

# 恶性梗阻性黄疸胆道引流术式研究进展

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收稿日期: 2023年11月27日; 录用日期: 2023年12月21日; 发布日期: 2023年12月28日

## 摘要

恶性梗阻性黄疸(MBO)是临床常见疾病, 梗阻因恶性肿瘤压迫、浸润胆道引起, 早期缺乏典型症状, 手术切除率低, 预后极差。目前临床MBO胆道引流方式众多, 如内镜逆行胆道引流(ERBD)、内镜鼻胆管引流(ENBD)、经皮肝胆道穿刺引流(PTBD)、超声内镜引导下胆汁引流(EUS-BD)等。本文对MBO的各种胆道引流术式进行系统综述, 为MBO的治疗提供参考意见。

## 关键词

恶性梗阻性黄疸, 内镜逆行胆道引流, 内镜鼻胆管引流, 经皮肝胆道穿刺引流, 超声内镜引导下胆汁引流

# Research Progress on Biliary Drainage Techniques for Malignant Obstructive Obstruction

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Received: Nov. 27<sup>th</sup>, 2023; accepted: Dec. 21<sup>st</sup>, 2023; published: Dec. 28<sup>th</sup>, 2023

## Abstract

Malignant biliary obstruction (MBO) is a common clinical disease. Obstruction is caused by malig-

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nant tumor compression and infiltration of the biliary tract, lacking typical symptoms in the early stage, low surgical resection rate, and extremely poor prognosis. At present, there are many clinical treatments for MBO, including endoscopic retrograde biliary drainage, endoscopic nasobiliary drainage, percutaneous transhepatic biliary drainage and endoscopic ultrasound-guided biliary drainage. This article provides a systematic review of various biliary drainage methods for MBO, providing reference opinions for the treatment of MBO.

## Keywords

MBO, ERBD, ENBD, PTBD, EUS-BD

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## 1. 引言

恶性梗阻性黄疸(Malignant Biliary Obstruction, MBO)是由胆管癌、胆囊癌、胰头癌、Vater 壶腹癌等压迫或浸润胆道引起血清胆红素升高、肝酶异常的疾病。主要临床表现为黄疸、腹痛、发热。临床上根据原发病灶可否切除, MBO 可分为可切除 MBO 和不可切除 MBO。可切除 MBO 能否耐受根治性手术[1], 不仅取决于肿瘤本身, 还取决于患者自身基本情况[2]。由于高胆红素血症及肝功能异常对手术安全性影响极大[3] [4], 对于部分可切除 MBO 患者术前胆道引流(Preoperative Biliary Drainage, PBD)十分必要, 且应综合考虑引流效果及 PBD 对手术的影响[5] [6]。对于不可切除的 MBO 患者应给予姑息性胆道引流缓解症状、保护肝脏, 并充分考虑引流术式的长期通畅性及对患者生活质量的影响。

目前临床上胆道引流的方式可分为外引流和内引流。外引流包括经皮肝穿刺胆道引流(PTBD)、内镜下鼻胆管引流(Endoscopic Retrograde Biliary Drainage, ENBD)或术后 T 管引流。内引流主要指内镜下胆管支架置入术(Endoscopic Biliary Stenting, EBS)或超声内镜引导下胆管引流(EUS-BD)。由于胆道引流方法和技术的多种多样, 关于哪种胆道引流术式为 MBO 的最佳引流方式一直存在争议, 故本文将对 MBO 的最佳胆道引流术式进行系统综述, 为临床决策提供参考意见。

## 2. 胆道引流进展史

著名外科医师 Whipple 于 1935 年首次提出 PBD 的概念, 他认为 PBD 一方面能改善梗阻性黄疸患者胰十二指肠切除术(Pancreaticoduodenectomy, PD)术前营养状况, 提高手术耐受性; 另一方面能降低术后肝衰竭、出血及感染的发生率。最初胆道引流包括两个阶段的程序, 首先是胆囊胃肠吻合术, 以缓解胆汁淤积, 后期再进行切除手术[7]。直至 20 世纪 60 年代, 出现了非手术外引流程序: 经皮肝穿刺胆道造影(Percutaneous Transhepatic Cholangiography, PTC)。1974 年 Molnar 和 Stocknm 首次将 PTC 应用于临床。至 70 年代, 随着经内镜逆行胰胆管造影(Endoscopic Retrograde Cholangiopancreatography, ERCP)技术的成熟, 通过 ERCP 置入胆道支架解除梗阻成为另一种重要方式。如今, ERCP 成为实现胆道引流的标准术式, PTBD 在大多数中心被视为二线治疗。

1996 年, Wiersema 等首次报道了 EUS 引导下的诊断性胆管造影; 2001 年, Giovannini [8]等首次报道了在胰腺癌等远端恶性胆道梗阻患者 ERCP 失败后以 EUS 引导的胆总管十二指肠吻合术(Cholecho Duodenostomy, CDS)手术成功。由于显著的技术进步, 在过去的二十多年中, EUS-BD 成为 PTBD 的替

代方法,并且最近欧洲胃肠内镜学会声明[9],在具备相应专业技术的情况下,对 ERCP 失败的远端胆管恶性梗阻患者采用 EUS-BD 而不是 PTBD。综合文献报道,EUS-BD 与 PTBD 技术成功率相当(86%~100%),EUS-BD 临床成功率相似或更高,不良反应较少[10][11]。

### 3. 外引流术式

#### 3.1. PTBD

PTBD 是在 X 线透视或 B 超引导下,经皮肝穿刺胆管并置入引流管,使胆汁流向体外或十二指肠。对于 MBO 患者,术中导丝不易通过梗阻处,单纯的外引流更常见。在近端或肝内胆管梗阻患者中,与 ERBD 相比,PTBD 引流更充分,所需引流时间更短、肝功能恢复效果更好。究其原因可能是因为 PTBD 引流管短粗,便于及时调整,引流更加充分,且在左、右肝管均不通时可行多根置管引流。

然而,有相关文献报道,PTCD 可能增加局部复发和导管窦道种植转移的风险,从而缩短患者生存期[12]。Takahashi 等[13]报道因行 PTBD 导致肿瘤腹腔种植转移的发生率为 5.2%,PTBD 导管道复发并不罕见,且这些患者的预后通常很差,即使在切除后也是如此。也有相关研究指出,PTBD 是播散转移的独立危险因素[14]。近期,比较可切除肝门部胆管癌患者两种术式的一项 RCT [15]表明 PTBD 组的死亡率更高。但也一些研究强调[16],胆管炎降低了肝胆切除成功的机会。而 PTBD 较少导致胆管炎,这种引流方法可以作为术前引流的首选,这将有利于肝脏残余的结果。故何种引流方式为可切除肝外梗阻患者首选的术前减黄方式,仍未形成统一推荐意见,应根据患者具体情况及各种引流技术在各级医院中开展情况合理选择。

欧洲胃肠内镜协会(ESGE) [17]建议对 Bismuth III 型和 IV 型的恶性肝门部狭窄采用 PTBD 或 PTBD 联合 EBS 进行姑息性引流,并根据当地专家意见进行调整。临床上,也有多项研究已经强调了 PTBD 在晚期肝门部狭窄中的益处。胆道引流治疗的成功率和不良反应的发生率与内镜医师或介入放射科医师的经验有关[18]。由于肝门部胆管癌在亚洲地区的发病率高于西方国家[19],因此放射科医师在 PTBD 方面有丰富的经验。故笔者认为,可推荐 PTBD 为不可切除高位 MBO 患者首选胆道引流方式。

#### 3.2. ENBD

ENBD 是一种引流胆汁、解除胆道梗阻的外源性手术。有学者认为,ENBD 操作成功率高,相较于 PTCD 引流更持久,且可最大程度减少种植转移风险,可避免部分急诊手术,应被推荐为 PBD 患者首选的胆道引流方式[20]。Fujii 等[21]人还报道,ERBD 组的胆汁或引流液培养阳性率明显 ENBD 组,并且腹部脓肿的方式率明显更高。张等[22]未发现 ENBD 组与 ERBD 组 PD 总体并发症的差异;腹部深部感染的发生率有显著差异,但伤口感染或肺部感染的发病率没有显著差异。有证据表明,PD 的感染并发症是影响 EBD 治疗的重要因素。因此术后 PD 并发症发病率的降低是评价 ENBD 和 ERBD 疗效的一个指标。在相关的文献中,只有 Kawakami 等[23]提出 ENBD 的并发症发生率显著低于 ERBD,而其他研究报告称,两组之间没有显著差异。据合并结果显示,ENBD 的并发症发生率明显低于 ERBD。因此,MBO 患者术前胆道引流可优先采用 ENBD。

ENBD 虽有较低并发症发生率及窦道转移率[24],但 ENBD 术后长期留置鼻胆管,可能引起喉部刺激不适及水电解质紊乱,且存在鼻胆管断裂、脱落及移位的风险。当鼻胆管功能障碍或患者不耐受时,鼻胆管可由胆道支架取代,即所谓的桥接 PBD。研究表明,桥接 PBD 可以缩短术前住院时间,并使 PBD 能够长期进行,而不会对 PD 后的预后造成负面影响[25]。无论哪种类型的 MBO,ENBD 患者的术前胆管炎、术前胰腺炎、术后胰瘘、支架功能障碍和并发症的发生率均低于 ERBD 患者。

在临床实践中,在充分考虑每位患者的身体状况及耐受程度的情况下,对于 MBO 患者的 PBD 应优先考虑 ENBD,出现鼻胆管功能障碍或患者不能耐受是,再更换为 ENBD。

## 4. 内引流术式

### 4.1. ERBD

ERBD 是一种相较于 PTCD 侵入性更小且生理上更为相似的引流方式。在最近的研究中,考虑到 MBO 患者生活质量,避免肿瘤的扩散和严重并发症,外科医生更倾向于内镜下胆道引流(Endoscopic Biliary Drainage, EBD)而不是 PTBD [13] [26] [27]。最新的一项纳入了 6 项 RCT 研究的荟萃分析结果表明:PTCD 与 ERBD 相比,与更多的术后并发症有关,考虑到两者相似的临床疗效,推荐 ERBD 作为恶性胆道梗阻的初始减压方式[28]。此外,临床上 PTBD 和 ENBD 在舒适度和依从性也不及 ERBD,一些指南也推荐 ERBD 作为恶性梗阻性黄疸的首选治疗方法[29]。

选择性胆管插管是治疗性 ERCP 的必要性前提,然而,通过 Vater 乳头标准插管进入胆总管的失败率高达 20%,目前这一失败率在专家手中下降到 5% [30]。ERCP 术后并发症发生率为 5%~10%,既包括 ERCP 相关并发症如胰腺炎、出血、急性胆管炎、穿孔等,也包括支架相关并发症如支架移位等。最近欧洲胃肠内镜协会指南报道了 ERCP 术中/术后胰腺炎、胆管炎和穿孔的发生率分别为 3.5~9.7%、0.5~3.0% 和 0.08~0.6%。此外,据报道 ERCP 术后胰腺炎的死亡率为 0.1~0.7% [31]。

目前,ERBD 是治疗姑息性 MBO 的标准治疗方法[32],但我们仍需牢记,严重和致命的 ERCP 相关的不良事件仍可能会发生,应早期精准识别高危患者以便围手术期监测及干预。

### 4.2. EUS-BD

EUS-BD 技术由 Giovannini 等人于 2001 年首次报道。EUS-BD 在解除胆道梗阻方面具有较高的技术和临床成功率,且相比于其他干预措施具有良好的不良事件发生率。EUS-BD 的主要缺点是在技术上具有挑战性,有较长的学习曲线。Attasaranya 等[33]的研究发现,EUS-BD 在前 3 年的训练中失败率为 38%,后 2 年的训练失败率为 11%。随后进行的 7 年的单中心单操作员病例系列( $n = 101$ )观察到,在研究的前 5 年中,前 50 例患者中有 5 例与手术相关的死亡,而在最后 2 年中,最后 51 例患者中仅有 1 例出现手术相关死亡。再者,可用于 EUS-BD 的工具和设备(支架、导丝)有限。所使用的大多数工具都是从 ERCP 设备中借来的。由于缺乏专用工具,该手术对许多患者来说可能具有技术挑战性。目前,EUS-BD 最常被用于 ERCP 失败或不可切除的远端胆道恶性梗阻患者[34]。

#### 4.2.1. 在 ERCP 失败后的 MBO 中的应用

目前许多文献探讨了 ERCP 失败后 EUS-BD 在缓解 MBO 中的作用。一项系统评价和荟萃分析显示[35],EUS-BD 技术成功率和临床成功率均为 90%~95%。Meta 分析显示,EUS-BD 手术相关不良事件发生率在 15%~24%之间,最常见的并发症为感染(包括胆管炎、胰腺炎、胆汁性腹膜炎)、出血、气腹和胆漏。在 EUS-HGS 中,也有经食管穿刺的报道[36],可导致气胸或纵膈炎。

鉴于 PTBD 仍然是 ERCP 失败后胆道梗阻的常规治疗措施,研究者比较了 PTBD 和 EUS-BD 的治疗效果。最近的随机对照试验发现[37],EUS-BD 和 PTBD 在解除胆道梗阻的技术和临床成功方面是等效的,多项回顾性研究和荟萃分析[38] [39] [40]也证明了类似的发现。在一项大项荟萃分析中,Moole 等[35]人发现 EUS-BD 和 PTBD 相比,胆道引流的合并优势比(odds ratio, OR)为 1,PTBD 为 3.1 (95%CI 为 1.1~8.4),表明 EUS-BD 可能比 PTBD 对恶性胆管狭窄患者更有效。目前的文献还表明,EUS-BD 的不良事件和并发症比 PTBD 低。一项随机试验发现[41],EUS-BD 的程序相关不良时间发生率(8.8%)显著低于 PTBD

(31.2%); 另一项研究[37]发现 EUS-BD 的再干预率较低。回顾性研究和荟萃分析发现了类似的结果, EUS-BD 显示出较低的感染并发症[39]、较少的重复干预和较少的术后疼痛[35]。

EUS-BD 相对于 PTBD 的其他优势包括: 患者的生活质量高(无外引流管); 更具生理性; 有肝转移和腹水的患者也可进行 EUS-BD [42]; 在 ERCP 失败后, 若操作者具备专业知识及相关设备完善, 能够在与失败的 ERCP 相同的疗程中进行 EUS-BD, 这将避免日后再次安排手术[35]-[44]。

故对于 ERCP 引导下胆道支架置入术失败的无法手术的恶性胆道狭窄患者, EUS-BD 似乎是一个很好的治疗选择, 具有较高的胆道引流成功率和较少的并发症, 明显优于 PTBD。对于 ERCP 失败和胆道、十二指肠解剖结构改变的患者, 在适当的操作者专业知识和基础设备可用的情况下, EUS-BD 应优于 PTBD。

#### 4.2.2. 在不可切除的 MBO 中的应用

与 ERBD 相比, EUS-BD 在原发性缓解 MBO 方面的技术成功率和临床成功率相似。Paik 等[45]人在 2018 年进行的一项非劣效性随机对照试验(RCT) (n = 125)发现, EUS-BD 和 ERBD 具有相似的技术成功率(93.8% vs 90.2%, P = 0.003, 非劣效率为 10%)和临床成功率(90% vs 94.5%, P = 0.049), 且 EUS-BD 的总体不良事件发生率更低(6.3% vs 19.7%, P = 0.03)。此外, EUS-BD 还具有较低的再干预率(15.6% vs 42.6%, P = 0.001)、较高的支架 6 个月通畅率(85.1% vs 48.9%, P = 0.001)。随后, 韩[46]及其同事的系统综述和荟萃分析, 证实了这些发现。Lyu 等[47]的研究结果也重申了这些发现。

故与 ERBD 相比, EUS-BD 的优势是: (1) 较低的再干预率和较高的 6 个月支架通畅率, 这两个优势可明显提高患者生活质量。(2) EUS-BD 避免了 ERCP 术中可导致急性胰腺炎的乳头操作, 这与 Paik 等[45]的 RCT 显示 EUS-BD 组急性胰腺炎发生率为 0%, ERCP 组为 14.8% (P = 0.001)的结果一致。(3) EUS-BD 允许操作者绕过恶性狭窄而不穿过它, 这可能导致肿瘤生长的频率低于 ERCP [48]。(4) 与 ERCP 相比, EUS-BD 用于初次姑息治疗也有成本优势[49]。(5) 当使用一部支架部署系统时, 它可能比 ERCP 更快。Paik 等人利用了这种系统, 发现 EUS-BD 和 ERCP 之间的手术时间存在统计学显著差异(5 分钟 vs 11 分钟, P < 0.001)。而且, 一步支架部署系统的应用具有降低胆汁泄露和延迟性管腔损伤风险的优势。

笔者认为, 在不可切除 MBO 患者, EUS-BD 较 ERBD 更具优势, 在技术成熟的中心可优先考虑 EUS-BD 为治疗方式。目前, EUS-BD 已是公认的 ERBD 的替代方案, 随着 EUS-BD 技术的进步与成熟, 有可能成为 MBO 患者的首选治疗方案。

## 5. 总结与展望

综上所述, MBO 是外科临床上的常见疾病。其最有效的根治性方法仍然是根治性手术。对于需要行 PBD 的高位梗阻患者推荐 PTBD, 其他患者应优先考虑 ENBD, 出现鼻胆管功能障碍或患者不能耐受时, 再更换为 ENBD。目前, ERBD 是治疗姑息性 MBO 的标准治疗方法。当 ERBD 失败或胆道、十二指肠解剖结构改变时, 在操作者专业知识和基础设备兼备时, EUS-BD 应优于 PTBD。笔者认为随着 EUS-BD 内镜工具的不断进步和 EUS-BD 应用的日益广泛, EUS-BD 成为 MBO 患者的首选方式指日可待。

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