No beneficial effect on survival but with a decreased postoperative adverse events for robotic surgery in patients with rectal cancer: A retrospective cohort study

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Abstract

Aim

To compare the oncologic outcomes in patients with rectal cancer receiving robotic *vs.* laparoscopic surgery.

Methods

The clinical data of patients with rectal cancer receiving robotic surgery (Robot group, n = 317) or laparoscopic surgery (Laparoscopy group, n = 224) were collected for outcomes assessment. The primary endpoints were the survival outcome. The secondary outcomes were postoperative adverse events and pathologic characteristics.

Results

Patients in the Robot group have significantly shorter operation time (163.6 ± 41.1 *vs.* 190.6 ± 52.5min), shorter time to 1st gas passing [2(1) *vs.* 3(1)d] and shorter hospital day [7(2) *vs.* 8(3)d], compared to those in Laparoscopy group ($P < 0.001$, respectively). The incidence of urinary retention short- and long term in Robot group is significant lower than in Laparoscopy group (1.9% *vs.* 10.7%; 0.6% *vs.* 4.0%, $P < 0.05$, respectively). TNM stage II and III was more frequently observed in the Robot group than that in the Laparoscopy group (94.3% *vs.* 83.5%), whereas stage I was more common in the Laparoscopy group than in the Robot group (5.7% *vs.* 16.5%). No significant difference in the overall survival (OS) and disease-free survival (DFS) were observed in Robot group and Laparoscopy group at 1-, 3- and 5-year. By a multivariable-adjusted analysis, the robotic surgery was not an independent prognostic factor for OS and DFS.

Conclusions

A beneficial effect on survival of the robotic surgery for rectal cancer could not be demonstrated. However, the robot is a feasible surgical procedure due to the decreased postoperative adverse event.

Introduction

Colorectal cancer ranks third in terms of incidence but second in terms of mortality worldwide[1]. Thus, it is of urgent need to improve every treatment method for colorectal cancer, including surgical procedures. Minimally invasive techniques have allowed the use of laparoscopic approaches in the treatment of patients with colorectal cancer based on similar or better perioperative and oncologic outcomes [2, 3], and it has been regarded as an alternative to conventional open surgery[4, 5, 6]. However, in rectal cancer, a laparoscopic approach is quite different and more difficult than that in colon cancer. Procedures such as dissection deep into the pelvis to accomplish a total mesorectal excision (TME) and obtain a specimen with complete margins, as well as a safe anastomosis, are technically challenging. Surgeons are faced with challenges such as a narrow pelvic cavity, anatomical complexity, and restricted surgical view during laparoscopic surgery, although previous studies reported that laparoscopic rectal cancer surgery was feasible[7, 8]. However, laparoscopic rectal surgery has been attributed limited dexterity with non-articulating unstable instruments, unnatural hand-eye coordination, and flat 2-dimensional (2D) vision[9]. Thus, the robotic system seems potentially suited for the surgical treatment of rectal cancer due to its theoretical advantages and it has been introduced in many centers since its first adoption in 2001[10].

The robotic system provides a high-definition 3-dimensional vision, attenuated physiologic tremor, robotic camera control, thus eliminating dependence on a surgical assistant and better ergonomics, resulting in reduced surgeon fatigue. However, there are not sufficient data to support the adoption of the robotic system instead of laparoscopic surgery for rectal cancer. Several previous studies documented that robotic surgery is equivalent to laparoscopic surgery with respect to the perioperative and oncologic outcomes[11, 12, 13]. To date, there are few reports with data to evaluate the short-term and long-term outcomes of robotic surgery compared with laparoscopic surgery for rectal cancer. No sufficient data from a large cohort is available to support the adoption of the robotic system for rectal cancer instead of laparoscopic surgery. Our center is one of the earliest hospitals that introduced da Vinci® surgical system (Intuitive Surgical, Sunnyvale, CA, USA) in China. Here we shared our comparative study data about short-term and long-term outcomes after robotic versus laparoscopic surgery for rectal cancer.

Methods

Patient selection

The prospectively collected records of all patients at the first affiliated hospital of Nanchang University between March 2011 and December 2018 with histologically proven rectal adenocarcinoma were retrospectively reviewed. All patients were separated into two groups: a Robot group, in which the patients received robotic surgery and an Laparoscopy group, in which the patients received laparoscopic surgery. All patients included in this study fit the following criteria: the disease was histologically defined rectal adenocarcinoma; all the patient underwent TME; tumor size was measurable, and pathological evaluation records of pelvic lymph nodes were complete; the patient had no history of malignancy in other organs; the clinicopathological and follow-up data of the patients were complete. The exclusion criteria were as follows: age>80 and <18 y; with other malignant tumors; TNM stage at 0, ; multi-visceral resection; palliative resection; restaging surgery; abdominal and pelvic exploration only; incomplete patient information.

Before surgery, all patients were informed of the detailed characteristics of both robotic and laparoscopic surgical procedures. After informed consent, the patients decided their preferred approach. The study protocol followed the Ethical Guidelines of the 1975 Declaration of Helsinki, revised in 2000. All related procedures were performed with the approval of the Internal Review and the Ethics Boards of the First Affiliated Hospital, Nanchang University.

Data collection and outcome evaluation

The following clinical and demographic information was collected: age, sex, body mass index (BMI)， carcinoembryonic antigen (CEA), American Society of Anesthesiologists (ASA) class , tumor location from anal verge, preoperative chemoradiotherapy (CRT), clinical T stage. The intraoperative and perioperative conditions (e.g., operation time, intraoperative bleeding, complications), postoperative adverse events (e.g., anastomotic leakage, bleeding, wound problem, urinary retention, ileus) and survival time were also collected.

The baseline characteristics of patients at enrolment were assessed within 24 hours before robotic or laparoscopic surgery. The primary outcomes for this study were survival outcome including overall survival (OS) and disease-free survival (DFS). The secondary outcomes were postoperative adverse events and pathologic characteristics. Patients were followed up for 5 years, or until Dec 31, 2018. Operative death was defined as death within 30 days of the operation or any time after the operation if the patient did not leave the hospital alive. Long-term complications were defined as postoperative complications that occurred after the 30th postoperative day[14].

Surgical procedures

All procedures, including robotic surgery using the da Vinci® surgical system and laparoscopic surgery, were performed or supervised by a single surgeon (T-Y Li). Briefly, same principle and steps were applied in both the laparoscopic and robotic surgery procedures: ligature of inferior mesenteric blood vessels close to the origin, mobilization of the sigmoid colon and rectum using sharp dissection, complete splenic flexure takedown for mid and low rectal cancer, clamping below the tumor, and washing of the rectal stump with 10% povidone-iodine before rectal transection. End-to-end anastomosis was then performed by either mechanical circular stapling or manual anastomosis. The anastomosis was tested with air inflation. Abdominoperineal excision was performed when the levator ani muscle had been invaded by the tumor. In some patients, a temporary ileostomy was conducted to protect the anastomosis, with digestive tract reconstruction performed 3 months later.

Statistical Analysis

In the univariate statistical analyses, the χ^2 or Fisher's exact test was used for categorical variables. Student's t-test and the Mann-Whitney U test were used for continuous variables. The results are presented as frequencies (percentages), mean ± standard deviation (SD) or median (interquartile range). Survival curves were obtained by Kaplan-Meier method, and the OS and DFS rates were compared by log-rank test. The Cox proportional hazard regression model was used to identify factors that were independently associated with OS and DFS. The candidate covariates for univariate analysis included age, sex, BMI, CEA, ASA class , tumor location, with robotic surgery, with preoperative CRT, with previous abdominal surgery, lymph nodes retrieved, proximal resection margin (PRM), distal resection margin (DRM), TNM stage, differentiation grade, circumferential resection margin (CRM), and lymphovascular invasion. Only factor which was $P < 0.05$ in univariate analysis could be analyzed in multivariate analysis using a stepwise method. A two-tailed $P < 0.05$ was considered statistically significant. All statistical analyses were performed using the SPSS 22 software package (SPSS, Chicago, Illinois, USA).

Results

Patients and clinical characteristics in the Robot and Laparoscopy groups

A total of 629 patients were initially screened and 541 patients with rectal adenocarcinoma were finally enrolled in this study; 317 patients were in the Robot group and 224 patients were in the Laparoscopy group (Fig. 1). The clinical characteristics of the two groups of patients were presented in Table 1. A similar sex distribution was observed in the Robot and Laparoscopy groups and most patients were men. Age, BMI, preoperative serum CEA, ASA class, lymphovascular invasion and CRM has no significant differences between the two groups. Tumor location from anal verge were significantly differently (0-5 cm was more common in the Robot group compared to 10.0-15.0 cm in the Laparoscopy group, P<0.001, respectively).

Intraoperative and postoperative conditions

General conditions of intraoperative and post-operative period are listed in Table 2. The operation time was significantly decreased in the Robot group than that in the Laparoscopy group (163.6±41.1 *vs.* 190.6±52.20 min, P<0.001).Time to 1st gas passing [2 (1) vs. 3 (1) d] and length of hospital stay [7 (2) vs. 8 (3) d) were significantly shorter in patients with robotic surgery than those receiving laparoscopy surgery (P<0.01, respectively). No significant differences were observed with regard to intraoperative bleeding volume, time to 1st soft diet and bowel movement.

The type and proportion of the postoperative adverse events associated with surgical treatment are described in table 3. The postoperative adverse events occurred in 50 of the 317 patients (15.8%) in the Robot group, which significantly lower than in the Laparoscopy group with 71 of the 224 patients (31.7%; $P < 0.001$). No significant differences were observed between the two groups with respect to the occurrence of short-term adverse event ($P > 0.05$, respectively), including anastomotic leakage (17 *vs*. 10), anastomotic bleeding (2 *vs.* 2), wound problem (13 *vs.* 6), ileus (1 *vs.* 0), intra-abdominal abscess (4 *vs.* 2), anemia (0 *vs.* 4) and ascites (1 *vs.* 1). But the occurrence of short-term urinary retention in the Robot group (1.9%) is significant lower than in Laparoscopy group (10.7%; $P = 0.002$). Additionally, the prevalence of long-term adverse events including ileus, adhesion, incisional hernia, anastomotic stricture, rectovaginal/rectovesical fistula had no significant difference between the two groups. However, the occurrence of long-term urinary retention in the Robot group (0.6%) is significant lower than in Laparoscopy group (4.0%; $P = 0.015$). The above findings indicated that the robotic surgery was a safe treatment for patients with rectal cancer, also exhibited the role in protecting inferior hypogastric plexus.

Postoperative pathological assessment

The postoperative pathological characteristics and outcomes of patients in the Robotic group were significantly different from those in the Laparoscopy group (Table 4). TNM stage II and III was more frequently observed in the Robot group than in the Laparoscopy group (94.3% vs. 83.5%, P <0.001). There was no significant difference with respect to lymph nodes retrieved between the two groups [13 (7) vs. 13 (6.3), P =0.389]. The prevalence of lymphovascular invasion and CRM involved also showed no significant difference between the two groups (23.7% vs. 20.1%, 1.3% vs. 0, P > 0.05, respectively). These findings demonstrated that the robotic-assisted surgery was applicable in the treatment of advanced tumors.

Survival analyses

No significant difference in the OS (96.6-, 88.4-, 87.3% *vs.* 96.8-, 87.4-, 77.7%, Fig. 2A, respectively, P > 0.05) and DFS (98.6-, 79.1-, 72.5% *vs.* 95.4-, 86.5-, 80.4%, Fig. 2B, respectively, P > 0.05) were observed in the Robot group and Laparoscopy group at years 1, 3 and 5. These findings indicated that robotic surgery showed the similar probability of OS and DFS compared to laparoscopic surgery, indicating its applicability in clinical practice.

Prognostic factors

In univariate analysis, factors associated with the 5-year OS and DFS were age, with preoperative CRT, TNM stage, differentiation grade and with lymphovascular invasion (Table 5). After adjusting for independent prognostic variables, TNM stage and differentiation group were the independent prognostic indicator for OS and DFS (P <0.05, respectively). The surgical approach (roboty or laparoscopy) was not associated with a longer OS and DFS.

Discussion

Robotic surgery has been taken as a new modality to surpass the technical limitations of conventional surgery. In this retrospective study, we aim to compare the short- and long-term oncologic outcomes in patients with rectal cancer who receive robotic surgery *vs.* laparoscopic surgery. Interestingly, we found patients underwent robotic surgery had lower tumor location and higher clinical T stage, compared to those receiving laparoscopic surgery. Operation on patients with lower tumor location and higher clinical T stage usually means more challenging and requires higher surgical techniques than those without, indicating robotic surgery may have advantages in rectal surgery on more sophisticated cases due to its better visualization and a finer and dexterous pelvic dissection within a narrow pelvic cavity.[15] Importantly, time to 1st gas passing and 1st soft diet and the length of hospital stay were significantly shorter in the robot group, indicating that robotic surgery might avail to enhance recovery after surgery. No significant difference was observed with respect to the most of postoperative short- or long-term adverse events, while the incidence of urinary retention is significantly decreased in patients with robotic surgery, compared to those with laparoscopic surgery, which also indicated the superiority of robotic surgery to laparoscopy on an easier identification of the inferior hypogastric plexus.

Postoperative pathological parameters that can measure the quality of rectal surgery are CRM positivity and number of harvested lymph nodes of the resected specimen, which both has no significant difference between robotic and laparoscopic surgical approach. CRM involvement rate in this study was 1.3% *vs.* 0 between the Robot and Laparoscopy group, which was comparable with the previous studies (0%-16%)[5, 7, 12, 16]. In the Robot group, there were totally 4 cases (4/317) with positive CRM, and local recurrence occurred in 2 cases with positive CRM. However, in the laparoscopy group, there were no cases with positive CRM, and local recurrence occurred in 12 cases (12/224) with negative CRM. A positive CRM did not seem to be translated to local recurrence. That CRM was not a prognostic factor for predicting survival by multivariate analysis could support this finding.

Cumulative OS and DFS, the gold prognosticator, indicates the long-term oncologic outcomes, and also reflect the superiority of surgical technique in cancer resection. Few previous studies showed the cumulative OS and DFS between the Robot and Laparoscopy group. Baek, et al[17] reported that the 3-year OS and DFS were 96.2% and 73.7% respectively, for patients with stages I-III rectal cancer who underwent robotic surgery from the 1-arm case series study. Pigazzi et al[18] presented similar 3-year oncologic results of robotic rectal cancer surgery with data from three different centers. Baek, et al[19] also compared the short- and long-term outcomes between robotic and laparoscopic ultra low anterior resection and coloanal anastomosis, and reported no difference was shown in local recurrence, 3-year OS, or DFS between the two groups. Park, et al[12] reported that the 5-year OS was 92.8% in robotic surgery, and 93.5% in laparoscopic surgical procedures, while the 5-year DFS was 81.9% and 78.7%, respectively. Here, we presented that the 1-, 3- and 5-year OS was 96.6-, 88.4-, 87.3% in the Robot group and 96.8-, 87.4-, 77.7% in the Laparoscopy group. The 1-, 3- and 5-year DFS was 98.6-, 79.1-, 72.5% in the Robot group and 95.4-, 86.5-, 80.4% in the Laparoscopy group.

Robotic surgery requires a surgeon to take a long time to learn to adapt to new surgical techniques, such as controlling consoles, manipulating new instruments, and cooperation with the surgical team[20, 21, 22]. Our team has adequate experience in robotic surgery, with nearly 200 cases of robotic surgery on rectal cancer per year, and that is why our study demonstrated the operation time and intraoperative bleeding were both significantly less than that of laparoscopy. The high cost of robotic surgery is also a problem, which make it cannot be widely recommended for patients. Nevertheless, the robotic system is continuously being improved and more advanced technologies will be developed, such as a novel Senhance® robotic system (TransEnterix Surgical Inc., Morrisville, NC, USA), which has been proved to be feasible and safe in general surgery, gynecology, and urology[23]. We suppose the cost of robotic system will become more and more acceptable

In conclusion, among patients with rectal cancer, the robotic surgery was not associated with an improved survival compared to the laparoscopic surgery, however, the robot surgery is a safe and feasible surgical procedure, especially for some sophisticated cases with lower tumor location. Further prospective randomized trials are needed to clarify these findings.

Declarations

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Conflict of interest disclosure

The authors confirm that they have no competing interests.

Ethics approval statement

The study was approved by the Ethics Committee of the Institutional Review Boards of the First Affliated Hospital of Nanchang University, and was performed in accordance with the Declaration of Helsinki and current ethical guidelines. Prior informed consent was obtained from all participants.

Patient consent statement

All patients were well informed of the detailed characteristics of both robotic and laparoscopic surgical procedures, and written consent was obtained from the study participants or their legal surrogates before enrollment.

Authors' contributions

XL, LLY, ZXH, HRS, ZZ, CT and TYL collected and analyzed the clinical and pathological data . All the surgery were performed and supervised by TYL, XL wrote and revised the paper.

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Tables

Table 1 Clinical and pathological characteristics of patients with rectal adenocarcinoma during hospitalization at enrollment

	Robot (n = 317)	Laparoscopy (n = 224)	*P* value
Age	58.9±12.4	58.8±12.4	0.989
Male, no. (%)	196 (61.8%)	149 (66.5%)	0.264
BMI (kg/m^2)	22.5±3.0	22.3±2.9	0.901
CEA	9.29±27.3	8.73±16.4	0.784
ASA class, no.(%)			
1	176 (55.52%)	121 (54.0%)	
2	129 (40.7%)	93 (41.5%)	
3	12 (3.8%)	10 (4.5%)	0.224
Tumor location from anal verge (cm)			
0-5.0	147 (46.4%)	57 (25.4%)	**<0.001**
5.1-10.0	161 (50.8%)	106 (47.3%)	0.427
10.1-15.0	9 (2.8%)	61 (27.2%)	<0.001
With previous abdominal surgery	30 (9.5%)	25 (11.2%)	0.520
With preoperative CRT	3 (0.9%)	4 (1.8%)	0.642
Clinical TNM stage*			**<0.001**
I	22 (6.9%)	43 (19.2%)	
II and III	295 (93.1%)	181 (80.8%)	

Data are expressed as the mean ± standard deviation (SD) or number of patients (percentages). The continuous variables were compared by using Student's t-test and the Mann-Whitney U test, and the categorical variables were compared by using the χ2 or Fisher's exact test between the Robot and Laparoscopy groups.

*Defined by magnetic-resonance imaging (MRI).

BMI, body mass index; carcinoembryonic antigen (CEA), ASA, American Society of Anesthesiologists; CRT, chemoradiotherapy, CRM, Circumferential resection margin.

Table 2 General conditions of intraoperative and postoperative period

	Robot (n = 317)	Laparoscopy (n = 224)	*P* value
Intraoperative			
Operation time (min)	163.6±41.1	190.6±52.2	**<0.001**
Conversion	0	0	
Bleeding (mL)	150 (100)	150 (100)	0.441
Adverse events			
Bladder injury	0	0	
Perforation of the rectum	0	0	
Disruption of colorectal anastomosis	0	0	
Post-operative			
Time to 1st gas passing (d)	2 (1)	3 (1)	**< 0.001**
Length of hospital stay (d)	7 (2)	8 (3)	**0.002**
Time to 1st soft diet (d)	4 (1)	4 (1)	0.784
Time to bowel movement (d)	2 (0)	2 (0)	0.553

Data are expressed as the mean ± standard deviation (SD), median (interquartile range) or number of patients (percentages). The continuous variables were compared by using Student's t-test and the Mann-Whitney U test between the Robot and Laparoscopy groups.

Table 3 Short- and long- term postoperative adverse events

	Robot (n = 317)	Laparoscopy (n = 224)	*P* value
Total, no. (%)	50 (15.8%)	71 (31.%)	**▯0.001**
Short-term			
Anastomotic leakage	17 (5.4%)	10 (4.5%)	0.636
Anastomotic bleeding	2 (0.6%)	2 (0.9%)	0.549
Wound problem	13 (4.1%)	6 (2.7%)	0.376
Urinary retention	6 (1.9%)	16(10.7%)	**0.002**
Ileus	1 (0.3%)	0	0.586
Intra-abdominal abscess	4 (1.3%)	2 (0.9%)	0.515
Anemia requiring transfusion	0	4 (1.8%)	0.060
Ascites	1 (0.3%)	1 (0.4%)	0.657
Long-term			
Ileus	2(0.6%)	5(2.2%)	0.216
Urinary retention	2(0.6%)	9(4.0%)	**0.015**
Adhesion	0	2(0.9%)	0.171
Incisional hernia	1(0.3%)	3(1.3%)	0.390
Anastomotic stricture	0	0	
Rectovaginal/rectovesical fistula	1(0.3%)	1(0.4%)	0.657

Data are expressed as number of patients (percentages). The categorical variables were compared by using the χ2 or Fisher's exact test between the Robot and Laparoscopy groups.

Table 4 Postoperative pathological characteristics and outcomes

	Robot (n = 317)	Laparoscopy (n = 224)	*P* value
TNM stage			**<0.001**
I	18 (5.7%)	37 (16.5%)	
II and III	299 (94.3%)	187 (83.5%)	
Differentiation Grade			**<0.001**
Well	12 (3.8%)	12 (5.4%)	0.382
Moderate	287 (90.5%)	186 (83.0%)	**0.010**
Poor	17 (5.4%)	14 (6.3%)	0.662
Mucinous	1 (0.3%)	12 (5.4%)	**<0.001**
Lymph nodes retrieved (no.)	13 (7)	13 (6.3)	0.389
PRM (cm)	10.82±11.22	14.00±3.70	0.066
DRM (cm)	2.60±0.70	3.28±1.10	**<0.001**
Lymphovascular invasion			0.325
No	242 (76.3%)	179 (79.9%)	
Yes	75 (23.7%)	45 (20.1%)	
CRM			0.117
Noninvolved (>1mm)	313 (98.7%)	224 (100%)	
Involved (≤1mm)	4 (1.3%)	0	

Data are expressed as number of patients (percentages). The continuous variables were compared by using the Mann-Whitney U test, and the categorical variables were compared by using the χ2 or Fisher's exact test between the Robot and Laparoscopy groups.

TNM, tumor node metastasis

Table 5 Univariate and multivariate analysis of factors associated with 5-year OS and 5-year DFS

Variables	5-year OS			5-year DFS		
	Univariate	Multivariate		Univariate	Multivariate	
	P	HR (95%CI)	*P*	*P*	HR (95%CI)	*P*
Age	**0.022**	1.028(1.008-1.049)	**0.005**	**0.035**		0.140
sex (male)	0.369			0.092		
BMI (kg/m^2)	0.307			0.311		
CEA	**0.005**	1.009 (1.003-1.014)	**0.002**	0.275		
ASA class	**0.044**		0.669	0.064		
Tumor location	0.066			**0.001**	0.873 (0.806-0.946)	**0.001**
With robotic surgery	0.815			0.473		
With preoperative CRT	**0.008**		0.057	**<0.001**	11.213 (3.971-31.661)	**<0.001**
With previous abdominal surgery	0.090			0.713		
Lymph nodes retrieved	0.740			0.133		
TNM stage	**0.004**	1.654 (1.107-2.472)	**0.014**	**<0.001**	1.771 (1.153-2.720)	**0.009**
Differentiation grade	**0.015**	1.638 (1.086-2.472)	**0.019**	**<0.001**	1.606 (1.079-2.392)	**0.020**
CRM (no involved)	0.302			0.743		
With lymphovascular invasion	**0.013**		0.123	**0.004**	1.820 (1.050-3.154)	**0.033**

Statistical analysis was performed using a multivariable Cox proportional hazard model. Statistically significant variables from the univariate analysis were included in the multivariate Cox regression models to assess their contribution to 5-year OS and DFS. Variables with P<0.05 were kept in the final model.

BMI, body mass index; ASA, American Society of Anesthesiologists; CRT, chemoradiotherapy; TNM, tumor node metastasis; CRM, circumferential resection margin; OS, overall survival; DFS, disease free survival.

HR: Hazard radio, 95%CI: 95% confidence interval

Figures

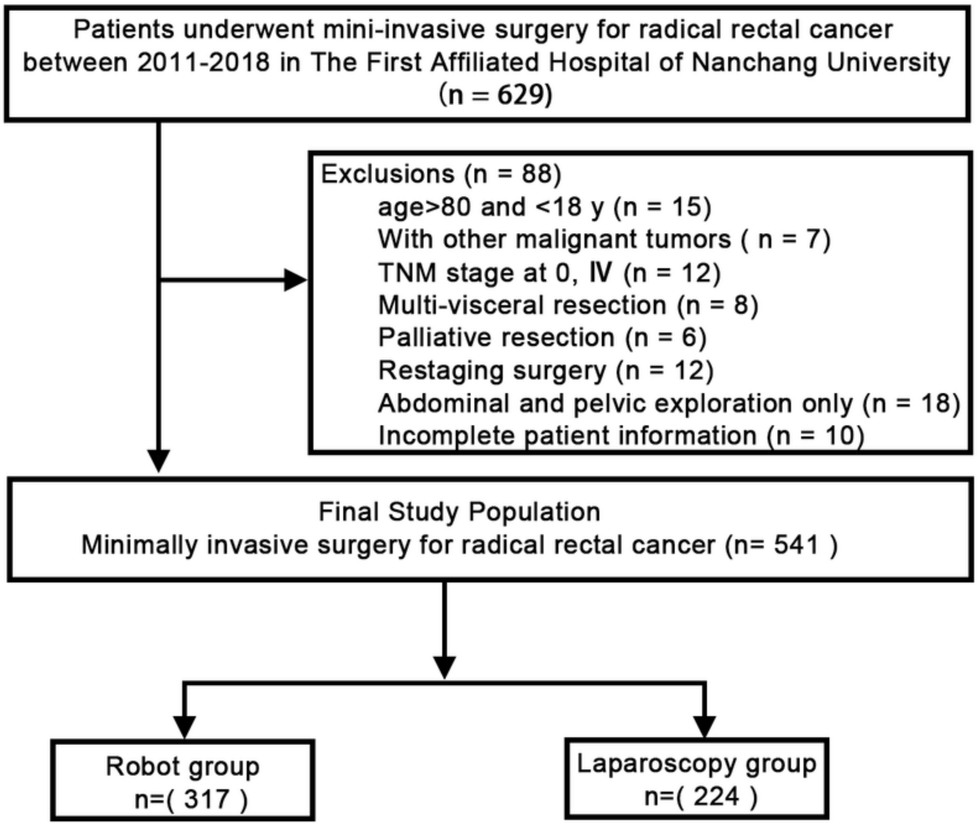

Figure 1

Flowchart of patient selection. Robot group, patients with robotic surgery; Laparoscopy group, patients with laparoscopic surgery.

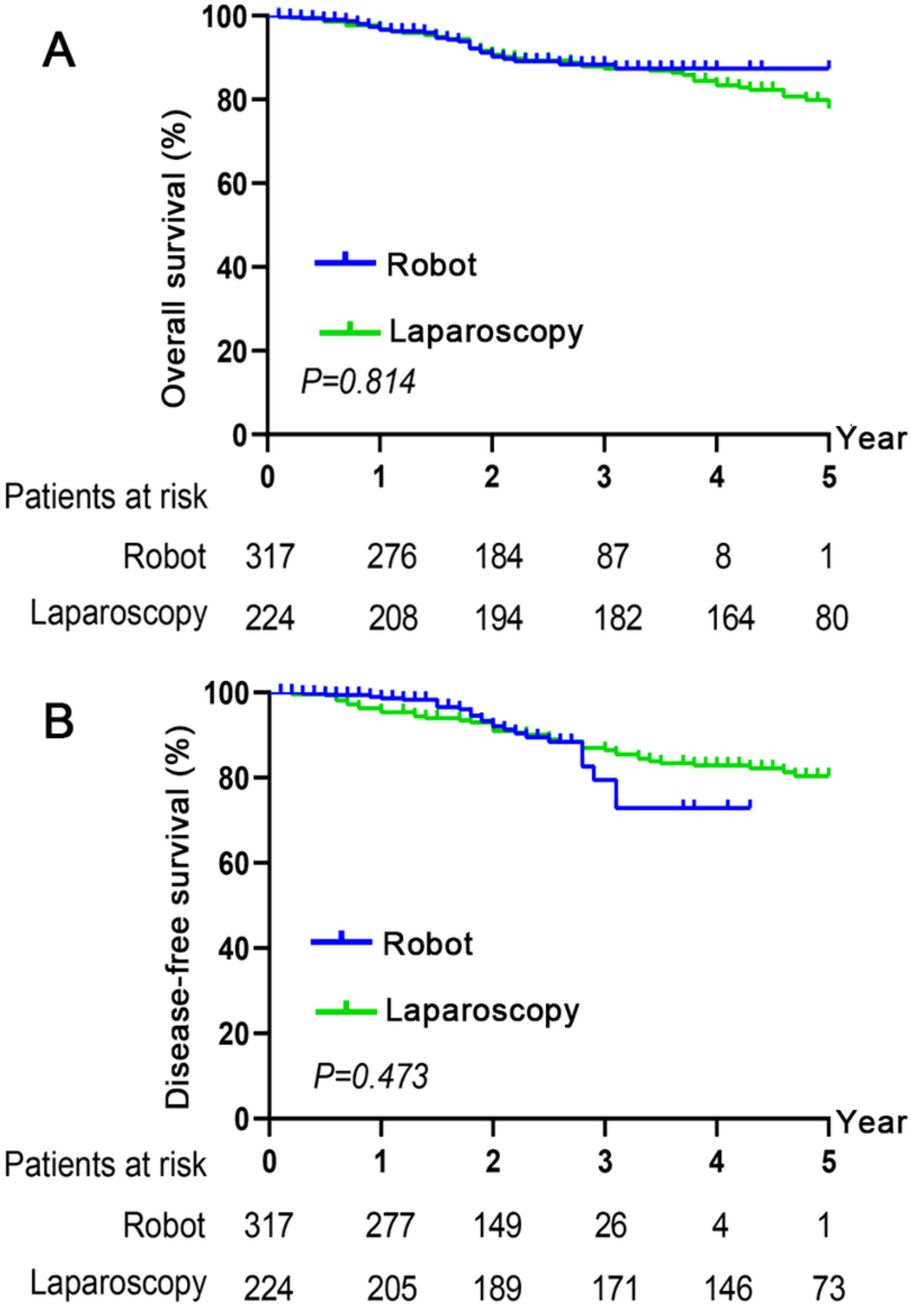

Figure 2

Kaplan-Meier curves for OS and DFS in the Robot and Laparoscopy groups. (A) The 1-, 3- and 5-year OS rate were 96.6-, 88.4-, 87.3% vs. 96.8-, 87.4-, 77.7% in the Robot and laparoscopy groups. (B) The 1-, 3- and 5-year DFS rate were 98.6-, 79.1-, 72.5% vs. 95.4-, 86.5-, 80.4% between the two groups. Both the OS and DFS has no significant difference in the Robot and Laparoscopy groups (P >0.05, respectively). OS, overall survival; DFS, disease-free survival.