



## COMPARISON OF CLINICAL EFFICACY AND SAFETY OF LCBDE VERSUS ERCP IN THE TREATMENT OF BILE DUCT STONES AND ANALYSIS OF RELATED FACTORS INFLUENCING POST-OPERATIVE ACUTE PANCREATITIS

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### Abstract

**Background:** Bile duct stones present a clinical challenge, and LCBDE (Endoscopic Retrograde Cholangiopancreatography) and ERCP (Laparoscopic Common Bile Duct Exploration) are two of the most prominent interventions.

**Objectives:** To compare the clinical efficacy and safety of these procedures, as well as to identify factors that influence post-operative acute pancreatitis.

**Methods:** This cross-sectional analysis was conducted at a tertiary care hospital in Lahore Pakistan between March 2022 and June 2023, enrolling 44 patients undergoing LCBDE and 92 patients undergoing ERCP. Inclusion criteria comprised patients aged 18-70 years with ultrasonographic evidence of cholecystolithiasis, among other parameters. A structured questionnaire was used to collect information extending from demographics to post-operative outcomes.

**Results:** The demographic characteristics of the two groups, including age, gender, and BMI, did not differ significantly. 70.45% of LCBDE patients had gallstones concurrently, compared to 53.26% of ERCP patients ( $p>0.05$ ). The number and magnitude of bile duct stones, as well as the duration of procedures, were comparable between groups. There were intraoperative complications in 13.6% of LCBDE patients and 19.0% of ERCP patients. Postoperatively, 11.4% of LCBDE patients and 14.4% of ERCP patients developed acute pancreatitis ( $p>0.05$ ). Other complications and the need for secondary interventions were statistically comparable ( $p>0.05$ ).

**Conclusion:** Both LCBDE and ERCP are efficacious and safe treatments for bile duct stones in a tertiary care setting. The outcomes of both procedures were comparable in terms of complications and clinical efficacy. Additional large-scale, randomized studies could support these findings.

**Keywords:-** Acute pancreatitis; Bile duct stones; Cholangiopancreatography; Common Bile Duct; Intraoperative Complications; Tertiary Care; Treatment Comparison.

### INTRODUCTION

Cholelithiasis, the clinical term for bile duct stones, is an urgent gastrointestinal concern that can manifest severe complications, including cholangitis and pancreatitis. In addition to obstructing

the normal flow and function of bile, a vital digestive fluid produced by the liver, these crystalline concretions in the bile ducts can cause infections, hepatitis and in severe cases, sepsis<sup>1-2</sup>. The medical community has developed numerous therapeutic modalities to treat this condition over the years, pursuing both efficacy and safety<sup>3</sup>.

Laparoscopic Common Bile Duct Exploration (LCBDE) and Endoscopic Retrograde Cholangiopancreatography (ERCP) are among the primary treatments. LCBDE, a minimally invasive surgical technique, provides direct access for the excision of bile duct stones, frequently utilizing either transcystic or choledochotomy technique<sup>4</sup>. This technique becomes especially advantageous when gallbladder stones are also present. In contrast, endoscopic ERCP uses a specialized duodenoscope to visualize and access the bile and pancreatic ducts. Its adaptability enables stone removal via balloons, baskets, or sphincterotomy, as well as other diagnostic and therapeutic procedures such as stenting and biopsies<sup>5</sup>.

Both LCBDE and ERCP have demonstrated commendable rates of efficacy in the treatment of bile duct stones. While ERCP is lauded for its minimally invasive nature and rapid recuperation times, it occasionally faces obstacles such as large or multiple stones or anatomical variations. Although more invasive by nature, LCBDE excels in situations with greater stone burdens or after abortive ERCP procedures<sup>6-8</sup>.

Neither procedure, however, is devoid of complications. Following biliary duct stone interventions, acute post-operative pancreatitis emerges as a major concern<sup>9</sup>. This complication not only introduces additional morbidity, but also prolongs hospitalization, increases healthcare costs, and has a significant impact on the patient's life. Diverse factors, including both patient-specific and procedural elements, contribute to this<sup>10</sup>.

Given the foregoing, the purpose of this study is to compare the clinical efficacy and safety of LCBDE and ERCP in the management of bile duct stones. Simultaneously, the purpose of this study is to identify and evaluate the numerous factors that influence the incidence of post-operative acute pancreatitis. As the medical landscape evolves, these insights become crucial for refining therapeutic protocols, optimizing clinical decisions, and ultimately improving patient outcomes.

## **MATERIAL AND METHODS**

### **Study Design and Setting**

It was a cross-sectional investigation conducted in a hospital of tertiary care in Lahore Pakistan.

### **Study Period**

The duration of the investigation was from March 2022 until June 2023.

### **Sample Size**

In this study, we included 44 patients who underwent LCBDE and 92 patients who were treated by ERCP.

### **Inclusion Criteria**

- During the study period, patients with bile duct stones who underwent either LCBDE or ERCP.
- Age ranging from 18 to 70 years.
- Both male and female patients were included.
- Patients who provided informed consent in writing.
- Classic biliary-type pain experienced at least once within the past 6 months.
- Ultrasonographic evidence of cholecystolithiasis.
- Platelet count  $\geq 100,000 \times 10^3/\mu\text{L}$  and prothrombin time  $\leq 3\text{s}$  of control.

- American Society of Anesthesiologists risk grade 1 or 2.

### **Exclusion Standards**

- Patients who had previously undergone bile duct surgery.
- Patients who cannot receive either LCBDE or ERCP.
- Patients who refused to participate in the study.
- History of bleeding disorders.
- Uremia.
- Insulin-Dependent Diabetes Mellitus

### **LCBDE (Laparoscopic Common Bile Duct Exploration)**

LCBDE is a minimally invasive surgical procedure specifically tailored to identify and extract stones from the common bile duct (CBD). Typically used for patients diagnosed with gallstones present in both the gallbladder and the CBD, the process begun by administering anesthesia. Subsequently, several diminutive incisions were made in the abdomen. Through one of these incisions, a laparoscope—a thin tube equipped with a camera—was introduced. This instrument offered a visual guide inside the abdomen, enabling to precisely identify and isolate the common bile duct<sup>11-12</sup>.

### **ERCP (Endoscopic Retrograde Cholangiopancreatography)**

ERCP is an advanced endoscopic technique aimed at diagnosing and treating certain conditions of the biliary and pancreatic ductal systems. The procedure commenced with the patient under sedation. An endoscope was passed down the patient's throat, through the stomach, and into the beginning of the small intestine. At this point, a contrast dye was introduced into the biliary or pancreatic ducts using a fine catheter passed through the endoscope. This allowed the internal structures to be visible on X-ray images. Gallstones or blockages that were identified in the ducts were removed. This is often achieved through a small incision (sphincterotomy) at the opening of the duct, facilitating the extraction of stones or placement of stents to keep the duct open<sup>13</sup>.

### **Data Collection**

A structured questionnaire was created to collect participant information. Three sections were included in the questionnaire:

1. Demographic information: Age, gender, occupation, marital status, etc.
2. Clinical Information: Procedure type (LCBDE or ERCP), coexisting gallbladder stones, number and size of bile duct stones, procedure duration, and intraoperative complications.
3. Post-Operative Data: Incidence of acute pancreatitis, length of hospital stay following the procedure, occurrence of any other post-operative complications, and need for secondary interventions.

During the trial period, all patients who underwent LCBDE or ERCP were identified. Those who met the inclusion criteria were approached and apprised of the purpose of the study. After obtaining written consent from participants, they were enlisted in the study. A trained member of the research team completed the structured questionnaire either through direct interviews or by examining medical records.

### **Statistical Analysis**

The data were analyzed statistically using SPSS 24.0. For quantitative and categorical variables, mean, standard deviation, frequency, and percentage were calculated, respectively. For categorical variables, the chi-square test was used to determine the relationship between the type of procedure (LCBDE vs. ERCP) and the incidence of post-operative acute pancreatitis. A p-value of less than 0.05 was regarded as statistically significant.

## Ethical Considerations

The Ethical Review Board of the tertiary hospital authorized the study. The purpose and procedures of the study were explained to all participants, and written informed consent was obtained. Throughout the research, the confidentiality of the participants' data was maintained.

## RESULTS

The demographic information of the study groups revealed that LCBDE group had mean age of  $48.12 \pm 8.73$  years, while ERCP group had mean age of  $45.40 \pm 7.10$  years. The age gap was not statistically significant ( $p > 0.05$ ). In terms of gender distribution, males comprised 29.5 and 27.2% of LCBDE and ERCP categories, respectively, while females comprised 70.5 and 72.8%. The gender disparity was also not statistically significant ( $p > 0.05$ ). The ratio of employed to unemployed was 25 to 75% in LCBDE group and 35.8 to 64.2% in ERCP group ( $p > 0.05$ ). The mean BMI for LCBDE was  $31.20 \pm 2.67$  and for ERCP it was  $30.09 \pm 2.59$ . This difference was not statistically significant ( $p > 0.05$ ). In terms of marital status, 93.2% of LCBDE group and 94.6% of ERCP group were married, respectively. The percentage of unmarried individuals was 6.8% for LCBDE and 5.5% for ERCP; there was no significant difference between the two distributions ( $p > 0.05$ ) (Table 1).

70.45% of LCBDE patients had coexisting gallbladder stones, compared to 53.26% of ERCP patients. Statistically, this difference was significant ( $p < 0.05$ ). In LCBDE group, average number of bile duct stones was  $2.65 \pm 1.13$ , while in ERCP group it was  $2.71 \pm 0.17$  ( $p > 0.05$ ). In terms of the average size of the bile duct stones, LCBDE group had an average size of  $5.43 \pm 2.54$  mm, while ERCP had  $5.28 \pm 2.10$  mm ( $p > 0.05$ ). LCBDE procedure lasted  $48.19 \pm 12.12$  minutes on average, which was longer than ERCP procedure ( $43.02 \pm 10.2$  minutes) ( $p > 0.05$ ). 13.6% of patients in LCBDE group and 19.0% of patients in ERCP group experienced intraoperative complications ( $p > 0.05$ ) (Table 2). In LCBDE group, 11.4% of patients were diagnosed with acute pancreatitis, compared to 14.4% in ERCP group ( $p > 0.05$ ). The average extent of post-procedure hospitalization for LCBDE group was  $4.2 \pm 1.5$  days compared to ERCP cohort ( $3.9 \pm 1.2$  days). However, this difference in duration was also not found significant ( $p > 0.05$ ). Regarding other post-operative complications, 18.2% of LCBDE patients and 21.7% of ERCP patients experienced them, respectively ( $p > 0.05$ ). Secondary interventions were required for 9.1% of patients in LCBDE and 9.8% of patients in ERCP group ( $p > 0.05$ ) (Table 3).

As per American Society of Anesthesiologists, compared to ERCP group, 59.1% of patients in LCBDE group fell into the Grade 1 risk category. Minor difference between the two procedures in the distribution of patients in Grade 1 risk category was not statistically significant ( $p > 0.05$ ). 40.9% of patients in the LCBDE group were classified as having a Grade 2 risk, while 45.7% of patients in the ERCP group fell into this category ( $p > 0.05$ ) (Figure 1). The LCBDE group averaged  $212 \pm 39$  and ERCP group averaged  $207 \pm 37 \times 10^3/\mu\text{L}$  platelets ( $p > 0.05$ ). LCBDE group had mean prothrombin time difference value of 1.23 seconds in contrast to ERCP group having 1.10 seconds. With a p-value of 0.224, this difference in the average prothrombin time difference was also not statistically significant (Figure 2). 36.4% of patients in LCBDE group experienced a single pain episode, compared to 37.0% of patients in ERCP group. The distribution between the two categories is extremely similar. For patients who reported 2 to 4 pain episodes, 45.5% were assigned to LCBDE group, while 41.3% were assigned to ERCP group. In the category of patients who experienced five or more pain episodes, 18.1% belonged to LCBDE group while 21.7% belonged to ERCP group (Figure 3).

Nine percent of LCBDE cohort and 9.8% of ERCP cohort experienced bleeding ( $p > 0.05$ ). Infection rates followed a similar pattern; 9.1% of LCBDE patients developed an infection, compared to 12.0% in the ERCP group, with no statistically significant variations. Bile leakage was observed in 6.8% of LCBDE-treated patients and in 9.0% of ERCP-treated patients. Cholangitis appeared in 4.5% of LCBDE patients and 4.3% of ERCP patients, with an identical ( $p > 0.05$ ). Regarding the

complications evaluated, there were no statistically significant differences in the incidence of complications between the two treatment groups (Table 4).

**Table 1: Demographic Information of Participants**

Parameters	LCBDE (n = 44)	ERCP (n = 92)	$\chi^2$	p-value
Age (Mean $\pm$ SD)	48.12 $\pm$ 8.73	45.40 $\pm$ 7.10	2.57	0.112
Gender n(%)				
Male	13 (29.5)	25 (27.2)	1.63	0.297
Female	31 (70.5)	67 (72.8)		
Occupation				
Employed	11 (25.0)	33 (35.8)	0.87	0.354
Unemployed	33 (75.0)	59 (64.2)		
BMI (Mean $\pm$ SD)	31.20 $\pm$ 2.67	30.09 $\pm$ 2.56	1.89	0.176
Marital Status n(%)				
Married	41 (93.2)	87 (94.6)	0.47	0.512
Unmarried	03 (6.8)	05 (5.4)		

**Table 2: Clinical Information and Intraoperative Data**

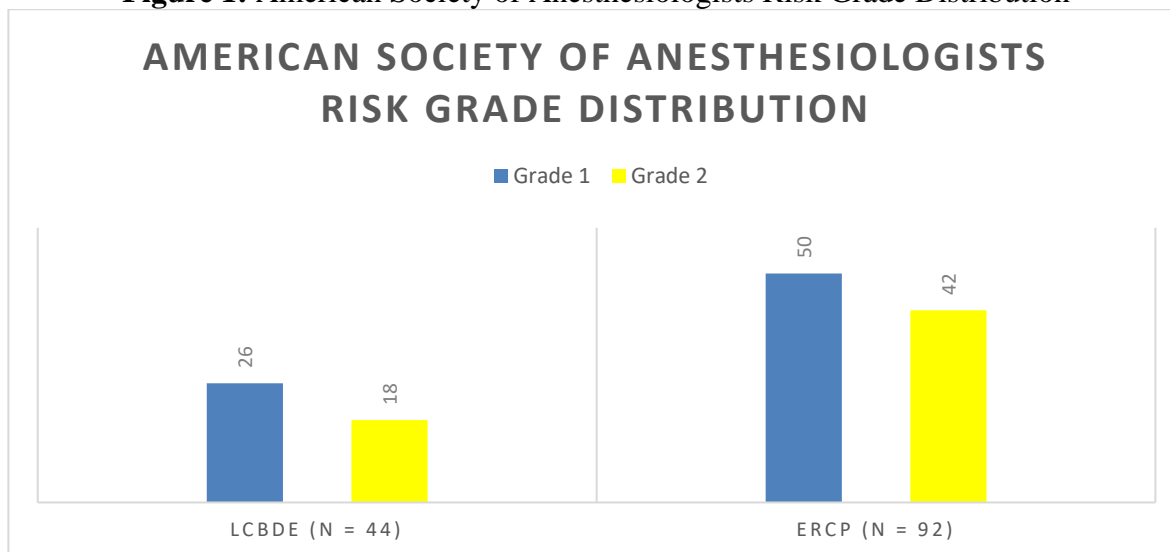
Parameters	LCBDE (n = 44)	ERCP (n = 92)	$\chi^2$	p-value
Coexisting gallbladder stones n(%)	31 (70.45)	49 (53.26)	3.72	0.049*
Number of bile duct stones (Mean $\pm$ SD)	2.65 $\pm$ 1.13	2.71 $\pm$ 1.17	0.34	0.567
Size of bile duct stones (Mean $\pm$ SD) mm	5.43 $\pm$ 2.54	5.28 $\pm$ 2.10	0.47	0.521
Procedure duration (Mean $\pm$ SD) mins	48.19 $\pm$ 12.12	43.02 $\pm$ 10.83	2.48	0.117
Intraoperative complications n(%)	6 (13.6)	18 (19.6)	1.23	0.243

\*indicated the significant values

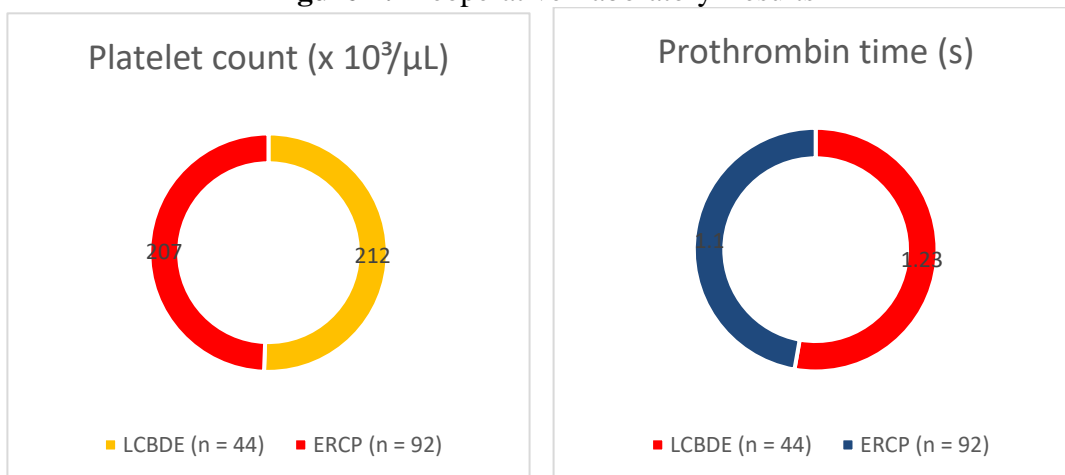
**Table 3: Post-Operative Data**

Parameters	LCBDE (n = 44)	ERCP (n = 92)	$\chi^2$	p-value
Incidence of acute pancreatitis n(%)	5 (11.4%)	13 (14.1%)	0.01	0.902
Length of hospital stay (Mean $\pm$ SD) days	4.2 $\pm$ 1.5	3.9 $\pm$ 1.2	1.48	0.22
Other post-operative complications n(%)	8 (18.2%)	20 (21.7%)	0.02	0.866
Need for secondary interventions n(%)	4 (9.1%)	9 (9.8%)	0.03	0.86

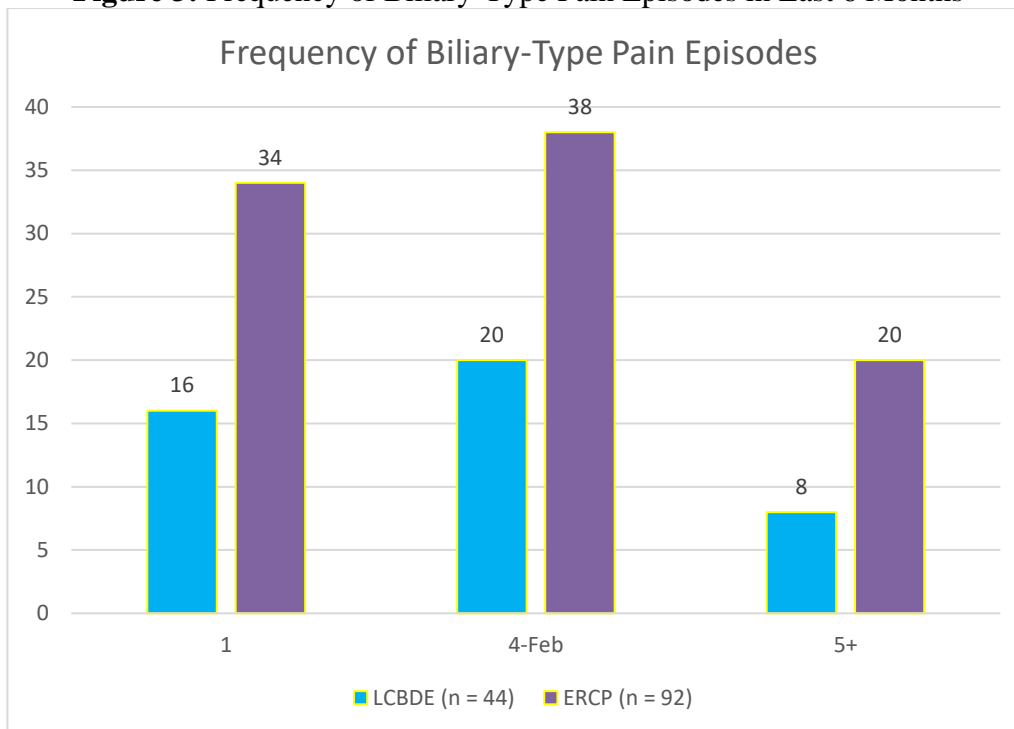
**Figure 1: American Society of Anesthesiologists Risk Grade Distribution**



**Figure 2: Preoperative Laboratory Results**



**Figure 3: Frequency of Biliary-Type Pain Episodes in Last 6 Months**



**Table 4: Incidence of Specific Post-Operative Complications**

Complications	LCBDE (n = 44)	ERCP (n = 92)	$\chi^2$	p-value
Bleeding n(%)	4 (9.1)	9 (9.8)	0.03	0.864
Infection n(%)	4 (9.1)	11 (12.0)	0.02	0.875
Bile leak n(%)	3 (6.8)	9 (9.8)	0.04	0.840
Cholangitis n(%)	2 (4.5)	4 (4.3)	0.15	0.692

## DISCUSSION

The search for effective and safe treatments for bile duct stones remains at the vanguard of gastroenterology <sup>14</sup>. In the present investigation, we conducted a comparative analysis of two prevalent bile duct stone removal techniques, LCBDE and ERCP. In addition, we sought to identify the factors influencing the incidence of post-operative acute pancreatitis, a serious complication requiring vigilant clinical care.

In terms of age, gender, employment status, BMI, and marital status, the demographics of the LCBDE and ERCP groups were similar. This similarity demonstrates that any observed differences

in outcomes are attributable to the procedures themselves and not to patient characteristics<sup>8, 15</sup>. Compared to the ERCP group, a markedly greater proportion of patients in the LCBDE group had concurrent gallstones. This may indicate a preference for LCBDE in patients with both gallbladder and CBD stones, possibly due to the comprehensive character of the procedure, which permits simultaneous management of both conditions<sup>16</sup>.

LCBDE took marginally longer to perform than ERCP, but the difference was not statistically significant. This suggested that, despite the fact that LCBDE is a surgical procedure and ERCP is endoscopic, the time required for both procedures is comparable. In addition, intraoperative complications were comparable between the two groups, supporting the notion that both procedures bear comparable operative risks<sup>8, 17</sup>. In the aftermath of both procedures, the incidence of post-operative acute pancreatitis was virtually identical. The lack of a statistically significant difference in this severe complication highlighted the significance of patient selection and the skill of the surgical team in mitigating its risk.

Hospitalization duration did not differ substantially between the two surgical procedures. This demonstrated that, despite the differing natures of the two procedures (one being surgical and the other endoscopic), recovery times were comparable. It is intriguing that there was no statistically significant difference between LCBDE and ERCP in terms of other post-operative complications or the need for secondary interventions. The similarity in outcomes may be indicative of the development of both techniques in contemporary medicine, reflecting the expertise and proficiency with which they are performed in tertiary care settings<sup>18</sup>.

In terms of anesthesia, the distribution of patients according to the American Society of Anesthesiologists risk grade was comparable between groups<sup>19</sup>. Similarly, laboratory parameters such as platelet counts and prothrombin time difference exhibited uniformity, highlighting the reliability of our patient selection criteria. Notably, there was no significant difference in the incidence of pain episodes prior to the procedure between the two groups. This demonstrated that the severity of preoperative symptoms is not inherently a determining factor when selecting between LCBDE and ERCP<sup>20</sup>. The incidence of complications, such as hemorrhage, infection, bile leakage, and cholangitis, was comparable between groups. These results were reassuring and suggest that both LCBDE and ERCP are relatively safe and effective in the management of bile duct stones when performed by trained professionals<sup>21</sup>.

## CONCLUSION

In this comparison of LCBDE and ERCP for the treatment of bile duct stones, both techniques demonstrated comparable efficacy and safety. The intraoperative and post-operative complications, including the incidence of acute pancreatitis, were statistically similar between the two modalities. In addition, the duration of the procedure, the length of hospitalization, and the postoperative outcomes, including the need for secondary interventions, were comparable for both techniques. Platelet counts, prothrombin time differences, and the distribution based on the American Society of Anesthesiologists risk grade were comparable between the two groups. However, the LCBDE cohort had a higher incidence of concurrent gallbladder stones. Rates of complications such as hemorrhage, infection, bile leakage, and cholangitis were comparable for both procedures. Collectively, these findings demonstrate that LCBDE and ERCP offer comparable technical outcomes in the management of bile duct stones when performed in tertiary care settings with competent expertise.

## CONFLICT OF INTEREST

None.

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