

恶性梗阻性黄疸的治疗策略新进展

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Choosing the appropriate strategy in managing malignant biliary obstruction

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Abstract

Most patients with pancreatic cancer develop

malignant biliary obstruction. Treatment of obstruction is generally indicated to relieve symptoms and improve morbidity and mortality. First-line therapy consists of endoscopic biliary stent placement. Recent data comparing plastic stents to self-expanding metallic stents (SEMS) have shown improved patency with SEMS. The decision of whether to treat obstruction and the means for doing so depend on the clinical scenario. For patients with resectable disease, preoperative biliary decompression is only indicated when surgery will be delayed or complications of jaundice exist. For patients with locally advanced disease, self-expanding metal stents are superior to plastic stents for long-term patency. For patients with advanced disease, the choice of metallic or plastic stent depends on life expectancy. When endoscopic stent placement fails, EUS guided biliary drainage, percutaneous transhepatic biliary drainage or surgical treatments are appropriate.

背景资料
 恶性梗阻性黄疸可以起患者肝、肾、胃肠、凝血、心脏功能紊乱, 增加感染风险, 术前胆道引流(preoperative biliary drainage PBD)是否对患者有益, 历来争议颇多, 所以恶性梗阻性黄疸的术前管理至关重要.

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Key Words: Malignant biliary obstruction; Preoperative biliary drainage; Self-expanding metallic stent

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摘要

大多数胰腺癌及壶腹周围癌可以表现出恶性梗阻性黄疸, 治疗主要包括缓解症状, 改善并发症发病率及死亡率. 首选的治疗方案是内镜下胆道支架置入. 最近, 使用塑料支

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■创新盘点

本文不仅回答了“可切除的肿瘤患者是否需行术前胆道引流、以何种方式引流”这个问题,而且全面系统地介绍了恶性梗阻性黄疸患者肿瘤各个阶段时对于黄疸的处理办法。

架和自费的金属支架的研究数据表明金属支架的开放时间更长,是否需要治疗梗阻性黄疸及使用何种方法治疗主要根据临床情况而定。对于肿瘤可切除的患者,术前胆道引流仅仅适用于手术会被推迟和存在黄疸并发症的患者;对于局部浸润化疗后可手术切除的患者,使用自费的金属支架更优于塑料支架;对于不可手术的侵袭性的患者,支架的使用类型根据患者的生存预期而定。当内镜放置支架失败时,超声引导下的胆道引流,经皮肝穿胆道引流或行旁路手术都是合适的治疗方案。

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关键词: 恶性梗阻性黄疸; 术前胆道引流; 金属支架

核心提示: 除外存在胆管炎、严重营养不良和低蛋白血症、黄疸引起肝肾衰竭、手术延迟黄疸恶化,或者化疗期间为了改善肝功能等情况,术前胆道引流需谨慎使用于可切除的胰腺癌及壶腹周围癌。

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0 前言

恶性梗阻性黄疸是胰腺癌、壶腹周围癌等患者最常见的临床表现^[1], 梗阻性黄疸常见的临床表现为: 皮肤巩膜黄染、瘙痒、恶心、尿黄和陶土样便, 长期的胆汁淤积可以导致肝功能损害、甚至肝功能衰竭, 病理生理改变主要包括肝功能损害、胃肠道功能紊乱、凝血功能障碍、感染、肾功能障碍和一些其他的需要全面评估和术前控制良好的不良反应, 梗阻性黄疸对心血管功能的抑制是值得关注的^[2,3]。大多数患者确诊时已有局部浸润不能手术, 或者已有远处转移, 仅有15%-20%的患者可行根治性切除^[4]。然而, 梗阻性黄疸患者行手术治疗会增加手术风险和术后并发症。虽然, 术前行胆道引流可以降低黄疸, 减少发病率和死亡率, 但是他的作用仍有争议, 很多研究^[5,6]表明术前胆道引流会增加术后严重并发症发病率。

1 肿瘤可切除患者术前胆道引流

恶性梗阻性黄疸患者术前是否需要胆道引流

历来争议颇多。早期的研究表明术前胆道引流(preoperative biliary drainage, PBD)可以降低胆红素水平^[7]、减少并发症发病率和死亡率^[8-11]。然而, 最新的研究显示不同的观点。有研究^[12-15]报道, 用PBD作为可切除肿瘤引起梗阻性黄疸的常规退黄治疗, 对术后的疗效没有益处, PBD应该有选择性的应用。

Fang等^[14]最近的一项Meta分析旨在研究PBD对于梗阻性黄疸的患者是否有益。6个试验组(4组经皮经肝胆道引流, 2组经内镜括约肌切开胆道引流)包括520例良恶性梗阻性黄疸的患者, PBD组(265例), 没有行PBD组(255例)进行对比, 两组死亡率没有显著差异($t = 1.12$, 95%CI: 0.73-1.71, $P = 0.60$)。PBD组的严重并发症(Clavien-Dindo分级, III或者IV级)发病率(0.599%)明显高于直接手术组(0.361%)($t = 1.66$, 95%CI: 1.28-2.16, $P < 0.001$)。两组住院时间也没有显著差异($P = 0.12$)。由上数据可知, 术前胆道引流组和直接手术组有相近的死亡率, 但可增加严重并发症发病率, 不建议作为术前常规治疗。这项研究的局限性在于所有的试验都有一定的偏倚, 并且, 任何一项试验都没有术后生活质量和费用的评估。在2014年, 一项基于模型的成本效益分析, 从英国国家服务中心6 mo以内的视角, 评估了每个患者平均费用和质量调整生命年。Morris等^[16]得出: 对于可切除的人壶腹周围癌, 术前避免使用胆道引流术可以显著降低患者费用。

一项较大的多中心随机对照研究, 将胰头癌早期手术和PBD的患者进行对比, 发现早期手术组和PBD组的严重并发症发病率分别为39%、74%($P \leq 0.001$), 死亡率和住院日没有显著差异^[17]。随后的一项研究^[18]报道: PBD组显著延长了住院时间(1 wk vs 5 wk), 术后生存时间没有显著影响, 对生存率没有益处。术前经内镜放置胆道支架增加了术后感染率, 术前胆道支架引流的不利影响多是由于支架的置入引起了胆道的细菌的繁殖。术前胆道引流需要选择性的使用, 而且胆道引流的合适时机仍不明确^[19]。最近Arkadopoulos等^[20]的研究表明: 即使是严重的梗阻性黄疸的患者, 也不应在胰十二指肠切除术前使用胆道引流, 因为术前胆道引流可以增加感染和术后发病率, 从而延误了一些确切的治疗。

总结以上的研究数据可知, 除外一些经典

的适应证如: (1)治疗胆管炎; (2)有严重营养不良和低蛋白血症; (3)治疗黄疸引起的肝脏衰竭或肾衰竭; (4)手术延迟时, 为防止黄疸进一步恶化; (5)化疗期间改善患者肝功能. PBD需谨慎使用于可切除的胰腺癌及壶腹周围癌, 尤其是施行较大损伤的胰十二指肠切除术的病例, 尽量避免使用, PBD引流的合适时间和发病率仍不明确, 需要更多的前瞻性随机对照试验来进一步研究.

2 肿瘤局部浸润和化疗患者胆道引流

2.1 塑料支架和金属支架 胰腺癌手术切除的远期预后较差, 近年来的研究^[21]显示化疗直接提高胰腺癌患者生存率. 对有局部浸润的病例, 化疗可能会使最终获得手术切除的机会. 接受以吉西他滨为基础的化疗方案的患者, 需要先进行退黄治疗, 以确保使用化疗药物的安全^[22]. 胆道支架置入引流已成为了化疗期间最常用的一种减黄方法.

一项回顾性研究^[23]指出: 在行胆道支架植入引流时, 使用塑料支架和金属支架在成功率, 减低胆红素, 胆汁细菌感染水平和术后并发症方面没有显著差异. 然而, Ge等^[24]的回顾性分析却有不同的观点, 他指出塑料支架的中位开放时间是53 d, 比预期的开放时间要短, 很多患者随后还需要再次更换支架. 最近, 一种新型的抗十二指肠内容物反流的塑料支架应用于胆道引流. 一项前瞻性随机对照研究^[25]表明: 对于恶性梗阻性黄疸的退黄治疗, 抗反流胆道塑料支架的开放时间显著短于正常塑料支架($P<0.003$). 这项研究的局限性在于样本量较小. 在化疗期间, 超过1/2的使用塑料支架的患者, 因为支架的再次梗阻或者胆管炎, 需要更换支架^[26].

为了延长支架开放的时间, 金属支架的研究逐渐取代了塑料支架. 研究^[27-31]表明, 在化疗期间金属支架的使用有很好的益处. Adams等^[27]的研究指出, 塑料支架的并发症发生率比金属支架高出7倍, 总的住院日高出3倍. 另一项Meta分析^[32]表明: 与塑料支架相比, 金属支架通畅时间更长, 再次梗阻率和需要再次更换导管频率更低, 不良反应更少; 同时他还指出高位肝门部梗阻时, 放置双边支架并不优于单边, 因为支架梗阻率或者治疗失败比率没有显著差异, 但是增加了不良反应的风险.

2.2 金属支架的类型 最近, 人们越来越关注不同的金属支架(self-expanding metallic stents, SEMS)类型在化疗或姑息治疗的患者中的运用. SEMS的种类主要包括无覆盖型金属支架(USEMSs)和全覆盖型金属支架(CSEMSs). USEMSs有一个网状的设计使得支架植入胆管壁不易移位, 同时, 也使得组织容易向内生长导致约20%的患者出现支架阻塞; CSEMSs的设计解决了组织向内生长的问题, 但是却增加了支架移位风险^[33-35]. 就USEMSs的组织内生长和CSEMSs的移位问题, 很多专家进行了研究.

Saleem等^[36]的一项Meta分析指出CSEMSs保持开放的时间更长, 比USEMSs平均多出61 d, 同时也指出了CSEMSs高移位、肿瘤生长和沉积形成率的弊端. 并且, CSEMSs和USEMSs有相似的胆管炎发病率. Almadi等^[37]却认为CSEMSs更易移位, 但并不能证明CSEMSs保持开放的时间更长. Kullman等^[38]的一项多中心随机对照研究和Lee等^[39]的一项回顾性队列研究也有同样的观点, 他们认为, 对于胆道远端梗阻的恶性黄疸者, CSEMSs和USEMSs在开放时间、生存时间、并发症发病率方面没有显著性差异, CSEMSs更易移位, USEMSs更易发生肿瘤向内生长.

为了降低金属支架的移位率, 而保持全覆盖金属支架的开放时间, 部分覆盖的金属支架被运用于实践. 通过少量数据的分析得出: 与CSEMSs对比部分覆盖的金属支架移位率和支架开放时间没有显著差异^[36]. Telford等^[40]的一项多中心随机对照研究将部分覆盖的金属支架和USEMSs进行对比, 发现两组在梗阻发生率和生存时间上没有显著差异, 部分覆盖的金属支架显著增加了不良反应(62% vs 44%, $P = 0.046$)和支架移位(12% vs 0%, $P = 0.0061$)的发生率. 最近, 一项关于部分覆盖金属支架和具有抗移位特性的USEMSs对比的随机对照研究^[41]指出: 对于缓解恶性梗阻性黄疸, 两组在支架开放时间, 患者的生存时间和并发症(包括胰腺炎和胆管炎)发生率方面没有显著差异. 部分覆盖的金属支架并没有能够延长支架的开放时间和减少支架的移位. 由以上研究可知, 部分覆盖的金属支架并没有很好的临床使用价值.

2.3 支架的选择

2.3.1 肿瘤局部浸润患者支架的选择: 由以上

■应用要点
本文可以指导临床工作者了解恶性梗阻性黄疸患者肿瘤各个阶段时对于黄疸的处理办法.

■名词解释

恶性梗阻性黄疸：是指由恶性肿瘤导致的直接或者间接胆道梗阻所引起的以高胆红素血症、组织和体液黄染、胆管扩张为主要临床表现的一类疾病。

数据可知, 对于局部浸润化疗后可获得手术机会的肿瘤患者是不建议使用塑料支架的。但是, 使用经内镜逆行性胰胆管造影术(endoscopic retrograde cholangio-pancreatography, ERCP)不能确诊恶性肿瘤的时候, 也不建议使用金属支架, 而选择塑料支架。超声内镜引导的定点细针穿刺细胞学检查对于中心明确的肿物, 和特异性的胆总管远端梗阻效果较好。特异性的胆总管远端梗阻包括慢性胰腺炎、自身免疫性硬化性胆管炎, 在这些情况下放置可移除的塑料支架是最好的选择。最近的很多研究表明CSEMSs和USEMSs在开放时间、生存时间、并发症发病率方面没有显著性差异, 但USEMSs更易发生肿瘤向内生长引起再次梗阻。所以, 对于怀疑恶性可能性大, 化疗后可能获得手术机会, 生存预期超过4 mo的患者, 建议使用全覆盖金属支架。

2.3.2 不可切除肿瘤患者支架的选择: 对于有远处转移不可手术切除的恶性侵袭肿瘤所致的梗阻性黄疸, 放置胆道支架的作用包括: 缓解黄疸和皮肤瘙痒、恢复胆红素水平后性缓解性化疗、预防一些不良反应如胆管炎、频繁的住院等。对于这些恶性侵袭性肿瘤, 生存预期短, 使用金属支架具有更长的开放时间, 已不再是追求的目标。Moss等^[42]的一项Meta分析表明: 使用金属支架的费用是使用塑料支架的15-40倍, 而且只有用于的生存时间超过4 mo的患者才有成本效益。Soderlund等^[43]得出了相似的结论, 他指出: 有远处转移的患者的生存时间和塑料支架的开放时间相近, 建议使用塑料支架, 金属支架只能用于没有远处转移的患者。

3 其他胆道引流方式

3.1 经皮经肝穿刺胆道引流 对于不能使用ERCP或重新置换胆道内支架的患者, 经皮经肝穿刺引流(percuteaneous transhepatic catheter drainage, PTCD)就成为了胆道引流的一个很好的选择。PTCD同样可以起到胆道引流、减低黄疸、改善患者情况和减少不良反应的效果^[44,45]。Zhang等^[46]的研究表明: 使用PTCD可以安全有效的缓解恶性侵袭性肿瘤引起的梗阻性黄疸。现在大多数病例使用胆道内外引流的方式, 支架通过梗阻的部位进入十二指肠, 如此重建内引流和正常的肝肠循环。许多专家倾

向于尝试停止使用外引流, 但外引流量较大, 或者存在败血症的病例除外, 因为这些情况下内引流的形成是延迟的。在以上的一些情况, 或者单独使用外引流的病例, 是因为导管不能通过梗阻的部位, 持续外引流会给患者带来很多的不适和不便。胆道外引流需要持续的护理, 包括排空和冲洗导管, 以防止导管的堵塞^[47]。PTCD可以引起细菌感染, 胆管炎及胆道出血, 内外引流或外引流都可能出现胆漏, 导管移位或再次梗阻。最近的一项研究^[48]表明: 经皮肝穿胆道内外引流可能会增加胆道感染率、降低胆道引流的有效率和患者的长期预后; 而胆道外引流对于恶性梗阻性黄疸的退黄治疗具有更好的疗效。综上可知, 对于不能使用ERCP的患者, 经皮肝穿胆道引流是一个很合适的选择, 除外存在败血症或外引流量较大的病例, 经皮肝穿胆道内引流具有更大的优势。

3.2 经皮穿刺放置支架 经皮肝穿胆道支架放置是缓解恶性梗阻性黄疸的又一个选择, 但在支架不易通过梗阻部位或有败血症的情况避免使用。Speer等^[49]一项很早的研究, 将两组随机分配的患者, 分别进行经皮肝穿和经内镜放置支架, 结果表明: 内镜下胆道支架放置具有更好的疗效和更低的死亡率, 经皮肝穿胆道支架放置具有更高的风险和发病率, 包括胆汁漏、出血等。以至于一直以来, 将内镜下胆道支架放置作为首先的治疗方案。然而最近的研究^[50,51]表明: 运用新的技术, 包括经皮肝穿胆道内金属支架的放置, 同样安全、有效。Lawson等^[52]最近的一项研究表明, 经皮肝穿胆道内金属支架植入对于缓解恶性梗阻性黄疸是一项安全有效的方法, 可以很好的缓解黄疸, 具有较低的并发症发病率, 对于不能使用内镜或者手术治疗的患者, 可以有效地改善生活质量。

3.3 超声内镜引导的胆道引流 目前, ERCP是用于各种胰腺胆道疾病的首选方案, ERCP术的成功率约为90%。近10年来, EUS引导的胆道引流术(EUS-biliary drainage, EUS-BD)广泛的应用于ERCP失败的患者。众多回顾性分析和前瞻性分析表明EUS-BD是一种安全有效的选择^[53], EUS-BD首先由Giovannini等^[54]报道, EUS-BD主要包括EUS引导的经肝内肝外导丝十二指肠乳头会师支架植入术, EUS引导的经十二指肠胆道支架成型术和EUS引导的经胃经肝胆道支架成形术。目

前, EUS引导的逆行支架植入术和EUS引导的胆囊引流术也有所报道。

很多研究^[55,56]报道, EUS-BD是一项操作灵活、安全、有效的技术。在使用ERCP失败或者不能使用ERCP的情况下, 比较PTCD及旁路手术减黄, EUS-BD是一项安全、有效的手段^[57-60]。使用金属支架有更长的通畅时间和更低的胆管炎发病率^[61], 然而, 需要更多的前瞻性、多中心随机对照研究来比较EUS-BD和其他胆道引流方式, 在适应证、并发症、选择的时机、成功率及术后疗效等方面的差异。

3.4 手术胆道引流 最后, 胆道旁路手术也是胆道引流的一种选择。Glazer等^[62]进行的一项旁路手术和内镜下支架放置在治疗不可切除的胰腺癌方面的Meta分析。研究表明: 两组的手术成功率、并发症发生率、死亡率没有显著性差异; 中位生存时间超过4 mo的患者, 旁路手术组的患者术后再次梗阻的发生率和住院时间明显低于内镜放置支架组。但是大多数这些研究采用的是金属支架运用之前的较早的数据。另一项Meta分析^[63]表明: 内镜下放置塑料支架组较旁路手术组有更低的并发症发病率、更高的再次梗阻发生率; 金属支架可以显著降低再次梗阻发生率, 和塑料支架的成功率没有显著差异, 内镜下放置金属支架是治疗恶性梗阻性黄疸的一个不错的选择。尽管如此, 对于生存预期超过6 mo的患者, 胆道旁路手术仍是一种合适的治疗方案。

4 结论

除外一些经典的适应证如: (1)治疗胆管炎; (2)有严重营养不良和低蛋白血症; (3)治疗黄疸引起的肝脏衰竭或肾衰竭; (4)手术延迟时, 为防止黄疸进一步恶化; (5)化疗期间改善患者肝功能, PBD需谨慎使用于可切除的胰腺癌及壶腹周围癌, PBD引流的合适时间和发病率仍不明确, 需要更多的前瞻性随机对照试验来进一步研究。对于局部侵袭性肿瘤和接受化疗的患者不建议使用塑料支架的, 而是金属支架, 金属支架通畅时间更长, 再次梗阻率和需要再次更换导管频率更低, 不良反应更少。对于CSEMSs和USEMSs, 两者在开放时间、患者生存时间、并发症发病率方面没有显著性差异, CSEMSs更易移位, USEMSs更易发生肿瘤向内生长。对于不能使用ERCP或者使用ERCP

失败者, EUS-BD是一项安全有效的选择。

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■同行评价

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