

机器人辅助腹腔镜与传统腹腔镜行结直肠癌手术的安全性和有效性比较

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摘要 结直肠癌是最常见的消化道恶性肿瘤之一, 严重威胁着患者的身体健康。外科手术是治疗结直肠癌的有效方法。目前, 微创手术因创伤小、恢复快等优点, 成为许多患者的首选。传统腹腔镜手术在技术上存在一定的难度, 它需要外科医生拥有丰富的腹腔镜操作经验。而达芬奇机器人拥有高清的 3D 镜头、灵活的机械臂以及更符合人体工程学的操作方式, 在设计上优于腹腔镜。但多项研究结果显示, 机器人结直肠手术的围手术期结果、远期结果与传统腹腔镜相比未见明显优势, 而费用却明显增加。目前, 机器人结直肠手术已被证实是安全可行的, 其便于进行体内肠吻合, 并可以缩短学习曲线。达芬奇机器人可在手术空间狭小、解剖复杂的盆腔内操作。在面对内脏肥胖、骨盆狭窄、低位肿瘤等病例时, 它的视觉系统也有助于辨认识别解剖层次, 更好的保留盆腔自主神经, 可能会促进泌尿与性功能的术后恢复。随着各领域的新技术不断发展和融合, 以及外科医生机器人手术经验的积累, 相信机器人手术在未来会拥有更广阔的应用前景。

关键词 结直肠癌; 腹腔镜; 机器人; 安全性; 有效性

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Comparison of safety and efficacy between robotic and conventional laparoscopic surgery for colorectal cancer

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Abstract Colorectal cancer is one of the most common digestive tract malignancies, which is a severe threat to human health. Surgery is an effective treatment for colorectal cancer. At present, minimally invasive surgery has become the first choice

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of many patients since its advantages of minor injury and quick recovery. Laparoscopic surgery is technically difficult, which requires rich experience of surgeons. The Da Vinci robot-assisted surgical system is equipped with high-definition 3D view, flexible robotic arm and good ergonomics, which is superior to laparoscopy. According to latest studies, the perioperative results and long-term results of robot-assisted colorectal surgery showed no obvious advantages over traditional laparoscopy, but the cost is significantly increased. However, robotic colorectal surgery is safe and feasible to perform intestinal anastomosis, which also has a shorter learning curve. Robotic surgery is more suitable for pelvic operation, which has narrow surgical space and complex anatomy. When dealing with visceral obesity, male pelvis and low tumor location, the visual system of robotic surgery system can identify the anatomical level, which may help to preserve pelvic autonomic nerve better during operation and accelerate the recovery of urinary and sexual function after surgery. With the continuous combination of new technologies in various fields and the accumulation of robotic surgery experience for surgeons, it is believed that the robotic surgery will be widely used in the near future.

Key words Colorectal neoplasms; Laparoscope; Robot; Safety; Validity

结直肠癌是最常见的消化道恶性肿瘤之一。据 2018 年的全球癌症统计结果, 目前男性和女性结直肠癌的发病率分别居第 3 位和第 2 位, 而结直肠癌死亡病例占总死亡病例的 9.2%, 居第 2 位^[1]。自 1990 年首次报道传统腹腔镜治疗结直肠疾病以来, 微创手术成为了结直肠外科发展的方向^[2]。腹腔镜手术与开腹手术相比, 复发率和总生存率无统计学差异, 但腹腔镜手术还具有创伤小、术中出血量少、术后肠道功能恢复快、不增加围术期并发症、住院时间短等优点^[3-6], 且便于临床教学和技术交流。就患者的短期生活质量而言, 腹腔镜手术是比开腹手术更好的选择^[7]。但随着临床上的不断应用, 传统腹腔镜的缺陷逐渐显露出来, 如二维视角缺乏立体感、手术过程需要经验丰富的助手进行配合、长时间手术会出现术者体位不适、手术器械缺乏灵活性、缺少触摸感、易受手部震颤影响^[8-9]。为克服这些问题, 达芬奇机器人手术系统(以下简称机器人)应运而生, 该系统有高清 3D 镜头和灵活的机械臂, 可过滤手部细震颤, 操作更符合人体工程学。

在结直肠外科领域, 第 1 台机器人结直肠手术是由 Weber P A 等^[10]在 2001 年进行的。Hashizume M 等^[11]也使用机器人成功地完成了结肠切除、远端胃切除和脾切除等手术。D'Annibale A 等^[12]在 2003 年进行了 53 例结直

肠手术, 认为机器人手术治疗结直肠恶性疾病与传统腹腔镜手术一样安全有效。机器人手术现在被认为是结直肠癌的治疗选择之一。但机器人与传统腹腔镜相比, 孰优孰劣尚不明确。本文通过对近期文献进行综述, 旨在比较机器人与腹腔镜在结直肠手术中的应用, 以评估近期机器人的安全性和有效性, 并对未来机器人结直肠手术进行展望。

1 来源与选择标准

使用 PubMed 数据库搜索 2015 年至 2020 年 4 月期间的“robotic”、“robot”“laparoscopic”、“robot-assisted”、“colorectal”、“colonel”、“rectal”等术语。文章的参考部分也被搜索并添加到相关研究。因为机器人手术是相对较新的技术, 所以多中心随机研究的数量有限。

2 机器人在结肠癌手术中的应用

虽然机器人结肠癌手术已经在多个国家和地区广泛开展, 但是缺乏有力的临床证据。本文通过收录的 10 篇高质量文献来探讨机器人在结肠癌手术中的安全性及有效性(见表 1)^[13-22]。

2.1 术中和围手术期效果

部分研究表明, 机器人辅助腹腔镜行结肠

癌手术的手术时间较长^[13, 16-19]，可能是由于在手术过程中机器人工作车需要多次移动、反复安装和重新摆放机器臂^[18]，这与近期荟萃分析结果一致^[23]。另有研究在进行了大量的机器人手术后，安装和对接时间可明显缩短，手术时间与传统腹腔镜相比没有统计学差异（113min 和 109 min, $P=0.59$ ）^[20]。

传统腹腔镜行结肠癌手术时中转开腹是比较常见的情况，多是由于术中出现难以控制的出血、腹腔内复杂粘连、肿瘤侵犯周围组织、肥胖等。Spinoglio G 等^[19]研究数据显示，机器人组中转率低于传统腹腔镜组（0% Vs 6.9%, $P=0.014$ ）。Ploat F 等^[14]的一项单中心前瞻性队列研究显示，机器人组中转率虽低于腹腔镜组，但差异无统计学意义（3.1% Vs 7.2%, $P=0.129$ ）。理论上来说，机器人辅助腹腔镜操控灵活，便于体内肠吻合^[24]，面对复杂手术时更容易处理。但由于传统腹腔镜发展较早，术者操作经验更丰富，机器人辅助腹腔镜的优势并不明显。

估计失血量在各文献中差异较大（见表1），这种差异可能源于术者操作的熟练程度。随着外科医生机器人手术经验的增加，估计失血量会减少^[25]。有研究认为，估计失血量主要与肿瘤大小和伴随疾病相关，与使用机器人辅助腹腔镜或传统腹腔镜无关^[15]。

机器人辅助腹腔镜组的住院时间和术后并发症与传统腹腔镜组相当，差异无统计学意义（见表1）。考虑到肿瘤患者常有伴发疾病，所以住院时间的异同未必是手术本身所造成。有荟萃分析认为机器人辅助腹腔镜手术可以有效地减少术中对胃肠道的刺激，从而促进肠功能恢复，缩短住院时间^[26]。

2.2 病理学结果及远期结果

传统腹腔镜手术中清扫淋巴结对技术要求

很高，需要主刀医生有丰富经验。而机器人凭借稳定的摄像平台和灵活的机械臂可以在清扫淋巴结时降低技术门槛，控制出血^[27-29]。有荟萃分析结果显示，机器人辅助腹腔镜行右半结肠切除术时提供的淋巴结数较多（ $MD-1.58$, 95% $CI -3.09$ to -0.07 , $P=0.04$ ）^[30]。包括 Park J S 等^[13]随机对照试验（Randomized controlled trials, RCT）在内的多数研究均显示清扫淋巴结数量没有统计学差异（见表1），说明机器人辅助腹腔镜治疗结肠癌的淋巴结清扫效果确切，在主刀医生传统腹腔镜操作经验较少时是一个很好的选择。

目前在远期疗效方面相关的 RCT 研究仍较少。Kim J C 等^[18]报道，机器人与腹腔镜结肠癌术后的两年无病存活率没有差异（分别为 90.2% Vs 92.2%, $P=0.543$ ）。Park J S 等^[13]在关于右半结肠癌的随机对照试验进行了5年的术后随访，结果显示机器人组和腹腔镜组之间无病生存率、总生存率均没有差异。Kang J^[22]等对开放、腹腔镜、机器人右半结肠切除术后的患者进行了中位数40个月的随访，3组患者的5年总生存率（ $P=0.83$ ）和无病生存率（ $P=0.91$ ）均无差异。有研究报道，相较于传统腹腔镜，机器人似乎可以提高晚期患者的5年存活率（78.6% Vs 64.9%, $P=0.02$ ）^[31]。从目前证据来看机器人辅助腹腔镜行结肠癌手术的远期疗效与传统腹腔镜近似。

2.3 花费

机器人辅助腹腔镜手术的设备采购、维护和一次性耗材的成本高昂^[32]。然而，也有研究认为机器人手术可以通过缩短住院时间和重症监护病房停留时间来节省部分费用，在总费用上与传统腹腔镜无统计学差异（ $P=0.632$ ）^[21]。

表 1 机器人辅助腹腔镜与传统腹腔镜行结肠癌手术的安全性和有效性比较
Table 1 Comparison of safety and efficacy between robotic and conventional laparoscopic surgery for colon cancer

研究者	出版年	研究类型	手术方式		手术部位 (例)	手术时间 (min)		中转率 (%)	估计失血量 (ml)		住院时间 (d)		术后并发症(%)		收获淋巴结数 (个)		总花费 (R/L)
			(R/L)	(L)		(R/L)	(L)		(R/L)	(L)	(R/L)	(L)	(R/L)	(L)			
Park JS ^[13]	2019	RCT	35/35	70/0	195 ± 41/ 129 ± 43.2 ^a	两组均无中转	35.8 ± 36.3/ 46.8 ± 31.3	7.9 ± 4.1/ 8.3 ± 4.2	17.1/20.0	29.9 ± 14.7/ 30.8 ± 13.3	\$12235.0 ± 1907.9/ \$10319.7 ± 1607.7 ^a						
Polat F ^[14]	2019	Prosp	206/172	267/111	165.73 ± 43.03/ 171.59 ± 46.58	3.1/7.2	NR	5 (3-30) / 5 (3-35)	2.3/7.2	16.38 ± 5.87/ 17.54 ± 7.33	NR						
Zhu XL ^[15]	2019	Retro	104/180	284/0	201.1 ± 59.1/ 195.4 ± 53.9	NR	166.9 ± 106.4/ 125.1 ± 101.3 ^a	10.7 ± 5.4/ 14.3 ± 6.4	NR	12.0 ± 5.2/ 12.6 ± 5.7	¥ 82585.6 ± 15465.6/ ¥ 65877.4 ± 17350.9 ^a						
Gerbard F ^[6]	2019	Retro	42/59	101/0	197 ± 25.3/ 137 ± 19 ^a	0/1.69	27 ± 26/ 31 ± 29	6 ± 2.3/ 7 ± 3.1	21.4/28.8	26 ± 11/ 23 ± 7	NR						
Yozgatli TK ^[17]	2019	Retro	35/61	96/0	286 ± 77/ 132 ± 40 ^a	两组均无中转	75 ± 70/ 73 ± 57	6 ± 3/ 6 ± 3	29/25	41 ± 12/ 33 ± 10 ^a	NR						
Kim J ^[18]	2018	Retro	20/53	73/0	170 ± 29/ 117 ± 33 ^a	0/3.9	NR	6 ± 2/ 6 ± 2	20.0/11.32	21 ± 7/ 22 ± 8	\$14800/ \$10500 ^a						
Spinoglio G ^[19]	2018	Retro	101/101	202/0	279 ± 80/ 236 ± 68 ^a	0/6.9 ^a	两组均 < 50ml	7.9 ± 5.2/ 7.9 ± 3.5	27.7/33.6	28.2 ± 10.6/ 30.4 ± 13.1	NR						
Vasudevan V ^[20]	2016	Retro	96/131	227/0	108.9 ± 46.3/ 113.2 ± 56.6	13.5/9.1	NR	5.7/6.6	7.3/3.1	NR	\$107219.8/ \$114853.1						
de'Angelis N ^[21]	2016	Retro	30/50	80/0	200.5 ± 29.5/ 204.1 ± 26.7	0/4	148.6 ± 31.59/ 164 ± 24.80 ^a	7.1 ± 3.1/ 8.2 ± 4.4	3.3/0	NR	NR						
Kang J ^[22]	2016	Retro	20/43	63/0	239.3 ± 59.3/ 236.4 ± 61.8	0/2.3	187.0 ± 205.2/ 101.3 ± 110.4	8.5/9.0	10.0/7.0	32.2 ± 18.1/ 32.3 ± 16.5	\$8788 ± 2.013/ \$4394 ± 1.634 ^a						

注：^a表示差异有统计学意义 (P < 0.05)。R：机器人辅助腹腔镜；L：传统腹腔镜；NR：缺失值；Retro：回顾性研究；Prosp：前瞻性研究；RCT：随机对照试验。

3 机器人在直肠癌手术中的应用

目前，机器人手术治疗直肠癌的多中心随机对照试验仍比较有限，本研究收录 11 篇文献探讨机器人在直肠癌手术中应用的安全性及有效性（见表 2）^[14, 33-42]。

3.1 术中和围手术期效果

手术时间较长被认为是机器人辅助腹腔镜手术的潜在缺陷。但随着整个机器人手术团队经验的增加，手术质量可能会逐步提高，从而缩短手术时间^[42]。

在中转率上，机器人辅助腹腔镜行直肠癌手术是否优于传统腹腔镜仍有争议（见表 2）。但在面对男性（adjusted $OR=2.44$, 95% CI : 1.05~5.71; $P=0.04$ ）、肥胖（adjusted $OR=4.69$, 95% CI : 2.08~10.58; $P<0.001$ ）和肿瘤位置较低（adjusted $OR=5.44$, 95% CI : 1.60~18.52; $P=0.007$ ）的患者时，传统腹腔镜中转风险更高^[36]。对于内脏脂肪较多的患者，机器人手术有利于降低术中失血量和并发症^[41]。传统腹腔镜在面对内脏肥胖、男性骨盆狭窄、肿瘤位置低等情况时无法获得足够的手术视野和操作空间，而机器人在灵活性和人体工程学方面的优势有助于克服这些困难。

Crippa J 等^[38]对 600 例接受微创直肠癌手术患者的临床资料进行分析，结果显示机器人组并发症发生率较低（37.2% Vs 51.2%, $P<0.001$ ），接受机器人手术可以减少术后并发症并缩短住院时间。但在多个随机对照试验中（见表 2），机器人组在术后并发症和住院时间方面未见明显优势，仍需更多的大样本研究进一步证实。

3.2 病理学结果及远期结果

在病理学结果上，机器人直肠癌手术是

否更具优势仍存在争议。虽然机器人组与腹腔镜组间环周切缘阳性率无统计学差异^[33, 36]，但机器人直肠癌手术标本远端切缘长度较长（2.8cm Vs 1.8cm, $P<0.001$ ）且环周切缘更加完整（ $P=0.079$ ）^[34]。此前也有研究发现机器人手术环周切缘更宽^[43-44]。机器人辅助腹腔镜能在狭小的空间中灵活操作，精确地进行分离和缝合，在肿瘤下限充分解剖。Fransgaard T 等^[45]报道，机器人直肠癌手术更能达到 R0 切除，但可能由于术者机器人操作熟练程度等原因，这种优势并不明显，仍需更为大量的临床研究进一步证实。Ploat F 等^[14]对机器人组和腹腔镜组进行了两年的随访，发现两组患者术后 12 个月、18 个月、24 个月的局部复发率（ $P=0.292$, $P=0.145$, $P=0.419$ ）、远处转移率（ $P=0.940$, $P=0.493$, $P=0.743$ ）、无病生存率（ $P=0.607$, $P=0.265$, $P=0.439$ ）和总生存率（ $P=0.103$, $P=0.197$, $P=0.197$ ）均无统计学差异。目前临床研究证据相对较少，远期效果尚待大量多中心的前瞻性随机对照研究结果来客观评价。

3.3 排尿功能及性功能结果

直肠癌手术有可能损伤盆腔自主神经，从而严重影响患者性功能和排尿功能。研究报道，虽然传统腹腔镜和机器人直肠癌手术均会导致膀胱和性功能障碍，但机器人手术恢复得更快^[46-47]。Kim M J 等^[33]的 RCT 也发现在术后 1 年，机器人组 66 例患者的性功能明显高于腹腔镜组的 73 例患者（ $P=0.032$ ）。荟萃分析提示，机器人手术可能会降低对患者泌尿生殖系统功能的损伤^[48]。而 Jayne D 等^[36]的 RCT 显示，无论使用机器人辅助腹腔镜还是传统腹腔镜，均成功地保留了自主神经，两组患者的膀胱功能和性功能在术前和术后 6 个月均无统计学差异，并且各组患者与其术前功能相比变化不大。Galata C

表 2 机器人辅助腹腔镜与传统腹腔镜行直肠癌手术的安全性和有效性比较

Table 2 Comparison of safety and efficacy between robotic and conventional laparoscopic surgery for rectal cancer

研究者	出版年	研究类型	手术方式		手术部位 (结肠/直肠)	手术时间 (min)	中转率 (%)	估计失血量 (ml)	住院时间 (d)	术后并发症 (%)	收获淋巴结 (个)
			(R/L)	(R/L)							
Kim MJ ^[33]	2018	RCT	66/73	0/139		339.2 (80.1) / 227.8 (65.6) ^a	1.5/0	100 (0~1000) / 50 (0~300) ^a	10.3 ± 3.4 / 10.8 ± 7.4	34.8/23.3	18 (7~59) / 15 (4~40) ^a
			28/29	0/57		55 (39~113) / 28 (19~80) ^a	4.8/8.3	200 (50~650) / 325 (100~800) ^a	3 (2~14) / 2 (2~11)	28.6/25	14 (8~20) / 13 (9~21)
Tolstrup R ^[35]	2018	RCT	25/26	0/51		152 ± 43 / 170 ± 57	4/38.5 ^a	NR	8.9 ± 5.6 / 9.5 ± 7.7	40/38.5	NR
Jayne D ^[36]	2017	RCT	237/234	0/471		298.5 ± 88.71 / 261.0 ± 83.24 ^a	8.1/12.2	NR	8.0 ± 5.85 / 8.2 ± 6.03	15.3/14.8	23.2 ± 11.97 / 24.1 ± 12.91
			18/33	0/51		394 ± 78.5 / 324 ± 80.9 ^a	22.2/0 ^a	1.8 ± 0.9 / 1.7 ± 1.1	12.6 ± 10.6 / 13.2 ± 7.5	33.33/36.36	14.3 ± 2.1 / 16.0 ± 3.8
Polat F ^[14]	2019	Retro	206/172	267/111		205.24 ± 41.57 / 217.88 ± 57.19	2.6/17.6 ^a	NR	NR	0/8.8 ^a	16.01 ± 8.04 / 15.26 ± 3.78
			317/283	0/600		324.1 (108.4) / 214.6 (71) ^a	5.05/13.8 ^a	NR	3 (3~5) / 5 (4~7) ^a	37.2/51.2 ^a	NR
Crolla RMPH ^[39]	2018	Retro	168/184	0/352		219 ± 47.4 / 172 ± 48.4	1.8/12.5 ^a	NR	6 (2~67) / 7 (3~104) ^a	30.4/39.7	14 (2~44) / 7 (0~44) ^a
			53/58	0/111		342 (249~536) / 192 (90~335) ^a	3.8/1.7	60.8 (0~400) / 47.4 (0~400) ^a	6 (3~17) / 8 (5~53) ^a	NR	18 (4~49) / 11 (3~27) ^a
Shiomi A ^[41]	2106	Retro	127/109	0/236		236.0 (123~484) / 237.0 (125~421)	0/0.9	10.0 (0~138) / 15.0 (0~489) ^a	7 (6~29) / 8 (6~44) ^a	9.45/23.85 ^a	26 (11~60) / 26 (7~63)
			50/25	0/75		313 (290~330) / 270 (200~305) ^a	2/32 ^a	NR	10.4 ± 4.7 / 11.1 ± 5.9	NR	NR

注：^a表示差异有统计学意义 ($P < 0.05$)，R：机器人辅助腹腔镜；L：传统腹腔镜；NR：缺失值；Retro：回顾性研究；Prospective：前瞻性研究；RCT：随机对照试验。

等^[37]对患者术前和术后1年的泌尿生殖系统功能进行评估,也得出阴性结论。达芬奇机器人具有放大的3D图像,更容易识别盆腔自主神经,同时可以过滤手部震颤以进行精细解剖,在保护性功能和泌尿功能方面可能具有潜在优势,但仍需大样本研究进一步证实。

3.4 花费

高昂的手术费用和维护成本是阻碍机器人手术广泛应用的重要原因之一。许多研究者批评机器人手术,因为其与传统腹腔镜相比不具备压倒性的优势且费用更高昂。然而,在已发表的多数研究中,外科医生缺少大量的机器人手术经验,并且样本量较小,因此在与腹腔镜手术这种已经比较成熟的方法进行比较时,对机器人手术的评价可能出现严重偏倚。最近有研究观察到,随着机器人手术经验的增加,患者总住院费用降低^[49-50]。

4 结语与展望

从设计上来说,达芬奇机器人与腹腔镜相比优势十分明显,包括高清3D镜头、易于进行体内缝合的机械臂、更符合人体工程学等。但从数据上来看,机器人结直肠手术的围手术期结果、病理学结果、远期结果和总住院费用等与腹腔镜手术相比并无明显的优势,可能是由于大部分研究中的外科医生仍处于机器人手术学习阶段,远不如对腹腔镜手术熟悉。

总的来说,机器人辅助腹腔镜行结直肠手术是安全可行的,大致与传统腹腔镜手术相当。此外,机器人手术可能会降低手术中转率、加快肠道功能恢复,且有利于进行体内肠吻合和缩短学习曲线。机器人的技术特点决定其非常适合空间狭小、解剖复杂的盆腔内操作,它的视觉系统也有助于辨识解剖层次、更好的保留

自主神经和促进泌尿与性功能的术后恢复。

机器人手术主要缺陷包括成本高昂、缺少触觉反馈容易造成术中损伤、反复装配机械臂费时费力且彼此间易互相干扰、手术时间延长等。针对这些问题,许多研究团队也在不断更新或开发新型手术平台以克服机器人手术现有的不足。现已投入临床使用的达芬奇Xi系统与前代相比体型更小,活动范围更大,可以将腹腔镜连接到任何机械臂上,避免其互相干扰。已有研究对达芬奇Xi与达芬奇Si进行了比较,达芬奇Xi在直肠癌手术中的对接时间和手术时间更短^[51-52]。使用达芬奇Si进行体内缝合或牵拉等操作时,有时会因为机械臂互相碰撞而影响操作,增加手术难度^[53-54]。已获得美国食品药品监督管理局(FDA)认证的单孔手术机器人达芬奇SP(Single Port)系统解决了这一问题^[55]。它仅有1根机械臂,机械臂前端为可弯曲的器械臂和3D摄像头。除达芬奇机器人系统外,还有越来越多的手术机器人被研发出来。Senhance机器人手术系统于2017年10月获得FDA批准,其摄像机控制系统具有眼球追踪功能,可以实时地将镜头对准外科医师注视的位置,术者还可通过前后移动头部来控制镜头缩放,其手柄还具有1:1的压力触觉反馈。目前,已有相关研究证实Senhance手术机器人在结肠手术中的安全性^[56]。若将来人工智能高度发展,机器人手术系统可能会具有识别能力,能够感知具体的手术场景并做出反应,与术者进行高效的配合。相信随着各领域的新技术与机器人手术的不断结合,以及机器人手术经验的积累,机器人手术的优势会在以后的研究中得到证实。

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