

Comparison of biliary stenting with t-tube drainage as a method of decompression in cases of open common bile duct exploration: A Randomized control trial

*Amit Jain¹, Irfan Hussain Khan²

¹(Associate Professor, Department of general surgery, Sawai Man Singh Medical College, Jaipur, India)

²(Assistant Professor, Department of general surgery, National Institute of Medical Sciences, Jaipur, India)

Corresponding author: Amit Jain1

Abstract: The decompression of biliary tree after CBD exploration for stones has been a topic of debate for many years. T-tube was conventionally used for this purpose, but now the biliary stents have provided an excellent alternative to the cumbersome t-tube. This randomized control study was done to compare the t-tube with biliary stent as method of decompression after CBD exploration. A total of 60 patients were enrolled into the study, 30 underwent t-tube placement while the rest were decompressed by a biliary stent following choledochotomy. Operative parameters and outcomes are compared. operative time, intraoperative blood loss, post-operative pain and discomfort, abdominal drain removal time, return of bowel sounds and hospital stay were all significantly lower in the stent group as compared to that in the T-tube group ($P < 0.05$ for all). Though two patients in t-tube group and only one patient in stent group had bile leak but the difference was not statistically significant. Biliary stent showed a clear advantage over t-tube as method of decompression of biliary tree in CBD exploration.

Keywords: Biliary stent, Choledocholithiasis, Choledochotomy T-tube,

Date of Submission: 18-11-2017

Date of acceptance: 30-11-2017

I. Introduction

Gall stone disease plays a noteworthy part in surgical practice all over the world. About 5-25% of adult population have or will have gall stones in their life time.^{1,2,3} 10-15% of these patients develops symptomatic choledocholithiasis, while 7-15% of CBD stones will be discovered during Cholecystectomy^{4,5,6}.

With the advent of endoscopic retrograde cholangio-pancreatography (ERCP), surgical removal of CBD stones has declined⁷. Still, surgical intervention is required in state of failed ERCP or in cases of CBD stone encountered during Cholecystectomy. Surgically, CBD stones can be dealt by both laparoscopic as well as open method. Laparoscopic CBD exploration can achieve success in almost 70-90% of CBD stones⁸. ERCP and laparoscopic removal of CBD stones requires sophisticated instruments and fine skills. And also these procedures have limitations in certain conditions such as multiple stones and big size stones.

The open method of choledochotomy comes to rescue in these conditions. Though its use has decreased now a days, open exploration used to be the only modus operandi for almost 100 years to remove CBD stones. Still, many centres of the developing country use open method due to lack of availability of instruments and trained personals for ERCP and Lap surgery. Moreover, the advantage of the lap surgery for the CBD exploration has not yet been established, which limits its applicability⁹. The classical method of open CBD exploration consists of supra-duodenal choledocotomy and insertion of a t-tube¹⁰. The problem of incision over CBD which may leak when closed primarily was a dreaded one. Insertion of a t-tube has been a tradition so as to decompress the CBD, in the event of an outflow obstruction, and it has also proved to be a safe and effective over the course of time. But this too is also not free from certain complications, which can be present in 10% of cases¹¹. Sometimes bile leak after removal of t-tube may result in high output fistula which may lead to severe morbidity and mortality In addition, keeping the t-tube for 3 weeks cause a significant concern to the patients and prevent an early return to normal duties^{12,13}.

Though many authors have advocated primary closure of CBD, but most of the surgeons have been sceptical to do this due to fear of outflow obstruction which may lead to bile leak with the further cascade of billioma and billiary peritonitis. Billiary stent can be a solution to this. It combines the benefit of t-tube (uninterrupted bile flow) and primary closure (No tube for 3 weeks), while avoiding the issue of bile leak. This study was performed to compare the clinical outcomes of billiary stent and T-tube drainage

with regards to ease of surgery, post-operative complications and to evaluate the benefits of billiary stenting in our centre.

II. Study Design And Patients

This prospective randomised control trial was done at a tertiary level teaching hospital of the state of Rajasthan in India between June 2014 and June 2016.

All the patients of choledocholithiasis who were planned for open CBD exploration were enrolled for the study, also the cases of failed ERCP for CBD stones were too included. The patients were assessed with routine blood profile including complete blood counts, liver function test, kidney functions test, coagulation screening and abdominal ultrasound. Diagnosis of choledocholithiasis was done by ultrasonography of abdomen and sometimes by MRCP in cases where usg failed to reveal the CBD stones while the conditions pointed towards it (Obstructive jaundice and raised alkaline phosphates). Decision to make a choledochotomy was based on either pre-operative diagnosis of choledocholithiasis or the CBD stones palpated preoperatively. Exclusion criteria was cholangitis, pancreatitis, malignancy and those who didn't consented for the surgery. The patients were informed about the details of the procedure and written informed consent was obtained. The patients were randomly grouped as; 1] t-tube group (T Group) 2] Biliary stent group (S group). Randomization was done with sealed envelope which was opened in operation theatre only. All the patients were operated by the same surgery unit led by a single surgeon. All study procedures were performed in accordance with the Declaration of Helsinki. 60 patients were enrolled for the study which were divided in two groups of 30 each.

III. Surgical Methods

All patients were given a pre-operative antibiotics shot. In the supraduodenal part of CBD, two stay sutures were taken with atraumatic 3-0 silk sutures and CBD opened with a vertical incision. Desjardin's choledocholithotomy forcep was used to retrieve the stones and then saline flushing done to remove any leftover stones or debris and to ensure patency. The clearance of duct was confirmed by a choledochoscope. After clearing the CBD, method of decompression was decided after opening the sealed envelope and was done in two ways. according to the group allotted.

1] T group – Here, a 14 or 16 Fr t-tube was used while keeping in the consideration of CBD size. Before placement of the T-tube, the back wall of the vertical stem was excised and a V-shaped wedge fashioned at the junction of the limbs to facilitate subsequent removal of the tube without disruption of the choledochotomy closure. The T-tube was brought out of the abdomen in a direct fashion, but some slack was allowed for postoperative abdominal distension. The T-limb was displaced to the upper limit of the choledochotomy so that closure can proceed from below using interrupted 3-0 silk sutures, ensuring that full-thickness bites of the duct are taken but avoiding narrowing of the lumen. Care was also taken to ensure that the tube itself is not caught by the suture. Saline was injected into the tube to check for leaks.

2] S group – In this group a 7 Fr DPT stent was used. Stent was inserted in CBD through choledochotomy incision with the help of choledochoscope and passed across the papilla. The distal protruding end in duodenum was kept of length not more than 1 cm so as to avoid peritoneal or retroperitoneal perforation and ulcer. Proximal end of the stent was kept at confluence of both right and left hepatic duct. In all patients, a subhepatic drain was placed necessarily.

IV. Post-operative management

Patients were managed in the surgery ward. Analgesics were given on demand. Patients were mobilized and oral liquids started on the first post-op day. Drain was removed on fourth post-op day.

In T group, T-tube cholangiogram was performed on day 15th. And if the t-tube output has decreased to minimal, t-tube was removed. While in S-group, upper GI endoscopy was performed at 4 weeks after the procedure to remove the stent (if it did not was expelled spontaneously) and to note any complication. All the post-operative complications were noted and pain was assessed by visual analogue score. Patients were followed for 6 months.

V. Statistical analysis

SPSS 22.0 software (IBM, New York, USA) was used for statistical analysis. . All the parameters were calculated on 95% confidence interval. Results were considered statistically significant if $p \leq 0.05$. Student's t test was used for parametric measurement and Mann Whitney U test for non-parametric measurements while analysing numerical values to compare both the groups. Pearson's Chi-Square test was used for parametric measurement and Fisher's exact correct test for non-parametric measurement, in case of comparison for categorical values.

VI. Results

In a study period of two years, total sixty patients of common bile duct stones being equally divided in two groups of 30 each (T-tube – T and biliary stent – S) were enrolled for the present study. After the surgery, all the patients were followed for a minimum period of 6 months.

The mean age of patients in T-tube group was 47.0 ± 18.5 years (range, 30–68 years) and that of stent group was 44.9 ± 14.3 years (range, 33–70 years). Five males (16.6%) and twenty five females (83.3%) were present in the T-tube group, while three males (10%) and twenty seven females (90%) were in stent group (Table 1).

The clinical presentation of CBD stones, co-morbidities, no of stone in CBD and diameter of CBD for both the groups is given in Table 1. No significant difference was observed with respect to these characteristics in both the groups. The mean operation time was 118 minutes (90-200) in the T-tube group and 104 minutes (50–125minutes) in the T-tube drainage group; the between-group difference was statistically significant ($P < 0.050$). Intraoperative blood loss was significantly lower in the stent drainage group as compared to that in the T-tube drainage group ($P < 0.05$). Post-operative discomfort and pain when analyzed on Visual Analogue Scale (VAS) was significantly lower in the stent group. Abdominal drain removal time was also less in stent group (2.8 ± 3) days while compared to T-tube group (3.8 ± 4). Recovery of bowel function was faster in stent group, though the difference was not statistically significant.

Post operative hospital stay was 5 (3-10) days in stent group while it was 8 in T-tube group and the difference was significant. Two patients (6.6%) in T-tube group developed bile leak while only one patient (3.3%) in stent group has associated bile leak. Both the patients were treated conservatively and did not required any further intervention.

Table. 1 Preoperative clinical characters of the patients

Variables	'T' Group n=30		'S' Group n=30		P value
	Mean \pm SD	Range (Min-Max)	Mean \pm SD	Range (Min-Max)	
Age (yrs)	47.0 ± 18.5	30–68	44.9 ± 14.3	33–70	0.22
Gender Male	5 (16.6%)	-	3 (10%)	-	NS
	25 (83.3%)	-	27 (90%)	-	NS
Female					
Symptoms					
1.Biliary Colic	22 (73.3%)	-	17 (56.6%)	-	NS
2.Ac Cholecystitis	8 (26.6%)	-	12 (40%)	-	NS
3.Jaundice	5 (16.6%)	-	7 (23%)	-	NS
Concomitant gallstones	26 (86%)	-	27 (90%)	-	NS
Total bilirubin (mg%)	2.3 ± 1.5	0.5-6	2.1 ± 1.9	1.0-5	0.33
No of CBD stones	2.9 ± 1.3	1-7	3.3 ± 1.0	1-5	0.52
CBD diameter (mm)	12 ± 4.1	8-17	13 ± 3.7	9-17	0.21
Diabetes Mellitus	3 (10%)	-	5 (16.6%)	-	NS
Hypertension	5 (16.6%)	-	6 (20%)	-	NS

Table. 2 Post-operative course of the patients

Variables	'T' Group n=30		'S' Group n=30		P value
	Mean \pm SD	Range (Min-Max)	Mean \pm SD	Range (Min-Max)	
Mean operative time (min)	118 ± 27	90-200	104 ± 18	50-125	0.020
Intra-operative blood loss (ml)	30 ± 8	10-150	21 ± 6	10-100	0.043
VAS Score	4.5 ± 2.2	1-7	2.0 ± 1.1	1-5	0.011
Abdominal drain removal time (days)	4 ± 1.5	3-12	3 ± 1.0	2-7	0.032
Bowel recovery time (days)	2 ± 1.3	1-4	2.1 ± 1	1-4	0.33 (NS)
Post-operative hospital stay (days)	6 ± 3	3-15	4 ± 2	2-9	0.018
Bile leakage	2 (6.6%)		1 (3.3%)		NS

VII. Discussion

Gall stone disease has been a common indication for abdominal surgery¹⁵. Before the advent of laparoscopy and ERCP, gall stones and CBD stones were removed through a single procedure. This procedure was very safe with morbidity below 15% and mortality below 1% in a patient up to 65 years old.¹⁶

Queries regarding the inevitability of T-tube insertion after a CBD insertion, be it open or laparoscopic, were raised by many surgeons across the world after the recent development of perioperative diagnostic tools, sophisticated instruments and advance operative techniques.

With the increase in number of choledochotomy procedures, the t-tube insertion which is technically demanding and is associated with a minimum 15 days waiting time of removal has been replaced by primary closures, ENBD, biliary stents¹⁴ and other ways to aid decompressions of CBD postoperatively with allegedly successful results.

With the advanced diagnostic techniques, surgeons are sufficiently enlightened about the number, size and location of the stone in biliary tree. Through availability of choledochoscope and other sophisticated instruments, possibilities of retained stones is mostly negligible. This reality again questions the necessity of t-tube insertion and thus causing a longer time of discomfort to the patients. The primary closure of CBD has proved to be an alternative, but in some conditions their is always a requirement of biliary decompression. Biliary stent thus provide the double benefit of avoiding the discomfort of the tube hanging out of abdomen for a fortnight as well as providing decompression of CBD, thus avoiding the danger of bile leak.

In our study of sixty cases, we performed open surgery for exploration of CBD and achieved the duct clearance by choledochoscopy following choledochotomy. The use of t-tube for biliary decompression after CBD exploration has been a standard practice.¹⁷ The use of a T-tube is not without complications and there are many reports of complications with T-tube.^{10,18}

In our study, it was proved statistically that use of biliary stent is a simple procedure and requires less operative time with less amount of intraoperative blood loss. The absence of a drainage tube from the abdomen improves patient's confidence, causes less post-operative pain and earlier return to work as reported earlier.¹⁹ The use of t-tube leads to loss of bile, which itself causes electrolyte imbalance, decreased digestion and absorption of intestinal contents, slowing down of intestinal peristalsis. All these factors affects generalized well being of patient and thus are associated with less patient satisfaction.²⁰ However, with the biliary stent, the biliary pressure is reduced without loss of bile, and this may help decrease postoperative complications.²¹ In our study, we had two cases of bile leakage in patients in whom the T-tube was used (6.6%), and one case among the (3.3%) in whom biliary stenting was done. There was no major complications noted in any of our patients. There have been reports of intraperitoneal leakage with subsequent biliary peritonitis.^{22,23} No such complication occurred in our patients and no deaths occurred in our study.

Their was a significant difference in hospital stay in both the groups in our study. In a group where biliary stent was placed, they remained in the hospital for a shorter period and were not burdened by a T-tube. In patients where the T-tube has been kept in place, there was the additional bothering of postoperative discomfort and cholangiography procedure.

VIII. Conclusion

In open choledochotomy, Choledochoscopy ensures clearance of the CBD biliary stent and abolish the need for a T-tube. Intra-operative bleeding, operative time and post-operative discomfort is also less while using biliary stent. From this study, we have concluded that after open CBD exploration for stones, biliary stent is a safe and effective method of biliary decompression with shorter hospital stays and better patient satisfaction.

Bibliography

- [1]. Schirmer BD, Winters KL, Edlich RF. Cholelithiasis and cholecystitis. *J Long Term Eff Med Implants*. 2005;15:329–338
- [2]. Shaffer EA. Epidemiology and risk factors for gallstone disease: has the paradigm changed in the 21st century? *Curr Gastroenterol Rep*. 2005;7:132–140
- [3]. Halldestam I, Enell EL, Kullman E, Borch K. Development of symptoms and complications in individuals with asymptomatic gallstones. *The British Journal of Surgery* 2004;**91**(6):734-8.
- [4]. Ahrendt SA, Pitt HA. Biliary tract. In: Townsend M, Ed. *Sabiston Textbook of Surgery*. Philadelphia: WB Saunders; 2004.p. 486–92
- [5]. Perez G, Escalona A, Jarufe N, Ibáñez L, Viviani P, García C, et al. Prospective randomized study of T - tube versus biliary stent for common bile duct decompression after open choledochotomy. *World J Surg* 2005; 29:869–72
- [6]. A randomised controlled study for comparison of primary closure of common bile duct versus t-tube drainage in case of choledocholithiasis MD Mokarram Ali, R K Kajla , Dharamveer Jajra *IJAMSCR* |Volume 4 | Issue 2 | April – June – 2016
- [7]. Williams JA, Treacy PJ, Sidey P, Worthley CS, Townsend NC, Russell EA. Primary duct closure versus T-tube drainage following exploration of the common bile duct. *The Australian and New Zealand Journal of Surgery*1994;**64**(12):823-6.
- [8]. Hunter JG. Laparoscopic transcystic common bile duct exploration. *Am J Surg* 1992;163:53-8.
- [9]. Tokumura H, Umezawa A, Cao H, et al. Laparoscopic management of common bile duct stones: transcystic approach and choledochotomy. *J Hepatobiliary Pancreat Surg* 2002;9:206–12
- [10]. Wills VL, Gibson K, Karihaloo C, et al. Complications of biliary T-tubes after choledochotomy. *ANZ J Surg* 2002;72:177–80.
- [11]. Tapia A, Llanos O, Guzman S, et al. Resultados de la coledocotomia clasica por coledocolitiasis: un punto de comparacion para tecnicas altetnativas. *Rev Chil Cir* 1995;47:563–8.
- [12]. Miguel Angel Mercado, Carlos Chan, Hector Orozco, et al. Bile duct injuries related to misplacement of “T tubes”. *Ann Hepatol* 2006;5:44–8.
- [13]. Placer G. Bile leakage after removal of T-tube from the common bile duct. *Br J Surg* 1990;77:1075.
- [14]. Chen CC, Wu SD, Tian Y, et al. The fading role of T-tube in laparoscopic choledochotomy: primary choledochorrhaphy and over pigtail j and endonasobiliary drainage tubes. *J Laparoendosc Adv Surg Tech A* 2010;20:807-811.

Comparison of biliary stenting with t-tube drainage as a method of decompression in cases of open.

- [15]. Marilee L Freitas, Robert L Bell, Andrew J Duffy. Choledocholithiasis: evolving standards for diagnosis and management. *World J Gastroenterol* 2006;12:3162–7.
- [16]. Chen SS, Chou FF. Choledochotomy for biliary lithiasis: is routine T-tube drainage necessary? *Acta Chir Scand* 1990;156: 387–90
- [17]. Mehmood A. Wani, M.S., Nisar A, et al. Primary closure of the common duct over endonasobiliary drainage tubes. *World J Surg* 2005;29:865–8.
- [18]. Gharaibeh KIA, Heiss HA. Biliary leakage following T-tube removal. *Int Surg* 2000;85:57–63
- [19]. Kelly MD. Results of laparoscopic bile duct exploration via choledochotomy. *ANZ J Surg* 2010; 80:694–698. [[PubMed](#)]
- [20]. Yakun Xu et al, Spontaneously removed biliary stent drainage versus T-tube drainage after laparoscopic common bile duct exploration, *Medicine (Baltimore)*. 2016 Sep; 95(39): e5011.
- [21]. Lee JS, Yoon YC. Laparoscopic common bile duct exploration using V-Loc suture with insertion of endobiliary stent. *Surg Endosc* 2015. [[PubMed](#)]
- [22]. Perez G, Escalona A, Jarufe N, et al. Prospective randomized study of T-tube versus biliary stent for common bile duct decompression after open choledochotomy. *World J Surg* 2005;29:869–72
- [23]. Tu Z, Li J, Xin H, et al. Primary choledochorrhaphy after common bile duct exploration. *Dig Surg* 1999;16:137–9

*Amit Jain. "Comparison of biliary stenting with t-tube drainage as a method of decompression in cases of open common bile duct exploration: A Randomized control trial." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)* 40.44 (2017): 40-44