



Prospective Randomized Study of T-Tube versus Biliary Stent for Common Bile Duct Decompression after Open Choledochotomy

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Abstract. The T-tube has been the alternative of choice for decompression following common bile duct (CBD) exploration. The development of laparoscopic surgery has suggested using a biliary stent as an alternative to the T-tube following choledochotomy. The purpose of this prospective randomized study was to compare clinical results obtained from patients who underwent open CBD exploration using a biliary stent versus those from patients with a T-tube for decompression. Between September 2000 and June 2002 a total of 81 patients were randomly assigned to a biliary stent or a T-tube as the decompression method following choledochotomy. An open CBD exploration was performed when CBD stones were suspected, in both elective and emergency settings. The length of the postoperative hospital stay was 6.8 ± 4.7 days for patients with the T-tube and of 5.2 ± 3.3 days for patients with the biliary stent ($p = 0.19$). Postoperative complications were observed in 13 patients (30%) with the T-tube and in 4 patients (11%) with the biliary stent ($p = 0.03$). One patient with a biliary stent was reoperated because of an intraabdominal abscess, and another patient was reoperated because of biliary peritonitis following T-tube removal. Three patients (7%) with a biliary stent and one patient (3%) with a T-tube were rehospitalized. There were no deaths. The T-tube and biliary stent were removed 27.1 ± 10.8 days and 34.9 ± 12.9 days after surgery, respectively ($p = 0.24$). The biliary stent is a safe alternative to the T-tube as a biliary decompression method following an open CBD exploration.

In Chile the prevalence of gallbladder stones is close to 5% in the general population [1]. Of all the patients with cholelithiasis, about 10% to 15% also have choledocholithiasis. There are basically two extraction methods for treating patients with common bile duct (CBD) stones endoscopically, using endoscopic retrograde cholangiopancreatography (ERCP), or surgically, using either open or laparoscopic surgery.

The T-tube has been the method of choice for CBD decompression following choledochotomy. It also permits direct chol-

angiography, which favors formation of a fistulous tract allowing instrumentalization and extraction of eventual residual stones [2]. Although it is a safe and effective method, the T-tube produces complications in up to 10% of patients. Some of these complications are serious, such as bile leak resulting from T-tube displacement or early removal without adequate tract formation, tract infection, or acute renal failure from dehydration due to inadequate water ingestion or very high outflow, particularly in elderly patients. In addition, having a bile drainage tube in place for at least 3 weeks causes significant discomfort in patients and delays their return to work [3–8].

A good alternative to CBD decompression is the use of internal biliary stents, widely used in endoscopic procedures and recently also as an alternative to the T-tube during laparoscopic choledochotomy. Several studies have demonstrated the usefulness of these stents and their advantages with respect to the T-tube, as they are associated with fewer complications and avoid the discomfort of the T-tube; there are as yet, however, no comparative controlled clinical studies comparing the use of the T-tube and the biliary stent during open choledochotomy for CBD decompression [9–12].

In a study carried out by our department using a canine choledocholithiasis model with open choledochotomy, it was shown that using a stent for internal bile drainage is as effective as the T-tube for CBD decompression [13]. Continuing along this line, a prospective randomized study was begun on patients who had open surgery with CBD exploration because of choledocholithiasis, using biliary endoprotheses or a T-tube as a postoperative decompression method. The aim of the study was to compare clinical short-term results obtained from patients who underwent open CBD exploration using a biliary stent versus a T-tube as a decompression method [14].

Material and Methods

The present study was done jointly by two university hospitals in Chile, the Hospital Clínico de la Pontificia Universidad Católica

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de Chile and the Hospital Clínico San Borja Arriarán. The research was approved by the ethic committees of both hospitals and supported by a project of the Division of Surgery of the Pontificia Universidad Católica de Chile.

Between September 2000 and June 2002 patients with gallbladder stones who had either elective or emergency surgery and either open or converted laparoscopic surgery were selected for the study. From this group, patients who underwent open CBD exploration due to choledocholithiasis were selected. The presence of stones in the CBD was established prior to surgery by abdominal ultrasonography (US), ERCP or cholangiographic magnetic resonance imaging (CMRI) or intraoperatively by cholangiography, flexible choledochoscopy, or US.

Patients were randomly assigned to the use of a biliary stent (Zimmon biliary stent, Wilson-Cook Medical Winston-Salem, NC, USA) (Fig. 1) or a T-tube (T-tube/latex; Forges, Kosa, Corp., Tokyo, Japan), following CBD exploration. For patients assigned to the use of a biliary stent, after the CBD stones were extracted the patients were subjected to exploration of the distal and proximal bile duct with a flexible choledochoscope (Olympus URF-P3) to verify the absence of residual stones. A guidewire was then introduced through the longitudinal choledochotomy as far as duodenum, using radioscopy to confirm its location. Next, the stent (5F or 6F depending on the CBD diameter) was advanced through the guide, positioning the distal end in the duodenum and the proximal end in the biliary tract. Finally, the guide was extracted, as shown in Figure 2.

For patients in the T-tube group, cholangiography was performed after the T-tube (12F, 14F, or 16F) was installed to check for residual stones and bile leak.

The CBD was closed with interrupted absorbable sutures (Vicryl 3-0 or 4-0; Johnson & Johnson, Sao Paulo, Brazil) in both groups. Intraoperative drainage was employed in all patients. It was removed before discharge from the hospital.

Patients were periodically assessed during the postoperative period until hospital discharge. All patients of the T-tube group were discharged with open drainage. Afterward they were controlled weekly for 30 days following hospital discharge. After this second control, cholangiography was performed through the T-tube, if it was normal, the T-tube was removed. During this same period, patients in the biliary stent group underwent upper gastrointestinal endoscopy to remove the stent.

Continuous variables were compared using Student's *t*-Test and proportions using the chi-squared test with Fisher's exact test. The differences were considered significant at $p < 0.05$.

Results

A total of 81 patients were included in this study, 44 assigned to the T-tube decompression group and 37 to the biliary stent group. The presence of CBD stones was confirmed in 62 patients (77%). The distribution of patients in each group with respect to age, sex, type of surgery, and total bilirubin and alkaline phosphatase levels were similar in the two groups, as shown in Table 1.

There were no deaths in this study. Postoperative complications were observed in 13 patients (30%) of the group assigned to the T-tube group and 4 patients (11%) assigned to the biliary stent group ($p = 0.03$) Table 2.

Three patients (7%) of the T-tube group had to be readmitted, one of whom was reoperated owing to biliary peritonitis after T-

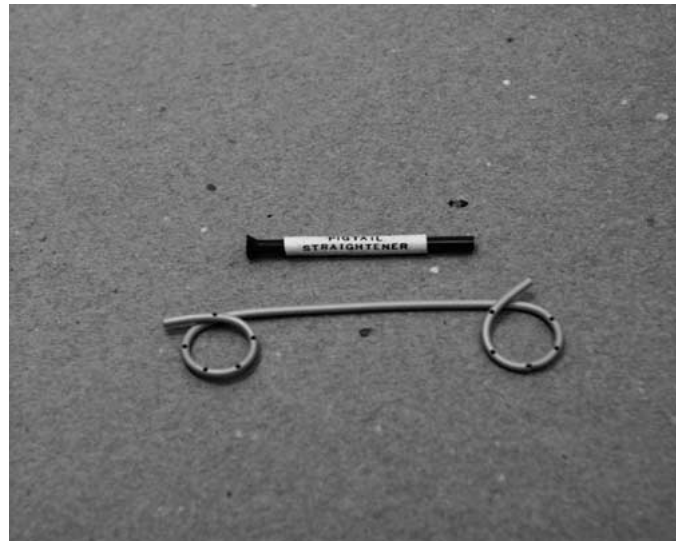


Fig. 1. Model of the biliary stent (Zimmon biliary stent from Wilson-Cook Medical).

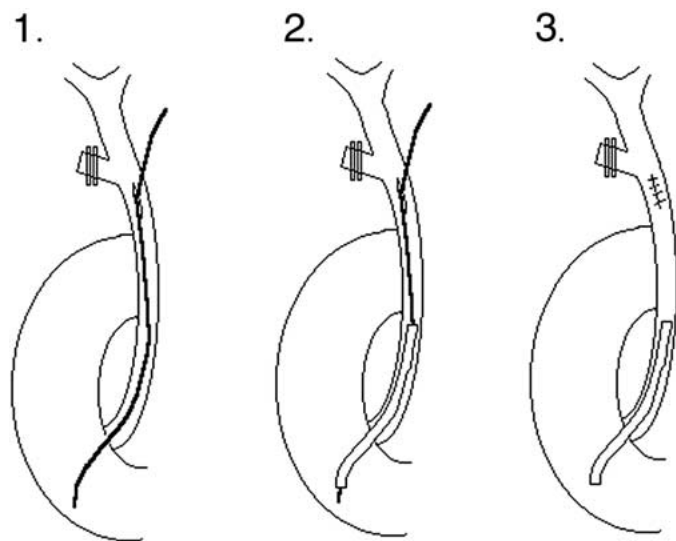


Fig. 2. Biliary stent installation. 1. A guidewire is introduced through the choledochotomy and is inserted until it reaches duodenum. 2. The stent is advanced through the guide, positioning the distal end in the duodenum and the proximal end in the biliary tract. 3. The guide is extracted.

tube removal. The other two were readmitted because of severe dehydration as a result of high outflow from the T-tube (in the absence of residual CBD stones) in one and the other due to intense pain following T-tube removal. Both patients were resolved after medical treatment. Among the patients with a biliary stent, one was reoperated because of a postoperative intraabdominal abscess and the other patient with a diagnosis of acute pancreatitis, who recovered with medical treatment. Two patients developed an infection of the T-tube tract, and in three patients residual CBD stones were observed, which were resolved by percutaneous extraction. In one patient the biliary stent was found completely inside the CBD and could not be extracted even after two ERCPs. The patient, however, is currently in good

Table 1. Characteristics of patients.

Characteristics of patients	T-tube (n = 44)	Biliary stent (n = 37)	<i>p</i> *
Age (years) mean ± SD	55.0 ± 16.3	56.9 ± 18.7	0.63
Sex			
Male	34 (77%)	28 (76%)	0.99
Female	10 (23%)	9 (24%)	
Surgery			
Open	18(41%)	21 (57%)	
Laparoscopy converted	26 (59%)	16 (43%)	
Settings			
Elective	40(91%)	34 (77%)	0.99
Emergency	4(9%)	3(23%)	
Total bilirubin (mg/dl)	2.2	1.9	0.58
Alkaline phosphatase (IU/dl)	308	454	0.16

n: number of patients. Gender and type of surgery are shown as the absolute number and percent. Total bilirubin and alkaline phosphatase are shown as the mean.

*Result of Student's *t*-test or the χ^2 test.

Table 2. Surgical results.

Surgical result	T-tube	Biliary stent	<i>p</i> *
Postoperative complications	13 (30%)	4(11)	0.03
Reoperation	1	1	NS
Postoperative stay (days), mean ± SD	6.8 ± 4.7	5.2 ± 3.3	0.19
T-tube or biliary stent removal (days), mean ± SD	27.0 ± 10.8	22.9 ± 12.9	0.24
Readmission	3 (7%)	1 (3%)	0.62

Result of Student's *t*-test or the χ^2 test.

condition and asymptomatic (Table 3). The postoperative hospital stay was 6.8 ± 4.7 days for T-tube patients and 5.2 ± 3.3 days for biliary stent patients (*p* = 0.19). The T-tube and biliary stent were removed 27.1 ± 10.8 and 34.9 ± 12.9 days after surgery, respectively (*p* = 0.24).

Discussion

Since its description, the T-tube has been the method of choice for CBD decompression following choledochotomy for years. Although it is true that the T-tube has been used and proven to be a safe, and effective method for postoperative biliary decompression, it is not exempt from complications, which are present in up to 10% of patients [3].

In this scenario the use of biliary internal drainage or a stent, widely used during endoscopic procedures, has emerged as an alternative to the T-tube. Once its utility was proven in an animal model, we set out to test its use and efficacy in a multicenter, controlled clinical trial [13].

To validate this method, patients operated on by either open surgery or converted laparoscopic surgery were included, as well as those who underwent emergency or elective surgery. In our study there were no significant differences between the groups.

In this study, the method for stent removal was through upper gastrointestinal endoscopy and not associated with ERCP, as has been described elsewhere [12]. This is possible only if choledochoscopy is available to ensure an absolute absence of CBD stones. Performing ERCP to remove the stent probably increases the morbidity rate as well as the cost. It is interesting to note the high frequency of complications in the T-tube patients with re-

Table 3. Postoperative complications.

Complication	T-tube	Biliary stent	<i>p</i> *
Total	13(30%)	4(11%)	0.03
T-tube wound infection	2	—	
Retained CBD stones	3	—	
Biliary peritonitis after T-tube removal	1	—	
Severe dehydration/pain	2	0	
Biliary stent retention	—	1	
Acute pancreatitis	0	1	
Intraabdominal abscess	0	1	
Wound infection	2	1	
Wound hematoma	1	0	
Pneumonia	2	0	

Result of Student's *t*-test

spect to other series [3]. This could be explained by our better recording of postoperative complications, as this was a prospective study compared with most of the other studies, which were retrospective. As a result, minor and later complications, such as wound hematomas or T-tube tract infections assessed in ambulatory settings, were recorded in our study with greater precision. Three patients (6.8%) had retained CBD stones in the T-tube group despite the fact that they had had a normal intraoperative cholangiogram. This may be explained by misinterpretation of the intraoperative cholangiogram, where air bubbles can mimic stones. In addition, choledochoscopy was not performed in this group, in contrast to the stent group. Choledochoscopy probably is more accurate than intraoperative cholangiography performed through the T-tube for diagnosing CBD stones. Under these conditions a statistically significant difference can be seen regarding the frequency of postoperative complications in the two groups, which was higher in the T-tube group.

Regarding complications that can be exclusively attributed to the postoperative decompression method, one patient in the biliary stent group experienced stent retention. It was not possible to remove it using ERCP, and it was decided to leave it in place. He remains asymptomatic more than 2 years following the operation. Another patient from the same group was subjected to cholecystectomy and CBD exploration after recuperation from acute pancreatitis. This patient was discharged in good condition, although readmission was needed because of a new episode of acute pancreatitis. It is difficult to determine what role the stent played in the development of this new episode, although no other causes of acute pancreatitis were identified in this patient.

It is important to note that there were no complications regarding endoscopic removal of the biliary stent, whereas there were at least two complications related to T-tube removal. One patient developed biliary peritonitis, probably as a result of T-tube tract fracture or incomplete tract development, despite of having complied with the established waiting periods before removal.

The use of T-tube requires postoperative cholangiography before its removal. We found that costs were equivalent in terms of the expenditure needed for performing upper gastrointestinal endoscopy to remove the stent. In conclusion, we believe that the biliary stent is as safe as the T-tube for decompression after CBD exploration.

Acknowledgement

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