Randomized Comparison of Postoperative Short-Term and Mid-Term Complications Between T-Tube and Primary Closure after CBD Exploration

Iqbal Muzaffar, Pai Zula, Yusuf Yimit, Ajim Tuergan Jaan and Hao Wen

ABSTRACT

Objective: To compare the postoperative short-term and mid-term complications in patients who underwent CBD exploration and closure by using T-tube or primary closure.

Study Design: Prospective randomized clinical trial.

Place and Duration of Study: Hepatobiliary Department of First Affiliated Hospital of Xinjiang Medical University, Urumqi, China, from August 2009 to March 2013.

Methodology: A total of 148 consecutive patients with Common Bile Duct Stones (CBDs) and CBD dilation were enrolled in this randomized study to undergo open cholecystectomy with CBD exploration. Pre-operative findings, postoperative short-term complications, postoperative follow-up (mid-term), and hospital stay were recorded and analyzed.

Results: A T-tube was inserted in 76 (51.35%) patients and the primary closure was done in 72 (48.64%) patients. There were no differences in the demographic characteristics and clinical presentations between the two groups. Compared with the T-tube group 8.97 ± 1.629 days, the postoperative stay in primary closure 5.34 ± 1.25 days was significantly shorter (p < 0.01). The incidence of overall postoperative short-term complications and mid-term complications were statistically but not significantly lower in the primary closure group (9.7%) than that in T-tube group (17.10%, p=0.189).

Conclusion: Complications in the primary closure group were lower than that in T-tube group but there was no significant statistical difference. So during open surgery for CBD stones, primary closure of CBD appeared safe and effective with shorter hospital stays and less complications.


INTRODUCTION

Choledocholithiasis develops in almost 10 - 15% of patients with cholelithiasis and different studies suggest that choledocholithiasis are encountered in about 7 - 15% of patients who had undergone cholecystectomy.\(^1\)\(^-\)\(^3\)

There are different technique for extraction of CBD stones, either by Endoscopic Retrograde Cholangio-pancreatography (ERCP), or surgically, by either an open or laparoscopic method.\(^4\)

Over the past two decades, the advancement in laparoscopic and endoscopic techniques has almost made open biliary surgery obsolete. Notwithstanding this, due to lack of training as well as equipment, many surgeons in the developing world are commonly required to perform open cholecystectomy and CBD exploration for choledocholithiasis. Therefore, open surgery is still a treatment of choice in many hospitals.

A successful transcystic extraction of Common Bile Duct (CBD) stones usually makes external biliary drainage unnecessary, and this approach is preferred whenever feasible. The transcystic approach, however, may be limited by stones too great in number or size and a cystic duct too small in diameter or implanted too low.\(^5\)

Open CBD exploration followed by T-tube drainage is a traditional surgical treatment for choledocholithiasis. Although it is true that the T-tube has been used and has proven to be a safe and effective method for postoperative biliary decompression, it is not exempt from complications, which occur in up to 10% of patients.\(^6\)\(^-\)\(^7\)

Primary closure of the CBD after exploration is not new. There are many reports, which support the direct closure of the duct immediately after exploration. With the help of a choledochoscope during surgery, direct visualization of the CBD is possible and retained stones are not a problem. In the authors' hospital, open CBD exploration is still the treatment chosen for CBD stones.

The aim of this study was to compare the clinical short-term and mid-term complications of primary closure of CBD versus T-tube drainage.

METHODOLOGY

The present study was done in Hepatobiliary Department of First Affiliated Hospital of Xinjiang Medical University,
Urumqi, China, from August 2009 to March 2013. A total of 250 patients with CBD stones were diagnosed by clinical presentation, physical examination, blood biochemical investigations, ultrasonography and Magnetic Resonance Cholangiopancreatography (MRCP). Out of 250 patients 28 underwent LCBDE (Laparoscopic Common Bile Duct Exploration) while remaining 222 underwent laparotomy. Of the 222 successfully treated patients, 74 underwent laparoscopic transcystic stone extraction and 148 required open CBD exploration.

The primary technique was open CBD exploration. The indications for this were diameter of CBD more than 0.8 cm, multiple or single stone, jaundice, pancreatitis, abnormal LFTs and the selection criteria for open cholecotony specified of failure of trans cystic exploration, multiple or single large stone which can not be approached through cystic duct.

The inclusion criteria in this study specified a patient more than 18-year of age. The exclusion criteria were patients who had CBD stricture, CBD malignancy or tumor, ampullary stenosis or tumor, intrahepatic duct stones, abnormal pancreatobiliary junction and acute pyogenic cholangitis. Informed consent for randomization to primary closure or T-tube drainage was requested of all patients; none refused. The 148 eligible patients were randomly assigned into two groups: primary closure group (n=72) and T-tube drainage group (n=76). Randomization was performed with the use of a computer-generated randomization schedule with blocks of 4 randomly assigned in numbers. In each block, 2 patients were assigned to the primary duct closure group and 2 patients were assigned to the T-tube drainage group.

All the operations were performed by a single group, and single surgeon (Pai Zula). All the patients underwent general anaesthesia.

After cholecystectomy, a supraduodenal cholecotony was done in the anterior surface of CBD 1 to 2 cm above supraduodenal portion. Then 5 mm flexible choledoscope (Olympus, Tokyo, Japan) was inserted into the CBD and maneuvered both proximally, and distally to visualize the location and number of stones. Any obvious stones were removed by either Randall ductal forcep or retrieval Dormia basket passed through the instrument channel of the choledoscope and removed the stones under direct vision. Then the intrahepatic duct and sphincter of oddi were inspected by choledochoscope. After confirmation of no residual stone, the Sphincter of Oddi was dilated by Bake’s dilator of 6 Fr caliber.

After complete clearance of the CBD, the patients were randomly assigned to primary duct closure or T-tube drainage. In the primary closure group, the cholecotomy was closed primarily with interrupted absorbable suture (6.0 vicryl), with the help of magnification loop glasses whereas in the T-tube drainage group, a latex rubber T-tube of appropriate size (16 - 20 Fr) was inserted into the CBD incision. After the tube had been positioned, the CBD incision was closed using interrupted sutures (4.0 or 5.0 vicryl) with the help of magnification loop glasses. Saline was flushed through the T-tube to rule out leakage.

In the end of the procedure, a subhepatic drain was placed in abdomen under the primary closure or T-tube closure. Patients resumed diet gradually. The abdominal drain was removed after 48 hours, if there was no evidence of bile leakage. Patients with T-tube drainage had the T-tube clamped on day 7. A postoperative cholangiogram was performed 4 weeks after the operation in outpatient clinic and the T-tube was removed if the cholangiogram was normal.

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 17. Continuous variable were described with mean and standard deviation, categorical data were described with percentages. Continuous variables were compared using Student’s t-test and proportions using the chi-square test or Fisher’s exact test. P-value < 0.05 was considered significant. Results were represented in tables.

**RESULTS**

In a total of 250 patients with CBD stone, removal was attempted during the study period, out of which 28 cases were dealt with laparoscopic common bile duct exploration. Of the remaining 222 patients, 123 underwent open transcystic approach and an open CBD exploration was performed on 148 patients. There were 76 (51.35%) patients randomly assigned to group-I (T-tube inserted) and 72 (48.64%) assigned to group-II (primary closure). There was no statistically significant difference in stone clearance, postoperative complications, time to removal of drain, diameter of CBD or stone number (sludge was excluded) between the two groups (Table I), but the hospital expenses, and postoperative hospital stay in primary closure group were statistically lower than that of T-tube drainage group.

There were 2 postoperative deaths: one in group-I (T-tube-related), and one in group-II. The death related to the T-tube was sudden and due to cardiac disease while the death related to primary closure group was due to breast carcinoma. Two patients required ICU (intensive care unit) admission due to cardiac problem. One or more biliary complications occurred in a total of 20 (13.51%) patients: 13 (17.10%) in group-I, and 7 (9.7%) in group-II (p=0.189, Table II). In group-I, 11 had a short-term complications, wound infection in 3 (3.94%) managed by antibiotics, 2 (2.63%) had a electrolyte
Table I: Demographic features, clinical presentation and follow-up of patients in both groups.

<table>
<thead>
<tr>
<th>Characteristics of patients</th>
<th>T-tube (n = 76)</th>
<th>Primary closure (n = 72)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>53.39 ± 12.6</td>
<td>55.04 ± 13.37</td>
<td>0.443</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>40 (52.6%)</td>
<td>45 (62.5%)</td>
<td>0.225</td>
</tr>
<tr>
<td>Male</td>
<td>36 (47.4%)</td>
<td>27 (37.5%)</td>
<td></td>
</tr>
<tr>
<td>Biliary colic</td>
<td>76 (100%)</td>
<td>72 (100%)</td>
<td>0.976</td>
</tr>
<tr>
<td>Icterus</td>
<td>29 (38.7%)</td>
<td>20 (27.8%)</td>
<td>0.162</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>12 (15.8%)</td>
<td>10 (13.9%)</td>
<td>0.745</td>
</tr>
<tr>
<td>Abnormal LFT</td>
<td>29 (38.5%)</td>
<td>20 (27.8%)</td>
<td>0.180</td>
</tr>
<tr>
<td>CBD diameter (mm)</td>
<td>11.08 ± 3.4</td>
<td>10.18 ± 2.2</td>
<td>0.059</td>
</tr>
<tr>
<td>Multiple stones</td>
<td>31 (40.8%)</td>
<td>22 (30.6%)</td>
<td>0.194</td>
</tr>
<tr>
<td>Single stone</td>
<td>26 (34.2%)</td>
<td>22 (30.6%)</td>
<td>0.910</td>
</tr>
<tr>
<td>Follow-up duration (months)</td>
<td>24.8 ± 12.15</td>
<td>25.4 ± 12.16</td>
<td>0.764</td>
</tr>
</tbody>
</table>

Table II: Comparison of short-term complications between T-tube and primary closure group.

<table>
<thead>
<tr>
<th></th>
<th>T-tube</th>
<th>Primary closure</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative complications</td>
<td>13 (17.10%)</td>
<td>7 (9.7%)</td>
<td>0.189</td>
</tr>
<tr>
<td>Minor bile leakage (&lt;100 ml)</td>
<td>2 (2.63%)</td>
<td>4 (5.55%)</td>
<td>0.367</td>
</tr>
<tr>
<td>Wound infections</td>
<td>3 (3.94%)</td>
<td>2 (2.77%)</td>
<td>0.694</td>
</tr>
<tr>
<td>Electrolytes imbalance</td>
<td>2 (2.63%)</td>
<td>0</td>
<td>0.166</td>
</tr>
<tr>
<td>Retained stone</td>
<td>1 (1.31%)</td>
<td>1 (1.38%)</td>
<td>0.976</td>
</tr>
<tr>
<td>T-tube displacement</td>
<td>2 (2.63%)</td>
<td>0</td>
<td>0.166</td>
</tr>
<tr>
<td>CBD hemorrhage</td>
<td>1 (1.31%)</td>
<td>0</td>
<td>0.329</td>
</tr>
<tr>
<td>Comparison of mid-term complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stricture</td>
<td>2 (2.63%)</td>
<td>0</td>
<td>0.166</td>
</tr>
<tr>
<td>Postoperative hospital stays (days)</td>
<td>8.97±1.62</td>
<td>5.34±1.25</td>
<td>0.001</td>
</tr>
</tbody>
</table>

n = number of patients.

restitution (hypokalemia) in hospital duration and managed by electrolyte replacement, 2 (2.63%) had minor bile fistula around T-tube but it ceased within 1 week by percutaneous peritoneal drain and T-tube drainage. In 2 patients there was displacement of T-tube at day 5 and 7 subsequently but there was no symptoms of bile fistula and recovered normally. One had retained intrahepatic duct stone, it was removed through T-tube tract by the use of cholecodoscope. In mid-term complications, 2 (2.63%) patients had a T-tube related bile duct stricture, reoperated and done Roux en Y (hepaticojejunostomy). In group-II, 9.7% patients had postoperative complications, all of whom were short-term complications, minor bile leakage in 4 patients (5.5%) but it was mild type of biliary leakages and subsided by itself within 3 - 7 days, wound infection in 2 (2.77%) and retained stone in one patient which was removed 3 months later by ERCP. In group-II, no patient had bile duct stricture in follow-up period. The postoperative hospital stay was 8.97 ± 1.629 days for T-tube patients and 5.34 ± 1.25 days for primary closure group with p < 0.001.

The total follow-up rate was 100%, and the follow-up period was 24.8 ± 12.15 months for T-tube and 25.4 ± 12.16 for primary closure group.

DISCUSSION

Traditionally, explorations of the common bile duct both by open surgery and laparoscopically has been closed by the placement of a T-tube. In the era of minimally invasive procedures, open laparotomy for CBD exploration may still be the choice in some hospitals in developing countries. But with the development in field of medical instruments and new medical techniques such as LCBD and choledochoscopy, magnifying surgical glasses and sutures the trend toward primary closure are increasing. The four requirements for a safe and successful primary closure of common bile duct are patent Vater's ampulla, complete removal of all intraductal calculi, absence of pancreatic pathology and meticulous suture of the duct.9,10

There are many possible complications associated with the use of T-tubes such as biliary leakage, retained stones, retained T-tube fragment, inflammatory polyps, sepsis, tube dislodgement, biliary fistula, bile peritonitis, bile duct stricture and an overall higher mortality.11,12 Despite this, T-tubes are still in vogue largely due to the theoretical advantages of providing temporary drainage during the period of ampullary edema and the possibility of retrieving a residual stone via the T-tube tract.13 This randomized and prospective study shows that hospital stay in the T-tube group (3 - 7 in primary group vs. 7 - 12 in T-tube) was longer than primary closure group which is in agreement with studies conducted by Zhang et al., Ambreen et al. and Kyoun Tah Noe.14-16 It was unacceptable to the majority of these patients to go home with a functioning T-tube, and prolonging the hospital stay would influence the total hospital expense, coupled with the increased complications. Dehydration in patients with functioning T-tubes at home were not suitable for discharge, and it kept the patients with the T-tube in the hospital until after the T-tube was clamped. Patients require extra hospital visits for T-tube cholangiogram and they need prolonged hospital stay which further worsens their economical conditions.

In T-tube group, wound infections, electrolyte imbalance, displacement, hemorrhage related to T-tube, biliary fistula around T-tube were more common. The main drawback of T-tube was that it was uncomfortable, require continuous management, and it restricts the patient's activity because of risk of dislodgement.17 It also affects the patient's life quality.18

Retained stones following CBD exploration remained a significant complication and it was reported in upto 10% of cases in relevant studies.19 The rate of retained stones in this series was 1.38% in both groups due to the meticulous use of the choledochoscope and repeated confirmation of duct clearance before duct closure. In T-tube group, only one patient reported with the retained stones during cholangiography and it was...
removed through the sinus tract of the T-tube using the choledochoscope.

In mid-term complications, stricture was reported as a long-term complication after T-tube removal in 2 patients (2.77%). Lateral distortion in the shape of the bile ducts occurred in a considerable number of patients with an indwelling T-tube such that an angle measured between the proximal and distal parts of the bile duct, decreased.20-22

In primary closure group, the postoperative hospital stay was shorter, and the hospital expenses were also lower than in the T-tube group. It has no effect on patient's life quality after discharge from hospital. Bile leakage following primary closure was the main criteria for assessing the success and safety of this procedure. In this study, 4 (5.5%) patients had bile leakage which was comparable to bile leakage in other reports as Haider et al. (7.8%).10 Out of these 4 cases, 3 were reported in the initial 1.5-year of our experience (4.16% versus 1.38% in the subsequent 2.5 years), which suggests that the risks was reduced with growth in experience due to the application of more advanced tool as the magnifying loop glasses and modifications in sutures. The biliary leakage was relatively more common in primary closure group probably due to high pressure in CBD. Intraoperatively, for complete clearance of CBD and ampulla we used Bakes dilator, choledochoscope and dormia basket which causes irritation and increases the risks of edema around the CBD wall which results in mild obstruction and postoperative minor biliary leakages in primary group. Nevertheless, primary duct closure was not suitable for all patients who had undergone laparoscopic choledochotomy. The use of primary closure was limited in the treatment of patients with severe acute biliary pancreatitis, acute pyogenic cholangitis, or ampullary stenosis because they required CBD decompression and drainage or other preferable therapeutic options. A CBD diameter that was too small (< 8 mm) might be a contraindication for primary closure because smaller diameter might increase the risk of bile duct stricture.23

The authors agree with Decker et al. that hospital stay is not a major criterion for assessing the outcome of surgery because discharge policies differ among institutions.5 Over the period of time, T-tube drainage was used less frequently as the approach changed from routine to a very selective use. To minimize postoperative complications, the indications for T-tube must be strictly followed, such as CBD stones secondary to intrahepatic duct stones or if there is undefined residual stone in the intrahepatic or extrahaepatic ducts on intraoperative cholechochoscopy; vague patency of the Oddi’s Sphincter or failure to pass cholechochoscope and Bakes dilator through Vater's ampulla due to edema or obstructed stones; acute suppurative cholangitis with severe edema of the CBD wall. T-tubes were still preferred, particularly in gastrectomy patients because they maintain an endoscopic access (required to deal with residual stones or other complication).24

There was a low complication rate in the primary closure group in 7 (9.72%) patients. Bile leakage was more common in primary closure group. On the other hand, most complications in the T-tube group were related to the use of the T-tube. Therefore, postoperative primary closure should be preferred in most cases after CBD exploration. T-tube decompression of the biliary tree should be preferred in selected cases with undefined intrahepatic stones and vague patency of biliary channel. In addition, the use of intraoperative cholechochoscopy and magnifying loop glasses can also avoid overlooked biliary problems.

CONCLUSION

Complications in primary group were relatively lower than that in T-tube group but there was no significant statistical difference. So during the open surgery for CBD stones, primary closure of CBD appeared safe and effective with shorter hospital stays and less complications. The use of T-tube decompression should be preferred in selected cases with undefined intrahepatic stones and vague patency of biliary channel.

REFERENCES


