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Feasibility of cholecystectomy in patients with silent common bile duct stones cohort prospective single arm multicentre study

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Abstract

Background The management of patients with concomitant gallbladder stones with silent CBDS still involves a wide range of debates, and there is little evidence regarding the recommendation of CBD clearance either before cholecystectomy or in the same session. In this study, we aimed to discuss the feasibility of performing LC with a wait-and-see strategy for patients with silent CBS.

Method Patients with silent CBDS identified during preoperative examinations for gallbladder stones were studied for the feasibility of performing LC with a wait-and-see strategy for silent CBS.

Results Sixty patients who presented with gallbladder stones with silent CBDS underwent LC between February 2023 and July 2023. Seventeen patients (28.3%) underwent laparoscopic acute cholecystectomy, and 43 (71.7%) patients underwent laparoscopic elective cholecystectomy; all of these procedures were completed laparoscopically. Two patients (3.3%) developed symptomatic CBDS, both of whom were treated medically without intervention. Sixteen patients (26.7%) experienced spontaneous CBDS during the follow-up period.

Conclusion Patients who present with symptomatic gall bladder stones either acutely or electively with asymptomatic CBDS can undergo laparoscopic cholecystectomy without suffering from CBDS with acceptable short-term outcomes.

Trial registration This study was registered at Suez med – IRB office under trial registration no. 6 and registered at clinicaltrials.gov (NCT06349876) in 31/3/2024.

Keywords Cholecystectomy, Silent stones, CBDS

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Background

Laparoscopic cholecystectomy (LC) has been widely accepted as the most effective method for treating symptomatic gallstone disease since its introduction to surgical practice in the twentieth century. It is the most commonly performed hepatobiliary operation worldwide [1].

Choledocholithiasis is a medical term for a condition in which stones are present in the bile ducts outside of the liver. The majority of these structures arise from the gallbladder and are often located in the distal portion of the common bile duct (CBD). The user's text is incomplete [2].

Concomitant CBD stones (CBDS) are found in 5–20% of patients who undergo laparoscopic cholecystectomy [3, 4].

Symptoms include abdominal pain, jaundice, and fever, but 5–12% of patients are asymptomatic [5].

There has been a discussion on how to handle common bile duct stones in people who also have gallbladder stones. According to current standards, patients who have been found to have common bile duct stones on imaging should be provided with the option of having the stones removed. This can be accomplished either through surgical intervention during laparoscopic cholecystectomy or by utilizing endoscopic retrograde cholangiopancreatography (ERCP) [6].

Guidance does not distinguish between patients who have symptoms and those who do not have symptoms of CBDS [7].

The natural history of CBDS is not well understood, and common bile duct stones are generally classified as primary or secondary stones based on the location of origin. Most of the stones found in the biliary tree are secondary stones [4].

Although cholelithiasis can result in many consequences, such as discomfort, biliary blockage, cholangitis, pancreatitis, biliary cirrhosis, and liver abscesses, not all individuals experience these issues. In some cases, common bile duct stones may naturally transit into the intestine without causing major symptoms [8].

There is uncertainty regarding whether all patients with CBD stones should have attempted duct clearance, either with ERCP or invasive bile duct exploration, due to the risk of complications and negative health outcomes [9].

To our knowledge, there is limited literature discussing the management of concomitant gallbladder stones and silent CBS. In this study, we will review the feasibility of performing LC with a wait-and-see strategy in silent CBSs.

Methods

We conducted a cohort prospective single-arm study combining many medical centers, guided by the STROBE Statement—Checklist, where we observed a group of patients diagnosed with gallbladder stones. These patients also had asymptomatic common bile duct stones that were identified during preoperative examinations for gallbladder stones. Patients with asymptomatic common bile duct stones were characterized by the presence of CBD stones without any discernible symptoms, along with normal liver enzyme values, bilirubin levels, and alkaline phosphatase levels. The patients in question underwent laparoscopic cholecystectomy procedures at various facilities in Egypt, including the General Surgery Department at Suez University, Qeft Teaching Hospital, and Qena University facilities. The surgeries took place between February 2023 and July 2023.

Ethical approval

The study was approved by the Institutional Review Board of the Suez Faculty of Medicine, Suez University (SUEZ MED - IRB Approval NO: 6). Written informed consent was obtained from all patients before their participation in the study. This study was registered at clinicaltrials.gov (NCT06349876).

Inclusion criteria

Age between 25 and 60 1-Patients with asymptomatic common bile duct stones. 2- Patients with normal bilirubin levels. 3- Patients with normal alkaline phosphate levels.

Exclusion criteria

1- Patients with history of jaundice. 2- Patients with abnormal liver function.

Procedure and follow-up

Patients who underwent laparoscopic cholecystectomy for symptomatic gallbladder stones were included in this study. All patients underwent preoperative abdominal ultrasound, alkaline phosphate level, bilirubin level, and selected CBDS imaging by magnetic resonance cholangiopancreatography (MRCP) if there was dilatation of the CBD with no definitive stone on ultrasound scan and other routine preoperative investigations, such as complete blood imaging, kidney function tests and coagulation profiling.

Subsequently, patients underwent a 6-month follow-up period involving abdominal ultrasonography and liver function testing, specifically assessing liver enzymes. Measurements of bilirubin and alkaline phosphatase levels were taken at 3 and 6 months. Additionally, any symptoms indicating the presence of common bile duct stones should be monitored. These symptoms include

Table 1 Patient demographics and operative data

All patients (N)	60 (100%)
Sex	
Female (N)	40 (66.7%)
Male (N)	20 (33.3%)
Age mean (range) in years	
40 (26–56)	
CBD* diameter (N)	
≤ 7 mm	13 (21.7%)
> 7 mm	47 (78.3%)
Type of cholecystectomy (N)	
Acute	17 (28.3%)
Elective	43 (71.7%)
Operative time (min), median (range)	
70 (42–90)	
Hospital stays (Hr), median (range)	
20 (12–31)	

*CBD, common bile duct

abdominal pain, nausea, changes in urine color or pale stools, pruritus, or any other visible signs of jaundice during a physical examination.

Outcome of interest

The primary outcome of interest was the occurrence of biliary manifestations within a period of 6 months following laparoscopic cholecystectomy. Biliary manifestations are characterized by abdominal pain and/or nausea and vomiting, reported changes in urine color and/or pale feces, itching, or any other obvious signs of jaundice during a physical examination. Individuals diagnosed with cholangitis with laboratory findings of obstructive jaundice or abnormally high liver enzyme levels.

Statistical analysis

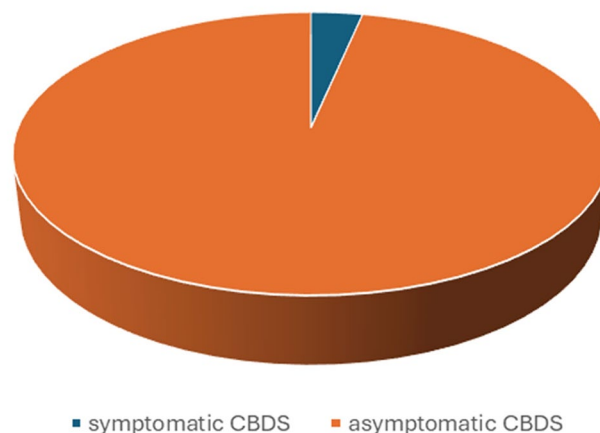
Descriptive statistics were used to summarize the baseline characteristics and clinical outcomes of the patients. Continuous variables are presented as the mean ± standard deviation (SD). Categorical variables are expressed as frequencies and percentages.

Results

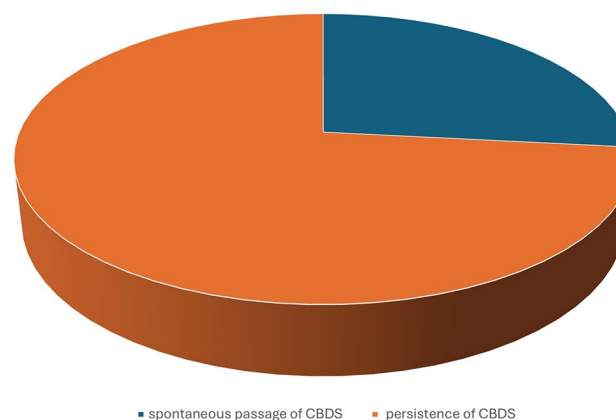
A total of 60 patients presented with gall stones with asymptomatic CBCS. were invited to participate in the study between February 2023 and July 2023, with a follow-up period of approximately 6 months (± 3). Of the 60 patients, 40 were females (66.7%), and 20 were males (33.3%). The age ranged from 26 to 56 years, with a mean of 40; the diameter of the CBD measured by abdominal ultrasound scan was ≤ 7 mm in 13 (21.7%) patients and > 7 mm in 47 (78.3%) patients. In 11 (18.1%) patients, abdominal ultrasound revealed CBD dilatation > 7 mm with no definitive stones, and these patients were investigated by MRCP, which confirmed the presence of stones.

Seventeen patients (28.3%) underwent laparoscopic acute cholecystectomy, and 43 (71.7%) patients underwent laparoscopic elective cholecystectomy; all of these

post operative complication

**Fig. 1** Post operative symptomatic CBDS show the percentage of symptomatic CBDS to asymptomatic CBDS

Passage of CBDS

**Fig. 2** Show the percentage of spontaneous passage of CBDS to persistence of CBDS

patients underwent laparoscopic surgery with no conversion, an operative time of 70 min and a median hospital stay of 20 h. Patient demographics and operative data are listed in Table 1.

During the postoperative follow-up, two patients (3.3%) developed symptomatic CBDS (Fig. 1).

one of whom developed symptomatic CBDS after one month and the other after forty days; both patients were treated medically without intervention with spontaneous passage of stones confirmed by abdominal scan.

At the 3-month follow-up, abdominal ultrasound revealed spontaneous passage of CBDS in 9 (14.8%) patients, and another 7 (11.7%) patients revealed spontaneous passage of CBDS at the 6-month follow-up (Fig. 2).

Thirteen patients [13/47 (27.6%)] had CBD diameters > 7 mm, and three patients [3/13 (23%)] had CBD diameters ≤ 7 mm.

Discussion

Relevant reports on managing asymptomatic CBDS discovered intraoperatively either by intraoperative cholangiogram or intraoperative ultrasound favour a wait-and-see strategy or managing asymptomatic CBDS diagnosed preoperatively by offering duct clearance either before LC or during an LC session.

In this study, we aimed to manage patients who presented with gallbladder stones with asymptomatic CBDS as two different entities, with a wait-and-see strategy for the treatment of asymptomatic CBDS and cholecystectomy for gallbladder stones.

There is general acceptance about the management of symptomatic or complicated common bile duct stones by endoscopic, laparoscopic, or even open surgical management of common bile duct stones; the choice of treatment is affected by many factors, including the timing of presentation, gall bladder status (pre- or post-cholecystectomy), availability of expertise and size of the stones [10].

The acceptance of managing symptomatic common bile duct stones (CBDS) has become a subject of dispute and contention in regard to quiet CBD stones. These stones may be detected during cholecystectomy using intraoperative ultrasonography or intraoperative cholangiogram, or they may be found incidentally during abdominal scanning for unrelated reasons.

Endoscopic retrograde cholangiopancreatography (ERCP) is the most common accepted method for the management of CBDS, and many reports have revealed an increased incidence of procedure-related complications, especially post ERCP pancreatitis (PEP), in the management of asymptomatic CBDS in comparison to symptomatic CBDS and an increased incidence of PEP in asymptomatic CBD stones compared to symptomatic CBD stones (11/67 [16.4%] vs. 8/358 [2.2%], respectively) [11].

In 2019, Hakuta et al. [12] conducted a study that examined the results of expectant and endoscopic treatment for asymptomatic CBD stones. The findings indicated that 6.1%, 11%, and 17% of the individuals who anticipated something had a combined occurrence of complications after 1, 3, and 5 years of observation, respectively. Conversely, the group that received the intervention experienced a complication rate of 32%. These numbers provide evidence for adopting a prudent and vigilant strategy rather than opting for endoscopic therapy in asymptomatic patients.

In a recent study conducted by Bunting et al. [13], many patients with small common bile duct stones

(CBDSs) were identified during surgery using routine intraoperative ultrasound (IOUS). Instead of immediately undergoing procedures to clear the bile ducts during or after surgery, these patients were managed with short-term expectant management as the first-line treatment for CBDS.

In this study, two patients (3.3%) developed symptomatic CBDS during the follow-up period and were treated conservatively with third-generation cephalosporin, oral urso-deoxycholic acid, analgesics and antispasmodics for one week, and liver function and abdominal scans were subsequently evaluated.

On the other hand, 16 patients (26.7%) experienced spontaneous CBDS during the follow-up period, thirteen patients (27.6%) had CBD diameters > 7 mm, and three patients (23%) had CBD diameters ≤ 7 mm. We suggest that this may be because of cholecystectomy on increased intraductal pressure.

One limitation of our study is the short duration of follow-up.

Conclusion

In conclusion, patients who present with symptomatic gall bladder stones either acutely or electively with asymptomatic CBDS discovered during preoperative evaluation can undergo laparoscopic cholecystectomy without CBDS removal, which is associated with accepted short-term outcomes.

We emphasize the need for incontrovertible randomized controlled trials (RCTs) to further substantiate the 'wait and see' approach as a reliable option instead of ERCP.

We suggest that future studies evaluate the effect of cholecystectomy and CBD diameter on the incidence of spontaneous CBDS.

Abbreviations

LC	Laparoscopic cholecystectomy
CBD	Common bile duct
CBDS	Common bile duct stones
ERCP	Endoscopic retrograde cholangiopancreatography
PEP	Post ERCP pancreatitis

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Author contributions

Ahmad A. Maklad, Mahmoud Eltantawy, Mohammed Siam and Mohamed Abdelshafy wrote the main manuscript text and prepared figures. All authors reviewed the manuscript.

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Data availability

These datasets can be accessed on request from Ahmad Maklad, General Surgery Department, Faculty of Medicine, Suez university, Suez city, Egypt. email: maklad2006@yahoo.com, upon the completion of a Data Usage Agreement.

Declarations

Ethics approval and consent to participate

The study was approved by Institutional review board of Suez Faculty of Medicine, Suez University (SUEZ MED - IRB Approval NO: 6). Written informed consent was obtained from all patients before their participation in the study.

Consent for publication

Written informed consent for publication of their clinical details and/or clinical images was obtained from the patient. A copy of the consent form is available for review by the Editor of this journal.

Competing interests

The authors declare no competing interests.

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