

Application Value of Fibrin-sealants in Laparoscopic Common Bile Duct Exploration (LCBDE)

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ABSTRACT

Introduction: Despite all recent developments in laparoscopic instruments and acquired experience with laparoscopic common bile duct exploration (LCBDE) for choledocholithiasis management, there is still a risk of post-operative bile leakage following common bile duct (CBD) primary closure. In this study we evaluate the application value of fibrin-sealant on post-operative bile leakage after LCBDE.

Patients and Methods: We report a perspective, analysis of 85 patients who had undergone primary duct closure of the CBD after LCBDE from January 2015 to November 2019. The study population was divided into two groups according to whether they received fibrin-sealants covering the choledochorrhaphy or not, analyzed the incidence of postoperative biliary leakage and other complications in each group.

Results: There were 85 patients in two study groups, 37 patients (43.55%) in fibrin-sealant group and 48 patients (56.45%) in control group. The incidence of biliary leakage in fibrin-sealant group was one patient (2.70%) and had Grade-A leakage while in control group were four patients (8.33%) two patients had Grade-A leakage and the other two patients had Grade-B leakage. When we analyzed the effect of fibrin-sealant, it was detected that the application of fibrin-sealant reduced the incidence of biliary leakage without any significant side effects in the fibrin sealant group.

Conclusion: Human fibrin-sealants reduced the incidence of biliary leakage without any significant side effects in patients who experienced CBD primary closure following LCBDE. Post-operatively, hemoglobin concentration level was significantly more in fibrin-sealant group than that of control group. Our surgery team also confirmed that during LCBDE hook and cut has better outcome than that of the hook and coagulation for the control of post-operative bile leakage in patients with choledocholithiasis.

Keywords: Fibrin-sealants; Laparoscopic common bile duct exploration (LCBDE); Choledocholithiasis; Bile leakage

Abbreviation: CBD: Common Bile Duct; CHD: Common Hepatic Duct; LCBDE: Laparoscopic Common Bile Duct Exploration; ERCP: Endoscopic Retrograde Cholangiopancreatography; LC: Laparoscopic Cholecystectomy; MRCP: Magnetic Resonance Cholangiopancreatography

INTRODUCTION

It has been reported that Endoscopic Retrograde Cholangiopancreatography (ERCP), followed by Laparoscopic Cholecystectomy (LC) in a second step, is the preferred option in most hospitals [1,2]. Despite this, the results of the endoscopic approach and Laparoscopic Common Bile Duct

Exploration (LCBDE) and LC in the same procedure are similar in terms of efficacy, but the overall duration of hospital stay is shorter and surgeons fees lower for LC+LCBDE [3,4]. Recent research has shown that primary closure of the Common Bile Duct (CBD) without T-tube drainage is a safe, feasible, cost-effective. Additionally, with primary closure of CBD, we could avoid T-tube related complications [5,6]. Bile leakage after

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Laparoscopic Common Bile Duct Exploration (LCBDE) remains one of the most important concerns for surgeons, especially when T-tube drainage is not used. The aim of the current study is to determine the application value of human fibrin-sealant to reduce the incidence of biliary leakage after LCBDE and CBD primary suture.

MATERIALS AND METHODS

Patient's selection

We carried out a perspective, analysis of 85 patients (40 males and 45 females) at the first affiliated Hospital of Harbin Medical University, Harbin, China. Patients for the study were selected from those presenting to the hospital with the suspicion of choledocholithiasis. All patients diagnosed gallbladder stones with CBD stones by ultrasound, Magnetic Resonance Cholangiopancreatography (MRCP), Computed Tomography (CT), clinical features and blood biochemical data, from January 2015 to November 2019 were included in this study. The protocol for the management of choledocholithiasis with cholecystolithiasis included LC and CBD primary repair following LCBDE for all cases. The study included total 85 patients who were divided into two study groups depending on whether they received human fibrin-sealant covering the CBD suture line or not. All patients were selected and diagnosed by two separate operative teams, the first operative team "Fibrin sealant group" in which choledochotomy was closed with continuous monofilament 4-0 absorbable suture and suture line was covered with human fibrin sealant and the second operative team "control group" in which choledochotomy was closed with continuous monofilament 4-0 absorbable suture alone. The human fibrin-sealant group (n=37) consisted of 18 males (48.65%) and 19 females (51.35%). The control group (n=48) consisted of 22 males (45.83%) and 26 females (54.17%).

Surgical technique

Total 85 patients received general anesthesia. The procedure was carried out in supine position with adjustable operative bed, and surgery was performed using a four-port technique for laparoscopic cholecystectomy. After dissecting the Calot's triangle, the cystic artery was clipped and transected. Double clips were applied on the cystic duct to prevent stone slippage into the common bile duct, and gallbladder was removed from the gallbladder bed. The cystic duct was kept intact, which enabled the exposure of the CBD by pulling the gallbladder during LCBDE. Supra duodenal choledochotomy was performed by using an electro cautery hook and cut through a vertical incision. A 5 mm flexible fiberoptic choledochoscope was used to investigate the CBD and CHD for residual stones. Through the choledochoscope, flushing with saline was done under pressure to facilitate clearance of small stones. Dormia basket also used to pull stones to the abdominal cavity. The choledochorrhaphy was done with continuous sutures using 4-0 monofilament absorbable suture without stent and T-tube placement. After primary closure of CBD, according to whether fibrin-sealant was used or not, the patients were divided into the fibrin sealant group or the control group. In the fibrin sealant

group, the choledochorrhaphy was covered with human fibrin sealant, mixing the two components of fibrin-sealant before application. If human fibrin sealant was not used, the patients were enrolled into the control group. The surgical operation ended with the placement of sub hepatic drainage tube to monitor the post-operative biliary leakage and other related complications. The sub hepatic drain was removed on day 3rd or 4th after the surgery and hospital discharge occurred once the absence of post-operative complications had been confirmed. In the occurrence of bile leaks, confirmed by laboratory, the sub hepatic drain was preserved until the absence of bile leaks.

Preparation of human fibrin sealant

Fibrin sealant human (FIBINGLURAAS[®]) is a kit of human fibrin sealant contains two components of plasma protein, namely lyophilized fibrinogen (human) and lyophilized thrombin (human), enclosed one vial of Sterile Water for Injection and one vial of calcium chloride solution for reconstitution, and one sterile medical materials package used for preparation and application.

Postoperative monitoring and long term follow up

All patients were examined on the evening of the surgery by the operating surgeon for general condition and any early postoperative complications such as bleeding from the port site or hematoma formation or any abnormal drain output as noticed by the color and amount in the drainage bag. In all patients, liver function test was done after 2 weeks, and ultrasonography of hepatobiliary system was done after 2 and 4 weeks of surgery to look for any collection and residual CBD stones. All patients received regular follow-up every 3 months until 24 months post-operatively.

Assessment of bile leakage

Bile leakage was defined and graded according to the criteria proposed by the ISGLS [7]. Briefly, bile leakage was defined as a discharge of fluid with an increased bilirubin concentration via the intra-abdominal drains on the post-operative day 3 or as the need for radiologic intervention and relaparotomy for bile collection and bile peritonitis, respectively. An increased bilirubin concentration in the drain fluid was defined as a bilirubin concentration at least 3 times higher than the serum bilirubin concentration at the same time. Grade A bile leakage has little or no impact on patient's clinical management, and additional diagnostic or therapeutic interventions are unnecessary. A bile leakage that needs to change in patients' clinical management, but can be treated without relaparotomy is defined as Grade B. A Grade A bile leakage requiring drainage for more than 1 week is also classified as Grade B. Patients with Grade C bile leakage require relaparotomy to control this complication.

Variables of the analysis

The total 85 patients were divided into two study groups depending on whether human fibrin-sealant had been used to cover the choledochorrhaphy (fibrin-sealant group) or the CBD

primary suture had been left uncovered (control group). Both groups were studied for the following variables: sample size, age, sex, previous abdominal surgery, history of previous cholecystectomy, preoperative cholangitis, preoperative cholecystitis, preoperative blood amylase, mean CBD diameter, mean operating time, conversion to open procedure, number of calculi removed, residual stones in CBD or CHD, ICU stay, length of hospital stay, post-operative length of hospital stay, pre-operative and post-operative change in hemoglobin, post-operative bile leakage, post-operative drainage volume first 24 hours after surgery and drain output.

Statistical analysis

Quantitative variables were expressed with measures of central tendency, determining the mean, median and range. Qualitative variables were calculated with absolute frequencies and percentages. Chi-square test was used for qualitative variables and Student's t-test was used for quantitative variables to determine the existence of significant differences between two study groups. A $p < 0.05$ was considered statistically significant. The statistical analysis was performed using the R version R-3.6.1.

RESULTS

In this study there were 85 patients of proven choledocholithiasis underwent LCBDE by transcholedochal route in two study groups, 37 patients (43.55%) in the fibrin-sealant group; the female-to-male ratio was 19:18 while 48 patients (56.5%) in control group; female-to-male ratio was 26:22, and the two study groups were comparable to each other in preoperative, operative and post-operative data distributions. Previous abdominal surgery was 11 cases in fibrin sealant group and 16 cases in control group. Preoperatively, amylase level was raised in 7 patients in two study groups, 2 patients in fibrin-sealant group and 5 patients in control group, while it was normal in rest of the patients. Preoperatively 31 patients were jaundiced, 13 patients in fibrin-sealant group and 18 patients in control group. The preoperative and operative data outcomes had no statistically significant differences in clinical data presentation, past surgical history anesthesia risk, mean CBD diameter and conversion to open procedure (Table 1).

Table 1: Comparison of perioperative and operative data between two study groups.

Variable	Fibrin-sealants group	Control group	p-value
Sample size	37	48	
Age(years) Median(Range)	63(20-86)	55(20-82)	0.173
Sex(Female/Male)	19/18(51.35%/48.64%)	26/22(54.16%/45.83%)	0.969
Past surgical history			
History of previous abdominal surgery(Yes)	11(29.72%)	16(33.33%)	0.905
Previous abdominal surgery(No)	26(70.28%)	32(66.67%)	
Previous cholecystectomy (Yes)	3(8.10%)	4(8.33%)	0.999
Previous cholecystectomy (No)	34(91.90%)	44(91.67%)	
Clinical data presentation			
Bilirubin in blood Umol/L Mean(S.D)	51.26(50.51)	60.62(59.94)	0.437
Preoperative blood amylase U/L Mean(S.D)	54.70(35.24)	69.77(48.90)	0.103
Preoperative hemoglobin gr/dl Mean(S.D)	14.87(1.04)	14.73(1.12)	0.561
Cholangitis (Yes)	1(2.70%)	6(12.50%)	0.218
Cholangitis (No)	36(97.30%)	42(87.50%)	
Cholecystitis (Yes)	34(91.89%)	39(81.25%)	0.278
Cholecystitis (No)	3(8.11%)	9(18.75%)	

ASA risk			
ASAI	3(8.10%)	1(2.08%)	0.062
ASAI	19(51.35%)	36(75.00%)	
ASAI	15(40.55%)	11(22.92%)	
Operative data Mean(S.D)			
Mean CBD diameter in mm Mean(S.D)	11.96(3.733)	11.31(4.27)	0.457
Number of calculi extracted Median(Range)	2(1-6)	1(1-10)	0.881
Intrahepatic calculi (Yes)	3(8.10%)	4(8.33%)	0.999
Intrahepatic calculi (No)	34(91.90%)	44(91.67%)	
Extraction lithiasis with pressurized irrigation	2(5.40%)	12(25.00%)	0.034
Extraction lithiasis with pressurized irrigation	35(94.60%)	36(75.00%)	
Operative time in minutes Mean(Range)	127.27(70-180)	136.54(80-200)	0.166
Conversion to open surgery (Yes)	0	0	0.232
Conversion to open surgery (No)	37(100%)	48(100%)	
Residual lithiasis (Yes)	0	0	0.232
Residual lithiasis (No)	37(100%)	48(100%)	

*Qualitative variables were analyzed by chi-squared test. Number of patients and percentage n (%) calculated for both fibrin-sealant and control groups.

*Quantitative Variables were analyzed by student's t-test. Descriptive statistics were calculated mean, standard deviation, median and range for both fibrin-sealant and control groups.

Post-operatively, hemoglobin concentration level was significantly more in fibrin-sealant group than that of control group. The other post-operative outcomes had no statistically significant differences in ICU stay, post-operative hospital stay, drainage volume during the first 24 hours after the surgery and drain output. The incidence of biliary leakage in fibrin-sealant

group was one patient (2.70%) and had Grade-A leakage while in control group were four patients (8.33%) two patients had Grade-A leakage and the other two patients had Grade-B leakage. In spite of the difference between two study groups, there was no statistically significant difference ($p=0.529$) (Table 2).

Table 2: Comparison of post-operative outcomes between two study groups.

Variable	Fibrin-sealants group	Control group	p-value
ICU stay (Yes)	1(2.70%)	0	0.895
ICU stay (No)	36(97.30%)	48(100%)	
Post-operative drainage volume (ml) first 24h	77.16(65.80)	87.08(81.48)	0.536
Post-operative bile leakage (Yes)	1(2.70%)	4(8.33%)	0.529
Post-operative bile leakage (No)	36(97.30%)	44(91.67%)	
Post-operative hemoglobin gr/dl Mean(S.D)	14.72(1.02)	14.05(1.09)	0.004

Post-operative drain output day Mean(Range)	5.13(3-9)	5.47(3-12)	0.371
Length of hospital stay Median(Range)	12(6-23)	11(6-23)	0.226
Length of post-operative hospital stay	6(3-16)	6(4-13)	0.551

However, when we analyzed the effect of fibrin-sealant, it was detected that the application of fibrin-sealant reduced the incidence of biliary leakage without any significant side effects in fibrin sealant group.

DISCUSSION

It has been demonstrated that endoscopic retrograde cholangiopancreatography (ERCP), followed by laparoscopic cholecystectomy (LC) in a second step and laparoscopic common bile duct exploration (LCBDE)+LC in the same procedure are similar in terms of efficacy for the treatment of choledocholithiasis, but overall duration of hospital stay is shorter and surgeons fee is lower for LC+LCBDE [1,3,4]. Single- and two-stage management for cholecysto-choledocholithiasis had similar mortality and complication rates; however, the single-stage strategy was better in terms of stone clearance, hospital stay and total operative time [8,9]. On the other hand endoscopic retrograde cholangiopancreatography effectiveness is between 75% to 90% and also has some failure related factors, such as postsurgical gastrointestinal anastomotic variations, duodenal diverticulum, embedded stones in the ampulla of Vater, intrahepatic bile duct stones and common bile duct strictures [10,11]. Some surgeons suggest endoscopic sphincterotomy plus laparoscopic cholecystectomy for the management of CBD stones, but a higher mortality rate and number of hospital admissions are noted for endoscopic sphincterotomy compared with laparoscopic common bile duct exploration [12,13]. Some researches also demonstrated that primary closure of CBD after LCBDE is safe and associated with fewer complications than T tube drainage, because there are many reports of complications with T tube drainage, including bile leakage after T tube removal, tract infection, electrolyte and nutritional disturbances [6, 14]. A primary closure of CBD following LCBDE combined with intraoperative choledochoscopy and D-J tube drainage is safe and feasible for choledocholithiasis treatment, but the prosthesis itself can be a cause of morbidity, in addition to the discomfort that an endoscopy causes the patients for its removal [15, 16]. Some studies demonstrated that the transcystic approach to LCBDE is the ideal method because exploration and choledochorraphy of the CBD can be avoided [17,18]. In addition, it has lower complication rate than the trans-CBD method. However, the success rate of bile duct stone removal by transcystic route is lower than that of the trans-CBD method. Therefore, many surgeons found that the application of this method was limited and converted to the trans-CBD approach [5, 19-21]. Gradually LCBDE has become one of the most popular surgical treatments for patients with choledocholithiasis. Few studies also showed that LCBDE is safe, feasible and effective for patients with cholecystolithiasis and choledocholithiasis [5,6]. In addition, anatomical damage to the sphincter of Oddi is avoided in

LCBDE, which can be very important especially in young individuals. For these reasons, LCBDE may become the major approach and demanding procedure to treat patients with choledocholithiasis in the future. However, many researches demonstrated that primary closure of CBD after LCBDE with choledochoscopy is still a technique in which bile leakage is the most frequently postoperative complication [5,15,22].

Fibrin-sealant is the combination of two materials consisting fibrinogen and thrombin. In the presence of calcium chloride and factor XIII, the thrombin converts fibrinogen into fibrin fiber matrix which is the final stable form of the agent [23,24]. The application of fibrin-sealant glue in patients with bleeding from the gallbladder bed during LC has been shown to reduce bleeding and also the rate of conversion to open surgery [25,26]. Moreover, the use of fibrin sealants during liver resection are able not only to enhance clot formation and promote wound healing but possibly work as a sealing device for postoperative leakage and fistula formation [16,19,27,28]. Although human fibrin sealant has been shown to reduce post-operative bleeding through enhance clot formation and to promote wound healing after operations, also with a little clear whether it can reduce post-operative bile leakage of the CBD primary closure after LCBDE in patients with choledocholithiasis. One of the recent study also demonstrated that the application of fibrin sealant glue on CBD primary closure following LCBDE significantly decreases postoperative serous drainage [29]. In current study, we detected that the use of human fibrin-sealant decreased the incidence of biliary leakage without any significant side effects in the fibrin sealant group. Our surgery team also confirmed that during LCBDE hook and cut has better outcome than that of the hook and coagulation for the control of post-operative bile leakage. Moreover after a primary closure of CBD, this increase the biliary pressure in CBD and seems to be better supported by the application of fibrin-sealant also may sealed the gap between two stitches, which significantly decreasing the incidence of bile leakage. This study has some limitations; the major one is that this study is a prospective study. In addition, all of the cases were from one hospital. Therefore, prospective randomized clinical trials with larger sample sizes are needed, that may contribute more evidence.

CONCLUSION

In this study, we evaluate the application value of fibrin-sealant on CBD primary closure following LCBDE. Post-operatively, hemoglobin concentration level was significantly more in fibrin-sealant group than that of control group. The outcomes indicate that fibrin-sealants reduced the incidence of biliary leakage without any significant side effects in patients who experienced CBD primary suturing after LCBDE. Our surgery team also confirmed that during LCBDE hook and cut has better

outcome than that of the hook and coagulation for the control of post-operative bile leakage in patients with choledocholithiasis.

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