

低位直肠癌经括约肌间保肛手术应用现状

丁健华, 张斌

背景资料

对于距离肛缘 <5 cm 的低位直肠癌, 传统的术式常常无法保肛, 不得不牺牲肛门行永久性造口, 以保证根治手术的彻底性。经括约肌间切除术 (intersphincteric resection, ISR) 突破了低位直肠癌远切缘不足的限制, 进一步提高了保肛率, 被认为是远端 2 cm 切缘法则的终结。

丁健华, 张斌, 火箭军总医院结直肠肛门外科 全军肛肠专病中心 北京市 100088

丁健华, 副教授, 主任医师, 主要从事结直肠肿瘤的临床和基础研究。

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作者贡献分布: 本文由丁健华与张斌共同完成。

通讯作者: 丁健华, 副教授, 主任医师, 100088, 北京市西城区新街口外大街16号, 火箭军总医院结直肠肛门外科。
jianhuading75@163.com
电话: 010-66343440

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Intersphincteric resection for low rectal cancer

Jian-Hua Ding, Bin Zhang

Jian-Hua Ding, Bin Zhang, Department of Colorectal Surgery, the General Hospital of the PLA Rocket Force, Beijing 100088, China

Supported by: the Clinical Research Fund of Beijing Municipal Science and Technology Commission, No. Z151100004015013.

Correspondence to: Jian-Hua Ding, Department of Colorectal Surgery, the General Hospital of the PLA Rocket Force, 16 Xijiekouwai Road, Xicheng District, Beijing 100088, China. jianhuading75@163.com

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Abstract

For low rectal cancer located < 5 cm from the anal verge, abdominoperineal resection (APR) with permanent sigmoid colostomy is usually used to ensure the R0 resection. Sphincter saving surgery has emerged in the last 20 years, and the introduction of intersphincteric resection (ISR) can successfully preserve the anal function and guarantee a radical tumor resection for patients with ultra-low lying tumors. Therefore, the use of APR has been consistently declining worldwide. Recently, a growing body of research on ISR has been reported. However, more evidence based results are needed to clarify some issues about ISR. In the current review, we discuss the indications for ISR and the oncological and functional outcomes following the procedure. Some technique issues of ISR are also discussed.

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Key Words: Intersphincteric resection; Low rectal cancer; Abdominoperineal resection

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摘要

对于距离肛缘 <5 cm 的低位直肠癌, 传统的腹会阴联合切除术常不得不牺牲肛门以保

同行评议者

李伟华, 教授, 主任医师, 福建省立医院肿瘤外科;
牛伟新, 教授, 主任医师, 复旦大学附属中山医院普外科

证根治手术的彻底性。近20年来随着保留肛门括约肌手术的进展, 尤其是经括约肌间切除术(intersphincteric resection, ISR)的推广, 在保证低位直肠肿瘤根治性切除同时成功实现了保肛。因此, 低位直肠癌选择传统腹会阴联合切除术的比率逐渐下降。国内外许多学者围绕该手术的适应证、疗效、术后控便功能等进行了研究, 相关循证数据相继报道。同时, 也有一些问题仍有待更多的研究来明确。本文对ISR保肛手术的适应证选择、肿瘤学结果、功能性结果和手术相关问题进行探讨。

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关键词: 经括约肌间切除; 低位直肠癌; 腹会阴联合切除术

核心提要: 经括约肌间切除术(intersphincteric resection, ISR)使部分既往不能保肛的低位直肠癌患者实现了保肛, 通过严格的手术适应证筛选, ISR是一种安全、可行的保肛术式。

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0 引言

尽管腹会阴联合切除术(abdominoperineal resection, APR)仍然是低位直肠癌(距离肛缘<5 cm)的标准术式, 越来越多的研究^[1-4]发现ARP不仅具有较高的环周切缘(circumferential resection margin, CRM)阳性率和肿瘤穿孔率, 并且患者术后远期生活质量欠佳。随着双吻合器技术、全直肠系膜切除术、新辅助治疗等技术的相继开展, 低位直肠癌保肛率显著上升。然而, 文献报道^[5-7]低位直肠癌永久性肠造口的比率高达30%-50%。其原因在于手术时远切端距离肿瘤下极至少需要1-2 cm, 以保证足够切缘, 防止术后复发, 而直肠末端至肛缘间还有长约2-4 cm的肛管, 其周围为肛门括约肌包绕。因此, 传统的低位前切除术(low anterior resection, LAR)常难于保证低位直肠癌足够的远切缘, 不得不牺牲肛门以保证根治手术的彻底性^[8]。

对于距离齿状线<1 cm的超低位直肠癌^[7], 如何在保证低位直肠癌手术彻底性的前提下

实现保肛, 仍然是结直肠外科极具挑战性的难题。1994年Schiessel等^[9]在《英国外科杂志》首次报道采用经括约肌间切除术(intersphincteric resection, ISR)成功实现了低位直肠癌的保肛。实施该手术的解剖基础是: 直肠末端肠壁环形肌层增厚, 并向肛管内延伸形成肛门内括约肌包绕肛管, 肛门内括约肌又被周围的外括约肌、耻骨直肠肌等包绕, 共同形成肛门直肠环实现肛门控便功能。在肛门内括约肌与其他括约肌之间存在先天的解剖间隙, ISR手术即在腹部游离直肠至盆底最低位后, 经肛门距离肿瘤下极1-2 cm处环形切开末端直肠壁及内括约肌, 进入上述内外括约肌间隙, 再沿间隙向近端游离与腹部会合, 然后经肛门拖出游离的直肠、乙状结肠, 直视下离断肠管移除标本, 行近端肠管与肛管手工吻合, 从而既保证了充分的肿瘤切缘又实现了保肛。该手术一经报道引起了广泛的关注, 日本学者Teramoto称之为极限保肛手术^[10]。由于该手术可保证绝大多数低位、超低位直肠癌实现1-2 cm切缘, 因此法国学者Rullier等^[11]认为该手术方式是肿瘤远切缘2 cm法则的终结, 所有直肠癌采用该手术均可实现技术上保肛。

然而ISR在国际上的推广并不迅速, 许多学者对该手术切除肿瘤的彻底性、术后肛门功能存在担忧, 而手术的适应证、具体操作过程等也有不同的观点。近十年来, 随着国际上多个中心研究结果的发表, 一些问题得到了明确的答案, 而围绕该手术的更深入研究的开展, 使我们对ISR术有了更系统全面的认识。

1 适应证选择

低位直肠癌行ISR手术适应证考虑以下几个方面: (1)位置: 上限为肿瘤下极距离肛直环上缘<2 cm的直肠癌, 高于该水平的直肠癌可采用传统LAR、双吻合器技术完成。下限为肿瘤下极距离内外括约肌间沟 ≥ 1 cm, 位置更低的直肠肛管癌采用ISR也无法获得1 cm以上的安全切缘; (2)浸润深度: ISR治疗T1、T2期直肠癌已达成共识。对于T3期肿瘤, 有学者担忧术后局部复发率高, 但既往多项研究^[4,12,13]结果表明, 只要术前评估预期可获得阴性环周切缘, 采用ISR切除T3期肿瘤安全、可行。而对于T4期肿瘤, 应作为ISR禁忌证^[9,14,15]。有学者对T4期肿瘤侵犯外括约肌者采用ISR术同时切除受侵犯部分外括约肌, 但切缘阳性率达36.7%, 且研

研究前沿
ISR手术的适应证、肿瘤学结果(肿瘤R₀切除率、术后复发率、影响术后复发的因素)、术后肛门功能和生活质量结果、手术相关问题(是否需要预防性造口? 吻合方式? 选择微创还是开腹手术?)等是需要探讨的问题。

□ 相关报道

2012年《英国外科杂志》报道, 共入选14项研究1289例ISR患者, R₀切除率97%, 中位随访56 mo, 局部复发率为6.7%, 5年生存率86.3%, DFS为78.6%, 显示了良好的手术根治性, 术后患者对肛门功能的满意度达90.8%。

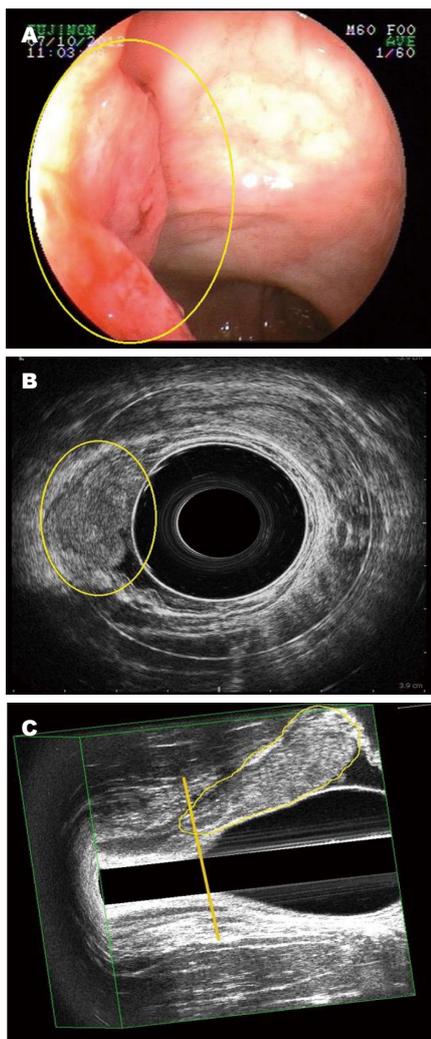


图 1 三维肛肠直结肠腔内超声行直肠癌术前评估。A: 结肠镜示低位直肠癌距肛缘4 cm; B: 腔内超声示uT3N0Mx; C: 三维模式示肿瘤下极超越肛直环平面。

究^[16,17]显示T4期为ISR术后局部复发的危险因素; (3)分化程度: 高、中分化直肠癌适宜, 而低分化直肠、黏液癌为术后复发危险因素, 不适宜本手术^[18]。

为获得良好适应证, 术前准确评估肿瘤浸润深度、是否能达到环周切缘阴性(>1 mm)至关重要。核磁共振成像(magnetic resonance imaging, MRI)为直肠癌术前分期最常用的方法, 其判断环周切缘受累的敏感性和特异性为85.4%和80%^[19]; 然而, 新辅助放化疗后由于肿瘤灶周围组织炎症反应和纤维化, MRI再次评估时准确性下降^[20]。国际上多个研究也推荐采用三维直肠腔内超声进行术前分期^[21,22]。我们的经验, 三维直肠腔内超声不仅能够准确进行肿瘤T分期, 并且可清晰显示耻骨直肠肌、内外括约肌的解剖结构, 并量化分析肿瘤下极与

耻骨直肠肌的距离、肿瘤浸润内外括约肌的深度, 对环周切缘的预估有重要作用(图1)。此外, 正如Rullier等^[23]和Kim等^[4]教授指出, 直肠指诊虽然简单, 但对有经验的医师, 指诊即可大体了解肿瘤浸润深度及肛门括约肌情况, 对部分病例即可明确是否适合ISR手术。

2 手术方法

2.1 腹部手术 常规采用开腹或腹腔镜4孔法(脐上缘、右下腹分别置入12 mm Trocar作为观察孔和主操作孔, 右上腹与左下腹直肌外缘分别置入5 mm Trocar作为辅助操作孔), 全程超声刀、中间入路法完成保留自主神经的标准全直肠系膜切除, 清扫肠系膜下血管根部及以下淋巴结, 自肠系膜下动脉根部或左结肠动脉分支下方切断肠系膜下动脉。充分游离左半结肠。保护上腹下神经、骶前神经及盆腔自主神经丛, 按直肠后方、两侧、前方顺序完全游离直肠系膜直至盆底, 直肠前壁分离注意保护两侧血管神经束。如镜下视野清晰, 操作空间充分, 可于正后方切断裂孔韧带进入肛提肌裂孔, 自直肠后外侧进入内括约肌间隙。常规行末端回肠预防性袢式造口。盆腔经左下腹Trocar孔置入26F双套管引流。

2.2 会阴部手术 碘伏消毒直肠肛管, 放置Lone Star自动拉钩(Lone Star Medical Products Inc., Houston, Texas, United States)固定, 避免过度牵拉损伤肛门括约肌。手术方式的选择依照低位直肠癌Rullier分型^[24], 即根据肿瘤下缘与肛直环的距离确定ISR手术方式, 确保远切缘距肿瘤下极至少1-2 cm。如肿瘤下缘距离肛直环≤1 cm, 采用部分ISR或次全ISR手术, 即自齿状线附近或齿状线与肛门括约肌间沟之间环形切除内括约肌全层; 如肿瘤下缘位于肛直环平面以下, 或侵犯内括约肌而未累及外括约肌, 则选择完全ISR手术, 即经肛门括约肌间沟环形切除全部内括约肌。远端缝闭避免术中肿瘤播散。沿内、外括约肌间隙自后方、侧方、前方向盆腔分离, 与腹部会师后, 经肛门拖出标本直视下切除肿瘤近端肠管, 切除组织标本送检病理(图2)。2-0可吸收缝线间断行结肠-肛管手工吻合(colorectal anastomosis, CAA)。

3 肿瘤学结果

ISR手术理论上实现了低位直肠癌足够的切缘, 从而实现了保肛, 但实际肿瘤学结果尚需要临

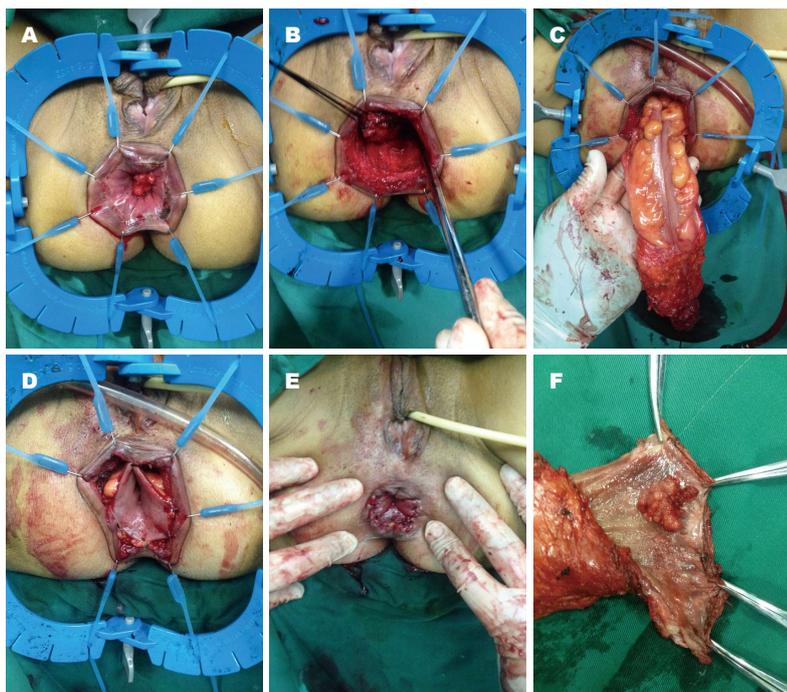


图 2 经直肠癌经括约肌间切除术会阴部操作过程。A: Lonestar拉钩暴露肛门即见肿瘤位于齿线处, 于内外括约肌间沟作环形切口; B: 沿括约肌间沟向上完全游离直肠, 外括约肌、耻骨直肠肌、盆底肌清晰可见; C: 自肛门部拉出包含肿瘤之肠管, 并于离断; D: 行手工结肠肛管吻合; E: 完成吻合、保肛成功; F: 切除标本见肿瘤位于齿线处, 远切缘足够充分。

创新亮点
本文系统性阐述了低位直肠癌ISR保肛手术的解剖学基础、手术适应证的选择、相关肿瘤学结果、术后肛门功能和生活质量、手术相关技术问题, 明确了ISR手术应用现状及注意要点。

床循证数据验证。近年来, 国际上研究结果陆续发表, R_0 切除率为87%-100%、术后局部复发率0%-15%, 而传统APR术后局部复发率为6.7%, 两者比较无明显差异^[15,25-31]。Martin等^[32]于2012年对所有已发表研究筛选后进行系统分析后发表于《英国外科杂志》, 共入选14项研究1289例ISR患者, R_0 切除率97%, 中位随访56 mo, 局部复发率为6.7%, 5年生存率86.3%, DFS为78.6%, 显示了良好的手术根治性。Saito等^[17]更远期的研究显示, 199例ISR平均随访78 mo, 7年OS: 78%、DFS: 67%、LFS: 80%。

由于研究设计及伦理等方面原因, 目前尚无低位直肠癌行ISR与APR直接比较的前瞻性研究, 一些回顾性研究^[1-4,17]显示两组术后DFS相当, APR复发率甚至高于ISR。Koyama等^[33]比较了77例ISR和33例APR, 结果显示局部复发率(7.8% vs 12.1%), 5年生存率(76.4% vs 51.2%), 两组病例TNM分期虽无差异, 但APR组分化程度更差, 高中分化腺癌的比例ISR组为94%, APR组为76%。最近, Kim等^[4]通过倾向得分匹配减少选择性偏倚, 多因素分析结果同样证实APR比ISR具有更高的5年局部复发率。

如何尽可能避免术后局部复发是ISR手术的重要问题, 研究显示T3、环周切缘阳性为高危因素^[34]。Komori等^[22]研究报道, ISR手术环周

切缘应 >2 mm、远切缘 >1.5 cm, 否则局部复发率明显上升。因此除了术前准确评估肿瘤浸润深度、环周切缘, 选择合适适应证外, 手术操作是关键。需要熟练的盆腔深部操作技巧, 同时熟悉肛门部括约肌解剖^[35], 经肛门切开直肠壁时必须深达括约肌间隙, 并准确沿括约肌间隙分离, 尤其对男性直肠前壁肿瘤者, 准确的手术操作是保证阴性环周切缘、远切缘的关键。术中切缘冰冻切片有助于评估手术是否彻底。

4 功能性结果

由于ISR手术切除了全部或部分肛门内括约肌, 而且吻合口位置接近肛门口, 术后肛门功能、生活质量也是备受关注的问题。研究^[36]显示, 术后短期内肛门功能下降, 但排便评分及肛肠测压结果均显示随时间逐渐改善, 术后24 mo失禁评分及肛门功能显著优于术后3 mo^[37]。在Martin等^[32]的荟萃分析中, 中位随访56 mo, 术后排便次数平均2.7次/d, 29.1%控制稀便功能下降, 23.8%控制气体功能下降, 18.6%有排便紧迫感, 但与切除肛门相比, 90.8%的患者对术后肛门功能表示满意, 愿意接受该手术, 其他研究也有类似结果^[15,25-31]。Koyama等^[33]比较了77例ISR和68例前切除患者, 术后5年, ISR组肛门失禁评分差于前切除组(8.1 vs 4.9), 但排便

应用要点

ISR可作为低位直肠癌保肛手术的可选方案。T1-3期直肠癌均可作为候选适应证。术前需严格评估预判环周切缘状态, 腹腔镜ISR是理想选择, 术后注意吻合口狭窄, 并加强功能锻炼, 可获得良好效果。

相关生活质量评分两组无差异。

为尽可能的保护术后肛门功能, 除了肿瘤位置、吻合口高度外^[38], 其他一些可能影响术后功能的因素值得注意。由于吻合口极低, 术后吻合口狭窄并不少见, 研究提示其为术后肛门功能下降的危险因素^[39], 我们也发现一些患者有明显的便次增多、排便不净感, 查体发现为吻合狭窄, 因此术后随访如发现有狭窄应尽早扩肛, 多数狭窄经简单手指扩肛即可解除。

术前新辅助放化疗在低位直肠癌治疗中应用越来越广泛。然而, 术前放化疗是ISR术后远期肛门功能不佳的危险因素^[27,37,40]。Nishizawa等^[41]对199例ISR平均随访78 mo, 术前放化疗组肛门失禁评分、生活质量评分均差于直接手术组^[17]。而且新辅助治疗反应越好, ISR术后肛门功能越差。术前放化疗可导致明显的神经变性, 从而影响肛门功能^[42]。但该效应具有普遍性, 并非ISR特有, 最近Beppu等^[43]报道了105例术前接受了新辅助放化疗的低位直肠癌患者, 其中46例行ISR, 41例行双吻合器前切除, 术后平均随访6.5年, 组间比较低位前切除综合征评分无统计学差异, 其中仅肛门失禁亚类(肛门排气、液状便)评分ISR低于前切除, 两组术后排便功能随时间逐渐改善。

因此, 如患者拟行ISR术保肛, 术前新辅助治疗对肛门功能的潜在影响应予考虑。同时术前应评估肛门功能, 并行肛肠测压, 如术前即存在明显肛门功能不佳, 是否行ISR及新辅助治疗应慎重考虑。

5 手术相关问题

5.1 预防性造口问题 ISR术后常规行预防性回肠造口是普遍被采用的方式, 90%以上的文献均予采用。然而也有少数学者未行预防性造口。Koyama等^[33]135例ISR未行预防性造口, 吻合口漏发生率17%, 单因素分析显示男性、术前化疗、部分ISR、侧方淋巴结清扫、肿瘤距离和直接吻合是危险因素, 该研究中排除了术前放疗患者。ISR吻合时在直视下手工吻合, 吻合较确切, 然而由于吻合口位于括约肌环内, 吻合口可能因受挤压而缺血^[44], 导致吻合口漏。文献报道ISR术后吻合口漏的发生率为5%-16%^[11,25-27], 盆腔脓肿发生率为5%, 大多也来源于吻合口漏^[27]。预防性回肠造口虽然并不能减少吻合口漏的发生, 但可明显减低后续危

害, 因此, 预防性回肠造口仍是目前主流方法。

5.2 直接吻合与储袋吻合 低位直肠癌前切除术后, 一些学者采用结肠储袋与直肠残端吻合, 以改善术后肛门功能。研究^[45]显示, 结肠储袋可改善术后肛门功能, 尤其在术后1年内。但术后2年, 结肠储袋与直肠端端吻合者无差异。在ISR手术中, 也有学者主张采用结肠储袋与肛管吻合。但Akasu等^[46]报道, 结肠储袋肛管吻合是发生严重吻合口漏的文献因素。即一旦发生吻合口漏, 行结肠储袋者后果严重。我们1例ISR患者行结肠储袋肛管吻合后发生吻合口漏, 继发储袋严重感染缺血坏死, 后再次手术切除储袋行永久性造口。因此, ISR是否行结肠储袋, 应综合考虑患者术前肛门功能、术中是否具有条件, 以及如果发生严重吻合口漏患者身体的耐受性等。

5.3 微创与开腹手术 国际上ISR手术前期报道绝大多数为开腹手术, 近年来关于腹腔镜ISR术的结果相继增多。Laurent等^[47]回顾性研究报道, 开腹ISR与腹腔镜ISR术后并发症率分别为28%、23%, 术后5年局部复发率分别为2%、5%、无病生存率分别为71%、70%, 总生存率分别为85%、82%, 两组比较均无统计学意义, 提示微创手术可以安全用于ISR操作。国内学者池畔教授回顾性分析48例开腹ISR与89例完全腹腔镜部分ISR术后的中期结果(平均随访时间32.3 mo), 结果证实两组间肿瘤学结果及肛门功能无显著统计学差异^[48]。其他研究^[7,45,49-54]也证明腹腔镜ISR术无论在彻底性、安全性还是功能性方面都是可行的。我们回顾了全军肛肠专病中心已完成的76例腹腔镜ISR手术, 结果显示本组患者均顺利完成标准腹腔镜TME及经肛门ISR手术, 无中转开腹及死亡病例, 手术时间195 min(120-360 min)、出血量100 mL(40-300 mL)、淋巴结清扫数目14枚(3-33枚)、肿瘤远切缘距离2 cm(1-3.5 cm)、R₀切除率98.6%、中位随访2年、局部复发率4.6%。

最近, 国外学者在手术步骤方面提出经肛ISR先行、腹腔镜TME后行的策略, 认为可能减少手术时间、降低操作难度, 提高CRM阴性率, 术后短期、长期结果和经腹手术无差异^[51,54]。另有长期随访^[55]结果(平均随访时间69 mo)表明ISR手术并不增加永久性肠造口的比率。此外, 机器人ISR手术也开始尝试, 其

3年生存率、无复发生存率、肛门功能等与腹腔镜ISR手术相比无差异^[56,57]。

6 结论

总之, ISR术使部分既往不能保肛的低位直肠癌患者实现了保肛, 对于术前肛门功能好、保肛意愿强烈、术前评估预期可实现环周切缘阴性的患者, 通过严格的手术适应证筛选, ISR是一种安全、可行的保肛术式。

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□名词解释

超低位直肠癌: 低位直肠癌的定义并不一致, 原因是对肿瘤远切缘的再认识(从5 cm到1 cm)和肛管长度的个体差异。对于距离齿状线<1 cm低位直肠癌, 国外学者提出超低位的概念。Rullier分型很好的阐述了低位直肠癌的最佳术式选择。

□ 同行评价

对于位于直肠下段的肿瘤来说, 保留肛门的难度较大, 特别是男性肥胖患者, 骨盆狭小, 保留肛门实属不易。ISR 的应用, 使原本不能保留的肛门得以保留。本文查阅了近10年的经括约肌间直肠癌根治术相关文献, 从手术要点、临床疗效等方面进行了回顾分析, 对临床实践有一定的指导价值。

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