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# Retrospective Clinical Study of the Effects of T-Tube Placement for Bile Duct Stricture

Authors' Contribution:

Study Design A  
Data Collection B  
Statistical Analysis C  
Data Interpretation D  
Manuscript Preparation E  
Literature Search F  
Funds Collection G

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**Background:** T-tube placement in the common bile duct (CBD) is a surgical alternative to bile duct reconstruction in cholecystectomy for cholecysto-choledocholithiasis, or gallstones. The aim of this retrospective clinical study was to investigate the incidence of late complications of T-tube placement.

**Material/Methods:** Retrospective review identified 35 patients who had T-tube placement during cholecystectomy. Clinical data were collected on surgical indications, patient demographics, and clinical symptoms. Ultrasound (US) was used to measure the diameter of the common bile duct (CBD), intrahepatic ducts, and presence or absence of stones in the CBD. Data from laboratory investigations included the aspartate aminotransferase-to-platelet ratio index (APRI), which was used as a non-invasive method to evaluate both cholestasis and liver fibrosis.

**Results:** Of the 35 patients included in the study, 33 (94.3%) underwent open cholecystectomy, CBD exploration, and T-tube placement due to cholecysto-choledocholithiasis. The remaining two patients (5.7%) underwent primary CBD repair and T-tube placement secondary to CBD injury. The mean follow-up period after T-tube placement was 69 months. In patients with T-tube placement, the CBD diameters ranged from 4–21 mm, were normal in 20 patients (57.1%), dilated in 15 patients (42.9%), with the mean CBD diameter being  $8.91 \pm 4.82$  mm. No residual or recurrent CBD calculus and no clinical or laboratory evidence of cholangitis or cholestasis were found.

**Conclusions:** A retrospective clinical study at a single surgical center, showed that T-tube placement during open cholecystectomy and CBD exploration was a safe procedure that did not result in late complications.

**MeSH Keywords:** **Cholangitis • Choledochostomy • Cholestasis**

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## Background

T-tube placement for biliary diversion is a well-established surgical approach performed for controlling bile flow and bile leakage through the common bile duct (CBD) in the surgical repair process of bile duct injuries and in the postoperative CBD exploration. The indications of this procedure include prevention of bile leakage after CBD exploration, postoperative biliary tract imaging, and removal of residual gallstones [1]. With the increased use of endoscopic retrograde cholangio-pancreatography (ERCP) for CBD stone removal, the use of T-tube placement for this purpose has gradually decreased [2].

Bile duct injuries usually occur from blunt abdominal injuries, gunshot or stab wounds and iatrogenically during cholecystectomy [3]. The incidence of gallstones is estimated to be 6% of the Turkish population, representing four million people [2,4,5]. Laparoscopy has led to an increase in the number of surgeries performed for symptomatic gallstones with a corresponding increase in bile duct injuries, estimated to be between 0.3–0.55% [6]. Among the different treatment options recommended for treatment of bile duct injury is primary repair with T-tube placement particularly for type D injury according to Strasberg classification [7].

In the previously performed studies, while the incidence rate of asymptomatic choledochal calculi was given as 4%, the choledocholithiasis rate in the patients with cholecystectomy has been reported as 10–15% [8]. Surgery is recommended for CBD stones if endoscopic treatment using ERCP fails [9,10]. This surgical option involves CBD exploration and stone extraction with a T-tube placement or biliary-enteric anastomosis done laparoscopically or through a laparotomy. Inappropriate management of CBD injuries can result in severe early or late complications some of which could be life-threatening.

Routine use of T-tube placement and bile drainage still remains controversial. Physical discomfort, cholangitis, tube displacement, bile leakage after tube removal, which could lead to increased mortality and morbidity are some of the reasons cited by proponents against the use of T-tube placement [2,11,12]. However, contrary to these arguments, T-tube placement is reported to reduce intrabiliary pressure and edema and may facilitate healing [2,13,14].

Other long-term complications such as biliary strictures, residual or recurrent CBD stones, recurrent cholangitis, intrahepatic stone formation, hepatic atrophy, secondary biliary cirrhosis, portal hypertension, and cholangiocarcinoma have been reported to be associated with T-tube placement [2,15]. The possible cause of CBD stricture following T-tube placement have been postulated to be due to the interruption of blood supply to the CBD leading to ischemic changes and fibrosis [16–20].

However, in the literature, there has been a lack of scientific data on the results of long-term follow-up to confirm some of the late postoperative complications of T-tube placement, and further clinical studies are needed [15]. The aim of this retrospective clinical study was to investigate the incidence of late complications of T-tube placement.

## Material and Methods

Hitit University School of Medicine ethic committee approved (2017-61).

Patients who underwent gallbladder and biliary surgical treatment with T-tube placement between 2008–2015 at our center were included in the study. Patients were reached through contact addresses in their medical records and invited to the hospital. Detailed information about history taken and further tests needed for the study were given, and informed consent was later obtained from those patients who opted to participate in the study. Patient demographics, surgical indications, and all other interventions after the initial T-tube placement surgery were recorded. Information on the presence or absence of cholangitis and early complications following T-tube placement were recorded, including T-tube displacement, T-tube impaction, bile leakage occurred before and following T-tube removal and whether or not they had cholangitis were examined through their clinical symptoms and their medical records.

To determine the indications of cholestasis, biochemical levels such as aspartate aminotransferase (AST), alanine transaminase (ALT), alkaline phosphatase (ALP), gamma-glutamyl transpeptidase (GGT), total and direct bilirubin values, and hematological parameters (thrombocyte count) were measured. Non-invasive liver fibrosis was assessed according to the AST-to-platelet ratio index (APRI). An APRI score  $\leq 0.5$  was defined as the absence of liver fibrosis, and APRI score  $> 1.5$  indicated the presence of significant liver fibrosis [21].

The diameters of the patients CBD and intrahepatic bile ducts were measured using hepatobiliary ultrasound (US). On US imaging, the nominal upper limit for the diameter of the CBD was defined as 8 mm; a CBD diameter  $< 8$  mm was defined as normal; a CBD diameter  $\geq 8$  mm was defined as dilated. The nominal upper limits for the diameters of the intrahepatic bile ducts (IHBD) were defined as 2 mm; IHBD diameters  $> 2$  mm were regarded as dilated [22]. The presence or absence of stones in the bile duct was recorded. The same radiologist interpreted all the US findings.

## Statistical analysis

Data were analyzed with SPSS version 22.0 software (SPSS Inc., Chicago, IL, USA). The data were presented as the mean  $\pm$

**Table 1.** Biochemical parameters of the patients studied.

Parameters	Reference	N	
	Normal range	Normal	High
AST	0–35 IU/L	32	3
ALT	0–35 IU/L	31	4
Total bilirubin	0–1.2 mg/dL	31	4
Direct bilirubin	0–0.4 mg/dL	35	0
ALP	0–120 IU/L	35	0
GGT	0–38 IU/L	28	7

AST – aspartate aminotransferase; ALT – alanine transaminase; ALP – alkaline phosphatase; GGT – gamma-glutamyl transpeptidase.

standard deviation (SD), and nominal variables were presented as the number of cases and as percentages (%).

## Results

Between 2008–2015 at our center, 60 patients underwent T-tube placement surgery, 35 of whom gave written informed consent to participate in the study. Of the patients studied, 74.3% were women (N=26), and 25.7% were men (N=9) (ratio 2.88: 1). The median age was 54±15 years for women, and 66.5±15 years for men. The oldest patient was 83 years old; the youngest patient was 29 years old. The prevalence of patients who were more than 60 years old was 45.7% (N=16).

Of the 35 patients in this study who underwent cholecystectomy for cholecysto-choledocholithiasis (or gallstones) 94.3% (N=33) underwent open cholecystectomy, common bile duct (CBD) exploration, and T-tube placement; the remaining 5.7% (N=2) underwent primary reconstruction surgery and T-tube placement for iatrogenic bile duct injury type D (according to the Strasbourg classification of bile duct injury) during laparoscopic cholecystectomy (LC). There were no symptoms or signs of cholangitis, such as upper right quadrant pain, jaundice or fever, in the postoperative history of the patients. Also, there was no recorded incidence of early complications, including T-tube displacement, T-tube blockage, or bile leakage following T-tube removal.

The mean postoperative follow-up period was 69.86±27.84 months (range, 21–111 months). The biochemical data from the patients studied are shown in Table 1. The aspartate aminotransferase-to-platelet ratio index (APRI) score was below the lower cut-off value (≤0.5) in all the patients. Thrombocytopenia was not found in any of the patients (Table 2).

In patients with T-tube placement, the CBD diameters ranged from 4–21 mm, were normal in 20 patients (57.1%), dilated in 15 patients (42.9%), with the mean CBD diameter being

8.91±4.82 mm. The intrahepatic bile duct (IHBD) measurements were found to be normal in 32 patients (91.4%) and dilated in 3 patients (8.6%). The relationship between the patient CBD and IHBD diameters are shown in Table 3. Of the 15 patients with dilated CBDs, none of these patients had residual or recurrent CBD stones.

## Discussion

This retrospective clinical study at a single surgical center showed that out of 35 patients included in the study, 33 (94.3%) underwent open cholecystectomy, common bile duct (CBD) exploration, and T-tube placement due to cholecysto-choledocholithiasis. The remaining two patients (5.7%) underwent primary CBD repair and T-tube placement secondary to CBD injury. In patients with T-tube placement, the CBD diameters ranged from 4–21 mm, were normal in 20 patients (57.1%), dilated in 15 patients (42.9%), with the mean CBD diameter being 8.91±4.82 mm. No residual or recurrent CBD calculus and no clinical or laboratory evidence of cholangitis or cholestasis were found.

The early and late complications following T-tube placement for the management of common bile duct (CBD) injury and cholecysto-choledocholithiasis are well documented. Recently, T-tube placement has gradually become regarded as being less favorable [2,11,23]. However, in this study, we chose to assess the clinical, laboratory, and radiological results of the patients undergoing T-tube placement.

A biliary stricture is regarded as the most serious long-term complication of T-tube placement and is characterized by biliary stasis with an associated elevation of the liver function tests [6]. The primary laboratory markers of the biliary stasis secondary to biliary stricture are elevated bilirubin and alkaline phosphatase (ALP) levels, with an increased ALP level of more than three-times the normal level being specific for biliary stricture [22].

**Table 2.** Hematological parameters of the patients studied.

	Reference	Frequency	Percent (%)
WBC	4–10×10 <sup>3</sup> /L (normal)	24	68.6
	<4×10 <sup>3</sup> /L	2	5.7
	>10×10 <sup>3</sup> /L	9	25.7
HGB	11–15 g/dL (normal)	27	77.1
	<11 g/dL	7	20.0
	>15 g/dL	1	2.9
HTC	37–45% (normal)	18	51.4
	<37%	17	48.6
	>45%	–	–
PLT	100–300×10 <sup>3</sup> /L (normal)	22	62.9
	<100×10 <sup>3</sup> /L	–	–
	>300×10 <sup>3</sup> /L	13	37.1
RBC	3.5–5.2×10 <sup>6</sup> /L (normal)	30	85.7
	<3.5×10 <sup>6</sup> /L	2	5.7
	>5.2×10 <sup>6</sup> /L	3	8.6

**Table 3.** Common bile duct (CBD) and intrahepatic bile duct (IHBD) diameters of the patients studied.

			IHBD		Sum
			Normal N (%)	Dilated n (%)	
UCD	<8 mm	Count	20 (100)	0 (0)	20
	≥8 mm	Count	12 (80)	3 (20)	15
	Sum	Count	32 (91.4)	3 (8.6)	35

UCD – ultrasonographic choledoch duct diameter; IHBD – interhepatic bile duct diameter.

The bilirubin and ALP values in all the patients in this study were normal. Furthermore, the aspartate aminotransferase-to-platelet ratio index (APRI) score, used for evaluating liver fibrosis, was found to be ≤0.5, indicating the absence of significant liver fibrosis in the patients. Also, thrombocytopenia, which can be observed in the patients with secondary biliary cirrhosis and portal hypertension, was not found in the patients in this study [24]. Therefore, from the clinical and laboratory findings of this study, T-tube placement did not cause CBD stricture or secondary biliary cirrhosis.

In a meta-analysis evaluating the results of comparative studies on T-tube placement and primary reconstruction surgery, no differences were found regarding early morbidity and mortality rates [2]. In another study comparing the early complications of T-tube placement and primary repair, bile leakage, T-tube displacement and T-tube blockage were found in those patients who had T-tube placement when compared with those with primary repair [14].

In this study, no data associated with the presence of early complications T-tube placement were found in the patient medical records. Therefore, we suggest that, to avoid early complications associated with T-tube placement, surgical principles should be strictly followed and care should be taken to protect both the T-tube and the surgical site. CBD stricture is the most common late postoperative complication associated with CBD injuries [25,26]. It has been reported in some clinical case series that, the complication of CBD stricture can develop as early as six months, and as late as 15 years, from the time of the initial CBD injury [27,28]. A minimum five-year follow-up has been suggested to exclude the development of biliary stricture after biliary-enteric anastomosis [29]. The average follow-up time in our study was 69 months, which we believe was sufficient for the evaluation of the late complications of the procedure.

CBD strictures are usually assessed using the diameter of the bile duct from radiological images, which in itself is

operator-dependent. There have been varied suggestions on what constitutes the normal range of CBD diameter (in mm) and that of a CBD stricture. It has been estimated that the size of the bile duct increases by one mm per each decade of life after 60 years [12]. In two separate studies, the maximum CBD diameter was found to be 9 mm after long-term follow-up, following T-tube placement [14,30]. In our study, the mean CBD diameter, after an average of 69 months follow-up, was found to be  $8.91 \pm 4.82$  mm following T-tube placement. This finding was consistent with previously published findings. However, in two separate studies evaluating the relationship between T-tube placement and the development of biliary stricture, no biliary stricture was recorded after long-term follow-up, and the authors speculated that there was no correlation between T-tube placement and the development of biliary stricture [23–31].

In our study, three patients out of 35 patients in the study were found to have a dilated proximal CBD and intrahepatic bile ducts (IHBD) using ultrasound, which suggested biliary stricture. However, the clinical and biochemical parameters of these patients were normal. Even though these patients had radiologically confirmed biliary duct dilatations, a biliary stricture cannot be confirmed to be present in the absence of clinical or biochemical parameters [11]. Furthermore, it has been reported that increased age (particularly >60 years), previous history of cholecystectomy, and removal of CBD stones are associated with the gradual development of biliary dilatation [15,32]. The three patients in our study with intrahepatic and extrahepatic bile duct dilatation were found to have undergone cholecystectomy, CBD exploration, and T-tube placement due to cholecysto-choledocholithiasis; two of these patients were also found to be older than 60 years. Therefore, we concluded that the intrahepatic and extrahepatic bile duct dilatation did not occur as a result of biliary stricture following T-tube placement.

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Several previously published studies have been conducted to evaluate recurrent or residual stone development in the bile duct following T-tube placement and primary repair [13,23,33]. However, none of these previous studies reported any significant difference between the two patient groups [13,23,33]. None of the patients in our study developed residual or recurrent stones in the CBD. Based on the results of the present study, combined with the findings of previously published studies, we believe that T-tube placement is not associated with an additional risk for recurrent or residual CBD stone. This study had several limitations, including a small study size and being conducted at a single center, with the lack of a control group. Future large, multi-center, controlled clinical studies are recommended in which the intrahepatic and extrahepatic bile duct diameters are measured before T-tube placement.

## Conclusions

In conclusion, a retrospective clinical study at a single surgical center, showed that T-tube placement during open cholecystectomy and CBD exploration was a safe procedure that did not result in late complications. We conclude that any complications associated with T-tube placement during CBD exploration and CBD injury repair as reported in literature can be avoided by adherence to strict surgical principles and T-tube care.

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## Conflict of interests

None.

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