

ORIGINAL ARTICLE

Advances in
Digestive Medicine

WILEY

Surgical outcomes of open choledochoduodenostomy in treatment of Sudanese patients diagnosed with benign obstructive jaundice: A single-center prospective study

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Abstract

Endoscopic ductal clearance is associated with failure of stone extraction, recurrent stone formation, and lethal morbidities that need emergent surgical drainage. There are limited hospital-based studies in Sudan and ongoing debate with fear among surgeons regarding choledochoduodenostomy (CDD) performance due to its high-risk morbidities. Hence, this study aimed to determine the surgical outcomes of CDD in the treatment of benign obstructive jaundice because of choledocholithiasis to reach excellent surgical practice. This is a prospective study conducted during the period between March 2021 and February 2023 at Ibn Sina specialized hospital, Khartoum, Sudan, on 81 patients diagnosed with benign obstructive jaundice due to secondary choledocholithiasis. They underwent elective open common bile duct exploration with side-to-side CDD. Benign obstructive jaundice was more prevalent in females (65.4%), in the ratio (2:1). Distribution of patients according to age ranged between 46 and 60 years, representing (45.7%) of patients. The most significant reported comorbidity was obesity (BMI ≥ 30 kg/m²) in (48.1%) of cases. Clinical scleral icterus was noticed in all (100%) patients. Magnetic resonance cholangiopancreatography revealed stones within the dilated common bile duct (2 cm) in (36.25%) of cases. The longest operative surgical time was 180 min in (48.75%) of patients. Postoperative complications were found in (6.2%) patients who had mild suppurative cholangitis. The mortality rate was zero. Side-to-side CDD is a safe, effective surgical procedure for permanent biliary drainage in patients who are diagnosed with benign obstructive jaundice. Moreover, if the facility for therapeutic endoscopic retrograde cholangiopancreatography (ERCP) is lacking, then common bile duct exploration with CDD should be the choice of treatment.

KEYWORDS

cholangitis, choledochoduodenostomy, choledocholithiasis, Sudan

1 | INTRODUCTION

Choledocholithiasis is a chronic biliary disease resulting from impaired metabolism of cholesterol, bilirubin, and bile acid. The incidence of cholelithiasis is 5%–15%. While choledocholithiasis accounts for 5%–30% of cases.^{1,2} Choledocholithiasis is divided into a primary type that originated within the common bile duct (CBD) due to infection or biliary stasis. The secondary type is more common and occurs because of stone migration from the gallbladder.³ Women and obese patients are commonly associated with CBD stones.^{4,5} The reported overall incidence of CBD stones in patients with gallstones was 11%–25%. In addition, about 10%–15% of cholecystectomies for symptomatic gallstones have CBD stones.⁶ Symptoms of CBD stones start with biliary colic until reaching serious complications like obstructive jaundice, ascending cholangitis, and biliary pancreatitis.^{1,2,7} About 5%–15% of patients are completely asymptomatic with normal liver enzymes. Clinical symptoms are detected in 8%–15% of younger patients and in 15%–60% of patients older than 60 years.^{3,8} Meanwhile, another study reported that 30% of elderly patients aged (65-years) had CBD stones.⁹ Specific diagnostic elements were the patient's history and physical examination, which were confirmed by further laboratory tests and radiological imaging. Jaundice and right hypochondrial pain are the most common symptoms of acute disease. Other clinical symptoms that reflect obstructive causes were steatorrhea, acholic stools, dark urine, pruritus, and weight loss. High levels of direct serum bilirubin and alkaline phosphatase are strong biochemical indicators for obstructive causes.^{10,11} In addition, alkaline phosphatase is considered a significant predictor with a cut-off value of 78 U/L and is associated with a high sensitivity and specificity of 97.6% and 72.6%, respectively. Radiological imaging has played an important role in the diagnostic process for treatment planning and patients follow-up. Trans-abdominal ultrasound (TUS) is the initial diagnostic radiological test but does not have high accuracy for CBD stone detection (sensitivity, 73%; specificity, 91%).³ In the literature, magnetic resonance cholangiopancreatography (MRCP) described as a useful preoperative non-invasive tool with higher accuracy rates than TUS and CT scan for the detection of CBD stones and evaluation of CBD dilation (≥ 7 mm on TUS or ≥ 10 mm on CT-scan). Moreover, MRCP has a high sensitivity and specificity estimated at 92% and 97%, respectively.^{3,11} Over the last decades, endoscopic retrograde cholangiopancreatography (ERCP) with stent placement applied for drainage of biliary obstruction replaced surgical interventions for CBD stones. However, ERCP has complicated difficulties in its performance even with expert endoscopists, and it

has a high failure rate that reaches up to 10%. Surgical CBD exploration with bypass, like choledochoduodenostomy (CDD), is a reliable alternative method recommended by the American college of surgeons.^{12,13} CDD is choledochotomy with stone extraction and permanent biliary drainage between the CBD and the duodenum, first described by Bernhard Riedel in 1892 AD. Because of its good long-term results, particularly in elderly patients, it is commonly indicated for choledocholithiasis (primary/secondary, retained/residual, recurrent or impacted), distal CBD strictures, ampullary stenosis, benign ampullary tumors, dilated CBD >20 mm in diameter, and failed or unavailable ERCP. CDD morbidities account for between 10% and 28%. Moreover, the literature reported a higher incidence of alkaline reflux gastritis (20.8%) and proved cholangitis (4.2%) within CDD cases.^{14,15} In Sudan, there are limited hospital-based studies on the implications of CDD due to ongoing debate among general and hepatobiliary surgeons regarding associated risky morbidities. Therefore, this study aimed to determine surgical outcomes regarding the safety and efficacy of CDD in the treatment of benign obstructive jaundice because of choledocholithiasis to achieve excellent surgical practice.

2 | METHODS

This is a prospective, observational, analytic, cross-sectional, hospital-based study conducted on 81 patients during the period between March 2021 and February 2023. The study received no grant funding and was conducted in the gastroenterological surgical department of Ibn Sina specialized hospital, Khartoum, Sudan. Our research complies with the guidelines for human studies and was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. Before the study commenced, ethical approval was obtained from the local research ethics committee of the Faculty of Medicine and Health Sciences, Omdurman Islamic University (committee meeting number (171) dated on Wednesday 13th January 2021) to use the Sudanese patients after they provided written and signed consent to publish this original article for the purpose of research and to collect medical data from international medical websites and medical literature. No clinical trials were involved in this study. A written consent was taken from each patient. Data in this study, including demographic characteristics, clinical presentation, provisional diagnosis, modalities of investigation, risk factors of choledocholithiasis, surgical indications, and postoperative complications, were collected by a questionnaire. Inclusion criteria are the following: Sudanese patients aged 15–75 years or more of either sex who are clinically

diagnosed as choledocholithiasis and confirmed by TUS and MRCP. In addition, the lower limit of the CBD size is 1.5 cm. In this study, preoperative esophagogastroduodenoscopy is crucial to verify the duodenal bulb's normal anatomy by directly visualizing it. This helps to identify deformities or abnormalities like strictures and ulcers that could complicate CDD postoperatively and improve surgical outcomes. As a result, a proper evaluation of the duodenal bulb ensures that the anastomotic site is appropriate and disease-free. These patients underwent elective open CBD exploration with side-to-side CDD procedure. Exclusion criteria included laparoscopic cholecystectomy, laparoscopic CBD exploration, bilioenteric fistula, ascending cholangitis, acalculous cholecystitis, cholangiocarcinoma, and carcinoma of the gallbladder. Also, all patients with incomplete records and any other comorbidity that precluded general anesthesia (GA). An elective open fundus-first cholecystectomy, CBD exploration, and side-to-side CDD proceeded with placement of patients in the supine position and performance of GA with endotracheal intubation. A nasogastric tube was inserted for gastric decompression to provide better operative field exposure. Through an extended right oblique subcostal incision, abdominal wall layers were dissected with an electro-cautery, and the peritoneum was opened. Between the stomach and the liver, the duodenum and the transverse colon, large packs were inserted to distract them away from the operative field. Deaver's retractors were used for direct exposure of narrowed triangle of Calot and CBD. Incision of the overlying peritoneum and fibrous adhesions dissection were done to clear Clot's triangle and CBD. After completion of the fundus-first cholecystectomy, the open choledotomy approach was performed through two 3-0 Vicryl stay stitches. An appropriate longitudinal CBD incision by scalpel at the supraduodenal location extending between 2 and 2.5 cm was made to be suitable for stone extraction by Disjagin forceps (Figure 1). Then, removal of tiny stones was achieved by forced flushing of sterile normal saline within the CBD using small-sized rubber catheter. The stone clearance of the CBD was confirmed by the usage of choledochoscope. The duodenum and pancreas were mobilized by an extensive Kocher's maneuver for a tension-free anastomosis. Through an electro-cautery, dissection about 1.5 cm transverse incision in the 1st part of the duodenum beyond the vein of Mayo was made. Choledotomy was ended through side-to-side CDD accomplished with interrupted 3-0 Vicryl stitches starting posteriorly, and knots' positions were outside of the anastomosis. While the anterior portion of the anastomosis performed using simple interrupted 3-0 Vicryl sutures. An intra-peritoneal drain was placed in the subhepatic region but not in direct contact with the anastomosis and



FIGURE 1 Intra-operative photo showed two stay stitches and appropriate longitudinal common bile duct (CBD) incision suitable for giant stone extraction.

left usually for 5 days. The peritoneum, abdominal muscles, and rectus sheath were closed by continuous running suturing using a Nylon 2-0 on round-bodied needle. Interrupted stitches of Vicryl 3-0 and Nylon 2-0 were applied to the subcutaneous fat and skin, respectively. The operative wound was cleansed, and a sterile dressing was applied. Postoperatively, patients were transferred to the post-anesthesia recovery room for monitoring of vital signs until fully awake. At the ward, analgesics, intravenous route (IV) antibiotics, and antiemetics were given to the patients. Early mobilization of the patients was encouraged regularly. On day 5, the nasogastric tube was removed and oral fluids were allowed if active bowel sounds were present. After 5 days of observation, patients were discharged once they were hemodynamically stable with a clean wound, tolerating oral feeding, adequate pain relief, and an empty intra-peritoneal drain or (amount was below 100 cc/day). All patients were asked to come to the referral clinic on day 7 for follow-up of postoperative surgical-related morbidities including wound infection, wound dehiscence, sepsis, hematoma, seroma, persistent fistula, and bile leak through the wound. On day 14, our patients came back for sutures removal. Regular postoperative follow-up continued up to 3 months. During follow-up visits, we were guided by comprehensive history, clinical examination, and investigations including liver function tests (LFT), pancreatic enzymes, TUS, and MRCP. Outcomes of patients were recorded and systematically arranged for evaluation. The clinical details of included patients were entered into a spreadsheet (Excel 2016 for Windows). This data were statistically analyzed by using SPSS version 26 (IBM SPSS Statistics for Windows, Chicago, Illinois, IBM Corp, USA). For comparison between groups,

chi-square statistical test was conducted. The statistical results were considered significant when the *p* value was <.05.

3 | RESULTS

In this study, 81 patients diagnosed with benign obstructive jaundice because of impacted choledocholithiasis underwent elective open fundus-first cholecystectomy, CBD exploration, and side-to-side CDD. Benign obstructive jaundice was more common in females 53 (65.4%) than males 28 (34.6%) with a ratio (2:1). The peak incidence of patients age ranged between 46 and 60 years (middle age), which represents 37 (45.7%) (Table 1). The most common presenting symptoms were scleral icterus with highly dark-colored urine, itching, and epigastric and right hypochondrial pain with dyspepsia noted in all (100%) cases. Moreover, 35 (43.2%) of patients had fever with rigor. Through abdominal examination, all cases (100%) had tenderness in the epigastric and right hypochondrial quadrants, with deep jaundiced sclera. Also, all patients in this study were afebrile. The significant comorbidities that increased the risk of benign obstructive jaundice because of choledocholithiasis were obesity (BMI ≥ 30 kg/m²) found in 39 patients (48.1%), diabetes mellitus in 25 patients (30.9%) and hypercholesterolemia in 17 patients (21%). Preoperative laboratory tests included: total WBC count was 4000–11,000 per microliter in all cases. Liver function tests showed abnormal values of direct bilirubin (>2.5 mg/dL) in all (100%) cases, alkaline phosphatase (>147 IU/L) in all (100%) cases, aspartate transaminase (>33 U/L) in 53 (65.4%) cases, and alanine transaminase (>36 U/L) in 28 (34.6%) cases. The bleeding profile was abnormal in 48 (59.3%) of cases. Moreover, there was no evidence of acute kidney injury through renal function tests in this study. Three-dimensional TUS showed gallstones with dilated CBD caliber >8 mm in all (100%) cases. MRCP revealed gallstones and multiple stones within dilated

CBD. This progressed into distal impacted stones and distal CBD stricture in all (100%) cases. Therefore, our variable measures of CBD diameter are as follows: 2.2 cm diameter in 13 (16.25%), 2 cm diameter in 29 (36.25%), 1.8 cm diameter in 22 (27.5%), and 1.6 cm diameter in 16 (20%) (Figure 2). Indications for surgical intervention in this study were choledocholithiasis associated with benign obstructive jaundice and dilated CBD in patients who had failed sessions of ERCP. These patients required open fundus-first cholecystectomy and CBD exploration that ended with side-to-side choledochoduodenostomy. The operative surgical time was 150 min in 14 cases (17.5%), 180 min in 39 cases (48.75%) and 240 min in 27 cases (33.75%). All cases had intra-peritoneal drains, which were removed within 5 days of fine postoperative care. Seventy-six (93.8%) patients in this study did not have morbidities. Meanwhile, mild suppurative cholangitis was found in 5 (6.2%) of cases. Moreover, broad-spectrum IV antibiotics, analgesic drugs, and ERCP stenting successfully treated these patients. All patients (100%) in this study had a short postoperative hospital stay extending up to 5 days. The mortality rate was zero. The results of this study were statistically significant (*p* value <.05).

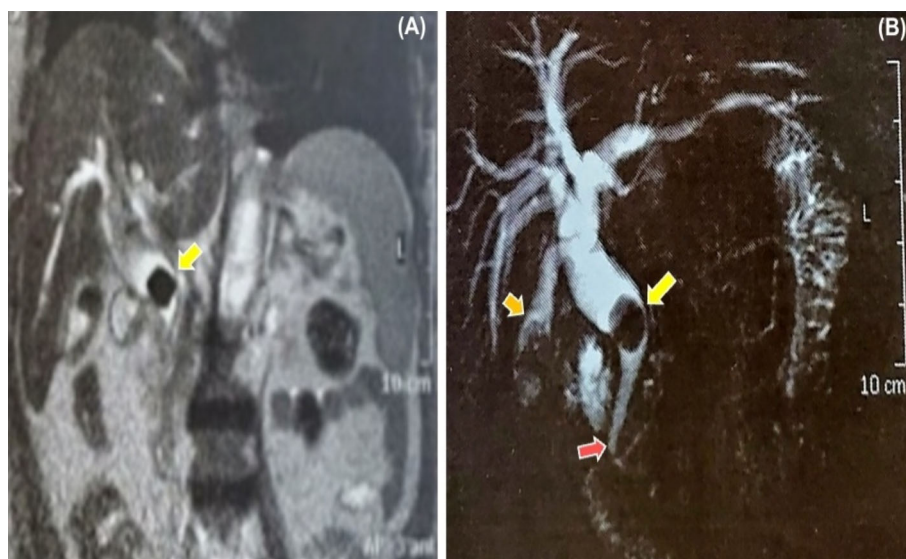
4 | DISCUSSION

Choledocholithiasis is a chronic biliary disease complicated by fetal risks like obstructive jaundice that need emergent ERCP with stent placement. This is a very important problem in the underdeveloped countries where other options like ERCP are widely unavailable or there is distal CBD stricture associated with technical difficulties. Then, the gold standard surgical approach is open CBD exploration with side-to-side CDD.^{12,13} Moreover, in Sudan there are limited hospital-based studies on CCD due to ongoing debate among general and hepatobiliary surgeons regarding associated high-risk morbidities. Hence, the aim of this study is to determine the surgical outcomes regarding the safety and efficacy of CDD in the treatment of benign obstructive jaundice because of choledocholithiasis to reach excellent surgical practice. Our study showed that complicated choledocholithiasis was more common in the female patients (65.4%). Our results align with the literature that found choledocholithiasis in female patients due to less exercise activities and high estrogen levels.⁴ The mean age of complicated choledocholithiasis was between 46 and 60 years, representing (45.7%) of cases. This disagreed with Fritz et al. study who reported the mean age of choledocholithiasis is 65 years old in 30% of cases.⁹ Another study also disagreed with our findings and reported complicated choledocholithiasis in patients aged above

TABLE 1 Age distribution of patients diagnosed with benign obstructive jaundice due to secondary choledocholithiasis.

Age (years)	Frequency	Percentage	<i>p</i> value
15–30	0	0	<.05
31–45	21	25.9%	<.05
46–60	37	45.7%	<.05
61–75	18	22.2%	<.05
>75	5	6.2%	<.05
Total	81	100%	

FIGURE 2 Preoperative MRCP images (A, B) showed multiple gallbladder stones complicated with secondary distal impacted giant common bile duct (CBD) stone and stricture.



70 years in between 15% and 60%.⁸ This is related to advanced age being associated with CBD expansion, CBD angulation, and periampullary diverticulum sized more than 15 mm. The most common clinical presentation of our patients was jaundiced sclera and recurrent epigastric or right hypocondrial pain with dyspepsia in all cases (100%). These findings were in agreement with the literature that reported jaundice and right hypocondrial pain as the most common symptoms.^{10,11} Our study clearly showed the predominance of benign obstructive jaundice due to secondary choledocholithiasis detected in females with a BMI in the obese category ($>30 \text{ kg/m}^2$) noted in (48.1%). These findings agreed with the literature that reported obese women who had increased hepatic cholesterol secretion could have gallstone disease and choledocholithiasis that leads to benign obstructive jaundice.⁵ Our study assesses the severity of obstructive jaundice caused by secondary choledocholithiasis through initial laboratory tests, including LFT, that showed elevated direct bilirubin ($>0.35 \text{ mg/dL}$) and elevated ALP ($>120 \text{ IU/L}$) in (100%) all cases. This is consistent with the literature that found direct bilirubin and ALP are strong indicators for the diagnosis of benign obstructive jaundice. Moreover, ALP has high sensitivity and specificity rates (97.6% and 72.6%, respectively).^{3,10,11} Our study reported (59.3%) of cases had an abnormal bleeding profile without evidence of clinical bleeding tendency due to progressive biliary obstruction associated with malabsorption of vitamin K and liver dysfunction that led to prolonged prothrombin time. Extensive revision of published studies in the literature was done and no findings focused on coagulopathies of obstructive jaundice due to choledocholithiasis. Radiological imaging had an important role in the diagnostic process for treatment planning and patients follow-up. Therefore, TUS showed

gallstones with dilated CBD caliper $>7 \text{ mm}$ in all (100%) cases. This showed that TUS is highly sensitive and accurate for gallstone detection but less so for CBD stones. Costi et al. study agreed with our findings and reported TUS sensitivity for detection of gallstones and CBD stones was 80%–100% and 70%–90%, respectively.¹⁶ Moreover, another study agreed with our findings that revealed a low accuracy of TUS in detection of CBD stones (sensitivity, 73% and specificity, 91%).³ In this study, all patients underwent preoperative MRCP for equivocal results on TUS, evaluation of CBD dilation, and detection of biliary obstruction level or causes that were planned for fundus-first cholecystectomy + CBD exploration with CDD. In addition, MRCP revealed gallstones and multiple stones within dilated CBD. This progressed into distal CBD stone impaction and stricture in all (100%) cases. Furthermore, MRCP reported the widest diameter of CBD is 2 cm in (36.25%) of patients. These findings are similar to the results of the literature that showed an excellent overall sensitivity and specificity of MRCP for accurate demonstration of variable sizes of CBD stones were 91%–100% and 95%–100%, respectively.^{3,11} Therefore, when the open approach of fundus-first cholecystectomy + CBD exploration with CDD has been planned, it is recommended to perform preoperative MRCP with TUS for diagnosis of secondary choledocholithiasis that is complicated by benign obstructive jaundice. An elective approach of open fundus-first cholecystectomy with CBD exploration that ended with side-to-side CDD performed in all cases (100%). Moreover, this study showed variability in the operative time and most cases had 180 min of operative time noted in (48.75%) of patients. Our results similarly align with findings of Shah et al. who reported when operative time exceeded 120 min, it indicates long-standing

secondary choledocholithiasis associated with regional dense omental adhesions on CBD and obscured distorted anatomy of the triangle of Calot that needs more operative time for meticulous safe dissection effort to avoid lethal intraoperative risks.¹⁷ In this study, mild forms of suppurative cholangitis were the most commonly diagnosed morbidity in (6.2%) of patients treated with broad-spectrum IV antibiotics and ERCP stent. These findings agreed with literature that reported obstructed biliary tree with choledocholithiasis described as the leading cause for acute cholangitis in 4.2% of cases and mortality rate that reached up to 88%–100%. This necessitates prompt biliary decompression by ERCP with stent and empirical broad-spectrum antibiotics.^{14,18} This is related to accurate surgical care that leads to a reduction of biliary sepsis risks postoperatively. Eventually, the overall mortality rate was zero. Our findings disagreed with the results of the literature that reported mortality rate of CCD ranged between 1% and 5%.¹⁴ This is related to the meticulous long-term regular follow-up of patients for 18 months that decreases the risk of fatal morbidities despite the difficulties associated with the eruption of armed clashes on 15 April 2023 between Sudanese armed forces and rapid support forces in Khartoum (the capital of Sudan) and various Sudanese states that resulted in severely compromised healthcare services, significant loss of lives, and ongoing outbreak threats. The main strength of our study is the applicability of side-to-side CDD in an elective setting due to its practicality with a lower morbidity rate in Sudanese patients diagnosed with benign obstructive jaundice to reach excellent practice at national surgical centers. In addition, this is the first prospective study describing surgical outcomes of side-to-side CDD in Sudan. Furthermore, the ongoing war in Sudan, small sample size, and low socioeconomic status of patients are limitations of our study that need to be addressed. Future studies are recommended to compare the findings of this study with larger sample sizes in the long term.

Side-to-side CDD is a safe, effective surgical procedure for permanent biliary drainage in patients who are diagnosed with benign obstructive jaundice. Moreover, if the facility for therapeutic ERCP is lacking, then CBD exploration with CDD should be the choice of treatment.

AUTHOR CONTRIBUTIONS

Wael Mohialddin Doush is responsible for original manuscript writing, editing, supervision, and critical revision of contents. Wael Mohialddin Doush, Elfatih Yousif Abdelrahim, and Osman Mohamed Almajzoub are responsible for data collection, data analysis, and manuscript design. Wael Mohialddin Doush is responsible for

manuscript drafting and revision. All authors read and gave their final approval of the manuscript to be published.

ACKNOWLEDGMENTS

The authors would like to thank their colleagues in the gastroenterological surgical department and operating room staff at Ibn Sina specialized hospital for their unlimited support and kind suggestions.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

Our research complies with the guidelines for human studies and was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. Ethical approval was obtained from the local Research Ethics Committee of the Faculty of Medicine and Health Sciences, Omdurman Islamic University, at the committee meeting number (171) dated Wednesday, 13th January 2021, to use the Sudanese patients after they have written and signed consent to publish this original article for the purpose of research and collected their medical data from the international medical websites and medical literatures. No clinical trials were conducted in this study. The Institutional Review Board (IRB) No. for this original article is (OIU-171).

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How to cite this article: Almajzoub OM, Abdelrahim EY, Doush WM. Surgical outcomes of open choledochoduodenostomy in treatment of Sudanese patients diagnosed with benign obstructive jaundice: A single-center prospective study. *Adv Dig Med*. 2026;13(1):e70013. <https://doi.org/10.1002/aid2.70013>