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“COMMON BILE DUCT PATHOLOGY - Scope of Laparoscopy illustrated case series analysis” --Manuscript Draft--

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Corresponding Author:	Eppa Vimalakar Reddy, MBBS, DNB(Gen Surg), DNB (Surg gastro) Sunshine Hospitals HYDERABAD, Telangana INDIA
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	Sunshine Hospitals
Corresponding Author's Secondary Institution:	
First Author:	Eppa Vimalakar Reddy, MBBS, DNB(Gen Surg), DNB (Surg gastro)
First Author Secondary Information:	
Order of Authors:	Eppa Vimalakar Reddy, MBBS, DNB(Gen Surg), DNB (Surg gastro) RAJU MUSHAM, MBBS, DNB (Gen Surg)
Order of Authors Secondary Information:	
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Abstract:	<p>INTRODUCTION</p> <p>In the era of minimally invasive surgery, laparoscopic common bile duct (CBD) exploration is the best choice for addressing different difficult CBD pathologies.</p> <p>METHODS</p> <p>In the current study, we have performed laparoscopy in twelve cases (five men and seven women) with failed Endoscopic retrograde cholangiopancreatography (ERCP) for CBD calculi (n=9), a retained stent (n=1), and CBD injuries (n=2).</p> <p>RESULTS</p> <p>The mean age of patients was 46.3 ± 8.9 yr. Trans cystic or trans ductal approach was used. In seven cases that underwent rendezvous procedure, two cases required Fogarty balloon trawl. Ureteroscopic guided stent removal was effective in one case. In the absence of choledocoscope, ureteroscope with laser lithotripsy was used in two cases of CBD calculi. Laparoscopy CBD exploration with impacted calculi extraction was effective in two cases of CBD calculi. The mean operation time was 100.3 ± 17.4 min. The pain score was 2.4 ± 0.5. The mean hospital stay was 2.7 ± 0.9 days. T-tube was not used in any of our cases. All of our cases CBD rent closed over the stent. Intra or post-operative cholangiogram was not done in any of our cases. Complete CBD clearance was achieved in all of our cases. Length of stay and pain score were minimal with no post-operative complications.</p> <p>CONCLUSION</p> <p>Even in failed ERCP cases, the first laparoscopic approach should be Rendezvous procedure with the help of Balloon trawl and ureteroscope which can avoid t-tube</p>

	insertion and also intraoperative cholangiogram.
Response to Reviewers:	<p>REVIEWER 1:</p> <p>1) Thank you for reviewing our manuscript, with due respect to the reviewer, the entire concept of this series has been misunderstood. In our series we are not reiterating the role of LCBDE in choledocholithiasis, we have clearly mentioned in our (title/series), which states (self explanatory) the spectrum of laparoscopy in CBD pathologies along with the role of rendezvous procedure and different methods of CBD exploration in the absence of a choledochoscope.</p> <p>2) Regarding the T-tube placement, we accept the reviewers comment to some extent, but it is not the case always (based on scientific evidence)</p> <p>3) With regards to the comments on small retrospective series, we would like to mention that the prestigious Cochrane review on laparoscopic CBDE had only 26 small series and still was considered as a standard as evidence, because of the rarity of usage of LCBDE in advanced endoscopic era. We would also like to put forth that in a developing country, where the referral system of cases are being not established when compared to a developed countries, with a fully established system having a case series of 12 in a calendar year is bound to be a good number. (As I am reviewer for many national and international journals, it is an observation that I would like you to think about and also that's why this same series got first prize in international conference).</p> <p>4) In reference to the authors comment "this manuscript does not add anything new to the literature", science is not all about adding new things, it is also about reviewing the past practice, correcting flaws and making science more practical to reach the maximum extent of the society. (because SCIENCE IS EVER CHANGING)</p> <p>5) To sum up my reply to the author we strongly backup our literature which would help and guide the future generation of doctors where to tackle the CBD while using different methods like rendezvous procedure, rigid ureteroscopy and laser lithotripter, feeding tube, balloon tawl at their convenience in this one series alone.</p> <p>Reviewer 2:</p> <p>1) Thank you for reviewing our manuscript, the details of the retained stent and bile duct injury are added under patients and methods and in results and discussion of the updated manuscript.</p> <p>2) Regarding poorly written manuscript, we would like to inform you that we are not from a native English speaking country to be compared with, but anyways we have updated our work and have resubmitted it. Hope it is up to your level of expectancy</p> <p>Chief editor review:</p> <p>1) We are willing to change the title of our series to "COMMON BILE DUCT PATHOLGY – Scope of laparoscopic illustrated case series analysis" as per your guidance as it appears to be a more apt title. Thank you on your insight regarding it.</p> <p>2) We would like to appreciate your beneficence for encouraging naive despite of language constrains. This would boost the morality of young budding surgeons.</p>

Title page

“COMMON BILE DUCT PATHOLOGY- Scope of Laparoscopy illustrated case series analysis”

AUTHORS : 1.Eppa vimalakar reddy, 2.Raju Musham.

AFFILIATIONS: 1.Dr.EPPA VIMALAKAR REDDY, M.B.B.S, D.N.B[Gen Surg], D.N.B[Surg Gastro].
Senior Surgical Gastroenteologist,
Hepato Pancreatico Biliary,Transplant surgeon
Department of Surgical Gastroenterology
2.Dr. RAJU MUSHAM ,M.B.B.S,D.N.B.[Gen Surg].
Registrar,surgical gastroenterology.

ADDRESS OF CORRESPONDENCE:

Dr. Eppa Vimalakar Reddy
Senior Surgical Gastroenteologist
Department of Surgical Gastroenterology
Sunshine Hospitals, Secunderabad
Telangana, Hyderabad-500003
Email: vimalakarreddy@gmail.com
Ph: +91-8220721103.

- **Guarantor of the article:** Dr.Eppa Vimalakar Reddy
- **Specific author contributions:** This study was conceived and planed by Eppa vimalakar Reddy. Eppa vimalakar Reddy, Raju Musham executed the study and drafted the manuscript. Eppa vimalakar Reddy performed critical revision and finalized the manuscript.
- **Financial support:** No specific funding was obtained for this study.

“COMMON BILE DUCT PATHOLOGY-Scope of Laparoscopy illustrated case series analysis”

Word Count: 1896

Study Highlights

WHAT IS KNOWN

- ERCP and LCBDE are two documented surgical procedures for cholecystocholedocholithiasis
- In cases with difficult pathologies and failed ERCP, LCBDE is performed

WHAT IS NEW HERE

- In failed ERCP cases, we have used different laparoscopic CBD Exploration procedures like using Rendezvous procedure in difficult CBD pathologies without T-tube insertion ,using rigid ureteroscope and laser lithotripter for CBD exploration in the absence of choledoscope, , which minimised clinical complications and avoided open surgery.
- We have compared these parameters across different studies with different surgical procedures.

ABSTRACT

INTRODUCTION:

In the era of minimally invasive surgery, laparoscopic common bile duct (CBD) exploration is the best choice for addressing different difficult CBD pathologies.

METHODS:

In the current study, we have performed laparoscopy in twelve cases (five men and seven women) with failed Endoscopic retrograde cholangiopancreatography (ERCP) for CBD calculi (n=9), a retained stent (n=1), and CBD injuries (n=2).

RESULTS:

The mean age of patients was 46.3 ± 8.9 yr. Trans cystic or trans ductal approach was used. In seven cases that underwent rendezvous procedure, two cases required Fogarty balloon trawl. Ureteroscopic guided stent removal was effective in one case. In the absence of choledoscope, ureteroscope with laser lithotripsy was used in two cases of CBD calculi. Laparoscopy CBD exploration with impacted calculi extraction was effective in two cases of CBD calculi. The mean operation time was 100.3 ± 17.4 min. The pain score was 2.4 ± 0.5 . The mean hospital stay was 2.7 ± 0.9 days. T-tube was not used in any of our cases. All of our cases CBD rent closed over the stent. Intra or post-operative cholangiogram was not done in any of our cases. Complete CBD clearance was

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4 achieved in all of our cases. Length of stay and pain score were minimal with no post-
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6 operative complications.
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10 11 12 13 14 **CONCLUSION:**

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17 Even in failed ERCP cases, the first laparoscopic approach should be Rendezvous
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19 procedure with the help of Balloon trawl and ureteroscopy which can avoid t-tube
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21 insertion and also intraoperative cholangiogram.
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28 Keywords

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31 Laparoscopy; Common bile duct exploration; Endoscopic retrograde cholangiopancreatography

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34 Abbreviations: common bile duct (CBD), cholecystocholedocholithiasis (CCL),

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36 Endoscopic retrograde cholangiopancreatography (ERCP), laparoscopic CBD exploration
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38 (LCBDE), laparoscopic cholecystectomy (LC)
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41 **“COMMON BILE DUCT PATHOLOGY - Scope of Laparoscopy illustrated** 42 43 **case series analysis”**

44 45 46 **Introduction**

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49 About 8 – 20% of patients with gallstones are at risk of developing common bile duct
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51 (CBD) stones known as cholecystocholedocholithiasis (CCL). The minimally invasive treatment
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53 options for CCL currently are endoscopic retrograde cholangiopancreatography (ERCP) or
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55 laparoscopic CBD exploration (LCBDE) followed by laparoscopic cholecystectomy (LC)[1]. To
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57 avoid open access morbidity, LCBDE without t-tube insertion can be safely performed in most of
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4 the cases by using intraoperative Rendezvous procedure. In this Rendezvous procedure, for the
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6 extraction of stones/stents ureteroscopy can be used in the absence of choledochoscope with (or)
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8 without laser and also balloon trawl helps in a few cases.
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11 Conventionally, T-tube drainage is used for the closure of CBD after choledochotomy and
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13 removal of CBD stones. LBCDE with primary closure without external drainage is associated with
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15 shorter operation time and post-operative stay, lower hospital expenses, and minimal postoperative
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17 complications and biliary complications compared to T-tube insertion[2].
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21 In the current study, we have explored the utility of the LCBDE procedure in failed ERCP
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23 cases using trans cystic and trans ductal approaches. We have also evaluated the benefits of primary
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25 closure of CBD over T-tube insertion based on existing literature.
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31 **Patients and Methods**

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33 In the current study, we have performed laparoscopy in twelve cases (five men and seven
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35 women) with failed Endoscopic retrograde cholangiopancreatography (ERCP) for CBD calculi
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37 (n=9), **retained stent for more than 6 months with lot of concretions formed around the stent which**
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39 **made ERCP stent removal difficult(n=1), and CBD injuries like cystic duct stump leak and lateral**
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41 **CBD injury where CBD stenting was not possible and laparoscopic drainage of collection and**
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43 **rendezvous procedure was done** (n=2). The mean age of patients was 46.3 ± 8.9 yr. The study
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45 protocol was approved by the Institutional Ethical committee of Sunshine Hospitals,
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47 Secunderabad, India. Informed consent was obtained from all the patients prior to enrollment and
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49 surgery. Study duration was from June 2019 to June 2020.
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56 Trans cystic or Trans ductal approach was used. LCBDE was performed by four-port
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58 technique in leg split, head up and sandbag position (Fig 1). In seven cases that underwent
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4 rendezvous procedure, two cases required Fogarty balloon tawl. Ureteroscopic guided stent
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6 removal was effective in one case (Fig 2). Laser rigid ureteroscopic-guided lithotripsy was
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8 effective in two cases with CBD calculi. Laparoscopy CBD exploration with impacted calculi
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10 extraction was effective in two cases of CBD calculi. (Table 1)
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13 14 **Statistical analysis**

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16 Student t-test was used to compare the distribution of each continuous variable of our study
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18 with other studies. The data was represented in mean \pm standard deviation (SD) format. Fisher
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20 exact test was performed to explore statistical significance of categorical variables. A 'p' value
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22 <0.05 was considered statistically significant. All the statistical analysis was performed using
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24 Graphpad prism.
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27 28 **Results and Discussion**

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30 All cases with CBD calculi presented with obstructive jaundice. The case with a retained
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32 stent in the left hepatic duct presented with recurrent cholangitis. The mean operation time was
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34 100.3 ± 17.4 min. The pain score was 2.4 ± 0.5 . The mean hospital stay was 2.7 ± 0.9 days. T-tube
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36 was not used in any of our cases. All of our cases CBD rent closed over the stent. In two cases
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38 of laparoscopic CBD injury, drainage of the collection and with the help of rendezvous procedure
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40 CBD stenting was done which avoided prolonged period of drain, biliary peritonitis, biliary
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42 stricture in future and patient could be discharged on the earliest post operative day. In case of
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44 retained stent because of lot of concretions LCBDE was done. we had to use choledoscope
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46 definitely, but despite of absence of choledoscope we could retrieve the stent using rigid
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48 ureteroscope and laser lithotripter was used to break the impacted concretions . Intra or post-
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50 operative cholangiogram was not done in any of our cases. Complete CBD clearance was achieved
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52 in all of our cases. Length of stay and pain scores were minimal with no post-operative
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4 complications. Even in failed ERCP cases, the first laparoscopic approach is rendezvous which
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6 can avoid choledochotomy.
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9 As shown in [Table 2](#), we have compared our data with different surgical approaches such
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11 as ERCP+LC, LCBDE + primary closure, LCBDE + T-tube insertion, specifically on critical
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13 clinical outcomes such as operative time, hospital stay, overall complications, retention or
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15 recurrent of bile stones.
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19 Qian et al have demonstrated the effectiveness of Laparoendoscopic rendezvous (LERV)
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21 over ERCP+LC in terms of lesser overall complications and reduced retention or recurrence of
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23 biliary stones[3].
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26 Compared to the data of Gad et al[4], operation time in our study is significantly lesser than
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28 the T-tube insertion group ($t=13.51$, $p<0.0001$) and primary closure group ($t=8.32$, $p<0.0001$).
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30 Hospital stay was shorter in our study compared to the T-tube insertion group ($t=12.37$, $p<0.0001$),
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32 but similar to the primary closure group ($t=0.37$, $p=0.71$)[4].
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36 A meta-analysis of 11 trials comprising of 1513 patients is in agreement with our study in
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38 reporting lower rates of technical failure and shorter hospital stay in LCBDE compared to
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40 ERCP+LC[5]. Our mean operative time corroborated with a large-scale single-center study
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42 (n=355) of LCBDEs with primary closure showing an overall success rate of 91.8% [6]. A study
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44 from Colombia (n=82) also showed a mean operative time of 106 min (100 – 130) with a hospital
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46 stay of 2 – 6 days following LCBDE with primary closure[7].
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49 Similar to our study, laparoscopic bile duct clearance without choledochoscopy was
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51 reported in 203 patients[8]. Fluoroscopically guided LCBDE achieved 92.1% success rate with a
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53 mean operative time of 79 minutes (45 – 180 minutes) and a median hospital stay of 2.4 days (1
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55 – 10 days)[8].
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4 Our mean operative time is lesser than the study of Bansal et al[9] (t=3.38, p=0.001), Di
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6 Mauro et al[10] (t= 4.64, p<0.0001) in failed ERCP cases due to primary closure of CBD rather
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8 than using T-tube insertion. Bansal et al and Di Mauro have used T-tube insertion in 22.9% and
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10 15.2% cases, respectively[9,10].
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13 **Conclusion**

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15 In the current study, we have achieved shorter operation time, lesser hospital stays, reduced
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17 overall complications, and no retention or recurrence of bile stones using LCBDE with primary
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19 closure without T-tube insertion and choledochoscopy. Our clinical outcomes are very promising
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21 in failed ERCP cases compared to other studies. Strategic planning regarding the appropriate
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23 surgical procedure (trans ductal or trans cystic) based on the location and size of calculi, difficult
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25 CBD etiologies can be treated laparoscopically thus paving the way for potentially beneficial
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27 minimally invasive surgeries.
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43 **DISCLOSURE**

- 44 ● The study protocol was approved by the Institutional Ethical committee of Sunshine Hospitals,
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46 Secunderabad, India.
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- 48 ● Informed consent was obtained from all the patients prior to enrollment and surgery.
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- 50 ● Registry and registration no.-N/A.
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- 52 ● Animal studies-N/A
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- 54 ● **Potential competing interests:** All the authors hereby declare no conflicts of interest.
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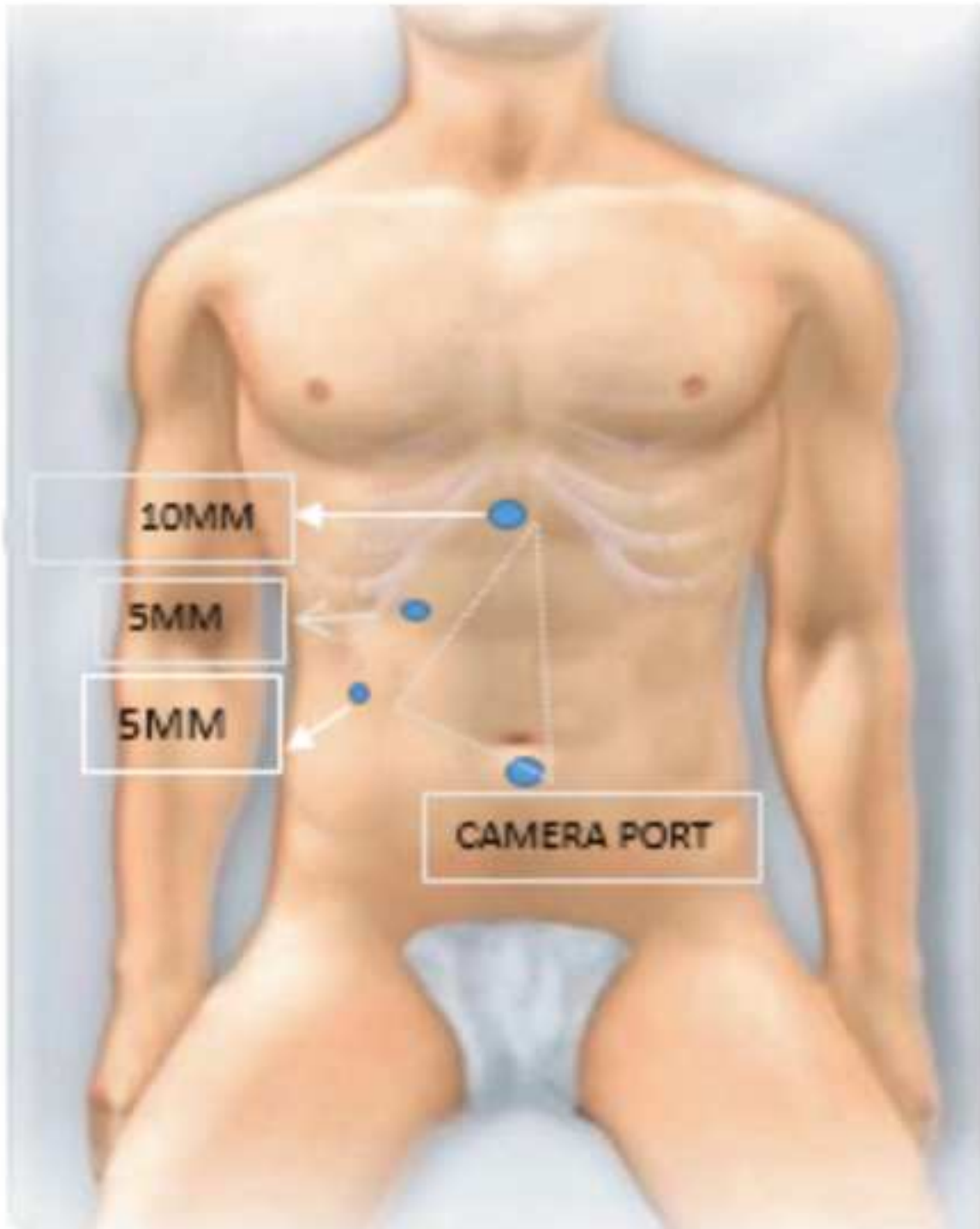
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4 Laparoscopic Common Bile Duct (CBD) Exploration: Experience of 355 Cases at a
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50 **Figure Legends**

51 Fig 1. Four-port technique for LCBDE procedure

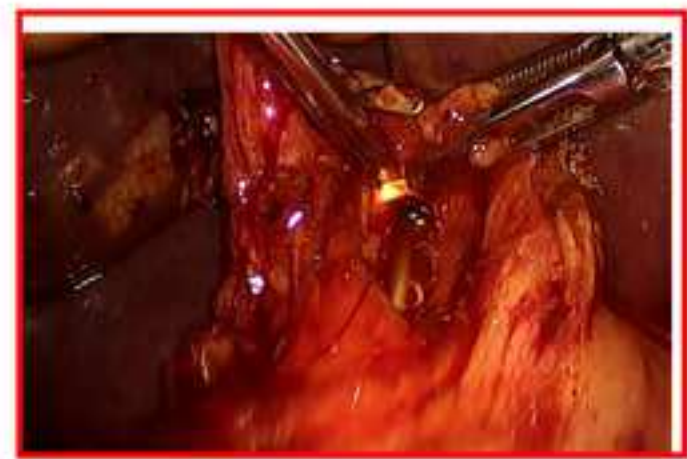
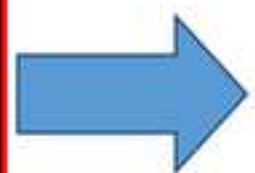
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55 Fig 2. Ureteroscope-guided stent removal
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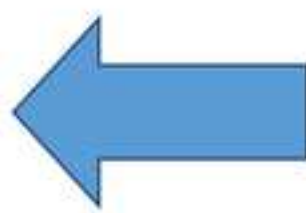
Fluoroscopic image showing fresh stent in CBD and RHD. Retained stent bit in LHD.



Passing rigid ureterscope into proximal CBD



Retained stent in LHD



Stent extracted using triprong grasper

Table 1. Demographic, clinical and operative variables in LCBDE cases

Age	Gender	CBD Pathology	Method of Removal	OT Time(min)	CBD Stent	Drain	Pain Score	Total Hospital Stay (days)	Bile Leak	Wound infection
65	M	Impacted distal CBD calculi	Laser rigid ureteroscopic guided lithotripsy	90	+	+	3	2	-	-
45	M	Retained stent	Ureteroscopic guided removal stent	100	+	+	3	3	-	-
55	F	CBD Calculi	Fogarty	120	+	+	2	2	-	-
45	M	CBD Calculi	Impacted calculi extraction	90	+	+	2	4	-	-
35	F	CBD Calculi	Rendezvous procedure, balloon sphincteroplasty).	120	+	+	3	2	-	-
39	F	IMPACTED DISTAL CBD CALCULI	Laser rigid ureteroscopic guided lithotripsy	80	+	+	2	2	-	-
45	M	CBD Injury	Rendezvous	90	+	+	3	3	-	-
32	F	CBD Calculi	Impacted calculi extraction	125	+	+	3	2	-	-
47	F	CBD Calculi	Fogarty	80	+	+	2	4	-	-
49	F	CBD Calculi	Rendezvous	110	+	+	2	2	-	-
53	M	CBD Injury	Rendezvous	90	+	+	2	4	-	-
45	F	CBD Calculi	Rendezvous	100	+	+	2	2	-	-

Table 2. Comparative analysis with existing studies

Parameter	Current study LCBDE in failed ERCP	Qian et al LERV	Qian et al ERCP+LC	Gad et al LCBDE with T-tube insertion	Gad et al LCBDE with Primary closure	Asuri et al LCBDE with Primary closure	Bansal et al LCBDE in failed ERCP	Di Mauro et al LCBDE in failed ERCP
Age (yr)	46.3 ± 8.9	56.3±15.5	58.2±16.0				47.8 – 15.2	61.73 – 18.9
Male:Female	5:7	68:55	64:73				24:59	9:24
Operation time (min)	100.3 ± 17.4	139.8±46.8*	107.7±40.6	263.6 ± 37.8*	191.1 ± 32.2*	98±26.8	144.3 – 44.4*	178.73 – 57.22*
Hospital stay (days)	2.7±0.9	12 (3 – 20)*	18 (5 -31)	7.6 ± 1*	3 ± 2.6		5 (3 – 21)	5 – 5.77
Pain Score	2.4±0.5							
Drain placed yes								
Retained or recurrent stones	0%	3.25%	16.79%*	0%	0%	0%	0%	9.09%
T-tube insertion	0%			100%	0%	0%	22.9%	15.2%
Overall complications	0%	3.25%	10.22%*	18.2%*	11.1%*	1.1%	4.82%	15.2%*

*:p value statistically significant