

术后肠麻痹结局测量指标的异质性分析与 标准化构建思考

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摘 要

术后肠麻痹(postoperative ileus, POI)是腹部手术后常见并发症, 严重影响患者康复并增加医疗成本。目前, 评估POI恢复的结局指标存在显著异质性, 限制了不同临床研究结果间的有效比较与整合分析, 阻碍循证医学实践推进。本文通过叙述性综述, 回顾现有文献中POI及胃肠功能恢复相关结局指标的定义、测量方式及其变异性特征, 分析异质性产生的主要原因。在此基础上, 本文介绍了核心结局集(core outcome set, COS)的概念及开发流程, 并总结了国际相关研究进展。最后提出, 未来结合加速康复外科(enhanced recovery after surgery, ERAS)理念, 构建符合中国临床实践的本土化核心结局集构想, 以推动术后胃肠功能恢复研究规范化发展。

关键词

术后肠麻痹, 胃肠功能恢复, 结局测量指标, 异质性, 核心结局集, 加速康复外科

Heterogeneity Analysis and Reflections on Standardized Construction of Outcome Measurement Indicators for Postoperative Ileus

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Abstract

Postoperative ileus (POI) is a common complication after abdominal surgery, which seriously affects patients' recovery and increases medical costs. At present, there is significant heterogeneity in the outcome indicators for evaluating POI recovery, which limits the effective comparison and integrated analysis of different clinical research results and hinders the progress of evidence-based medicine practice. Through a narrative review, this paper reviews the definitions, measurement methods and variability of POI and outcome indicators related to gastrointestinal function recovery in the existing literature, and analyzes the main reasons for the heterogeneity. On this basis, the concept and development process of core outcome set (COS) were introduced, and the international research progress was summarized. Finally, it is proposed that in the future, combined with the concept of enhanced recovery after surgery (ERAS), a localized core outcome set concept in line with Chinese clinical practice should be constructed to promote the standardized development of post-operative gastrointestinal function recovery research.

Keywords

Postoperative Ileus, Recovery of Gastrointestinal Function, Outcome Measurement Indicators, Heterogeneity, Core Outcome Set, Enhanced Recovery after Surgery

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1. 前言

术后肠麻痹(Postoperative ileus, POI)通常指手术后非机械因素引起的胃肠道动力暂时的减弱或停止,导致胃肠功能恢复延迟,主要表现为腹胀、无排气排便、恶心呕吐等症状[1][2]。POI在腹部手术后发生率较高,可达10%~30% [3],不仅延长住院时间[4],还增加医疗负担[5]。作为外科临床实践里的关键问题,在当下加速康复外科(Enhanced recovery after surgery, ERAS)理念越来越普及的背景下,术后胃肠功能恢复已成为全球范围内重点关注的领域。有效防治POI对改善患者预后、合理利用医疗资源非常重要。近年来,各种POI防治措施的研究层出不穷[6]-[8],目的就是促进POI早期恢复,同时改善临床结局和医疗效率。评估这些措施并将其应用于临床实践是下一步工作重点。但现有的随机对照试验(Randomized controlled trial, RCT)在评估POI和胃肠功能恢复时,面临方法学挑战[9]。最突出的问题就是结局测量异质性,包括指标选择、定义标准、测量时间、测量工具以及评价方法不一致。这些问题普遍存在于结直肠、胃癌等术后,甚至小肠梗阻中也同样存在[10][11]。因为缺乏统一的框架来描述新干预措施在临床研究中的有效性[12],导致Meta分析偏差增大、证据合成困难,并阻碍临床决策和指南制定。

解决这一问题的方法是制定一个公认的核心治疗效果标准,即核心结局集(Core outcome set, COS),它的开发已是国际上解决研究异质性的主流趋势。有效性试验核心结局指标(Core outcome measures in effectiveness trials, COMET)倡议专门推动特定疾病的COS建立,提高RCT价值和Meta分析质量[13]。目前国际上针对肠道手术POI和小肠梗阻的胃肠恢复,已有初步COS探讨[11][14],大多用德尔菲(Delphi)共识法综合患者、医生和研究者等多方视角。不过中文文献里对这类方法学问题的关注较少。本综述通过回顾现有研究中POI与胃肠功能恢复结局测量指标的异质性现状,分析原因,并探讨共识构建的前景,

为未来临床研究和本土标准化提供参考。

2. POI 结局指标异质性分析

2.1. POI 的定义演变

早期文献多关注临床表现,简单定义 POI 为术后无排气或排便的时间[15]。后来研究指出,这忽略了生理恢复过程的个体差异,且预测实际恢复和出院时机的价值不大,于是开始加入耐受口服饮食等功能指标[16]。但至今无统一标准,一项全球调查显示[1],不同研究用的症状组合、影像学标准和时间阈值差异很大。

2.2. 常用结局指标分类定义

2.2.1. 二元结局

主要是 POI (包括“正常”POI、延长性 POI、复发性 POI)发生率为,通常定义为术后某段时间内出现症状的患者比例。但这个“某段时间”差异很大,从术后 1 到 7 天不等[1]。

2.2.2. 时间相关结局

最常用、最直接的临床指标是首次排气和首次排便时间[17],广泛用于胃癌、结直肠、妇科及胸科等多种术后恢复评估[10][18]-[20]。这些指标测量依赖患者主观报告,易有回忆偏倚和报告标准不统一的问题。此外,不同研究对“首次”的定义(如患者感知到的具体时刻)不一致,且询问频率(如每小时记录或每日询问)不同。

耐受经口饮食时间是评估患者上消化道恢复的关键指标[21]。ERAS 核心目标之一就是促进早期经口进食。包括 ERAS 方案在内的很多研究以腹部术后患者耐受经口饮食时间来评估胃肠功能恢复[22][23]。但不同研究或临床实践中对“耐受”的定义(如食物性质、摄入量、持续时间、伴随症状的严重程度)不同。此外,医生的临床决策、患者的饮食习惯和心理因素以及术后管理方案都可能影响开始进食的时机和耐受性,降低了不同研究间可比性。

肠鸣音恢复时间是反映肠道蠕动功能开始的早期体征。传统上通过腹部听诊评估,但其主观性强,且听诊时刻、频率和持续时间缺乏标准化。近年来有研究尝试开发实时分析系统以实现定量评估[24][25],但肠鸣音恢复与后续排气、排便等功能恢复相关性并非绝对,其作为独立预测指标的临床价值存在争议[26][27]。

2.2.3. 复合终点指标

复合指标结合多个单一事件来定义胃肠功能恢复,如 GI-2 (耐受固体饮食并排便)和 GI-3 (进食固体食物并排便/排气)[16][28]。一个患者可能排气较早但排便延迟,复合指标减少这种误判,可更好捕捉胃肠功能恢复这一多维概念[29][30]。其局限性在于:(1) 不同研究可能采用不同的元素组合(如“排气 + 饮食 + 排便”或“排气 + 排便”)[31],且单一指标异质性带到复合指标中,增大变异;(2) 复合指标可能掩盖各组成元素恢复的不同步性,不利于深入分析影响特定功能的病理机制或干预措施的特异效应[17];(3) 复合指标事件发生率可能低于单一元素,增加样本量需求、研究成本与实施难度[30][32]。

2.2.4. 患者报告结局(Patient-Reported Outcomes, PROs)

PROs 从患者角度评估症状体验,对于全面理解术后恢复至关重要[33]。常用如视觉模拟量表 VAS、数字评分量表 NRS 等量化腹胀、呕吐等症状[34];生活质量问卷(如 SF-36)和术后恢复质量评分(QoR)也是衡量术后恢复所用方法[35][36]。一些研究使用胃肠症状评分(GIS)或患者评估的便秘症状量表(PAC-

SYM)来评估术后胃肠道功能障碍严重程度[37]。PROs 存在量表、评估时点、回忆期(如过去 24 小时或即时感受)不统一等问题[38], 且症状感知受文化、耐受度和期望等主观因素影响。此外, 现有工具多借鉴自其他疾病, 缺乏广泛验证的专用术后 PROs 工具。

2.2.5. 其他辅助结局

主要包括腹部 X 线平片(观察肠腔积气、液气平面分布和肠管扩张程度), 腹部 CT (更精确评估肠壁水肿、肠管直径、气体分布模式及排除机械性梗阻); 近年来, 床旁超声肠道动力学监测逐渐兴起[27], 具有无辐射、实时、可重复的优势, 但大规模验证仍有限。影像学指标客观性较强, 但其评估多用于诊断而非动态恢复监测, 作为结局指标的敏感性和特异性有限; 此外, 辐射暴露、检查时机、设备差异和解读主观性也限制了其在多中心研究中的标准化应用。

一些研究探索了炎症或肠屏障标志物在预测 POI 发生和恢复不良中的作用[39] [40], 但多停留在探索层面, 其临床转化价值和结局测量标准化仍需进一步验证。

2.2.6. 临床与经济相关指标

术后住院时间(LOS):反映恢复速度、并发症及医疗资源消耗的重要指标[4] [5]。大量疗效评价研究均纳入 LOS [6]。然而, 除了出院标准不一致, 出院还受到诸多非医疗因素(如医院政策、医保支付、家庭支持、自我认知等)影响。例如, 不同保险类型患者在达到医疗准许出院后, 实际出院延迟时间存在显著差异[41]。因此, 尽管 LOS 易于测量, 但其作为直接替代指标效度有限, 需谨慎解读。

鼻胃管重置率与 POI 再入院率:反映恢复失败的硬终点指标。例如, 有研究表明早期口服营养可改善 POI 但会增加呕吐和鼻胃管再置入风险[21] [42]。出院后肠梗阻是腹部手术后常见的再入院原因, 给医疗系统带来沉重负担[43] [44]。然而, 这些事件的发生率相对较低, 需要大样本才能检测出差异[42]。此外, 各项事件定义标准和记录依赖于医疗编码的准确性, 可能存在漏报或误报[1] [45]。尽管如此, 作为患者安全和服务质量的重要指标, 它们在评估干预措施对严重不良结局的影响方面具有不可替代的价值。

2.2.7. 结构化评分

美国 ERAS 协会与围术期质量倡议联合提出的 I-FEED 评分系统[46], 已被部分国际研究采用[47] [48], 具有符合 2022 年 POI 研究 COS 中“使用经过验证的工具衡量胃肠道恢复情况”要求的潜力。但不同研究对各部分权重和记录频率存在差异, 且在中国和亚洲人群验证较少, 其评分阈值和临床决策切点的适用性需进一步本土化验证。

3. 异质性的根源与影响分析

3.1. 病理生理机制复杂与定义不统一

POI 是术后胃肠功能恢复核心不良事件, 但它的病理生理机制复杂、多变, 很多因素还不清楚[2] [7] [49]。临床表现从轻微肠动力减弱到严重肠梗阻都有, 很难定出一个单一、客观的诊断标准[16]。定义不统一直接放大了结局指标的异质性, 因为“恢复”的起点和终点因定义而异, 这是异质性最根本的原因。

3.2. 手术类型对功能恢复的影响差异

不同手术对胃肠功能的干扰和恢复模式本来就差别很大。胃肠道手术直接涉及肠道解剖和功能, POI 发生率高[3], 评估多看排气/排便和进食情况; 非腹部手术(如胸腔镜肺切除或脊柱融合)不直接操作肠道, 麻醉、疼痛和体位等因素间接诱发胃肠抑制, POI 率低, 指标更侧重症状评分或住院天数[20] [37]。此外, ERAS 协议的加入可能会增加不确定性, 一项网络 Meta 分析显示, ERAS 应用在结直肠手术中缩短住院时间的效果优于胸科手术[50]。

3.3. 研究方法学差异

方法学差异是结局指标异质性最直接来源，主要体现在结局选择、测量时点、数据收集方式以及盲法实施等多个环节的不一致。不同利益相关方关注的重点不同，患者更关注症状缓解，临床医生往往优先考虑住院时间和资源利用效率，而研究者倾向于选择易量化和统计的指标。即使相同结局指标，其定义和计算方式也常变化，例如，不同研究以连续变量或分类变量报告 GI-3 [28] [51]。测量时点缺乏标准，记录从手术结束还是麻醉醒来，每小时记录或每日评估甚至仅在出院时回顾询问[19] [22]，导致数据精确度不同。数据收集依赖患者报告或医护记录，易受回忆偏倚和不完整影响，尤其在忙碌临床环境中。此外，盲法困难加剧偏倚：如电针、穴位按摩等干预难以实施盲法，可能产生期望偏差[18]。最后，RCT 和回顾性研究对终点敏感度要求不同，使得变异存在不同研究设计之间[6]。方法学问题在低质量研究中更突出，干扰证据质量和合成。

3.4. 对循证医学实践的影响

结局指标异质性严重阻碍循证医学实践。我们之前的一项伞状评价综述发现[6]，POI 干预 Meta 分析的局限主要源于结局变异，限制可靠效应估计，从而干扰证据合成，产生高异质性和不确定结论。同时，临床决策支持系统算法因数据非标准化而效率低下[52]，制约决策支持和指南制定，最终延缓临床转化和患者获益。

4. COS 构建理论基础

4.1. COS 的概念、价值与 COMET 倡议

COS 是临床试验里推荐必须测量的最小标准结局指标集[13]，目的是减少选择性报告偏倚，让不同研究更容易比较，浪费资源减少，也让证据更能真正指导临床和政策指定[53]。国际 COMET 倡议专门推动其研发、传播与应用，建立数据库并提供开发指导[54]。

4.2. COS 开发流程

4.2.1. 系统评价确定现有指标范围

系统评价把现有研究报告过的所有结局指标都梳理一遍，列出完整清单，看清研究全貌、异质性和空白。例如开发孕期营养 COS 时，研究者回顾了大量文献，最终从数百篇文章中提取了相关结局，为后续共识形成奠定了坚实的基础[55]。这一步不仅收集研究较多的结局，还可能识别重要但未充分测量的领域，确保 COS 基于全面证据，增强内容有效性和针对性。

4.2.2. 利益相关者参与

要让 COS 真有用、大家接受，关键在于纳入多元化的利益相关者视角，包括患者、临床医生、研究者等。例如，在儿科重症监护 COS 的开发中，家庭作为关键的利益相关方参与其中，他们的意见直接影响了最终核心域和具体结局的确定[56]。有效参与应贯穿各个阶段，确保最终结果代表各方关注的问题，具有广泛实用性。

4.2.3. 共识形成

生成长列表后，需通过结构化共识方法筛选核心结局。最常见的是改良 Delphi 法，通常两三轮，让大家匿名给每个结局的重要性评分，每轮汇总反馈给下一轮，意见慢慢集中。例如，在腓总神经病变 COS 开发中，研究者通过多轮 Delphi 调查，最终就 31 个结局达成了共识[57]。最终常召开面对面共识会议，各方代表讨论、投票，敲定最终列表。

4.2.4. 测量工具选择与验证

确定核心结局后, 需为每个结局选择或制定适当的、经过验证的测量工具, 形成核心结局测量集。选择工具应遵循科学标准, 如参考“健康测量工具选择共识标准”COSMIN 指南, 评估工具的信度、效度、反应度及适用性[58]。例如, 在气道管理研究中, 研究者对 11 个结局确定了标准一致的定义和测量工具[59]。特别是 PROs, 需确保工具能准确捕捉患者体验和感受[60]。此步骤是 COS 能否成功实施的关键, 直接影响不同研究数据的可比性与可合并性。

5. 术后胃肠功能恢复 COS 的探索与实践进展

5.1. 现有相关 COS 研究概述

POI 专用 COS 开发尚处于早期阶段, 但已取得标志性进展, 2022 年国际合作组发表了首个肠道术后 POI 临床研究 COS [14], 最终确定了 24 个核心结局, 强调客观临床测量与患者主观体验的平衡。但该 COS 仅定义了“测量什么”, 未提供“如何测量”的具体工具或统一定义, 仍需进一步工作。此前, Chapman 等(2020)发表的协议奠定了基础, 计划同时构建 POI 和小肠梗阻的胃肠恢复 COS [11]。这些工作表明国际研究正从指标异质性讨论转向标准化实践, 但现有 COS 开发往往缺乏标准化, 测量工具变异大, 仍旧影响 Meta 分析[61]。

结直肠手术是 POI 高发领域, 对 COS 的需求最为迫切。一项针对腹腔镜结直肠手术 ERAS 结局报告图谱研究显示[62], 57 项 RCT 中报告了 86 个独特结局, 胃肠恢复指标报告率最高(25.6%), 结果定义和测量工具差异很大, 没有统一的标准, 异质性极大。目前尚未有独立的结直肠手术恢复 COS, 国际研究为开发专门针对该子领域的定制 COS 奠定基础。

目前中国尚无公开发表的 POI 或胃肠功能恢复专用 COS。临床实践主要依赖 ERAS 指南和专家共识[63]-[65], 缺乏 Delphi 共识过程和患者公众参与, 指标选择仍以专家经验为主, 异质性问题突出。中国临床试验中, 资源、文化和中西医结合等因素使得结局测量往往受限, 直接应用国际 POI COS 确定的结局可能降低可比性和实用性[61][66]。其中大多数指标, 如 POI 发生率及持续时间、呕吐、排气排便、营养支持、鼻胃管放置、吻合口漏、腹腔感染、腹膜炎、肠切开等事件类指标通用且易测量, 因为它们基于客观临床症状或事件记录, 与中国 ERAS 指南高度兼容, 但存在定义阈值不同(如延长性 POI 起点); 记录频率标准化问题受到护理模式及家庭支持影响, 如每日或每小时评估呕吐持续时间; 营养耐受定义有中西差异, 中国偏好早期口服半流质饮食过渡到固体饮食, 西方多强调耐受以固体饮食[16], 这也使得将口服营养耐受纳入 POI 诊断产生差异。少数指标不是特别适用或有测量挑战, 例如入住 ICU、鼻胃管引出量和器官损伤/衰竭, 受公立医院资源有限(ICU 床位紧缺、设备不标准化、监测工具不足)影响, 可能难以精确测量, 导致实际应用受限; 患者报告类指标(如腹痛严重度、肠麻痹感知、恶心等)虽可测量, 但文化因素如中国人更隐忍症状导致低估[67], 另外, 中国患者对医疗服务的整体期望值较低, 一些国际评分问卷可能不敏感, 且不能量化一些中医特异性指标的评估, 需中文版跨文化工具整合中医概念[68], 否则不准确; 基于胃肠功能的出院准备情况、再入院等通用, 但不完全适用, 因为受非医疗因素影响(如出院后随访、医保政策和医院床位周转会干扰住院时间等资源指标的准确性) [41] [44], 导致漏报率高或与本土 ERAS 指标冲突。总体上, 没有绝对无法测量的指标, 但定义差异、测量工具本土化需求及中西医整合挑战突出, 强调开发本土化 COS 的必要性。

5.2. 本土化 COS 构建思考

整合 ERAS 理念: ERAS 方案通过优化围手术期措施减少手术应激、加速康复, 已成为现代胃肠外科标准实践。其核心理念是减少并发症, 因此术后并发症仍是核心评价内容。国际 ERAS 学会结直肠手

术围手术期护理指南推荐纳入 POI 发生率、I-FEED 评分、营养耐受时间等指标[69]。同时, ERAS 强调以患者为中心的快速恢复, 评价体系正向更全面、动态的恢复过程指标扩展, 如早期胃肠功能恢复、术后首次下床活动时间和住院时间等反映整体康复速度的指标[70]。国际趋势是将 POI COS 与 ERAS 框架结合, 因此, 在构建整合 ERAS 理念的 COS 时, 必须包含能够灵敏反映加速康复过程的指标, 同时兼顾安全性和以患者为中心的终点。针对 POI, 开发兼容中医干预的复合指标, 例如将耐受固体饮食并排便与针灸后特异性指标(穴位刺激后肠鸣音恢复时间)整合, 通过多中心 RCT 验证兼容性, 解决中医中药对肠动力影响的量化问题。

将患者自我感知纳入评估框架: ERAS 的成功不仅体现在客观指标的改善, 更在于提升患者的整体康复体验和生活质量。研究发现, 胃肠道动力恢复当天与患者自主性评分的改善密切相关[71], 提示将 PROs 纳入术后评估至关重要。一项研究认为 PROs 应作为质量指标之一与生存终点一起, 以提供有价值的、高度全面的癌症护理[72]。外科患者在 ERAS 路径下的恢复体验涉及身体、心理、社会好几个层面[73], 一般临床指标往往抓不住手术对患者心理、社会功能和自我健康感受的影响。这点在中国的研究里尤其明显[74], 本土 COS 必须将经过验证的 PROs 工具标准化纳入, 才能真正做到以患者价值为导向的外科康复评价。如针对中西医结合干预 POI 研究, 评价工具中要加入中医综合征结果, 如评估腹胀、气滞等, 与国际指标并行测量, Delphi 共识过程要有中医专家参与, 最终的 COS 将包括通用的 POI COS 和核心中医综合征集, 解决中医药干预下的特异性指标与国际通用指标的兼容问题[75]。

跨文化、跨医疗体系普适性: 患者对结局的看法和优先级有明显的文化差异。研究发现, 中低收入国家因为资源有限, 更注重可及性和实用性, 而高收入国家则强调标准化和 PROs 的深度整合[66]。对于 POI 和胃肠功能恢复, 中国患者可能更调整体和谐、家庭支持及中西医结合干预的价值, 而西方患者更关注个体自主和功能独立[67]。将国际共识本土化是 COS 在中国临床实践中成功应用的前提, 因此, 需针对中国患者、家属及医护人员做调研, 了解它们的独特偏好、价值认知及术后恢复期望[68], 通过系统跨文化研究, 纳入多方利益相关者, 确保 COS 文化敏感性, 同时保留客观性核心指标, 避免文化偏见漏掉重要结局[76]。这种本土化探索能为调整和补充国际 COS 提供关键依据, 确保最终形成的 COS 既与国际接轨, 又真正符合中国患者的实际。

6. 推动共识构建的未来策略

6.1. 与专业学会、期刊及指南制定机构合作

促进 COS 广泛采纳与实施的有效路径是与主要利益相关方建立合作。跟相关专业学会联手, 通过学术会议和指南推广 COS, 影响临床研究实践; 例如, 几个国际学会联合发布的远程访问甲状腺手术的一致声明, 为标准临床实践提供了框架[77]。其次, 核心期刊在该类文章投稿须知中可加入 COS 报告规范, 从根本上规范研究设计[78]。最后, 与临床实践指南制定机构合作, 将 COS 纳入指南推荐的结局评估框架, 能够让它在临床决策和医疗质量评估中得到系统性应用。这种多渠道合作能从研究到实践全程推动, 加速 COS 真正用起来。

6.2. 开展基于 COS 的临床试验示范研究

光有理论共识不够, 得实践验证。做高质量、严格按 COS 统一工具和指标的示范性临床试验, 是证明价值、带动大家采纳的最好方式。这类研究发表出来, 能给出高级别证据, 也能清楚展示用 COS 后研究结果更聚焦、更可比, 对患者、医生以及研究者都更有意义。此外, 还可探索亚组(如专门针对结肠直肠手术)适用性, 反过来验证和优化 COS。示范研究一旦成功, 会带动后续跟进, 在领域内形成使用 COS 的新常态。

7. 结论

术后肠麻痹和胃肠功能恢复评价指标的异质性是当前临床研究的普遍问题，主要源于定义模糊、测量工具不一、评估时间点差异等多种因素，严重干扰证据合成和临床转化。构建核心结局集是解决这些问题的有效方法，未来研究应遵循 COMET 倡议，融入 ERAS 理念，推动包括患者感知和体验的 COS 开发与验证。另外，一定重视本土化调整，结合中国患者特点、医疗资源和诊疗习惯，形成共识性 COS。通过专业学会、期刊报告规范和政策引导，促进 COS 强制使用与定期更新，才能规范评估标准，提升研究质量和可比性，让外科患者真正获益。

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