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论 著

## 腹腔镜与开腹低位直肠癌保肛术安全性的Meta分析

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**摘要: 目的** 分析腹腔镜与传统开腹手术在低位直肠癌保肛术中的安全性。**方法** 按照拟定的标准, 筛选出13篇比较腹腔镜与开腹术式在低位直肠癌保肛治疗中安全性的文献, 运用Meta分析对相关临床指标进行综合分析。**结果** 开腹组(OS组)的手术时间较腹腔镜组(LS组)少16.86 min (MD = 16.86, 95%CI: 9.74~23.98,  $P = 0.000$ )、术中出血量较LS组多115.16 mL (MD = -115.16, 95%CI: -141.90~-88.42,  $P = 0.000$ )。两组术中清扫的淋巴结数目比较, 差异无统计学意义 (MD = 0.03, 95%CI: -0.66~0.72,  $P = 0.930$ )。LS组环周切缘(CRM)癌肿的阳性率较OS组高 ( $\hat{OR} = 2.67$ , 95%CI: 1.07~6.68,  $P = 0.040$ )。LS组术后切口并发症发生率比OS组低 ( $\hat{OR} = 0.20$ , 95%CI: 0.08~0.50,  $P = 0.001$ )。两组术后吻合口瘘、肠梗阻和泌尿系并发症发生率比较, 差异无统计学意义 (均  $P > 0.05$ )。LS组术后肛门首次排气时间较OS组早 (SMD = -1.61, 95%CI: -2.20~-1.01,  $P = 0.000$ )、住院时间较OS组短2.78 d (MD = -2.78, 95%CI: -3.84~-1.71,  $P = 0.000$ )。两组术后肿瘤局部复发率和远处转移率比较, 差异无统计学意义 (均  $P > 0.05$ )。**结论** 与OS比较, LS在低位直肠癌保肛术中对患者损伤小、术后恢复快。两种术式在肿瘤的安全性上无明显区别。

**关键词:** 低位直肠癌; 腹腔镜; 保肛; Meta分析

**中图分类号:** R735.37

## Meta-analysis of safety in laparoscopic and open surgery for preserving anus in low rectal cancer

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**Abstract: Objective** To compare the safety in laparoscopic and traditional laparotomy for anus-preserving radical resection in low rectal cancer. **Methods** According to the established criteria, 13 literatures were screened to compare the safety of laparoscopic and laparotomy in anus-preserving treatment of low rectal cancer. Meta-analysis method was used to comprehensively analyze the relevant clinical indicators. **Results** The operation time in open surgery group was 16.86 min shorter than that in laparoscopic surgery group (MD = 16.86, 95% CI: 9.74~23.98,  $P = 0.000$ ), and the intraoperative blood loss was 115.16 mL higher than that in LS group (MD = -115.16, 95%CI: -141.90~-88.42,  $P = 0.000$ ). There was no significant difference in the number of lymph nodes dissected between the two groups (MD = 0.03, 95%CI: -0.66~0.72,  $P = 0.930$ ). The positive rate of circumferential margin cancer in laparoscopic surgery group was higher than that in open surgery group ( $\hat{OR} = 2.67$ , 95%CI: 1.07~6.68,  $P = 0.040$ ). The incidence of incision-related complications in laparoscopic surgery group was smaller than that in

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open surgery group, the difference between the two groups was statistically significant ( $\hat{OR} = 0.20$ , 95% CI: 0.08 ~ 0.50,  $P = 0.001$ ). In the incidence of anastomotic leakage, intestinal obstruction and urinary complications after operation between the two groups, the differences were not statistically significant (all  $P > 0.05$ ). The first time of anal exhaust in laparoscopic surgery group was earlier than that in open surgery group (SMD = -1.61, 95%CI: -2.20 ~ -1.01,  $P = 0.000$ ) and the hospital stay in laparoscopic surgery group was 2.78 d less than that in open surgery group (MD = -2.78, 95%CI: -3.84 ~ -1.71,  $P = 0.000$ ). There was no significant difference in local recurrence rate and distant metastasis rate between the two groups (all  $P > 0.05$ ). **Conclusion** Laparoscopic surgery in the anus-preserving surgery for low rectal cancer has less injury and faster recovery than open surgery. There was no significant difference between the two methods in safety.

**Keywords:** low rectal cancer; laparoscopy; anus preservation; Meta-analysis

随着腹腔镜技术的不断发展,在低位直肠癌保肛根治术中,腹腔镜手术已经得到越来越多的认可。然而,开腹术式和腹腔镜术式在术中安全性、术后并发症和肿瘤安全性等方面哪种更具优势,目前尚无明确定论<sup>[1-2]</sup>。本文通过收集两种术式的相关临床指标,结合大量文献进行综合统计分析,探讨两种术式的安全性。

## 1 资料与方法

### 1.1 检索策略

采用主题词与自由词结合的方法,检索在PubMed、万方和中国知网数据库2008年1月—2018年1月发表的关于“腹腔镜与开腹术式治疗低位直肠癌安全性比较”的相关研究。中文检索词为:低位直肠癌、腹腔镜、保留肛门。英文检索词为:rectal neoplasms、laparoscopy、operation、anal canal。

### 1.2 纳入标准

①研究内容为腹腔镜与开腹术式在低位直肠癌保肛根治性手术中的应用对比;②低位直肠癌的定义为:腹膜反折以下,肿瘤下缘距肛管直肠环交界处小于5 cm或距肛缘小于7 cm的直肠肿瘤<sup>[3-4]</sup>;③相关数据完整,包括患者基本信息、手术相关资料、术后并发症和术后肿瘤情况;④研究类型为随机对照试验或设计良好的队列研究、病例对照研究。

### 1.3 排除标准

①非根治性保肛手术,如因心肺肝功能不全和感染等因素而实行姑息性手术;②因肠穿孔和肠梗阻等原因而实行急诊手术,无充足的术前准备;③存在其他部位不可切除的肿瘤;④未进行腹腔镜与开腹手术对照分组。

### 1.4 统计学方法

采用Newcastle-Ottawa Scale (NOS)量表对纳入

的文献进行研究质量评价及风险偏倚评估。二分类变量采用Mantel-Haenszel (M-H)法进行统计,运用比值比(odds ratio, OR)或相对危险度(relative risk, RR)作为合并统计量。连续性变量采用Inverse Variance (IV)法进行统计,均数差(mean difference, MD)或标准化均数差(standardized mean difference, SMD)作为合并统计量。 $P < 0.05$ 为差异有统计学意义。采用Review Manager 5.3软件提供的异质性检验方法,使用 $Q$ 值检验和 $I^2$ -square检验对文献进行异质性分析,如文献异质性分析为 $P > 0.1$ 且 $I^2 < 50\%$ ,则采用固定效应(fixed effect, FE)模型;当 $I^2 \geq 75\%$ 即出现重度异质性时,采用亚组分析或敏感性分析。如无法找出异质性所在或 $P \leq 0.1$ 、 $I^2 \geq 50\%$ 时,则采用随机效应(random effect, RE)模型。采用Cochrane协作网提供的Review Manager 5.3软件对数据进行分析,并绘制森林图,纳入的研究数如大于10项,同时绘制漏斗图评估异质性,即观察是否存在发表偏倚。

## 2 结果

### 2.1 文献基本情况

按照检索策略及筛选标准,从万方数据库纳入文献8篇<sup>[5-12]</sup>,PubMed纳入文献3篇<sup>[13-15]</sup>,中国知网数据库纳入文献2篇<sup>[16-17]</sup>。文献筛选流程图见图1。文献基本资料见表1。共纳入病例1 271例,其中腹腔镜(laparoscopic surgery, LS)组(LS组)657例,开腹手术(open surgery, OS)组(OS组)614例。纳入的13篇文献NOS量表评估结果见表2。

### 2.2 Meta分析结果

**2.2.1 基本信息比较** 纳入文献的基本信息包括患者年龄、男性比和肿瘤位置,两组比较,差异均无

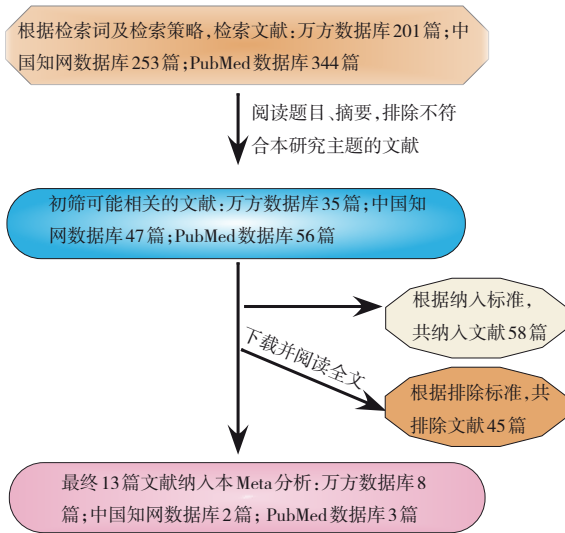


图 1 文献筛选流程图

Fig.1 Flow chart of literature screening

统计学意义,不存在明显的失衡。见表 3。

**2.2.2 术中相关资料** 对手术时间进行异质性分析,剔除了杨世斌等<sup>[10]</sup>手术时间的数据,文献由重度异质性 ( $P=0.000, I^2=97%$ ) 降为中度异质性 ( $P=0.030, I^2=53%$ )。结果显示:LS 组手术时间较 OS 组多 16.86 min ( $MD=16.86, 95\%CI: 9.74 \sim 23.98, P=0.000$ )。见图 2。同法得出以下结果:LS

组术中出血量较 OS 组少 115.16 mL ( $MD=-115.16, 95\%CI: -141.90 \sim -88.42, P=0.000$ )。见图 3。两组淋巴结清扫数目比较,差异无统计学意义 ( $MD=0.03, 95\%CI: -0.66 \sim 0.72, P=0.930$ )。见图 4。LS 组环周切缘 (circumferential resection margin, CRM) 癌肿阳性率较 OS 组高 ( $OR=2.67, 95\%CI: 1.07 \sim 6.68, P=0.040$ )。见图 5。

**2.2.3 术后并发症** LS 组术后切口并发症发生率比 OS 组低 ( $OR=0.20, 95\%CI: 0.08 \sim 0.50, P=0.001$ )。见图 6。两组术后吻合口瘘 (漏)、肠梗阻和泌尿系并发症发生率比较,差异无统计学意义 (均  $P>0.05$ )。见图 7~9。

**2.2.4 术后情况** LS 组术后肛门首次排气时间较 OS 组早 ( $SMD=-1.61, 95\%CI: -2.20 \sim -1.01, P=0.000$ )。见图 10。LS 组住院时间较 OS 组短 2.78 d ( $MD=-2.78, 95\%CI: -3.84 \sim -1.71, P=0.000$ )。见图 11。两组术后肿瘤局部复发率和远处转移率比较,差异均无统计学意义 ( $OR=1.04, 95\%CI: 0.44 \sim 2.48, P=0.930; OR=1.09, 95\%CI: 0.57 \sim 2.08, P=0.790$ )。见图 12 和 13。

表 1 纳入文献的基本资料

Table 1 Basic information of included literature

文献	LS 组				OS 组			
	例数	年龄/岁	性别(男/女)/例	肿瘤分期	例数	年龄/岁	性别(男/女)/例	肿瘤分期
曾文革 <sup>[5]</sup>	71	32~71	48/23	I~IV	62	30~72	41/21	I~IV
郭永锋 <sup>[6]</sup>	45	49~64	19/26	II~III	45	51~65	21/24	II~III
李鸢 <sup>[7]</sup>	50	36~72	26/24	/	50	41~75	29/21	/
潘涛 <sup>[8]</sup>	30	36~74	14/16	/	30	38~72	15/15	/
王兴 <sup>[9]</sup>	39	31~75	16/23	I~III	36	35~77	13/23	I~III
杨世斌 <sup>[10]</sup>	28	34~73	18/10	/	56	30~85	36/20	/
袁龙 <sup>[11]</sup>	65	/	/	/	62	/	/	/
周克勤 <sup>[12]</sup>	40	38~78	26/14	/	40	36~76	25/15	/
LAURENT <sup>[13]</sup>	110	22~82	72/38	I~III	65	30~86	45/20	I~III
KUO <sup>[14]</sup>	28	25~88	17/11	/	30	26~77	19/11	/
YAMAMOTO <sup>[15]</sup>	22	34~68	16/6	I~III	22	35~69	16/6	I~III
龚绍江 <sup>[16]</sup>	73	44~69	41/32	I~IV	84	40~69	45/39	I~IV
王存川 <sup>[17]</sup>	56	58±12	33/23	A~C	32	59±9	18/14	A~C

表2 NOS量表质量评估及偏倚风险评价  
Table 2 Quality assessment and bias risk assessment of NOS scale

文献	选择性			可比性		结局			得分
	1	2	3	4	5	6	7	8	
曾文革 <sup>[5]</sup>	*	*	*	*	*	*	/	*	7*
郭永锋 <sup>[6]</sup>	*	*	*	*	*	*	*	*	8*
李鸷 <sup>[7]</sup>	*	*	*	*	/	*	/	/	5*
潘涛 <sup>[8]</sup>	*	*	*	*	/	*	*	*	7*
王兴 <sup>[9]</sup>	*	*	*	*	*	*	*	*	8*
杨世斌 <sup>[10]</sup>	*	*	*	*	*	*	*	/	7*
袁龙 <sup>[11]</sup>	*	*	*	*	*	*	/	/	6*
周克勤 <sup>[12]</sup>	*	*	*	*	/	*	*	*	7*
LAURENT <sup>[13]</sup>	*	*	*	*	*	*	*	*	8*
KUO <sup>[14]</sup>	*	*	*	*	*	*	/	/	6*
YAMAMOTO <sup>[15]</sup>	*	*	*	*	*	*	/	/	6*
龚绍江 <sup>[16]</sup>	*	*	*	*	*	*	*	*	8*
王存川 <sup>[17]</sup>	*	*	*	*	*	*	/	/	6*

注：“1”表示有独立的、确定的方法和人员，病例恰当；“2”表示连续或有代表性的系列病例；“3”表示对照组与病例组为同一人群；“4”表示研究起始没有要观察的指标；“5”表示在进行设计和统计分析时，考虑了病例组与对照组的可比性，该研究进行了重要混杂因素的控制；“6”表示确定了暴露因素，有相关的固定档案记录(如手术记录)；“7”表示符合评价前规定的适当随访时间；“8”表示病例组和对照组的随访充分完整；“\*”表示是、肯定、符合；“/”表示否、不符合；“5”最高可给“2\*”，其他最高只给“\*”；总分≥6\*为中高质量文献。

表3 患者基本信息分析结果  
Table 3 Analysis results of basic information of patients

指标	纳入文献数	检验模型	合并统计量	合并统计量(95%CI)	P值
年龄	7	固定(FE)	均数差(MD)	0.33(-1.03, 1.70)	0.630
男性比	12	固定(FE)	比值比(OR)	0.97(0.77, 1.24)	0.840
肿瘤位置	5	固定(FE)	均数差(MD)	0.00(-0.12, 0.13)	0.940

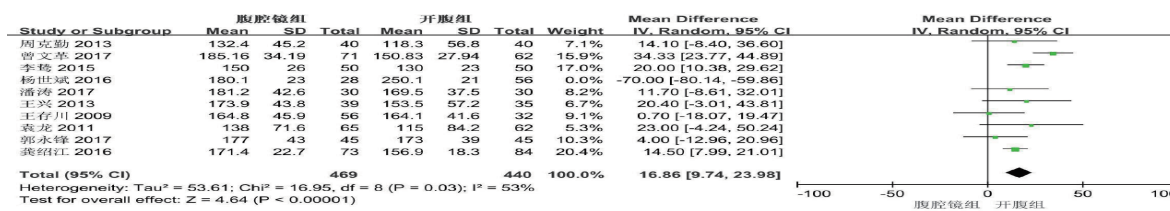
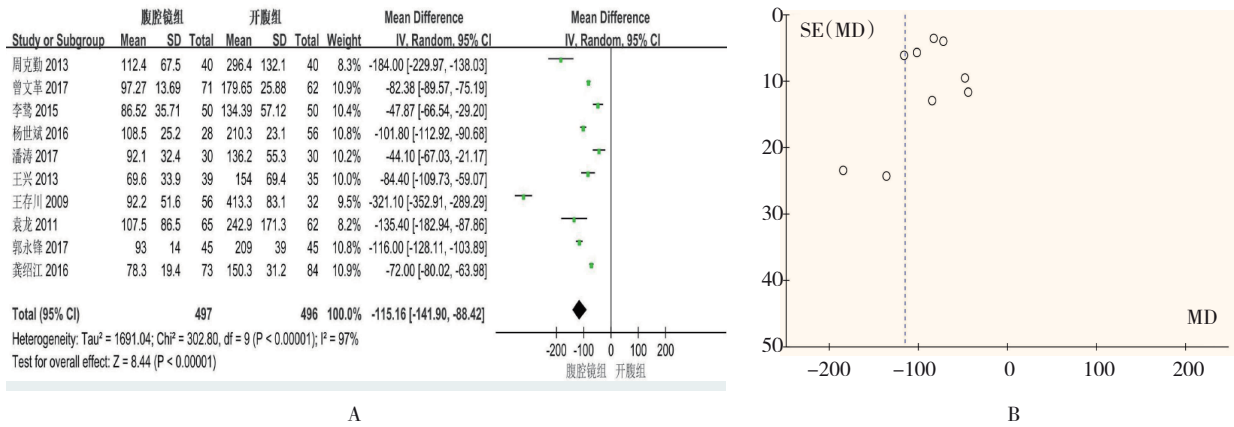


图2 两组手术时间比较的森林图

Fig.2 Forest chart of comparison of operation time between the two groups



A: 森林图; B: 漏斗图

图 3 两组术中出血量比较

Fig.3 Comparison of bleeding volume during operation between the two groups

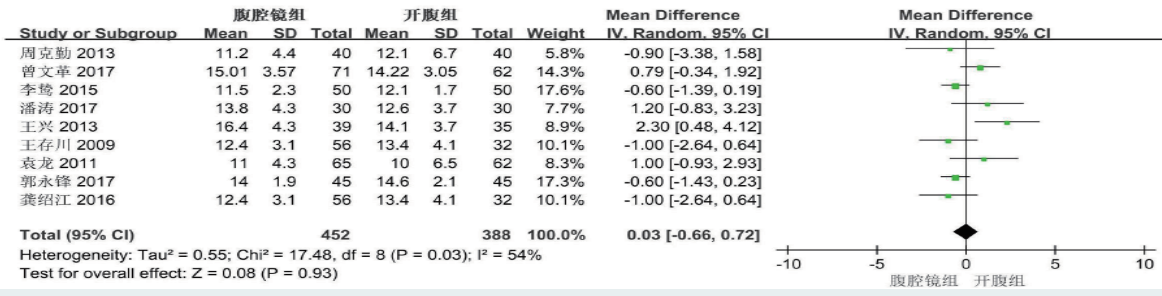


图 4 两组淋巴结清扫数目比较的森林图

Fig.4 Forest chart of comparison of number of lymph nodes between the two groups



图 5 两组 CRM 阳性率比较的森林图

Fig.5 Forest chart of comparison of positive rate of CRM between the two groups

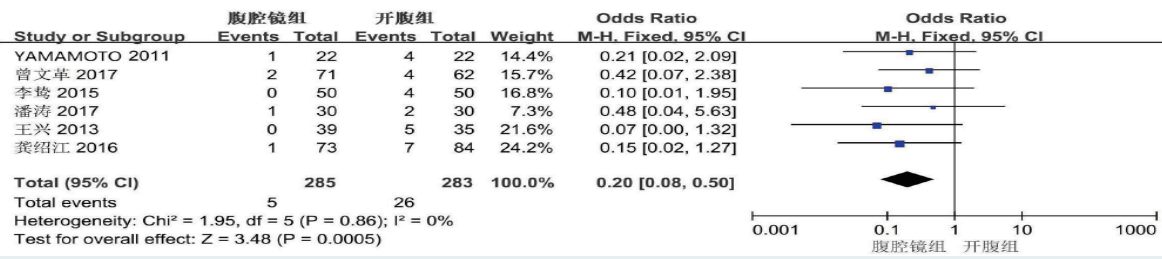


图 6 两组术后切口并发症发生率比较的森林图

Fig.6 Forest chart of comparison of postoperative incision complications between the two groups

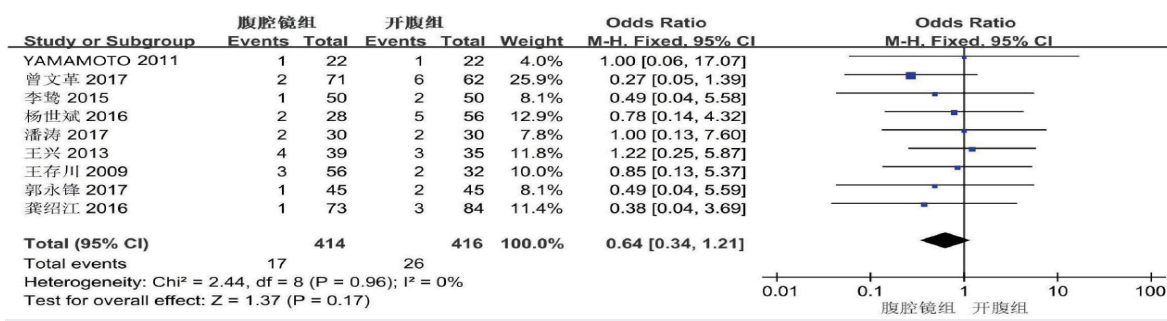


图 7 两组术后吻合口瘘(漏)比较的森林图

Fig.7 Forest chart of comparison of anastomotic leakage after surgery between the two groups

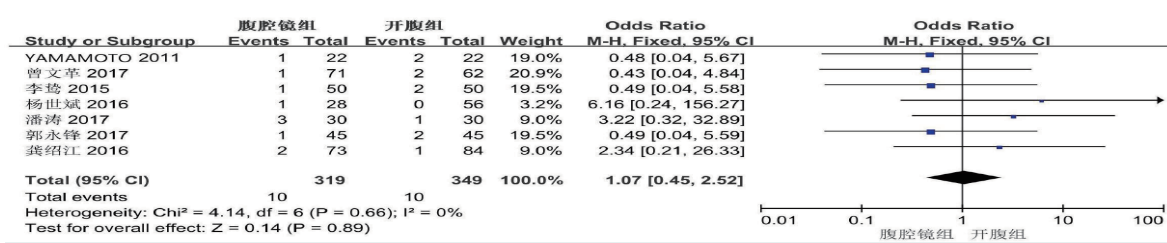


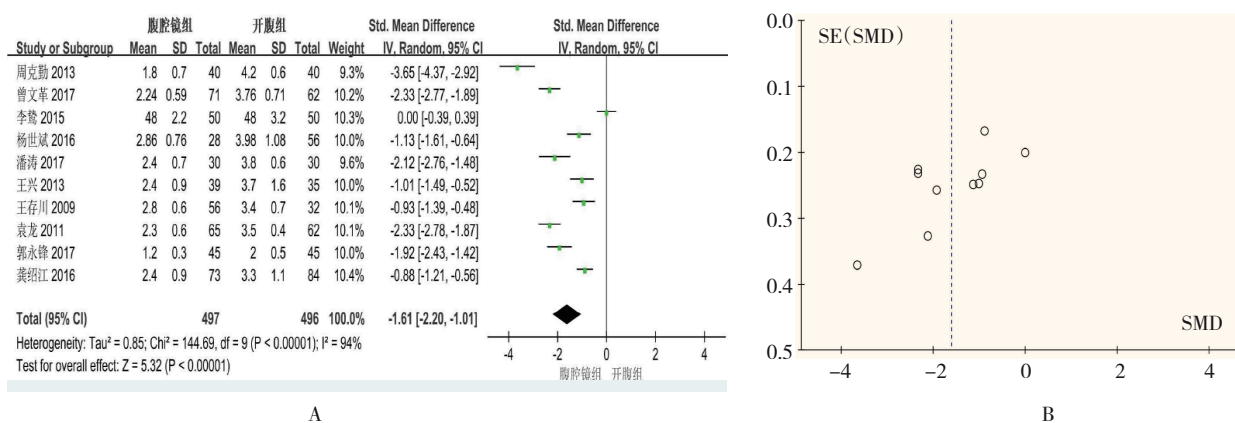
图 8 两组术后肠梗阻比较的森林图

Fig.8 Forest chart of comparison of intestinal obstruction after surgery between the two groups



图 9 两组术后泌尿系并发症比较的森林图

Fig.9 Forest chart of comparison of urinary complications after surgery between the two groups



A

B

A: 森林图; B: 漏斗图

图 10 两组术后肛门首次排气时间比较

Fig.10 Comparison of first anal exhaust time after surgery between the two groups

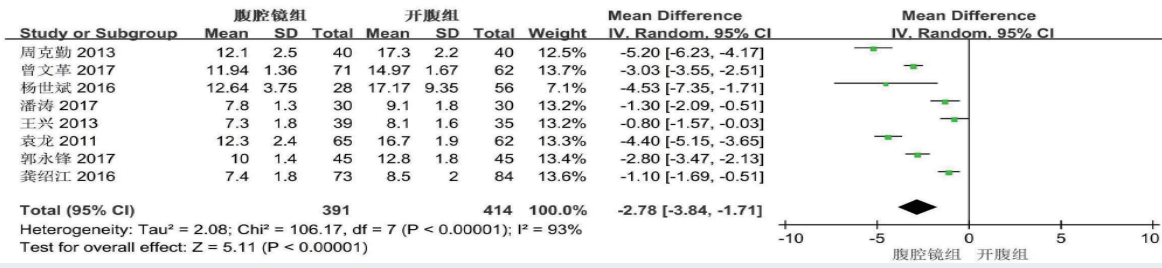


图 11 两组住院时间比较的森林图

Fig.11 Forest chart of comparison of hospital stay between the two groups



图 12 两组术后局部复发率比较的森林图

Fig.12 Forest chart of comparison of local recurrence rate after surgery between the two group



图 13 两组术后远处转移率比较的森林图

Fig.13 Forest chart of comparison of distant metastasis rate after surgery between the two groups

### 3 讨论

#### 3.1 腹腔镜术式的优势

本研究 LS 组的术中出血量为 30~477 mL, OS 组为 76~800 mL, 合并分析后得出 LS 组术中出血量较 OS 组少 115.16 mL。笔者认为, 腹腔镜术中出血量少与腹腔镜可提供更清晰的视野、易于发现并及时处理细小的出血点和止血效果更确切有关。文献<sup>[18-19]</sup>报道, LS 组术后切口相关并发症发生率比 OS 组低, 与微创技术切口小、对腹壁结构损伤小、切口血运好、不易感染、术后疼痛轻和易于护理等有关。本研究中, LS 组术后肛门首次排气时间较 OS 组早。在 YAMAMOTO 等<sup>[15]</sup>的报道中, LS 组可进食液体、固体时间分别为 1 或 2 d、2 或 3 d, OS 组分别为 2~11 d、3~12 d。李昌荣<sup>[20]</sup>的 Meta 分析显示, LS 组的术后肛门首次排气时间较 OS 组早 1.05 d (WMD = -1.05, 95%CI: -1.70~-0.41, P < 0.01), 正常饮食时间较

OS 组早 0.95 d (WMD = -0.95, 95%CI: -1.34~-0.55, P < 0.01)。腹腔镜依靠器械操作, 避免了人手对脏器大范围的触摸翻动, 也可预防手套材质对组织的影响, 且脏器暴露于外界的范围小。因此, 术后脏器组织自身反应小、粘连少, 使术后胃肠道功能恢复快, 能在早期就加强患者营养, 提高免疫功能, 从而缩短住院时间<sup>[21-22]</sup>。笔者认为, 腹腔镜术式在术中出血量、切口并发症和术后恢复等方面较开腹手术具有优势, 而两种术式术后其他并发症比较, 差异无统计学意义。

#### 3.2 腹腔镜术式的劣势

本研究 LS 组与 OS 组的手术时间分别为 132.4~390.0 min 和 115.0~416.5 min, OS 组的手术时间比 LS 组少 16.86 min。在 KUO 等<sup>[14]</sup>关于腹腔镜手术学习曲线的研究中, 显示第一阶段 (初始 18 个月) 与第二阶段 (后 6 个月) 的平均手术时间为 402.1 min (210~570 min) 和 331.4 min (210~450 min)。腹腔镜手术作为新兴起的手术方式, 操作上过于依赖器械, 术者无

法用自己的手进行触摸感知,操作技术难度较大。因此,腔镜手术学习曲线较开腹手术长<sup>[23]</sup>。

### 3.3 术后肛门功能

纳入本文的文献中,评估术后肛门排便功能所采用的方法和指标不一致,无法将其合并分析。曾文革等<sup>[5]</sup>的研究中,OS组患者术后第1年的Wexner评分为(11.94±1.25)分,排便功能优良率为66.07%;而LS组的Wexner评分为(9.37±1.09)分,排便功能优良率为84.85%(两组比较,均 $P<0.05$ ),该文献还指出,无论哪种术式,术后直肠肛管静息压(anal resting pressure, ARP)、肛管最大收缩压(maximal squeeze pressure, MSP)和直肠最大耐受容量(maximal tolerable rectal volume, MTV)均较术前下降,且OS组下降更明显。LAURENT等<sup>[13]</sup>研究表明,两组术后排便频率、排便急迫性和控便能力比较,差异均无统计学意义。在排便功能上,目前没有权威的研究能表明两种术式有明显差异<sup>[24]</sup>。

马章春<sup>[25]</sup>对低位直肠癌患者行括约肌间切除术(intersphincteric resection, ISR),结果显示,手术前后患者ARP、MSP变化对肛门功能的影响不明显,肛门排便失禁的独立危险因素为:患者术前行新辅助放化疗、吻合口与肛缘的距离 $<2\text{ cm}$ 、肿瘤下缘与肛缘距离 $<5\text{ cm}$ 。马磊等<sup>[26]</sup>研究表明,在术后3、6和12个月,完全ISR组术后肛门排便功能良好率较部分ISR组和保留齿状线ISR组低( $\chi^2=4.384, P=0.026$ ;  $\chi^2=4.227, P=0.018$ ;  $\chi^2=4.654, P=0.015$ )。由此可见,吻合口位置和肛门括约肌的完整性对排便功能非常重要。术后患者的生活质量与肛门的排气排便功能息息相关,需严格把握保肛的适应证,尽量避免肛门括约肌损伤,以保证肛门的功能<sup>[27-28]</sup>。

### 3.4 肿瘤安全性

本研究纳入有关CRM阳性率的报道3篇,LS组CRM阳性率均高于OS组,合并分析后,差异仍有统计学意义。但两组术后肿瘤局部复发率和远处转移率比较,差异均无统计学意义。MARIJNEN等<sup>[29]</sup>研究发现,术后病理CRM阳性患者2年局部复发率可达13.1%,而当距离肿瘤阳性的切缘大于2 mm时,2年局部复发率降为3.3% ( $P<0.01$ );该研究将距离阳性切缘小于1 mm的患者分为术后辅助放疗与不放疗组,两组术后复发率分别为17.3%和15.7%,差异无统计学意义 ( $P=0.980$ ),表明术后放疗对局部复发率影

响不大。ANDERSON等<sup>[30]</sup>的Meta分析显示,LS组与OS组肿瘤局部复发率分别为7.0%和8.0%,3年总体生存率分别为76.0%和69.0%,两组比较,差异均无统计学意义。在狭窄的盆腔进行腔镜操作,难度较开腹术式大得多,如要降低术后复发率,前提是要保证足够的切缘范围和CRM阴性。因此,需严格把握腔镜术式的适应证<sup>[31]</sup>。患者基础情况、肿瘤分期、术前新辅助治疗、术中是否进行根治性切除和术后综合治疗是影响患者预后的关键<sup>[32-33]</sup>。

综上所述,与开腹术式相比,腹腔镜术式可降低术中出血量及术后切口并发症的发生率,安全性较高,有利于术后快速康复,能缩短住院时间。两种术式在达到同样的根治效果和其他综合治疗上,肿瘤局部复发率和远处转移率比较,差异均无统计学意义。另外,本研究腔镜术式CRM阳性率较高,该指标对肿瘤局部复发率具有重要的意义,但肿瘤局部复发率两组比较,差异无统计学意义,可能与样本量较少有关,尚需要更大样本量的试验进行验证。

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