

doi: 10.13241/j.cnki.pmb.2018.21.007

· 临床研究 ·

恶性胆道梗阻患者所行经皮穿刺肝内胆管引流术中成功置入金属支架的术前影响因素分析*

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摘要 目的:探讨恶性胆道梗阻患者行 PTBD(Percutaneous Transhepatic Biliary Drainage)术中金属支架置入成功率的影响因素。**方法:**回顾性搜集 2010 年 10 月-2017 年 1 月上海市第一人民医院收治的因患有近端恶性胆道梗阻行 PTBD 术患者的相关临床资料。比较不同原发病患者支架置入情况。根据患者支架置入是否成功将其分为支架组和非支架组,比较患者的一般临床特征。**结果:**胰腺癌、胃癌和胆囊癌为本研究中数量上前 3 位的肿瘤,将以上 3 组分别按照支架置入数行 χ^2 检验,其中胰腺癌($n=18$, 支架=6)和胃癌($n=14$, 支架=11)有统计学意义。将 50 例患者分为支架组($n=28$)和非支架组($n=22$),组间比较差异有统计学意义的因素包括:白细胞计数(支架组= $6.40 \pm 3.40 \times 10^9/L$, 非支架组= $10.74 \pm 6.41 \times 10^9/L$),中性粒细胞计数(支架组= $4.90 \pm 3.06 \times 10^9/L$, 非支架组= $8.92 \pm 6.25 \times 10^9/L$),胆道感染(支架组=9, 非支架组=15)。进一步将该 50 例患者分为 6 组:胰腺癌-胆道感染组、胃癌-胆道感染组、其他肿瘤-胆道感染组、胰腺癌+胆道感染组、胃癌+胆道感染组、其他肿瘤+胆道感染组。将以上 6 组分别按照支架置入数行 χ^2 检验,胰腺癌+胆道感染组($n=11$, 支架=1, $P=0.001$)有统计学意义。**结论:**PTBD 术对于恶性胆道梗阻是一种有效的姑息治疗手段。胆道感染是 PTBD 术中支架置入成功的不利因素,胰腺癌合并胆道感染会显著降低 PTBD 术中支架置入成功率。

关键词:近端恶性胆道梗阻;金属支架置入;胆道感染;胰腺癌;胃癌

中图分类号:R815;R735.8 **文献标识码:**A **文章编号:**1673-6273(2018)21-4035-06

Metal Stent Implantation during Percutaneous Transhepatic Biliary Drainage for Palliative Treatment of Proximal Malignant Biliary Tract Obstruction: a Retrospective Analysis of Pre-procedure Factors*

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ABSTRACT Objective: To investigate the preprocedure factors of successful stent implantation during percutaneous transhepatic biliary drainage for palliative treatment of proximal malignant biliary tract obstruction. **Methods:** We retrospectively analyzed preprocedure factors of 50 patients with proximal malignant biliary tract obstruction receiving percutaneous transhepatic biliary drainage from October 2010 to January 2017. We separated the 50 patients by histological diagnosis and successful stent implantation to analyze the significance. **Results:** Firstly, we separated the 50 patients by histological diagnosis. Pancreatic cancer ($n=18$), gastric cancer ($n=14$) and gallbladder carcinoma ($n=7$) were the top three quantitatively. We analyzed the three groups each for successful stent implantation by χ^2 test, and the statistically significant comparisons were pancreatic cancer (stent=6) and gastric cancer (stent=11). Then the 50 patients with low malignant biliary tract obstruction were separated into two groups: stent group ($n=28$) and non-stent group ($n=22$). the statistically significant comparisons of preprocedure factors included leukocyte count, neutrophil count, biliary infection. Based on these results above, finally we separated patients into 6 groups according to the results above: pancreatic cancer- biliary infection ($n=7$, stent=5), gastric cancer- biliary infection ($n=10$, stent=7), other malignancy- biliary infection ($n=9$, stent=7), pancreatic cancer+ biliary infection ($n=11$, stent=1), gastric cancer+ biliary infection ($n=4$, stent=4), other malignancy+ biliary infection ($n=9$, stent=4). We analyzed the 6 groups each for successful stent implantation by χ^2 test, and the statistically significant comparison was pancreatic cancer+ biliary infection group ($P=0.001$). **Conclusions:** Percutaneous transhepatic biliary drainage is an effective treatment for palliation of proximal malignant biliary tract obstruction. During percutaneous transhepatic biliary drainage procedure, biliary infection is bad for stent implantation. Pancreatic cancer combined with biliary infection will deeply reduce the stent implantation rate.

* 基金项目:国家自然科学基金青年基金项目(81502648)

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(收稿日期:2018-06-25 接受日期:2018-07-20)

Key words: Proximal malignant biliary tract obstruction; Metal stent implantation; Biliary infection; Pancreatic cancer; Gastric cancer

Chinese Library Classification(CLC): R657.4; R735.8 **Document code:** A

Article ID: 1673-6273(2018)21-4035-06

前言

恶性胆道梗阻是指胆汁排出道的任何一段因恶性肿瘤导致的胆管腔内梗阻狭窄或管壁外浸润压迫等,造成胆汁排泄不畅,甚至完全堵塞的胆管机械性梗阻,最为常见的引起胆道梗阻的恶性肿瘤为胰腺癌和胆管癌^[1]。胆道梗阻常会导致胆道扩张和感染,并且伴随着胆道梗阻的加剧,胆管内压力的增加和内皮细胞通透性改变,使胆红素进入血液,并会进一步造成感染、胆管硬化、肝衰竭、肝肾综合征等高风险不良预后^[2]。

按照梗阻位置,胆道梗阻通常被分为两种主要类型:梗阻点位于胆囊管汇合处以下的胆总管;梗阻点位于胆囊管汇合处以上的肝总管和/或肝内胆管。后一种类型又可分为四种类型(Bismuth-Corlette 分型 I-IV 型)^[3]。本研究主要探讨的近端胆道梗阻包括梗阻点位于胆囊管汇合处以下的胆总管类型和 Bismuth-Corlette 分型 I 型。Bismuth-Corlette II-IV 型主要由胰腺癌、胆管癌、壶腹癌、转移性淋巴结外压造成;而近端胆道梗阻主要由胆管癌、胆囊癌、肝细胞癌、局部进展的胰腺癌、转移性肿瘤或淋巴结造成^[4]。

经皮穿刺肝内胆管引流术(percutaneous transhepatic biliary drainage, PTBD) 对于恶性胆道梗阻是一种有效的姑息治疗方式^[5],也是内镜下逆行胰胆管造影术(Endoscopic Retrograde Cholangiopancreatography, ERCP)失败后的备选治疗方式之一。对于梗阻性黄疸患者,PTBD 术不仅能够改善生活质量,而且能够为患者带来确实的短期生存获益^[6]。尤其对于近端胆道梗

阻的患者,PTBD 术中胆道支架置入与胆道搭桥手术相比引流效果更好,并发症更少^[7]。目前,关 PTBD 术中成功置入支架的影响因素并未完全明确。因此,本研究通过搜集对比 PTBD 术前患者相关数据,分析了术中支架置入的影响因素。

1 材料与方法

1.1 病例资料

回顾性搜集 2010 年 10 月 -2017 年 1 月上海市第一人民医院收治的因患有近端恶性胆道梗阻行 PTBD 术患者的相关资料,患者 PTBD 术前均签署知情同意书。

1.2 治疗方法

所有 PTBD 术均在 DSA (Digital Subtraction Angiography) 室于 X 光透视下进行。患者取仰卧位,由术者进行穿刺点局部麻醉,应用 22 G 千叶(Chiba)针由右侧第 9、10 肋间穿刺进入右侧肝内胆管或由剑突下穿刺进入左侧肝内胆管。注入对比剂使肝内胆管显影,插入导丝(Radifocus Glide Wire M; 泰尔茂,日本东京)至肝内胆管内,通过导丝引导下插入血管鞘(Radifocus Introducer II; 泰尔茂,日本东京)及 Cobra 造影导管(Radifocus angiographic catheter; 泰尔茂,日本东京),应用导丝导管配合通过胆道内狭窄梗阻区域。如导丝导管能够通过狭窄梗阻区域进入肠道内,则经导丝引导下插入金属胆道支架(MTN-DA; 南京微创,中国南京)于狭窄处释放,再经导丝引导下插入内外引流管(Multipurpose Drainage Catheter; 库克,美国印第安纳),尾端于肠道内成袢固定(如图 1 所示)。

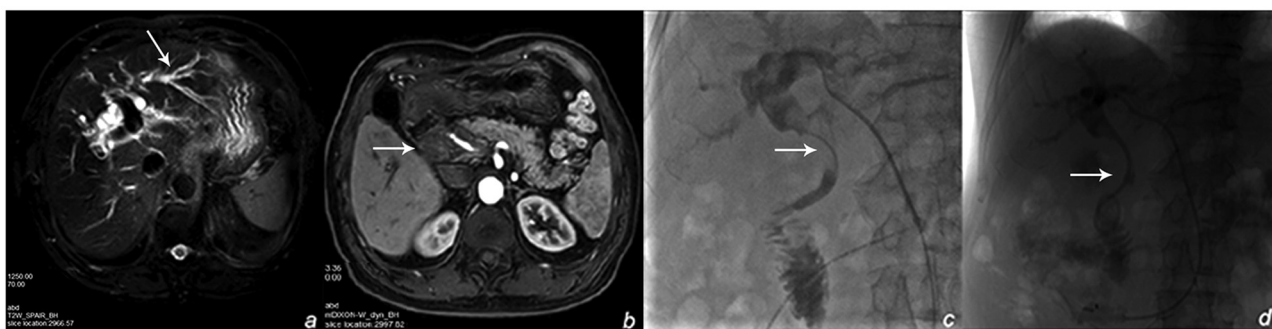


图 1 PTBD 术中成功置入支架病例

Fig.1 A patient with malignant biliary tract obstruction was succeeded in stent implantation during PTBD.

A 71-year-old male patient with recurrent gallbladder carcinoma received PTBD. Axial T2W SPAIR image (a) demonstrates the obvious dilated intrahepatic bile duct (arrow). Axial dynamic enhancement image in arterial phase (b) demonstrates the recurrent tumor obstructs the bile duct (arrow).

Percutaneous transhepatic cholangiography (c) demonstrates the stenotic region (arrow). The biliary metal stent implantation and internal-external drainage (d, arrow) were passed through the stenotic region and in an appropriate position.

如应用导丝导管不能够通过狭窄梗阻区域进入肠道内,则于导丝引导下插入外引流管(Multipurpose Drainage Catheter, 库克,美国印第安纳),尾端于肝左右胆管汇合处成袢固定(如图 2 所示)。术后引流管均接引流袋引流。PTBD 术中,部分患者所行的胆道穿刺由彩色多普勒引导进行。由彩色多普勒引导应用 18 G 穿刺针经过上述所述区域穿刺进入肝内胆管,后续操作

亦同上述。

近端恶性胆道梗阻的诊断由多方面共同组成,包括:恶性实体肿瘤病史、明显高于正常范围的血液总胆红素指标、肝内胆管扩张和肿瘤压迫胆管走行区域的影像学表现。

1.3 胆道感染的诊断标准

恶性胆道梗阻患者满足以下一项即可诊断为胆道感染:发

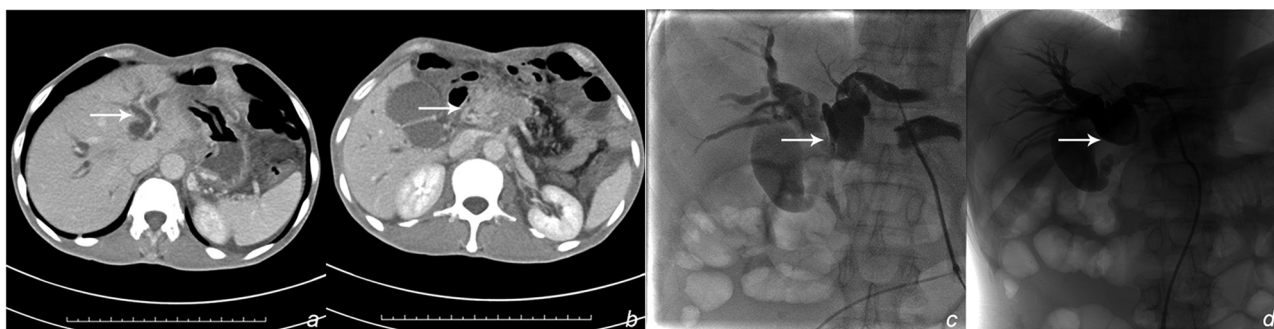


图2 PTBD术中未能成功置入支架病例

Fig.2 A patient with malignant biliary tract obstruction was failed in stent implantation during PTBD.

A 62-year-old male patient with recurrent gastric cancer received PTBD. Axial contrast-enhanced CT image (a) in the portal venous phase demonstrates the obvious dilated intrahepatic bile duct (arrow). Axial contrast-enhanced CT image (b) in the portal venous phase demonstrates the recurrent tumor (arrow) which obstructed the bile duct. Percutaneous transhepatic cholangiography (c) demonstrates the dilated intrahepatic bile duct (arrow). An external drainage was placed in the dilated intrahepatic bile duct (d, arrow).

热(体温 $>38^{\circ}\text{C}$),外周血白细胞计数 $>9.15\times 10^9/\text{L}$ 并且中性粒细胞比率 $>70\%$ 、中性粒细胞计数 $<2\times 10^9/\text{L}$ 、血培养或胆汁培养阳性结果。

1.4 统计学分析

采用SPSS 20.0进行统计学分析,两组计量资料和计数资料的比较分别采用t检验和 χ^2 检验,以 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 患者的基本信息

2010年10月-2017年1月,上海市第一人民医院共行PTBD术143例,其中符合恶性近端胆道梗阻的患者共50例,均可纳入本研究。该50名患者术前信息如表1所示。50名患者中,有11名患者PTBD术前行ERCP术失败,剩余39名患者均由消化内科医生评估后考虑不适合行ERCP术,原因如下:特殊的肿瘤位置、因手术而导致局部解剖位置关系改变等。这50例PTBD术均无手术相关性死亡或围术期严重并发症的发生,如出血性休克、感染性休克、早期的支架梗阻等。所有由胰腺癌引起的梗阻,无论是原发或转移性胰腺癌,均在胰腺区域(主要为胰头区域)。所有术中置入的支架及引流管均在目标位置,手术成功率为100%,临床成功率为88%(如表1所示)。

2.2 按照病理类型分类

胰腺癌、胃癌和胆囊癌为本研究中数量上前三位的肿瘤,首先行胰腺癌数据统计,具体过程如下:按照胰腺癌、非胰腺癌与支架成功、支架失败在例数上行四格表 χ^2 检验,得出 $P=0.015$ 。按照上述方式分别行胃癌及胆囊癌数据的分析,得出对应的P值。因其余肿瘤类型数据量较小,故未行上述分析。详细数据及统计学分析结果如表2所示。其中,胰腺癌和胃癌在支架置入方面有统计学意义。在PTBD术中,胰腺癌引起的近端胆道梗阻不利于胆道支架置入,而胃癌引起的近端胆道梗阻有利于胆道支架置入。

2.3 按照支架置入成功与否分类

为分析PTBD术中胆道支架置入的影响因素,将50名患者按照支架置入成功与否分为2组:支架组($n=28$)和非支架组($n=22$)。在分析的所有术前因素当中(如表3所示),有统计学意

义的因素包括:白细胞计数(支架组 $=6.40\pm 3.40\times 10^9/\text{L}$,非支架组 $=10.74\pm 6.41\times 10^9/\text{L}$),中性粒细胞计数(支架组 $=4.90\pm 3.06\times 10^9/\text{L}$,非支架组 $=8.92\pm 6.25\times 10^9/\text{L}$),胆道感染(支架组 $=9$,非支架组 $=15$)。由于白细胞计数和中性粒细胞计数均为提示感染的相关指标,故认为术前胆道感染是恶性近端胆道梗阻患者PTBD术中支架置入成功的影响因素。

表1 纳入患者的一般临床信息

Table 1 The clinical general information of patients

	Total (n=50)
Sex(male)	39
Age(years)	64.10 $\pm$ 9.82
Bismuth type I	18
Failure in ERCP before PTBD	11
Alternate structures due to operations	20
Leukocyte count($\times 10^9/\text{L}$)	8.31 $\pm$ 5.39
Neutrophil count ($\times 10^9/\text{L}$)	6.67 $\pm$ 5.10
Neutrophil ratio(%)	77.19 $\pm$ 9.34
Hemoglobin(g/L)	104.22 $\pm$ 21.42
Hematocrit(%)	31.13 $\pm$ 6.09
Platelet count($\times 10^9/\text{L}$)	203.84 $\pm$ 94.35
Serum potassium(mmol/L)	3.66 $\pm$ 0.56
Prothrombin time(sec)	13.80 $\pm$ 4.42
Total bilirubin(umol/L)	268.34 $\pm$ 164.97
Fever ($>38^{\circ}\text{C}$)	11
Biliary infection	24
Color doppler ultrasound guided Biliary puncture	32
Stent implantation	28
Clinical success in biliary drainage	44

Note: a stands for the decrease of bilirubin levels $>50\%$ after stent implantation within one month.

2.4 整合肿瘤类型与胆道感染因素分析支架置入情况

基于以上结果,将该50名患者分为6组:胰腺癌-胆道感

染组、胃癌 - 胆道感染组、其他肿瘤 - 胆道感染组、胰腺癌 + 胆道感染组、胃癌 + 胆道感染组、其他肿瘤 + 胆道感染组。首先行胰腺癌数据统计,具体过程如下:按照胰腺癌 - 胆道感染组、非胰腺癌 - 胆道感染组与支架成功、支架失败在例数上行四格表

χ^2 检验,得出 $P=0.634$ 。按照上述方式分别行其余 5 组数据的分析,得出对应的 P 值。各组的病例总数、支架置入数及统计学分析结果如表 4 所示。

表 2 病理诊断和比较
Table 2 Histological diagnosis and comparison

Diagnosis	Frequency	Stent	Non-stent	P value
Pancreatic cancer	18	6	12	0.015*
Gastric cancer	14	11	3	0.045*
Gallbladder carcinoma	7	5	2	0.634
Colorectal cancer	3	1	2	
Liver cancer	3	2	1	
Cholangiocarcinoma	3	1	2	
Ampullary carcinoma	1	1	0	
Lung cancer	1	1	0	
Total	50	28	22	

Note: * stands for that the comparison was statistically significant($P<0.05$).

表 3 支架组与非支架组 PTBD 术前各指标的比较
Table 3 Comparison of the parameters before PTBD between stent group and non-stent group

	Stent group(n=28)	Non- stent group(n=22)	P value
Sex(male)	22	17	1.000
Age(years)	64.46± 9.54	63.64± 10.36	0.771
Bismuth type I	11	7	0.585
ERCP failed before PTBD	6	5	1.000
Alternate structures due to operations	12	8	0.642
Leukocyte count($\times 10^9/L$)	6.40± 3.40	10.74± 6.41	0.008*
Neutrophil count ($\times 10^9/L$)	4.90± 3.06	8.92± 6.25	0.010*
Neutrophil ratio(%)	75.0± 9.1	79.9± 9.2	0.065
Hemoglobin(g/L)	106.84± 22.44	100.89± 20.06	0.335
Hematocrit(%)	31.82± 6.49	30.25± 5.55	0.37
Platelet count($\times 10^9/L$)	194.68± 79.77	215.50± 111.06	0.444
Serum potassium(mmol/L)	3.73± 0.54	3.58± 0.59	0.338
Prothrombin time(ec)	13.48± 3.80	14.20± 5.18	0.572
Total bilirubin(umol/L)	282.18± 190.58	250.73± 127.36	0.509
Fever(>38 °C)	3	8	0.067
Biliary infection	9	15	0.011*
Color doppler ultrasound guided biliary puncture	20	12	0.217
Clinical success in biliary drainage	26	18	0.451

Note: * stands for that the comparison was statistically significant($P<0.05$).

a stands for the decrease of bilirubin levels >50 % after stent implantation within one month.

3 讨论

对于恶性实体肿瘤引起的胆道梗阻,ERCP 是姑息治疗首选^[8]。但因既往肠道手术导致局部解剖结构改变、局部肿瘤侵蚀

等原因,ERCP 术中难度增加,伴有一定的失败率。其中,对于既往肠道手术导致局部解剖结构改变的患者,ERCP 成功率为 70-92 %^[9]。如果 ERCP 失败,胆道搭桥手术 (Surgical Biliary Bypass)、PTBD、内镜超声引导下的胆道引流术(Endoscopic UL-

trasound-guided Biliary Drainage, EUS-BD) 均可作为候选治疗方案。与经皮胆道支架置入术相比,胆道搭桥手术在手术成功率、围手术期并发症及死亡率方面均无明显统计学差异^[10],但因我院收治的恶性胆道梗阻患者一般为恶性肿瘤终末期,患者及家属因手术创伤等原因对于胆道搭桥手术接受程度不高,故

我院开展该手术较少。EUS-BD 是近年来才出现的一种新型治疗方式,并且目前研究认为其优于 PTBD,因为 EUS-BD 具有较为稳定的成功率、更低的疼痛评分^[11-13]。但我院无 EUS-BD 相关设备,所以在我院 PTBD 术仍是恶性胆道梗阻患者 ERCP 术失败后的首选。

表 4 6 组间总数和支架置入的比较

Table 4 Comparison of the 6 following groups (the frequencies of stent implantation)

	Frequency	Stent	Non-stent	P value
Pancreatic cancer- biliary infection	7	5	2	0.634
Gastric cancer- biliary infection	10	7	3	0.522
Other malignancy- biliary infection	9	7	2	0.279
Pancreatic cancer+ biliary infection	11	1	10	0.001*
Gastric cancer+ biliary infection	4	4	0	0.186
Other malignancy+ biliary infection	9	4	5	0.689
Total	50	28	2	

Note: * stands for that the comparison was statistically significant($P < 0.05$).

胆道感染是一种具有潜在生命威胁的系统性疾病。多种理论揭示感染进入胆道路径,包括肠道细菌逆行进入胆道、经门脉系统的细菌种植、肠道细菌的血行转移等^[14]。本研究,有 24 例患者被诊断为胆道感染,其中 9 例成功置入胆道支架,15 例置入胆道支架失败。胆道感染可能是恶性梗阻性黄疸患者行 PTBD 术中支架置入成功的影响因素。分析原因考虑:胆道梗阻可以导致免疫缺陷状态和胆道内压力的上升,而后者被认为是引起胆道感染的关键因素^[15,16];在此基础上,胆道感染导致局部胆管水肿、黏连,从而使原本狭窄的胆管梗阻更加严重,导致 PTBD 术中导丝导管通过困难,影响术中支架置入率。目前,国际公认指南(Tokyo Guidelines)对于胆道感染的诊断、病情评估和治疗方式均作出了详细的阐释^[17]。胆道感染最为常见的致病菌为大肠杆菌和克雷伯菌属^[18],在血培养后经验性使用抗菌药物是推荐的治疗方式。经验性抗菌治疗能够控制细菌,减轻胆管局部水肿、黏连状态,从而增加 PTBD 术中胆道支架置入率。

恶性胆道梗阻合并胆道感染对于患者预后和生活质量均有较严重影响^[19]。本研究中,我们将 26 例诊断为非胆道感染的患者分为三组:胰腺癌 - 胆道感染组($n=7$,支架置入率 = 71.4 %)、胃癌 - 胆道感染组($n=10$,支架置入率 = 70.0 %)、其他肿瘤 - 胆道感染组($n=9$,支架置入率 = 77.8 %)。上述非胆道感染的各种肿瘤类型中,支架置入率均明显高于本研究中平均支架置入率(56.0 %),故胆道感染是恶性梗阻性黄疸患者行 PTBD 术中影响支架置入率的不利因素。

恶性胆道梗阻可能导致多种严重后果,包括胆管炎、肿瘤治疗的延误、生活质量的降低和死亡率的增加等^[20]。胰腺癌是导致恶性胆道梗阻的最常见疾病之一。胰腺癌的 5 年生存率小于 5 %^[21,22],而胆道梗阻的出现将进一步降低生存率。手术切除是唯一可以治愈胰腺癌的方式^[23]。对于合并胆道梗阻的胰腺癌患者,内镜下的胆道引流是根治术前推荐的治疗方式^[24,25]。本研究中,18 例胰腺癌患者均因肿瘤分期较晚复发等原因无法接受根治性手术治疗。而其中只有 6 例患者成功置入胆道支架,

支架置入率较低(33.3 %)。在 18 例胰腺癌患者当中,合并胆道感染者 7 例。相比较于 50 例患者的总体支架置入率(56.0 %),胰腺癌 - 胆道感染组($n=7$,支架置入率 = 71.4 %)的支架置入率仍较高,而胰腺癌 + 胆道感染组 ($n=11$, 支架置入率 = 9.1 %, $P=0.001$)的支架置入率相当低。分析原因考虑胰腺癌肿块不仅对于胆道外壁有着外压作用,而且肿块向胆道内壁浸润生长,导致胆道内壁光滑程度降低,加上胆道感染引起的局部胆管内壁水肿黏连,使 PTBD 术中导丝导管难以通过,降低胆道支架置入率。

目前,胃癌是世界范围内死亡率第二、东亚范围内发病率第一的恶性肿瘤^[26]。据统计,1.3-2.3 %的恶性梗阻性黄疸由转移性胃癌引起^[27,28]。沿着肝胃韧带转移的胃癌淋巴结是引起胆道梗阻的主要原因之一。^[28,29]而最常见的梗阻部位是胆囊管周围^[27,28,30]。本研究中,14 例胃癌患者中,有 11 例术中成功置入支架,支架置入率 (78.6 %) 明显高于本研究中总体支架置入率 (56.0 %)。分析原因,胃癌引起的胆道梗阻多数为转移性淋巴结导致的胆管外压性梗阻,胆管内壁的浸润较为少见,胆道内壁完整、光滑,有利于 PTBD 术中导丝导管通过和支架置入。

综上所述,PTBD 术对于恶性胆道梗阻是一种有效的姑息治疗手段。胆道感染是 PTBD 术中支架置入成功的不利因素,胰腺癌合并胆道感染会显著降低 PTBD 术中支架置入成功率。但本研究仍有不足之处,包括本研究为回顾性的研究、研究中纳入患者数量较少。此外,部分患者诊断为胆道感染为临床诊断,缺少细菌学证据。

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