

· 胆道疾病 ·

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胰管支架对胆总管插管困难患者内镜逆行胰胆管造影术后胰腺炎的影响

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摘要: **目的** 通过观察术中置入胰管支架的胆总管插管困难患者内镜逆行胰胆管造影(ERCP)术后胰腺炎(PEP)发生率,了解胰管支架置入对PEP的防治效果,为临床治疗提供依据。**方法** 回顾性分析2016年1月—2024年12月在郑州大学第一附属医院初次接受ERCP且术中胆总管插管困难的186例胆道疾病患者临床资料,根据胰管支架置入情况分为5Fr-5 cm支架组($n=67$)、7Fr-5 cm支架组($n=46$)以及未置入胰管支架的对照组($n=73$)。比较3组患者基线资料、术中操作方式、术后情况。正态分布的计量资料多组间比较采用单因素方差分析,进一步两两比较采用LSD- t 法;非正态分布的计量资料多组间比较采用Kruskal-Wallis H 秩和检验,进一步两两比较采用Dunn法。计数资料组间比较采用 χ^2 检验或Fisher精确概率法。采用Logistic回归分析困难插管患者PEP的影响因素。**结果** 患者总PEP发生率为12.37%(23/186)。对照组PEP发生率、术后腹痛评分和术后住院时间均高于5Fr-5 cm支架组和7Fr-5 cm支架组(P 值均 <0.01),且对照组PEP以中-重型为主(55.56%)。单因素Logistic回归分析显示,憩室内乳头、双导丝插管、针刀预切开、胆总管网篮联合球囊取石、术中组织活检、置入胰管支架、插管时间 ≤ 10 min、插管次数 ≤ 5 次、术前CRP ≤ 5 mg/L是PEP的影响因素(P 值均 <0.05);多因素Logistic回归分析显示,术中胰管置入支架、针刀预切开和术中组织活检是PEP发生的独立影响因素(P 值均 <0.05)。**结论** ERCP术中置入胰管支架可有效降低困难插管患者PEP的发生风险,针刀预切开和术中组织活检会增加困难插管患者PEP的发生风险。

关键词: 支架; 胰胆管造影术, 内窥镜逆行; 胰腺炎**基金项目:** 河南省中医药科学研究专项课题(2022ZY1030)

Influence of pancreatic stent on pancreatitis after endoscopic retrograde cholangiopancreatography in patients with difficult common bile duct intubation

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Abstract: Objective To investigate the incidence rate of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP) in patients with difficult common bile duct intubation undergoing pancreatic duct stenting during surgery, as well as the effect of pancreatic duct stenting in the prevention and treatment of PEP, and to provide a basis for clinical treatment. **Methods** A retrospective analysis was performed for the clinical data of 186 patients with biliary tract disease who underwent initial ERCP and had difficult common bile duct intubation in The First Affiliated Hospital of Zhengzhou University from January 2016 to December 2024, and according to the condition of pancreatic duct stenting, the patients were divided into control group

with 73 patients (without pancreatic duct stenting), 5Fr-5 cm stent group with 67 patients, and 7Fr-5 cm stent group with 46 patients. The three groups were compared in terms of baseline data, intraoperative procedures, and postoperative outcomes. A one-way analysis of variance was used for comparison of normally distributed continuous data between multiple groups, and the least significant difference *t*-test was used for further comparison between two groups; the Kruskal-Wallis *H* rank sum test was used for comparison of non-normally distributed continuous data between multiple groups, and the Dunn method was used for further comparison between two groups; the chi-square test or the Fisher's exact test was used for comparison of categorical data between groups. The Logistic regression analysis was used to investigate the influencing factors for PEP in patients with difficult intubation during ERCP. **Results** The overall incidence rate of PEP was 12.37% (23/186). Compared with the 5Fr-5 cm stent group and the 7Fr-5 cm stent group, the control group had a significantly higher incidence rate of PEP, a significantly higher score of postoperative abdominal pain, and a significantly longer length of postoperative hospital stay (all $P < 0.01$), and 55.56% of the patients in the control group had moderate-to-severe PEP. The univariate Logistic regression analysis showed that intradiverticular papilla, double guide wire intubation, needle knife precut, the application of basket and balloon for removal of common bile duct stones, intraoperative biopsy, pancreatic duct stenting, intubation time ≤ 10 minutes, frequency of intubation ≤ 5 times, preoperative CRP ≤ 5 mg/L were influencing factors for PEP (all $P < 0.05$), and the multivariate Logistic regression analysis showed that intraoperative pancreatic duct stenting, needle knife precut, and intraoperative biopsy were independent influencing factors for the onset of PEP (all $P < 0.05$). **Conclusion** Pancreatic duct stenting during ERCP can effectively reduce the risk of PEP in patients with difficult intubation, while needle knife precut and intraoperative biopsy can increase the risk of PEP in patients with difficult intubation.

Key words: Stents; Cholangiopancreatography, Endoscopic Retrograde; Pancreatitis

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内镜逆行胰胆管造影(endoscopic retrograde cholangiopancreatography, ERCP)术后胰腺炎(post ERCP pancreatitis, PEP)是ERCP最严重并发症之一,发生率可达2%~7%,重症PEP甚至会危及生命^[1]。既往通过非甾体消炎药和补液预防PEP,但效果欠佳^[2]。ERCP术中置入胰管支架引流胰液可有效降低PEP发生率,长支架引流范围更广,但会增加胰腺损伤风险;短支架引流效果差,且过早脱落风险增加;不同周径胰管支架对胰液的引流量不同,可能会影响PEP的预防效果,因疾病类型、患者情况及研究设计等方面差异,现有结论存在矛盾^[3]。此外,胆道困难插管是影响ERCP手术成功率和PEP发生率的重要因素之一,针刀预切开、双导丝插管等技术是最常用的处理方式,但存在增加术后出血、胰腺炎、穿孔等风险^[4]。因此,本研究旨在统计ERCP困难插管患者置入胰管支架情况及PEP发生率,分析影响困难插管患者PEP发生的可能因素,为优化胰管支架置入预防PEP提供循证依据。

1 资料与方法

1.1 研究对象 回顾性纳入2016年1月—2024年12月在郑州大学第一附属医院接受ERCP治疗术中出现困难

插管的胆道疾病患者临床资料。纳入标准:(1)年龄 > 18 岁;(2)术前影像学诊断为胆总管结石或梗阻性黄疸;(3)ERCP手术指征明确,且为初治患者,有原始十二指肠乳头;(4)术前影像学检查和血液学检验结果均排除胰腺炎诊断;(5)符合胆管困难插管定义的患者^[5]。排除标准:(1)合并有急性胰腺炎或既往有急、慢性胰腺炎病史者;(2)有胆胰管汇合异常或合并胰腺分裂者;(3)有胆肠吻合、胃肠吻合、结肠造瘘等手术史者;(4)严重心肺功能障碍不能耐受手术者;(5)妊娠期或哺乳期妇女。PEP的定义及严重程度分级参考Cotton标准^[6]。

1.2 研究方法 患者分组:根据术中胰管支架置入情况,将患者分为未置入支架的对照组、置入5Fr-5 cm支架组和置入7Fr-5 cm支架组。

围手术期管理:患者常规禁食6 h、禁水2 h以上,术前肌注山莨菪碱10 mg;术前100 mg哌罗美辛栓纳肛;口服利多卡因胶浆10 mL,丙泊酚静脉麻醉,若患者存在心肺功能储备差、高龄、操作时间延长等情况,由麻醉医师评估后行气管插管全身麻醉;患者术后均禁食、抑酸、抑酶、静脉营养支持治疗,12 h生命体征监测;无发热、腹痛等症状,血淀粉酶恢复正常,即可流质饮食。

手术流程:内镜医师ERCP操作例数均超1 000例。

采用Olympus TJF-260型电子十二指肠镜、Boston Scientific导丝及取石网篮、Cook MyoSite单猪尾胰管支架(5Fr、7Fr)。使用切开刀和导丝行ERCP胆管插管,初始行单导丝引导插管法,当插管困难时,依次尝试双导丝、胰管支架辅助插管、经胰管预切开或十二指肠乳头针刀预切开等技术辅助插管。插管成功后,根据术中患者具体情况选择后续操作:如经内镜乳头括约肌切开术、胆道结石球囊和/或网篮取石、胆道狭窄球囊扩张或胆道支架置入、可疑恶性肿瘤者行胆道组织病理活检等。对于导丝或造影剂进入胰管的病例,均予置单猪尾胰管支架(5Fr或7Fr),并经X线确认支架位置,以预防PEP。

1.3 观察指标 于手术前后24 h用酶联免疫吸附试验检测C反应蛋白(CRP)、丙氨酸转氨酶(ALT)和总胆红素(TBil)水平,用BMD法(基准计量法)检测血淀粉酶。插管顺利进入胆管或回抽证实有胆汁者视为胆管插管成功,插管时间为自十二指肠乳头插管开始至胆总管插管成功的操作时间。PEP指ERCP术后新发腹痛、血淀粉酶高于正常值上限(125 U/L)3倍且持续24 h以上。此外,采集患者十二指肠穿孔、导丝穿孔、括约肌过度切开、术后延迟性出血及住院时间等信息。

1.4 统计学方法 使用SPSS 25.0统计软件进行数据分析。正态分布的计量资料以 $\bar{x}\pm s$ 表示,多组间比较采用单因素方差分析,进一步两两比较采用LSD-*t*法;非正态分布的计量资料以 $M(P_{25}\sim P_{75})$ 表示,多组间比较采用Kruskal-Wallis *H*秩和检验,进一步两两比较采用Dunn法。计数资料组间比较采用 χ^2 检验或Fisher精确概率法。采用Logistic回归分析困难插管患者PEP的影响因素。 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 一般资料 共有296例胆道疾病患者接受ERCP手术并出现胆道困难插管,排除95例合并胰腺疾病和/或接受治疗性胰管支架置入、5例未记录置入胰管支架周径、10例病历资料不完善,最终186例患者纳入研究,其中未置入支架73例(对照组),5Fr-5 cm支架组67例,7Fr-5 cm支架组46例。患者基线资料比较见表1。

2.2 ERCP术中情况比较 术中3组间十二指肠乳头特征、插管方式、乳头预切开方式、胆总管取石方式、胆道支架置入类型及组织活检比例进行比较,差异均无统计学意义(P 值均 >0.05)(表2)。

2.3 术后并发症及住院情况比较 患者总PEP发生率为12.37%(23/186)。对照组PEP发生率、术后腹痛评分和术后住院时间均高于5Fr-5 cm支架组和7Fr-5 cm支架组(P 值均 <0.01),且对照组PEP以中-重型为主(55.56%)(表3)。

2.4 PEP影响因素分析 单因素Logistic回归分析显示,憩室内乳头、双导丝插管、经针刀预切开、胆总管网篮联合球囊取石、乳头和/或胆管组织活检可增加PEP发生风险(P 值均 <0.05);胰管内植入支架、插管时间 ≤ 10 min、插管次数 ≤ 5 次、术前CRP ≤ 5 mg/L可降低PEP发生风险(P 值均 <0.05)(表4)。将单因素Logistic回归分析差异有显著性的因素纳入多因素Logistic回归分析中,采用向后逐步回归法分析显示,术中胰管植入5Fr-5 cm支架和7Fr-5 cm支架均可降低PEP发生率(P 值均 <0.01);经针刀预切开和术中乳头和/或胆管组织活检均可升高PEP发生率(P 值均 <0.05)(表5)。

表1 ERCP困难插管患者基线资料比较

Table 1 Comparison of baseline information of patients with difficult intubation in ERCP

项目	对照组($n=73$)	5Fr-5 cm 支架组($n=67$)	7Fr-5 cm 支架组($n=46$)	统计值	P 值
男[例(%)]	47(64.38)	33(49.25)	26(56.52)	$\chi^2=3.27$	0.20
年龄(岁)	65.58 \pm 15.06	64.42 \pm 15.91	64.37 \pm 14.21	$F=0.13$	0.88
术前诊断[例(%)]				$\chi^2=2.70$	0.26
胆管结石	63(86.30)	60(89.55)	44(95.65)		
胆管狭窄/占位	10(13.70)	7(10.45)	2(4.35)		
合并症[例(%)]				$\chi^2=7.42$	0.28
无明显合并症	37(50.68)	36(53.73)	20(43.49)		
高血压	23(31.51)	21(31.34)	21(45.65)		
糖尿病	10(13.70)	4(5.97)	4(8.70)		
冠心病	3(4.11)	6(8.96)	1(2.17)		
血液检查					
术前CRP(mg/L)	12.97 \pm 1.51	16.05 \pm 2.56	15.86 \pm 2.45	$F=0.69$	0.50
术前ALT(U/L)	46(29~88)	48(31~99)	55(31~69)	$H=0.08$	0.96
术前TBil(μ mol/L)	34.0(16.5~57.0)	34.0(16.0~53.0)	35.0(22.0~54.0)	$H=0.67$	0.72

表2 ERCP困难插管患者术中情况比较

Table 2 Comparison of intraoperative conditions in patients with difficult intubation in ERCP

项目	对照组(n=73)	5Fr-5 cm 支架组 (n=67)	7Fr-5 cm 支架组 (n=46)	χ^2 值	P值
十二指肠乳头特征[例(%)]				10.58	0.23
半球形乳头	10(13.70)	8(11.94)	13(28.26)		
小乳头	14(19.18)	16(23.88)	8(17.39)		
冗长乳头	10(13.70)	14(20.90)	5(10.87)		
憩室旁乳头	21(28.77)	19(28.36)	9(19.57)		
憩室内乳头	18(24.66)	10(14.93)	11(23.91)		
导丝引导插管[例(%)]				0.68	0.71
单导丝引导插管	63(86.30)	59(88.06)	38(82.61)		
双导丝引导插管	10(13.70)	8(11.94)	8(17.39)		
插管时间 ¹⁾ [例(%)]				2.30	0.32
≤10 min	25(34.25)	18(26.87)	10(21.74)		
>10 min	48(65.75)	49(73.13)	36(78.26)		
插管次数 ¹⁾ [例(%)]				1.68	0.43
≤5次	66(90.41)	57(85.07)	38(82.61)		
>5次	7(9.59)	10(14.93)	8(17.39)		
乳头预切开方式[例(%)]				4.91	0.30
经胆管预切开	56(76.71)	48(71.64)	30(65.22)		
经胰管预切开	8(10.96)	13(19.40)	12(26.09)		
针刀预切开	9(12.33)	6(8.96)	4(8.70)		
胆总管取石[例(%)]				3.61	0.46
球囊取石	21(28.77)	19(28.36)	17(36.96)		
球囊联合网篮取石	42(57.53)	41(61.19)	27(58.70)		
未取石	10(13.70)	7(10.45)	2(4.35)		
胆道支架置入类型[例(%)]				1.51	0.83
内镜鼻胆管引流	46(63.01)	38(56.72)	26(56.52)		
“圣诞树”塑料支架	22(30.14)	24(35.82)	18(39.14)		
胆道金属支架	5(6.85)	5(7.46)	2(4.34)		
活检情况[例(%)]				1.67	0.80
胆道活检	9(12.33)	6(8.96)	5(10.87)		
乳头活检/切除	1(1.37)	3(4.48)	1(2.17)		
未取活检	63(86.30)	58(86.57)	40(86.96)		

注:1)插管时间和插管次数分组规则参考文献[7]。

表3 ERCP困难插管患者术后并发症及住院情况比较

Table 3 Comparison of postoperative complications and hospitalization conditions in patients with difficult intubation in ERCP

项目	对照组(n=73)	5Fr-5 cm 支架组 (n=67)	7Fr-5 cm 支架组 (n=46)	统计值	P值
PEP[例(%)]	18(24.66)	4(5.97) ¹⁾	1(2.17) ¹⁾	$\chi^2=17.12$	<0.01
PEP程度分级[例(%)]				$\chi^2=6.76$	0.03
轻型	8(44.44)	4(100.00)	1(100.00)		
中-重型	10(55.56)	0(0.00)	0(0.00)		
腹痛评分(分)	1.64±0.98	1.10±0.53 ¹⁾	1.04±0.67 ¹⁾	$F=12.16$	<0.01
消化道出血[例(%)]	6(8.22)	3(4.48)	3(6.52)	$\chi^2=0.83$	0.66
消化道穿孔[例(%)]	2(2.74)	1(1.49)	2(4.35)	$\chi^2=0.85$	0.67
术后住院时间(d)[例(%)]	2.48±1.59	1.69±0.84 ¹⁾	1.54±0.86 ¹⁾	$F=11.41$	<0.01
2周内支架自行脱落[例(%)]		51(76.12)	8(17.39)	$\chi^2=37.70$	<0.01

注:与对照组比较,1)P<0.01。

表4 影响ERCP困难插管患者PEP的单因素Logistic分析
Table 4 Univariate Logistic analysis of PEP in patients with difficult intubation in ERCP

项目	β 值	SE	Wald χ^2	P值	OR(95%CI)
男性	0.18	0.46	0.16	0.69	1.20(0.49 ~ 2.93)
年龄<60岁	-0.07	0.45	0.03	0.87	0.93(0.39 ~ 2.23)
胰管置入支架情况					
未置入支架			12.96	<0.01	1.00
置入5Fr-5 cm支架	-1.64	0.58	7.92	<0.01	0.19(0.04 ~ 0.89)
置入7Fr-5 cm支架	-2.69	1.05	6.60	0.01	0.07(0.01 ~ 0.53)
憩室内乳头	1.56	0.61	6.51	0.01	4.75(1.44 ~ 15.74)
插管时间≤10 min	-2.16	1.04	4.33	0.04	0.12(0.02 ~ 0.88)
插管次数≤5次	-2.70	0.77	12.21	<0.01	0.07(0.02 ~ 0.31)
双导丝插管	1.03	0.49	4.50	0.03	2.81(1.08 ~ 7.30)
经胆管预切开	-0.94	0.49	3.80	0.06	0.39(0.15 ~ 1.07)
经胰管预切开	0.20	0.59	0.11	0.74	1.22(0.38 ~ 3.90)
经针刀预切开	2.12	0.75	8.08	<0.01	8.37(1.93 ~ 36.23)
网篮联合球囊取石	1.51	0.64	5.59	0.02	4.54(1.29 ~ 15.88)
组织活检	2.35	0.49	23.34	<0.01	10.52(4.05 ~ 27.32)
合并糖尿病	0.89	0.62	2.04	0.15	2.43(0.72 ~ 8.21)
术前CRP≤5 mg/L	-1.34	0.53	6.43	0.01	0.26(0.09 ~ 0.74)
术前ALT<40 U/L	-0.95	0.53	3.19	0.07	0.39(0.14 ~ 1.10)
术前TBil<17.1 μ mol/L	-0.77	0.65	1.44	0.23	0.46(0.13 ~ 1.63)
2周内胰管支架脱落	1.59	1.11	2.05	0.15	4.91(0.56 ~ 43.42)

表5 影响ERCP困难插管患者PEP发生的多因素Logistic分析
Table 5 Multivariate Logistic analysis of PEP in patients with difficult intubation in ERCP

项目	β 值	SE	Wald χ^2	P值	OR(95%CI)
胰管置入支架情况					
未置支架			15.11	<0.01	1.00
置入5Fr-5 cm支架	-3.24	1.19	7.38	<0.01	0.04(0.00 ~ 0.77)
置入7Fr-5 cm支架	-6.24	1.63	14.57	<0.01	0.00(0.00 ~ 0.05)
针刀预切开	2.71	1.33	4.16	0.04	15.01(1.11 ~ 202.96)
组织活检	4.15	1.12	13.68	<0.01	63.27(7.03 ~ 569.61)

3 讨论

ERCP作为胆胰疾病重要诊疗技术已在国内外得到广泛应用,困难胆管插管常预示术后并发症高发^[8-10]。有研究显示,胆道困难插管患者中,PEP发生率高达30%^[11]。本研究中困难插管患者PEP总发生率为12.37%,未置入胰管支架的对照组PEP发生率为24.66%,与上述研究接近。另外,术中胰管显影或导丝反复进入胰管均将显著提高PEP发生率,术中置入胰管支架是降低PEP的标准措施^[12]。本研究中5Fr-5 cm支架组和7Fr-5 cm支架组PEP发生率均显著低于对照组(P 值均<0.01)。

国内外指南推荐非甾体抗炎药如吲哚美辛栓作为PEP混合风险或高风险患者的基础预防药物,其他预防药物包括大剂量乳酸林格氏液、舌下含服硝酸甘油等^[2]。胰管支架可以将胰液及时引流到肠内,减轻胰管内压力,从而预防PEP发生^[12]。因此,对于PEP高危患者,推荐预防性胰管支架置入并采取联合预防措施。理论上,胰

液引流量越大,PEP的预防效果越好。研究显示,周径3Fr胰管支架PEP发生率(17.5%)高于5Fr支架组(10.5%)^[13]。本研究5Fr-5 cm支架组PEP发生率为5.97%,虽然高于7Fr-5 cm支架组的2.17%,但差异无统计学意义($P>0.05$)。

针刀预切开是经典的ERCP困难插管补救技术,但穿孔、PEP和出血发生率明显高于常规插管^[14]。本研究发现,针刀预切开可提高PEP发生率($P=0.04$)。当导丝落入胰管后,选择经胰管括约肌预切开,有利于观察胆胰隔的位置,寻找胆管开口,与针刀预切开相比稳定性明显增强,插管成功率更高,PEP发生率也显著降低^[15],但本研究中经胰管预切开对困难插管患者PEP发生率影响不显著($P=0.74$)。

十二指肠壶腹部及肝外胆管占位性病变的病理诊断相对困难,通过细胞刷刷检胆管癌的诊断率仅为32.5%^[16]。超声或CT引导下穿刺活检无法准确定位,容易损伤血管,诊断阳性率仅40.0%左右^[17]。为了提高活检成功率,本研究在ERCP术中用活检钳夹持导丝,循导丝将活

检钳带到病灶处活检。本研究有25例患者用该方法获取病理组织,成功率为100%,与既往研究类似^[18]。然而,活检后胰腺炎发生率有所增加,通过Logistic回归分析显示,组织活检是影响PEP发生的独立危险因素($P<0.01$)。

目前指南或专家意见尚未明确PEP最佳预防措施。笔者团队在困难插管ERCP术中倾向于胰管支架置入,具体选择5Fr还是7Fr或周径更大胰管支架,取决于胰管粗细、壶腹部或胆总管下段狭窄或梗阻程度,以减少术中操作引起的支架脱落、置入失败、出血和穿孔等风险为宗旨。但对于胰管支架周径的选择标准,仍需大规模随机对照试验,评估其预防效果,为临床治疗提供循证依据。

因本研究是单中心回顾性分析,选择偏倚无法避免,研究结果仍需多中心研究进一步验证。另外,纳入研究的186例患者中23例出现PEP,样本量偏小,影响结论的可靠性,仍需增大样本进一步分析。

综上所述,本研究认为ERCP术中置入胰管支架可有效降低困难插管患者PEP发生风险,十二指肠乳头针刀预切开和术中乳头和/或胆管组织活检会增加困难插管患者PEP发生风险。

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