

# 胆漏的位置可能是影响首次内镜逆行胰胆管造影术成功的相关因素

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**摘要:**【目的】探究胆漏的位置可能是影响首次内镜逆行胰胆管造影术(ERCP)成功的相关因素。【方法】回顾性分析广州医科大学附属第二医院自2012年6月至2017年4月行肝胆手术后疑似胆漏患者的临床资料。所有患者均行ERCP,分为胆囊管漏组(9例)和肝内胆管漏组(10例),统计分析白细胞计数、肝功能变化及治愈情况。【结果】19例患者均顺利完成治疗,术后未出现出血、穿孔、感染休克等严重并发症。两组患者手术前后白细胞计数、肝功能及改善情况比较差异无统计学意义( $P>0.05$ )。把首次ERCP成功者分为A组( $n=11$ ),失败者为B组( $n=8$ )。单因素分析性别、年龄、术前ALT、AST、TBIL及手术类型与首次ERCP成功的影响无统计学意义( $P=0.650$ 、 $P=0.869$ 、 $P=0.481$ 、 $P=0.620$ 、 $P=0.340$ 、 $P=0.362$ )。而白细胞计数( $P=0.015$ )及胆漏的位置( $P=0.020$ )有统计学意义。精确Logistic回归分析显示胆漏的位置有统计学意义( $P=0.0004$ ,  $OR=5.448$ ,  $95\%CI=2.347\sim+\infty$ )。【结论】内镜逆行胰胆管造影术(ERCP)治疗胆漏是安全和有效性的。胆漏的位置可能是影响首次ERCP成功的相关因素。

**关键词:**内镜;胆漏;支架

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## Location of Bile Leakage may be a Relevant Factor Influencing the Success of the First ERCP

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**Abstract:**【Objective】To investigate the location of bile leakage as a relevant factor influencing the success of the first endoscopic retrograde cholangiopancreatography (ERCP) procedure.【Methods】A retrospective analysis was conducted to investigate clinical data coming from the Second Affiliated Hospital of Guangzhou Medical University from June 2012 to April 2017. Data were collected from patients with suspected biliary leakage HBP post-operation. All of the patients having undergone ERCP procedure were divided into the cystic duct leakage group (9 cases) and the intrahepatic bile duct leakage group (10 cases). A statistical analysis was performed on WBC counts, liver function changes, and improvement of the disease.【Results】All of the 19 cases had successfully completed the ERCP treatment with no serious postoperative complications. Especially, GI bleeding, perforation, infection and shock were not found. Unfortunately, no significant differences were observed in WBC counts, liver function changes and improvement between the two groups before and after the operation ( $P>0.05$ ). Interestingly, the first successful ERCP procedure was assigned as Group A ( $n=11$ ), the first unsuccessful ERCP procedure was assigned as Group B ( $n=8$ ). A univariate analysis on the influence of gender, age, preoperative ALT, AST, TBIL and surgery type on the success of the first ERCP procedure had shown no statistical difference ( $P=0.650$ ,  $P=0.869$ ,  $P=0.481$ ,  $P=0.620$ ,  $P=0.340$ ,  $P=0.362$ ), while there were statistical differences in WBC count

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( $P=0.015$ ) and bile leakage location ( $P=0.020$ ). An exact Logistic regression analysis had shown that there was a significant difference in the location of bile leakage ( $P=0.0004$ ,  $OR=5.448$ ,  $95\%CI=2.347\sim+\infty$ ).【Conclusions】Bile leakage treated with ERCP method is safe and effective. The location of bile leakage is a relevant factor influencing the success of the first ERCP procedure.

**Key words:** endoscopic; biliary leak; stent

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医源性胆管损伤是肝胆手术后罕见的严重不良事件之一,尽管手术技术及设备不断改进,但是不良事件的发生率并未改变<sup>[1]</sup>。从国内外临床统计数据显示,80%的医源性胆管损伤来源于胆囊切除术,尤其是腹腔镜胆囊切除术(laparoscopic cholecystectomy, LC)<sup>[2]</sup>,其他常见的医源性因素包括肝切除术、胆道探查术等。其中约80%的胆管损伤存在胆漏<sup>[3-4]</sup>。渗漏的胆汁进入腹腔造成胆汁性腹膜炎,或被包裹形成胆汁瘤,为细菌的生长和入侵提供有利条件,促使患者容易发生脓毒血症。因此,医源性胆漏必须及时诊断和处理。在这种情况下,提出了确定性治疗包括手术、经皮肝胆管引流(percutaneous transhepatic cholangial drainage, PTCD)和内镜。再次手术是侵入性治疗方式,非专科医生初次修复的成功率只有17%~27%。不仅发生狭窄风险高,而且还对后续的专科修复造成不利影响<sup>[5]</sup>。PTCD可解决44%~70%胆漏<sup>[6-7]</sup>,然而PTCD导管需要在体内留置数月,对生活有负面影响。随着内镜技术和设备的进步,内镜逆行胰胆管造影术(endoscopic retrograde cholangiopancreatography, ERCP)可以识别95%以上的胆漏部位<sup>[8-10]</sup>。内镜不仅是检测胆漏的标准诊断方法,而且已经成为胆漏管理的替代治疗选择<sup>[11-12]</sup>。大多数研究描述ERCP治疗胆囊切除术或肝切除术后胆漏的有效性,很少有报道描述影响内镜治疗结果的因素。本研究基于广州医科大学附属第二医院ERCP技术平台对疑似胆漏患者行内镜下治疗,探讨内镜治疗在肝胆外科手术后胆汁渗漏的有效性和影响内镜治疗结果的相关因素。

## 1 材料与方 法

### 1.1 一般资料

收集2012年6月至2017年4月在广州医科大学附属第二医院行肝胆手术后疑似胆漏患者19

例,经磁共振胰胆管成像(magnetic resonance cholangiopancreatography, MRCP)或腹部增强计算机断层扫描(computed tomography, CT)确证后均行内镜逆行胰胆管造影术(ERCP)。所有患者均签署书面知情同意书,并获得广州医科大学附属第二医院伦理委员会批准。

### 1.2 纳入标准和排除标准

**纳入标准:**患者近期有上腹部手术病史;患者术后短期内出现寒战高热、腹膜炎等临床异常表现;实验室检查白细胞计数和中性粒细胞比例升高,肝功能异常者;手术后短期内腹腔引流管可见胆汁样液体流出;腹部增强CT或MRCP证实胆汁渗漏。

**排除标准:**患有严重的心肺功能不全;并发脓毒血症、肝肾功能衰竭,生命体征不稳;影像学检查提示胆管横断;ERCP插管不成功或者导丝不能进入肝内胆管;胆管组织缺损严重;病人未完成预期治疗,失访或者随访资料不全。

### 1.3 内镜干预措施和分组标准

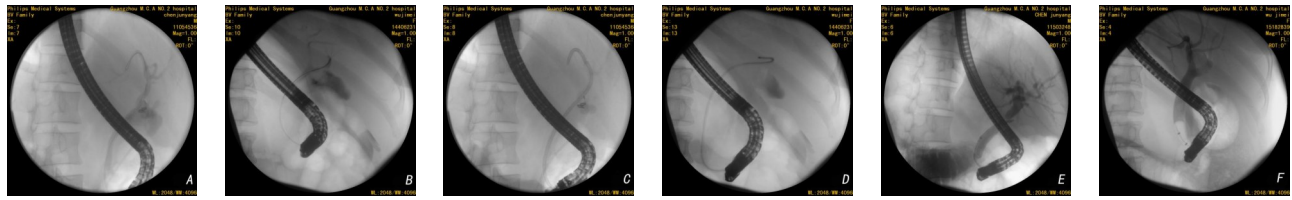
术前排除ERCP绝对禁忌证,常规行ERCP术前准备。在全麻下将十二指肠镜插至十二指肠降部,找到十二指肠乳头,先行逆行胰胆管造影,明确胆漏部位。根据胆漏部位分为胆囊管漏组和肝内胆管漏组。所有患者均内镜下行括约肌切开,以降低胆道内压力,促进胆汁经乳头流出。由内镜医生确定插入直径7Fr或10Fr胆管支架(图1A-D)。

### 1.4 术后管理

术后广泛运用抗生素,术后复查血常规、肝功能指标,记录临床症状是否改善,引流管量,复查CT了解积液减少情况。若上述情况明显改善视为内镜治疗成功,反之被视为失败。

### 1.5 术后随访

1、4周复查血常规、肝功能、腹部超声或者CT等检查,12周内镜下拔出支架,内镜造影评估胆漏愈合情况(图1E、F),若未愈合,则更换支架。随访时间持续1年。



A: Extravasation of contrast from the cystic duct remnant; B: Extravasation of contrast from the intrahepatic duct; C: Biliary stent overpassing the cystic duct; D: Biliary stent as close as possible to leakage location; E: No leakage of cystic duct by ERCP; F: No leakage of intrahepatic bile duct by ERCP.

图1 ERCP操作简图

Fig. 1 Sketch of ERCP procedure

## 1.6 统计学处理

采用SPSS 24.0软件进行统计分析,非对称分布的计量数据,采用中位数和四分位数间距 $M(P_{25} \sim P_{75})$ 表示,两组数据比较用Mann-Whitney  $U$ 检验。计数或分类变量, $n < 40$ 或理论频数 $T < 1$ ,组间比较采用Fisher确切概率法。因变量与自变量间的影响关系采用精确Logistic回归分析。检验标准 $\alpha = 0.05$ ,  $P < 0.05$ 为差异有统计学意义。

## 2 结果

### 2.1 各组患者临床资料分析

纳入本研究共计19例患者,根据胆漏部位分为胆囊管漏组和肝内胆管漏组,进行回顾性分析。结果发现两组在性别、年龄、WBC、ALT、AST、TBIL

之间差异无统计学意义,手术类型有统计学意义( $P = 0.001$ ;表1)。

### 2.2 术后临床指标和随访结果

本回顾性研究共纳入19例患者,胆囊管漏组9例,肝内胆管漏组10例。ERCP治疗术后1周,胆囊管漏组和肝内胆管漏组WBC分别为 $7.7(6.7 \sim 8.2) \times 10^9/L$ 和 $8.3(7.1 \sim 8.7) \times 10^9/L$ ;ALT分别为48(44~52)和53(50~60)U/L;AST分别为43(39~46)和49(43~58)U/L;TBIL分别为28(26~30)和29(26~31)mmol/L。两组术前、术后1周的WBC、ALT、AST、TBIL相比无统计学意义( $P = 0.178/P = 0.327$ ,  $P = 0.286/P = 0.054$ ,  $P = 0.177/P = 0.110$ ,  $P = 0.305/P = 0.426$ ),两组术后临床检验改善情况相比无统计学意义( $P = 0.567$ ,  $P = 0.540$ ,  $P = 0.870$ ,  $P = 0.565$ ;表2)。肝内胆管漏组术后出现1例胰腺炎,1例需行经皮穿刺

表1 19例胆漏患者临床资料特征

Table 1 Clinical data characteristics of 19 cases of bile leakage

$[P_{50}(P_{25} \sim P_{75})]$

	Cystic duct group	Intrahepatic duct group	Z	P
n	9	10		
Gender (Male/Female)	4/5	6/4	-	0.656
Age/years	57(42, 66)	60(44, 67)	-0.245	0.806
Surgery type			-	0.001
LC	7	1		
Liver resection	2	9		
WBC( $\times 10^9/L$ )	11.8(11.1, 13.7)	13.0(12.0, 14.8)	-1.348	0.178
ALT/(U/L)	78(71, 83)	82(76, 84)	-1.066	0.286
AST/(U/L)	67(61, 70)	72(64, 77)	-1.350	0.177
TBIL/(mmol/L)	32(29, 33)	34(29, 38)	-1.026	0.305

WBC: white blood cells; ALT: alanine aminotransferase; AST: aspartate aminotransferase; TBIL: total bilirubin; LC: laparoscopic cholecystectomy

引流。

表2 两组ERCP前后临床检验及改善情况比较

Table 2 Comparison of clinical examination and improvement between pre-and post-ERCP [P<sub>50</sub>(P<sub>25</sub>~P<sub>75</sub>)]

Items	n	Clinical examination level pre-and post-ERCP			
		WBC×(10 <sup>9</sup> /L)	ALT/(U/L)	AST/(U/L)	TBIL/(mmol/L)
Cystic duct group	9	11.8(11.1~13.7)/	78(71~83)/	67(61~70)/	32(29~33)/
		7.7(6.7~8.2)	48(44~52)	43(39~46)	28(26~30)
Intrahepatic duct group	10	13.0(12.0~14.8)/	82(76~84)/	72(64~77)/	34(29~38)/
		8.3(7.1~8.7)	53(50~60)	49(43~58)	29(26~31)
Z		-1.348/-0.980	-1.066/-1.924	-1.350/-1.598	-1.026/-0.797
P		0.178/0.327	0.286/0.054	0.177/0.110	0.305/0.426
diff		4.8(3.8~6.0)	22(22~37)	24(14~30)	4(1~7)
Z		-0.572	-0.613	-0.164	-0.576
P		0.567	0.540	0.870	0.565

diff=median(pre-ERCP) - median(post-ERCP); WBC: white blood cells; ALT: alanine aminotransferase; AST: aspartate aminotransferase; TBIL: total bilirubin; LC: laparoscopic cholecystectomy

19例胆漏患者中,胆囊管漏组首次ERCP治疗成功8例,成功率为89%。肝内胆管漏组首次ERCP治疗成功3例,成功率为30%。术后4周,两组患者临床检验改善情况相比无统计学意义(P=0.682、P=0.512、P=0.681、P=0.595;表3)。12周后再次内镜下造影,胆囊管漏组中1例需再次内镜干预。而肝内胆管漏组多数需多次更换支架。两组患者最终经多次内镜下干预使临床治愈率达100%。跟踪随访1年,未见异常表现。

2.3 精确 Logistic 回归分析内镜治疗失败的相关

表3 ERCP术后4周临床检验改善情况比较

Table 3 Comparison of improvement of clinical examination 4 weeks after ERCP [P<sub>50</sub>(P<sub>25</sub>~P<sub>75</sub>)]

	Cystic duct group (n=9)	Intrahepatic duct group (n=10)	Z	P
WBC(×10 <sup>9</sup> /L)	6(5.1~6.7)	5.6(5.1~8.6)	-0.410	0.682
ALT/(U/L)	44(37~50)	47(39~49)	-0.656	0.512
AST/(U/L)	40(32~46)	41(35~44)	-0.411	0.681
TBIL/(mmol/L)	10(9~13)	7(5~19)	-0.532	0.595

WBC: white blood cells; ALT: alanine aminotransferase; AST: aspartate aminotransferase; TBIL: total bilirubin

因素

为了评估上述描述的参数是否可以预测胆漏内镜治疗的结果,把首次ERCP成功者分为A组(n=11),失败者为B组(n=8)。首次ERCP成功作为结果变量,两组独立样本间进行秩和检验、Fisher精确检验。首先用单变量评估患者性别、年龄、术前白细胞计数、ALT、AST、TBIL、手术类型及胆漏的位置与首次ERCP成功的关系,最后进行创建精确 Logistic 回归分析影响首次ERCP治疗成功的变量。单因素分析性别、年龄、术前ALT、AST、TBIL及手术类型对首次ERCP成功的影响无统计学意义(P=0.650、P=0.869、P=0.481、P=0.620、P=0.340、P=0.362),白细胞计数(P=0.015)及胆漏位置(P=0.020)有统计学意义(表4)。精确 Logistic 回归分析显示胆漏的位置有统计学意义(P=0.0004, OR=5.448, 95%CI=2.347~ +∞;表5、6)。

3 讨论

以腹腔镜技术为主的手术已成为肝胆外科主要的手术方式,医源性胆漏数量也逐渐增加,这就需要采用微创的方式来处理这些胆漏,并尽可能降低胆漏相关不良事件的发生率。内镜在胆漏的早

表4 临床基本特征影响首次ERCP成功的单因素分析

Table 4 Univariate analysis of relationship between clinical data and the success of the first ERCP [ $P_{50}$ ( $P_{25}$ ~ $P_{75}$ )]

Items	Univariate analysis		
	Group A	Group B	<i>P</i>
Gender(Male/Female)	5/6	5/3	0.650
Age/years	57 (36~67)	60 (49~65)	0.869
Clinical examination results before ERCP			
WBC( $\times 10^9/L$ )	11.8(11.0~13.6)	13.4(12.5~15.1)	0.015
ALT(U/L)	78(72~84)	80(77~84)	0.481
AST(U/L)	67(62~76)	69(66~75)	0.620
TBIL(mmol/L)	32(29~34)	33(30~41)	0.340
Surgery type			
LC	7	1	0.362
Liver resection	4	7	
Location of bile leakage			
Cystic duct	8	1	0.020
Intrahepatic bile duct	3	7	

WBC: white blood cells; ALT: alanine aminotransferase; AST: aspartate aminotransferase; TBIL: total bilirubin; LC: laparoscopic cholecystectomy

表5 精确Logistic回归分析结果

Table 5 Results of exact logistic regression analysis

	Valve	Exact <i>P</i>	Mid <i>P</i>
WBC	0.4934	0.7273	0.6818
Location of bile leakage	16.3063	0.0004	0.0002

WBC: white blood cells

期诊断和治疗得到充分的肯定。目的是降低经乳头的压力梯度,允许胆汁优先流入十二指肠而不是在渗漏部位溢出,促使胆漏部位愈合<sup>[13]</sup>。可通过多种内镜技术来实现,如括约肌切开(endoscopic sphincterotomy, EST)、鼻胆管引流(endoscopic nasobiliary drainage, ENBD)、胆管支架(endoscopic biliary stenting, EBS)、完全覆盖自膨式金属支架(fully

covered self-expandable metal stents, FCSEMS)或两组技术的结合。内镜治疗医源性胆漏是安全、有效的,且被认为是胆漏的一线治疗方式<sup>[14-16]</sup>。

在本回顾性研究中,所有患者均采用括约肌切开联合胆管支架置入,胆管支架放置的位置主要根据渗漏部位决定。胆囊管漏组胆管支架近端越过渗漏部位至少2 cm,而肝内胆管漏组,因肝内胆管直径较小,则支架近端尽可能靠近渗漏部位。所有患者经内镜下治疗后临床症状、肝功能及炎症反应均得到明显改善。本研究通过单因素分析显示,患者的性别、年龄、术前ALT、AST、TBIL及手术类型对首次ERCP成功的影响无统计学意义,而白细胞计数及胆漏的位置有统计学意义。精确Logistic回归分析显示胆漏的位置有统计学意义。胆囊管漏

表6 精确参数和优势比估计

Table 6 Estimation of exact parameter and Odds Ratio

	Parameter estimation			Odds Ratio estimation		
	Valve	95%CI	<i>P</i>	Valve	95%CI	<i>P</i>
Location of bile leakage	1.6952	0.8064~+∞	0.0008	5.448	2.347~+∞	0.0008

组中多数患者(89%)经历首次ERCP后可以达到临床治愈。肝内胆管漏组中,多数患者(70%)需要超过2次ERCP治疗,3例患者经历首次ERCP达到临床治愈。这与其他临床研究结果相似<sup>[17]</sup>。其他相关研究表明,与单独括约肌切开术相比,括约肌切开术联合胆管支架置入可明显降低胆漏治疗失败的风险,封堵渗漏的成功率超过90%<sup>[8,14]</sup>。尽管ERCP广泛运用于胆漏的治疗,仍有胆漏需多次内镜或介入干预,甚至需要手术<sup>[18-19]</sup>。Adler<sup>[10]</sup>等回顾分析接受ERCP治疗的518例胆漏患者,其中有462例(89.2%)经历首次ERCP后胆汁渗漏获得临床治愈,首次ERCP治疗失败患者中,有44例患者接受额外ERCP试图解决胆漏,结果有22例患者临床获益,12例最终接受PTCD和手术获得改善。因此,ERCP技术无疑为医源性胆漏的诊断和治疗提供了丰富的治疗手段。即使多次内镜治疗失败,减少胆汁渗出,控制感染,为确定性手术创造条件。

胆囊切除术后胆漏部位75%位于胆囊管残端,Luschka管占10~15%<sup>[20-22]</sup>。肝切除术后多见于肝内胆管胆漏和肝门部或肝总管胆漏。Fathy<sup>[23]</sup>等报道了有效的胆管支架置入在胆囊切除术后胆囊管残端或Luschka管胆漏的良好疗效,但对其他部位的渗漏只有40%的成功率。Dechené<sup>[24]</sup>等回顾内镜治疗60例肝切除术后胆漏,所有患者均内镜下行括约肌切开术,56例患者放置胆管支架,研究结果表明,内镜治疗的成功率为77%,平均接受内镜治

疗2.6次。在治疗成功的患者中,跨越胆漏部位放置胆管支架成功率更高(82% vs. 48%)。尽管重复进行ERCP可以使胆囊切除术后持续性渗漏受益,但在肝切除术后持续性渗漏的患者中进一步的内镜治疗并没有优势,而应考虑早期的替代干预措施。胆囊管残端和Luschka管都是大的导管,可经乳头有效的降低胆道压力梯度,从而逆转胆汁从这些导管外渗出的流动,使其正常流过胆道进入十二指肠。其他部位的渗漏发生在较小的外周胆管水平,如肝切除术后肝脏切面,胆管暴露面积增加,为胆汁流动提供了低阻力管道,经乳头压力梯度的降低不能有效地传导到这些部位,因此不太可能逆转这些部位胆汁的流动。因此,胆漏的位置是内镜治疗成功的预测指标。

本研究报告括约肌切开术联合胆管支架治疗术后胆漏的有效性。由于研究的局限性,尚无标准化的胆管支架置入方案。相对较小的样本量是主要的限制性。并未统计评估渗漏程度、支架直径大小、首次ERCP治疗间隔时间等与胆漏愈合相关的因素分析。因此,根据个体病例和内镜医生的判断来执行。

综上所述,ERCP对LC术后和肝切除术后持续胆漏的单一治疗同样有效。首次ERCP中确定胆漏位置并指导持续性渗漏患者的进一步干预,并且在首次ERCP时放置胆管支架,以最大程度地提高成功治疗的机会。首次ERCP治疗的成功与胆漏的位置有关以及为治疗胆漏的胆道干预。

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