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## Laparoscopic Management of Common Bile Duct Stones using Semi-rigid Ureteroscope- a Single Centre Prospective Observational Study

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## ABSTRACT

**Background:** Minimally invasive and endoscopic techniques are increasingly being used by surgeons nowadays in the management of patients with cholelithiasis and choledocholithiasis. However, there is a high failure rate in the extraction of large impacted stones using the conventional flexible choledochoscope by the laparoscopic approach. Improvisation of this technique will reduce the failure rate. The present study explored the safety, feasibility, and efficacy of a semirigid ureteroscope (SRUS) in the laparoscopic management of common bile duct (CBD) stones.

**Methods:** A prospective observational clinical study was carried out in an experienced GI surgical unit from January 2020 to December 2021. It included 36 patients diagnosed with radiologically proven gallstone disease with bile duct calculi who underwent Laparoscopic CBD exploration (LCBDE) and stone extraction using SRUS with lap cholecystectomy (LC) as a single-stage procedure. The success rate in terms of complete CBD clearance is the primary outcome measure. Post-procedure complications, 24 hr pain score, in-hospital stay, and patient satisfaction score are the secondary outcome measures.

**Results:** Mean age of the study subjects was 50.45±9.12 years. The most common clinical symptom was biliary colic followed by jaundice. The primary outcome measure of complete CBD clearance was achieved in 94%. A complication following surgery was bile leak in one patient (3%). There were no surgical site infections or T-tube related complications. The average WHO 24-hour pain score was 4.9±1.9. The mean in-hospital stay was 3.3±1.4 and the mean patient satisfaction score was 2.42±0.3.

**Conclusion:** Laparoscopic approach avoids the complications of endoscopic retrograde cholangiopancreatography (ERCP) sphincterotomy/sphincteroplasty and keeps the sphincter of Oddi (SOD) intact. LCBDE with SRUS is a safe and effective single-stage approach without any radiation hazards. The pneumatic lithotripter with its pneumatic ballistic effect is more efficacious, cost-effective, and safe as compared to other lithotripsy techniques. This lithotripter is capable of dealing with different varieties of stones regardless of their composition, size and degree of impaction. However, future comparative studies are needed to prove the superiority of this technique.

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## INTRODUCTION

Minimally invasive surgeries and endoscopic techniques are increasingly becoming standardized nowadays in hepatobiliary diseases. Choledocholithiasis is no exception to this and needs an individualized tailored approach depending on the clinical situation. Gallstones constitute a significant health problem worldwide including India, with an incidence ranging from 6% to 10% in the

adult population [1]. Majority of the gallstones are cholesterol stones which are formed in the gallbladder and migrate down into the CBD as secondary stones [2]. CBD stones are found in 10-15% of patients having gallstone disease [3]. Compared to younger age groups, its incidence is much higher in older age groups. In patients aged more than 60 years with gallstone disease, concurrent CBD stones are seen in 20-25%. Serious consequences like cholangitis and gallstone pancreatitis may occur as a result of complete or incomplete bile duct obstruction of CBD stones [4].

CBD stones can be managed either by endoscopic or surgical approach [5]. Various studies have concluded that LCBDE is superior to endoscopic clearance in terms of safety and efficacy [6]. The National

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Institute for Health and Care Excellence (NICE) guidelines suggest that LCBDE is an APT and suitable approach in the management of CBD stones [7]. Traditionally LCBDE is performed using a flexible choledochoscope. However, it has inherent problems and maintenance is difficult [5,8]. In addition expensive techniques like cholangioscopy-guided electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL) are needed as an adjunct to fracture large impacted stones. On the contrary, SRUS with pneumatic lithotripsy (that is used for urinary tract stones) is easily available at an affordable cost for managing large impacted CBD stones [8,9]. Hence this study was undertaken to investigate the efficacy, safety and feasibility of Semi-rigid ureteroscope in the laparoscopic management of common bile duct stones at a tertiary hospital.

## MATERIALS AND METHOD

A prospective clinical study was conducted between January 2020 to December 2021 in our GI surgical unit. The study population included patients with radiologically proven CBD stones with a CBD diameter of >8mm (arbitrarily) and irrespective of the LFT values. Post ERCP failure cases were also included in this study. Patients with CBD diameter <8 mm, acute cholangitis, severe acute biliary pancreatitis, evidence of cirrhosis, severe adhesive bowel syndrome due to prior open procedures and those unwilling or unfit to undergo laparoscopic surgery were excluded from the study.

The aim of our study was to describe the clinical presentation, biochemical data, and imaging characteristics in the study population. The primary outcome measure of the study was the success rate in terms of complete CBD clearance by the LCBDE approach using SRUS and mechanical lithotripter. The secondary outcome measures are intraoperative and post-procedure complications, 24 hr pain score, in-hospital stay, and patient satisfaction score, obtained on an indigenous scale of 1 to 3.

## METHODOLOGY:

The study was pursued after due approval from the Institutional Ethics Committee. A total of 36 patients with CBD stones diagnosed using a magnetic resonance cholangiopancreatography(MRCP) were included in the study after obtaining an informed consent. The patient's symptoms were recorded. All of them underwent baseline blood investigations, which included an LFT in particular. All were subjected to an ultrasound abdomen, an upper GI endoscopy, and an MRCP. The MRCP data were analyzed to assess the gallbladder (GB) wall thickness, number of CBD stones, CBD stone size, and CBD diameter. All the study participants underwent cardiorespiratory evaluation using an echocardiogram and a pulmonary function test. Those patients deemed fit for LCBDE were subjected to the procedure under general anaesthesia. A summary of the demographic data is depicted in Table 1.

## Semirigid Ureteroscope Specifications:

The semirigid ureteroscope used for this procedure has a seven-degree telescope for improved visualization with an atraumatic tip design. It has a separate attachment with two irrigation channels and a two-way port for a single working channel. The working channel can simultaneously accommodate both a guidewire and a pneumatic lithotripter probe for stone manipulation. It has two irrigation ports for saline irrigation which is two-way and helps to dilate the CBD for improved visualization. The size of the scope is- 9.8Fr x 430 mm with a 6.4 Fr working channel.

## Pneumatic Lithotripter:

Pneumatic lithotripter works on the principle of electro-pneumatic ballistic energy applied by the impact of the projected air on the CBD stone. The internal mechanism has no contact with water; therefore problems such as hanging and clogging are never encountered.

## Operative Procedure:

Through a routine four-port approach for a standard laparoscopic cholecystectomy, Callot's triangle is dissected and critical view of safety established. Cystic artery is then clipped and cut. Then the cystic duct is clipped as it prevents any migration of gallstones into the CBD during manipulation of the GB. Our preferred approach is the routine transcholedochal route after delineating the supra duodenal part of the CBD. A choledochotomy is made in the supraduodenal part of CBD. Then a separate 5 mm port is inserted in line with the CBD, midway between the epigastric and midclavicular port, through which the SRUS is inserted for CBD exploration.

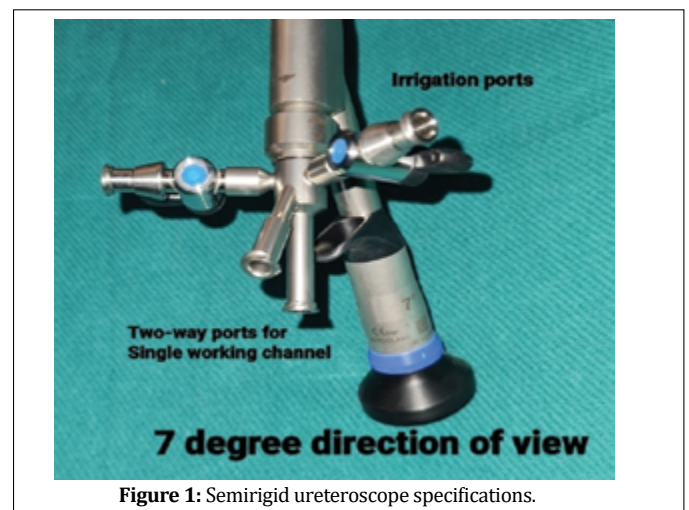


Figure 1: Semirigid ureteroscope specifications.

Table 1: A Summary of the demographic profile of the study population.

S.No	Characteristics	No(%)
1	Total no of Patients(n)	36
2	Post Endoscopic retrograde cholangiopancreatography failure patients	8(33%)
3	Completed laparoscopically- Using semirigid ureteroscope	34(94 %)
4	Need for bilioenteric anastomosis - <b>Lap choledochoduodenostomy</b>	6(17%)
5	Dormia basket extraction	18(50%)
6	Pneumatic Lithotripter assisted patients	19(53%)
7	Patients with impacted stones in the distal CBD	11(31%)
8	Patients with CBD closure over T tube	28(78%)
9	Conversions- (Dense adhesions, suspect Mirizzi)	2 (6%)
10	Mean operative time	186 mins
11	Intra op Complications - CBD injury	<b>Nil</b>

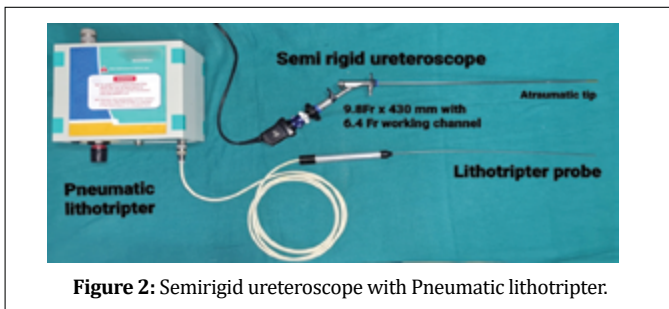


Figure 2: Semirigid ureteroscope with Pneumatic lithotripter.

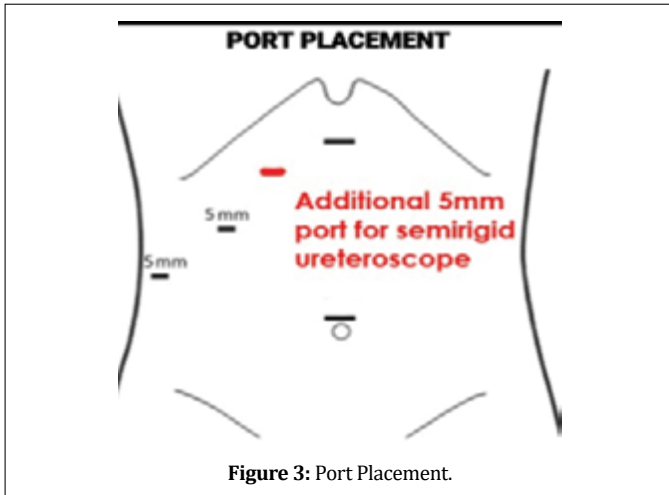


Figure 3: Port Placement.



Figure 4: Theatre setup.

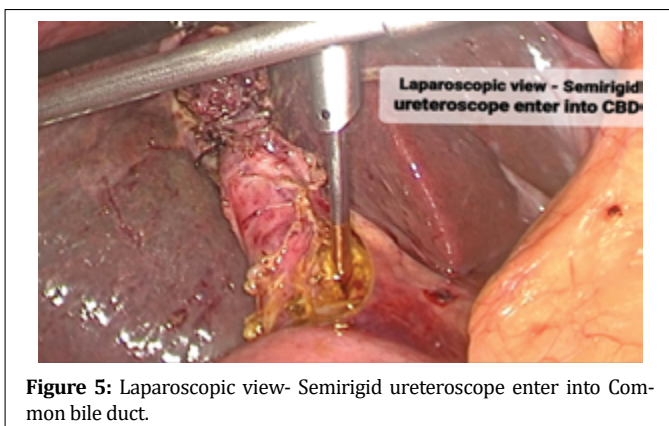


Figure 5: Laparoscopic view- Semirigid ureteroscope enter into Common bile duct.

Under laparoscopic guidance, SRUS is inserted into the CBD to visualize the bile duct distal to the choledochotomy. Then larger sized stones more than 1 cm or those impacted in the distal CBD are broken with a mechanical lithotripter probe, and inserted through one of the working channel of the SRUS. The stones are broken by a pneumatic ballistic effect and the fragmented stones are either flushed into the duodenum or flushed out of the choledochotomy. The smaller fragments can be retrieved using grasping forceps. We also use a basket

to entangle the stones to be removed through the choledochotomy. After stone clearance, the SRUS is passed distally up to the ampulla to ensure complete distal clearance. SRUS is then passed proximally through the choledochotomy and any proximal stones are cleared in a similar fashion. The retrieved stone fragments are collected in an endo bag. The choledochotomy is then closed over a 14 Fr T tube with 3-0 vicryl intracorporeal sutures. The peritoneal cavity is then suctioned out of all the irrigation fluid and a 28 Fr drain tube is kept in the Morrison's pouch.

The procedure was completed laparoscopically in 34 patients using SRUS with complete ductal clearance. Laparoscopy was converted to open in 2 patients because of dense adhesions. All the patients were routinely given parenteral third-generation cephalosporins for 3 days, converted to oral antibiotics for the next two days, and discharged postoperatively. Patient demographic data, intraoperative findings, duration of in-hospital stay, post-intervention events, and Patient satisfaction scores were recorded.

**RESULTS:**

A total of 36 patients were included in the study. Among this, 19 (53.0%) were males, and 17 (47.0%) were females. The mean age of the study subjects was 50.45±9.12 years. The Majority of them presented with biliary colic (72.0%), followed by jaundice (50.0%). Other symptomatic presentations were as furnished in (Table 2). The majority of the study population had multiple stones (56%) with a stone diameter of more than 1 cm (75%), impacted stone in the distal CBD in 11 (31%) (Table 3). Among this, successful laparoscopic CBD exploration was performed in 34 patients, need for bilioenteric anastomosis in the form of laparoscopic choledochoduodenostomy in 6 (17%) patients, dormia basket was used for stone retrieval in 18(50%) patients, pneumatic lithotripter was used for breaking the stone in 19(53%) patients. There were conversion to open CBDE in two patients because of dense adhesions and suspected Mirizzi syndrome. The mean operative time was 186 minutes. Postoperative bile leak was encountered in one patient. During the first 24h after surgery, the pain scores were measured by the WHO visual analogue scale and the mean was 4.9± 1.9. The In-hospital stay was 3.3±1.4. The mean patient satisfaction score was 2.42±0.3; measured on an indigenous verbal rating scale of 0-3 during discharge. There were no postoperative T tube related complications (Table 4).

Table 2: Distribution of the study population based on presenting symptoms.

Presenting symptoms	N=36
Biliary colic	26(72%)
Jaundice	18 (50 %)
Fever	14 (39%)
Pruritus	12( 33%)
Vomiting	4 (11%)

Laboratory findings & MRCP data of the study subjects were as follows:

Table 3: Distribution of the study population based on presenting symptoms.

Laboratory parameters	N=36
Total bilirubin	5.15 ± 4.62
Alanine Aminotransferase (ALT)	96.04 ± 75.32
Aspartate transaminase (AST)	70.72 ± 56.82
Alkaline Phosphatase (ALP)	327.6 ± 168.96
MRCP characteristics	
CBD diameter >8mm	36(100%)
Stone diameter > 10mm	27(75%)
Stone diameter ≤ 10mm	9(25%)
Multiple stones	20(56%)
Single stone	16(44%)

Outcome and complications among the study subjects:

**Table 4:** Distribution of the study subjects based on primary and secondary outcome.

PRIMARY OUTCOME MEASURES	
<b>Success</b> -Complete CBD Clearance by LCBDE using SRUS with/ without mechanical lithotripsy	<b>34/36(95%)</b>
<b>Conversion to Open CBD exploration</b>	<b>2/36(5%)</b>
SECONDARY OUTCOME MEASURES	
Post-procedure complications	
Bile leak	<b>1(3%)</b>
Bleeding	0
Wound infection	0
T- tube related complications	0
<b>24 hr pain score (WHO VAS)</b>	<b>4.9±1.9</b>
(mean±SD)	
<b>In hospital stay</b>	<b>3.3±1.4</b>
(mean±SD)	
<b>Patient Satisfaction Score</b>	<b>2.42±0.3</b>
(mean±SD)	

## DISCUSSION:

CBD stones are the most common cause of nonmalignant bile duct obstruction. Approximately, 5 in 1000 people is reported to develop gallstones causing biliary obstruction [10]. CBD stones are either primary stones or secondary stones depending upon the site of origin. Secondary stones originate from the GB and migrate into the CBD. 10% to 15% of patients with GB stones have CBD stones [11]. Primary stones originate within the CBD itself. The diagnosis of primary CBD stones is by using Saharia's criteria. Saharia's criteria for diagnosis of primary CBD stones includes a past history of cholecystectomy with or without CBD exploration, at least a two years symptom-free interval following initial biliary tract intervention, easily crushable soft light brownstones in the CBD, and no evidence of a long cystic duct remnant or a biliary stricture resulting from the previous surgery [12].

CBD stones can be asymptomatic or symptomatic. The clinical symptoms of CBD stones include biliary colic, jaundice, and fever. CBD stones can present with life-threatening complications like cholangitis and pancreatitis as well [13]. The new ASGE 2019 high risk criteria for choledocholithiasis includes CBD stones on an ultrasound, total bilirubin >4mg/dl with dilated common bile duct, clinical evidence of ascending cholangitis which indicates to proceed with ERCP directly. Intermediate risk criteria includes abnormal liver function test, age >55, dilated CBD on ultrasound, where further evaluation with endoultrasound and MRCP is necessary [14]. The traditional method of managing CBD stones is by open CBD exploration. Open CBD exploration is associated with a higher incidence of surgical site infections and prolonged in-hospital stay, with an overall morbidity rate of 13% [15].

With the advent of endoscopic and laparoscopic techniques, open CBDE has become a salvage technique for the failure of minimally invasive methods. Similar to any other minimally invasive procedures, LCBDE has the advantage of faster patient recovery and better post-procedure patient comfort. The postoperative morbidity rates have also significantly reduced [16].

ERCP and stone retrieval has become a standard technique for managing CBD stones. But the pitfalls of ERCP are that larger stones cannot be handled with ease. ERCP requires expensive techniques like electrohydraulic, mechanical, or LASER lithotripsy as adjuncts to manage larger stones in the CBD. Moreover, such lithotripsy techniques are not universally available at all centers. Though the success rate of ERCP for clearing the CBD of smaller stones (<1cm) is considerable, the same cannot be reflected for larger (>1cm) and impacted CBD stones. In addition, the success of CBD cannulation and clearance depends on the individual expertise of the endoscopist. Theradiation exposure risk is present in case of ERCP techniques for both the patient and the endoscopy team [17]. In contrast, LCBDE with or without mechanical lithotripsy has no risk of radiation exposure and can handle larger-sized CBD stones effectively. The sphincter of Oddi (SOD) prevents reflux of duodenal contents into the bile duct. Compared to the laparoscopic approach which keeps the SOD intact, the endoscopic

approach in managing CBD stones requires sphincterotomy or balloon sphincteroplasty and it enhances the rate of bactibilia due to duodenobiliary reflux [18]. In our study, the reasons for failure of the endoscopic approach to clear the CBD are due to distal CBD stricture, deformed duodenum, impacted stones, and periampullary diverticulum.

Laparoscopic CBD exploration (LCBDE) has been widely available, which is a single-stage procedure with shorter hospital stay and better patient satisfaction. LCBDE can be done either through a transcystic route or transcholedochal route. Transcystic route is preferred in small to medium-sized stones. Transcholedochal route is preferred in large stones and aberrant cystic duct course or insertion [19]. Although T tube is used in this approach as a conventional way, these days after stone retrieval, bile duct clearance proximally and distally is confirmed by using either a choledochoscope or ureteroscopy before primary closure of the CBD. It avoids T tube related complications like T tube displacement, tube site infection, nutritional and electrolyte disturbances, patient inconvenience, etc., and reduces the operative time and overall in-hospital stay [20].

The major difficulty faced in LCBDE is in the management of large impacted CBD stones with a flexible choledochoscope. A comparison of flexible choledochoscope with a SRUS is provided in the table. As the semirigid ureteroscopy has been sturdier, durable with seamless working ability, we prefer it to break the large impacted stones.

A thorough search of the available literature of LCBDE using Ureteroscopy and comparison with our study is furnished in the below table.

In the present study, the success rate was 94% and only 6% (2/34) were converted to open CBD exploration because of dense adhesions and suspected Mirizzi syndrome. No patients were converted due to equipment failure. Bile leak was the only post-operative complication that was present in 3%(1/34) of the study population. In our study, the procedure was completed laparoscopically in 34/36 (94%) which includes 8(33%) post ERCP failure patients. In a similar study by Imraan I Sardiwalla et al, the procedure was completed laparoscopically in 32(86.5%)patients with 28(75.7%)post ERCP failure cases and converted to open CBDE in 5(13.5%) because of equipment failure, cirrhotic liver and impacted stones [21]. In another study conducted by Muneer Khan et al, 7(8.75%) patients were post-ERCP failure cases and one patient (1.25%) needed conversion as a result of difficult dissection secondary to extensive dense adhesions [8].

SRUS is easily available where much harder stones are broken during urological interventions. Compared to urinary tract stones, CBD stones are much easier to break. Hence we have utilised the SRUS instead of a flexible choledochoscope to address the CBD stones and in particular for impacted CBD stones. There are no postoperative septic complications noted in the study subjects. The limitation of our study is that it is an observational single centre study design. In the near future, further randomized controlled trials comparing the efficacy and safety of flexible choledochoscope with the SRUS will give further insights into the pros and cons of each technique or will prove the superiority of one technique over the other.

## CONCLUSION:

Laparoscopic CBD exploration with SRUS is a single-stage, safe, feasible and effective approach, with excellent success rates without any radiation hazards. It is cost-effective and easily available. The laparoscopic approach avoids the complications of ERCP and keeps the SOD intact. It is especially preferred in multiple stones, large impacted stones, proximal stones, and in cases where biliary enteric anastomosis is required. The pneumatic lithotripter with its pneumatic ballistic effect is more efficacious, cost-effective, and safe as compared to other lithotripsy techniques. This lithotripter is capable of dealing with different varieties of stones regardless of their composition, size and degree of impaction. LCBDE with SRUS also has the advantage of good patient satisfaction, a shorter in-hospital stay and minimal morbidity. Thus SRUS can be considered a viable alternative to the flexible choledochoscope in the laparoscopic management of CBD stones. However, future RCTs will throw some light on the superiority of this technique over the flexible choledochoscope.

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