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Comparison on the Efficacy of Three Duct Closure Methods after Laparoscopic Common Bile Duct Exploration for Choledocholithiasis

Utho D Stati Data Uscri Lite Fui	rs' Contribution: Study Design A ata Collection B stical Analysis C Interpretation D pt Preparation E erature Search F nds Collection G	ABCDEFG ABCDEFG BCD BCD BCD BCD AEFG	Ancheng Qin* Jianwu Wu* Zhiming Qiao Min Zhai Yijie Lu Bo Huang Xinwei Jiang	Department of Hepatobiliary Surgery, Suzhou Municipal Hospital, The Affiliated Suzhou Hospital of Nanjing Medical University, Suzhou, Jiangsu, P.R. China			
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	Bacl Material/M	kground: Methods:	Laparoscopic common bile duct exploration (LCBDE) ledocholithiasis or the cases of endoscopic retrograd there is no clear consensus on the optimal duct closu evaluate the efficacy of 3 duct closure methods after In this analysis, 189 patients with choledocholithias 2018. According to different duct closure methods, group (n=66), common suture group (n=64) and ba	is currently the best approach for complex cases of cho- e cholangiopancreatography (ERCP) failure. Nevertheless, are method after LCBDE. The purpose of this study was to r LCBDE for choledocholithiasis. is underwent LCBDE between June 2014 and December these patients were divided into T-tube drainage (TTD) arbed suture group (n=59). The operation time, suturing			
		Results:	post-operative common bile duct (CBD) diameters we discharge, the incidence of complications and recurre The operation time, suturing time, and amount of in significantly less than those in the common suture g the TTD group, the suturing time, tube-carried time, group and the barbed suture group (P <0.01). The po	were all compared among the 3 groups. Six months after ent stones was observed. Intraoperative bleeding in barbed suture group were both group and the TTD group (P <0.01). When compared with and LOS were decreased markedly in the common suture ost-operative CBD diameters in the 3 groups were all sig-			
	Con	clusions:	nificantly larger than the pre-operative CBD diameter the 3 groups regarding the incidence of complication Barbed suture shortened the suturing time, operat amount of intraoperative bleeding in patients with cl the common suture and TTD.	ers (P<0.01). There was no statistical significance among as and recurrent stones (P>0.05). ion time, tube-carried time, and LOS, and lessened the noledocholithiasis after LCBDE. It was more effective than			
	MeSH Ke	eywords:	Choledocholithiasis • Common Bile Duct • Draina	ge • Laparoscopy • Sutures			
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Background

Gallstones are one of the most common digestive disorders worldwide, with the prevalence of 10% to 20% in adults in developed countries [1]. As a manifestation of gallstones in the common bile duct (CBD), choledocholithiasis occurs in 5% to 20% of patients with cholelithiasis [2,3]. It is universally recognized that the timely removal of CBD stones is of great importance. Nevertheless, the optimal treatment strategy for choledocholithiasis remains unclear. At present, minimally invasive surgical and endoscopic techniques mainly used in the treatment of patients with choledocholithiasis include single-stage procedures, such as laparoscopic cholecystectomy (LC) and laparoscopic common bile duct exploration (LCBDE), and 2-stage procedures, such as endoscopic retrograde cholangiopancreatography (ERCP) before or after LC [4,5]. These 2 options are effective in the detection and extraction of CBD stones. LC+LCBDE, however, has the advantages of less procedures, lower failure rate, shorter length of stay (LOS), and lower medical costs [6–8].

LCBDE is currently the best approach for complex cases of choledocholithiasis or the cases of ERCP failure [9]. It is performed to extract the stones through the cystic duct or CBD, but the transcystic duct can only be used in a very few patients due to some limitations [10,11]. As for the management of CBD after LCBDE, T-tube drainage (TTD) and primary suture are usually adopted. In recent years, some studies have demonstrated that primary suture of CBD is effective and safe after LCBDE, superior to TTD [12–14]. In laparoscopic surgery, however, suturing is regarded as one of the most difficult and time-consuming tasks due to the slipping or unraveling of knots.

Barbed suture, proposed by Mansberger first in 1951 [15], has been reported to facilitate laparoscopic suturing. The unidirectional barbed thread, a novel absorbable thread without knots, can decrease the laparoscopic suturing difficulty and improve the suturing speed by enabling the running sutures without knots [16]. To date, the barbed suture has been used in a variety of surgical fields, including urology department [17–19], gynecology department [20,21], oncology department [22], and general surgery department [23–25]. The purpose of this study was to evaluate the efficacy and safety of TTD, common suture, and barbed suture after LCBDE for choledocholithiasis, and to provide more evidence for selecting the optimal duct closure method after LCBDE.

Material and Methods

Participant selection

Between June 2014 and December 2018, a total of 189 patients with choledocholithiasis underwent LCBDE at the Department of

Hepatobiliary Surgery, Suzhou Municipal Hospital, The Affiliated Suzhou Hospital of Nanjing Medical University, China. According to different duct closure methods after LCBDE, these patients were divided into a TTD group (n=66), a common suture group (n=64), and a barbed suture group (n=59). The study was approved by the Ethical Committee of Suzhou Municipal Hospital (approval No. KL901028), and all the patients signed the informed consent.

The patients must conform to the following conditions, including 1) older than 18 years old of age; 2) choledocholithiasis diagnosed by color doppler ultrasound, magnetic resonance cholangiopancreatography (MRCP), or computed tomography (CT); 3) the inner diameter of CBD was more than 0.8 cm; 4) unobstructed bottom opening of the bile duct through cholangiography; 5) patient agreed to participate in this study and signed the consent inform. The exclusion criteria were as follows: 1) patient with acute obstructive suppurative cholangitis, biliary pancreatitis, biliary tract cancer, or biliary malformation; 2) distal stenosis of CBD or dysfunction of papillary muscles via the choledochoscopy; 3) complication with acute hepatitis, and other conditions that could cause hepatic injury; 4) patients with cardiac, pulmonary, and renal insufficiency intolerable to laparoscopic surgery; 5) patients with coagulation disorders or conspicuous bleeding tendency; 6) patients who was taking part in other trials or had taken other trial drugs one month before enrollment; 7) patients unsuitable for this study based on the assessment of the supervising surgeons and anesthetists.

Operation techniques

All the patients underwent general anesthesia and took a supine position after successful artificial pneumoperitoneum. Through the quadripuntal method, trocars were punctured into the abdominal cavity to expose the Calot triangle, and to determine the junction of the cystic duct and CBD. Then, the cystic artery was cut off to dissociate the junction of the cystic duct and CBD. Meanwhile, the upper clip of cystic duct was occluded to prevent the stones from falling into the CBD. The gall bladder was pulled towards upper right and the ligamentum hepatoduodenale was separated to make the CBD exposed. Finally, the stones were extracted after 1.0 to 1.5 cm of the CBD was cut open along the long axis of its anterior wall.

After LCBDE, the incision of the CBD in the common suture group and the barbed suture group was sutured with the common absorbable thread and the unidirectional barbed absorbable thread, respectively. Suturing methods were as follows: in common suture group, the common absorbable thread (type W9106, Johnson & Johnson Services, Inc., USA.) was used to continuously suture the CBD. During suturing, the first needle was knotted, and the last needle was knotted with the other primary suturing needle. In barbed suture group, the unidirectional barbed thread (type SXMD1B402, Johnson & Johnson Services, Inc., USA.) was adopted to continuously suture the CBD, with no need for knotting during suturing. The first needle should be slightly higher than the incision part, and the other needle was done after passing through the coil. A needle was back after suturing completion, and the redundant thread was occluded using an absorbable clip closely adhering to the bile duct wall. The incision was pressed mildly with a dry gauze after suturing, the laparoscopic type of biomedical glue was sprayed locally under no condition of bile leakages, and then a multihole vacuum drainage tube was placed in the small epiploic foramen to observe whether there was leakage of bile-like liquid or not. At last, the drainage tube was removed when the drainage volume was less, and the cholorrhagia was absent.

The procedures of TTD group were the same as other 2 groups before CBD suturing. TTD was placed after the bottom of CBD was confirmed unobstructed. The anterior wall opening of CBD was sutured discontinuously with the absorbable thread, and the water injection test was used to observe whether there was bile leakage or not. An abdominal drainage tube was placed routinely, and the removal of abdominal drainage tube was the same as other 2 groups.

Outcome measures

In the post-operative observation period, the operation time, suturing time, amount of intraoperative bleeding, tube-carried time, LOS and hospitalization costs were all recorded and compared among the 3 groups. The CBD diameters were compared pre- and post-operatively among the 3 groups.

Six months after discharge, the incidence of complications, such as biliary fistula, choleperitonitis and biliary stricture, and recurrent stones were observed among the 3 groups. Biliary fistula was defined as the post-operative cholorrhagia continuously for 3 days or the volume of single-drainage bile more than 100 mL per day. Choleperitonitis was defined as the presence of bile in the ascites through the puncture or reoperation, which could be diagnosed as local or systemic peritonitis. Biliary stricture was defined as the shrunken diameter of bile duct and distal cholangiectasis by MRCP. Recurrent stones referred to the presence of stones within 6 months after complete extraction of CBD stones [26].

Statistical analysis

SAS 9.4 software (SAS Institute Inc., USA) was used to analyze the data. Shapiro-Wilk test was used to confirm whether the measurement data conformed to the normal distribution. The data with normal distribution were expressed by the mean±standard deviation (SD) and were compared with

t-test or analysis of variance; while those with skewed distribution were expressed by the median and quartile [M(Q25, Q75)] and were compared with rank-sum test. The enumeration data were presented as n (%) with chi-square. The value of *P* less than 0.05 was considered statistically significant.

Results

Baseline characteristics of patients

Between June 2014 and December 2018, 189 patients with choledocholithiasis underwent LCBDE. Among these patients, there were 106 males and 83 females. The age of patients ranged from 21 to 84 years old, with the average age was 57.62 ± 15.66 years. The maximal diameters of CBD stones were 1.4 cm in common suture group, 1.5 cm in barbed suture group, and 1.7 cm in the TTD group, respectively. The baseline characteristics of patients in the 3 groups are listed in Table 1. No significant differences were shown among the 3 groups regarding the age, gender, aspartate transaminase (AST), alanine transaminase (ALT), total bilirubin (TBIL), direct bilirubin (DBIL), inner diameter of CBD, hepatolith and number of CBD stones (all P>0.05, Table 1).

Operative outcomes

The comparison on the operative outcomes of patients in the 3 groups is listed in Table 2. The operation time, suturing time and amount of intraoperative bleeding in barbed suture group were both significantly less than those in common suture group and TTD group, and there was statistical significance (P<0.01). When compared with TTD group, the suturing time, tube-carried time, and LOS were decreased markedly in common suture group and barbed suture group (P<0.01). No significant difference was presented among the 3 groups regarding the hospitalization costs (P>0.05).

Changes of pre- and post-operative CBD diameters

No significant differences were shown among the 3 groups regarding the pre- and post-operative CBD diameters (all *P*>0.05, Table 3; Figure 1). However, the post-operative CBD diameters in the 3 groups were all significantly larger than the pre-operative ones, and there was statistical significance (*P*<0.01, Table 3; Figure 1).

Incidence of complications and recurrent stones

There were 3 patients (4.69%, 3 out of 64 patients) in the common suture group, 3 patients (5.08%, 3 out of 59 patients) in the barbed suture group and 2 patients (3.03%, 2 out of 66) in the TTD group who respectively suffered biliary fistula. No significant difference was presented among the 3 groups

Variables	Commo	on suture group (n=64)	Barbe	d suture group (n=59)	т	TD group (n=66)	Ζ/ χ²	Р
Age (year)	50	(61.50, 71.00)	62	(38.00, 69.00)	64	(50.00, 70.00)	0.330	0.848
Male (n,%)	35	(54.69%)	35	(59.32%)	36	(54.55%)	0.365	0.868
AST (U/L)	43	(22.50, 81.50)	37	(26.00, 94.00)	31.5	(21.00, 87.00)	2.110	0.348
ALT (U/L)	74	(27.50, 172.00)	58	(27.00, 187.00)	42	(24.00, 135.00)	1.957	0.376
TBIL (µmol/L)	16.85	(12.15, 40.95)	25.1	(17.00, 35.80)	21.85	(14.60, 42.10)	4.526	0.104
DBIL (µmol/L)	7	(3.50, 24.10)	12	(8.20, 20.60)	12.6	(5.30, 27.60)	5.663	0.059
Inner diameter of CBD (cm)	0.9	(0.90, 1.10)	0.9	(0.80, 1.10)	0.9	(0.90, 1.10)	0.419	0.811
Hepatolith (n, %)	0		2	(3.39%)	2	(3.03%)	-	0.466
Number of CBD stones (n, %)							1.887	0.762
1	28	(43.75%)	29	(49.15%)	31	(46.97%)		
2	29	(45.31%)	26	(44.07%)	26	(39.39%)		
3	7	(10.94%)	4	(6.78%)	9	(13.64%)		

Table 1. Baseline characteristics of patients [M(Q25, Q75)].

Table 2. Comparison on the operative outcomes of patients in the 3 groups [M(Q25, Q75)].

Variables	Common suture group (n=64)	Barbed suture group (n=59)	TTD group (n=66)	Z	P	P ₁	P ₂	P ₃
Operation time (min)	77.5 (68.5, 88.5)	65 (55.0, 70.0)*#	77.5 (65.0, 90.0)	41.753	<0.001	0.997	<0.001	<0.001
Suturing time (min)	11.0 (9.0, 13.0)*	9.0 (8.0, 10.0)*#	16.5 (15.0, 19.0)	121.119	<0.001	<0.001	<0.001	<0.001
Amount of intraoperative bleeding (mL)	60 (50.0, 80.0)	35 (25.0, 45.0)*#	60 (30.0, 75.0)	34.298	<0.001	0.432	<0.001	<0.001
Tube-carried time (day)	6 (5.0, 7.0)*	5 (4.0, 6.0)*	32.5 (31.0, 35.0)	131.186	<0.001	<0.001	<0.001	0.316
LOS (day)	8 (7.0, 9.0)*	8 (7.0, 9.0)*	12 (11.0, 15.0)	125.818	<0.001	<0.001	<0.001	0.980
Hospitalization costs (yuan)	16289 (14604.5, 17436.5)	16194 (13026, 17694)	15945.5 (12541, 19487)	0.855	0.652	0.963	0.852	0.591

* $P_{<}0.01$ versus TTD group; # $P_{<}0.01$ versus common suture group. P_{j} , P_{z} and P_{3} represent the comparisons between the common suture group and the TTD group, between the barbed suture group and the TTD group, and between the common suture group and the barbed suture group, respectively.

regarding the incidence of biliary fistula (*P*=0.82). None of the patients encountered other complications or recurrent stones.

Discussion

With the development of medical techniques and instruments, LCBDE has become a preferential option for choledocholithiasis,

with the advantages of complete removal of stones, simultaneous management of the gallbladder and CBD stones, and maintenance of the integrity of the sphincter of Oddi [27]. It is conducted either through the CBD or the cystic duct. Although the transcystic duct is considered a safe and feasible approach, it is limited due to stringent requirements for the size, number, and location of stones, as well as the diameter and shape of cystic duct anatomy [10,11,28]. Currently,

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CBD diameter (cm)	Common suture group (n=64)	Barbed suture group (n=59)	TTD group (n=66)	Ζ/ χ²	Р
Pre-operation	0.9 (0.9, 1.1)	0.9 (0.8, 1.1)	0.9 (0.9, 1.1)	0.419	0.811
Post-operation	1.1 (1.0, 1.2)	1.1 (1.0, 1.2)	1.1 (1.0, 1.2)	0.870	0.647
Ζ	-5.935	-4.351	-5.455		
Р	<0.001	<0.001	<0.001		

Table 3. Changes of pre-operative and post-operative CBD diameters among the 3 groups [M(Q25, Q75)].



Figure 1. Changes of pre- and post-operative CBD diameters of patients in the 3 groups. * P<0.01 versus pre-operation.

LCBDE via the CBD is popular in the treatment of choledocholithiasis, but there is no clear consensus on the optimal duct closure method after LCBDE.

In the present study, we compared the efficacy and safety of 3 duct closure methods after LCBDE, including TTD, common suture, and barbed suture for choledocholithiasis. The results showed that when compared with the TTD group, the suturing time, tube-carried time, and LOS were decreased markedly in the common suture group and the barbed suture group, which suggested the primary suture of CBD was superior to TTD after LCBDE, consistent to the results of other studies [27,29,30]. TTD is a traditional management method after LCBDE for choledocholithiasis, which provides an easy percutaneous access for cholangiography and extraction of residual stones [13]. Nevertheless, it is easy to cause disturbance of water and electrolytes due to a lot of bile loss and relevant complications induced by T-tube insertion [28]. Primary suture is conductive to preserving the integrity of CBD and post-operative normal physiological function. It can decrease post-operative complications and shorten the LOS [31]. Additionally, the patients with primary suture don't need to carry T tube or drainage pack, which is of great importance for relieving post-operative pain and improving quality of life [10].

The results of the present study demonstrated that the operation time, suturing time, and amount of intraoperative bleeding in the barbed suture group were both significantly less than those in the common suture group and the TTD group, indicating that the barbed suture had the shortest operation time, suturing time, and least amount of intraoperative bleeding. Although primary suture is a significantly less procedure than TTD, but its common suture needs to tie a knot in a very limited visual field. It has been confirmed that about 50% of suture failures is caused by unraveling or slipping of the knots [32]. Barbed suture, a special suture with self-anchoring, unidirectional barbs, can prevent the slipping of suture after passing through the tissue. It is unnecessary to tie a knot after the initial tightening. This suture has a closure equivalence with Maxon because it can provide a safe, tension-free tissue approximation [33], but during laparoscopic suturing, it has a shorter suturing time, less amount of intraoperative bleeding and operation time bleeding by eliminating the need for knots.

In terms of CBD diameters, the post-operative CBD diameters in the 3 groups were all significantly larger than the pre-operative ones, which might be associated with the compensatory hyperplasia of the bile duct after LCBDE, indicating that the efficacy of common suture, barbed suture and TTD was similar in the improvement of CBD diameter. As for complications, there were 3 patients in the common suture group, 3 patients in the barbed suture group, and 2 patients in the TTD group who respectively suffered biliary fistula, and no other serious complications occurred. Moreover, none of the patients encountered recurrent stones among the 3 groups. The risk factors for recurrent stones primarily include continuous dilation of the bile duct, bile stasis, abnormal location of papillae, and duodenal-biliary reflux [34,35]. Based on these study findings and our study findings, different duct closure methods after LCBDE might be irrelevant to recurrent stones. However, more large-scale studies are required to confirm this.

The limitation of the present study was short follow-up duration. No significant difference was shown among the 3 groups regarding the incidence of complications. Hence, it is very necessary to prolong the follow-up duration to further evaluate the incidence of compilations.

Conclusions

Barbed suture can shorten the suturing time, operation time, tube-carried time, and LOS, and it can lessen the amount of intraoperative bleeding in patients with choledocholithiasis after LCBDE. It is more effective than the common suture and TTD.

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However, more large-scale studies with long follow-up duration are needed to verify the clinical value of the barbed suture.

Conflict of interests

None.

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