

ADVANTAGES OF USING A ROBOTIC STAPLER IN RECTAL CANCER SURGERY

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ABSTRACT

To compare short-term postoperative outcomes in patients undergoing robotic total mesorectal excision (TME) after the use of robotic and laparoscopic staplers. Over a 5-year period, 196 patients were divided into 2 groups according to the use of laparoscopic (LS) or robotic stapler (RS). Patient demographics and postoperative complications were compared. A total of 145 (74%) robotic TME were performed using the LS and 51 (26%) the RS. No conversions to laparoscopy or laparotomy were observed, in either group. Transection of the rectum using one or two firings was achieved in a higher proportion of RS cases (91%) compared with LS cases (60%; $p < 0.001$). The anastomotic leakage (AL) rate was 4% in the RS group vs. 7% in the LS group ($p > 0.05$). However, when three or more firings were needed for the rectal transection, the risk of AL increased (3.4% with ≤ 2 firings vs. 10.7% with ≥ 3 firings, $p = 0.006$). Our data confirm that multiple stapler firings for rectal transection have a major impact on AL. The robotic stapler simplifies the transaction, so that rectal division requires fewer stapler firings, with a potential reduction in the incidence of AL.

INTRODUCTION

Minimally invasive surgery for total mesorectal excision (TME) remains technically challenging, mostly because of poor manoeuvrability within the pelvis. The unfavourable entry angle makes it extremely difficult to introduce a laparoscopic linear stapler and transect the rectum low in the pelvis with only one or two firings. It has been demonstrated that three or more firings significantly increase the rate of anastomotic leakage (AL) (hazard ratio 7.8, 95% confidence (CI) 3.8-16.3).^{1, 2} Therefore, one of the most important technical and practical innovations of the robotic system is the use of the robotic stapler (EndoWrist Stapler, Intuitive Surgical, Inc.) (Fig. 1), which is introduced into the operative field by the assistant surgeon but is fully controlled by the surgeon. The stapler has a range of 108° side-to-side articulation and 54° up-and-down, enabling more precise positioning. Moreover, the stapler is capable of measuring tissue compression before and during stapler firing, making automatic adjustments. It then displays feedback to guide the surgeon towards 100% clamp completion. Only when the stapler is completely closed is the firing function enabled. The autonomy of the console surgeon on placement of the robotic stapler allows an easy antero-posterior placement of the stapler in the pelvis. With the increasing use of fluorescence (ICG) in the assessment of rectal perfusion, a robotic stapler allows a much accurate placement on a well-perfused bowel. This may have implications on the incidence of postoperative ischaemia and anastomotic leak.

With this systematic review and meta-analysis, we aimed to provide a comprehensive overview of the current data regarding safety of the robotic stapler, reporting on postoperative outcomes.

METHODS

A retrospective analysis was performed based on a prospectively maintained database. Patients eligible for inclusion included those with a rectal tumour at baseline considered to require complete TME who had undergone a robotic approach in a single centre over a 5-year period (May 2013 – May 2018). Patients were divided into two groups, based on the type of stapler employed to transect the rectum in the pelvis: LS or RS. Data recorded included patient demographics (sex, age, body mass index (BMI), American Society of Anesthesiologists (ASA) grade) and postoperative complications, including AL and reoperations.

Surgical technique

All patients underwent robotic TME using single docking full robotic technique,³ divided into the following five modules. 1) Patient set-up: patient and robotic car set up, port placement, access and exposure, and docking; 2) Inferior mesenteric artery exposure and ligation, development of medial to lateral plane and inferior mesenteric vein division. 3) Left colonic and splenic flexure mobilisation, using an infracolic three-step approach. 4) Rectal dissection. 5) Rectal stapling, specimen extraction, anastomosis and closure. For the rectal transection, two types of staplers could be employed: LS – laparoscopic 45 mm stapler (Echelon FLEX™ Endopath®, Ethicon), which is introduced through the assistant trocar; RS – robotic 45 mm stapler (EndoWrist Stapler, Intuitive Surgical), which is introduced through a 12 mm robotic trocar, replacing the previous 8 mm trocar in R1, and which is fully controlled by the main surgeon at the console.

Statistical analysis

Descriptive statistics are presented, with mean and standard deviation (SD) or median and lower – upper quartiles (LQ, UP) for quantitative variables. Comparison of differences between groups was carried out using Chi-Squared analysis, with Fisher's exact test when any value observed in the contingency table was less than 5. Differences between median values of the groups were assessed using Mann-Whitney U test. Odds ratios (OR) were computed for dichotomous and continuous risk factors between groups and logistic regression was performed, selecting those variables that showed a $p < 0.25$ in the univariate analysis.

In the meta-analysis, continuous variables representing the postoperative outcomes were analyzed by the weighted mean difference (WMD). The Q test and I^2 statistic were used to evaluate heterogeneity among studies. A Cochran Q statistical P value < 0.10 and/or $I^2 > 50\%$ was taken to indicate significant heterogeneity. Publication bias was tested using funnel plots.

All statistical analyses were conducted using SPSS® version 22 software (SPSS, Inc., Chicago, IL) and p -values of < 0.05 were considered statistically significant.

RESULTS

Over 5 years, 205 robotic TME were performed in our centre. Of these, nine patients were excluded from our analysis due to a lack of data; thus, 196 were included for further

analysis. The demographic characteristics of each group are shown in Table 1. Most patients were male (70%), with a median age of 69 (LQ, UQ: 61, 77) years. Median follow-up was 31 (LQ, UQ: 14, 47) months. A total of 145 (74%) TME were performed using the LS and 51 (26%) using the RS. The median operation time was similar between the two groups: 240 (LQ, UQ: 210, 290) minutes in the LS group vs. 250 (LQ, UQ: 140, 300) minutes in the RS group. The median length of hospital stay was 6 (LQ, UQ: 4, 9) days.

There were no conversions to laparoscopy or laparotomy. For both groups, the median number of firings required to transect the rectum was similar: 2 (LQ, UQ: 2, 3) in the LS vs. 2 (LQ, UQ: 2, 2) in the RS group. However, transection of the rectum using only 1 or 2 firings was achieved in just 60% of cases in the LS group compared to 91% in the RS group ($p<0.001$). All remaining cases required three or more firings.

Major complications were lower in the RS group (Table 1). There was a difference in the primary endpoint, i.e. the rate of AL between the groups, which was 7% in the LS group vs. 4% in the RS group, which was not statistically significant ($p=0.735$).

Results for the univariate and multivariable analysis, common factors that influenced AL are shown in Table 2. Results indicate that compared with less than 2 firings, when more than three firings were needed for the rectal transection, there is a 2.40% increased odds of AL and the results remains consistently higher 2.51% even after controlling for other variables. The difference however is not statistically significant.

DISCUSSION

The aim of this study was to investigate the impact of the RS on the rate of anastomotic leak. We have shown that it can be reduced by using the RS. In our experience, there were no significant differences in the median number of firings between the groups (two firings); however, it was possible to achieve complete rectal transection within two firings in 91% of cases with the robotic stapler, but only 60% of cases with the laparoscopic stapler ($p<0.0001$). When three or more firings were needed to transect the rectum (which occurred in 40% of LS cases but only 9% of RS cases), the risk of AL increased, as shown in Table 2. This was not statistically significant (3.4% vs. 10.7%, $p=0.06$), probably due to the small sample size.

The laparoscopic rectal transection phase is a critical step due to the narrow space and the limited traction manipulation. The main advantage of the robotic stapler is undoubtedly its 90°

of articulation, which may provide more accurate firings in the confined space of the pelvis. Fewer stapler firings have been shown to translate to lower rates of AL,^{1, 2} which was also noted in our study. Although not statistically significant, our data show a trend toward decreased AL for the RS group compared to the LS group (4% vs. 7%), which is probably due to the reduced number of firings required when using the RS.

There is a lack of data regarding postoperative outcomes after the use of the RS. Table 3 outlines key data published in previous studies and compares them with our study. Although results are not statistically significant, perhaps due to the small number of AL in every study the rate tends to decrease in all cases. To date, the RS has comparable outcomes to the LS⁴ but seems to require fewer firings for a rectal section ($p < 0.05$).^{5, 6} In our study, short-term outcomes and postoperative complications were also similar between the groups.

This is a retrospective, non-randomized study, so there are some inevitable biases. Our study is an observational study with a small sample size from a unique centre. As the majority of patients in the LS group were operated earlier, it could be a bias regarding the learning curve. However, the surgeons had already achieved proficiency in managing the stapler at the beginning of this study. A multicentre trial could be worthwhile to assess the safety of the robotic stapler and its role in reducing the rate of anastomotic leakage. Even so, we believe that despite the small sample size we have demonstrated the utility of this device in robotic rectal cancer surgery.

CONCLUSIONS

The use of the robotic stapler is safe and useful. It may help reducing the number of firings needed for rectal transactions and providing robotic surgeons with good control and autonomy for stapler firing.

Although the development of an anastomotic leak is multifactorial and unpredictable, our experience indicates that fewer stapler firings trend toward fewer leaks. Thus, the advantages of the robotic stapler in a narrow pelvis may lead in improved outcomes in robotic rectal cancer surgery. However, a randomised control trial or a large multicentre study is needed to confirm these findings.

COMPLIANCE WITH ETHICAL STANDARDS

- No funding.
- Authors have no conflict of interest.
- All procedures performed in studies involving humans were in accordance with ethical standards of the institutional research committee and the 1964 Helsinki declaration and its later amendments.
- Informed consent was obtained from all participants.

TABLES

Table 1. Patient characteristics.

	Laparoscopic stapler n = 145	Robotic stapler n = 51	p value
Age, median (LQ, UQ) (years)	69 (61, 76)	72 (60, 77)	0.591
Sex, male:female (%)	72:28	67:33	0.774
BMI (kg/m ²)	27 (24, 29)	26 (23, 29)	0.172
ASA			
I	9%	16%	
II	72%	65%	0.216
III	17%	12%	
IV	2%	7%	
Firings			
≤2	60%	91%	<0.001
≥3	40%	9%	
Total operative time, mean (SD) (min)	247 (81)	284 (96)	0.017
AL (n, %)	10 (7)	2 (4)	0.735
Radiological leak (%)	6.3	2	0.540
Reoperation due to AL (%)	0.7	2	0.454
LOS, median (LQ, UQ), days	6 (5)	6 (6)	0.450
30-day readmission	12 (8)	6 (12)	0.277
Follow-up, in months (median, LQ, UQ)	36 (27, 52)	9.5 (5, 14)	<0.0001

AL, anastomotic leak; ASA, American Society of Anesthesiologists grade; BMI, body mass index; LQ, lower quartile, UQ, upper quartile; LOS, length of hospital stay; P-values in bold means Statistically significant

Table 2. Univariate and multivariate analysis of risk factors for anastomotic leakage (AL) in all patients (n=196)

Variable	Anastomotic leakage n (%)	Univariate analysis			Multivariable analysis		
		OR	95% CI	p-value	OR	95% CI	p-value
Stapler				0.452			0.996
LS	10 (6.9)	1.00			1.00		
RS	2 (3.9)	1.82	0.38 - 8.58		1.01	0.08 - 12.06	
Firings							0.200
≤2	4 (3.4)	1.00		0.067	1.00		
≥3	6 (10.7)	3.39	0.92 - 12.54		3.51	0.52 - 23.85	
Age in years				0.230			0.857
<75	11 (7.7)	1.00			1.00		
≥75	2 (3.2)	0.39	0.08 - 1.82		0.85	0.15 - 4.75	
Sex				0.107			0.998
Female	1 (1.6)	1.00			1.00		
Male	12 (8.3)	0.18	0.02 - 1.44		0.00	0.00 - 0.00	
BMI				0.745			0.543
<30	9 (6.1)	1.00			1.00		
≥30	3 (7.5)	1.25	0.32 - 4.86		1.63	0.34 - 7.81	
ASA				0.987			0.928
<III	9 (5.7)	1.00			1.00		
≥III	3 (10)	0.99	0.21 - 4.73		1.09	0.18 - 6.53	
Preoperative radiotherapy				0.338			0.532
Yes	4 (9.8)	1.00			1.00		
No	9 (5.6)	1.83	0.53 - 6.26		4.30	0.04 - 416.74	
Preoperative chemotherapy				0.542			0.680
Yes	4 (8.3)	1.00			1.00		
No	9 (5.8)	1.47	0.43 - 4.98		0.38	0.01 - 37.84	

ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; OR, odds ratio.

FIGURE LEGENDS

Fig. 1. The da Vinci[®] robotic stapler (EndoWrist Stapler, Intuitive Surgical, Inc.).



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