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ORIGINAL ARTICLE

Retrospective Study

Laparoscopic cholecystectomy plus common bile duct exploration for extrahepatic bile duct stones and postoperative recurrence-associated risk factors

Jia-Hua Liao, Ju-Shi Li, Tie-Long Wang, Wen-Shen Liu

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Jia-Hua Liao, Ju-Shi Li, Wen-Shen Liu, Department of Hepatobiliary Surgery, Shaoyang Central Hospital, Shaoyang 422000, Hunan Province, China

Tie-Long Wang, Department of Organ Transplantation, The First Affiliated Hospital of Sun Yat-sen University, Guangzhou 510080, Guangdong Province, China

Corresponding author: Jia-Hua Liao, MMed, Attending Doctor, Department of Hepatobiliary Surgery, Shaoyang Central Hospital, No. 36 Qianyuan Lane, Hongqi Road, Shaoyang 422000, Hunan Province, China. 15773969392@163.com

Abstract

BACKGROUND

There remain controversies regarding the surgical treatment of extrahepatic bile duct stones (EHBDSs) in clinical practice.

AIM

To explore the curative effect of laparoscopic cholecystectomy (LC) plus common bile duct exploration (CBDE) for the surgical treatment of EHBDSs and to analyze the risk factors that affect postoperative stone recurrence.

METHODS

Eighty-two patients with EHBDSs admitted between March 2017 and March 2023 were selected. Among them, patients treated with open choledocholithotomy plus LC or open cholecystectomy (OC) were set as the control group (n = 40), and those treated with LC plus CBDE served as the observation group (n = 42). The surgical outcomes of the two groups were compared, the surgical complications and Gastrointestinal Quality of Life Index (GIQLI) scores were counted, and the one-year prognostic recurrence was recorded. Independent factors for postoperative recurrence were determined using univariate and multivariate analyses.

RESULTS

The two groups were comparable in the stone residual rate (P > 0.05). The operation time (P < 0.05), intraoperative bleeding (P < 0.05), and total complication rate (P = 0.005) were lower in the observation group than in the control group. The observation group exhibited a marked increase in the GIQLI score, which was higher than the control group (P < 0.05). A lower one-year recurrence rate was

determined in the observation group *vs* the control group (P = 0.027). Sphincter of Oddi dysfunction [odds ratio (OR) = 5.712, P = 0.007] and the treatment scheme of open choledocholithotomy plus LC or OC (OR = 6.771, P = 0.008) were the independent risk factors for one-year recurrence in patients after surgery.

CONCLUSION
LC plus CBDE for patients with EHBDSs can reduce stone residuals, intraoperative bleeding, complications, and postoperative recurrence.

Key Words: Laparoscopic cholecystectomy; Common bile duct exploration; Extrahepatic bile duct stones; Stone recurrence

Core Tip: This research project included 82 patients with extrahepatic bile duct stones (EHBDSs) for a comparative analysis of the clinical advantages of laparoscopic cholecystectomy (LC) plus common bile duct exploration (CBDE) *vs* open choledocholithotomy plus LC or open cholecystectomy for EHBDSs and an exploration of the risk factors for postoperative stone recurrence. It was found that for patients with EHBDSs, treatment with LC plus CBDE can reduce stone residue and intraoperative bleeding, as well as lower complication and postoperative recurrence rates. Our findings can shed new light on the optimization of treatment for patients with EHBDSs.

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INTRODUCTION

Cholelithiasis, including gallstones and bile duct stones (BDSs), is a commonly occurring disease that frequently requires hepatobiliary surgery[1] and affects approximately 10%-15% of the adult population[2]. With the improved living standards of Chinese residents, the incidence of BDSs has exhibited an upward trend in recent years, particularly among the middle-aged and elderly population[3]. This could be associated with factors such as the enhancement of living standards, aging, and alterations in dietary habits, which result in the gradual deterioration of organ functions in middle-aged and elderly patients, weakening of the digestive system function, and decline of gallbladder function. This causes bile stasis and induces the development of cholecystitis and gallstones[4,5]. BDSs, as a common complication of gallbladder stones, are often accompanied by chronic cholecystitis and cholangitis, thus considerably impacting patients' health[6].

BDSs can be classified into primary and secondary types. The former is directly formed within the extrahepatic bile duct, which may be related to bacterial infections or abnormal bilirubin metabolism[7], while the latter is mostly caused by the displacement of gallbladder stones or intrahepatic BDSs to the extrahepatic bile duct[8]. Although the mortality rate of BDSs is not high, its incidence cannot be overlooked[9]. A previous study collected statistics on 262 patients with BDSs and found that the postoperative recurrence rate was 19.48%[10].

Conventional treatment approaches, such as open cholecystectomy (OC) plus common bile duct exploration (CBDE), have definite therapeutic efficacy; however, they present with various issues such, as numerous T-tube-related complications and impacts on patients' daily lives[11]. With the advancement of minimally invasive surgical techniques, endoscopic technology has been widely used for the treatment of biliary system diseases[12]. Nevertheless, because of the complex anatomical structure of the biliary tract, there is a need for a unified standard for the selection of endoscopic surgical modalities. In recent years, the combination of laparoscopic technology and the emphasis on the protection of sphincter function has enabled laparoscopic cholecystectomy (LC) plus CBDE to demonstrate its advantages in the treatment of BDSs[13]. This technology can be used to treat BDSs, reduce the risk of complications, and enhance patient satisfaction.

There is some controversy about using this technology for the treatment of extrahepatic BDSs (EHBDSs)[14,15]. This study aims to explore the clinical effect of LC plus CBDE in treating EHBDSs.

MATERIALS AND METHODS

Patient data

This was a retrospective study, and the research subjects were 82 patients with EHBDSs who were admitted to Shaoyang Central Hospital between March 2017 and March 2023. Among them, the control group consisted of 40 patients who were treated with open choledocholithotomy plus LC or OC, of which there were 18 males and 22 females. In addition, the

observation group comprised 42 patients who were treated with LC plus CBDE, of which there were 17 males and 25 females.

Eligibility and exclusion criteria

Inclusion criteria: All patients were diagnosed with EHBDSs based on their clinical symptoms in combination with laboratory and imaging examination results, aged ≥ 18 years, and had complete medical records.

Exclusion criteria: Patients with intrahepatic BDSs, bile duct tumors, or bile duct malformations, those intolerant to the surgical method or allergic to the drugs used, as well as those with abnormal coagulation mechanisms, were excluded.

Treatment methods

The control group was treated with the conventional open choledocholithotomy plus LC or OC. In some cases, the abdominal cavity was accessed *via* a 10-15 cm incision in the right abdomen. After locating the gallbladder, separation and resection were performed according to the conventional procedure. The common bile duct, cystic duct, and common hepatic duct were identified, and their positions were confirmed *via* syringe puncture. The peritoneal tissue on the anterior wall of the common bile duct was dissected, and a longitudinal incision of approximately 1 cm was made on the anterior wall of the common bile duct. An electronic choledochoscope was inserted for exploration, and the stones were removed using a stone extractor. In other cases, the gallbladder was routinely removed laparoscopically after the pneumoperitoneum was identified. Then, a 10-15 cm incision was made in the right abdomen to enter the abdominal cavity, and an open choledocholithotomy was performed.

In the observation group, LC plus CBDE was performed. Routine disinfection and draping were performed before the operation. Then, a small 2-3 cm incision was made below the umbilicus, and a CO_2 pneumoperitoneum environment was established *via* puncture. Subsequently, laparoscopic instruments were introduced into the abdominal cavity for exploration, with a focus on observing Calot's triangle and the adhesions between the gallbladder and liver. After confirming the condition of the gallbladder, auxiliary operation holes were established using the xiphoid process in the right upper abdomen. The gallbladder was routinely resected and sent for pathological examination. The peritoneal tissue on the anterior wall of the common bile duct was dissected, and a longitudinal incision of approximately 1 cm was made on the anterior wall of the common bile duct. An electronic choledochoscope was inserted for exploration, and the stones were removed using a stone extractor.

After the procedure, bile drainage was regularly monitored, and the timing of the T-tube removal was determined based on the nature of the drainage fluid.

Both surgical techniques employed standardized surgical practices and the surgical skills or experience of the surgeons performing the operations on patients in both groups were comparable.

Endpoints

(1) Statistics and comparison of baseline data (gender, age, stone diameter, number of stones, disease course, and sphincter of Oddi function with sphincter of Oddi dysfunction meeting the Rome IV criteria[16]) of the two groups was performed; (2) The surgical outcomes of the two groups were compared, including stone residuals, operation time, and intraoperative bleeding; (3) The surgical complications of the two groups were statistically analyzed, including bile leakage, abdominal pain, biliary tract infection, and diarrhea; (4) The patient's quality-of-life levels in both groups before and six months after surgery were assessed using the Gastrointestinal Quality of Life Index (GIQLI)[17]. The total score of this index is 144, and the score is directly proportional to the patient's quality-of-life level; (5) The recurrence of the two groups one year after the surgery was statistically recorded. All patients were followed up for 12 months after the end of treatment, with outpatient reexamination performed once every three months. The recurrence of stones was examined by magnetic resonance imaging, computed tomography, and B-ultrasound, and the recurrence rate was recorded; and (6) Univariate and multivariate analyses were performed to detect the independent factors of postoperative recurrence.

The evaluators who collected and statistically analyzed the above data were unaware of the experimental purpose and information related to this study. Moreover, the measurement methods for the aforementioned observation indicators were standardized and uniform throughout the study, and the collection, management, and analysis of data adhered to the same protocol.

Statistical analysis

In this study, the statistical analysis software SPSS 20.0 (SPSS Inc., Chicago, IL, United States) was used to conduct statistical analyses on the collected data. To determine whether the differences were statistically significant (threshold: $P < 0.05$), the count data were tested using the chi-square test and expressed as χ^2; the measurement data (mean ± SD) were confirmed using the Shapiro-Wilk test to determine the normal distribution, and a two-tailed independent sample *t*-test was utilized for comparisons between the two groups. A binary logistic regression test was adopted for the multivariate analysis of postoperative recurrence. In addition, the sample size of this study was estimated by using the sample size calculation formula for binomial proportions. This study met the minimum sample size requirement for each group (approximately 21 cases per group).

RESULTS

Baseline data

The comparison of the patient's baseline data, presented in Table 1, showed no statistical inter-group differences in sex, age, stone diameter, number of stones, disease course, and sphincter of Oddi function ($P > 0.05$) to suggest comparability.

Comparison of surgical outcomes

The inter-group comparison of surgical outcomes (Table 2) demonstrated a comparable stone residual rate ($P > 0.05$) but shorter operation time ($P < 0.05$) and less intraoperative bleeding ($P < 0.05$) in the observation group compared to the control group.

Comparison of postoperative complications

By comparing the occurrence of postoperative complications, it was found that both groups experienced bile leakage, abdominal pain, biliary tract infection, diarrhea, and gastrointestinal bleeding after surgery. However, the total complication rate was lower in the observation group than in the control group ($P = 0.005$). These results are presented in Table 3.

Quality of life

The impact of surgical techniques on the overall health of patients was analyzed using the GIQLI (Figure 1A). The data showed no significant inter-group difference in GIQL scores before the operation ($P > 0.05$). A marked rise in the GIQL score was observed postoperatively in both groups, with higher scores in the observation group compared to the control group ($P < 0.05$).

Postoperative stone recurrence rate

The recurrence rates of the two groups one year after the surgery were compared. There were 3 cases of recurrence in the observation group, compared to 10 cases in the control group. The recurrence rate in the observation group was statistically lower than that in the control group ($P = 0.027$), as shown in Figure 1B.

Univariate analysis of stone recurrence

We divided the patients into recurrence and non-recurrence groups according to stone recurrence. Through univariate analysis, it was found that the sphincter of Oddi function and treatment scheme were statistically different between the recurrence and non-recurrence groups ($P < 0.05$), which suggests that these factors were potential influencing factors for recurrence one year after surgery (Table 4).

Multivariate analysis

Values were assigned to the sphincter of Oddi function and treatment regimen that showed differences in the univariate analysis (Table 5), and a multivariate logistics regression analysis was performed. It was found that the sphincter of Oddi dysfunction [odds ratio (OR) = 5.712, $P = 0.007$] and the treatment regimen of open choledocholithotomy plus LC or OC (OR = 6.771, $P = 0.008$) were independent risk factors for stone recurrence in patients one year after the operation (Table 6).

DISCUSSION

In recent years, the incidence of cholecystitis and gallstones has been increasing annually, which has become an increasingly common health problem[18]. These diseases affect patients' daily lives and can pose a serious threat to their long-term health[19]. Given the high recurrence rate, surgery is becoming the primary treatment course[20]. For most patients, cholecystectomy is an effective treatment for cholecystitis and gallstones. However, traditional laparotomy procedures, including cholecystectomy and CBDE, are traumatic, and patients may encounter postoperative complications, such as bile leakage and abdominal infection, which affect their postoperative recovery, lower their quality of life, and may adversely influence their long-term outcomes[21]. Therefore, it is important to identify safer and more effective surgical methods to mitigate surgical trauma and enhance the postoperative quality of life of patients for the treatment of cholecystitis and gallstones.

The comparison of surgical outcomes revealed that despite an equivalent stone residual rate, the operation time and intraoperative bleeding were significantly lower in patients undergoing LC plus CBDE compared with those undergoing open choledocholithotomy plus LC or OC. Thus reflecting the superiority of LC plus CBDE in terms of safety, precision, and efficiency. The possible reason for these improvements could be that laparoscopic surgery, as a minimally invasive technique, accesses the abdominal cavity *via* small incisions, thus minimizing damage to the surrounding tissues and reducing intraoperative bleeding[22]. In addition, laparoscopy offers an enlarged surgical field of vision and a direct view of the interior of the biliary tract, thereby facilitating more accurate stone localization and stone removal operations and reducing the likelihood of stone residuals[23].

Both groups of patients presented with complications, such as abdominal pain, biliary tract infection, and diarrhea. The overall complication rate in patients treated with open choledocholithotomy plus LC or OC was significantly higher than those treated with LC plus CBDE. Both surgical approaches may result in bile leakage, but LC may increase the risk of

Table 1 Baseline data

	Control group (n = 40)	Observation group (n = 42)	χ^2	P value
Sex				
Male	18	17		
Female	22	25	0.171	0.679
Age				
≤ 65 years old	12	16		
> 65 years old	28	26	0.597	0.440
Stone diameter				
≤ 10 mm	19	24		
> 10 mm	21	18	0.764	0.382
Number of stones				
Single	30	28		
Multiple	10	14	0.687	0.407
Disease course				
≤ 2 years	25	21		
> 2 years	15	21	1.300	0.254
Sphincter of Oddi function				
Normal	28	32		
Abnormal	12	10	0.400	0.527

Table 2 Surgical outcomes

	Stone residual	Operation time (min)	Intraoperative bleeding (mL)
Control group (n = 40)	7	171.25 ± 48.51	52.05 ± 72.34
Observation group (n = 42)	2	144.24 ± 47.89	20.60 ± 16.94
t/χ^2	3.402	2.537	2.741
P value	0.065	0.013	0.008

Table 3 Postoperative complications

	Bile leakage	Abdominal pain	Biliary tract infection	Diarrhea	Gastrointestinal bleeding	Total
Control group (n = 40)	2	5	3	3	1	14
Observation group (n = 42)	0	2	1	1	0	4
χ^2						7.761
P value						0.005

bile leakage because of the limited operating space and high technical difficulty. Biliary tract infection is a common complication of biliary tract surgeries. Open surgeries have a relatively higher risk of infection because of the prolonged operation time and extensive trauma. Therefore, laparoscopic surgeries offer enhanced safety. The study by Tracy *et al*[24] mentioned that prolonged surgery may increase the incidence of biliary complications associated with cholecystectomy. Moreover, the GIQLI score of the observation group after the operation was significantly higher compared with the preoperative level and that of the control group, indicating that LC plus CBDE is more conducive to improving the patient's quality of life. This may be because the observation group had relatively better surgical outcomes and a significantly lower incidence of postoperative complications, which is beneficial for the smooth recovery of post-surgical patients.

Table 4 Results of univariate analysis

	Recurrence group (*n* = 13)	Non-recurrence group (*n* = 69)	X^2	*P* value
Sex				
Male	6	29		
Female	7	40	0.076	0.783
Age				
≤ 65 years old	3	36		
> 65 years old	10	33	3.713	0.054
Stone diameter				
≤ 10 mm	6	39		
> 10 mm	7	30	0.475	0.491
Number of stones				
Single	6	36		
Multiple	7	33	0.159	0.690
Disease course				
≤ 2 years	11	46		
> 2 years	2	23	1.663	0.197
Sphincter of Oddi function				
Normal	5	53		
Abnormal	8	16	7.771	0.005
Treatment scheme				
Open choledocholithotomy plus laparoscopic or open cholecystectomy	10	30		
Laparoscopic cholecystectomy plus common bile duct exploration	3	39	4.897	0.027

Table 5 Assignment table

Variable	Assignment
Sphincter of Oddi function	Normal = 0, abnormal = 1
Treatment scheme	Open choledocholithotomy plus laparoscopic or open cholecystectomy = 1, laparoscopic cholecystectomy plus common bile duct exploration = 0

Table 6 Results of multivariate analysis

	Estimate	Std Error	*P* value	OR	Lower 95%CI	Upper 95%CI
Sphincter of Oddi function	1.743	0.643	0.007	5.712	1.620	20.143
Treatment scheme	1.913	0.726	0.008	6.771	1.631	28.102

OR: Odds ratio; 95%CI: 95% confidence interval.

Further analysis revealed that the recurrence rate of open choledocholithotomy plus LC or OC was significantly higher than that of LC plus CBDE. This may be because laparoscopic surgery allows doctors to identify and handle the biliary structures more clearly, which may contribute to reducing the risks of stone residuals and recurrence. Finally, through binary logistic multivariate analysis of the influencing factors for one-year recurrence after surgery, we discovered that the sphincter of Oddi dysfunction and treatment scheme of open choledocholithotomy plus LC or OC were independent risk factors. The sphincter of Oddi governs the process of bile flowing from the liver into the small intestine[25]. Sphincter

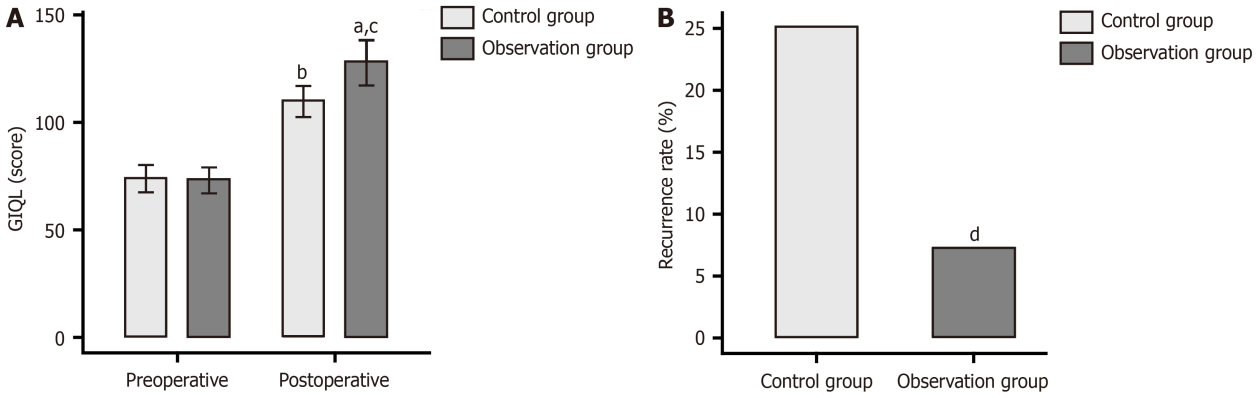

Figure 1 Quality of life and recurrence rate 1 year after surgery in two groups. A: Quality of life; B: Recurrence rate 1 year after surgery in two groups. [a]*P* < 0.05 *vs* the control group. [b]*P* < 0.05, [c]*P* < 0.01, *vs* the preoperative score within the group. [d]*P* < 0.05. GIQL: Gastrointestinal Quality of Life.

of Oddi dysfunction may result in cholestasis and bacterial infection in the biliary tract, thus creating an environment that is conducive to stone formation and increasing the risk of postoperative recurrence[26]. Open choledocholithotomy plus LC or OC results in greater surgical trauma and a longer recovery period, which may increase the risk of postoperative complications, including biliary stricture and infection, which leads to the recurrence of stones. This also raises our awareness of the importance of the evaluation and management of the sphincter of Oddi function, and selecting the most suitable surgical method may help diminish the risk of recurrence. Furthermore, Chae *et al*[27] found through multivariate analysis that a stone diameter of ≥ 15 mm was an independent risk factor for stone recurrence after cholecystectomy, which suggests that for the prediction of patient recurrence, we might also need to consider the patient's stone diameter.

This study has several limitations. First, the sample size included in this study was relatively small. When grouping based on the recurrence status, the number of patients was further reduced, which may influence the stability of the multivariate analysis. Second, not all patients with BDSs were suitable for laparoscopic surgery. For those with severe adhesions or abnormal anatomical structures, open surgery may be necessary. Third, as this study is a single-center analysis, the research findings obtained may not apply to other settings or populations. If a multi-center study can be conducted, more diverse data can be obtained, and the results can be verified in different settings. Fourth, as a retrospective analysis, there may be an inherent selection bias when patients are assigned to the observation or control groups. Therefore, prospective analysis needs to be performed to randomize patient grouping to avoid introducing confounding variables that affect the comparability between groups. Finally, the follow-up period of this study is relatively short. It is hoped that in future studies, the follow-up period can be extended and the sample size can be increased to enrich our research findings.

CONCLUSION

In conclusion, for patients with EHBDSs, the treatment modality of LC plus CBDE can reduce stone residuals, intraoperative bleeding, complications, and postoperative recurrence.

FOOTNOTES

Author contributions: Liao JH designed and performed the research and wrote the paper; Liao JH and Li JS designed the research and supervised the report; Liao JH, Wang TL and Liu WS designed the research and organized the data; Liao JH designed the research and contributed to the analysis. All authors approved the manuscript.

Institutional review board statement: This study was approved by the Ethic Committee of Shaoyang Central Hospital.

Informed consent statement: Patients were not required to give informed consent to the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

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