

直肠癌新辅助治疗后采用观察与等待策略的患者报告的肠道功能： 一项病例对照研究

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摘要

背景: 对于新辅助治疗后达到临床完全缓解的局部晚期直肠癌患者, 观察与等待策略是保肛手术的非手术替代方案。接受这种器官保留方法的患者的肠道功能数据有限。

目的: 比较接受观察等待策略和保肛手术(全直肠系膜切除术)的直肠癌患者的肠道功能。

设计: 采用患者报告结果的回顾性病例对照研究。

设定: 综合癌症中心。

患者: 21名患者接受了观察等待策略, 根据年龄、性别和肿瘤距肛缘的距离, 与190名接受保肛手术患者中的21名患者进行了1:1配对。

主要结局指标: 使用Sloan-Kettering癌症纪念中心肠道功能量表测定肠道功能。

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结果: 观察等待组的肠道功能在总体评分（中位总分，76对55； $p<0.001$ ）和各子量表上均更高，其中子量表排便急迫/沾染衣物的差异最大（中位评分，20对12； $p<0.001$ ）。

局限: 回顾性设计、小样本、手术至问卷完成时间的差异。

结论: 使用经验证的综合性肠道功能障碍量表比较观察等待策略与保括约肌手术，等待观察策略与整体更好的肠道功能相关。视频摘要见

<http://links.lww.com/DCR/B218>。

关键词: 结直肠手术；患者报告结局；直肠癌；“观察与等待”策略。

前言

新辅助治疗（neoadjuvant therapy, NAT）和保括约肌全直肠系膜切除术（sphincter-preserving total mesorectal excision, SPTME）使局部晚期直肠癌患者获得了良好的局部控制和生存¹。然而，这两种方法的联合治疗与明显的肠道功能障碍有关，这可能会永久地影响患者的生活质量²。研究表明，经NAT和SPTME治疗后肛门直肠存在多种功能障碍^{3,4}，诸如肛门内括约肌功能障碍⁵、肛管感觉减退⁶、直肠肛管抑制反射缺失⁷、直肠存储的顺应性和容量降低⁸。

基于肿瘤预后相关的有利的回顾性数据，那些已经达到临床完全缓解的患者，即NAT后10%至40%的直肠癌患者在直肠内已无临床上可检测的肿瘤，可提倡采用以器官保留为目的的“观察与等待”

（watch-and-wait, WW）方案⁹⁻¹¹。除了那些令人鼓舞的肿瘤学结果外，人们对采用WW方法治疗的患者报告结局越来越感兴趣。直肠癌患者非常关心治疗后的功能预后和长期生活质量。这反映在Wrenn等人¹²最近发表的一篇文章中，该文章描述了肿瘤预后良好的患者最关心的事项包括避免造口及手术并发症。器官保留的替代方法可能有助于避免这些问题。

目前尚缺乏WW患者和SPTME患者肠道功能比较的数据。先前的研究发现¹³，根据LARS（低位前切除综合征）评分和EORTC-CR38评分^{14,15}，采用WW策略治疗的患者中有多达三分之一可出现肠道功能受损，而SPTME患者的大便失禁Vaizey评分显著升高¹⁶。然而，应该注意的是这些评分系统在对肠道功能的多维影响的综合评价方面可能受到限制。因此，我们的这一病例对照研究使用了更全面的问卷—纪念斯隆-凯特琳肠道功能问卷

（Memorial Sloan Kettering Bowel Function Instrument, MSK BFI），旨在比较这两组患者报告的肠道功能。

方法

患者选择

这项研究得到了纪念斯隆-凯特琳（MSK）癌症中心机构审查委员会的批准，并获得了知情同意的豁免。我们回顾性分析了2011年11月1日至2017年8月31日期间在MSK接受WW方案或SPTME治疗的直肠癌患者。我们排除了有大便失禁史、炎症性肠病、IV期疾病或资料缺失的患者。接受SPTME的患者如果接受了直肠扩大切除术（即超出标准TME平面

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的切除，包括切除邻近的盆腔器官、盆腔脏器切除术或盆壁侧方清扫术）、发生吻合口漏和/或盆腔脓肿，则被排除在外。

NAT包含：(i) 仅行放化疗，在5至6周的时间内共给予28次放疗，总剂量为5600 cGy，同时使用化疗药物（氟尿嘧啶或卡培他滨）增敏；或(ii) 全程新辅助治疗，包括8次的FOLFOX（叶酸、氟尿嘧啶和奥沙利铂）诱导化疗或16周的卡培他滨联合奥沙利铂化疗，然后给予放化疗，如之前的文献所描述¹⁷。

所有WW治疗组患者均为临床完全缓解，即根据MSK标准NAT后无临床可检测的原发肿瘤¹⁸：(i) 平坦的白色瘢痕伴毛细血管扩张，无溃疡或结节形成；(ii) MRI呈T2低信号，淋巴结未见；(iii) 弥散加权MRI未见肿瘤信号。在190例接受保留肛门括约肌手术患者中，根据年龄（<50岁、51-65岁和>65岁）、性别（男性和女性）和肿瘤距肛缘的距离（±5cm）等变量，按1:1配对确定了21例作为对照组。

通常在完成NAT后8至12周，根据外科医生的偏好采用标准的开腹或微创方法进行TME手术。根据肿瘤位置，采用手工缝合或双吻合器法完成结肠-直肠或结肠-肛管一期端端吻合。根据肿瘤位置、患者特点和外科医生的判断，可进行临时的转流性袢式回肠造口术。

MSK BFI

MSK BFI问卷专为评估直肠癌SPTME后肠道功能而设计¹⁹，是目前使用的此类量表中最为全面的²⁰。它由18个问题组成，让患者在4周的时间范围内进行回顾。问卷中将14个问题分为3个子量表，即饮食、

排便急迫/沾染衣物和排便频率，并添加了另4个单独的问题，以获得18到90分的总分，其中90分对应最佳的肠道功能。

MSK BFI总分是使用线性量表和等权重评分系统得出的，除了一个问题询问每24小时排便次数，每个问题均有五个可能的答案选项：从“从不”到“总是”。该设计是基于大量的文献回顾、半结构化的专家访谈、患者意见以及临床相关变量的多因素分析，从而可对SPTME后的肠道功能进行全面而详细的评估。该问卷的主要优势在于细致的问题设计，可对TME术后肠道功能障碍进行综合的评价，同时也强调与临床重要变量和生活质量的相关性，这些都体现在评分系统中。

作为标准临床诊疗的一部分，患者使用已经过验证的基于网络的系统完成MSK BFI问卷²¹。我们将WW治疗组患者在NAT结束后完成的第一份问卷的得分，与SPTME患者在肠道连续性恢复后完成的第一份问卷的得分进行了比较。

统计学分析

使用SAS 9.4版软件（SAS Institute Inc., Cary, NC）进行统计学分析。分类变量用频率和百分比表示，连续变量用中位数和范围表示。两治疗组之间，使用卡方检验和Fisher精确检验对分类变量进行比较，使用Wilcoxon秩和检验对连续变量进行比较。数据缺失的患者被排除在分析之外，本文稿根据STROBE指南进行撰写²²。

结果

按 WW 策略治疗并且 MSK BFI 数据完整的 28 例患者中，2 例因肿瘤再生长、5 例因未找到合适的匹配对照而被排除在外。

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其余21例患者组成WW组（图1）。WW组患者在人口统计学或临床变量方面与配对的SPTME组无显著性差异（表1）。WW组患者在NAT结束后完成的第一份MSK BFI调查问卷的中位时间为5个月（范围，1-77个月）；SPTME组患者在恢复肠道连续性后完成第一份MSK BFI调查表的中位时间为5个月（范围，4-37个月）（ $p = 0.62$ ）。

WW组患者的MSK BFI总分（中位数分别为76 vs 55； $p < 0.001$ ），以及所有子量表的分数均显著地比SPTME组高（图2）。差异最大的是排便急迫/沾染衣物子量表（中位数分别为20 vs. 12； $p < 0.001$ ）；且在WW组中，四个子量表中的每一问题的得分都较SPTME组更高。

在排便频率子量表中，WW组患者的中位分数为24，而SPTME组患者的中位分数为21（ $p = 0.01$ ），前一组患者的排便频率较低（排便次数/24小时，中位数分别为2 vs 5； $p = 0.002$ ）。在饮食子量表中，WW组患者的中位分数为16，而SPTME组患者的中位分数为13（ $p = 0.008$ ），这主要是因为SPTME组中饮食限制和某些固体食物摄入会增加每天的排便次数。WW组还报告了更少的排便不完全及簇状排便次数，以及更好的肛门控制排气功能。

讨论

本研究采用综合量表评估与肠道功能有关的患者报告结局，发现进行NAT后，采

用WW策略的患者肠道功能比接受SPTME治疗的患者明显更好。通过MSK BFI问卷在整体和特定方面的评估结果均显示WW组患者报告的肠道功能更好。此外，我们的研究发现，与SPTME组相比，WW组患者调整常规饮食的需要更少，簇状排便的可能性更小，排便不完全的情形也减少，这表明WW组患者的肠道功能更好。

直肠癌患者的肠道功能不佳，除全直肠系膜切除术外，还与放化疗有关²。但是，尚不清楚在NAT后接受WW策略患者的肠道功能情况。

我们的研究结果表明，两组间最显著的差异是在排便急迫/沾染衣物子量表中，这是SPTME术后患者肠道功能最常受到影响的方面；这也在其它评估方式（如LARS评分系统）得到了验证¹⁴。MSK BFI饮食子量表是衡量肠道功能的一个部分，这部分在其他问卷如LARS评分系统中并没有得到评估；有趣的是在WW组中，这项得分也较好。

FIGURE 1.

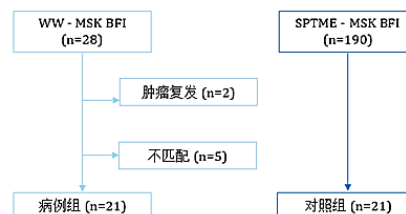


图1. 患者队列。WW=观察与等待；SPTME=保括约肌全直肠系膜切除术；MSK BFI=纪念斯隆-凯特林肠道功能问卷。

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表1. 患者一般特征

特征	WW (n=21)	SPTME (n=21)	p值
年龄, 中位数(范围)	68 (45–92)	66 (44–73)	0.27
性别, n (%)			1
男	10 (48)	11 (52)	
女	11 (52)	10 (48)	
肿瘤距肛缘, 中位数 (范围), cm	6.5 (3–12)	8 (3–13)	0.09
AJCC 临床分期, n (%)			0.54
I	1 (5)	0	
II	7 (33)	6 (29)	
III	13 (62)	15 (71)	
新辅助治疗, n (%)			0.12
放化疗	6 (29)	2 (10)	
全新辅助治疗	15 (71)	19 (90)	
吻合方式, n (%)			
器械缝合		19 (90)	
手工缝合*		2 (10)	
临时襻式回肠造口, n (%)		19 (90)	
AJCC 病理分期, n (%)			
pCR		8 (38)	
I		6 (29)	
II		2 (10)	
III		5 (24)	

WW=观察与等待; SPTME=保括约肌全直肠系膜切除术; AJCC, 美国癌症联合委员会; pCR, 病理完全缓解。

*包括一例部分括约肌间切除。

我们关于便失禁的研究发现与Habr-Gama等人的研究结果一致²³。该研究报告, 与接受经肛门局部切除术的患者相比, WW组患者的克利夫兰临床失禁指数得分更高²⁴。但是, 该研究仅关注肛门失禁, 这限制了其评估LARS全部症状的能力。该研究也未用SPTME患者设立对照组。Hupkens等¹³在最近的一项交叉匹配研究中, 评估了采用WW策略患者的多个生活

质量领域, 通过LARS评分系统发现三分之一的患者有重度LARS症状。作者指出, 重度LARS的高发生率可能与NAT的组成部分的盆腔放疗有关。我们认为, 一些其他因素也可能影响了他们的研究结果。与MSK BFI相比, LARS评分系统并没有对LARS提供全面的评估²⁰, 这表明了LARS评分系统并不是针对SPTME患者术后肠道功能改变的多维度的综合评估, 而可能

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只是一个更好的筛选工具而已。此外，Juuil等²⁵的最新研究发现，在50至79岁的健康人群中，有9%的男性和19%的女性有重度的LARS症状，在对直肠癌患者讨论相关治疗方法时，需要考虑其对肠道功能的影响。尽管如此，根据先前的文献，新辅助放疗似乎对保留直肠患者的肠道功能产生不良的影响²⁶。

关于哪些患者是WW治疗组患者的最佳对照组尚存在争议。由于医生可能都不会对NAT的临床反应不完全的患者给予非手术治疗²⁷，WW治疗组患者的肠道功能与NAT反应不完全的患者的临床相关性可能有限。尽管如此，我们认为肠道功能障碍的风险更多地是与直肠残端距离（即结肠直肠吻合口距离）和放射治疗有关，而非与肿瘤对新辅助治疗的反应有关。尽管我们的样本量很小，有趣的是我们研究中38%的SPTME对照组患者达到了病理完全缓解，并且我们未观察到他们的MSK BFI总评分与病理不完全反应患者的评分之间存在显著性差异。

本研究的局限性包括样本量小和观察性的研究设计。WW治疗组患者是从用于直肠癌患者的临床诊疗的回顾性数据库中筛选的，而不是来自于基于研究方案的WW注册数据库。这可能导致选择性偏倚，因为对调查问卷做出反馈的潜在患者总数是未知的。由于相同的原因，我们无法确定潜在的选择性偏倚在对照组中的真实影响。为了减少与选择性偏倚相关的不足，我们对患者进行SPTME术后与肠道功能较差的最相关的变量进行了交叉匹配²⁸。这种方法排除了5例潜在合格的WW治疗组患者，因为我们无法找到年龄相近、接受相似的新辅助治疗，且治疗后的肿瘤距肛缘

距离相似的对照者。回顾性研究中WW的治疗选择往往倾向年龄较大且肿瘤更靠近括约肌的患者²⁹，而这两种变量可能与肠道功能不良有关，因此可能导致选择性偏倚。应该注意的是，SPSTME组中只有2例患者进行了手工缝合，其中一例进行部分括约肌切除术。排除这两例患者后的分析结果是相似的。最后，由于患者不都在规定的时间范围内完成MSK BFI调查问卷，因此数据的时间间隔使得难以对我们的发现进行外部验证。我们对时间间隔的影响进行了探索性的亚组分析，但是由于样本量较小，正式的分析是不可行的。值得注意的是，在治疗1年内和在治疗后1年以上完成问卷的患者获得了相似的结果。

尽管有以上局限性，我们仍是第一个使用经过验证的问卷工具对采用WW治疗策略的患者报告肠道功能进行全面评估的研究，问卷的设计特别适合用于对器官保存策略的潜在影响的评估。

结论

与保留括约肌的手术相比，采用WW治疗策略与患者报告的总体肠道功能良好之间存在相关性。这是通过MSK BFI量表确定的，该量表是最全面的、经过验证的评估肠道功能障碍的调查工具。与SPTME组患者相比，WW治疗组患者的肠道功能可能有所改善；我们的这一发现需要谨慎解读，因为入组患者尚未考虑手术并发症的影响，而且大多数患者的放疗和/或手术对括约肌造成损害的风险也较低。对于WW治疗组患者的短期和长期肠道功能障碍，还需要在前瞻性试验中进行进一步研究。

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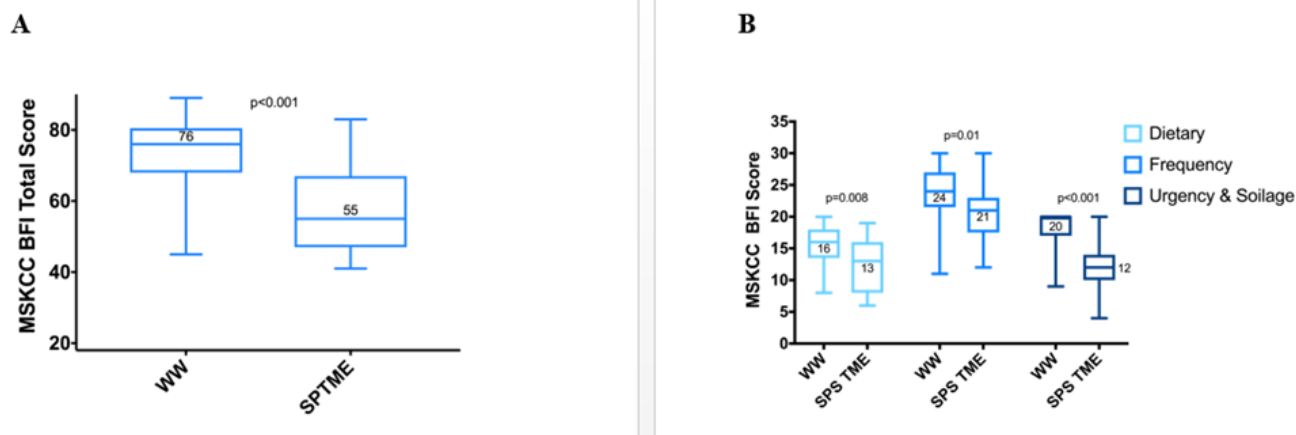


图2. MSK-BFI评分, 含四分位和全范围 (每组n=21)。(A) 总得分; (B) 分项得分。MSK BFI=纪念斯隆-凯特林肠道功能问卷; WW=观察等待; SPTME=保留括约肌的全直肠系膜切除术。

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