

Original Article

Technical Feasibility and Oncological Outcomes of Robotic Transabdominal Intersphincteric Resection for Distal Rectal Cancer

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Key Words

Distal rectal cancer;

Robotic intersphincteric resection

Purpose. To evaluate the technical feasibility and oncological outcomes of robotic intersphincteric resection within our institution.

Methods. A total of 30 patients who underwent robotic intersphincteric resection for rectal cancer from November 2013 to July 2024 were retrospectively enrolled. Data on patient characteristics and perioperative outcomes were collected.

Results. The mean operative time was 355.37 (\pm 81.03) min, while the blood loss was 166.67 (\pm 127.53) ml. Clavien-Dindo grade \geq III complications that required reoperation occurred in 4 patients (13.33%). There was no complication-related mortality. The median follow-up period was 32.00 (4-77) months. The estimated 3-year disease free survival and overall survival were 64.5% and 88.9%, respectively.

Conclusions. The present study indicated that robotic approach could be safely applied for transabdominal top-down intersphincteric resection with acceptable perioperative and oncological outcomes. However, further recruitment of cases with long term follow up are needed to accumulate more scientific data.

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Colorectal cancer ranks as the third most common type of cancer, and it is the second leading cause of cancer-related deaths worldwide, with rectal cancer comprising approximately one-third of these cases.¹ As surgical techniques and neoadjuvant therapies have improved throughout the decades, the focus has shifted from abdominoperineal resection (APR) with permanent colostomy to intersphincteric resection (ISR) and coloanal anastomosis for distal rectal cancer.²

When ISR was first introduced,³ the surgery was carried out by both abdominal and perineal surgeons.

The left colon and the rectum were mobilized down to the levator ani by the abdominal surgeon, while the perineal surgeon circularly incised the anal mucosa, exposed and circumferentially divided the internal sphincter, and continued upward dissection into the pelvic cavity under guidance of the abdominal surgeon. Transanal total mesorectal excision (taTME)⁴ was later shown to provide a better distal resection margin, less circumferential resection margin involvement since the anatomy landmark was more clearly visible under transanal laparoscopy guidance.

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Following the development of a robotic platform, specifically the da Vinci Surgical System, which addressed the technical limitations of the laparoscopic approach, the adoption of the robotic method for rectal cancer treatment has considerably increased. The da Vinci Surgical System not only provides improved ergonomics but also eliminates physiological tremors. It adds an extra working arm, enhances dexterity with articulated instruments offering 7 degrees of freedom, and introduces a magnified 3-dimensional stereoscopic stable camera controlled by the surgeon.⁵

Some authors have published studies on robotic ISR. Park et al. reported 3-year local recurrence rates ranging from 1.9% to 11.5%, with a weighted mean of 6.7%. Additionally, the reported 3-year overall survival (OS) and disease-free survival (DFS) rates were as follows: OS = 89.0-98.6% (weighted mean = 93.8%) and DFS = 84.1-95.9% (weighted mean = 89.6%).⁶

Although robotic techniques for rectal cancer are expanding, more evidence is needed on robotic ISR for low rectal cancer. We hypothesized that with the increased maneuverability of the current robotic system, the ISR procedure can be simplified and safely performed by transabdominal approach.

Materials and Methods

Study population

We conducted a retrospective study including consecutive patients admitted to National Taiwan University Hospital who received robotic transabdominal ISR with the da Vinci robotic platform between November 2013 and July 2024. Patients were eligible for inclusion if they were (1) diagnosed with clinically resectable T1-T3 distal rectal cancer located at the surgical anal canal (approximately 5 cm from the anal verge) and (2) 18 years of age or older. Exclusion criteria for the robotic approach were as follows: (1) severe multiple comorbidities; (2) previous multiple abdominal surgeries; (3) locally advanced which could not achieve R0 resection or stage 4 disease. Finally, a cohort of 30 patients was enrolled.

Data collection

Clinical and demographic data (sex, age, BMI, American Society of Anesthesiologists (ASA) score, clinical staging, tumor location, neoadjuvant chemotherapy, and previous abdominal surgery), intraoperative data (operative time, blood loss, and diverting enterostomy), and postoperative outcomes (30-day morbidity, mortality, reoperation rate, and length of hospital stay) were retrospectively collected.

Postoperative complications were classified according to the Clavien-Dindo classification.⁷ Complications classified as Clavien-Dindo grade I and II were minor complications that did not require invasive management, whereas Clavien-Dindo grade III and IV complications required surgical, endoscopic, and radiologic intervention (grade III) or were life-threatening complications requiring intensive care unit management (grade IV).

Pathological staging was performed according to the TNM classification (AJCC Cancer Staging System, 8th edition). The distal margin, tumor size, and harvested lymph nodes were evaluated.

Long-term outcomes were analyzed, including the rates of both local and distal recurrence, and OS.

Surgical techniques

Bowel preparation was started 2 days before the surgery. Neomycin and metronidazole were given at the same time to reduce intestinal bacteria. Cefmetazole (1 g) was given 30 min to 1 h before surgery as a prophylactic antibiotic.

The surgery was started with four 8 mm trocars placed at the mid-upper, left upper, and left and right lower abdomen, while a 12 mm assistant port was made in the right abdomen. The distance of every trocar was set at least 8 cm (Fig. 1). All patients received single docking total robotic surgery with the da Vinci Xi Surgical System after they were placed in the Trendelenburg position with the left side higher.⁸

We started from the inferior mesenteric vein (IMV) and inferior mesenteric artery (IMA) dissection. After adequate lymph node dissection (at least D2 to D4 lymph node dissection according to the clinical lymph

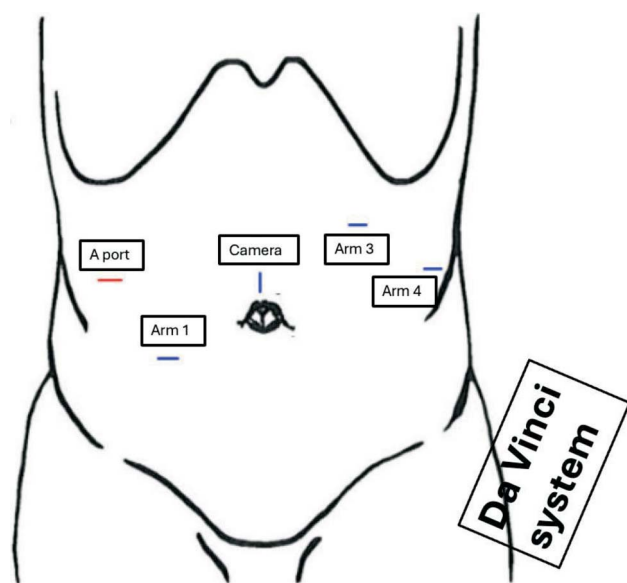


Fig. 1. Robotic ports and arms setting. The camera port trocar is set over the supraumbilical area. The right lower port for Arm-1 is set over McBurney point. The ports for Arm-3 and Arm-4 are set over the right upper quadrant. The distance of every trocar was set at least 8 cm. The A-port is set over right abdomen for assistant.

node status), IMA low ligation was performed by preserving the left colic artery. The left colon was mobilized, from lateral to medial, upward to the splenic flexure and downward to the presacral area. The puborectal muscle was separated from the rectal tube and the intersphincteric groove was accessed below the mesorectal envelope's lower margin. Incision of the intersphincteric space between the internal and external anal sphincter was performed.⁹ After the rectum was transected, transabdominal specimen extraction was done via the left lower abdominal incision. The coloanal anastomosis was re-established with the double-stapling technique (size: 31 mm). A protective ileostomy was created when there were anastomotic imperfections, anastomosis under tension, previous pelvic irradiation, ultralow anastomosis in patients older than 70 years, and significant co-morbidities.^{10,11}

Follow-up

Adjuvant chemotherapy or management for solitary metastasis was provided based on histopatho-

logical staging.¹² All patients were followed up every 3 months within the first 2 years after the surgery, every 6 months within 3-5 years, and annually thereafter. Tumor marker testing, computed tomography, and colonoscopy were performed alternately at every visit.

Study outcomes

The primary outcome of the study was the peri-operative outcomes. Secondary endpoints were the recurrence rate and OS.

Statistical analysis

All analyses were carried out using SPSS version 23. Continuous data are expressed as the mean \pm standard deviation, and categorical data are presented as the number and percentage. Cumulative recurrence rate, OS and DFS were quantified using Kaplan-Meier curves.

Results

During the study, a total of 34 patients with distal rectal cancer were assessed for the study enrollment from 2013 to 2024 (Fig. 2). Among all, 30 patients had a clinical staging below stage 3. All 30 patients received robotic ISR and achieved R0 resection during the surgery. No patient lost follow up by the end of year 2024. The median follow-up period of the study population was 32.00 (4-77) months.

The clinical and demographic characteristics of the study cohort are presented in Table 1. All patients had distal rectal cancer [30 (100%)]. Among these patients, there were 18 male (60.00%) and 12 female (40.00%) patients. A total of 18 (60.00%) patients had clinical stage III disease. 11 (36.67%) patients underwent neoadjuvant radio-chemotherapy. Although 5 (16.67%) patients had a history of abdominal surgery, it did not affect the robotic procedure.

The mean operative time was 355.37 (\pm 81.03) min, while the blood loss was 166.67 (\pm 127.53) ml. A total of 17 (56.67%) patients received a diverting

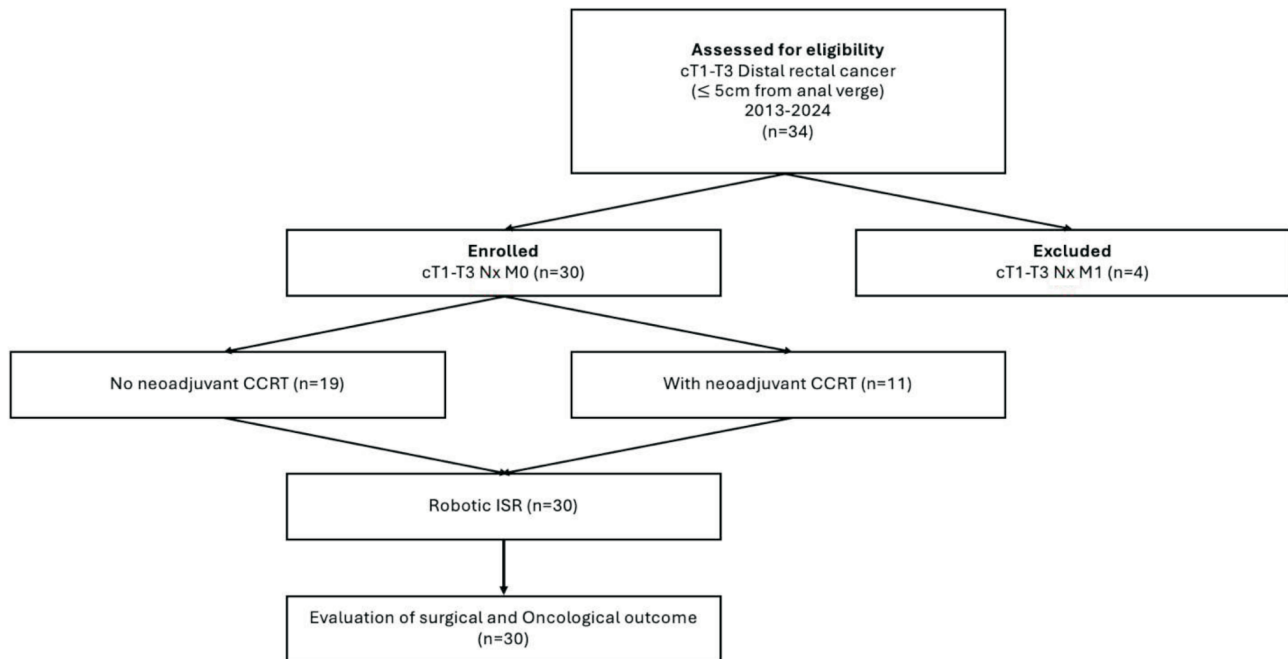


Fig. 2. Flowchart for patients recruited for robotic ISR.

Table 1. Demographic and clinical characteristics

Total cases, n	30	
Sex, n (%)		
Male	18	60.00%
Female	12	40.00%
Age, mean (±SD) (years)	62.27	13.95
BMI, n (%)		
< 18.5	1	3.33%
18.5-24.9	15	50%
25-30	13	43.34%
> 30	1	3.33%
ASA, n (%)		
1-2	12	40.00%
3-4	18	60.00%
Preoperative clinical staging, n (%)		
Stage I	9	30.00%
cT1N0M0	1	3.33%
cT2N0M0	8	26.67%
Stage II	3	10.00%
cT3N0M0	3	10.00%
Stage III	18	60.00%
cT2N1M0	1	3.33%
cT3N1M0	3	10.00%
cT3N2M0	14	46.67%
Tumor location, n (%)		
Distal rectum	30	100%
Neoadjuvant CCRT, n (%)	11	36.67%
Previous abdominal surgery, n (%)	5	16.67%

ostomy mainly due to preoperative radio-chemotherapy, old age, and a high comorbidity status. The mean length of hospitalization was 19 (± 11.93) days. The 30-day postoperative morbidity rate was 20.00% (6 patients). The rate of severe postoperative complications (Clavien-Dindo grade ≥ III) was 13.33% (4 patients). The most common major complications were postoperative acute bleeding and rectovaginal fistula, requiring reoperation in 4 (13.33%) cases. The 30-day postoperative mortality rate was 0% (0 patients) (Table 2).

Pathological data and long-term outcomes are presented in Table 3. The mean distal margin of the tumor

Table 2. Intraoperative and postoperative outcomes

Operative method, n (%)		
Robotic ISR	30	100%
Operative time, mean (±SD) (min)	355.37	81.03
Diverting ostomy, n (%)	17	56.67%
Blood loss, mean (±SD)	166.67	127.53
30-day morbidity, n (%)	6	20.00%
Clavien-Dindo I-II	2	6.67%
Clavien-Dindo III-IV	4	13.33%
Reoperation, n (%)	4	13.33%
Hospital stay, mean (±SD) (days)	19	11.93
30-day mortality, n (%)	0	0%

was 1.42 (\pm 1.35) cm. Distal margin positivity was not documented in any case. All patients had more than 12 lymph nodes removed, with a mean of 25.03 (\pm 18.03) harvested. A total of 12 (40.00%) patients were diagnosed with pathological stage III disease. 14 (46.67%) patients received adjuvant treatment.

Follow-up was completed for all patients. A total of 9 patients (30.00%) developed tumor recurrence or progression during the follow-up. Among them, 3 patients experienced local recurrence, while 4 patients

concurrently developed local recurrence and distal metastases. Distal metastasis was observed in 2 cases.

Fig. 3 shows the analysis of long-term outcomes in terms of DFS and OS. Of 30 patients, the estimated 3-year DFS and OS were 64.5% and 88.9%, respectively.

Discussion

We performed a retrospective analysis of a single surgeon's experience in a tertiary referral center on robotic transabdominal ISR for low rectal cancer. We aimed to assess the effectiveness of this minimally invasive approach in ensuring both short-term and long-term surgical outcomes. According to our results, robotic transabdominal ISR is a safe and feasible procedure. Surgical candidates should be carefully chosen to ensure optimal long-term oncological outcomes.

A meta-analysis conducted by Lee et al.¹⁸ found that robotic ISR was significantly longer than laparoscopic ISR (330.3 ± 99.3 min vs. 287.6 ± 81.7 min; MD, 41.89; 95% CI, 15.51-68.27; $p = 0.002$). The average operation time in our study was $355.37 (\pm 81.03)$ min. Although robotic ISR requires a longer time, it provides better exposure of the narrow pelvis, aiding in the identification of anatomical landmarks for a safer oncological procedure.¹⁹ Moreover, the robotic system enhances the accuracy of the dissection plan and lymph node procedures by allowing superior visualization, improved dexterity, and increased accuracy.

Table 3. Pathological characteristics and long-term outcomes

Distal margin, mean (\pm SD)	1.42	1.35
Tumor size, mean (\pm SD)	3.44	1.60
Harvested LN, mean (\pm SD)	25.03	18.03
Pathological staging, n (%)		
Stage 0	2	6.66%
pT0N0M0	2	6.66%
Stage I	8	26.67%
pT1N0M0	1	3.33%
pT2N0M0	7	23.34%
Stage II	8	26.67%
pT3N0M0	8	26.67%
Stage III	12	40.00%
pT1N1M0	2	6.67%
pT2N1M0	3	10.00%
pT3N1M0	6	20.00%
pT3N2M0	1	3.33%
Adjuvant treatment, n (%)	14	46.67%
Recurrence, n (%)	9	30.00%
local	3	10.00%
Local + distal	4	13.33%
Distal	2	6.67%
Mortality at follow-up, n (%)	6	20.00%

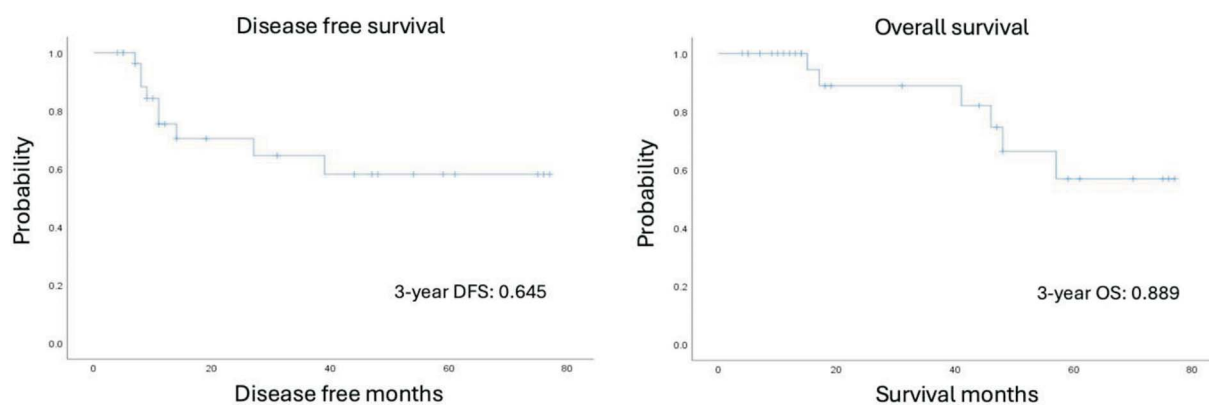


Fig. 3. Kaplan-Meier curve of all patients.

Complication rates for robotic ISR range from 15.2% to 40.7%, with an average of 20.5%.¹⁵ This variation may be attributed to differences in data collection quality between studies. Kazou et al.²⁰ summarized the outcomes of open and laparoscopic ISR from 22 articles. The post-operative morbidity rate of open ISR and laparoscopic ISR varies from 7.5-38.3% and 12.5-32.1% respectively, while the mortality rate was 0-1.7% and 0-1.1%.

In the present study, we had a morbidity rate of 20% and mortality rate of 0%, which seems to be comparable to open and laparoscopic ISR. We reported complications according to the Clavien-Dindo grading system in our study. We observed that 13.33% of patients experienced Clavien-Dindo grade \geq III complications. In comparison, Lee et al.¹⁸ and Piozzi et al.¹⁷ reported complication rates of 9.52% and 17.8%, respectively. The most common postoperative complications mentioned in other studies include acute bleeding, anastomosis leakage, postoperative ileus, and anastomotic stricture. In this study, 3 (10.00%) of our patients experienced acute bleeding, and 1 (3.33%) patient developed a rectovaginal fistula. There were no instances of anastomosis leakage. Lack of tactile feedback could potentially cause undetected tissue injury and bleeding, and the high power of robotic instruments might result in burn injuries to the vaginal area during the dissection of the recto-vaginal plane. Anastomosis leakage was not observed in our patients primarily due to protective ileostomy for patients with a high risk of anastomosis leakage, particularly older adults with significant comorbidities and those who underwent preoperative radio-chemotherapy. To prevent anastomotic stricture, we employed a 31 mm double-stapling technique for coloanal anastomosis,^{21,22} released the splenic flexure to reduce tension on the anastomosis, and performed a high dissection with low ligation of the inferior mesenteric vessels to maintain adequate blood supply.

Park et al.⁶ reported 3-year OS rates ranging from 89.0% to 98.6% with a weighted average of 93.8% and DFS rates ranging from 84.1% to 95.9% with a weighted average of 89.6% for robotic ISR. Kazou et al.²⁰ demonstrated a 0-22.7% local recurrence rate, 77% 3-year DFS and 81.6% 3-year OS for open ISR,

while laparoscopic ISR had a 2.6-8.2% local recurrence rate, 75-90.5% 3-year DFS and 86.6-94.8% 3-year OS. Another study Lin et al.²³ conducted in Taiwan for rectal cancer \leq 6 cm from the anal verge showed a 22.5% local recurrence rate, 56.6% 3-year DFS and 73.6% 3-year OS for laparoscopic TME.

In our study, our estimated 3-year DFS and OS were 64.5% and 88.9%, while the local recurrence rate was 23%. We had a slightly higher recurrence rate and worse 3-year DFS compared to Kazou et al. This difference may be attributed to the low implementation rate of neoadjuvant treatment, with 36.7% patients with clinical T3 or node positive disease receiving surgery directly, an inadequate number of cases (particularly during the COVID-19 pandemic), and inadequate long-term follow-up. However, post-operative systemic treatment was administered based on the pathological status, the 3-year overall survival rate of these patients appears to be comparable.

There are still controversies over the indications for robotic ISR. As an alternative to abdominal perineal resection, ISR is an anus-preserving technique for treating patients with low rectal cancer. General indications for robotic ISR are T1-T3 low rectal cancer (1-5 cm from the anal verge) with well/moderate tumor differentiation.¹³⁻¹⁵ With the advancement of the robotic surgery, the indications of robotic ISR were extended. Park et al.¹⁶ extended the indications to clinical stage T4 patients with downstaging, and Piozzi et al.¹⁷ extended the indications to patients with post-nCRT clearance of external anal sphincter/levator ani muscle (EAS/LAM) infiltration (regardless of T stage) if a curative resection was considered technically feasible.

In this study, we only recruited patients that achieved the general indications for ISR, including T1-T3 low rectal cancer. None of our patients had poor tumor differentiation. Robotic transabdominal ISR was initially not considered for patients with extensive cancer status; therefore, we only had a limited number of cases. After the robotic ISR technique matured, the indications of robotic ISR in our institute could be extended under the premise of achieving R0 resection.

This study has several limitations, including its retrospective design, very limited patient sample size,

insufficient long-term follow-up, lack of functional outcome and quality of life analysis. Of all patients, one had sexual dysfunction while 15 patients required temporary or long-term anti-diarrheas agent for post-operative low anterior resection syndrome (LARS). However, the severity and the duration of these symptoms were not evaluated since some patients continue their further treatment at the Oncologist clinic, making it difficult to follow up and complete the functional and quality of life questionnaires regularly. In the future, our aim is to establish a questionnaire to evaluate the patients' functional and quality of life. While the study demonstrated that robotic ISR is a safe procedure, there is potential for improvement in long-term recurrence outcomes. Therefore, randomized studies involving highly skilled surgeons with standardized operative techniques, carefully selected candidates and neoadjuvant treatment for designated patients are necessary to demonstrate the surgical benefits of robotic ISR.

Conclusion

By using robotic approach, we can simplify the ISR procedure. That is, the whole surgery can be performed transabdominally with the sparing of the time-consuming transanal procedure.

Declarations of Interest

None.

Financial Disclosure

None to declare.

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原 著

運用機器人手術進行低位直腸癌之經腹腔肛門括約肌間切除術的可行性和癌症治療成果評估

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目的 探討機器人括約肌間切除之手術及腫瘤學預後。

方法 本回溯性研究分析了 30 位接受機器人括約肌間切除手術之低位直腸癌病患。這些病例來自單一醫療中心，蒐集期間為 2013 年 11 月至 2024 年 7 月，並追蹤至 2024 年 12 月。我們整理了病患的臨床資訊、腫瘤分期與病理結果，並分析了手術結果、五年疾病復發率與五年整體存活率。

結果 本研究收案 30 位低位直腸癌病患。機器人括約肌間切除的平均手術時間為 355.37 (± 81.03) 分鐘，流血量為 166.67 (± 127.53)。Clavien-Dindo grade \geq III 的併發症發生於 4 位 (13.33%) 病患，且這些病患也因併發症接受了二次手術。然而，沒有病患因機器人括約肌間切除手術及其併發症而死亡。術後追蹤時間中位數為 32.00 (4-77) 個月。所有病患，三年整體存活率與無疾病存活率各為 64.5% 和 88.9%。

結論 本研究表明，機器人技術可安全地應用於經腹腔自上而下的括約肌間切除手術，且具有可接受的手術結果和腫瘤學預後。然而，此研究需進一步招募更多病例並進行長期追蹤，才得以累積更多的科學數據。

關鍵詞 低位直腸癌、機器人括約肌切除術。