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Research Article

MINIMALLY INVASIVE MANAGEMENT OF COMMON BILE DUCT STONES: A PROSPECTIVE STUDY COMPARING PRIMARY CLOSURE AND T-TUBE DRAINAGE

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ABSTRACT

Different techniques of CBD closure have evolved over the years in the laparoscopic management of CBD stones which includes primary closure and T tube closure. The aim of this study was to compare primary closure with T-tube drainage in the surgical management of common bile duct stones regarding efficacy and outcome. The study was conducted during June 2015 to May 2018 in the Department of Surgery, IGMC, Shimla, including 40 diagnosed cases of symptomatic CBD stones. Proper comparative evaluation between the two techniques at preoperative, intraoperative, and postoperative levels was done. Primary closure results in less operative time and shorter hospital stay as compared to equal complication rates but prolonged duration of drainage with T-tube drainage. It can be concluded from the study that primary closure is a feasible and less morbid alternative for selected patients.

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INTRODUCTION

CBD stones are the most prevalent complication in patients with gallstones—occurring in approximately 10–15% of patients—and should be removed immediately to prevent severe morbidity. Although it is the major modality of treatment endoscopically via ERCP, surgical approaches are indicated in some cases. Surgical removal of the CBD stones may be either open or laparoscopic.^{1,2}

Laparoscopic CBD exploration is emerging as a preferred method for managing such cases, thereby replacing the more invasive open surgery. Post laparoscopic stone extraction CBD can be either closed primarily or via a T-Tube³. The T-tube was used by convention, as it ensures decompression of bile, is allowed for postoperative cholangiography, and could be used to monitor bile output. However, it carries risks of complications, such as bacteraemia, dislodgement of tube, obstruction and/or fracture of tube⁴. Further tube too, when removed, would have its leakage.⁵ The bile duct syndrome might burden a patient with the presence of a drainage tube for weeks before definitive treatment⁶. Additionally, the incidence of recurrent stones may be higher than T-tube drainage, as the tube is a foreign body around which bile pigments and salts can precipitate. All of these lead to prolonged lengths of

hospital stay.^{7,8,9,10} On the other hand, primary closures offer the advantages of a simpler procedure with less recovery time but raises concerns about potential bile duct obstruction or leaks. This study will compare these two in view of their operative outcomes and post-operative complications to determine the optimal approach.

MATERIAL AND METHOD

It was a single centre, prospective ,observational study conducted during June 2015 to May 2018 in the Department of Surgery, IGMC, Shimla, including 40 diagnosed cases of symptomatic CBD stones. IRB opinion was taken.

Inclusion Criteria

- Patients of all age groups with biliary colic pain and obstructive jaundice.
- Diagnosis of CBD stones through ultrasonography and/ or MRCP with CBD diameter ≥ 8 mm.
- Intrahepatic duct dilation and elevated alkaline phosphatase or gamma-glutamyl transferase levels.
- ASA grade I-III.

Exclusion Criteria

- Clinical or radiological evidence of cholangitis, pancreatitis, or cirrhosis.
- Gallbladder empyema, liver masses, or malignancies.
- Pregnancy and previous upper gastrointestinal surgery.

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 Patients with contraindications to general anaesthesia or ASA grade IV-V.

Patient data were collected using a structured proforma that included patient's demographic information, clinical history, preoperative investigations, operative details, and post-operative outcomes. Parameters evaluated included:

- Age, gender, BMI.
- Operative time, duration of drainage, post-operative complications, and hospital stay.

The data were analysed using descriptive and inferential statistics. Results were expressed as means and standard deviations. Statistical significance was evaluated using p-values, with p<0.05 considered significant.

- Primary Closure (Group I): The mean operative time was 98.3 minutes (±11.65).
- T-Tube Drainage (Group II): The mean operative time was significantly longer at 132.6 minutes (±12.00).
- Statistical Significance: p<0.001, indicating a significant difference in operative times.

BMI and Operative Time: Table 3

BMI categories were analysed for their influence on operative time. Normal-weight patients (BMI 18.51-24.99 kg/m²) had the shortest mean operative time of 108.2 minutes. Overweight patients required the longest operative time at 163 minutes, suggesting a correlation between higher BMI and prolonged surgery.

Table I Details of age(in years) and sex of 20 patients

Age group	20-30	31-40	41-50	51- 60	61 -70	71-80	Total
Male	4	0	2	2	0	0	8
	2	2	8	8	10	2	32
Total	6	2	10	10	10	2	40

Most of the patients (75%) were in the age group of 41-70 years while 20% were in range of 20-40 years with 5% being >70 years.

Table 2 Shows the sex of patients in Group I and Group II

Sex	Group I (primary closure)	Group II (T-tube)	Total
Male	0	8	8
Female	20	12	32

Table 3 BMI(Kg/m²) and mean operative time(in minutes) of patients of group I and group II

Weight of Patients (BMI)	Group I Primary closure	Group II T-Tube	Mean operative time in group I (mins)	Mean operative time in group II (mins)
Under weight (17.30 -18.50 kg/m²)	2	1	120	120
Normal weight(18.51-24.99 kg/m ²)	9	17	94	127
Over weight(25.00-29.99 kg/m²)	7	2	103	150
Obese(over 30.00k kg/m)	2	0	90	0

Table 4 Duration of drainage tube(in days) in group I and group II

Groups	Mean (days)	Standard deviation	P-value
Group I (Primary Closure)	4.7	± 1.703	0.142
Group II (T-Tube)	5.9	± 1.792	

RESULTS

Patient Demographics

The age of the patients ranged from 24 to 77 years, with a mean age of 53.45 years. Among the 40 patients, 80% were female (n=32), and 20% were male (n=8). The distribution of age and gender is detailed in Table I.

Surgical Procedure Distribution: Table 2

- Group I (Primary Closure): All patients were female (n=20).
- Group II (T-Tube Drainage): Comprised 40% males (n=8) and 60% females (n=12).
- Operative Time:

Drainage Duration

The duration of drainage was longer in Group II:

- Group I: Mean of 4.9 days (± 1.703).
- Group II: Mean of 5.7 days (± 1.792).
- Statistical Significance: p=0.140 (not significant).

Hospital Stay

- Group I: Mean hospital stay was 6.4 days (± 3.35).
- Group II: Mean hospital stay was 7.1 days (±1.51).
- Statistical Significance: p=0.674 (not significant).

Complications

None of the patients under study had any per-operative complications like air embolism, subcutaneous emphysema, pneumothorax, bleeding from abdominal wall, gastrointestinal tract perforation, solid visceral injury, major vascular injury which have been otherwise reported in literature. No post-operative complications like port site infection, abscess or deep vein thrombosis were seen in any patient of both the groups.

Postoperative Complications

- Bile Leak: Occurred in 5% of patients (n=2).
- Total Complications: Both groups reported an overall complication rate of 12% (n=4).

Out of 40 patients, 2 had bile leaks. One patient had a bile leak through the abdominal drain, another had a persistent bile leak through the T-tube.

The bile leak through the T-tube was due to a stricture in the lower common bile duct, which was diagnosed on a T-tube cholangiogram. The patient underwent endoscopic retrograde pancreatocholangiography with sphincterotomy and common bile duct stenting. After this procedure, the bile leak gradually decreased over 3-4 days, and the T-tube was removed. The patient was then discharged.

The bile leak through the Ryle's tube was due to a leak of sutures at the choledochotomy site. The patient also underwent endoscopic retrograde pancreatocholangiography with sphincterotomy and common bile duct stenting. None of the patients had paralytic ileus in our study.

Drainage (Ryle's) Tube

A drainage tube (14F Ryle's tube) was kept in Morrison's space in all 40(100%) patients. This tube was kept for minimum of 3 days. Mean duration of drainage in all (40) patients was 5.1 days

In group I there were 14 patients (70%) in which duration of drainage tube was between 0-5 days, 6 patients (30%) were having duration more than 5 days. In group II there were 10 patients (50%) in which duration of drainage tube was between 0-5 days, 10 patients (50%) were having duration more than 5 days. Mean duration of drainage in group I was 4.7 days with standard deviation ± 1.703 and mean duration of drainage in group II was 5.9 days with standard deviation ± 1.792 with p-value 0.142. Duration of drainage tube in group I and group II is given in **Table 5**.

DISCUSSION

The laparoscopic technique involved cholecystectomy with common bile duct exploration. Patients underwent general anaesthesia and pneumoperitoneum . A 5-port technique was used, with the midclavicular port dedicated to choledochoscopy. The first 10 mm trocar was introduced by Hasson's technique below the umbilicus for insufflation of carbon dioxide and for insertion of a 30 degree angled laparoscope. Other trocars were placed under direct vision, the second 10mm trocar was introduced in the epigastric region, the third 5mm trocar in the right anterior axillary line in right hypochondrium, the fourth 5mm trocar in the midaxillary line and the last fifth 5mm trocar below the coastal margin, 1-3cm medial to the midclavicular line.

The common bile duct was explored via a longitudinal

incision in the distal common hepatic duct. Choledochoscopy was performed to identify and remove stones using various techniques, including basket extraction, balloon catheter, forceps, or milking.

After stone clearance, the common bile duct was closed primarily using interrupted absorbable suture (vicryl 3-0) or with a T-tube drain, depending on the clinical situation. Cholecystectomy was then completed. Postoperatively, patients received analgesia and were monitored for complications. T-tube drainage was removed on the 10th postoperative day after a confirmatory cholangiogram. Patients with primary closure were discharged earlier. Primary closure demonstrated a significantly shorter operative time compared to T-tube drainage. This finding aligns with previous studies emphasizing the simplicity of primary closure over the complicated placement and securing of a T-tube. The age of patients in the present study ranged from 24 to 77 years, with a mean age of 53.45 years. 8 patients (20%) were male and 32 (80%) were female. This is in concurrence to previous studies^{11,12,13}Higher BMI was associated with longer operative times, reflecting the technical challenges posed by obese patients. Surgeons should consider BMI as a critical factor in preoperative planning.

The mean time taken for completion of the procedure in the present study was 114.05 minutes (range 90 to 150 min.). Mean time taken for operation in group I was 98.30 minutes with standard deviation ± 11.65 and mean time taken for operation in group II was 132.6 minutes with standard deviation ± 12.00 with p-value <0.001 reflecting that in laparoscopic CBD exploration primary closure require significantly less time to operate than T-tube. This is in alignment with previous studies $^{14.15}$. In a recent study by Cai *et al.*, 16 the duration of the operation in primary closure group was shorter than in T-tube group $(92.4 \pm 15.2 \text{ vs. } 125.7 \pm 32.6 \text{ min, } P < 0.05)$, which is almost similar to the results of present study.

Although drainage duration was slightly longer for T-tube patients, the difference was not statistically significant. However, prolonged drainage in T-tube patients may increase discomfort and restrict mobility, impacting the quality of life.

Bile leakage occurred equally in both groups, suggesting comparable safety profiles. Notably, the absence of severe complications in either group highlights the overall safety of laparoscopic management. Of the 40 patients, 2 experienced bile leaks postoperatively through the Ryle's tube drain. One patient was from the primary closure group, and one patient was from the T-tube group.

These results are comparable to those reported by Cai et al. (61) and Lee et al. (2014). Cai et al. found a bile leakage rate of 4.5% in the primary closure group and 4.0% in the T-tube group. Lee et al. reported a bile leakage rate of 3.9%

In the present study mean hospital stay was 6.4 days in group 1 and 7.4 days in group 2, ranging from 4 to 15 days in all patients. This is similar to previous studies^{12,17}. Both groups demonstrated similar hospital stays, with no significant differences. However, the trend toward shorter stays in the primary closure group reflects its potential for earlier recovery and reduced healthcare costs.

Primary closure offers several advantages, including shorter operative times, reduced need for postoperative care, and

improved patient comfort. These benefits make it a compelling choice for managing CBD stones in appropriate cases.

Despite its historical popularity, T-tube drainage is associated with patient discomfort and the risk of external contamination or bile loss. Advances in surgical techniques and imaging may render it less favourable in the future.

The study's small sample size, non randomisation and singlecentre design limit the generalizability of the findings. Future research with larger cohorts and randomized controlled trials is essential to confirm these results.

CONCLUSION

This study demonstrates that primary closure is a safe and an effective alternative to T-tube drainage in the laparoscopic management of CBD stones. With shorter operative times and comparable complication rates, primary closure reduces patient morbidity, enhances recovery and offers better cost efficiency. However, patient selection should be based on individual risk factors, including BMI and ductal anatomy. Further studies with larger sample size and randomisation are warranted to refine patient criteria and validate these findings.

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