

论著·循证医学

预康复对胃肠道择期手术患者术后恢复效果的系统评价

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[摘要] **目的**·系统评价预康复对择期行胃肠道手术患者术后恢复的影响。**方法**·系统检索PubMed、EMbase、Cochrane Library、Web of Science、CINAHL、中国生物医学文献数据库 (CBM)、中国知网、万方、维普数据库, 检索时限均为建库至2022年1月31日。按照预先设定的标准筛选文献, 对文献质量进行评价并提取资料, 对纳入的随机对照试验采用RevMan 5.4进行meta分析。主要观察指标为术后总体并发症发生率和手术部位感染发生率, 次要观察指标为住院天数、6 min步行试验 (6-minute walk test, 6MWT)、医院焦虑抑郁量表 (Hospital Anxiety and Depression Scale, HADS) 评分, 以及死亡率和预康复执行的依从性。**结果**·共纳入16篇文献, 其中英文15篇, 中文1篇, 共1 616例研究对象, 纳入研究的总体质量较好。Meta分析结果显示, 相较于对照组, 实施了预康复的试验组患者术后总体并发症的发生率降低 [比值比 (odds ratio, OR)=0.57, 95%置信区间 (confidence interval, CI) 0.35~0.94, $P=0.030$], 手术部位感染发生率降低 ($OR=0.64$, 95%CI 0.46~0.90, $P=0.009$), 住院天数缩短 [均数差值 (mean difference, MD)=-2.45, 95%CI -3.17~-1.73, $P=0.000$]。2组患者术前6MWT水平的差异无统计学意义; 试验组术前6MWT水平相较于基线的提升程度优于对照组 ($MD=24.19$, 95%CI 3.77~44.60, $P=0.020$)。2组患者术前HADS评分和术后死亡率差异均无统计学意义。**结论**·预康复有利于降低胃肠道择期手术患者术后总体并发症发生率, 尤其是手术部位感染发生率, 从而缩短住院天数, 有利于患者康复。

[关键词] 胃肠道手术; 预康复; 术后恢复; 系统评价; meta分析

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Effect of prehabilitation on outcomes in patients undergoing elective gastrointestinal surgery: a systematic review

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[Abstract] **Objective**·To systematically evaluate the effect of prehabilitation on outcomes in patients undergoing elective gastrointestinal surgery. **Methods**·PubMed, EMbase, Cochrane Library, Web of Science, CINAHL, Chinese BioMedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), Wanfang and VIP Database were searched systematically from the establishment of each database to January 31, 2022. The literatures were screened, and evaluated according to the preset inclusion and exclusion criteria. The literature quality was evaluated and the data were extracted. Meta-analysis was performed on randomized controlled trials by using RevMan 5.4. The main observation indexes were the postoperative complication rate and the incidence of surgical site infection. The secondary indexes were hospitalization days, 6-minute walk test (6MWT), Hospital Anxiety and Depression Scale (HADS) score, mortality and compliance of prehabilitation execution. **Results**·Sixteen articles were included, including 15 articles in English and 1 article in Chinese, with a total of 1 616 patients. The overall quality of the included researches was good. The meta-analysis results showed that compared with the control group, the incidences of postoperative complications and surgical site infection were reduced [(odds ratio, OR)=0.57, 95% (confidence interval, CI) 0.35~0.94, $P=0.030$; $OR=0.64$, 95%CI 0.46~0.90, $P=0.009$]; the length of hospital stay was shortened [mean difference (MD)=-2.45, 95%CI -3.17~-1.73, $P=0.000$] in the experimental group after the implementation of prehabilitation. There was no significant difference in preoperative 6MWT level between the two groups. Compared with the baseline, the change of 6MWT level before operation of the experimental group was bigger than that of the

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control group ($MD=24.19$, $95\%CI$ 3.77–44.60, $P=0.020$). There were no significant differences in the preoperative HADS score and the postoperative mortality between the two groups. **Conclusion** Prehabilitation can reduce the incidence of postoperative complications, especially surgical site infection, in patients undergoing elective gastrointestinal surgery, thus shortening the length of hospital stay and promoting the recovery of patients.

[Key words] gastrointestinal surgery; prehabilitation; postoperative recovery; systematic review; meta-analysis

外科手术是大多数胃肠道肿瘤患者首选的治疗手段,但手术不可避免地给患者带来巨大的应激反应,包含生理(心跳加快、呼吸急促等)和心理(紧张、焦虑、易怒等)2个方面。围术期应激反应不利于患者的术后康复,甚至会导致术后并发症的发生,从而延长住院时间,增加医疗成本^[1-3]。因此,加速康复外科(enhanced recovery after surgery, ERAS)理念下围术期护理优化的重点在于减轻手术应激反应,改善患者术后的活动能力和营养状态^[4]。“预康复(prehabilitation)”的概念由ERAS延伸而来,指的是在择期手术前增强个体功能的过程,目的是提高机体面对大手术应激反应的耐受性,并试图在改善术后结局方面发挥作用^[5]。预康复的组成内容各不相同,一般包括运动锻炼、营养支持或心理干预3个部分^[6]。近年来,胃肠道手术预康复成为新的研究热点,已发表的研究包括多种不同的预康复方案和效果评价。随着新证据的出现,预康复对胃肠道手术术后结局的影响尚不明确^[7-8]。本研究旨在评价预康复的实施对胃肠道择期手术患者术后恢复的影响,以期对胃肠道手术患者的预康复临床实践提供循证依据。

1 资料与方法

本研究已在PROSPERO数据库注册,注册号为CRD42021288139。

1.1 文献纳入与排除标准

1.1.1 纳入标准 ①研究类型为随机对照试验(randomized controlled trial, RCT)。②研究对象为初次行择期胃肠道手术的成年患者。③干预措施:试验组包括单独或者联合多种方式(多模式)实施术前预康复策略;对照组包括标准术前护理、给予安慰剂、仅术后康复、术前准备指导以及围术期常规护理(例如戒烟、戒酒等);2组术后执行一致的康复方案。④主要结局指标:术后总体并发症的发生率(采用Clavien-Dindo外科手术并发症分级系统^[9]对术后的

并发症进行定义和分级)、胃肠术后常见并发症手术部位感染(surgical site infection, SSI)发生率;次要结局指标:住院天数、6 min步行试验(6-minute walk test, 6MWT)、医院焦虑抑郁量表(Hospital Anxiety and Depression Scale, HADS)评分,以及死亡率和预康复执行的依从性。

1.1.2 排除标准 ①无法获取全文。②重复发表。③缺失重要数据。

1.2 检索策略

系统检索PubMed、EMbase、Cochrane Library、Web of Science、中国生物医学文献数据库(CBM)、CINAHL、中国知网(CNKI)、万方、维普(VIP)数据库,检索时限均为建库至2022年1月31日,检索采用主题词与自由词结合的方式。英文检索词为“gastric cancer/gastric carcinoma/gastric tumor*/colorectal cancer/colorectal tumor*/colorectal carcinoma/gastrointestinal neoplasms/stomach neoplasms/gastroenteric tumor*/gastrointestinal surgery”“prehabilitation/preoperative optimization/preoperative care/surgical preparation/preoperative exercise/perioperative rehabilitation/perioperative nutrition”“randomized/RCT”,中文检索词为“胃癌/结直肠癌/胃肠道癌症/胃肠道肿瘤/胃肠道手术”“预康复/围术期康复/术前锻炼/术前快速康复/围术期营养/术前优化”,并通过滚雪球的方式追加符合纳入标准的文献。

1.3 文献质量评价和资料提取

2名接受过循证方法学培训的研究者(本文第二和第三作者)独立检索各数据库并根据纳入和排除标准完成文献的筛选和质量评价,如有分歧则请第三方定夺。文献的质量评价使用Cochrane协作网对RCT的真实性评价工具(2011),将文献质量分为A级(完全满足标准,发生各种偏倚的可能性小)、B级(部分满足标准,发生各种偏倚的可能性中等)、C级(完全不满足标准,发生各种偏倚的可能性高)^[10]。2

名研究者采用统一的标准独立进行纳入文献的资料提取, 完成后将2人的结果进行比对, 如有分歧或者遗漏则请第三方协助解决。文献资料提取包括第一作者、发表年份、研究对象、样本量、干预措施、结局指标等。

1.4 统计学分析

使用 RevMan 5.4 软件进行 meta 分析。当不同研究之间的临床异质性不明显时 ($P>0.1$, $I^2<50\%$) 选择固定效应模型进行分析, 反之 ($P\leq 0.1$, $I^2\geq 50\%$) 则需要分析异质性的来源后选择随机效应模型进行分析。二分类变量资料采用比值比 (odds ratio, OR) 作为效应量, 连续性变量资料采用均数差值 (mean

difference, MD) 作为效应量, 计算 95% 置信区间 (confidence interval, CI), $P<0.05$ 为差异有统计学意义。定性资料采用描述性分析。

2 结果

2.1 文献筛选流程

初检共获得 1 512 篇文献, 经筛选 (图 1) 后, 最终纳入 16 篇文献, 其中英文文献 15 篇, 中文文献 1 篇。

2.2 纳入研究的基本信息

16 个研究^[11-26] 的基本信息如表 1 所示, 共纳入 1 616 例研究对象。

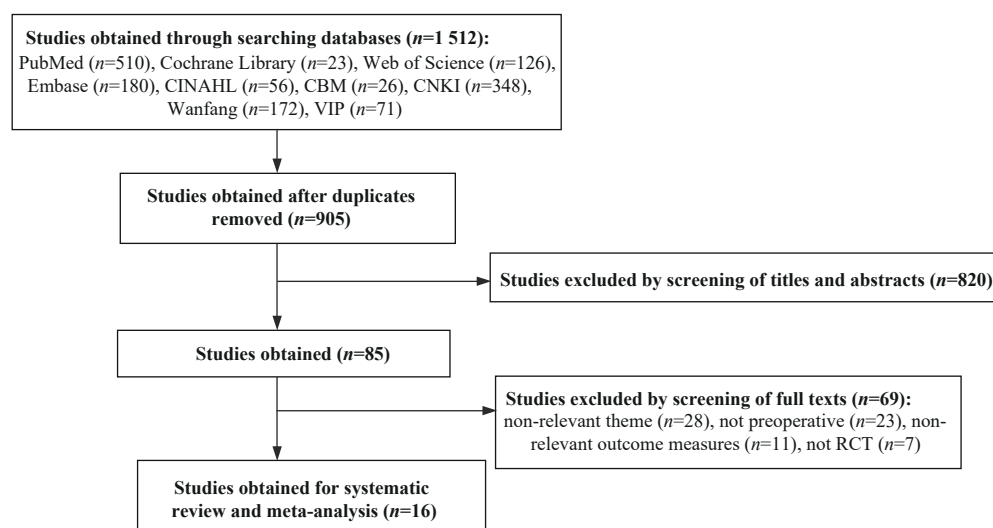


图 1 文献筛选流程图

Fig 1 Flowchart of the study screening

表 1 纳入研究的基本信息

Tab 1 Basic information of the selected studies

Study	Population	Sample size (I/C)	Intervention method	Control method	Follow-up	Outcome
LÓPEZ-RODRÍGUEZ-ARIAS, 2021 ^[11]	Adults, elective surgery for colon or rectal neoplasm	10/10	A 30-d trimodal prehabilitation program with recommendations on physical exercise, nutritional supplementation, and relaxation exercises to be performed at home before surgery and the first 30 d after hospital discharge	Standard care	12 weeks postoperative	①②⑥
BARBERAN-GARCIA, 2018 ^[12]	Adults, elective major abdominal surgery with high risk	62/63	A personalized prehabilitation program based on their health conditions and social circumstances which encompassed 3 major steps: motivational interview to assess the patients' adherence profile and to codesign the characteristics of the physical activity program with the patient; personalized program to promote daily physical activity; supervised high-intensity endurance exercise training program	Standard care	Before discharge	①②③④⑤⑥

Continued Tab

Study	Population	Sample size (I/C)	Intervention method	Control method	Follow- up	Outcome
BOUSQUET-DION, 2018 ^[13]	Adults, elective surgery for colon or rectal neoplasm	37/26	A 4-week multi-modal home-based exercise program with once-weekly supervision consisted of exercise intervention, nutritional intervention and anxiety-reduction strategies	Standard care	8 weeks postoperative	①②③ ④⑥⑦
OMMUNDSEN, 2018 ^[14]	>65 years, elective colorectal cancer surgery and fulfilling predefined criteria for frailty	53/63	A 3-week pragmatic tailored intervention based on the results of the geriatric assessment	Standard care	3 months postoperative	①②⑤ ⑥
BURDEN, 2017 ^[15]	Adults, elective colorectal cancer surgery with preoperative weight loss >1 kg per 3–6 months	55/45	Oral supplementation (10.1 KJ, 0.096 g of protein per mL) at a dose of 250 mL daily for a minimum of 5 d before the operation	Bottled water	30 days postoperative	①②⑥ ⑦
GILLIS, 2016 ^[16]	Adults, elective surgery for colon or rectal neoplasm	22/21	A whey protein supplement was provided in a quantity that matched the patient's need according to the estimated deficit in dietary protein intake for approximately 4 weeks leading up to the surgery	Placebo	4 weeks postoperative	③⑥
GILLIS, 2014 ^[17]	Adults, elective surgery for colon or rectal neoplasm	38/39	A 4-week trimodal prehabilitation program at home included exercise intervention, nutrition intervention, and coping strategies to reduce anxiety	Standard care	8 weeks postoperative	①③④ ⑥
FUJITANI, 2012 ^[18]	≤80 years, elective total gastrectomy, body weight loss of 10 percent or less within 6 months before entry	127/117	Preoperative oral supplementation of 1 000 mL/d in the form of an immunonutrient-enriched enteral feed added to normal diet for 5 d consecutively before the surgery	Normal diet	Before discharge	①②⑥
BURDEN, 2011 ^[19]	Adults, elective surgery for colon or rectal neoplasm	54/62	Oral supplementary drink of 400 mL daily, and dietary advice for 10 d before the operation	Dietary advice only	Before discharge	①②⑥
SMEDLEY, 2004 ^[20]	Adults, elective moderate to severe lower gastrointestinal surgery	48/50	Oral nutritional supplement in small, frequent quantities between meals for 7 d before the operation, the volume consumed was recorded	Normal diet	Before discharge	①②⑥ ⑦
GIANOTTI, 2002 ^[21]	Adults, major elective surgery for malignancy of the gastrointestinal tract	102/102	Oral nutritional supplement (1 000 mL/d) of a formula enriched with arginine, ω-3 fatty acids, and RNA for 5 d before the operation	Standard care	30 d after discharge	①②⑤ ⑥
BRAGA, 2002 ^[22]	Adults, elective surgery for gastrointestinal neoplasm, body weight loss of 10% or more within 6 months before entry	50/50	Oral nutritional supplement (1 000 mL/d) added to normal diet for 7 d consecutively before the surgery	Normal diet	30 d after discharge	①②⑤ ⑥
KABATA, 2015 ^[23]	Adults, elective, radical gastrointestinal and abdominal cancer surgery	54/48	Oral nutritional supplement (400 mL/d) added to normal diet for 14 d consecutively before the surgery	Normal diet	30 d postoperative	①⑤⑥
BARKER, 2013 ^[24]	Adults, elective upper and lower gastrointestinal surgery	46/49	Three packs of 237 mL of oral nutritional supplement per day for 5 d before the surgery	Standard care	30 d postoperative	①②⑤ ⑥
BERKEL, 2022 ^[25]	≥60 years, elective surgery for colon or rectal neoplasm	28/29	A personalized 3-week (3 sessions per week, 9 sessions in total) supervised exercise program	Standard care	90 d postoperative	①②⑥
HUANG, 2014 ^[26]	Adults, elective, radical gastrointestinal, cancer surgery	41/41	Oral nutritional supplement (25 mL/kg) for 7 d before the surgery	Normal diet	Before discharge	①②⑥

Note: I—Intervention group; C—Control group. ① the rate of postoperative complications; ② length of hospital stay (day); ③ 6MWT; ④ HADS; ⑤ mortality; ⑥ SSI; ⑦ compliance with the program.

2.3 纳入研究的质量评价

对纳入的文献进行质量评价,如图2所示,“+”表示满足标准,“-”表示未满足,“?”表示文献中未提及或者描述不清楚。纳入研究的总体质量较好,

6篇文献质量等级为A级。

2.4 Meta分析结果

2.4.1 术后并发症的发生率 4项研究^[13-14,17,25]使用





Note: "+"—up to the standard; "-"—failure to meet the standard; "?"—not mentioned or described clearly in the literature.

图2 纳入文献的风险偏倚

Fig 2 Risk bias of the included studies

Clavien-Dindo 系统对术后并发症进行了统计和分级, 研究合并效应量异质性较小 ($P=0.230$, $I^2=31\%$), 故选择固定效应模型进行 meta 分析; 结果 (图3) 显示, 试验组患者术后并发症的发生率低于对照组 ($OR=0.57$, $95\%CI$ 0.35~0.94, $P=0.030$)。对腹部手术后常见并发症 SSI 进行分析, 有 13 项研

究^[11-13, 15, 17-19, 21-26] 报告了术后 SSI 的发生率, 各项研究合并效应量异质性很小 ($P=0.630$, $I^2=0$), 选择固定效应模型进行 meta 分析; 结果 (图4) 显示, 试验组患者术后 SSI 的发生率低于对照组 ($OR=0.64$, $95\%CI$ 0.46~0.90, $P=0.009$)。

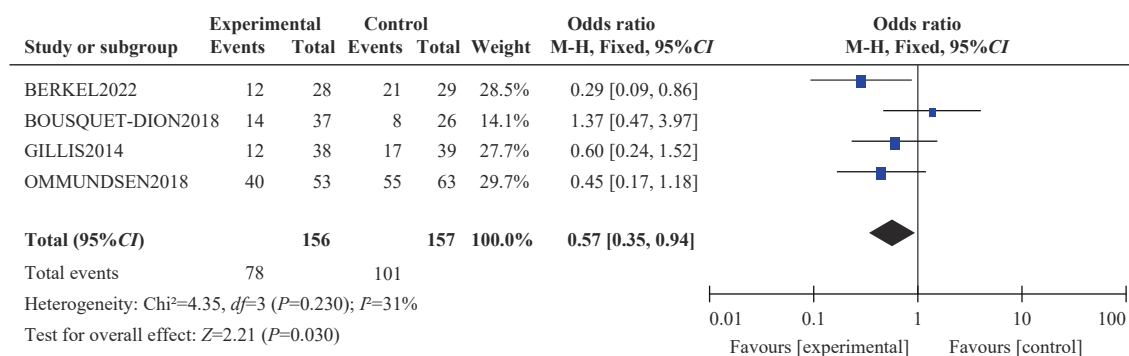


图3 预康复对术后总体并发症发生率影响的森林图

Fig 3 Forest plot: the effect of prehabilitation program on the incidence of postoperative complications

2.4.2 住院天数 8项研究^[11-12, 20-22, 24-26] 报告了住院天数, 研究合并效应量异质性很小 ($P=0.540$, $I^2=0$), 选择固定效应模型进行 meta 分析, 结果 (图5) 显示

试验组患者的住院天数少于对照组 ($MD=-2.45$, $95\%CI$ -3.17~-1.73, $P=0.000$)。

2.4.3 6MWT 共纳入4项研究^[12-13, 16-17], 6MWT 的

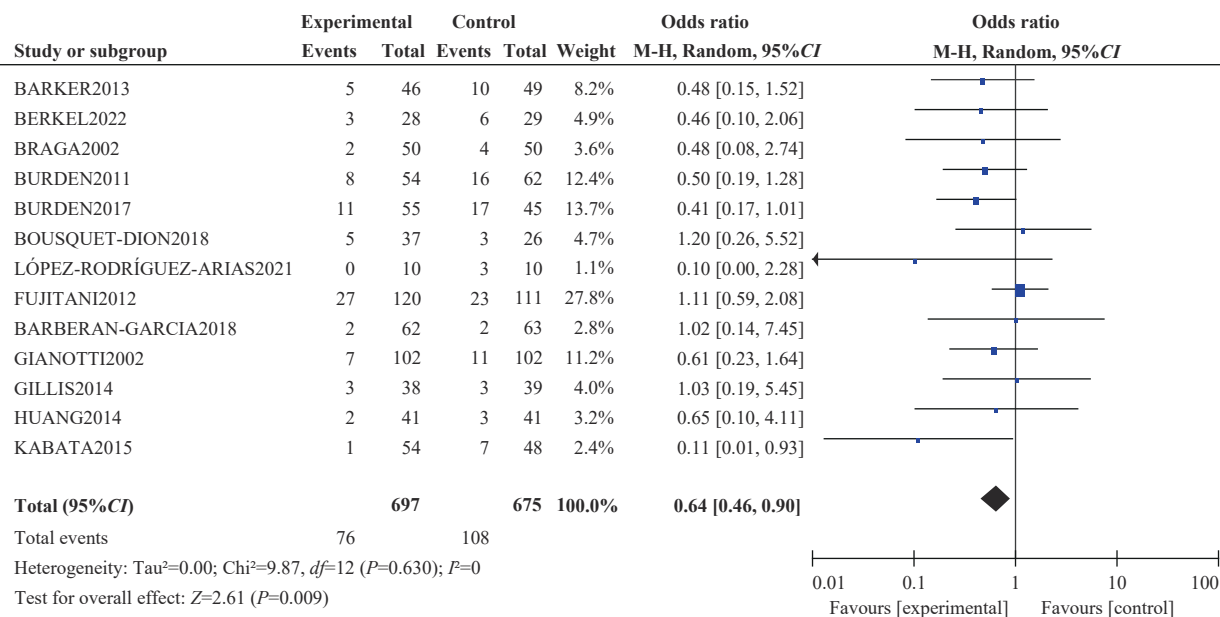


图4 预康复对术后SSI发生率影响的森林图

Fig 4 Forest plot: the effect of prehabilitation program on the incidence of surgical site infection

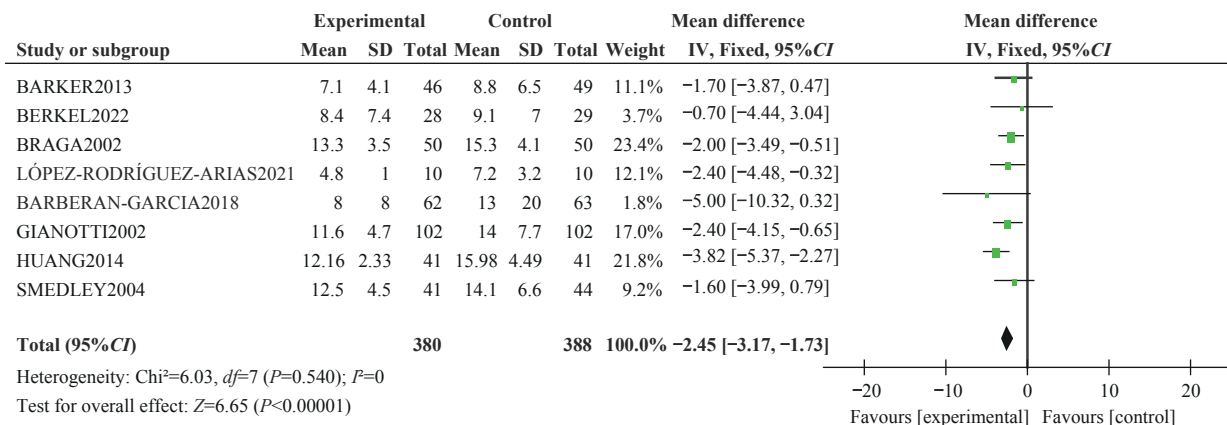


图5 预康复对住院天数影响的森林图

Fig 5 Forest plot: the effect of prehabilitation program on the length of hospital stay

报告分为术前6MWT的水平及术前6MWT较基线的变化,分别进行合并。2项研究^[12-13]报告了术前6MWT的水平,合并效应量异质性很小($P=0.880$, $I^2=0$),选择固定效应模型进行meta分析,结果显示2组差异无统计学意义($MD=2.46$, $95\%CI -28.73\sim 33.66$, $P=0.880$)。3项研究^[13,16-17]报告了术前6MWT较基线的变化,合并效应量异质性较大($P=0.110$, $I^2=55\%$),选择随机效应模型进行meta分析;结果(图6)显示试验组术前6MWT水平相较于基线有所提升,且提升的程度优于对照组($MD=24.19$, $95\%CI 3.77\sim 44.60$, $P=0.020$)。

2.4.4 术前HADS评分 共纳入2项研究^[12,17],合并效应量的异质性可接受($P=0.240$, $I^2=27\%$),选

择固定效应模型进行meta分析。结果显示2组术前HADS评分差异无统计学差异($MD=1.08$, $95\%CI -1.06\sim 3.22$, $P=0.320$)。

2.4.5 术后死亡率 6项研究^[12,14,21-24]报告了术后死亡率,其中3项^[14,23-24]为术后30d内的死亡率,合并效应量异质性很小($P=0.830$, $I^2=0$),选择固定效应模型进行分析,结果显示2组差异无统计学意义($OR=0.54$, $95\%CI 0.13\sim 2.18$, $P=0.380$)。2项^[21-22]为出院后30d内死亡率,合并效应量异质性很小($P=0.710$, $I^2=0$),选择固定效应模型进行meta分析,结果显示2组差异无统计学意义($OR=0.66$, $95\%CI 0.11\sim 4.03$, $P=0.650$)。仅1项研究^[12]为住院期间死亡率,无法进行合并。

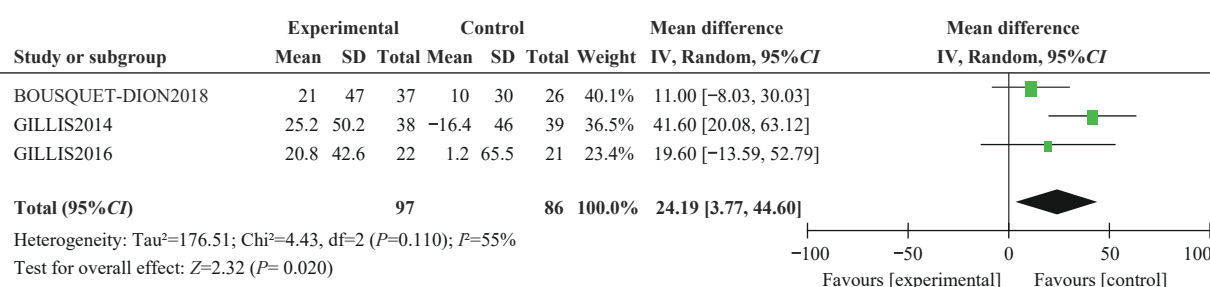


图6 预康复提升术前6MWT水平的森林图

Fig 6 Forest plot: the effect of prehabilitation program on the change of preoperative 6MWT

2.4.6 预康复方案执行的依从性 3项研究^[13,15,20]

报道了患者执行预康复方案的依从性情况,是使用日记本、手册等方式进行记录。由于测量工具和结果描述的方式不同,无法进行合并。此3项研究中的依从性均较好。

3 讨论

3.1 纳入研究的方法学质量评价

本研究共纳入16篇RCT,英文15篇、中文1篇。其中2篇详细描述了如何进行随机分组和分配隐藏,对研究对象、干预实施者和结局测评者均做到了盲法,记录了失访情况并对结果进行了意向性分析;有4篇文献由于干预措施的限制,无法对研究对象实施盲法,但是对干预者和结果测评者做到了设盲,不会对研究结果产生影响;因此,该6篇文献质量评价等级为A级。有9篇文献均做到了随机化,其中3篇没有对研究对象及干预实施者采取盲法;5篇没有做到分配隐藏,1篇没有对失访情况进行记录和分析,属于高风险偏倚。1篇中文文献没有描述随机分组和分配隐藏的方式,未对研究对象、干预者以及结果测评者设盲,存在高偏倚风险。总体而言,纳入研究的质量等级较好。

3.2 预康复有利于降低胃肠道手术后总体并发症发生率及SSI发生率

胃肠道手术患者,尤其是恶性肿瘤患者,营养不良的发生率很高^[27]。研究^[28-29]发现,术前营养状况与术后并发症的发生显著相关。SSI是腹部手术后常见的并发症之一,不仅会增加患者痛苦,降低生活质量,而且会增加切口疝、病死率等的风险^[30]。多项研究^[31-32]表明,合并营养不良和肌少症是结直肠术后发生SSI的危险因素。预康复策略中,术前的营养补充,

保障了患者每日热量和蛋白质的摄入,能够纠正患者的营养不良,并且为术后的高代谢状态提供能量储备,降低术后并发症的发生。与此同时,营养支持能够与术前的运动锻炼相互作用,为机体合成代谢提供底物,使得预康复的获益最大化。本研究结果显示,预康复能够降低胃肠道手术后总体并发症的发生率和SSI的发生率,这与加拿大学者GILLIS等^[33]2018年的研究结果一致。

3.3 预康复有利于增加胃肠道手术患者的功能储备,加快术后康复,从而缩短住院天数

围术期患者处于肌肉代谢的高分解状态。据报道,高达70%的结直肠癌患者存在不同程度的肌肉减少症^[34],而肌肉数量和质量的减少会增加炎症反应的风险,进一步导致并发症的发生^[35-36]。预康复的运动锻炼增加了患者的肌肉力量和有氧代谢能力,为患者提供了功能储备以应对术后肌肉萎缩,从而加快术后康复。6MWT是国内外公认的用来评价患者功能状态的方法,行走的距离越长,代表患者的功能状态越好^[37]。本研究纳入了3项研究,结果显示试验组术前6MWT与基线水平的差值更大,住院天数更短,表明预康复能够增加胃肠道手术患者术前的功能储备,有利于术后康复,从而缩短住院时间。这与英国学者MOUG等^[38]的一项随机对照研究结果相似。

3.4 其他方面

围术期焦虑等心理问题始终困扰着大多数患者,严重影响患者的生活质量。对手术以及死亡的恐惧、紧张甚至会改变患者对疾病和治疗的认知,降低依从性^[39-40]。心理干预常常作为多模式预康复的组成部分,旨在通过术前的心理干预缓解患者的焦虑和恐惧,减轻痛苦,从而更加积极地配合治疗和康复。本研究结果显示,预康复对胃肠道手术患者术前HADS

评分没有改善作用,这可能与本研究只涵盖了中英文文献,且纳入的2项研究样本量较少有关,未来需要更多研究来确定心理预康复的效果。在术后死亡率方面,由于纳入的研究数量少,死亡率的测量时间点不同等因素,均未显示出统计学意义。

3.5 局限性

本研究纳入的研究中,预康复的干预措施包含了单独的体育锻炼^[25],单独的营养补充^[15-16,18-24,26]和多模式的预康复计划^[11-14,17]等多种组成,且持续时间、依从性等也各不相同,使得本研究中干预措施的异质性较为显著。另一方面,主要结局指标之一的并发症发生率,也是本研究临床异质性的重要来源。尽管纳入meta分析的9项研究均使用Clavien-Dindo系统进行并发症的收集,但由于并发症种类繁多使得meta分析结果的可靠性受到限制。这也进一步提示研究者,未来需要进一步对预康复干预措施的组成、持续时间和结果测量等进行标准化探索,从而更为准确地评估预康复对胃肠道手术患者临床结局的影响。

3.6 小结

预康复对于促进胃肠道择期手术患者的术后恢复科学可行,能够改善患者的营养状态,增强功能储备,降低术后并发症的发生率,缩短住院时间。虽

然目前各项研究在预康复的适用对象、具体内容和方式、持续时间及结果测量等方面尚未统一,但基于更优化的ERAS理念而发展出的多模式预康复策略已成为围术期临床路径的新趋势。今后应进一步对预康复的最佳方案、科学评价指标及结局判断标准等展开研究,以更好地促进预康复的临床应用,加快患者康复。

利益冲突声明/Conflict of Interests

所有作者声明不存在利益冲突。

All authors disclose no relevant conflict of interests.

作者贡献/Authors' Contributions

章雅青、方芳负责研究设计;台瑞和余倩负责完成文献检索、质量评价和资料提取;方芳和台瑞负责完成meta分析;章雅青、方芳、台瑞、余倩参与论文写作和修改。所有作者均阅读并同意了最终稿件的提交。

The study was designed by ZHANG Yaqing and FANG Fang. TAI Rui and YU Qian completed the literature retrieval, literature quality evaluation and data extration. The meta-analysis was performed by FANG Fang and TAI Rui. The manuscript was drafted and revised by ZHANG Yaqing, FANG Fang, TAI Rui and YU Qian. All the authors have read the last version of paper and consented for submission.

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