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· 文献综述 ·

## 不同解剖部位恶性梗阻性黄疸术前胆道引流的适应证与临床争议

赵学安<sup>1</sup>, 秦文科<sup>1</sup>, 李昕<sup>2</sup>, 周文策<sup>2</sup>

(1. 兰州大学第二临床医学院, 甘肃 兰州 730000; 2. 兰州大学第二医院 普通外科, 甘肃 兰州 730000)

### 摘要

恶性梗阻性黄疸是由胆道梗阻引起、以高胆红素血症为主要特征的严重病理生理紊乱。为改善高胆红素血症对机体的不良影响并降低术后并发症发生风险, 术前胆道引流(PBD)常作为围术期管理的重要策略。然而, PBD是否能够带来明确的临床获益仍存在较大争议。本综述系统梳理相关研究, 重点探讨PBD在不同解剖部位胆道梗阻中的适应证、引流方式及临床价值, 旨在为恶性梗阻性黄疸患者的外科治疗决策提供循证依据。

### 关键词

黄疸, 阻塞性; 胆管肿瘤; 胰腺肿瘤; 术前胆道引流; 综述

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## Indications and clinical controversies of preoperative biliary drainage at different anatomical sites in malignant obstructive jaundice

ZHAO Xuean<sup>1</sup>, QIN Wenke<sup>1</sup>, LI Xin<sup>2</sup>, ZHOU Wence<sup>2</sup>

(1. The Second Clinical Medical School, Lanzhou University, Lanzhou 730000, China; 2. Department of General Surgery, the Second Hospital of Lanzhou University, Lanzhou 730000, China)

### Abstract

Malignant obstructive jaundice is a severe pathophysiological disorder characterized primarily by hyperbilirubinemia secondary to biliary obstruction. To mitigate the adverse effects of hyperbilirubinemia and reduce postoperative complications, preoperative biliary drainage (PBD) has long been employed as a perioperative management strategy. Nevertheless, whether PBD confers definitive clinical benefits remains a subject of considerable debate. This review systematically summarizes the current literature, with particular emphasis on the indications, approaches, and clinical value of PBD in relation to obstruction at different anatomical sites, aiming to provide evidence-based guidance for surgical decision-making in patients with malignant obstructive jaundice.

### Key words

Jaundice, Obstructive; Bile Duct Neoplasms; Pancreatic Neoplasms; Preoperative Biliary Drainage; Review

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作者简介: 赵学安, 兰州大学第二临床医学院硕士研究生, 主要从事肝胆胰疾病临床与基础方面的研究。

通信作者: 周文策, Email: zhouwc129@163.com

恶性梗阻性黄疸是胆管癌、胰头癌及壶腹周围癌等疾病常见临床表现,发生率高达70%~90%<sup>[1]</sup>。根治性手术切除是唯一可能实现长期生存的治疗手段。以胆囊管与肝总管汇合点为界,胆道梗阻分为高位和低位两类:其近端(肝总管及以上水平)为高位梗阻,远端则为低位梗阻<sup>[2]</sup>。长期胆道梗阻会影响人体的各个器官功能和生理,增加术后并发症发生率和病死率<sup>[3-4]</sup>,严重威胁患者预后。因此,通过术前胆道引流(preoperative biliary drainage, PBD)解除胆道梗阻,可能成为逆转此类病理状态的关键干预措施。胆道引流主要包括内镜和经皮穿刺两种途径。内镜逆行胰胆管造影(endoscopic retrograde cholangiopancreatography, ERCP)技术是治疗梗阻性黄疸的有效方法,其操作成功率高、患者耐受性好且并发症发生较少,已被广泛作为一线治疗手段<sup>[5]</sup>。经皮肝穿刺胆管引流(percutaneous transhepatic cholangial drainage, PTCD)是在影像引导下经肝穿刺扩张胆管实现胆道通路的技术,该方式具有定位准确、创伤性小、可迅速缓解梗阻症状等优点。尽管引流技术已日趋成熟并广泛应用于临床,但其在围术期管理中的实际获益仍存争议,尤其是针对不同解剖部位梗阻的适应证、引流方式选择及相关风险仍需进一步明确。系统评估PBD在不同梗阻部位患者中的临床应用效果与循证依据,对指导个体化治疗、改善手术预后具有重要的临床意义。

## 1 高位恶性胆道梗阻

肝门部胆管癌(hilar cholangiocarcinoma, HCCA)又称Klatskin肿瘤,是导致高位胆道梗阻的代表性疾病,约占胆道恶性肿瘤的40%~60%<sup>[6]</sup>。基于肿瘤沿胆道树轴向延伸范围的差异,Bismuth-Corlette分型为手术方案提供了重要依据<sup>[7]</sup>。尽管联合大范围肝切除对HCCA手术意义存在一定临床争议,但多个国家和地区的指南或专家共识多推荐Bismuth-Corlette III~IV型肿瘤应联合半肝及以上范围的肝切除<sup>[8-11]</sup>。HCCA特殊的解剖位置导致其胆道梗阻引发的肝功能损害更为严重,术前精准评估肝储备功能成为手术安全的关键环节。因此,PBD的实施需要综合考量胆红素水平、剩余肝体积(future liver remnant, FLR)、Bismuth-Corlette分型及全身状况,其风险与获益的精准平衡仍是当

前临床决策的难点。

### 1.1 PBD的适应证与胆红素阈值争议

HCCA行PBD的必要性和实施时机仍缺乏统一标准,迄今为止缺乏有效的循证医学证据支持。多项研究试图明确PBD胆红素的阈值:法国Farges等<sup>[12]</sup>报道术前血清胆红素水平 $>50 \mu\text{mol/L}$ 与右肝切除术后病死率增加相关;我国有学者提出将胆红素水平降至 $\leq 75 \mu\text{mol/L}$ 可减少术中输血并改善生存<sup>[13]</sup>;李斌等<sup>[14]</sup>则建立了首选计划保留侧肝叶进行PTCD的“短周期”(3~4周内)胆道引流方案,将术前血清总胆红素水平 $\leq 85 \mu\text{mol/L}$ 作为肝储备功能可耐受大范围肝切除的标准;波兰Wronka等<sup>[15]</sup>推荐对胆红素水平 $\geq 102.6 \mu\text{mol/L}$ 者常规进行引流,胆红素水平在 $42.75\sim 102.6 \mu\text{mol/L}$ 者个体化考虑,而胆红素水平 $< 42.75 \mu\text{mol/L}$ 者不建议引流;此外,多项研究一致认为胆红素水平 $> 171 \mu\text{mol/L}$ 是预后不良的独立危险因素<sup>[16-19]</sup>;亦有研究将引流的临界值提高至 $218.75 \mu\text{mol/L}$ <sup>[20]</sup>,意大利Ratti等<sup>[21]</sup>则建议对黄疸时间长( $> 15 \text{d}$ )或胆红素水平 $> 256.5 \mu\text{mol/L}$ 应积极引流。

PBD在不同国家和地区的指南中亦存在显著差异。欧美等指南<sup>[8,22]</sup>多推荐HCCA术前实施PBD,但并无明确的推荐意见。日本指南<sup>[9]</sup>推荐首选内镜下鼻胆管引流(endoscopic nasobiliary drainage, ENBD)途径胆道引流,联合肝切除者术前血清总胆红素水平应 $\leq 50 \mu\text{mol/L}$ 。《中国临床肿瘤学会(CSCO)胆道恶性肿瘤诊疗指南-2024》<sup>[23]</sup>中建议合并胆管炎、长时间胆道梗阻、血清总胆红素水平 $> 200 \mu\text{mol/L}$ 或拟行大范围肝切除者行胆道引流,引流目标值为 $50 \mu\text{mol/L}$ 以下。在《肝门部胆管癌诊断和治疗指南(2025版)》<sup>[11]</sup>中建议在总胆红素水平 $> 100 \mu\text{mol/L}$ 、伴有胆管炎、营养不良、拟行新辅助治疗等情况下实施,引流理想目标为 $< 51 \mu\text{mol/L}$ 。而《肝门部胆管癌诊疗湖南专家共识(2025版)》<sup>[24]</sup>中不推荐常规进行PBD,但在合并胆管炎、长时间胆道梗阻、门静脉栓塞(portal vein embolization, PVE)术前准备、血清总胆红素水平 $> 200 \mu\text{mol/L}$ 、计划接受大范围肝切除术(FLR $< 40\%$ )等情况下考虑PBD。

综合现有的文献,欧美地区的相关研究和指南对PBD的必要性仍持保守态度,而中国、日本、韩国等临床中心则更倾向于积极实施术前引流策略。目前该领域仍缺乏高质量研究,亟须多中心

协作研究进一步明确PBD的适应证与目标值。基于现有证据,不推荐常规实施PBD,而应在多学科讨论基础上实施个体化治疗。尽管PBD的最佳胆红素阈值尚存争议,目前临床实践中多以术前总胆红素水平 $<85\ \mu\text{mol/L}$ 或 $50\ \mu\text{mol/L}$ 为常见目标。因此,在进行联合大范围肝切除前,建议最好将胆红素水平降低至 $<85\ \mu\text{mol/L}$ ,以降低肝切除术后肝功能衰竭的风险。

## 1.2 基于 Bismuth-Corlette 分型的引流路径选择策略

目前,ERCP或PTCD已成为梗阻性黄疸的最常用胆管引流方法,但二者各具局限性。内镜引流通常会破坏Oddi括约肌的功能,增加胆管炎、胰腺炎、出血及穿孔的风险<sup>[25]</sup>。PTCD可实现针对性区域引流,操作简便,尤其对于HCCA引流成效显著。但也存在感染、脱位等并发症发生的风险<sup>[26]</sup>,其中最大的担忧是可能存在肿瘤沿导管种植转移的风险<sup>[27-28]</sup>。

荷兰一项多中心回顾性研究<sup>[29]</sup>中得出结论,不可切除HCCA患者初始胆道引流成功率仅为45%,未来对HCCA患者的研究应侧重于改善胆道引流。因此,临床实践中在明确需要进行PBD的患者中,选择ERCP还是PTCD作为引流方式,也是一个持续存在且值得深入探讨的关键问题。Kloek等<sup>[30]</sup>发现,内镜组初始引流的成功率为81%,而PTCD组为100%,内镜组感染并发症更为常见,他们的结果表明,对于可切除的HCCA患者,术前经皮PBD可能优于内镜PBD。日本10个高容量HCCA术前管理方案经验中表明现在ENBD已成为大多数中心的首选引流策略<sup>[31]</sup>,在日本最新指南中也推荐将ENBD作为可切除HCCA胆管梗阻的首选胆道引流方式<sup>[9,31]</sup>。然而,Nooijen等<sup>[32]</sup>经过长期随访发现,在患者生存率、再入院率和引流方面没有发现PTCD和内镜引流的长期差异。

综上所述,关于HCCA患者PBD是选择通过内镜还是经皮路径仍无统一标准。单纯比较两种技术的总体优劣难以得出普适性结论,因为患者的个体差异对引流成功率和并发症发生风险具有决定性影响。因此,当前的研究趋势正逐渐从“技术之争”转向“精准引流”策略的制定,而Bismuth-Corlette分型为引流路径选择提供了关键解剖学依据。一般来说,Bismuth-Corlette I~II型HCCA患者首选内镜下胆道引流,对于Bismuth-Corlette III~IV型

引起的高位梗阻来说引流效果较差,成功率相对较低<sup>[33]</sup>。研究<sup>[34-35]</sup>发现,Bismuth-Corlette III~IV型HCCA患者通过PTCD引流发生胆管炎的风险显著降低。在不可切除HCCA患者的姑息治疗中,使用双侧金属支架植入术的内镜治疗优于双侧塑料支架植入术,晚期HCCA患者总生存期更长,临床成功率更高,支架通畅时间更长<sup>[36-37]</sup>。

## 2 低位恶性胆道梗阻

低位恶性胆道梗阻病变主要发生于胆总管下段、胰头及壶腹区域,患者早期常无特异症状,进行性黄疸是其最常见的临床表现,最终仅有15%~20%的患者有机会接受根治性手术<sup>[38]</sup>。与高位胆道梗阻相比,低位梗阻在解剖结构和干预策略上均存在明显差异。首先,低位梗阻通常仅累及胆总管下段,解剖路径相对单一,引流目标明确,只需解除其梗阻即可实现全肝胆汁引流,一般无需多支胆管分别引流。其次,该区域解剖关系复杂,毗邻众多器官与脉管系统,肿瘤易压迫胆管造成梗阻和形成血管包裹。ERCP等操作往往会造成相应区域组织水肿和炎症反应,从而增加后续手术难度,使“盲目减黄”成为潜在风险<sup>[39]</sup>。第三,手术方式存在差异,胰十二指肠切除术(pancreaticoduodenectomy, PD)作为低位梗阻的主要根治方式,切除范围广、操作难度大、术后并发症发生率高,而PBD是否能够降低术后并发症的发生率、改善患者预后,目前仍存在显著争议,成为临床决策中的重要考量。

### 2.1 低位恶性梗阻PBD的争议和现状

低位恶性胆道梗阻因其解剖结构集中、周围组织关系复杂及手术方式特殊,使得PBD的适应证和临床价值更具争议,“是否必要”与“利弊权衡”的讨论成为该领域的研究焦点。早在1935年Whipple等<sup>[40]</sup>便提出可先行胆囊造瘘术减黄,3~4周后再行根治性手术。然而,后续大量临床实践与研究并未证实该策略的明确获益。近年多项研究均不推荐术前常规应用,指出不仅未减少术后并发症的发生或改善预后,甚至还增加了术后并发症的发生风险、延长住院时间及医疗费用<sup>[41-43]</sup>。2010年,van der Gaag等<sup>[44]</sup>报道了一项多中心随机试验,研究最终纳入了102例PBD患者和94例早期手术患者,通过比较两组术后并发症、住院时

间等特征,研究发现胰腺癌患者常规PBD会增加并发症的发生率。然而,这项研究可能存在一些问题,因为研究纳入的患者胆红素水平范围为39.3~249.7  $\mu\text{mol/L}$ ,可能获益的重度梗阻性黄疸患者被排除在外<sup>[45]</sup>;此外,该研究中所使用经内镜引流方式的并发症发生率较其他研究更高<sup>[46]</sup>,提示研究中引流的质量可能影响到了研究的结果。一项更新的Meta分析<sup>[47]</sup>显示,尽管PBD可降低胆汁漏风险,但其延长了住院时间,并显著增加了术后胰瘘、腹腔内感染、手术部位感染及败血症的发生风险。值得注意的是,该研究中胆汁漏结局存在异质性,且未进一步按关键因素胆红素水平进行亚组分析。另一项Meta分析<sup>[48]</sup>表明现有证据呈现显著异质性,接受PBD患者的发病率、感染发生和术后胰瘘显著高于非引流的患者,但在血清总胆红素水平低于256.5  $\mu\text{mol/L}$ 时,两组之间差异失去了统计学意义。这提示PBD的获益可能局限于特定黄疸阈值以上患者。

尽管大量研究<sup>[49-54]</sup>证实严重梗阻性黄疸会显著增加PD后的并发症发生风险,但关于PBD的具体胆红素干预阈值仍未达成共识,其建议阈值差异显著,研究结果为128~380  $\mu\text{mol/L}$ 不等。尽管国内外各指南对低位恶性胆道梗阻的PBD策略存在一定分歧,但其循证基础与核心理念基本一致,即不建议常规应用,仅推荐特定高危人群。《胰腺癌诊疗指南(2022版)》<sup>[55]</sup>中明确指出PBD主要是为了缓解胆道梗阻,改善肝功能,纠正凝血异常,从而降低手术死亡率。对症状严重,伴有发热、败血症、化脓性胆管炎患者可PBD,一般于引流术2周以后,胆红素水平下降至初始数值一半以下、肝功能恢复、体温和血常规正常时可施行手术,同时强调不推荐术前常规行PBD。

## 2.2 重度黄疸引流策略的循证依据与临床推荐

对于重度黄疸的低位梗阻患者,PBD则可能成为改善肝功能、降低围术期并发症的重要辅助手段。有研究<sup>[50]</sup>发现,病理变化往往在血清总胆红素水平 $\geq 250$   $\mu\text{mol/L}$ 变得明显。一项基于血清胆红素分层分析的研究<sup>[56]</sup>表明,对于血清总胆红素水平 $\geq 250$   $\mu\text{mol/L}$ 的重度黄疸患者,行PBD能有效改善PD术后的结局指标。该研究共纳入358例患者,其总胆红素水平分布于40.0~374.7  $\mu\text{mol/L}$ 之间,通过科学分层有效减少了极端数据干扰,从而确立了以总胆红素为依据的PBD决策参考,

为临床实践提供了重要的循证依据。

解剖位置决定了内镜下胆道引流是治疗低位胆道梗阻的一线干预措施。Inamdar等<sup>[57]</sup>一项大样本研究比较了内镜与经皮胆道引流的不良事件,他们发现尤其是对于胰腺癌患者,就不良事件发生率而言,内镜引流优于经皮引流。Zhang等<sup>[58]</sup>比较了PD前恶性远端胆道梗阻患者行ENBD和内镜下胆管支架引流的结局,指出ENBD可作为该类患者术前引流的优选方法;尽管ENBD在患者耐受性与引流效果方面表现更佳,但其可能增加感染风险。日本指南<sup>[59]</sup>同样推荐,对于可切除的远端胆管梗阻,内镜下胆道引流为最适宜方式。然而,内镜下引流也存在明显局限,尤其是支架置入后可引发不同程度的胆管周围纤维化,导致组织水肿与解剖结构扭曲,从而增加手术难度、延长手术时间,并可能提高术后并发症发生率。李炜等<sup>[39, 60]</sup>也报道了类似发现,对支架作为异物影响后续手术操作及恢复表示担忧。

## 3 总结与展望

PBD作为改善恶性梗阻性黄疸的常规干预手段,其应用价值与适应证在不同解剖部位中存在持续争议。现有证据表明,高位与低位恶性胆道梗阻在病理生理基础、手术方式、并发症谱系和术前评估策略存在显著差异,因此PBD的实施应严格遵循个体化原则。对于HCCA等高位梗阻患者,PBD可在特定条件下改善肝功能状态,降低术后发生肝衰竭风险,尤其在术前胆红素水平显著升高、FLR不足或合并营养不良者中更为重要。在引流方式上,Bismuth-Corlette I~II型病变可优先考虑内镜下引流,而Bismuth-Corlette III~IV型复杂梗阻则更适宜PTCD引流,未来联合引流或精准引流策略逐渐受到重视。拟行大范围肝切除者,建议将血清胆红素水平降至85.5  $\mu\text{mol/L}$ 以下。相比之下,低位梗阻PBD应更为慎重,既往随机试验及Meta分析提示其未显著降低并发症发生率,反而可能增加感染等风险,仅在胆管炎、重度黄疸或手术延迟等情况下推荐实施。

综上所述,不推荐对所有恶性梗阻性黄疸患者常规行PBD。未来应进一步围绕解剖结构、生理功能及肿瘤特征建立精准评估体系,通过多中心、前瞻性研究进一步验证和优化PBD的适应证

和操作策略,明确“是否引流、为谁引流、何时引流及如何引流”,构建基于循证医学的个体化术前管理路径,最终改善患者治疗结局。

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## 本刊对来稿中统计学处理的有关要求

1. 统计研究设计: 应交代统计研究设计的名称和主要做法。如调查设计(分为前瞻性、回顾性或横断面调查研究); 实验设计(应交代具体的设计类型, 如自身配对设计、成组设计、交叉设计、正交设计等); 临床试验设计(应交代属于第几期临床试验, 采用了何种盲法措施等)。主要做法应围绕四个基本原则(随机、对照、重复、均衡)概要说明, 尤其要交代如何控制重要非试验因素的干扰和影响。

2. 资料的表达与描述: 用 $\bar{x} \pm s$ 表达近似服从正态分布的定量资料, 用 $M(IQR)$ 表达呈偏态分布的定量资料; 用统计表时, 要合理安排纵横标目, 并将数据的含义表达清楚; 用统计图时, 所用统计图的类型应与资料性质相匹配, 并使数轴上刻度值的标法符合数学原则; 用相对数时, 分母不宜小于20, 要注意区分百分率与百分比。

3. 统计分析方法的选择: 对于定量资料, 应根据所采用的设计类型、资料所具备的条件和分析目的, 选用合适的统计分析方法, 不应盲目套用 $t$ 检验和单因素方差分析; 对于定性资料, 应根据所采用的设计类型、定性变量的性质和频数所具备条件以分析目的, 选用合适的统计分析方法, 不应盲目套用 $\chi^2$ 检验。对于回归分析, 应结合专业知识和散布图, 选用合适的回归类型, 不应盲目套用简单直线回归分析, 对具有重复实验数据的回归分析资料, 不应简单化处理; 对于多因素、多指标资料, 要在一元分析的基础上, 尽可能运用多元统计分析方法, 以便对因素之间的交互作用和多指标之间的内在联系进行全面、合理地解释和评价。

4. 统计结果的解释和表达: 当 $P < 0.05$  (或 $P < 0.01$ ) 时, 应说明对比组之间的差异有统计学意义, 而不应说对比组之间具有显著性(或非常显著性)的差别; 应写明所用统计分析方法的具体名称(如: 成组设计资料的 $t$ 检验、两因素析因设计资料的方差分析、多个均数之间两两比较的 $q$ 检验等), 统计量的具体值(如 $t=3.45$ ,  $\chi^2=4.68$ ,  $F=6.79$ 等)应尽可能给出具体的 $P$ 值(如 $P=0.0238$ ); 当涉及总体参数(如总体均数、总体率等)时, 在给出显著性检验结果的同时, 再给出95%置信区间。

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