

## A Prospective Study on Endoscopic Stone Extraction followed by Laparoscopic Cholecystectomy under same anaesthesia

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### Abstract:

**Background:** The ideal management of common bile duct (CBD) stones associated with gall stones is a matter of debate. The best outcome in addressing simultaneous cholelithiasis (gallstone disease [GSD]) and choledocholithiasis is single-session endoscopic stone extraction (ESE) with laparoscopic cholecystectomy (LC) (common bile duct stone [CBDS]). Traditional rendezvous with an intraoperative cholangiogram is accompanied with a number of technical (bowel distention, frozen Calot's triangle, intraoperative cholangiogram restriction, and so on) and logistical challenges (lack of trained personnel and equipment for ESE in the operating room). To examine the safety of the technique and solve the disadvantages of the conventional rendezvous strategy, we adapted our ESE-LC approach (tandem ESE-LC).

**Methods:** A prospective study of individuals with GSD and suspected CBDS was undertaken in SIMS Hospital, Vadapalni Chennai, from 2017 to 2019. Tandem ESE-LC entails performing ESE and LC on the same day under the same general anaesthetic, with ESE conducted in the endoscopic suite using carbon dioxide insufflation, bile duct clearing achieved using a balloon/basket, and the procedure validated by an occlusion cholangiogram. After that, patients were sent to the operating room for LC. The procedure's primary result was bile duct clearing, as well as the procedure's safety.

**Results:** The research comprised 84 patients out of 112 who were examined for eligibility (median age: 52 years). The most prevalent presenting symptom was biliary colic (n = 48), followed by acute cholecystitis (n = 22). The median stone size and number of stones were 1 (1–6) and 4 mm (3–10), respectively. The bile ducts were cleared in all of the patients. In 10 patients, stenting was performed. Calot's dissection was difficult and frozen in 20 and 22 patients, respectively, during surgery. In 26 of the patients, the cystic duct was short and broad. In 12 of the patients, a subtotal cholecystectomy was done. The average length of stay in the

hospital after surgery was 1 (0–12) days. On a day-care basis, three patients received tandem ESE-LC. One patient required percutaneous drainage for gall bladder fossa collection after endoscopic retrograde cholangiopancreatography, and another required percutaneous drainage for post–endoscopic retrograde cholangiopancreatography pancreatitis. After a median of 17 (3–28) months of follow-up, no patient had retained CBDS.

**Conclusion:** Tandem ESE-LC is a safe and successful approach for treating GSD and CBDS in the same patient.

### **Introduction:**

Gallstone disease is one of the most common reason for hospital admission. CBD stones are classified in primary and secondary stone on the basis of the site of origin. Clinical presentation varies from asymptomatic to life threatening conditions such as acute biliary pancreatitis and cholangitis. Patients are categorized in low, intermediate and high risk of choledocholithiasis using clinical, biochemical and imaging factors. Patients with low risk of choledocholithiasis should receive cholecystectomy without further evaluation while it has been recognized the importance of sequential use of EUS-ERCP in patients with intermediate risk of choledocholithiasis to triage patients in need for treatment. Patients with high risk of choledocholithiasis should receive ERCP before performing cholecystectomy although randomized clinical trial showed no benefit for preoperative ERCP over operative cholangiography and common duct exploration.<sup>1-4</sup> Patients should be received an informed consent and antiplatelet and anticoagulation treatment should discontinued for the appropriate drug-specific interval in according to the recent guideline. Routine administration to all patients undergoing to ERCP is considered unnecessary unless cholangitis or immunosuppression is present or biliary drainage is predicted to be incomplete.<sup>4-7</sup> All patients undergoing to ERCP should be administered prophylactic drugs such as rectal indomethacin or diclofenac because of consistently reduced risk of post ERCP pancreatitis according to several meta-analysis and ESGE guideline. Endoscopic treatment is based on selective in cannulation of the CBD and performing adequate endoscopic sphincterotomy. In case of failed biliary access several reasonable options could be chosen. CBD stone can be removed with either a basket or a balloon catheter in 85-90% of cases and the choice of the better device depends on common bile duct and stone size<sup>2-5</sup>.

Cholelithiasis is associated with common bile duct stones in 20% of cases (CBDSs).<sup>1</sup> The symptoms of these individuals range from asymptomatic to life-threatening illnesses including cholangitis or pancreatitis.<sup>1</sup> Endoscopic stone extraction (ESE) followed by cholecystectomy

or vice versa are two treatment options for gallstone disease (GSD) and CBDS. <sup>2</sup> Surgical surgery for CBDS is an option, however it was not chosen because to ESE's high success rate and low morbidity. <sup>2,3</sup> Laparoscopic cholecystectomy (LC) with intraoperative endoscopic retrograde cholangiopancreatography (ERCP) had the highest success rates in common bile duct (CBD) clearance in a recent meta-analysis of 20 studies pertaining to the management of GSD and CBDS with laparoscopic and endoscopic approaches. The majority of studies used the rendezvous strategy to perform intraoperative ESE (RV). <sup>3-8</sup> The RV entails a laparoscopic Calot's dissection followed by a cystic duct cannulation through an incision. If stones are found, an intraoperative cholangiogram is done, followed by surgical cannulation of the bile duct. LC is done after ESE. <sup>6,9</sup> The RV is connected with a slew of drawbacks. Tzovaras et al<sup>5</sup> discovered that the guidewire could not be navigated into the duodenum in more than 10% (6/50) of patients who had the rendezvous technique. Other issues include the possibility of the incision being extended across the cystic duct to the CBD, as well as bowel distention caused by endoscopic air insufflation. <sup>5</sup> ElGeidi et al<sup>10</sup> began their investigation with LC and intraoperative ESE with RV, however due to intestinal distention, they revised the protocol to do ESE after the LC was completed. Intraoperative cholangiography has a number of drawbacks, the most notable of which being subjective interpretation in predicting CBDS. <sup>11</sup> To circumvent the difficulty of bowel distention, a few additional studies have used the strategy of finishing LC with intraoperative cholangiography and then doing ESE in the operating room (OR) after closing laparoscopic ports. <sup>8-10,12,13</sup> We opted to handle our patients with a modified single session ESE and LC to take advantage of the benefits of single session ESE and LC while avoiding the difficulties of doing an intraoperative cholangiography, which is seldom performed in day-to-day practise (tandem ESE-LC). As a result, ESE was carried out in an endoscopic suite with carbon dioxide insufflation. Insufflation with carbon dioxide was chosen because it generates less gut distention. <sup>14</sup> Following ESE, the patient was sent to the OR under the same anaesthetic for LC.

## **METHODS**

From 2017 to 2019, a prospective descriptive research was undertaken at the Institute of Gastroenterology, SIMS Hospital, Vadapalni Chennai, on patients hospitalised with cholelithiasis and probable choledocholithiasis. Patients who met the American Society for Gastrointestinal Endoscopy's high-risk choledocholithiasis criteria were diagnosed with suspected choledocholithiasis.<sup>15</sup> CBDS on transabdominal ultrasound, clinical ascending

cholangitis, total bilirubin levels  $> 4$  mg/dL, or dilated CBD on ultrasound ( $>6$  mm) and a total bilirubin level of 1.8–4 mg/dL are some of the symptoms. Patients under the age of 18 who had no stone on ERCP were excluded from the research. Acute right upper quadrant discomfort lasting at least 15 minutes but not longer than 6 hours was characterised as biliary colic.<sup>16</sup>

Patients who were scheduled for simultaneous operations were examined as outpatients and then hospitalised on the day of the scheduled ESE, with the exception of those who went to the emergency room. There is just one endoscopic suite available. The theatre complex, which has twelve surgery rooms, is one storey below the endoscopic suite and is connected to it by a specialised theatre elevator. After allowing for an unforeseen ERCP delay, patients were listed for the procedure with OR allotment choices. In the event that the OR was unavailable at a certain time of day, elective endoscopic retrograde cholangiography (ERC) was scheduled to avoid any delays throughout the shift. The protocol included telling the operating room when the ESE procedure was about to begin, when biliary cannulation was accomplished, and when the process was finished. Three endoscopists, each with at least 500 ESE operations under their belts, performed the surgery. LC was performed by four surgeons, with each having performed at least 400 procedures.

All patients fasted for 8 hours before to the surgery in preparation for tandem ESE-LC. Before the surgery, a 500- to 1000-ml bolus of Ringer's lactate was given intravenously (IV) combined with a diclofenac (100 mg) rectal suppository to achieve adequate hydration. ESE was started in the endoscopic suite under general anaesthesia with the patient prone, and IV third-generation cephalosporin was administered as a surgical prophylactic before LC. Piperacillin/tazobactam (4000mg/500mg) injection was given to patients with cholangitis. ESE was carried out utilising an Olympus TJF-150 (Japan) camera and carbon dioxide insufflation. A sphincterotome was used to selectively cannulate the CBD in ESE. In situations where selective cannulation was not possible, a precut sphincterotomy was done. Cholangiography was conducted after cannulation to confirm the presence of calculi. To clear the CBD, a balloon sweep or CBD basketing procedure was used. An occlusion cholangiogram was used to confirm CBD clearance. The stent was inserted in the event of CBD clearance failure, biliary pancreatitis, or cholangitis. Following ESE, the patients were transferred to the OR under the same general anaesthetic and transported utilising the Baines circuit, where LC was conducted following TAP block. The average duration from the end of the endoscopic surgery to the commencement of the laparoscopic procedure was 30 minutes, including the TAP block period. The traditional four-port LC approach was used. The cystic duct was severed and separated after Calot's dissection. The retro-infundibular approach was used in the case of a frozen Calot's

triangle. Subtotal cholecystectomy was performed if full dissection was thought to provide a risk of biliary damage.

**Postoperative Care and Follow-up** The patients were moved to the recovery ward for monitoring before being moved to the ward if they recovered well. After 4 hours of tandem ESE-LC, the patients were invited to move around and given an oral progressive food as tolerated. Patients who tolerated oral fluids without the need for IV fluids and discomfort that could be managed with oral analgesics were eligible for release. We discovered that patients could achieve the aforementioned requirements by the end of the procedure day, thus we began providing the treatment as a day-care surgery later in the trial. All patients were given a three-day supply of pantoprazole and diclofenac pills when they were discharged. If nonsteroidal anti-inflammatory medications were not an option, Tramadol was prescribed. Clinical examinations were performed on the patients after three days and one month. Poh et al. reported the follow-up protocol that was used.<sup>9</sup> All patients were followed up with a clinical examination for three months, then a phone call every three months. On a standard proforma, follow-up information was collected, including questions concerning gallstone-associated symptoms and whether additional treatment or procedures related to GSD were necessary or recommended.

**Measures of Success** The incidence of unsuccessful bile duct clearance was used as the primary efficacy outcome. A clean occlusion cholangiogram following ESE was classified as bile duct clearing.<sup>9</sup>

Procedural problems (bleeding; conversion to open; wound infection; bile duct damage; clinical pancreatitis), length of postprocedural hospital stay, death, readmission, and reintervention were all considered secondary outcomes. After completing tandem ESE-LC, post-ERCP pancreatitis was defined as new onset or persistent pancreatic type discomfort at least 3 hours later, with rise in amylase levels higher than 276 IU/L or lipase levels greater than 1000 IU/L 2 hours later.<sup>4</sup> Serum amylase and lipase tests, as well as abdominal imaging, were done on these people. There were no routine examinations to detect post-ERC pancreatitis. Any biliary system stones discovered within a year following the index surgery were considered retained stones.

A specific proforma was used to collect data. Various demographic and clinicopathological characteristics were documented, including the duration of symptoms at presentation, ASA class, liver function tests, and imaging. Intraprocedural findings (ESE and LC) were recorded. The investigator also kept track of outcome factors. SPSS was used to enter and analyse the data (version 24.0; SPSS Inc., Chicago, IL, USA).

## RESULTS:

84 patients were included in this study. The baseline clinical and biochemical parameters and imaging findings of the patients included in the study are shown in Table below. Fifty patients had comorbidities. The most common presentation was biliary colic (n = 48, 57%). The median duration of complaints was 7 days (range = 1–365). Eleven patients had features of systemic inflammatory response syndrome. Ultrasound, computed tomography and Magnetic resonance cholangiopancreatography were performed in 26, 56 and 22 patients, respectively and the dilated CBD was noted in 88% of patients. CBDSs could be demonstrated on preoperative imaging in 93% patients.

All patients had successful CBD clearance after cannulation. Two patients with impacted CBDS of a size 10 mm required the Dormia basket for retrieval. The rest were managed with balloon trawling. In two patients, biliary cannulation could not be achieved in the first sitting, and the patient underwent precut sphincterotomy. The same patients had successful cannulation, and ESE-LC was performed one week later. Stenting was performed in 10 (12%) patients. 6 patients had biliary pancreatitis, and 2 patients had ascending cholangitis. Two other patients had bilirubin levels of 10 mg/dL; hence, stenting was performed. There was no anaesthesia-related event during shifting of the patient from the endoscopic suite to OR. Intraoperatively, 26 patients had features of acute cholecystitis. 10 patients had impacted stone in the gall bladder neck, causing mucocele and empyema, requiring gall bladder decompression by aspiration before dissection. Calot's triangle was frozen in 22 patients, for whom retroinfundibular technique was performed. The short and wide cystic duct was encountered in 31% patients. Subtotal cholecystectomy was performed in 14% patients.

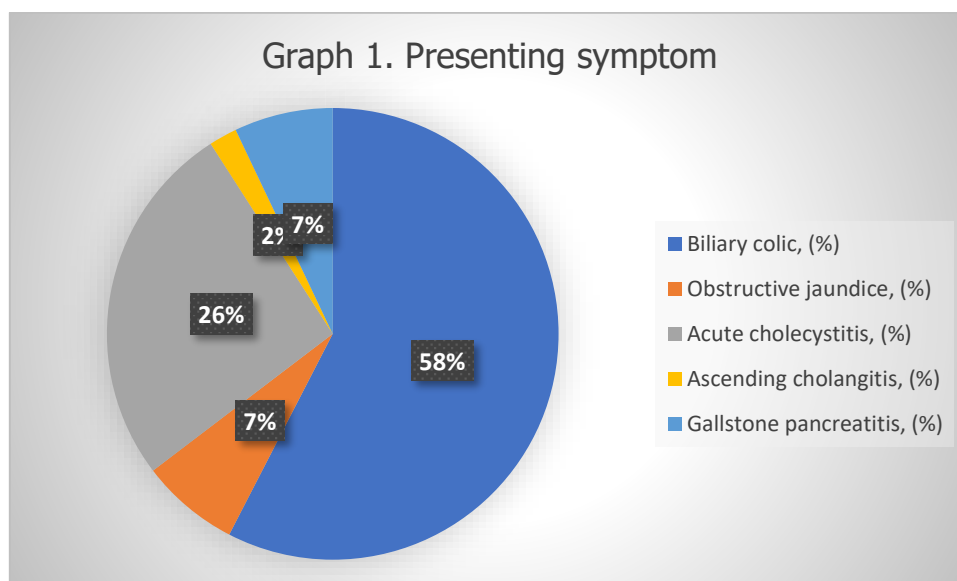
Bile duct clearance was achieved in all patients. The median postprocedural hospital stay was 1 day (0–13), with 6 patients undergoing the procedure on a day-care basis. Two patients developed moderately severe post-ERC pancreatitis (transient acute kidney injury). Imaging showed a gall bladder fossa collection of 20 ml, which was managed by image-guided aspiration (20 ml of pus), and the patient was treated with culture-based antibiotics and was discharged 5 days after readmission. No conversion to open cholecystectomy, bleeding, surgical site infection, bile duct injury or mortality was noted in our patients. After a median follow-up of 18 months (3–28 months), there was no biliary event in the study group.

Table 1

Age, in years (median, range)	52(24-77)
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Gender (Male: female)	34:50
Previous surgeries, n (%)	38(45%)
ASA, (I, II, III)	34/40/10
BMI (median, range)	24(18-36)
Serum Bilirubin, in mg/dL (median, range)	3 (0.7–10)
SGOT, in IU/mL (median, range)	144 (13–528)
SGPT, in IU/mL (median, range)	195 (8–623)
Serum ALP, in IU/mL (median, range)	220 (45–1045)
CBD stone size, in mm (median, range)	4 (3–10)
CBD diameter, in mm (median, range)	8 (5–16)

ASA, American Society of Anesthesiology score; ALP, Alkaline phosphatase; BMI, body mass index; CBD, common bile duct; DM, Diabetes Mellitus; HT, Hypertension; IHD, Ischemic heart disease; SGOT, serum glutamic-oxaloacetic transaminase; SGPT, serum glutamic-pyruvic transaminase.



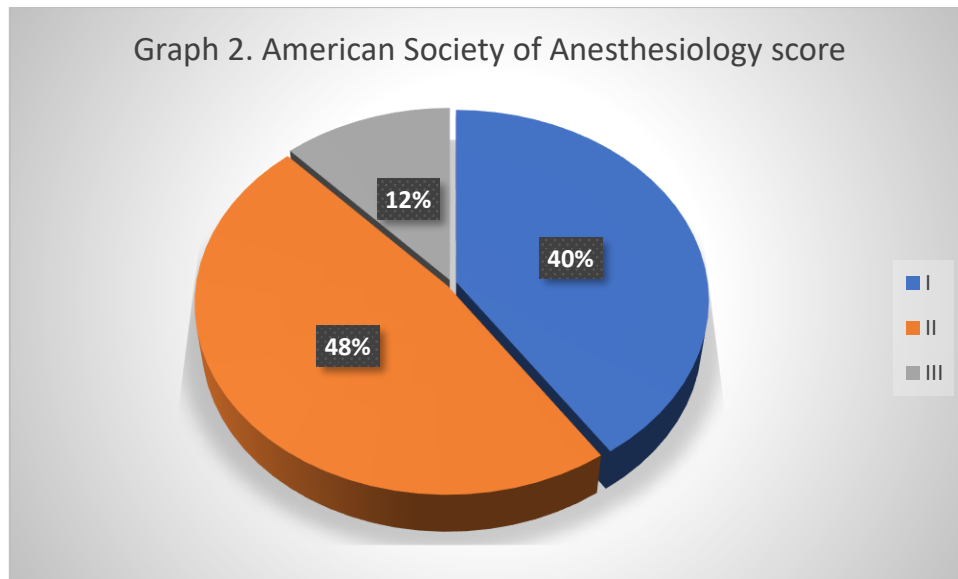
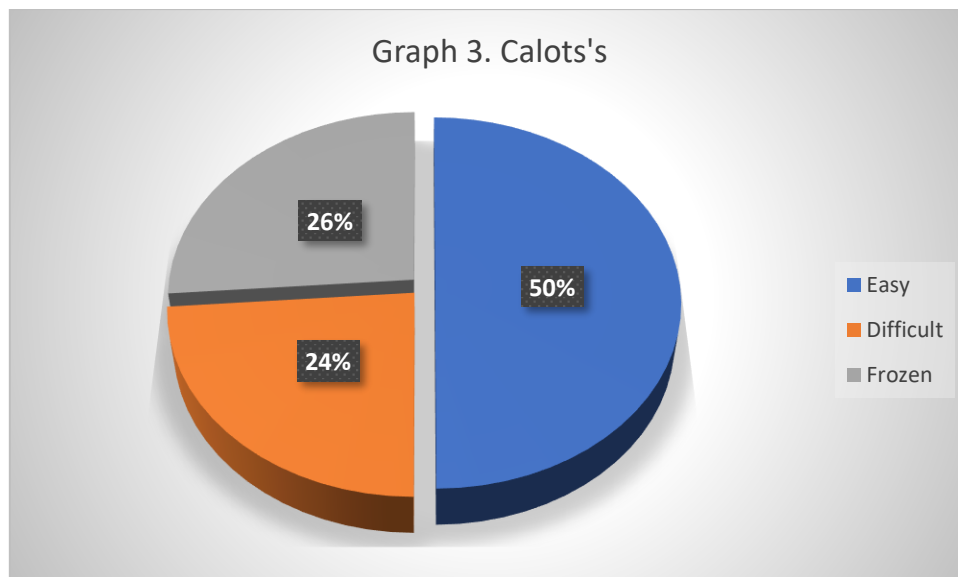


Table 2

ERCp	n(%)
Success, n (%)	84 (100%)
No. of CBD stones (median, range)	1 (1–6)
Stenting, n (%)	10 (12%)





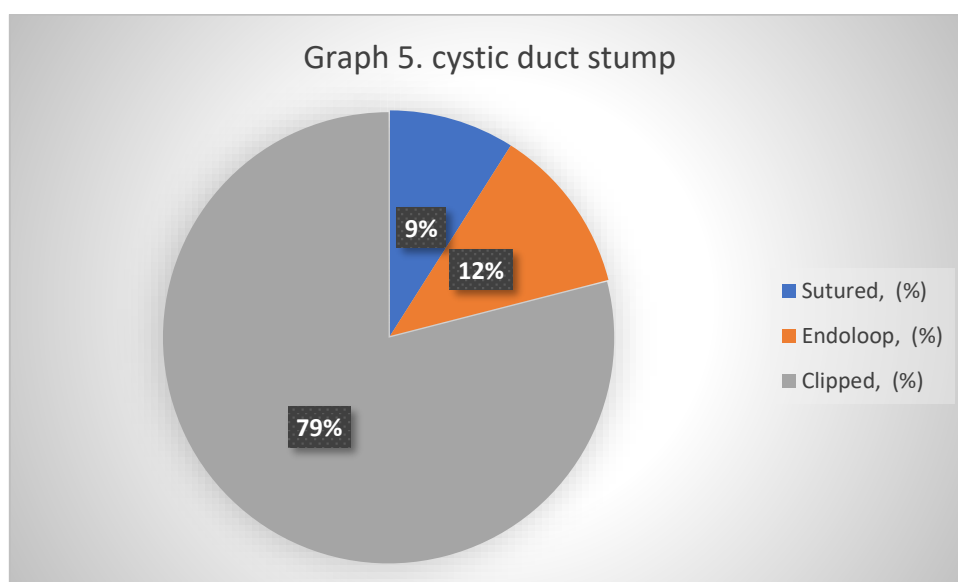
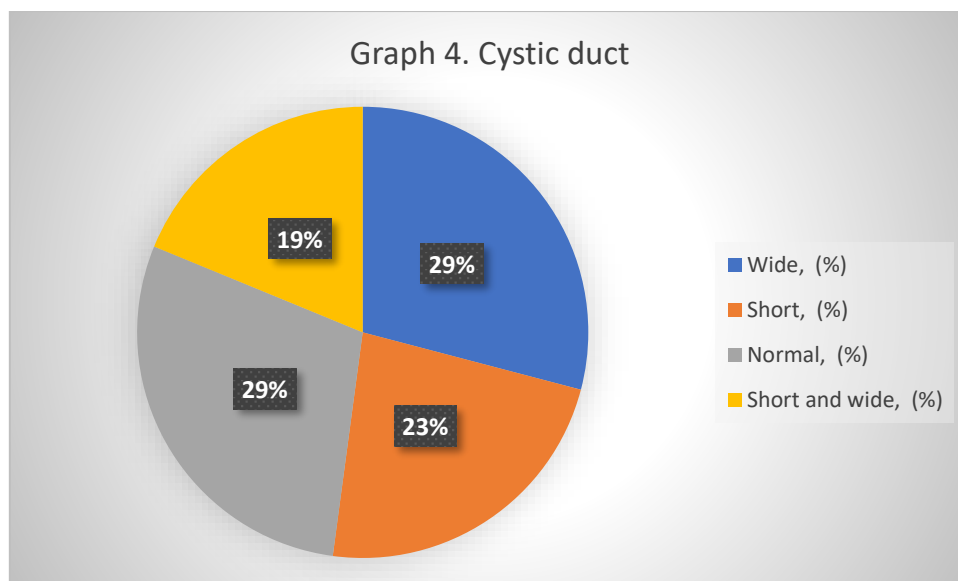


Table 3 Details of Postprocedural Outcomes.

Duration of postprocedural hospital stay, in days (median, range)	1(0-3)
Readmission, n (%)	1 (2%)
Post-ERC pancreatitis	1 (2%)
Retained CBD stones, n (%)	0
Bile leak, n (%)	0
GB fossa collection, n (%)	1 (2%)

## DISCUSSION

The ideal management of CBD stones with gallstones remains a matter of debate. As discussed, treatment options include ERCP to clear the bile duct along with a laparoscopic cholecystectomy (pre-, intra- or postoperative), and laparoscopic bile duct exploration along with LC. ERCP is undoubtedly the treatment of choice in patients with postcholecystectomy CBD stones, acute cholangitis, or acute pancreatitis with persistent biliary obstruction. However, in good-risk patients, the ideal treatment is still unclear. Postoperative ERCP is clearly unsatisfactory as it would entail a second surgery if it fails and also puts the patient at a risk of cystic duct stump blowout and bile leak, apart from being technically difficult. Intraoperative ERCP along with LC is an upcoming modality that is touted to combine the benefits of both single-stage and two-stage procedures. However, the armamentarium is often unavailable, greater technical expertise is required for intraoperative ERCP and it mandates a high degree of cooperation and coordination between the surgeons and endoscopists and is yet to gain popularity. Preoperative ERCP followed by laparoscopic cholecystectomy has been the standard of care for patients with choledocholithiasis and cholelithiasis. However, laparoscopic CBD exploration is fast increasing in popularity as it provides the advantages of a single procedure, preserves the biliary sphincter, avoids complications of two different procedures along with the possible benefit of possible shorter stay and attendant lower costs. Though it has several advantages, it is a technically difficult procedure, with a definite learning curve, needs instruments and paraphernalia and prolongs the operative time when compared to a laparoscopic cholecystectomy. A number of randomized trials have been performed comparing the two. However, most of these are underpowered to answer the question of the better procedure (sample sizes were calculated only in few studies).

Among alternative techniques for treating simultaneous cholelithiasis and choledocholithiasis, single-session LC with intraoperative ERCP has been proven to have the highest success rate.

<sup>2</sup> The major reason of worry in choledocholithiasis management is failed bile duct clearance and residual CBDS. At a median follow-up of 18 months, none of our patients had retained CBDSs or biliary episodes. Bowel distention following endoscopic insufflation is a problem with the rendezvous technique, which is the most popular single-session procedure. <sup>3</sup> Other technical problems documented include Mirizzi syndrome, problematic Calot's in acute cholecystitis, lateral CBD damage, and trouble interpreting an intraoperative cholangiogram. <sup>4,5,8</sup> Fifty percent of our patients had Calot's triangle that was difficult or frozen. During

transcystic intraoperative cholangiography, the short and broad cystic duct poses a considerable risk of lateral CBD damage. This high-risk trait was present in about one-third of our patients, underlining the difficulties of doing intraoperative cholangiography in this scenario. In theory, RV reduces the risk of post-ERC pancreatitis by lowering the risk of oedema and pancreatic duct cannulation.<sup>5</sup> In our study, the rate of post-ERC pancreatitis was 2%, which was equivalent to other recent studies.<sup>4,8</sup> Another method of accomplishing ESE-LC in a single session is to complete LC first, then ESE in the OR. Endoscopists' concerns about increased failure rates in an unfamiliar environment, as well as logistical issues such as performing ERC in the supine position, availability of endoscopic accessories, added cost, and endoscopists' apprehension about increased failure rates in an unfamiliar environment, have all been raised.<sup>4</sup> Our method, tandem ESE-LC, has already been described.<sup>17</sup> The method, however, was included in a single-session ESE and LC, therefore the specifics and results were not documented separately. We chose tandem ESE-LC because it allowed us to shorten the hospital stay without jeopardising patient safety. To solve the limitations of single-session ESE-LC while keeping its benefits, we adjusted our strategy to do ESE in the endoscopic suite followed by LC in the OR. In our institute, LC and ESE are frequently performed in isolation as day-care procedures. In our study, six patients had day-care tandem ESE-LC. The use of carbon dioxide for endoscopic insufflation and TAP block for postoperative analgesia, we feel, helped.<sup>15</sup> There were no noteworthy secondary outcomes, with the exception of 2 patients who had clinical pancreatitis with gall bladder fossa collection. Similar to the rendezvous method, endoscopists and the operating team (surgical teams, anaesthetists, theatre room availability, and paramedical support) must coordinate.<sup>5,9</sup> Following the conclusion of ESE, none of the anaesthetized patients had to wait for an operating room. Because failure cannulation or bile duct clearing might result in LC being postponed, appropriate patient counselling is essential. One patient in the trial experienced unsuccessful cannulation but then had a successful tandem ESE-LC one week later. The following are the study's shortcomings. There is no control group in the study, thus no definite conclusion can be drawn regarding the suggested approach vs the standard procedures used. In all of the cases, standard imaging such as MRCP or EUS was not used to confirm choledocholithiasis. If the endoscopic suite and operating room are in different buildings, the surgery may not be possible. Because of the rising complexity of endoscopic treatments and cooperative operations, ORs and endoscopic suites are likely to be connected.

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