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Original Article

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Efficiency of the Robotic Platform in Improving the Rate of Sphincter Preservation in Patients With Mid and Low Rectal Cancer

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Abstract

Background: The aim of this study was to investigate whether the robotic platform can have a positive impact on the rate of sphincter preservation in patients with rectal tumors, undergoing robotic total mesorectal excision (TME), in comparison with laparoscopic or open TME. We also analyzed and compared short-term outcomes.

Methods: A prospectively collected robotic database was reviewed and compared with the trust and national data. Three groups were designed according to the surgical technique: open, laparoscopic and robotic. This includes all resections for mid and low rectal cancer which were performed with the robotic platform, over a period of 4 years, versus the trust data for the same period.

Results: Two hundred ninety-seven patients with mid and low rectal cancers were analyzed. Demographics for the groups (gender, age, and body mass index) were similar but distance from anal verge was shorter in the robotic group (7 vs. 8.5 cm, P < 0.001). The percentage of abdominoperineal resection (APR) rate was significantly lower in the robotic group (13.5% vs. 39.6% vs. 52.4% for the open group, P < 0.001). Median length of stay, complication rate, and positive circumferential resection margin (CRM) rate for the robotic group were also statistically significantly lower than those for both laparoscopic and open groups.

Conclusion: Robotic surgery for mid and low rectal cancer is safe and feasible, and could help surgeons perform ultra-low anterior resections, rather than APRs and save patients' sphincters. Positive CRM is low, which could lead to improved oncological outcomes.

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Introduction

It is still not clear about the best surgical approach for rectal cancer. There were two randomized trials published in 2016, the ALACART and the American ACOSOG, where they both raised concerns about oncology and functionality with laparoscopic surgery for rectal cancer [1, 2]. Their updates in 2019 reassured the critics of laparoscopy that long-term results were not worse than open surgery [3, 4]. It is clear that open rectal cancer surgery is disabling, associated with increased rate of complications, and it could potentially lead to inferior specimen quality. Hence, minimally invasive methods for rectal cancer are now established and justified [5, 6]. When comparing the different approaches for minimally invasive rectal surgery, evidence is emerging around the benefits of robotics, promising to overcome some of the disadvantages of laparoscopic surgery and give patients the opportunity to avoid open surgery, especially in high-risk groups [7].

With the robotic platform, we can benefit from better magnified 3D view, better control, articulated instruments, tremor filtration, motion scaling, focused precision surgery and standardization of surgery.

This study compares robotically assisted versus laparoscopic and open surgery for cancer. We aimed to see if the robotic platform can increase sphincter preservation in patients with mid and low rectal cancer. We also compared the efficiency in short-term outcomes.

Materials and Methods

Patients

Characteristics and outcomes of 297 patients with mid and low rectal cancer were analyzed. Ninety-six patients with rectal cancer undergoing robotic rectal resections for mid and low rectal adenocarcinoma within a period of 4 years were prospectively collected. Two hundred and one patients had laparoscopic or open resections. Our hospital is a tertiary care referral center for rectal cancer patients and one of the largest and busiest English trusts. Ten colorectal surgeons with established colorectal practice performed rectal cancer resections; two of them performed all the robotic rectal resections, while all of them performed laparoscopic or open rectal resections.

Our study followed the guidance for good clinical practice and its requirements [8]. Ethics committee approval was obtained by our institution and all patients gave their written consent. All patients are within established ERAS protocols.

Staging followed National Institute of Care and Excellence (NICE) guidelines [9]. We excluded patients younger than 18 years old, with upper rectal cancers, metastatic cancers, patients that underwent emergency operations for obstructing tumors, patients with tumors invading the external sphincter, prostate or vagina that would require abdominoperineal resection (APR) or pelvic exenteration and patients with types of cancer that would require APR as therapeutic approach, regardless whether an ultra-low resection could be technically feasible.

Rectal cancer was categorized into upper (11 - 15 cm), middle (6 - 10 cm), and lower (≤ 6 cm) according to the distance from the anal verge. The distance from the anal verge was measured preoperatively, by performing rectal magnetic resonance imaging (MRI) in all patients. Patients with upper rectal cancer were excluded from the analysis.

Neoadjuvant therapy was given to patients with T3c or above rectal cancer, or threatened circumferential resection margin (CRM). Most surgeons performing laparoscopic and open resections also gave neoadjuvant therapy in patients with T3a, T3b tumors, in order to improve the R0 resection rates.

As per NICE guidance, long course chemo-radiation is used wherever it is indicated.

Patients' characteristics that were calculated and analyzed included age, body mass index (BMI), sex and American Society of Anesthesiologists (ASA) physical status classification.

We used the eighth edition American Joint Committee on Cancer (AJCC) [10]. Distance from anal verge was also calculated and analyzed.

APR rate, CRM positivity, distal resection margin, lymph nodes harvested, quality of total mesorectal excision (TME), conversion rates, mortality, length of stay (LoS) and complications according to Clavien-Dindo classification [11] were also analyzed and compared.

Primary endpoint was if the robotically assisted rectal resections had increased rates of sphincter preservation. This was calculated by the APR rate. Secondary endpoints were perioperative and short-term outcomes.

Operative technique

The operative technique for the robotic group is standardized and previously published [12]. Firefly™ is used routinely for checking the vascularity of the anastomosis, before stapling the rectum, before cutting the colon and after the anastomosis is performed.

Laparoscopic and open resections are also standardized. Each colorectal surgeon used their own standardized approach, in the way that is more comfortable for them and is similar to one of the robotic groups. All surgeons used the medial-to-lateral mobilization first and high ligation of inferior mesenteric artery in D3 lymphadenectomy. They all performed complete splenic flexure mobilization and then TME between the nerves (nerve-sparing TME) followed by anterior and lateral dissection.

Statistical analysis

Data analysis was undertaken using SPSS (Statistical Product and Service Solutions for MAC). Data presentation for categorical data was number (%) while for numerical variables mean ± SEM or median in cases that normality assumption was violated. Chi-square test with Fisher's exact correction when applicable was used for comparing categorical values. Non-parametric tests were used to compare the three techniques.

The test under the null hypothesis assumes that the mean ranks and the distributions across the categories are the same. In order to assess whether the type of surgery combined with other factors affects the sphincter preservation, we used the analysis of covariance test (ANCOVA). Specifically, we considered sphincter preservation, as the dependent variable, with age, BMI, gender, use of neoadjuvant as predictors. Interactions between the categorical factors were considered as well. Initially, the normality assumption of residuals was violated while the constant variance of residuals assumption (homoskedasticity) was met (Levene's test > 0.05).

In order to improve the normality assumption, sphincter preservation was transformed into a logarithmic scale. The normality assumption was improved, as the histogram was more symmetric. After keeping all the significant variables and conducting the analysis with and without the outlying point, the significance of the independent variables was the same for all analyses.

The following data were also analyzed for short-term outcomes: LoS, complications, 30-day mortality, readmissions, conversion rate, operative time and positive CRM. P values < 0.05 were considered to be statistically significant.

Results

Group characteristics

The demographics of the 297 patients undergoing rectal resections are summarized in Table 1.

The mean age was similar among the three groups: 65 years (21 - 85) for the laparoscopic and robotic groups (range 34 - 82) and 66 years for the open group (range 31 - 87).

The laparoscopic group included 50% of male patients, which was statistically significantly less than both robotic (64%) and open (76%) groups (P < 0.001).

Patients of the robotic group had higher BMI (27 kg/m^2) than both laparoscopic (26 kg/m^2) and open groups (23.5 kg/m^2), but this did not reach statistically significant difference.

Table 1. Patient and Tumor Characteristics

Variables	Robotic	Laparoscopic	Open	National
N	96	96	105	
Mean age, years	65 (36 - 82)	65 (21 - 85)	66 (31 - 87)	66 (31 - 87)
BMI, kg/m^2	27 (19 - 37.7)	23.5	26 (16.8 - 34)	27
Gender				
Male	66 (67%)	48 (50%)	74 (70.5%)	64%
Female	33 (33%)	48 (50%)	31 (29.5%)	32%
ASA				
I	16 (15%)	17 (17%)	12 (11%)	12
II	69 (72%)	68 (68%)	65 (59%)	53
III	11 (13%)	15 (15%)	30 (28%)	27
Stage				
I	33 (35%)	34 (34%)	41 (39%)	30%
II	22 (21%)	24 (24%)	40 (38%)	32%
III	32 (34%)	28 (28%)	22 (21%)	33%
IV	4 (4%)	2 (2%)	0 (0%)	5%
Not found/pathological complete response	5 (5%)	8 (8%)	2 (2%)	

ASA: American Society of Anesthesiologists; BMI: body mass index.

ASA score index was slightly different between groups, with 28% of patients in the open group to be ASA III, while ASA III was 13% in the robotic and 15% (P < 0.05) in the laparoscopic group. This was statistically significantly higher for the open group.

LoS

The median LoS was 6 days for the robotic group (range 3 - 30), 8 days for the laparoscopic group (range 4 - 50) and 11 days for the open group (range 3 - 134). The robotic group had significantly less LoS than both laparoscopic and robotic groups (P < 0.001) (Table 2).

Complications

Thirty-one patients (30%) from the robotic group had complications, while 47 (49%) from the laparoscopic and 73 (69.5%) from the open group P < 0.001). The complications are categorized according to Clavien-Dindo classification as minor (Clavien-Dindo I-II) and major (Clavien-Dindo III-IV).

Despite that the overall complications were statistically significantly less for the robotic group, the major complications (Clavien-Dindo III-IV) for the robotic group were 8.3%, while it was similar (7.1%) for the laparoscopic group (P = 0.118); for the open group, it was 13.6% and it was statistically significantly more for both other groups (P = 0.022) (Table 2).

Short-term oncological outcomes

The distance from anal verge was statistically significantly shorter for the robotic group (7 cm), in comparison with laparoscopic or open group (8.5 cm) (P < 0.001).

Positive CRM was observed in two cases in the robotic group (2.1%), versus seven cases in the laparoscopic (7%) and 16 cases in the open group (15.5%). This was statistically significantly superior for the robotic group than both laparoscopic and robotic groups (P = 0.001).

The quality of TME was incomplete in one case in the robotic group (1%), while it was incomplete in 16 cases in the laparoscopic (16%) and 18 cases (17.5%) in the open groups, so the robotic group had statistically significantly better quality of TME than both laparoscopic and open groups (P = 0.001).

The robotic group harvested 35 lymph nodes (range 6 - 131), while the laparoscopic group removed 29.5 lymph nodes (7 - 80) and the open group removed 25 (3 - 84); this was not statistically significant (P = 0.107).

Table 2. Length of Stay and Complications

Variables	Robotic	Laparoscopic	Open	National	P value
Length of stay (median, range), days	6 (3 - 30)	8 (4 - 50)	11 (3 - 134)	7 (5 - 11)	0.04
Overall complications	30%	49.4%	69.5%		< 0.001
Major complications - Clavien-Dindo III-IV	8 (8.3%)	7 (7.3%)	13 (13.6%)		0.022

Table 3. Oncological Outcomes

Variables	Robotic	Laparoscopic	Open	National	P value
N	96	96	105		
Distance from anal verge (median, range), cm	7 (2 - 10)	8.5 (3 - 11)	8.5 (3 - 10)		< 0.001
Positive CRM	1%	7%	15.5%	8	< 0.001
Incomplete TME (Quirke grade III)	1%	16%	17.5%		< 0.001
LN	35 (6 - 131)	29.5 (7 - 80)	25 (3 - 84)		0.107
Conversion	1%	3%			0.125
Mortality	0%	0%	1%	1.8%	0.908
APR rate	13.5%	39.6%	52.4%	35%	< 0.001
Distal resection margin (median, range), mm	18 (1 - 60)	25 (0 - 90)	27.5 (0 - 150)		0.03
Operative time, min	320 (220 - 460)	310.5 (187 - 544)	261 (133 - 548)		0.022
Neoadjuvant	32%	54.5%	72.7%	34	< 0.001

APR: abdominoperineal resection; CRM: circumferential resection margin; LN: lymph node; TME: total mesorectal excision.

The distal resection margin was less for the robotic group (15 mm, range 1 - 60 mm) and similar for the laparoscopic (25 mm, range 0 - 90 mm) and the open groups (27.5 mm, range 0 - 150 mm).

The conversion to open surgery was 1% for the robotic versus 3% for the laparoscopic group; this did not reach statistically significant difference (P = 0.125).

The 30-day mortality was similar for all three groups (0% for both laparoscopic and robotic groups and 1% for the open group; P = 0.908).

The APR rate was 13.5% for the robotic group, versus 39.6% for the laparoscopic and 52.4% for the open group (P = 0.001).

Time to complete the operation was 320 min (220 - 460) for the robotic group and 310.5 min for the laparoscopic group (187 - 544). However, both groups had significantly longer operative times than the open group (261 min, range 133 - 588; P = 0.022).

Neoadjuvant chemoradiation was given in significantly less patients in the robotic group (33%) versus 51% for the laparoscopic group and 71% for the open group.

Table 3 summarizes the short-term oncological outcomes.

Discussion

The advantages of the Da Vinci technology are: stable 3D views, non-operator dependent, better ergonomics, tremor filtration, motion scaling, and instruments with multiple degrees of freedom.

These advantages seem to be more beneficial in prostate and rectal surgery, as the pelvis is limited in space. In addition to that robotic systems for advanced colorectal cancer offer technical advantages for complex and precise surgeries [13].

The clinical impact of introducing robotic colorectal surgery in Sheffield has multiple advantages.

It is clear now that minimally invasive surgery is more cost-effective than open resection. Robotic surgery can be more cost-effective according to a large American study, by achieving certain thresholds in quality of life, instrument costs, and postoperative outcomes [14].

Another study among 15,893 US patients, who had five types of common oncological procedures, found significant variation in perioperative costs according to surgical technique for both patients (out-of-pocket costs) and payers (total payments); the robotic approach was associated with lower out-of-pocket costs for all studied oncological procedures [15].

A meta-analysis of more than 5,000 patients also showed the benefits of robotic versus laparoscopic surgery in less ileus, less conversion, and less LoS [16].

Our data confirm these findings, with the reduction of complications and LoS, factors that lead to increased costs. The reduction of LoS was 2 days when compared with laparoscopic resections and 5 days when compared with the open group.

The CRM is one of the main prognostic factors in rectal cancer. Since the initial description of its clinical importance in 1986, the involvement of this margin has been associated with a poor prognosis and is a powerful predictor of both development of distant metastases and survival [17]. The oncological advantages of introducing robotic surgery in Sheffield is the reduction of positive cancer margin involvement by 6% from the laparoscopic group and 14.5% from the open group.

Another study designed to have long-term survival data, published by Kim, concludes that robotic resection has a survival benefit up to 10% depending on the staging [18].

Robotic surgery for the treatment of rectal cancer is an emerging technique that can overcome some of the technical drawbacks posed by conventional laparoscopic approaches, improving the scope and effect of radical operations [19].

The ROLARR trial [20], which is the largest randomized controlled trial (RCT) to date, comparing laparoscopic and robotic rectal resections, found that robotic rectal resections have less chances to be converted to open than laparoscopic resections, but not in a statistically significant presentage (8.1% vs. 12.2%, P > 0.05).

However, 1 year after the publication of this, the same authors published the update of ROLARR; by exploring and adjusting for potential learning effects, they concluded that, in the hand of surgeons that have passed their learning curve for robotic surgery, the conversion to open surgery would be less and the result would be statistically significant [21].

The latest and biggest RCT to date is the REAL trial, comparing robotic and laparoscopic surgery for mid and low rectal cancer, and concluding that patients in the robotic group had better postoperative gastrointestinal recovery, shorter hospital stay, fewer APRs, fewer conversions to open surgery and fewer intraoperative complications than patients in the laparoscopic group [22].

In our series, the conversion rate was very low (1.1%), with only one conversion, due to system failure to recognize the camera.

Furthermore, use of the robotic stapler could potentially help increase sphincter preservation and decrease anastomotic leak, compared to conventional laparoscopy, due to its technological advantages.

In this series, we used the robotic stapler in the last 25 procedures, when it became available with our new system. Although in this series, a statistical benefit was not demonstrated, there is a potential benefit of its use. Due to the large range of motion and 90° of articulation, it could provide a benefit when used in difficult areas like narrow male pelvis in obese male after chemoradiation. The robotic stapler has a comparable level of safety as a 45 mm laparoscopic stapler and is more cost-effective and by reducing the number of firings, it could lead to decreased anastomotic leak [23, 24].

The technical advantages of the robotic platform can be proven from the fact that we had a reduction in permanent stoma rates by 26.1% from laparoscopy and 38.9% from open surgery. And it is widely accepted now that APRs are disabling and associated with more complications, decrease in survival and impaired functional outcomes and quality of life; thus, all effort is making to perform ultra-low resections and save patient sphincters [25, 26].

In UK, NBOCAP data show a 11% conversion, 25.5% permanent stoma rate, 4.5% 30-day mortality, 92% complete resection and 9 days median LoS [27].

Our data for the robotic group are superior to the national data in all these aspects, with values of 1.1% conversion rate, 13.5% permanent stoma formation, 0% mortality, 98.9% CRM (-) and 6 days of median LoS.

This is a high-volume study and, there are not many studies in the literature comparing the efficiency of the various surgical techniques in patients with mid and low rectal cancer, excluding upper rectal cancers and cancers that would lead to an APR by default. Its limitation is that it is a single institution and not randomized.

Conclusion

The use of the robotic platform results in more patients ending up keeping their sphincters and not having permanent stomas. Oncological outcomes are very good, which could lead to increased survival too.

Robotic surgery for mid and low rectal cancer is safe and feasible, and could help surgeons perform ultra-low anterior resections, rather than APRs and save patients' sphincters. Positive CRM is low, which could lead to improved oncological outcomes.

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None to declare.

Financial Disclosure

None to declare.

Conflict of Interest

None to declare.

Informed Consent

Informed consent has been obtained.

Author Contributions

Thalia Petropoulou wrote the manuscript and collected the data. Panagiota Kitsanta collected the histology reports. Kassiani Theodoraki did the statistical analysis. Shwan Amin did final checks and corrected the paper writing.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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