International Surgery

Comparison of clinical outcomes between percutaneous transhepatic biliary drainage with local lithotripsy and ERCP alone for treating intrahepatic bile duct stones

--Manuscript Draft--

Manuscript Number:	INTSURG-D-25-00030
Full Title:	Comparison of clinical outcomes between percutaneous transhepatic biliary drainage with local lithotripsy and ERCP alone for treating intrahepatic bile duct stones
Article Type:	Original Article
Keywords:	Keywords: Percutaneous transhepatic biliary drainage; Local litholysis; ERCP; Intrahepatic bile duct stones; Clinical efficacy; Complications; Recurrence rate
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Abstract:	Objective: To compare the efficacy of percutaneous transhepatic biliary drainage (PTCD) combined with local litholytic therapy versus endoscopic retrograde cholangiopancreatography (ERCP) alone for treating intrahepatic bile duct stones. Methods: A retrospective study of 160 patients divided into joint group (JG, n=80; PTCD with litholytic therapy) and ERCP group (EG, n=80). Parameters compared included surgical metrics, short-term efficacy indicators, liver function tests, inflammatory markers, complications, and recurrence rates. Results: The JG showed significantly shorter operative times, less blood loss, shorter hospital stays, lower costs, and faster recovery than the EG (all P<.05). At 3 months postoperatively, liver function indicators (TBIL, ALT, AST, ALP) and inflammatory markers (CRP, PCT) were significantly improved in the JG compared to the EG. Perioperative complication rates (7.5% vs. 18.75%) and 12-month recurrence rates (7.5% vs. 18.8%) were lower in the JG (P=.035). Conclusion: Combined PTCD with local litholytic therapy offers advantages over ERCP alone, including reduced trauma, faster recovery, improved liver function, and lower complication and recurrence rates.

Comparison of clinical outcomes between percutaneous transhepatic biliary drainage with local lithotripsy and ERCP alone for treating intrahepatic bile duct stones

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The authors declare no potential conflicts of interest.

This study was supported by the Key Specialty Construction Project of Shanghai Pudong New Area Health Commission (PWZzk2022-17).

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Keywords: Percutaneous transhepatic biliary drainage; Local litholysis; ERCP; Intrahepatic bile duct stones; Clinical efficacy; Complications; Recurrence rate

Introduction

Intrahepatic bile duct stones represent a prevalent benign condition affecting the biliary system, with increasing incidence observed in China, particularly among middle-aged and elderly populations. This condition significantly compromises patients’ quality of life and may precipitate severe complications, including cholangitis and pancreatitis.

Without proper management, it can progress to serious sequelae such as liver abscesses or, in rare cases, malignant transformation into cholangiocarcinoma[1,2].

Currently, Endoscopic Retrograde Cholangiopancreatography (ERCP) is widely employed as the conventional approach for treating intrahepatic bile duct stones. However, ERCP as a standalone procedure entails considerable surgical trauma, elevated rates of postoperative complications, and increased long-term recurrence rates[3,4]. These limitations are particularly evident in patients with multiple or large stones, where the efficacy of ERCP monotherapy is frequently suboptimal.

In recent years, Percutaneous transhepatic cholangiography drainage (PTCD) has demonstrated unique advantages in managing biliary diseases[5]. PTCD establishes an external drainage pathway that not only provides immediate relief from biliary obstruction but also creates favorable conditions for subsequent localized therapeutic interventions[6]. Concurrently, local litholysis, a minimally invasive technique utilizing chemical solvents to dissolve stones, has gained recognition for its reduced invasiveness and minimal patient discomfort[7]. However, comprehensive studies comparing the efficacy of PTCD combined with local litholysis versus conventional ERCP treatment remain limited, and the differential outcomes between these therapeutic approaches have not been adequately evaluated in clinical settings.

Methods

Study Design

This retrospective cohort study was approved by the Shanghai East Hospital's ethics committee and conducted in compliance with the Declaration of Helsinki. The study period spanned from December 2022 to January 2024, and included patients diagnosed with intrahepatic bile duct stones. Patient selection was performed through the hospital's information system. Participants were categorized based on the treatment received into the joint group (JG, receiving PTCD combined with local litholytic therapy) and the ERCP group (EG, receiving ERCP alone). Various clinical indicators were compared between the two groups to evaluate the differences in treatment efficacy for intrahepatic bile duct stones.

Patient Selection

The sample size for this retrospective study was estimated using the formula for comparing the means of two populations in medical statistics, as follows:

$$N = \frac{2\delta^2(t_\alpha + t_\beta)^2}{(\mu_1 - \mu_2)^2}$$

(δ represents the standard deviation of the two populations, typically the larger value among the two samples; μ1 and μ2 are the means of the two populations, which can be estimated using sample means).

Setting α=0.05 (two-tailed) and β=0.10, the calculated required sample size per group was 72. Allowing a 10% dropout rate, each group consisted of 80 patients, resulting in a total sample size of 160.

Inclusion criteria included: (1) age between 18-85 years, (2) diagnosis of intrahepatic bile duct stones requiring surgical intervention, and (3) receipt of surgical treatment. Exclusion criteria encompassed: (1) coagulation dysfunction, (2) malignant tumors, (3) severe cardiopulmonary, hepatic, or renal dysfunction, (4) acute cerebrovascular events or myocardial infarction within the past 3 months, and (5) incomplete clinical data.

Data Collection

Patient information was collected via the hospital information system and categorized as follows: (1) baseline data, including gender, age, BMI, disease duration, number of stones, alcohol consumption, smoking status, and underlying diseases, (2) basic surgical parameters, including operative time and intraoperative blood loss, (3) short-term efficacy indicators, including hospital stay duration, hospitalization cost, time to drainage tube removal, and time to first postoperative flatus, (4) liver function parameters before treatment and three months postoperatively (TBIL, ALT, AST, and ALP levels), (5) inflammatory markers before surgery and 24 hours postoperatively (CRP and PCT), (6) incidence of perioperative complications, and (7) recurrence rate at 12-month follow-up [8].

Data Utilization

To minimize data bias, data collection and processing were conducted by two independent personnel. One individual collected data via the hospital information system and anonymized patient information using numerical identifiers (e.g., Patient 1, Patient 2). The project supervisor then reviewed the data for accuracy before forwarding it to a data analyst for statistical processing. All personnel received training on clinical data handling to ensure confidentiality and patient privacy protection.

Statistical Analysis

Data collection and statistical analysis were conducted using EXCEL 2021 and IBM SPSS 22.0 software. Measurement data were tested for normality and expressed as mean ± standard deviation (mean ± SD). An independent sample t-test was used for comparison between the two groups, and categorical data were expressed as percentages and analyzed using the chi-square test. Differences were considered statistically significant at *P* value <.05.

Results

Between December 2022 and January 2024, 183 patients with intrahepatic bile duct stones were screened at our hospital. 23 patients were excluded due to not meeting inclusion criteria (n=13), having sigmoid colon tumors (n=1), or other reasons such as incomplete medical records (n=9) **(Figure 1)**. Subsequently, 160 patients were randomized into the joint group (n = 80) and the ERCP group (n = 80). Finally, all patients enrolled in the randomization were incorporated into the analysis.

Comparison of baseline clinical data between the joint group and the ERCP group

Firstly, we analyzed and compared the baseline clinical characteristics of both groups. No statistically significant differences were found between the two groups concerning gender, age, BMI, disease duration, number of stones, alcohol consumption, smoking status, and underlying diseases (all *P*>.05). This indicates that the groups were wellmatched **(Table 1)**. The joint group had a mean patient age of 65.8 ± 9.4 years, while the ERCP group had a mean age of 66.7 ± 10.9 years. Most patients were female (66% [105/160]), and a minority had comorbidities such as hypertension (18% [29/160]), diabetes (7.5% [12/160]), or hyperlipidemia (27% [43/160]).

Comparison of basic surgical indicators between the joint group and the ERCP group

The basic surgical parameters, such as operative time and intraoperative blood loss, were collected and compared between the two groups. The findings indicated that the joint group exhibited significantly reduced operative time (JG: mean 83, SD 14.37 vs EG: mean 100, SD 12.54; $P<.05$) and intraoperative blood loss (JG: mean 27, SD 10.43 vs EG: mean 49, SD 9.75; $P<.05$) compared with the ERCP group **(Figure 2)**.

Comparison of short-term efficacy indicators between the joint group and the ERCP group

The duration of hospital stays, hospitalization costs, time until drainage tube removal, and time until the first postoperative flatus were collected and compared between the two groups. The results indicated that the duration of hospital stays (JG: mean 11, SD 3.06 vs EG: mean 15, SD 3.96), hospitalization costs (JG: mean 2.8, SD 0.55 vs EG: mean 3.5, SD 0.87), time until drainage tube removal (JG: mean 5, SD 1.48 vs EG: mean 7, SD 1.75), and time until the first postoperative flatus (JG: mean 38, SD 6.52 vs EG: mean 37, SD 7.74) were significantly lower in the joint group compared to the ERCP group (all $P<.05$) **(Figure 3)**.

Comparison of liver function indicators before and after treatment between the joint group and the ERCP group

Before treatment, there was no statistically significant difference between the two groups in the liver function indicators TBIL, ALT, AST and ALP levels (all $P>.05$). When compared again 3 months after treatment, in the joint group, the TBIL (JG: mean

15.53, SD 3.766 vs EG: mean 17.61, SD 3.774), ALT (JG: mean 31.53, SD 8.574 vs EG: mean 34.85, SD 8.914), AST (JG: mean 28.96, SD 6.613 vs EG: mean 35.60, SD 6.626) and ALP (JG: mean 105.6, SD 12.56 vs EG: mean 116.7, SD 18.81) levels were significantly reduced compared with the ERCP group (all $P<.05$) **(Figure 4)**.

Comparison of inflammatory indicators between the joint group and the ERCP group

There was no statistically significant difference in inflammatory markers including C-reactive protein (CRP) ($P=.280$) and procalcitonin (PCT) ($P=.846$) levels between the two groups of patients before surgery. When compared 24 hours after surgery, the CRP (JG: mean 45.81, SD 6.809 vs EG: mean 69.94, SD 13.70; $P<.05$) and PCT (JG: mean 0.805, SD 0.211 vs EG: mean 1.116, SD 0.286; $P<.05$) levels in the joint group were significantly lower than those in the ERCP group **(Figure 5)**.

Comparison of perioperative complication rates between the joint group and the ERCP group

The findings of statistical analysis indicated that 3 cases of acute pancreatitis, 2 cases of cholangitis, and 1 case of incisional infection occurred in the joint group during the perioperative period. The overall complication rate was (7.50% [6/80]), which was significantly lower than (18.75% [15/80]) of the patients in the ERCP group ($P=.035$) **(Table 2)**.

Comparison of follow-up recurrence rates between the joint group and the ERCP group

The follow-up results showed that the recurrence rates of patients in the joint group were 2.5%, 5.2% and 7.5% respectively at 3 months, 6 months and 12 months of follow-up. At 12 months of follow-up, the recurrence rate of the joint group (7.50% [6/80]) was significantly lower than that of the ERCP group (18.75% [15/80]) ($P<.05$) **(Figure 6)**.

Discussion

This study compares the clinical effects of PTCD joint with local litholysis treatment versus simple ERCP for intrahepatic bile duct stones. The findings indicate that the joint treatment shows significant advantages in terms of surgical trauma, postoperative recovery, liver function improvement, inflammation control, and long-term prognosis. Specifically, the joint treatment group exhibited shorter surgery time, less blood loss, faster postoperative recovery, lower complication rates, and reduced long-term recurrence rates. These findings provide important clinical evidence for selecting treatment options for intrahepatic bile duct stones.

Firstly, regarding basic surgical indicators, this investigation revealed that the operative time and intraoperative blood loss were decreased in the joint group compared to the ERCP group. This result is in agreement with the findings of Cai's team, which noted that PTCD has the characteristics of shorter operation time and less trauma compared to ERCP, which causes more harm to patients [9]. The authors of this paper believe this may be because PTCD can accurately target the bile duct under ultrasound guidance, establishing a direct drainage channel and reducing damage to surrounding tissues during surgery. In contrast, ERCP requires access through the duodenal papilla, making the operation relatively complex and increasing the risks of extended surgery time and bleeding [10,11]. Additionally, local litholysis treatment reduces stone volume via chemical dissolution, laying a solid foundation for subsequent mechanical fragmentation, which helps further shorten the operation time [12].

In terms of recent efficacy indicators, the results suggest that the joint group's inpatient stay time, hospitalization expenses, catheter removal time, and first postoperative gas passage time were all better than those of the ERCP group. The authors analyze that the reasons for these differences can be summarized as follows: (1) the drainage channel established by PTCD is more direct, effectively relieving biliary obstruction and promoting bile drainage, and (2) the minimally invasive nature of local litholysis treatment reduces gastrointestinal tract stimulation, facilitating early recovery of gastrointestinal function. This conclusion is similar to the findings of Henry's team, which reported a 98% surgical success rate among 64 patients undergoing PTCD, with good postoperative recovery and relatively short hospitalization duration [13].

Regarding liver function improvement, the study found that 3 months post-surgery, the joint group exhibited markedly reduced levels of TBIL, ALT, AST, and ALP compared to the ERCP group. The authors analyze that the reasons for these phenomena include: (1) PTCD can quickly and effectively relieve biliary obstruction, improving cholestasis, (2) local litholysis treatment avoids traditional mechanical fragmentation damage to the bile duct wall, reducing secondary liver cell damage, and (3) the combined application of both treatment methods may produce a synergistic effect, further benefiting liver function recovery. This aligns with the conclusions of Singh's team, which found through a retrospective analysis of 20 severe cholangitis patients that the PTCD surgical success rate reached 100%, with rapid postoperative recovery and no surgery-related complications, significantly improving liver function after surgery [14].

About inflammation indicators, the study found that 24 hours post-surgery, in the joint group, the levels of CRP and PCT were notably lower compared to the ERCP group, suggesting that the combined treatment plan better controls postoperative inflammatory responses. Previous studies have pointed out that cholestasis leads to the abnormal accumulation of bile components in liver cells, bile ducts, and the systemic circulation, resulting in a systemic inflammatory response through mechanisms such as direct cellular damage, oxidative stress responses, immune system activation, and impaired intestinal barrier function [15,16]. The reasons the joint group was able to significantly improve the patient's inflammatory state may include: (1) PTCD's precise drainage reduces the stimulation of cholestasis on tissues, hence even though both groups experienced worsened inflammatory states post-surgery, the impact was comparatively smaller in the combined intervention [17], (2) local litholysis treatment avoids tissue damage and inflammatory responses that may be caused by mechanical fragmentation [18], and (3) the combination of the two treatment methods optimized bile duct drainage effectiveness, reducing the risk of infection. This result correlates with the findings of Pedersoli's team, which also emphasized the importance of reducing inflammatory responses to prevent bile duct damage [19].

Regarding perioperative complications, the total incidence rate was significantly lower in the joint group (7.50%) compared to the ERCP group (18.75%). The analysis of this difference may be related to the following points: firstly, PTCD operations under ultrasound guidance are precise, reducing the risk of injury [20]; secondly, local litholysis treatment avoids complications that may result from excessive mechanical fragmentation [21]; thirdly, the combined application of the two treatment methods improves the completeness of stone clearance, reducing the complications caused by residual stones. The findings align with the research by Liu et al. who also found that the combined treatment plan significantly lowers the incidence of complications [22]

Finally, regarding follow-up results, this study found that over a 12-month follow-up period, the proportion of recurrences in the joint group (7.5%) was significantly lower than that in the ERCP group (18.75%). This conclusion provides a good clinical reference for combined intervention. The authors analyze that the reasons for this phenomenon can be summarized as follows: firstly, PTCD creates an artificial channel that effectively relieves biliary obstruction and provides an ideal path for stone clearance, laying a foundation for the expulsion of stones of varying diameters [23]; secondly, local litholysis treatment has advantages for small stone fragments, where the dissolving agent can directly act on the bile duct stones, especially on fragments that are difficult to remove through mechanical means, thus significantly lowering the risk of residual stones, which is one of the key reasons for the lower postoperative recurrence rate [24]; finally, combined intervention measures integrate the advantages of mechanical stone removal and pharmacological litholysis, ensuring bile drainage while cleaning bile duct wall deposits, and preventing subsequent bacterial infections and inflammatory responses by ensuring bile duct patency, all leading to better treatment outcomes [25].

Conclusion

In summary, compared with simple ERCP, PTCD combined with local litholysis intervention helps to alleviate perioperative trauma, accelerate postoperative recovery progress and liver function restoration, and improves postoperative systemic inflammatory states. Additionally, the combined intervention is highly safe, with a low recurrence rate during postoperative follow-up. The innovations of this study lie in systematically evaluating the application value of PTCD combined with local litholysis treatment for intrahepatic bile duct stones, providing clinical references for subsequent interventions. Furthermore, it thoroughly compares the differences in various clinical indicators of this combined approach against traditional ERCP treatment, providing detailed data support for clinical treatment option selection. However, this study also has several limitations. As a single-center retrospective study, there may be selection bias; furthermore, the relatively small sample size may limit the generalizability of the findings. Future exploration plans to conduct multi-center, large-sample, randomized controlled studies to verify the efficacy and safety of this treatment plan. Additionally, it is necessary to conduct molecular biology studies to explore the specific mechanisms by which this combined treatment plan improves outcomes, providing a theoretical basis for optimizing treatment plans.

Funding

This study was supported by the Key Specialty Construction Project of Shanghai Pudong New Area Health Commission (PWZzk2022-17).

Authors' Contributions

Dr. Lijun Han designed the study and contributed to the conception and design of the research. Dr. Di Wang was responsible for data collection and analysis, and drafted the manuscript. All authors contributed to the interpretation of the data, critically revised the manuscript for important intellectual content, and approved the final version to be published.

Data Availability

The datasets used or analyzed during the current study are available from the corresponding author on reasonable request. All data are anonymized to protect patient privacy and comply with relevant ethical regulations.

Conflicts of Interest

The authors declare that they have no competing interests.

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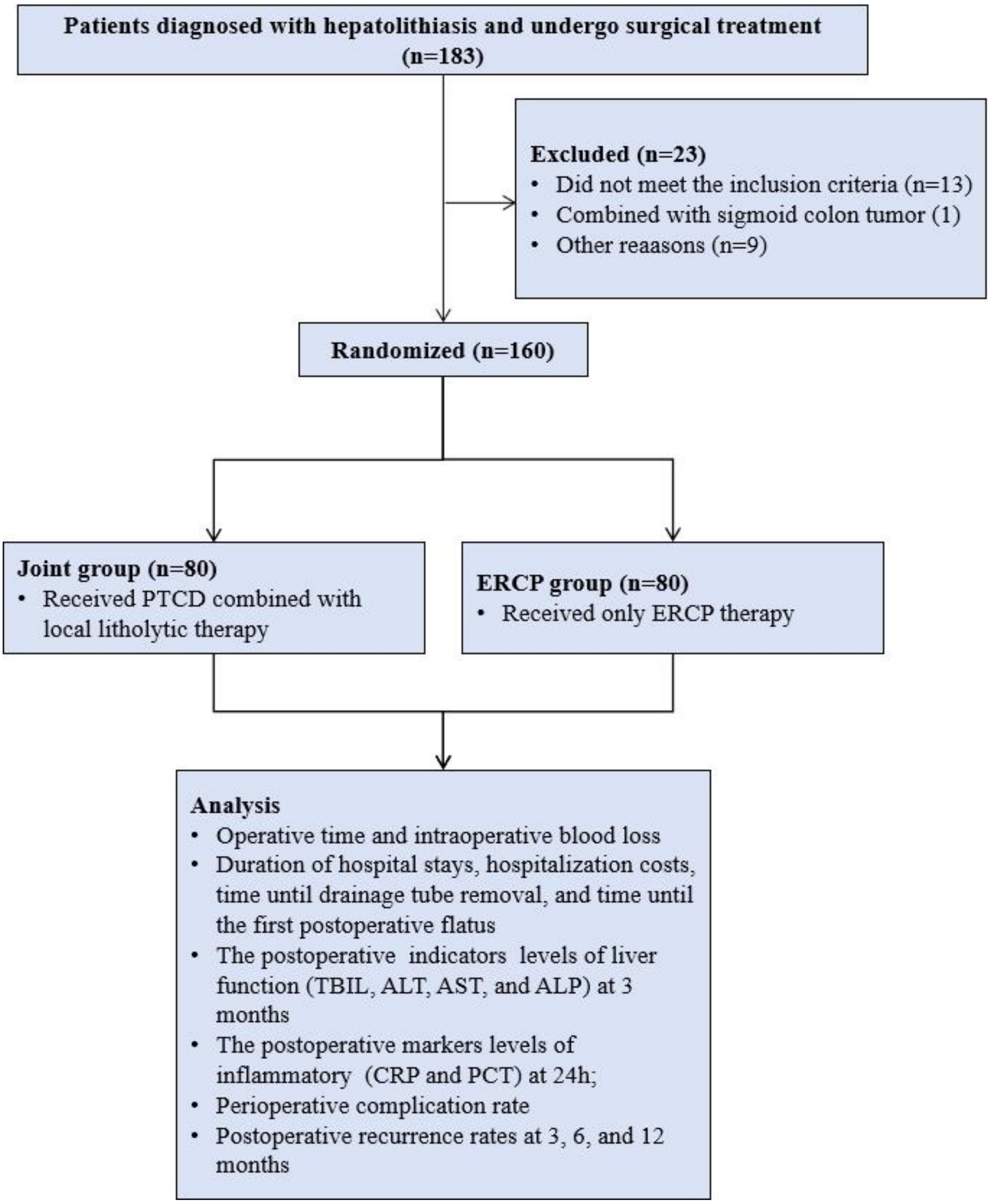

Figure 1. Flowchart of Study Design.

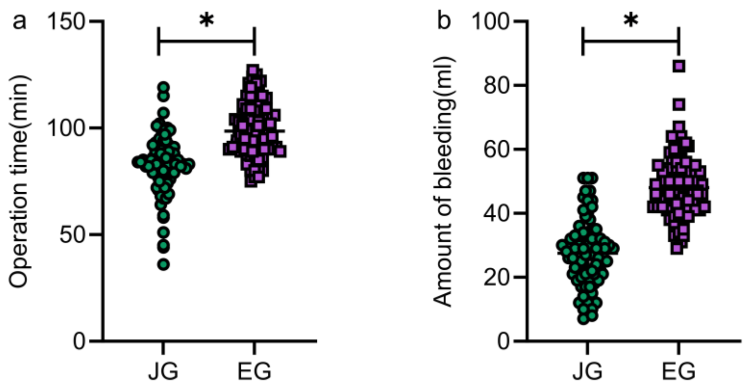

Figure 2. Comparison of basic surgical indicators between the joint group and the ERCP group.

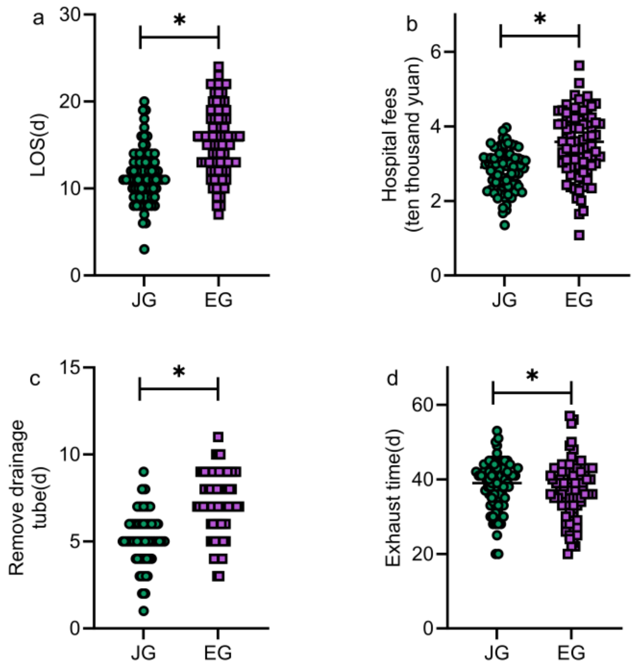

Figure 3. Comparison of short-term efficacy between the joint group and the ERCP group.

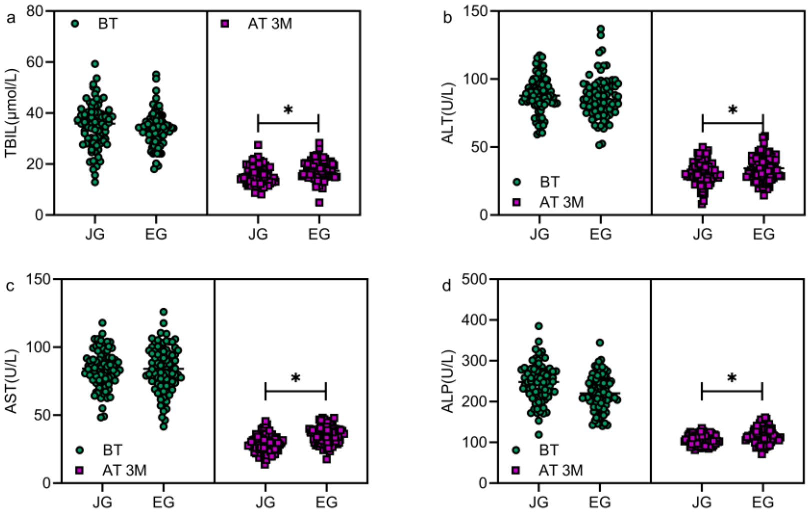

Figure 4. Comparison of liver function indicators before and after treatment between the joint group and the ERCP group.

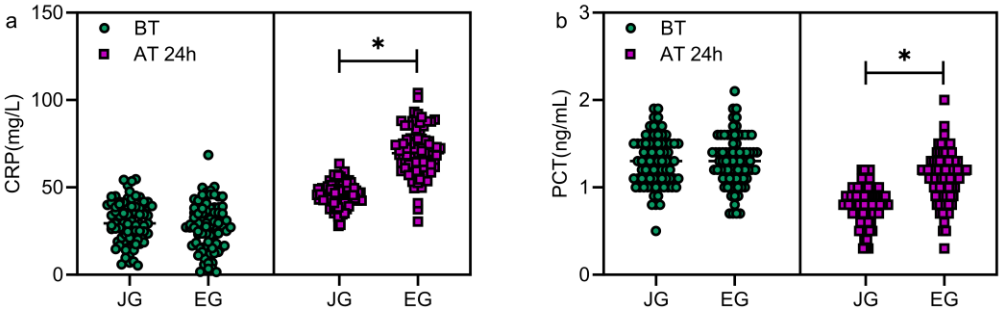

Figure 5. Comparison of inflammatory indicators between the joint group and the ERCP group.

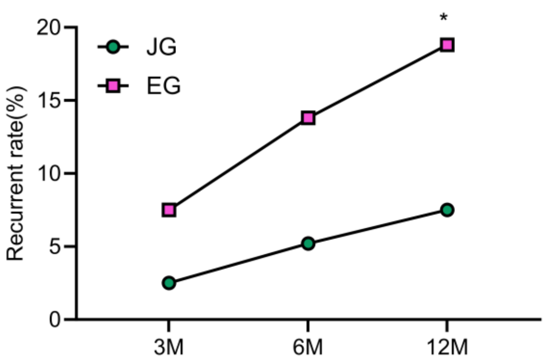

Figure 6. Comparison of follow-up recurrence rates between the joint group and the ERCP group.

Figure 1. Flowchart of Study Design. Abbreviations: JG, Joint group, patients jointly received PTCD and local litholytic therapy; EG, ERCP group, patients received only ERCP therapy; ERCP, Endoscopic Retrograde Cholangiopancreatography; TBIL, Total bilirubin; ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; ALP, Alkaline phosphatase; CRP, C-reactive protein; PCT, procalcitonin.

Figure 2. Comparison of basic surgical indicators between the joint group and the ERCP group. **(A)** Operation time in the combined group and the ERCP group (n=80 per group). **(B)** Intraoperative blood loss in the combined group and the ERCP group (n=80 per group). Data are presented as mean ± standard deviation. Compared with the ERCP group, *P<.05. Abbreviations: JG, Joint group, patients jointly received PTCD and local litholytic therapy; EG, ERCP group, patients received only ERCP therapy.

Figure 3. Comparison of short-term efficacy between the joint group and the ERCP group. The joint group had significantly lower mean values for hospital length of stay **(A)**, hospitalization costs **(B)**, time to drain removal **(C)**, and time to first postoperative flatus **(D)** than the ERCP group (P<.05). Data are presented as mean ± SD. Compared with the ERCP group, *P<.05. Abbreviations: JG, Joint group; EG, ERCP group; LOS, Length of stay.

Figure 4. Comparison of liver function indicators before and after treatment between the joint group and the ERCP group. Before treatment, there were no statistically significant differences in TBIL **(A)**, ALT **(B)**, AST **(C)**, and ALP **(D)** levels between both groups (P>.05). At 3 months postoperatively, the joint group demonstrated significantly lower levels of TBIL, ALT, AST, and ALP compared to the ERCP group (P<.05). Data are presented as mean ± SD. Compared with the ERCP group, *P<.05. Abbreviations: JG, Joint group; EG, ERCP group; BT, Before treatment; AT 3M, After treatment 3 months; TBIL, Total bilirubin; ALT, Alanine aminotransferase; AST, Aspartate aminotransferase; ALP, Alkaline phosphatase.

Figure 5. Comparison of inflammatory indicators between the joint group and the ERCP group. Preoperatively, there were no statistically significant differences in CRP **(A)** and PCT **(B)** levels between

the two groups (*P*>.05). At 24 hours postoperatively, in the joint group, the levels of CRP and PCT were reduced compared to the ERCP group (*P*<.05). Data are presented as mean ± SD. Compared with the ERCP group, *P<.05. Abbreviations: JG, Joint group; EG, ERCP group; BT, Before treatment; AT 24h, After Treatment 24 hours.

Figure 6. Comparison of follow-up recurrence rates between the joint group and the ERCP group. At 12 months of follow-up, the recurrence rate in the joint group was lower than that in the ERCP group (*P*<.05). Data shown as mean ± SD. vs. ERCP group, **P*<.05. Abbreviations: JG, Joint group; EG, ERCP group; 3M, 3 months.

Table1. The Characteristic summary based on the joint group and the ERCP group

Characteristic	Joint group (n=80)	ERCP group (n=80)
Gender, n (%)		
Male	25 (31)	30 (38)
Female	55 (69)	50 (62)
Age (years), mean (SD)	65.78 (9.40)	66.66 (10.86)
BMI (kg/m^2), mean (SD)	24.01 (2.91)	24.20 (3.24)
Average disease duration (months), mean (SD)	14.31 (5.11)	15.64 (4.82)
Number of stones, mean (SD)	2.65 (1.20)	2.86 (1.19)
Smoking history, n (%)	10 (13)	9 (11)
Drinking history, n (%)	15 (19)	18 (23)
Comorbidities, n (%)		
High blood pressure	16 (20)	13 (16)
Diabetes	5 (6)	7 (9)
Hyperlipidemia	23 (29)	20 (25)

Table 2. Comparison of perioperative complication incidence between both groups.

Groups	N	Acute pancreatitis, n (%)	cholangitis, n (%)	Incision infection, n (%)	lung infection, n (%)	Overall incidence, n (%)
JG[a]	80	3 (4)	2 (3)	1 (1)	0 (0)	6 (8)
EG[b]	80	7 (9)	4 (5)	3 (4)	1 (1)	15 (19)
χ^2						4.440
P value						.035

[a]JG: Joint group.

[b]EG: ERCP group.