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· 专题研究 ·

新型自脱落式胆道支架在腹腔镜胆总管探查术中的应用 (附视频)

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摘要

背景与目的: 腹腔镜胆总管探查术(LCBDE)是治疗胆总管结石的常规方法,术中胆道支架置入(BSI)可能降低术后胆汁漏风险,但支架可能存在滞留、过早脱落等风险。本研究探讨新型自脱落式BSI在LCBDE治疗胆囊结石合并胆总管结石中的安全性和有效性。

方法: 回顾性分析2019年6月—2020年12月西安交通大学第一附属医院收治的胆囊结石合并胆总管结石的患者临床资料,将行LCBDE联合新型自脱落式BSI的患者作为观察组,行LCBDE联合一期缝合的患者作为对照组。所用支架直径5 Fr,长度5 cm,主体上有长度标识,其防滑侧翼采用同向开口,可预防支架过早脱落及长期滞留,螺旋尾部留置于十二指肠乳头外,可在消化道流体带动下牵引支架通过消化道排出体外。BSI方法:胆道镜下直视胆总管末端乳头内口,将0.035"导丝插过十二指肠乳头,使用取石网篮外鞘作为推送器将支架沿着导丝推入胆道内,当支架主体1 cm标记处通过乳头内口后,边退镜边推送支架,当支架末端完全脱离镜头后,撤除导丝完成直视下BSI。比较两组患者一般资料、术前血液化验指标、胆总管结石数量及最大直径、BSI所需时间、手术时间、术后并发症、术后住院时间,记录观察组胆道支架脱落率。

结果: 观察组纳入43例,对照组纳入52例。两组患者在术前一般资料、血常规、肝功能、胆总管直径及胆管结石大小上均具有可比性(均 $P>0.05$)。观察组BSI操作耗时中位时间14(10~20) min,但两组总体手术时间无明显差异[125(55~210) min vs. 116(50~200) min, $P>0.05$]。对照组术后有2例轻度胆汁漏(<50 mL/d),延长带管时间好转,观察组未观察到胆汁漏发生,两组之间胆汁漏发生率无明显差异($P>0.05$)。高淀粉酶血症在两组患者中均能观察到,无明显临床表现,保守好转,其发生率在两组间无明显差异(11.6% vs. 3.8%, $P>0.05$)。两组术后总并发症发生率无明显差异(16.3% vs. 9.6%, $P>0.05$)。观察组中位带管时间及中位术后住院时间均明显短于对照组[1(1~3) d vs. 2(1~5) d; 2(2~6) d vs. 3(2~8) d, 均 $P<0.05$]。观察组术后2 d复查腹部X片提示支架均在位,2周后支架脱落率88.4%,术后1个月所有患者支架均脱落。

结论: LCBDE术中联合自脱落式BSI安全有效,可缩短术后拔管时间和术后住院时间。

关键词

胆总管结石病;腹腔镜胆总管探查术;支架;引流术

中图分类号: R657.4

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Application of a new self-shedding biliary stent in laparoscopic common bile duct exploration (with video)

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Abstract

Background and Aims: Laparoscopic common bile duct exploration (LCBDE) is a traditional method for treating common bile duct stones. Intraoperative biliary stent implantation may reduce the risk of postoperative bile leakage but may give rise to prolonged retention or premature shedding of the stent. This study investigated the safety and effectiveness of implantation of a new type of self-shedding biliary stent in LCBDE for cholecystolithiasis with choledocholithiasis.

Methods: The clinical data of patients with concomitant cholecystolithiasis and choledocholithiasis treated in the First Affiliated Hospital of Xi'an Jiaotong University from June 2019 to December 2020 were retrospectively analyzed. Patients receiving LCBDE plus biliary stent implantation were selected as the observation group, and those undergoing LCBDE with primary closure were set as the control group. The stent used was 5 Fr in diameter and 5 cm in length, with a length scale marked in the main body, its anti-skid side wings opened toward the direction of the head to prevent the premature detachment or prolonged retention of the stent, and a spiral tail left outside the duodenal papilla for being pulled out under the drive of digestive tract fluid. The stent placement method was advancing the choledochoscope to the end of the common bile duct, endoscopically inserting a 0.035" guidewire through the duodenal papilla, using the outer sheath of the stone basket as a pusher to push the stent into the bile duct over the guide wire, pushing the stent while retrieving the choledochoscope when the 1-cm mark of the stent body passed through the inner orifice of the papilla, and removing the guidewire to complete the placement of the stent under the direct vision when the end of the stent completely disengages from the lens. The general data of patients, preoperative blood test results, the number and maximum diameter of common bile duct stones, the time for intraoperative biliary stent implantation, operative time, postoperative complications, and length of postoperative hospital stay were compared between the two groups, and the rate of stent shedding in observation group was recorded.

Results: Forty-three patients in the observation group and 52 patients in the control group were included. The general preoperative data, blood routine test, liver function parameters, common bile duct diameter and size of bile duct stones were comparable between the two groups (all $P>0.05$). The median time for stent implantation in observation group was 14 (10–20) min, but there was no significant difference in overall operative time between the two groups [125 (55–210) min *vs.* 116 (50–200) min, $P>0.05$]. In control group, there were 2 cases of mild bile leakage (<50 mL/d) after operation, which was improved after prolonging the abdominal drainage time. No bile leakage was observed in observation group, but there was no significant difference in the incidence of bile leakage between the two groups ($P>0.05$). Hyperamylasemia was observed in both groups, which caused no obvious clinical symptoms and was cured with conservative treatment. Its incidence rates showed no significant difference between the two groups (11.6% *vs.* 3.8%, $P>0.05$). There was no significant difference in the overall incidence of postoperative complications between the two groups (16.3% *vs.* 9.6%, $P>0.05$). The median time of abdominal drainage and length of postoperative hospital stay was significantly shorter in observation

group than those in control group [1 (1-3) d vs. 2 (1-5) d; 2 (2-6) d vs. 3 (2-8) d, both $P<0.05$]. In observation group, the abdominal X-ray showed that the stents were all in place on postoperative day 2, the rate of stent detachment was 88.4% after two weeks, and all stents fell off one month after the operation.

Conclusion: Using the new type of self-shedding biliary stent in LCBDE is safe and effective, and it can reduce the time of abdominal drainage and length of postoperative hospitalization.

Key words Cholelithiasis; Laparoscopic Common Bile Exploration; Stents; Drainage

CLC number: R657.4

腹腔镜胆总管探查术(laparoscopic common bile duct exploration, LCBDE)是治疗胆囊结石合并胆总管结石的首选术式^[1-2],胆汁漏是术后常见并发症之一。术中留置T管可减少胆道一期缝合(primary suture, PS)后的胆汁漏风险,但患者疼痛增加、生活质量降低^[3]。术中置入跨越乳头的胆道支架置入(biliary stent implantation, BSI)可以同时起到胆道减压、免除留置T管的双重目的,其安全性及有效性在LCBDE^[4]、肝脏移植^[5]等手术中已得到验证。笔者团队设计了一种可在胆道镜直视下置入、深度可控的自脱落式胆道支架,简化了操作,目前已在临床应用近3年。本文总结2019年6月—2020年6月接受LCBDE联合术中自脱落式BSI的患者,并与联合一期缝合者对比,分析该方法的有效性及其安全性。

1 资料与方法

1.1 一般资料

回顾性收集2019年6月—2020年12月西安交通大学第一附属医院肝胆外科收治的209例胆囊结石合并胆总管结石患者临床资料。本研究纳入标准:(1)首次影像学明确诊断胆囊结石合并继发性胆总管结石;(2)无急性梗阻性化脓性胆管炎或急性中重度胰腺炎;(3)胆总管直径8~20 mm;(4)美国麻醉医师协会(American Society of Anesthesiologists, ASA)评分II级或更低;(5)术中置入可脱落式胆道支架。排除标准:(1)术前或术中接受内镜下逆行性胰胆管造影术(endoscopic retrograde cholangiopancreatography, ERCP);(2)中转开腹或留置T管;(3)ASA评分III级或更高。入组流程见图1,最终纳入43例行LCBDE+自脱落式BSI患者(观察组)与同期52例行LCBDE+一期缝

合的患者(对照组)。

本研究为回顾性研究,符合《赫尔辛基宣言》的要求,患者及其家属在治疗前均签署知情同意书,并通过西安交通大学第一附属医院伦理委员会审批(伦理批件号:XJTU1AF2022LSK-082)。

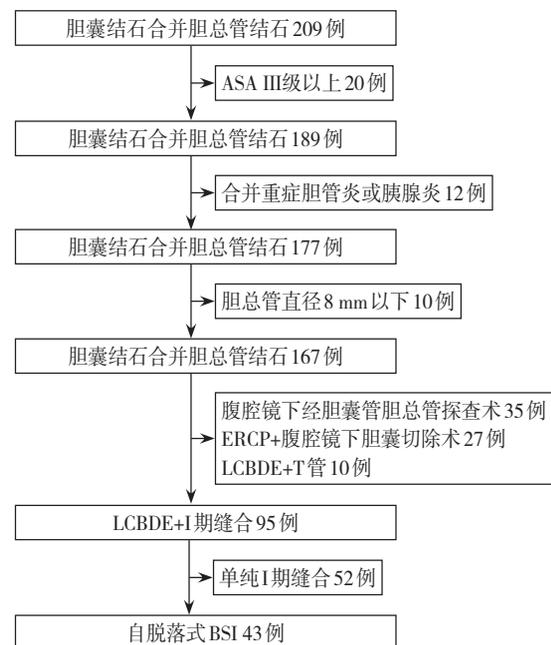


图1 研究入组流程

Figure 1 Inclusion process of the study

1.2 自脱落式胆道支架

本研究中所采用的自脱落式胆道支架为笔者团队自行设计(专利号:CN201811177838.2),材料为聚乙烯,未量产,环氧乙烷灭菌后包装备用。支架由引流管主体、防滑侧翼及螺旋尾部构成(图2)。支架主体直径5 Fr,可通过胆道镜2.2 mm的工作钳道,长度5 cm,同时主体上有长度标识,易于镜下判定已通过十二指肠乳头的主体长度;防滑侧翼采用同向开口(ERCP所用胆道支架

为防止脱落的反向开口),可预防支架过早脱落及长期滞留。螺旋尾部留置于十二指肠乳头外,有多个侧孔,可在消化道流体带动下牵引整个引流管通过消化道排出体外,实现自动拔管过程。

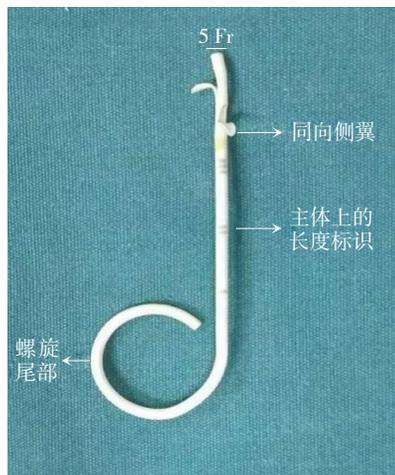


图2 自脱落式胆道支架

Figure 2 The self-shedding biliary stent

1.3 手术过程

LCBDE 手术具体流程与既往本中心研究^[2]类似。采用4孔法,首先游离胆囊三角,血管夹结扎胆囊管及胆囊动脉,暂不离断。剪刀打开胆总管前壁,置入胆道镜探查肝内外胆管并取出结石,明确结石无残留后,胆道镜下BSI:将取石网篮(NTSE, Cook Incorporation, 美国)拆解,留下外鞘(外径4.5 Fr)作为支架推送器备用。胆道镜下直视胆总管末端乳头内口,将0.035"导丝插过十二指肠乳头。若导丝难以通过,可经钳道插入网篮外鞘对准乳头内开口,在网篮外鞘辅助下将导丝插入十二指肠内。成功完成导丝留置后,使用网篮外鞘作为推送器将支架沿着导丝推入胆道内。当1 cm 标记处通过乳头内口后,边退镜边推送支架。当支架末端完全脱离镜头后,撤除导丝完成直视下BSI,4-0或5-0可吸收线(PDS)间断缝合胆总管开口。最后按常规方法切除胆囊,胆囊窝留置引流管1根(视频1)。

1.4 术后处理及观察指标

患者术后均按照快速康复原则处理,第1天恢复流食,减少补液量;术后第2天复查腹部超声观察腹腔有无积液,尽早拔出引流管,择期出院。观察组术后第1天复查腹部平片观察支架位置。

观察指标:胆总管结石数量及最大直径、BSI成功率、术中BSI所需时间(从乳头插管至支架释放完毕)、手术时间(从切皮开始至伤口缝合)、手术相关并发症、术后住院时间及术后2周及1个月支架在位率等。

术后胰腺炎定义:术后出现持续性的胰腺炎相关的临床症状,如新出现的或加重的腹部疼痛,伴有术后24 h血清淀粉酶超过正常上限的3倍^[6]。术后胆管炎定义:术后出现发热、腹痛黄疸加重、白细胞升高和/或血培养为肠源性细菌,经胆道引流后缓解,没有其他感染灶证据^[7]。胆汁漏定义:术后引流管内可见胆汁样液体,且胆红素浓度在血清胆红素浓度3倍以上^[7]。



视频1 腹腔镜下胆总管切开取石+术中新型自脱落式BSI

Video 1 Laparoscopic common bile duct exploration and intraoperative BSI with the new self-shedding biliary stent

扫描至移动设备观看手术视频:



<http://www.zpwz.net/zgptwkzz/article/abstract/PW220226>

1.5 随访

采用门诊或电话随访患者。术后1个月复查血常规、肝功能、腹部超声,术中BSI者复查腹部X线了解。随访时间截至2021年12月。

1.6 统计学处理

应用SPSS 26.0统计软件进行分析。正态分布的计量资料以均数±标准差($\bar{x} \pm s$)表示,组间比较采用t检验;偏态分布的计量资料以中位数(范围)[M (IQR)]表示,组间比较采用Mann-Whitney U检验。计数资料以例数(百分比)[n (%)]表示,组间比较采用 χ^2 检验或Fisher确切概率法。 $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 术前资料分析

两组患者在性别比例、年龄分布、合并慢性

疾病比例、血常规、肝功能指标、胆总管直径及胆总管结石最大径上均无明显差异(均 $P>0.05$)(表1)。

表1 观察组与对照组术前资料比较

Table 1 Comparison of the preoperative data between observation group and control group

因素	观察组(n=43)	对照组(n=52)	$t/\chi^2/Z$	P
性别[n(%)]				
男	20(46.5)	25(48.1)		
女	23(53.5)	27(51.9)	0.02	0.88
年龄(岁, $\bar{x}\pm s$)	42.9±16.8	43.5±13.9	0.45	0.65
合并慢性疾病[n(%)]				
高血压	15(34.9)	10(19.2)		
糖尿病	8(18.6)	7(13.5)	0.20	0.91
冠心病	9(20.9)	6(11.5)		
白细胞($\times 10^9/L$, $\bar{x}\pm s$)	5.97±2.17	6.64±3.24	1.16	0.25
血红蛋白(g/L, $\bar{x}\pm s$)	131.3±17.6	134.7±18.5	-0.83	0.41
丙氨酸氨基转移酶[U/L, $M(IQR)$]	77.3(8.3~1031.6)	90.0(2~959.6)	-0.221	0.83
天门冬氨酸氨基转移酶[U/L, $M(IQR)$]	45.3(5~531.1)	57.6(13~983.0)	-0.734	0.46
总胆红素[$\mu\text{mol/L}$, $M(IQR)$]	18.1(6.1~175.8)	18.6(4.1~193.5)	-0.536	0.59
白蛋白(g/L, $\bar{x}\pm s$)	41.6±5.4	39.6±5.3	1.764	0.08
胆总管直径[mm, $M(IQR)$]	11(9~18)	10(8~15)	-1.84	0.07
胆总管结石直径[mm, $M(IQR)$]	6(1~8)	6(2~9)	-0.587	0.56

2.2 术中及术后数据

观察组所有患者均完成术中BSI,成功率100%。术中及术后数据见表2。观察组BSI操作耗时中位时间14(10~20)min,但两组之间的总体手术时间无明显差异($P>0.05$)。对照组术后有2例轻度胆汁漏($<50\text{ mL/d}$),延长带管时间好转,观察组未观察到胆汁漏发生,但两组之间胆汁漏发生率无明显差异($P>0.05$)。高淀粉酶血症在两组患者中均能观察到,发生率无明显差异($P>0.05$),但由于无明显临床表现,无特殊处理。总体上两组术后并发症发生率无明显差异[16.3%(7/43) vs. 9.6%(5/52), $P>0.05$]。观察组术后中位带管时间及中位住院时间明显短于对照组(均 $P<0.05$)。术后2d复查腹部X片提示支架均在位,2周后支架脱落率88.4%,术后1个月所有患者支架均脱落。

表2 观察组与对照组术中、术后资料比较

Table 2 Comparison of the intra- and postoperative variables between observation group and control group

项目	观察组(n=43)	对照组(n=52)	χ^2/Z	P
出血量[mL, $M(IQR)$]	59.5(10~80)	56.0(19~80)	-1.39	0.16
手术时间[min , $M(IQR)$]	125(55~210)	116(50~200)	-1.32	0.89
术后并发症[n(%)]	7(16.3)	5(9.6)	0.95	0.33
胆汁漏	0(0.0)	2(3.8)	1.67	0.19
胆道感染	2(4.7)	1(1.9)	0.57	0.45
高淀粉酶血症	5(16.6)	2(3.8)	2.09	0.14
引流管拔出时间[d, $M(IQR)$]	1(1~3)	2(1~5)	-2.40	0.02
术后住院时间[d, $M(IQR)$]	2(2~6)	3(2~8)	-2.57	0.01
支架在位[n(%)]				
术后2d	43(100.0)	—	—	—
术后2周	5(11.6)	—	—	—
术后1个月	0(0.0)	—	—	—

3 讨论

LCBDE 治疗继发性胆总管结石符合胆道外科医生关注的 Oddi 括约肌功能保护^[8], 但胆管切开一期缝合可能带来的胆汁漏、胆管狭窄等风险也是限制其广泛推广的因素^[9]。虽然术中留置 T 管是临床上常用来降低术后胆汁漏的措施, 但目前多项随机对照研究均提示留置 T 管与一期缝合相比并不能降低术后胆道相关并发症^[10], 且增加手术时间、术后住院时间及降低患者生活质量^[11], 放置 T 管在 LCBDE 中优势并不明显。笔者在临床工作中亦有类似体会, 本单位 LCBDE 中留置 T 管的例子只有 7.1% (10/140)。术中放置鼻胆引流管 (endoscopic nasobiliary drainage, ENBD) 是 T 管的一种替代方法, 国内研究^[12-13]证实三镜联合 (腹腔镜、胆道镜、十二指肠镜) “一步法” 治疗继发性胆总管结石可缩短住院时间、节省医疗费用, 但受限于大多数手术室内无十二指肠镜及繁琐的操作过程。术中胆道支架内引流理论上可避免了 T 管或 ENBD 外引流法导致胆汁丢失所致的电解质紊乱等并发症, 同时还能对胆道进行有效减压, 扩大一期缝合的适应证。本研究自脱式支架采用新型设计, 与一期缝合相比较具有以下优势。

3.1 新型自脱式胆道支架操作简便, 未增加手术时间

目前缺乏无专门用于腹腔镜或开腹术中的胆道支架, 已报道研究中使用的多为改制于 ERCP 的胆道支架或自行研制的 J 支架, 如 DePaula 等^[14]报道在 LCBDE 时放置 ERCP 胆道支架引流, Kim 等^[15]将 ERCP 支架头端侧翼剪掉以利于支架自行脱落, 田明国等^[16]采用自制 J 型自脱落胆道支架或眼镜蛇形自行脱落胆道支架^[17]。以上研究虽然使用的支架不用, 但具有类似的操作步骤^[14-17], 均较为繁琐: 需先通过胆道镜置入导丝顺利通过十二指肠乳头, 将导丝自胆道镜身退出, 然后再沿着导丝经过穿刺器将支架推入胆道; 若要直视判断支架进入的深度, 则需再次经胆道开口进胆道镜观察或术中拍片。BSI 完成后, 为保证不至于过早脱落, 部分研究^[16]使用可吸收线将支架和胆管壁缝合在一起。但本研究中采用适于胆道镜下操作的 5 Fr 的支架, 所有操作均在直视下完成, 无须反复进出胆道镜, 简化操作, 支架置入深度可控。虽然操作耗时 14 min, 但并未明显增加总体的手术时间。

3.2 新型自脱落式支架脱落率高

术中胆道支架置若不能自行脱落, 需再次进行内镜拔出操作, 这是外科医生最担心的问题。研究^[14]结果显示, 使用常规的 8.5 Fr ERCP 支架具有防脱落反向侧翼, 基本不会自行脱落, 术后 3~4 周需再使用内镜取出, 将 ERCP 支架头端翼剪掉可增加脱落率, 术后 (11.5±9.5) d, 44 例患者中 36 例自行脱落, 但仍有 8 例须再次内镜取出^[15]。不同于常规 ERCP 支架, 尾部螺旋的 J 型支架可明显增加脱落率。在纳入 150 例使用直径 3 mm 的 J 型支架的研究^[16]中, 术后 13.6 d, 149 例患者支架完全排出体外, 脱落率高达 99.3%。在 ERCP 治疗中, 采用“猪尾”设计的可脱落支架可充分引流胆道, 在 104 例中 103 例术后在 9~14 d 内脱落并经消化道自行排出体外^[18]。与以上研究类似, 本研究所采用的支架同样采用螺旋尾部设计, 术后 2 周支架脱落率 90% 左右, 术后 1 个月完全脱落, 完全避免二次内镜操作。在动物实验中, 术后 5~7 d 胆道端端吻合口在胶原蛋白含量及抗张强度接近正常胆管组织^[19]。在临床上, 胆汁漏在充分的内外引流的情况下, 愈合的时间在 7~10 d^[20]。因此胆道内支架最主要的引流时间在术后 7 d 内。本研究自脱落支架采用同向防滑侧翼设计, 可避免过早脱落和长期滞留, 术后 2 d, 100% 在位, 保证术后早期胆道充分减压。

3.3 新型自脱落式胆道支架可能降低术后胆汁漏风险, 未增加术后并发症

动物实验^[21]提示, 术中 BSI 与一期缝合相比, 可明显降低术后胆汁漏发生率 (0 vs. 25%, $P < 0.05$)。目前临床上有多篇研究^[3,5,10]证实术中胆道支架内引流可安全用于临床, 即使在急性胆源性胰腺炎中亦具有应用价值^[22], 但缺乏术中胆道内支架与一期缝合对比的临床研究。目前只有一篇纳入 46 例的回顾性研究^[23]提示术中胆道支架内引流优于一期缝合, 可降低术后并发症发生率。纳入 12 篇临床研究的系统分析提示, T 管组的总体并发症发生率高于胆道支架组和一期缝合组, 胆道支架组的胆汁漏发生率低于 T 管组, 而 T 管组和一期缝合组胆汁漏率无差异, 提示胆道支架组胆汁漏发生率可能低于一期缝合组^[24]。本研究结果与上类似, 虽然一期缝合组胆汁漏例数多于胆道支架组, 但两组发生率无明显差异。

胆道感染及高淀粉酶血症也是 LCBDE 术后的

常见并发症^[25-26], 本研究中两组发生率无明显差异, 提示胆道内引流支架不是发生胆道感染或高淀粉酶血症的因素。胆道感染多与注水压力过多、操作时间过长、胆道结石未尽等因素有关, 因此在取石操作时在视野清晰的条件下适量注水即可, 同时尽量完整取出结石破裂残渣, 取出的结石数量与术前磁共振一致以保证结石取尽。术后高淀粉酶血症多与导丝或网篮反复刺激乳头引起胰管开口水肿有关, 如本研究所示, 多无临床表现, 不足以诊断急性胰腺炎。

3.4 新型自脱落式胆道支架临床优势

术中胆道支架除了可能降低临床胆汁漏的优势外, 还可能缩短住院时间、带管时间、减少医疗费用等。何俊等^[27]比较了术中BSI与留置T管在LCBDE中的应用, 前者腹腔引流管放置时间(3.33 ± 0.77) d、住院时间(4.80 ± 0.80) d、住院费用($11\,954.47 \pm 1\,098.00$)元, 明显低于后者腹腔引流管放置时间(6.12 ± 0.85) d、住院时间(7.17 ± 0.70) d、住院费用($13\,419.64 \pm 1\,470.90$)元。付金强等^[28]、李慧华等^[29]及何松狮等^[30]的研究中均指出, 术中留置胆道支架在住院费用及术后住院时间上比放置T管更有优势。在术中胆道支架和单纯一期缝合的对比研究中, 两者的平均住院时间分别为7.21 d和8.26 d ($P=0.06$), 虽然没有显著性差异, 但存在缩短趋势^[23]。与以上研究类似, 本研究术中观察组术后住院时间及带引流管时间均显著低于单纯缝合组, 这可能与胆道内压力低、局部炎症反应轻有关。

综上, LCBDE术中使用自制可脱落式胆道支架内引流可安全、有效, 可减少术后带腹腔引流管时间及术后住院时间。

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