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Does robotic rectal cancer surgery improve the results of experienced laparoscopic surgeons? An observational single institution study comparing 168 robotic assisted with 184 laparoscopic rectal resections

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Abstract

Background The role of robotic assistance in colorectal cancer surgery has not been established yet. We compared the results of robotic assisted with those of laparoscopic rectal resections done by two surgeons experienced in laparoscopic as well as in robotic rectal cancer surgery.

Methods Two surgeons who were already experienced laparoscopic colorectal surgeons in 2005 started robotic surgery with the daVinci SI system in 2012. All their rectal cancer resections between 2005 and 2015 were retrieved from a prospectively recorded colorectal database of routinely collected patient data. Multi-organ resections were excluded. Patient data, diagnostic data, data on preceding operations and neoadjuvant treatment, perioperative and operative data, logistic data, and short-term outcomes were gathered. Multivariable analyses (multiple linear and logistic regression) were used to assess differences in several outcomes between the two resection methods while adjusting for all potential confounders we could identify. Results are presented as adjusted mean differences for continuous outcome variables or as adjusted odds ratios (OR) for dichotomous outcome variables.

Results Three hundred and fifty-two patients with rectal cancers were identified: 168 robotic and 184 conventional laparoscopic cases, 178 operated by surgeon A and 174 operated by surgeon B. Adjusted mean operation time was 215 min in the robotic group which was 40 min (95% CI 24–56; $p<0.0005$) longer than the 175 min in the laparoscopic group. Robotic treatment had significantly lesser numbers of conversions (OR 0.09 (0.03–0.32); $p<0.0005$) and other complications (SSI and anastomic leakage excluded) (OR 0.32 (0.15–0.69); $p=0.004$), adjusted for potential confounders.

Conclusions Our study suggests that robotic surgery in the hands of experienced laparoscopic rectal cancer surgeons improves the conversion rate and complication rate drastically compared to conventional laparoscopic surgery, but operation time is longer.

Keywords Rectal cancer · Laparoscopic rectal resection · Robotic rectal resection · Surgical experience

The role of robotic assistance in colorectal surgery has not been established yet. There are many publications that show at least equivalent results for robotics [1–16]. Other reports show lower conversion rates in robotics [17–26]. However, Patel et al. showed that in more than 80% of comparative studies with non-significant differences spin (defined previously as "specific reporting that could distort the interpretation of results and mislead readers") occurred in favour of robotics [27]. Disadvantages are prolonged operative time and costs [28–33]. In case of rectal cancer only one randomized controlled study has recently been published. In this ROLARR trial, there were no differences in the primary endpoint conversion nor in any of the secondary endpoints: intraoperative complications, postoperative complications, plane of surgery, circumferential resection margin positivity, 30-day mortality, bladder dysfunction, and sexual dysfunction [34]. Experience in laparoscopy and in robotic surgery was varying between surgeons of the ROLARR trial.

Notwithstanding the lack of evidence, there is a worldwide rise in robotic colorectal surgeries. We also were

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fascinated by the theoretical advantages as superior 3-D vision, stable self-controllable camera, instruments with more degree of freedom, and better ergonomics. Two experienced laparoscopic colorectal surgeons in our hospital started robotic colorectal surgery in 2012 using the daVinci Si system. This observational study compares the prospectively recorded results of laparoscopic and robotic rectal cancer surgery of these experienced surgeons between 2005 and 2015.

Methods

According to the local board of the Amphia Hospital, no approval of an ethics committee and no informed consent were required. The study complies with the Declaration of Helsinki on research ethics, and patient data were handled confidentially. In 2005, both surgeons already were experienced laparoscopic colorectal surgeons (at that time for 8 and 10 years). In January 2005, they introduced an institution-wide enhanced recovery program after colorectal surgery that in essence remained the same throughout the years. We retrieved all robotic-assisted laparoscopic and conventional laparoscopic rectal cancer cases of the two surgeons from the prospectively recorded Amphia colorectal database since the start of this registry in 2005 until 2015. Multi-organ resections were excluded. The database contains patient data, diagnostic data, data on preceding operations and neoadjuvant treatment, perioperative and operative data, logistic data, and short-term outcomes. In case of mid- and low-rectal tumors, patients were extensively informed about pro's and con's of low anterior resection without permanent stoma or resection with permanent colostomy and their decision was always respected as long as oncologic principles were preserved. From 2014, all rectal cancer operations were performed robotically assisted unless there was not enough allotted access to the robot. The SURPASS perioperative checklist was introduced in 2008 as part of its implementation study [35]. At the same time, we introduced a bundle of care to prevent postoperative infections [36].

All perioperative ERAS principles were used from 2005 on, but two principles have been changed during the years. The use of thoracic epidural anesthesia has been almost completely abandoned. In 2013, we introduced a 3-day course of preoperative oral antibiotic prophylaxis (OAP). OAP is an oral solution consisting of tobramycin and colistin, which is administered four times daily during the last three preoperative days. No bowel preparation was given.

The outcome variables of this study are listed in Table 2. Operative time was defined as time from incision until closure. For pathology TNM 5 classification was used; positive circumferential margin (CRM) was defined as < 1 mm margin [37]. Ileus was defined as reinsertion of a gastric tube post operatively. Anastomotic leakage was defined as any radiologic or operative sign of a defect of the anastomosis, including deep abscesses next to the anastomosis. Surgical site infections (SSI) were recorded during 30 days or during hospital stay if longer than 30 days. SSI were defined according to the Centers for Disease Control and Prevention (CDC) criteria [38]. Since 2008, the SSI registration is double checked by dedicated and trained infection control personnel of the laboratory for Microbiology and Infection Control. Mortality was defined as 30-day or in-hospital mortality. Discharge criteria were pre-defined and were the same during the studied period. Length of stay (LOS) was defined as postoperative length of stay in days.

Statistical analysis

Of the continuous outcome variables presented in Table 2 crude (unadjusted) differences between both treatment groups were tested using the two-sample *t*-test or Mann–Whitney test. For the dichotomous outcome variables, the chi-squared or Fisher's exact test was used. Only the univariable *p* values of these tests were presented. All explanatory variables presented in Table 1 served as potential confounders for the effect of robotic treatment in the multivariable analyses. Year of operation ranging from 2005 to 2015 was included in the regression models as a linear time trend variable, being one of the explanatory covariables along with treatment. This time trend variable served as proxy variable in order to adjust the treatment effect for underlying trends in better perioperative care, fast track, better imaging, better postoperative care, introduction of auditing data by registries, etc. The variables ASA, pathology T, and pathology *N* were also treated as numeric trend variables in the analyses.

The analysis of the continuous outcome variables was performed using multiple linear regression analysis with all explanatory variables of Table 1 entering the model along with robotic treatment. Length of stay was logarithmically transformed prior to analysis. Adjusted means of the continuous outcome variables in either treatment group and adjusted mean differences between both treatment groups with 95% confidence intervals and *p* values were estimated.

The dichotomous outcome variables were analyzed using multiple logistic regression analysis. Due to the paucity of outcomes, a stepwise forward variable selection method was used to enter potentially confounding covariates along with robotic treatment. At each step, a confounder was selected into the model based on the smallest *p* value below 0.10 and eliminated from the model based on the largest *p* value above 0.20. For the outcome mortality, the respective cutoffs for the *p* value were 0.05 and 0.10. Differences between both treatment groups were quantified by means of odds

Table 1 Explanatory variables by treatment group

Explanatory variable	Laparoscopic *N* (%) or mean ± SD or median(range) *N* = 184	Robotic *N* (%) or mean ± SD or median(range) *N* = 168	Total *N* (%) or mean ± SD or median(range) *N* = 352
Male	103 (56.0%)	113 (67.3%)	216 (61.4%)
Age (years)	68.1 ± 10.7	67.0 ± 9.64	67.6 ± 10.2
BMI (kg/m^2)	25.8 ± 3.90	26.4 ± 3.86	26.1 ± 3.89
ASA I	34 (18.5%)	27 (16.1%)	61 (17.3%)
ASA II	104 (56.5%)	116 (69.0%)	220 (62.5%)
ASA III	45 (24.5%)	25 (14.9%)	70 (19.9%)
ASA IV	1 (0.5%)	0 (0%)	1 (0.3%)
Previous TEM	4 (2.2%)	6 (3.6%)	10 (2.8%)
Neoadjuvant radiotherapy	92 (50.3%)	98 (58.3%)	190 (54.1%)
Neoadjuvant chemotherapy	23 (12.7%)	46 (27.4%)	69 (19.7%)
OAP	10 (5.4%)	130 (77.8%)	140 (39.9%)
Operation year	2009 (2005–2015)	2014 (2012–2015)	2012 (2005–2015)
Senior surgeon A	83 (45.1%)	91 (54.2%)	174 (49.4%)
Operation type			
Hartmann anterior	14 (7.6%)	9 (5.4%)	23 (6.5%)
Low anterior resection	122 (66.3%)	112 (66.7%)	234 (66.5%)
APR	48 (26.1%)	42 (25.0%)	90 (25.6%)
iAPR	0 (0%)	5 (3.0%)	5 (1.4%)
Diverting ileostomy	78 (63.9%)	71 (63.4%)	149 (63.7%)
Pathology T[a]	T3 (T0-T4)	T3 (T0-T4)	T3 (T0-T4)
Pathology N	0 (0–2)	0 (0–2)	0 (0–2)

BMI and pathology T had 2 missing observations in the laparoscopic group; neoadjuvant radiotherapy and chemotherapy had 1 missing observation in the laparoscopic group and SDD had 1 missing observation in the robotic group

[a]In pathology T, the category in situ was ranked between T0 and T1

Table 2 Outcome variables by treatment group

Outcome variable	Laparoscopic *N* = 184	Robotic *N* = 168	Total *N* = 352	Univariable *p* value
Continuous variables	Mean ± SD or median (range)	Mean ± SD or median (range)	Mean ± SD or median (range)	
Operation time (min)	172 ± 48.4	219 ± 47.4	195 ± 53.5	< 0.0005
Length of stay (days)	7 (3–104)	6 (2–67)	6 (2–104)	0.029
Lymph nodes	7 (0–44)	14 (2–44)	10 (0–44)	< 0.0005
Dichotomous variables	*N* (%)	*N* (%)	*N* (%)	
CRM+	4 (2.2)	8 (4.8)	12 (3.4)	0.24
Conversion	23 (12.5)	3 (1.8)	26 (7.4)	< 0.0005
SSI superficial	21 (11.4)	8 (4.8)	29 (8.2)	0.032
SSI deep	7 (3.8)	7 (4.2)	14 (4.0)	1.00
Anastomotic leakage (only low anterior resection)	*N* = 122 10 (8.2)	*N* = 112 5 (4.5)	*N* = 234 15 (6.4)	0.29
Any other complication[a]	73 (39.7)	51 (30.4)	124 (35.2)	0.074
Mortality	9 (4.9)	1 (0.6)	10 (2.8)	0.021

The numbers of missing observations of operation time were ten in the laparoscopic group and four in the robotic group; mortality had one missing observation in the robotic group

[a]Excluding SSI's and leakage

ratios of robotic to laparoscopic treatment with 95% confidence intervals and p values.

As the effect of treatment on several outcome variables was tested, a more stringent significance level alpha of 0.005 than the traditional 0.05 was used per efficacy test.

Results

352 patients with rectal cancers between 2005 and 2015 were identified: 168 robotic and 184 conventional laparoscopic cases, 178 operated by surgeon A and 174 operated by surgeon B. All 168 robotic cases and 15 of the 184 conventional laparoscopic cases were operated between 2012 and 2015. Patient characteristics and preoperative factors are shown in Table 1. The two treatment groups were well in balance as regards age, BMI, preceding TEM, neoadjuvant radiotherapy, surgeon, type of operation, use of diverting ileostomy, and N-stage. However, in the robotic group, there were more men (67 vs. 56%), more neoadjuvant chemotherapy (27.4 vs. 12.7%) and, because of recent introduction, more OAP (selective digestive decontamination: 77.8 vs. 5.5%).

Results of the multivariable analyses

In the robotic group, adjusted geometric mean length of stay was 13.2% shorter than in the laparoscopic group (7.0 vs. 8.1 days), which was not significant (95% CI −30.5 to +8.3%; $p=0.21$). The p value of the crude (unadjusted) comparison was 0.029. Adjusted mean operation time was 215 min in the robotic group which was significantly 40 min (95% CI 24–56; $p<0.0005$) longer than the adjusted mean of 175 min in the laparoscopic group. The adjusted mean number of lymph nodes increased from 11.3 in the laparoscopic group to 12.5 in the robotic group. This increase of 1.2 lymph nodes was not significant (95% CI −1.0 to +3.5; $p=0.29$) in contrast to the crude (unadjusted) comparison ($p<0.0005$).

Effects of robotic treatment on the dichotomous outcomes are presented in Table 3 as robotic to laparoscopic treatment odds ratios, with 95% confidence intervals and p values, adjusted for the forwardly selected sets of confounders. Robotic treatment had significantly lesser numbers of conversions and other complications (respective p values <0.0005 and 0.004). On superficial SSI and on mortality, no significant effects of robotic treatment were seen after adjustment (p values 0.20 and 0.63); the unadjusted effects in Table 2 had respective p values of 0.032 and 0.021.

Discussion

We found that in robotic rectal cancer surgery compared to conventional laparoscopy the conversion rate and complication rate are lowered and operation time is lengthened.

What do these results add to the discussion on robotic surgery in colorectal cancer? First of all this dispute resembles in many aspects the discussion on laparoscopy in general [39]. Early adopters face new problems and adoption is reluctant. Proponents are enthusiastic but cannot prove its oncological superiority. In rectal cancer, early trials like CLASSIC and COLOR were flawed by little experience in laparoscopy [40, 41]. Later trials like COLOR II showed oncologic equivalence [42]. Whereas there seems to be no oncologic superiority, the short-term benefits like less pain, shorter hospital stay, less blood loss, and cosmetics are generally accepted [39–41]. Nowadays most dedicated colorectal surgeons have adopted laparoscopy, although the extent of its use differs immensely between countries [43]. Recent randomized controlled trials like ACOSOG Z6051 and ALaCaRT could not prove non-inferiority of laparoscopy in colorectal cancer patients for the chosen primary outcome, being a set of pathology items [44, 45]. To our knowledge, these results have not led to changes in practice of rectal surgeons.

Furthermore, the results of our study have to be interpreted with caution. This “every day practice” study has the potential bias of an observational study where the

Table 3 Effect of robotic treatment on the dichotomous outcome variables presented as robotic to laparoscopic odds ratios (OR) with 95 confidence intervals (CI) and p values, adjusted for confounders

Dichotomous outcome	OR (95% CI)	p value	Adjusted for
CRM+	1.00 (0.15–6.72)	1.00	Previous TEM, operation year, senior surgeon, pathology N
Conversion	0.09 (0.03–0.32)	<0.0005	Male, BMI, neoadjuvant radiotherapy
SSI superficial	2.54 (0.61–10.6)	0.20	Previous TEM, OAP, ASA, operation year
SSI deep	1.19 (0.39–3.67)	0.76	Previous TEM
Anastomotic leakage	0.49 (0.16–1.52)	0.22	ASA, neoadjuvant radiotherapy
Any other complication	0.32 (0.15–0.69)	0.004	Age, OAP, senior surgeon, operation type Diverting ileostomy
Mortality	2.14 (0.10–48.1)	0.63	ASA, previous TEM, operation year

comparability of the treatment groups may be affected by a number of confounders. In a period of 10 years circumstances change. Also in our institution colorectal surgery has been evolving since 2005. Prospective databases and outcome analysis were introduced in 2005 and since 2009 benchmarking with national and regional registries was done. Centralization of colorectal surgery from two to one location was established in 2006. The perioperative SURPASS checklist and a bundle of care were introduced in 2008 to decrease postoperative wound infections [35, 36]. Looking for a next step to improve our results in colorectal cancer surgery, we started robotics in 2012 as theoretical advantages like better 3D vision and more precise dissection could lead to better results. Our first experiences, like less complications and a drastically lower conversion rate, were encouraging and so the department decided end 2013 to perform all rectal cancer cases with robotic assistance. From then on, almost all cases in our institution were performed by the two surgeons. In 2013, we introduced preoperative oral antibiotic prophylaxis (OAP). Obviously, all these alterations could not have been made in a randomized study. With statistical modelling, we tried to correct the treatment effect for a number of confounders, including the year of operation, but probably not all confounders have been taken into account. Confounders relating to overall morbidity may have been overlooked. But it is hard to think of unknown confounders influencing conversion rate and operative time other than the learning curve or fitness of the surgeons.

The learning curve as such was not considered in our study. We believe in an everlasting learning curve, but in this study the learning curve of the rectal resection in itself would be compensated by the learning curve of the robotic technique as the surgeons were novices in the robotic technique.

In contrast to the weaknesses of our study, there are some important strengths. A lot of factors did not change over time: the perioperative care was standardized the whole period as the enhanced recovery program was maintained in almost all aspects; the surgeons were the same and the prospective database was completed by the same three people during the entire period.

Considering the beforementioned remarks, we think our study contributes to the discussion about robotic surgery as it may give insight into the role of robotics in rectal cancer surgery by high volume rectal surgeons and institutions.

First, the conversion rate is drastically lowered when experienced laparoscopic surgeons perform the operation robotically. This is in contrast to the ROLARR trial in which experience among surgeons varied [34]. A low conversion rate is important because, in general, conversion is associated with more complications, longer hospital stay, and worse long-term outcome [46–57]. In just a few studies, conversion does not affect patients outcomes [58–60]. One might argue that our 12.5% conversion rate in the laparoscopic cases is too high for experienced surgeons. In the COREAN trial, the conversion rate was only 1.2%, generated by seven experienced surgeons [61]. On the other hand, our conversion rate in conventional laparoscopy did not differ from those in the COLOR II, the ALaCaRT trial, and ACOSOG Z6051 trial nor did it differ from the ROLARR trial [34, 42, 44, 45]. With robotic assistance, conversion seems to be no important issue anymore. There may be several explanations for this. Patient selection is not one of them in our series as there was no statistically differences in age, BMI, ASA classification and previous operation or neo-adjuvant therapy. In general, conversion should be pre-emptive and not reactive to complications [62]. In most cases, conversion is a result of precaution and frustration: for instance the vision is not good enough; the target organ cannot be reached with instruments or the camera assistance is poor. Better and stable vision, self-control of the camera and a third instrument, better access due to a higher degree of freedom of motion with robotic instruments and working with a dedicated team may all be factors that lessen the nature and extent of problems and frustrations encountered. In our situation, these factors are inherent to the use of the robot.

The second conclusion that can be made is that robotic assistance leads to longer operative time. Docking time is just a minor part of the lengthening of the procedure. We believe that reasons why robotic assistance is more time consuming may be an interesting field of research. Factors related to the surgeon and the level of stress, to the robotic technique itself, and to hardware may be involved. Ozden et al. have recently shown that in their hands operation time with the Xi system was about 11% less than with the SI system [63].

Our third conclusion is that in our series robotic surgery is associated with less short-term morbidity, which is similar to most series. In the univariable analysis, differences in wound infections may be the result of the introduction of bundle of care and OAP during the studied period, but the differences were not confirmed in a multivariable analysis. It is the aggregate of other complications that decreases after robotics.

Are these conclusions reason enough to defend the costs of robotic surgery? Initial costs of laparoscopy are more than in open surgery. Likewise, initial costs of robotic-assisted surgery are more than that in conventional laparoscopy. We did not perform an analysis of costs. The lowered short-term complication rate and the reduced conversion rate will affect in-hospital costs. After conversions, the complication rate is higher and the hospital stay is longer. The mid-term outcomes like time to return to work and secondary health care costs also rise. In case of a substantial decline in conversion rate, also the impact of the known long-term benefits of laparoscopy will have a positive influence on the cost–benefit ratio. The direct health care costs associated with treatment of adhesion-related complications within the first 5 years after surgery were studied in our country. In their cost model of adhesion-related complications, ten Broek et al. show that these costs are $2350 following open surgery and $970 after laparoscopy [64]. These effects should be considered when calculating expenses and may counterpart the initial higher expenses in robotic surgery.

The cost–benefit ratio has always to be considered in finding the exact role of new techniques. Future studies should focus more on finding the right indication for the use of robotic abdominal surgery. In colorectal surgery, distinction should be made between right-sided, left-sided, and rectal surgery. These groups of surgery differ in difficulty, rate of conversion, and sort of complications. Therefore, the advantages of robotics will differ between groups.

In cost calculation, the volume of surgery is also a factor. The gain of robotic surgery may differ between low volume and high volume centres. The debate on the use of robotic surgery or other innovations should not be conducted without taking into account the influence of volume on the outcome of surgery.

In contrast to other industries in medicine, technology tends to raise costs. To justify a new technology, the direct gain and the future perspectives should be considered. The development of new robots and the introduction of future advanced techniques in robotic surgery are a promising perspective and therefore the present robot technology should not solely be assessed on the basis of costs.

Apart from the items discussed, there are other aspects that have to be considered in choosing an operative technique. Important issues are the preservation of urinary and sexual function after rectal surgery. We did not quantify or measure these functions. There are case-matched studies that compare favorable for urinary and erectile function after robotic surgery [65–70]. The ROLARR trial shows no differences at 6 months in urinary and sexual dysfunction. Future randomized trials including urodynamic studies are needed to study the effect of robotic rectal surgery on urinary and sexual function.

Ergonomics in robotic or laparoscopic surgery probably is an underestimated topic. Laparoscopy is associated with occupational injuries of surgeons. For socioeconomic and personal reasons, a reduction of these occupational injuries must be pursued. There are a number of studies that show less physical and mental strain in robotic surgery compared to laparoscopic surgery [71–76]. These are important factors that contribute to the acceptance of a new operative technique.

In the meantime, other operative techniques for rectal cancer have emerged. TaTME is a promising technique that may lower the rate of positive circumferential resection margins and the conversion rate of conventional laparoscopy [77–79]. Reduced costs are an advantage of this technique over robotics and there are also theoretical advantages like no double stapling technique and the possibility to work synchronously with two teams.

On the other hand, robotic assistance has the potential to be an interface between the surgeon and the patient that provides skills and senses a human being lacks. These future developments cannot be realized with TaTME without robotic assistance.

Future studies like COLOR III hopefully will clarify what will be the role of the new operative techniques that have emerged in rectal cancer surgery in the past 20 years [80]. Not only short--term results and oncologic results must be taken into account, but also functional results, surgeon well-being, and ultimately costs.

Conclusion

Robotic surgery compared to conventional laparoscopic surgery in rectal cancer by experienced laparoscopic surgeons improved the conversion rate and complication rate drastically, but operation time was longer.

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Compliance with ethical standards

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