

Original Article

# Robotic versus Laparoscopic Intersphincteric Resection for Low Rectal Cancer: Comparison of Short-term Clinical Outcomes

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## Key Words

Intersphincteric resection;  
Laparoscopic surgery;  
Robotic surgery

**Purpose.** The intersphincteric resection (ISR) technique has been employed to extend the opportunity for sphincter preservation in patients with low rectal cancer. The aim of this study was to compare the short-term outcomes for robot-assisted and laparoscopic ISR for rectal cancer.

**Methods.** One hundred and six patients with rectal cancer who underwent curative resection between November 2009 and April 2014 were included. Patients were classified into the laparoscopic group (n = 31), and the robotic group (n = 75). Data analyzed include estimated blood loss, operating time, time to first flatus passage, time to normal diet, length of hospital stay, histopathologic status including distal resection margin, status of circumferential resection margin (CRM), and number of lymph nodes harvested.

**Results.** Analyses on clinical results revealed mean estimated blood loss of 110.3 ml (range, 30-300 ml) in the laparoscopic group, and 69.7 ml (range, 30-200 ml) in the robotic group, indicating statistically significant difference ( $p = 0.004$ ). The mean operating time was 382.1 minutes (range, 210-600 minutes) in the laparoscopic group, and 466.2 minutes (range, 285-720 minutes) in the robotic group, also showing statistically significant difference ( $p < 0.001$ ). In contrast, there were no statistically significant differences in length of postoperative hospital stay, resumption of oral diet, and regaining of bowel peristalsis between these two operative procedures ( $p = 0.937, 0.149, \text{ and } 0.071$ , respectively).

**Conclusions.** The findings showed that robotic ISR, a minimally invasive approach for rectal cancer, has acceptable morbidity and mortality rates as well as reasonable oncological outcomes, but is currently too expensive with longer operating time compared with conventional laparoscopy.

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The greatest surgical challenge for low rectal cancer is radical tumor removal with sufficient surgical resection margins and restoration of bowel continuity to reach an acceptable quality of life. The devel-

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opment of surgical stapling devices provided sphincter preservation in most patients with rectal cancer.<sup>1</sup> However, for patients with bulky tumors, particularly in a narrow pelvis, stapling devices are still technically difficult to apply. Schiessel et al. first reported the intersphincteric resection (ISR) technique which has been employed to increase sphincter preservation by achieving greater distal clearance for patients with distal rectal cancers.<sup>2</sup> Several retrospective studies have shown that ISR is a safe and efficient surgical procedure for low rectal cancer treatment with surgical mortality of less than 1.6% and morbidity around 15%-18.8%. The local recurrence rate ranges from 2.5%-6.6%, and the 5-year survival rate is approximately 82%-96%.<sup>3</sup>

Several studies have shown that laparoscopic surgery provides benefits in the early postoperative period, including a shorter hospital stay, faster reappearance of bowel peristalsis, and resumption of oral diet, without increasing patients' morbidities or mortalities.<sup>4-6</sup> With advances in surgical technique and operative management, laparoscopic rectal surgery has become more widely used in recent years. However, laparoscopic surgery still has limitations such as restricted degrees of motion by the instruments, amplification of tremors, and assistant-dependent camera holding and viewing.<sup>7,8</sup> Robotic surgery has been developed to overcome the shortcomings of laparoscopic surgery. Compared with laparoscopic surgery, the robotic surgical system has three-dimensional visualization, tremor-free movements, stable operating platform, and superior dexterity by increasing degrees of motion.<sup>9-12</sup> This study aimed to assess the short-term oncological and clinical outcomes in low rectal cancer patients treated with either laparoscopic or robot-assisted surgical procedure.

## Materials and Methods

Patients with low rectal malignancy who received either conventional laparoscopic or robot-assisted ISR at Taipei Medical University Hospital (Taipei, Taiwan) between November 2009 and April 2014 were retrospectively chart reviewed. Laparoscopic ISR

has been performed since 2009. In December 2011, robotic surgery was introduced. Patients with biopsy proven malignancy of the rectum were arranged staging assessment including colonoscopy, chest radiography, abdominal sonography, pelvic magnetic resonance imaging (MRI), routine biochemistry and hematological studies, and measurement of carcinoembryonic antigen level. Patients were treated neoadjuvantly if they met all the following criteria: primary rectal cancer with no synchronous colon cancer; histological diagnosis of adenocarcinoma; no evidence of distant metastases; staging by magnetic resonance images belonging to T3 or T4 lesion, or nodal positive diseases; age between 18 years and 75 years; Eastern Cooperative Oncology Group (ECOG) performance score  $\leq 2$ ; and no history of prior chemotherapy or radiation therapy to the pelvis. Radiotherapy was administered five times per week with a daily fraction of 180 cGy. Twenty-five treatments were delivered to pelvis with a cumulative radiation dose of 4500 cGy, and then a boost of 540 cGy was added to the tumor bed for a total dose of 5040 cGy. Chemotherapy began with 5-fluorouracil-based regimens. Total mesorectal excision (TME) with ISR technique was performed six to eight weeks after completing chemoradiation therapy if the low rectal cancer initially showed no external sphincter or levator ani invasion.

### Minimally invasive surgical technique

All procedures were performed by a single surgeon (KLJ). The patient was placed in a 30-degree Trendelenburg position and at 15-degree right lateral tilting to prevent blocking of the operative field by the intestines. A five-port technique was routinely used in the robotic procedure. The abdomen was entered using the open method. A 10-mm port was placed 3 cm right and upward from the umbilicus as an optic port. The abdomen was then insufflated with CO<sub>2</sub> to create pneumoperitoneum with an intra-abdominal pressure of 12-15 mmHg. After inspecting the entire abdomen, a 8-mm port was placed in the right lower quadrant 10 cm away from the umbilicus and two other 8-mm ports were respectively placed in the left upper and lower quadrants. Another 12-mm port was

placed in the right upper quadrant as on-table assistant port.

The hybrid technique was adopted. The colon was mobilized from its lateral attachment and high ligation of the inferior mesenteric vessel was performed with laparoscopic procedure. Whether the splenic flexure of the colon was mobilized depended on the colon length. Then the da Vinci robotic system was docked after placing the robot in between the patient's legs and the following steps were performed. (1) The standard TME involved complete dissection down to the pelvic floor. Along the dissection plane, the intersphincteric space was entered from the posterior side of the rectum by separating the anococcygeal ligament. Circular dissection of the intersphincteric space was then performed from the bilateral lateral side to the anterior part. (2) After placing the patient in a high lithotomy position, the anal part of the operation was performed. The self-retaining retractor (Lone Star Retractor System®, Lone Star Medical Products Inc., Houston, TX) was used for easy perineal exposure. Incision started from the dentate line, followed by cephalic dissection to reach the abdominal dissection. (3) The specimen was extracted transanally. (4) A straight neorectum was created by pull-through of the descending colon and hand-sewn coloanal anastomosis was then performed.

### Conventional laparoscopic versus robot-assisted surgery

The outcomes measured for comparison between the conventional laparoscopic and the robotic groups included estimated operating time, blood loss, time to first flatus passage, time to normal diet, length of hospital stay, histopathologic status including distal resection margin, status of circumferential resection margin (CRM), and number of lymph nodes harvested.

### Statistical analysis

Statistical analysis was performed using SAS for windows (SAS, Cary, NC, USA). Categorical variables were compared using chi-square test while continuous variables were compared using student t-test.

Differences were considered significant if the *p* value was smaller than 0.05.

## Results

Records of consecutive rectal cancer patients with low rectal malignancy receiving a sphincter-saving operation involving the ISR technique and hand-sewn coloanal anastomosis from November 2009 to April 2014 were reviewed retrospectively. Table 1 shows the patient demographics and clinical results. As can be seen, 31 patients were treated with laparoscopic surgery, and 75 with robot-assisted surgery. There

**Table 1.** Demographic characteristics of patients and clinicopathologic results according to different surgical procedure

	Robotic	Laparoscopic	<i>p</i>
Age	57.3 ± 10.7	53.8 ± 15.2	0.192
Sex (male)	27 (36.0%)	11 (35.5%)	0.960
Distance from anal verge, cm	3.84 ± 1.18	3.71 ± 1.16	0.600
Preoperative chemoradiation	56 (74.7%)	30 (96.7%)	0.004*
Pretreatment T stage			0.697
T1	3 (4.2%)	0 (0.0%)	
T2	7 (9.7%)	3 (10.0%)	
T3	58 (80.6%)	26 (86.7%)	
T4	4 (5.6%)	1 (3.3%)	
Pretreatment N stage			0.441
N0	20 (27.8%)	12 (40.0%)	
N1	33 (45.8%)	11 (36.7%)	
N2	19 (26.4%)	7 (23.3%)	
Estimated blood loss (mL)	69.7 ± 53.4	110.3 ± 80.4	0.004*
Operating time (min)	466.2 ± 79.2	382.1 ± 95.4	< 0.001*
Diverting colostomy (Yes)	21 (28.0%)	12 (38.7%)	0.128
Hospital stay (d)	15.6 ± 7.4	15.7 ± 11.0	0.937
Time to first flatus (d)	3.0 ± 1.2	3.5 ± 2.3	0.149
Time to normal diet (d)	6.7 ± 2.0	5.8 ± 2.7	0.071
Distal resection margins (cm)	2.16 ± 1.51	1.82 ± 1.60	0.342
CRM (involved)	9 (12.0%)	5 (16.1%)	0.559
Lymph nodes retrieval number	14.8 ± 7.4	13.8 ± 6.7	0.495

yp = posttreatment pathologic stage; CRM = circumferential resection margin.

were 11 females (35.5%) and 20 males (64.5%) with a mean age of 53.8 years (range, 25 to 88 years) in the laparoscopic group. In the robotic group, 27 were females (36%) and 48 were males (64%) with a mean age of 57.3 years (range, 30 to 89 years). The mean distance from the anal verge to the lowest border of the tumor was 3.7 cm (range, 2.5 to 6.0 cm) in the laparoscopic group, and 3.8 cm (range, 1.5 to 8.0 cm) in the robotic group. Among the 102 patients with histology-proven adenocarcinoma, two had neuroendocrine tumor, and two had gastrointestinal stromal tumor. Among those with rectal adenocarcinoma, 30 patients (96.8%) of the laparoscopic group and 56 patients (74.7%) of the robotic group received neoadjuvant chemoradiotherapy (CRT) followed by surgery, with their initial MRI staging as followed: five patients had T2N1 rectal tumors, 17 patients were T3N0, 29 patients were T3N1, 27 patients had T3N2 lesion, 3 for T4N1, and 5 for T4N2 disease.

Analysis on clinical results revealed mean operating time of 382.1 minutes (range, 210-600 minutes) in the laparoscopic group, and 466.2 minutes (range, 285-720 minutes) in the robotic group, indicating statistically significant difference ( $p = 0.004$ ). The mean estimated blood loss was 110.3 ml (range, 30-300 ml) in the laparoscopic group, and 69.7 ml (range, 30-200 ml) in the robotic group, also revealing statistically significant difference ( $p < 0.001$ ). Twelve patients (38.7%) in the laparoscopic group received diverting stoma, including 10 patients (32.3%) received it during operation, and the other two patients (6.5%) had neorectum necrosis developed 7 to 10 days after surgery and received emergency laparotomy with a diverting colostomy. In contrast, 21 patients (28%) in the robotic group received diverting stoma; among them, two (2.7%) had emergency operation due to anastomotic leakage. There was no statistically significant difference between these two groups ( $p = 0.128$ ). As for clinical outcomes, there were no statistically significant differences in length of postoperative hospital stay, resumption of oral diet, and regaining of bowel peristalsis between these two operative procedures ( $p = 0.937, 0.149, \text{ and } 0.071$ , respectively). On pathologic examination, the mean distal resection margin was 1.8 cm (range, 0-3.0 cm) in the laparoscopic group

and 2.2 cm (range, 0.1-7.0 cm) in the robotic group, indicating no statistically significant difference ( $p = 0.342$ ). CRM involvement represents tumor presence directly at the resection margin or with a minimal distance of less than 1 mm between the tumor and the resection margin. In addition, complete clearance of CRM denotes a minimal distance of 1 mm between the tumor and the resection margin. In the present study, CRM involvement was found in 5 patients (16.1%) in the laparoscopic group and 9 patients (12%) in the robotic group, showing no statistically significant difference ( $p = 0.559$ ). The mean number of lymph nodes harvested was 13.8 (range, 5-28) in the laparoscopic group and 14.8 (range, 2-42) in the robotic group, again indicating no statistically significant difference ( $p = 0.495$ ).

## Discussions

The incidence of rectal cancer has remained on the rise both among those of younger age and in the Asia-Pacific region.<sup>13</sup> In the United States of America approximately 132,700 new cases of colorectal cancer are diagnosed each year, of which 39,610 are rectal cancers.<sup>14</sup> About 50-60% of rectal carcinomas are considered locally advanced rectal cancers (LARC), which are characterized by high incidence of systemic and local recurrence and low possibility of long-term survival.<sup>15</sup> Neoadjuvant CRT, state-of-the-art treatment for LARC, has been shown to increase tumor resectability, thus achieving the high success rate of sphincter-saving operations.<sup>16-19</sup> One of the oncological principles of rectal cancer surgery is to attain an adequate bowel resection margin for preventing the risk of microscopic tumor expansion. According to the practice guidelines for managing rectal cancer, the distal resection margins should be  $\geq 2$  cm.<sup>20</sup> Consequently, a 1-cm distal resection margin has been suggested to be adequate for patients receiving preoperative CRT.<sup>21,22</sup> Traditionally, low rectal cancer located less than 5 cm from the anal verge is treated by abdominoperineal resection (APR) with a permanent colostomy. The development of surgical stapling devices has provided an aid in sphincter preservation for

most patients with low rectal cancer. (1) However, for patients with bulky and low-lying tumor, particularly in a narrow pelvis, stapling devices are still technically difficult to apply. Despite the advances in multimodality therapy, sphincter preservation remains a surgical challenge for patients with low-lying rectal tumors. ISR has been described as an ultimate surgical technique for increasing sphincter preservation by achieving greater distal resection margins for patients with low-lying rectal cancers. In the present study, the tumors were located at a mean of 3.80 cm from the anal verge. Traditionally, all of these patients would have required APR, followed by an abdominal colostomy. The ISR technique used in this study achieved sphincter preservation while maintaining adequate resection margins.

Laparoscopic resection of rectal cancer is safe but technically demanding with a steep learning curve. The technical challenges of conventional laparoscopic surgery include limited range of motions of instruments in a narrow pelvic cavity, an inadequate visual field with an unstable camera view, relative loss of dexterity and retraction of assistant beyond direct control of the surgeon.<sup>7,8</sup> The advantages of the da Vinci robotic system, such as the seven degrees of freedom of movement mimicking movements of the surgeon's wrist, the three-dimensional view, no tremor at all, scaled-down movements and superior ergonomics, are extremely useful for pelvic surgery. These advantages have been best demonstrated by urologists in robot-assisted radical prostatectomy. In a short span of 3 years, robotic radical prostatectomy has increased from 41% to nearly 80% in 2008.<sup>23</sup> Multiple robot-assisted reports are mature enough to demonstrate safety, efficiency and reproducibility, with oncological and functional outcome comparable to open surgery.<sup>24-26</sup> In general, most studies reported a longer operating time for robot-assisted surgery. This together with the lack of tactile feedback and higher cost are disadvantages of robotic surgery. Data of the present study showed that robotic ISR for rectal cancer achieved acceptable morbidity and mortality rates and reasonable oncological outcomes, but is currently too expensive with longer operating time compared with conventional laparoscopy.

One of the important issues for prognostic impact is the CRM of surgical specimens. It was concluded by the Norwegian Rectal Cancer Project that a CRM of 2 mm or less confers a poorer prognostic factor in patients with rectal cancer.<sup>27</sup> The present data showed higher CRM rate (13.2%) in patients undergoing ISR. In this study, 84.3% of the patient population had locally advanced colorectal cancer. Detailed analysis on the distribution of cancer staging of patients in the published literature revealed that for study cohorts comprising a higher number of locally advanced patients, the CRM positivity exceeded 10%. In the series of Rullier et al., most of their 92 cases had LARC and received preoperative neoadjuvant CRT, and their positive CRM rate was 11%.<sup>28</sup> The present findings are consistent with previous results showing higher percentage of advanced patients. This explains why low CRM positivity of 3% and 4% were reported by Schiessel and Portier, respectively.<sup>29,30</sup>

This study observed in patients undergoing ISR procedure several surgically related anorectal disorders, such as swelling and painful hemorrhoid, neorectal mucosal prolapse, and anal stenosis. However, little attention has been paid to anorectal disorders after ISR and its management. In the present study, 80 patients (75.5%) experienced swelling and painful hemorrhoids after the surgery and the operating time was strongly associated with the occurrence of hemorrhoids. Forty-five patients (42.5%) developed anal stenosis, necessitating anal dilatation under spinal anesthesia. Traditionally, splenic flexure of the colon takedown mobilization was routinely performed for rectal cancer surgery. To ensure good blood supply and better wound healing at the anastomotic site, tension-free approach is essential through splenic flexure takedown, especially in patients with very low rectal cancer. In addition, this study has found that male gender and body mass index were associated with anal stenosis. Twelve patients (11.3%) had neorectal mucosal prolapse and the occurrence of rectal prolapse was on average 98 days after ISR. Further prospective randomized trials are needed to assess the long-term functional outcomes of patients complicated with anorectal disorders after ISR for low rectal cancer.

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原 著

## 低位直腸癌使用腹腔鏡或機器人輔助手術 兩種不同手術方式進行“經肛門括約肌間分離 手術”，其臨床和病理學上的分析和比較

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**目的** “經肛門括約肌間分離手術”是提高“低位直腸癌”病人肛門保留的手術方式。本研究的目的，在比較腹腔鏡微創手術、或機器人輔助手術這兩種不同手術方式進行“經肛門括約肌間分離手術”，其臨床上和病理學上的差異。

**方法** 自民國 98 年 11 月到民國 103 年 4 月，我們對 106 位接受“經肛門括約肌間分離手術”的患者進行回顧性的分析。其中包括了 31 位病人接受腹腔鏡微創手術，75 位病人接受機器人輔助手術。臨床的資料，包括了病人的年齡，性別，臨床分期，手術時間，出血量，手術後臨床情況，和病理結果進行分析研究。

**結果** 在腹腔鏡組上，平均估計失血量是為 110.3 毫升（範圍，30-300 毫升），在機器人輔助手術這組平均估計失血量是 69.7 ml（範圍，30-200 毫升）。估計失血量在這兩組之間有顯著性的差異（ $p = 0.004$ ）。在腹腔鏡組平均手術時間為 382.1 分鐘（範圍，210-600 分鐘），機器人輔助手術組為 466.2 分鐘（範圍 285-720 分鐘），平均手術時間在這兩組間有統計學上顯著差異（ $p < 0.001$ ）。在平均住院天數，手術後恢復正常飲食，及手術後腸胃道開始蠕動時間上，在腹腔鏡組和機器人輔助手術組兩組並無統計學上的差異（ $p = 0.937, 0.0149, 0.071$ ）。

**結論** 我們提出我們以微創手術治療低位直腸癌的經驗。根據我們目前的研究結果顯示，機器人直腸手術的臨床結果，不管在住院日數，手術併發症，腫瘤學上的分析，和轉換成其他方式手術的比率，都與腹腔鏡微創手術沒有明顯統計學上的差異，但仍需更多的前瞻性實驗設計，和更大量的資料統計，才能再做更進一步的臨床結果，甚至長時間腫瘤學上預後分析的結論。

**關鍵詞** 機器人輔助手術、經肛門括約肌間分離手術、低位直腸癌。