

A COMPARATIVE STUDY OF T-TUBE VERSUS ANTE GRADE STENTING OF CBD AFTER OPEN CBD EXPLORATION FOR CHOLEDOCHOLITHIASIS

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ABSTRACT

with biliary stent insertion.

Background: Choledocholithiasis is the second most common complication of cholelithiasis¹ and causes non-malignant biliary obstruction.²

Once CBD stones are confirmed, they were extracted out as early as possible to prevent complications. ^{3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21} CBD stones can be removed by endoscopic retrograde cholangiopancreatography (ERCP), or surgically, by an open or laparoscopic method but Open exploration is the principal method practicing from 100 years. ⁵ After choledochotomy, it can further be managed either by primary closure of CBD, by T-tube drainage or by primary closure

Aim: To compare the post-operative outcomes in patients of choledocholithiasis with or without cholelithiasis who underwent open CBD exploration followed by T-tube insertion or biliary stent placement.

Study design: This was randomized comparative study conducted on 24 diagnosed patients of choledocholithiasis with or without cholelithiasis in the Department of Surgery, Ajmal Khan Tibbiya College, F/O Unani Medicine AMU, Aligarh during January 2020 to October 2022. Patients were divided in two groups (Group A and Group B), each having 12 patients.

Methods: selected patients in the study were underwent CBD exploration for choledocholithiasis. out of which 12 patients in Group A underwent CBD exploration followed by T-tube placement and 12 patients in Group B underwent biliary stent insertion after open CBD exploration.

Result: There were 22 females and 2 males out of 24 patients enrolled in the study. Mean operating time was significantly less in biliary stent group as compared with T-tube group (50.17+6.534 & 59.08+7.179, 'p'=0.0043 and 't'=3.182). duration of post-operative hospital stay was less in group B as compared with group A (7.167+1.850 & 16.08+1.929 where 'p'= 0.001 and 't'=11.56) which was statistically highly significant. wound infection was observed in 5 patients (41.6%) of T-tube group and 3 patients (25%) of biliary stent group. There were no post-operative complications in our study in both the groups.

Conclusion: primary closure with biliary stent is better than T-tube placement after common bile duct exploration in terms of operating time, post-operative hospital- stay, post-operative complications, patient's satisfaction, quality of life and early return to normal activity.

INTRODUCTION

Choledocholithiasis is the second most common complication of cholelithiasis¹ and causes non- malignant biliary obstruction.² These stones are identified in 10-15 % of patients undergoing surgery for symptomatic gallstone disease¹0,20.

Traditionally CBD stones were diagnosed during intra-operative cholangiography. With the advancement in imaging techniques such as Ultrasonography, Magnetic Resonance Cholangiopancreatography (MRCP), Endoscopic retrograde

Cholangiopancreatography (ERCP) and Endoscopic Ultrasound that allows more accurate methods for identifying CBD stones. ¹⁰

CBD stones will require surgical or endoscopic removal to relieve biliary obstruction and to prevent complications such as Biliary colic, obstructive jaundice, suppurative cholangitis and Pancreatitis. ¹⁰

CBD stones can be removed by endoscopic retrograde cholangiopancreatography (ERCP), or surgically, by an open or laparoscopic method 3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21

Open exploration was the principal method practicing from 100 years. Many surgeons still performing this procedure because lack of skilled and experienced laparoscopic surgeons and unavailability of the equipments.⁵

After choledocholithotomy, it can further manage either by primary closure of CBD, or by T-tube drainage or by primary closure with biliary stent insertion.

In our study we assess the efficacy, safety and post-operative outcomes in patients of choledocholithiasis undergoing choledocholithotomy followed by T-tube placement or biliary stent placement .

Materials and Methods

It is a randomized interventional clinical and comparative study carried out in the department of surgery, Ajmal Khan Tibbiya College, AMU, Aligarh entitled "Comparative study between T-tube versus antegrade stenting of CBD after open CBD exploration for choledocholithiasis" during January 2020 to October 2022. There were 24 Patients enrolled in the study who randomly divided into two groups.

- Group A (12 patient) received T-tube after open CBD exploration for choledocholithiasis.
- Group B (12 patients) received CBD stent after open CBD exploration for choledocholithiasis.

Patients were evaluated on the basis of history, clinical features (Pain, jaundice, fever, nausea/vomiting) physical examination (icterus, tenderness, guarding &rigidity, palpable lump) and biochemical (Hemogram, RBS, LFT, RFT, Triple Test, BT, CT) as well as radiological parameters (X-ray chest, USG abdomen, MRCP, ERCP etc). and then selected for the procedure according to the inclusion and exclusion criteria of the study.

- Inclusion criteria: Patients age >18 years, Patients with either gender, Hyperbilirubinemia in presence of gallstone disease, patients of cholelithiasis with choledocholithiasis or choledocholithiasis alone and confirmed by USG, ERCP, MRCP, CBD diameter >/=8 mm, Patients willing to enroll in the study.
- Exclusion criteria: Patients <18 years, Patients with cholangitis, pancreatitis, pancreatic pathology causing jaundice, renal failure, malignancy and evidence of ampullary obstruction, Bile duct stenosis.

All the selected patient underwent open choledocholithotomy with or without cholecystectomy and decision were taken randomly per-operatively for T-tube or biliary stent placement. Sub hepatic drain was placed in all patients for 24-48 hours.

Patient were evaluated on the basis of post-operative assessment including pain, fever, vomiting, tachycardia, hypotension, icterus, bile duct injury, biliary leakage, T-tube dislodgement, pancreatitis, cholangitis, retained CBD stones, wound infection, duration of hospital stay, re admission and re operation were observed and recorded.

T-tube was removed following T-tube cholangiography 2 weeks after surgery where as biliary stent was removed endoscopically after 4 to 6 weeks.

LFT and USG abdomen was done to rule out post-operative jaundice and any retained stone in CBD respectively.

All the patients of both groups follow up post-operatively after 2 weeks, 4 weeks and 3 months.

I.OBSERVATION AND RESULT

This was randomized comparative study conducted on 24 diagnosed patients of choledocholithiasis with or without cholelithiasis in the department of Surgery, Ajmal Khan Tibbiya College, F/O Unani Medicine AMU, Aligarh during January 2020 to October 2022. Patients were divided in two groups (Group A and Group B), each having 12 patients.

Out of which 12 patients in Group A underwent CBD exploration followed by T-tube placement and 12 patients in Group B underwent biliary stent placement after open CBD exploration for choledocholithiasis.

It was observed in our study that female patient in both groups were more as compared to male patient 22 females and 2 males out of 24 patients enrolled in the study.

Pre-operative complaints was abdominal pain at right hypochondriac region which was present in all patients (100%) of both the groups. Jaundice was present in 4 patients (33.3%) of each groups. Fever was present in 1 patient (8.3%) of group A and 2 patients (16.6%) of group B.

Vomiting was present in 4 patients (33.3%) of group A and 5 patients (41.66%) of group B.

Pre-operative signs were tenderness was present in 4 patients (33.3%) in group A and 2 patients (16.66%) in Group B. Guarding and rigidity was present in 1 patient (8.3%) of each group. Palpable lump was present in 1 patient (8.3%) of group A and 0 (0%) in group B.

The mean of total bilirubin before surgery was 2.599 mg/dl in patients of Group A which reduced to 1.226 mg/dl after surgery with 't' = 1.537, 'p' = 0.1526, which shows non -significant difference. While in Group B, mean of total bilirubin preoperatively was 1.568 mg/dl that reduced to 0.8958 mg/dl post-operatively with t=1.727, p=0.1121 which also shows non-significant difference, liver enzymes also show non-significant difference in both groups.

On post-operative assessment, we found epigastric pain were present in 6 patients (50%) of Group A and 4 patients (33.3%) of group B. Vomiting in 7 patients (58.3%) of Group A and 2 patients (16.6%) in Group B. Fever was present in 3 patients (25%) of Group A and no patient in Group B

Operating time in (Group A Mean \pm SD 59.08 \pm 7.179 , Group B Mean \pm SD

50.17±6.534 where 'p'= 0.0043, 't'= 3.182) which shows significant difference between both the groups. the mean duration of post-operative hospital stay in (group A Mean±SD 16.08±1.929, group B Mean±SD7.167±1.850 where 'p'=

16.08±1.929, group B Mean±5D7.167±1.850 where 'p'= <0.0001,'t'=11.56) which shows significant difference between both the group.</p>

No patient in our study were experienced post-operative complications (CBD injury, Cholangitis, pancreatitis, biliary leakage, bile duct stenosis) in both the groups.

Wound infection was observed in 5 patients (41.6%) of T-tube group and 3 patients (25%) of biliary stent group.

T-tube was removed following post-operative T-tube cholangiography after 2 weeks

CBD stent was removed endoscopically after 4-6 weeks.

DISCUSSION

In the laparoscopic era, laparoscopic common bile duct exploration (LCBDE) is a cost effective, efficient and minimally invasive method for treating choledocholithiasis²². But due to lack of experience in laparoscopic surgery and skilled endoscopists and unavailability of equipments in small hospitals, open surgery is still a treatment of choice⁵.

After open CBD exploration, it can further manage either by primary closure of CBD, by T-tube drainage or by primary closure with biliary stent placement 10

Hence the present study was designed to evaluate the feasibility, safety, efficacy and post-operative outcomes of primary closure over CBD stent in comparison to T-tube placement after open CBD exploration in patients of choledocholithiasis. To achieve this purpose, a randomized study was carried out in the department of Surgery, Ajmal khan Tibbiya College and Hospital, Aligarh Muslim University, Aligarh.

24 Patients were included in the study and were divided into two groups, Group A (T-tube insertion, n=12) and Group B (stent placement, n=12)

Our study reveals that female patients dominate as only one male patient were enrolled in each group.

According to Schwartz's Principles of Surgery, gallstone disease is three times more common in women than men. 23

In our study we observed that the liver function test is improved more quickly in patients of biliary stent group as compared to T-

tube group as mentioned in many studies. The significant difference was reported by Abd El Wahab A.E et. Al^3 and Ambreen M et al^5 with p value 0.003 and 0.01 respectively.

In our study, it was statistically proved that biliary stent requires less operative time than T-tube placement (mean Group A 59.08 min, Group B 50.17 min) Yeshwant Ganpatrao K et al 22 reported the mean operating time (105min in biliary stent , 124 min in T-tube drainage), Gyalpo M et al 10 noted mean operating time in (stent group 121.6 min and 136.2 min in T-tube group). We infer from the above observations that placement of T-tube significantly affects the operating time. The operating time for primary closure over a stent was better in our study than Gyalpo M et al 10 (121.6min), Kim and Lee 16 (mean 188.3 minutes), Swamygowda et al 19 (average 146 minutes), Yeshwant Ganpatrao K et al 22 (mean 105 minutes).

On the basis of post-operative assessment, we found in our study that epigastric pain was present in 6 patients (50%) of group A and 4 patients (33.3%) in group B. Vomiting in 7 patients (58.3%) of group A and 2 patients (16.6%) in group B. Fever was present in 3 patients (25%) of group A and no patient in biliary stent group. Icterus was present in 3 patients (16.6%) and 1 patient (8.3%) of group A and group B respectively. Tachycardia and hypotension were absent in both the groups.

Gyalpo T¹⁰ reported post-operative pain and vomiting present in 1(5%) patient of stent group and 3(15%) patients in T-tube group which is less than our study. Abd El Wahab A.E et al³ reported 1 patient had post-operative jaundice in T-tube group while no patient in stent group developed jaundice. On comparing post-operative clinical parameters which was mentioned above implies that patient in CBD stent group developed less symptoms as compared to T-tube group.

In our study mean duration of post-operative hospital stay (group A 16.08 days, group B 7.16 day 'p'= <0.0001). Gyalpo T et al 10 reported post-operative hospital stay (7.05 days for stent group and 9.5 days in T-tube group). Abd El Wahab A.E et al 3 reported post-hospital stay (stent Group 6.40 days, T-tube Group 22.80 days) Ahmad omar M et al 18 reported (3.9 days in T-tube and 2.9 days in biliary stent group), Xiao LK 24 reported (5.62 days in stent group ,7.79days in t-tube group). Sunil kumar A et al 25 reported (7.63days in stent group, 13.6 days in T-tube group). Yeshwant ganpatrao K 22 (7 days in stent group and 10 days in T-tube group). Amit jain et al 26 reported (5 days in stent group , 8 days in T-tube group). Perez G et al 27 reported (6.8 days in T-tube group and 5.2 days in biliary stent group). Kim E.K et al 16 , Nathonson L.K et al 28 , Isla A.M et al 12 also reported short hospital stay in biliary stent group as compared with T-tube group.

The shorter hospital stay for the biliary stent group in our study may be attributed to many factors as less postoperative pain and analgesia requirement, less postoperative complications, faster return to normal bilirubin level, rapid return to normal activity. No patient in our study were experienced post-operative complications (CBD injury, Cholangitis, pancreatitis, biliary leakage, bile duct stenosis) in both the groups. Abd El Wahab et al³ reported post-operative complications (50% in T-tube group while no complication is stent group). Sunil kumar A et al^{25} reported overall post-operative complications was 20% in biliary stent verses 50% in T-tube group. Amit jain et al²⁶ reported postoperative biliary leakage in two patients (6.6%) of T-tube group and one patient (3.3%) of stent group. Swamygowda et al¹ observed post-operative complications (one in stent and six patients in T-tube). Xu Y et al²¹ and Mir I.S et al²⁹ reported one patient of biliary leakage in T-tube group while no patient in stent group.

Khalaf A.M et al¹⁵ observed post-operative complications higher in T-tube group which includes acute pancreatitis (two patients), cholangitis (two patients) and in one case accidental displacement of T-tube was noticed while only one patient in biliary stent group presented biliary peritonitis immediately after operation. Lyon M et al¹⁷ reported biliary leakage (11.2% in T-tube, 0% in biliary stent group).). Prez G et al²⁷ reported (30% in T-tube, 13% in stent group). From the above comparisons we refrain that post-operative complications were less in stent group as compared with T-tube group.

In present study, wound infection were observed in 5 patients (41.6%) of T-tube group and 3 patients (25%) of biliary stent group.

Wound infection reported in other studies Hesham A.R¹¹ (reported 26.6% in T-tube, 13.3% in stent), Gyalpo T¹⁰ reported (40 % in T-tube, 5% in biliary stent), Qaiser Jalal¹⁴ (reported 22% in stent placement patients) which is similar to our study. Swamygowda¹⁹ reported (9% in biliary stent and 13% in T-tube) which is less than our study. Gyalpo T et al¹⁰ reported T-tube site infection in 3 patients (15%) and Perez G²⁷ reported two patients of T-tube tract infection which is more than our study in which only one patient experienced T-tube site infection and no patient experienced T-tube tract infection.

In our study, there is no need of readmission and reoperation in both groups. Our study in terms of re-admission and re-operation is better than Omar MA ¹⁸ reported (readmission: 3 in T-tube, 0 in Stent group), Gyalpo T¹⁰ reported (readmission: 1(5%) in stent, 4 (20%) in T-tube group), Qaiser jalal ¹⁴ reported four patients (18%) required re-admission in stent placement patients. Swamygowda ¹⁹ reported (readmission: one in T-tube, no in biliary stent, re-operation: one in T-tube, no in biliary stent). Khalaf AM ¹⁵ reported re-operation required in one patient of biliary stent group while no patient required re-operation in T-tube group. Perez G²⁷ reported (re-admission: 3 patients (7%) in T-tube, 2 patients (5.4%) in biliary stent). Nathonson LK²⁸ reported 4 patients (9.7%) required re-operation in choledochotomy group while 2 patients (4.4%) in ERCP group require re-operation.

CONCLUSION

Common bile duct stones require extraction to avoid complications. There is no evidence given in the literature that one procedure is superior to other. It was observed in our study that primary closure over biliary stent is better than T-tube placement after common biles duct exploration in terms of operating time, post-operative hospital stay, post-operative complications, patients satisfaction, quality of life, early return to normal activity.

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