suture disruption and bile leak. That is why CDD is considered a salvage procedure in this category of patients **(22)**.

Performing CDD has significantly led to lengthening of operative time when compared to the opposing group. This result is considerably predicted because CDD entails more technical steps in form of Kocher's maneuver, duodenotomy and fashioning a more sophisticated choledocho-duodenal anastomosis, in contrast to the simple PC of choledochotomy. On the other hand, CDD surprisingly did not elongate the hospital stay, which was very close to that of the other group, suggesting that CDD does not pile up the economic burden on both patients and local resources.

There was no significant difference between the two groups in terms of demographic characteristics like age and gender, and post-operative complications like bile leak, cholangitis, bile stricture, pancreatitis and the need for re-intervention. This implies that PC can be comparable to CDD to achieve morbidity-reduced post-operative course.

The overall postoperative morbidity in our work was 12.5% (5 out of 40 patients); CDD was charged of three patients with complications, whereas PC was responsible for only two patients. This was consistent with published studies which have quoted the morbidity burden ranging from 5 to 36.8%⁽²³⁾. In our study, post-operative cholangitis existed only in the CDD group with incidence of 10% (2/20 patients) over a mean follow up of 27 ± 6 months. It has been reported that bactibilia is common after CDD probably owing to reflux of duodenal contents into the biliary ducts, but later proven otherwise, as the aetiology is mainly attributed to stasis due to anastomotic stricture^(24,25).

Another complication, the one which is considered dreaded for this procedure, is a duodenal leak which occurred in two cases, single case (5%) in CDD group with failed conservative management and required reoperation with hepaticojejunostomy, and the other case (5%) in PC group was managed conservatively with controlled external fistula and resolved spontaneously. This rate correlates with the published leak rate of 2–7%, where successful conservative management of minor duodenal leak has been reported. Although post-operative pancreatitis has been largely proven in previous literature to complicate supra-duodenal choledochotomy with an incidence of 5.7%⁽²⁴⁾, it has not been reported in our series.

Currently, CDD is being accepted as the method of choice for the treatment of CBD strictures and complicated bile duct stones not amenable to successful treatment by ERCP with excellent outcomes in 80–95% cases⁽²²⁾. However, to our best knowledge, scanty research tried to study the use of CDD in non-complex cases of CBD stones. We assume that CDD is superior to PC in: 1-achieving excellent drainage in the majority of patients, 2-less liability of stricture formation and 3-providing a life-long biliary drainage, without the need for reintervention in case of recurrent formation of CBD stones. In a study conducted by Bosanquet and his co-workers, it was concluded that CDD still a relatively safe and effective surgical technique for the management of obstructive jaundice in both benign and malignant disorder especially after failure of ERCP⁽¹⁸⁾.

IOC is used in our hospital as a diagnostic tool intraoperative in all patients in this cohort to ensure

complete CBD clearance as an alternative to choledochoscope which is not available in our hospital. A success rate of IOC ranges from 86 to 98%⁽²⁵⁾. our group has extensive experience in interpreting IOCs, and we did not find any false-positive cases or residual stones among our patients.

Limitations of the study

The limitations in the present study are relatively small study population from a single centre, retrospective study design, relatively short period of follow up and unavailability of settings for laparoscopic approach for CBD exploration. Therefore, we recommend adoption of future multi-centric and prospective studies with longer follow up to consolidate our results in both open and laparoscopic approaches.

5. Conclusion

In the setting of choledochotomy closure after CBDE for cholelithiasis and failed ERCP, Choledochoduodenostomy (CDD) could be comparable to Primary Closure (PC) in terms of post-operative morbidity like biliary stricture, bile leak, cholangitis, pancreatitis and re-intervention rates, and hospital stay. However, CDD is significantly associated with longer surgical duration.

Conflict of Interest: None to declare.

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