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Are Previous Experience with Laparoscopy and the Inclusion in a Group of Surgeons with Prior Robotic Experience Required to Perform Robotic Rectal Cancer Surgery?

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Abstract

Introduction: Robotic rectal surgery could decrease the learning curve but the necessity of previous experience with laparoscopy or the importance of being part of a group of surgeons with previous robotic experience have not been analyzed yet.

Material: A total of 81 patients with rectal cancer were included in the study. Patients were divided into 3 groups of 27 patients each that were assigned to three surgeons. One had previous laparoscopic experience, but was included in a group without prior robotic experience. Another surgeon also had previous experience with laparoscopy and was included in a group with prior robotic experience. The third surgeon had no prior experience with laparoscopic rectal cancer surgery, but he was included in a group with robotic experience.

Results: Conversion and intra-operative complication rates were lower in patients treated by the two surgeons who were included in a group with prior robotic experience. The $CUSUM_{OT}$ curve also showed that operative time decreased earlier in these two surgeons, the incidence of postoperative re-interventions was higher among these two groups.

Conclusion: No previous experience with laparoscopic surgery for rectal cancer is required to begin robotic surgery if it is performed by a group of surgeons with prior robotic experience.

Keywords: Learning curve; Rectal cancer; Robotics

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Introduction

Laparoscopic rectal cancer surgery is a complex procedure requiring a high number of cases to overcome the learning curve. According to several studies, 40-90 procedures must be carried out to obtain standardized outcomes, although it has been demonstrated that oncologic results do not change during the learning period [1-6].

Robotic surgery, which provides surgeons with a three-dimensional surgical view, enhanced dexterity and precision in the use of the surgical instruments and the ability to control the operative field by manipulating the camera, may reduce the number of cases required to overcome the learning curve for mesorectal excision. Indeed, several studies report a shortening in the learning curve from 15 to 35 cases with the use of this robotic technique [7-10].

Some studies claim the importance of implementing preclinical training programs in robotic surgery, but they do not evaluate the necessity of prior experience with laparoscopic rectal cancer surgery, either in relation or not to these robotic training programs [11].

Consequently, the aim of the present study is to assess whether prior experience with laparoscopic rectal cancer surgery and the inclusion in a group of surgeons with previous robotic experience in the treatment of this condition may affect the learning curve and the short-term clinical and oncologic outcomes after surgery.

Table 1: Results per surgeon and comparison between them.

	Total	Surgeon 1 (n=27)	Surgeon 2 (n=27)	Surgeon 3 (n=27)	p	p Surgeon 1 & 2 vs 3 (*)	p Surgeon 2 & 3 vs 1 (#)
Age (years), mean (SD)	64.62(10.78)	64.59(10.93)	65.41(10.60)	63.85(11.16)	0.872	0.654	0.988
Male n (%)	52 (64.2)	14 (51.9)	18 (66.7)	20 (74.1)	0.222	0.19	0.101
Female n (%)	29 (35.8)	13 (48.1)	9 (33.3)	7 (25.9)			
Weight (kg), mean (SD)	73.77(12.57)	75.48(14.92)	73.15(12.45)	72.67(10.20)	0.684	0.581	0.389
Height (cm), mean (SD)	163.60(8.66)	162.74(9.53)	162.37(9.24)	165.70(6.89)	0.305	0.124	0.529
BMI (kg/m^2), mean (SD)	27.50(3.73)	28.39(4.00)	27.65(3.67)	26.46(3.38)	0.162	0.078	
Comorbidity Index					na	na	na
1 n (%)18	8 (9.9)	4 (14.8)	1 (3.7)	3 (11.1)			
2 n (%)18	17 (21.0)	4 (14.8)	3 (11.1)	10 (37.0)			
3 n (%)18	24 (29.6)	7 (25.9)	12 (44.4)	5 (18.5)			
4 n (%)18	23 (24.8)	10 (37.0)	6 (22.2)	7 (25.9)			
5 n (%)18	8 (9.9)	2 (7.4)	4 (14.8)	2 (7.4)			
6 n (%)18	1 (3.7)	0	1 (3.7)	0			
ASA					na	na	na
I n (%)	7 (8.6)	0	4 (14.8)	3 (11.1)			
II n (%)	44 (54.3)	12 (44.4)	13 (48.1)	19 (70.4)			
III n (%)	30 (37.0)	15 (55.6)	10 (37.0)	5 (18.5)			
IV n (%)	0	0	0	0			
PreopHb (gr/dl), mean (SD)	12.9(1.59)	12.51(1,68)	13.13(1.35)	13.04(1.72)	0.314	0.559	0.13
PreopHto (%), mean (SD)	39.40(4.73)	38.54(4.28)	40.31(3.96)	39.35(5.76)	0.396	0.948	0.252
Tumor location (cm), mean (SD)	9.01(4.38)	8.97(4.05)	9.19(4.43)	8.89(4.79)	0.946	0.858	0.846
Neoadjuvant therapy					0.399	0.206	0.293
Yes n (%)	52 (64.2)	19 (70.4)	18 (66.7)	15 (55.6)			
No n (%)	29 (35.8)	8 (29.6)	9 (33.3)	12 (44.4)			
MBP					-	-	-
Yes n (%)	81 (100)	27 (100)	27 (100)	27 (100)			
No	0	0	0	0			
Tiempo prep system (min), mean (sd)	53.64(19.26)	59.81(25.46)	52.41(18.57)	48.70(9.05)	0.81	0.87	0.531
Operative time (min), mean (SD)	176.91(45.27)	194.44(55.42)	165.37(39.83)	170.93(33.96)	0.098	0.403	0.487
Type of surgery					na	na	na
Anterior resection n (%)	61 (75.3)	22 (81.5)	18 (66.7)	21 (77.8)			
Hartmann n (%)	5 (6.2)	0	3 (11.1)	2 (7.4)			
Abdominoperineal resection n (%)	15 (18.5)	5 (18.5)	6 (22.2)	4 (14.8)			
Ileostomy, n (%)	32 (40)	14 (51.9)	9 (33.3)	9 (33.3)	0.302	0.385	0.122
Transfusion, n (%)					na	0.999	0.333
Yes	1 (1.2)	1 (3.7)	0	0			
No	80 (98.8)	26 (96.3)	27 (100)	27 (100)			
Intraop complications, n (%)					na	0.66	0.04
Yes	5 (6.2)	4 (4.8)	0	1 (3.7)			
No	76 (93.8)	23 (85.2)	27 (100)	26 (96.3)			
Conversion, n (%)					Na	0.153	0.014
Yes	10 (12.3)	7 (25.9)	2 (7.4)	1 (3.7)			
No	71 (87.7)	20 (74.1)	25 (92.6)	26 (96.3)			
Postop Complications, n (%)					0.064	0.999	0.043
Yes	17 (21.0)	2 (7.4)	9 (33.3)	6 (22.2)			
No	64 (79.0)	25 (92.6)	18 (66.7)	21 (77.8)			

Re-intervention, n (%)							
Yes	6 (7.4)	0	3 (11.1)	3 (11.1)	na	0.395	0.171
No	75 (92.6)	27 (100)	24 (88.9)	24 (88.9)			
Length of stay (days), median [p25; p75]	7 [5; 10.50]	7 [5; 9]	7 [6; 15]	5 [7; 10]	0.692	0.635	0.702
Mortality, n (%)	0	0	0	0	-	-	-
Length of specimen (cms), median [p25; p75]	16 [14.50; 20]	16 [15; 20]	16 [13; 20]	16 [14; 20]	0.652	0.844	0.494
Distance from the tumor to the distal margin (cms), median [p25; p75]	2.40 [1.10; 3.50]	2,50 [1; 4]	2.50 [1.50; 3.50]	1,5 [1; 3]	0.328	0.137	0.393
Harvested lymph nodes, median [p25; p75]	12 [9; 18]	15 [9; 18]	8 [12; 18]	14 [9; 18]	0.796	0.736	0.626

SD: Standard Deviation; na: Not Applicable. Comparative analysis carried out between the surgeries performed by surgeons with experience in laparoscopic rectal resections and the surgeon with limited experience (*) and between the surgeries performed by a surgeon included in a group without robotic experience and surgeons included in a group with robotic experience (#).

Material and Methods

A prospective database of 250 patients was analyzed. The patients underwent surgery for rectal cancer from January 2008 through January 2016 in the Coloproctology Unit of the University Hospital Virgen del Rocío in Seville. The protocol established by the multidisciplinary assessment committee of our hospital determined whether patients should be administered preoperative long-course chemoradiotherapy.

Of the 250 patients in the database, 81 patients with rectal cancers located <16 cm from the anal verge were finally included in our study. They were divided into three groups of 27 patients and were assigned to three different surgeons who were robotic surgery novices. Surgeon 1 had a large experience with rectal cancer surgery, both laparoscopic and open approach (more than 100 cases in each procedure), but was included in a group without prior experience in robotic surgery. Surgeon 2 also had extensive experience in both laparoscopic and open rectal cancer resections (more than 100 cases in each technique) and was included in a group with experience in robotic colorectal resections. Surgeon 3 had limited experience with rectal resection (less than 20 cases in each procedure), but he was part of a group with a experience of over 150 robotic rectal resections. None of them had previous robotic experience in rectal cancer or in other robotic procedures.

The number of cases allocated to each surgeon (27) was established considering previous publications [7-8,10,12-13], which suggest that 27 is the lowest number of cases necessary to overcome the learning curve in robotic rectal cancer resections.

Variables

Besides age and sex, the following variables were included in our study: BMI, tumor location, tumor stage, neoadjuvant therapy, surgical procedure (anterior resection with or without protective ileostomy, Hartmann procedure or abdominoperineal resection), intra and postoperative complications and conversion rates.

Operative time was defined as the time taken from pneumoperitoneum induction to completion of skin closure. Console time was considered as the time spanning from the beginning of the resection using the console to the removal of the specimen through a *Pfannenstiel* incision plus the time required to perform the anastomosis. In the case of Hartmann procedures and abdominoperineal resections, console time ends when the specimen section is completed. Specimen length, margins and postoperative stage were also recorded.

A written consent form signed by the patients was required before surgery to record all the variables in a database reviewed and approved by an ethical committee.

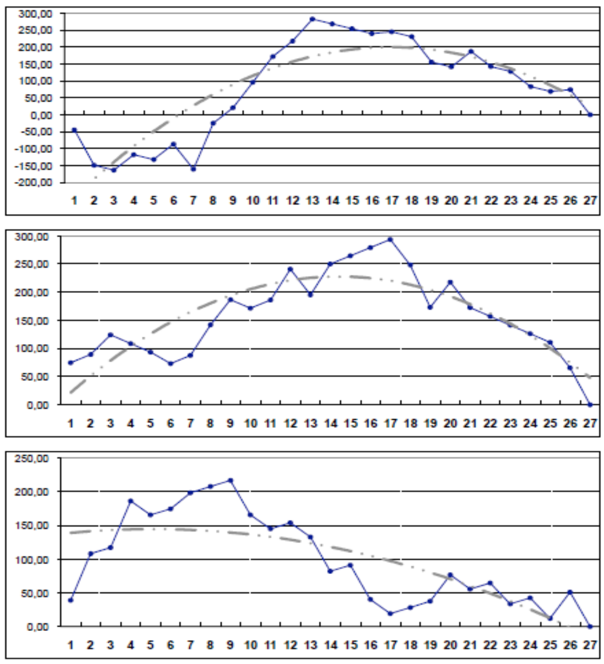

Figure 1: Surgeons 1, 2 and 3 $CUSUM_{OT}$ curves for the first rectal robotic cases.

Statistical Analysis

Qualitative variables were expressed as absolute frequencies and percentages and quantitative variables as means and Standard Deviation (SD) or as median and interquartile range ([p25; p75]) for data with non-symmetrical distribution. The statistical analysis of data was performed on contingency tables using Fisher's exact test or chi square test to analyze qualitative variables and variance analysis or Student's t-test for quantitative variables. Kruskall-Wallis or Mann-Whitney U tests were used to examine non-Normal quantitative variables.

The 81 patients included in our study were divided into 3 groups and were assigned to three different surgeons. Groups were compared with one another as follows: a group formed by patients allocated to surgeons 1 and 2 (with previous experience with laparoscopic rectal cancer resection) was compared with the group assigned to surgeon 3 and another group formed by patients assigned to surgeons 2 and 3 (included in a group with experience in robotic colorectal surgery) was compared to the group allocated to surgeon 1. Considering the

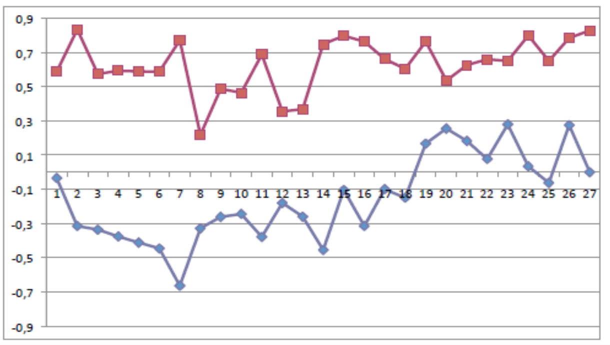

Figure 2: Surgeon 1. $CUSUM_{su}$ curve (blue) and probability of success (red) in each case.

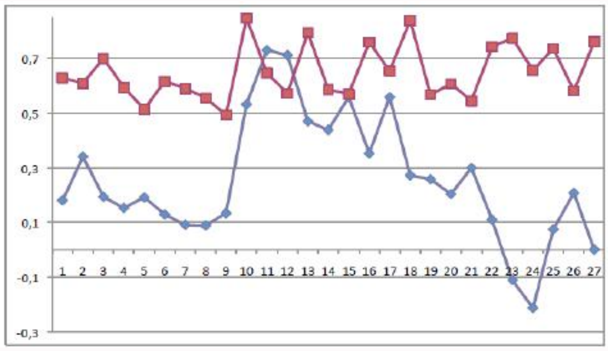

Figure 3: Surgeon 2. $CUSUM_{su}$ curve (blue) and probability of success (red) in each case.

earliest outcomes, variables showing a statistically significant value of $p<0.05$ underwent multivariate analysis.

Patients in each group were chronologically arranged from the earliest to the latest date of surgery. $CUSUM_{OT\ (Operating\ Time)}$ was determined for every patient by means of the following equation:

$CUSUM_{OT}$ value=C (i+1) + (Xi-mean Xi)

As no patient died during the study, it was not necessary to calculate the risk-adjusted CUSUM value (RA-CUSUM).

In order to calculate the CUSUM plot to measure the correlation between success and learning curve ($CUSUM_{su}$), "success" was defined as a surgical procedure not showing any of the following parameters or events: conversion to open surgery, intra-operative complications, postoperative complications and/or mortality. We then applied the equation:

$CUSUM_{SU}$ value (n) = Σ (xi - T) + $(-1)^{xi}$pi

where xi represents the presence or absence of the event being studied; T stands for the observed probability of the event, in this case the probability of "success" (64.2% in this case) and pi is the individual probability of failure in our population, once we apply to every value a logistic regression model which included the variables of age, gender, BMI, tumor location and operating time and which met the requirements for success.

Data were analyzed using the statistical software IBM SPSS 19.0 (SPSS. Inc., Chicago, IL).

Results

A total of 81 patients were included in the study; 52 males and 29 females with a mean age of 64,62 (SD=10.78) and mean BMI of 27.50 (SD=3.73). The procedures included 32 anterior resections with ileostomy, 29 anterior resections without ileostomy, 5 Hartmann procedures and 15 abdominoperineal resections. All patients were diagnosed of rectal cancers located 9.01 cm (SD=4.38) from the anal verge. All the characteristics are shown in (Table 1).

Our study population was divided into 3 groups according to the surgeon in charge of the surgical procedure. Differences between the three groups can be seen in (Table 1).

The comparative analysis of the three groups revealed no differences. A new analysis was carried out between the two groups of patients assigned to the two surgeons with previous laparoscopic experience and the group assigned to the surgeon without such

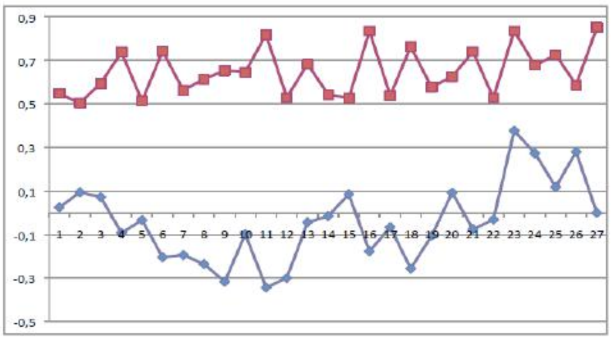

Figure 4: Surgeon 3. $CUSUM_{su}$ curve (blue) and probability of success (red) in each case.

Table 2: Tumor stage per surgeon (Absolute frequencies).

	Total	Surgeon 1	Surgeon 2	Surgeon 3
		Tp		
RC	9	2	5	2
TIS	3	2	1	0
T1	2	1	0	1
T2	21	11	5	5
T3	45	11	15	19
T4	0	0	0	0
		Postop N		
N0	52	15	16	21
N1	22	7	10	5
N2	7	5	1	1
		Postop M		
M0	79	26	26	27
M1	2	1	1	0

experience. Again the results revealed no significant differences. Next, a combined analysis was performed of the cases assigned to surgeons 2 and 3, who were included in groups with robotic experience, and the cases assigned to surgeon 1, who was not included in a group with robotic experience. The univariate analysis yielded significant differences in conversion rates (5.6 % *vs.* 25.9%) p=0.014, intra-operative complications (1.9% *vs.* 14.8%) p=0.040 and postoperative complications (27.8% *vs.* 7.4%) p=0.043 (Table 1).

The comparison of the $CUSUM_{OT}$ curves (Figure 1) plotted for each surgeon showed a decrease in operative time after cases 13, 17 and 9 for each surgeon respectively. $CUSUM_{SU}$ curves (Figures 2-4), which show the probability of success for each surgeon; reveal how success rate increases as the number of cases progresses (upward trend). Moreover, a higher probability of success is observed in the cases assigned to surgeons 2 and 3 (p>0.5) than in the cases assigned to surgeon 1.

Discussion

Rectal cancer surgery is a complex procedure which involves total or partial mesorectal excision, a precise and highly complicated technique. In order to obtain satisfactory oncologic outcomes, the dissection should proceed through the "Holy plane" described by Professor Heald [14].

The complexity of this surgical technique is determined by such factors as the reduced operative field of the pelvic cavity, particularly in the case of male patients; the tumor diameter which may impair visualization at this level; the probability of infiltration of adjacent organs like the prostate or the vagina and the use of neoadjuvant therapy, which affects tissue elasticity.

The use of the laparoscopic technique for mesorectal excision introduces a series of factors which increase the complexity of the procedure: two-dimensional surgical view, loss of the visual depth perception, limited mobility of straight laparoscopic instruments with fixed tips and the need for an assistant to move the camera and other instruments. As a result, laparoscopic rectal cancer surgery has an estimated learning curve of 65 cases [1-5].

Robotic surgery, on the other hand, provides a three-dimensional surgical view, a stable camera platform and articulated instruments. Hence, it offers the possibility of shortening the learning curve to 24-27 cases [15].

Nevertheless, the analysis of the learning curve of robotic rectal surgery has not taken into account the previous experience of surgeons with laparoscopy or their inclusion in a group with prior robotic experience.

Recently, Guend et al. [11] published a study to determine the number of cases required for establishing a robotic colorectal cancer surgery program as well as the impact of this program on the learning curve of individual surgeons. According to the results, establishing this program requires 75 cases. Moreover, the authors claim that this sort of programs may shorten the number of cases in an individual surgeon's learning curve to 25-30. In our study, we have observed that the inclusion in a group of surgeons with previous robotic experience affects both conversion rates and operative time. However, the study conducted by Guend et al. [11] does not analyze rectal tumors exclusively, nor does it indicate the previous laparoscopic experience of the surgeons included in the program or of the novice surgeons.

There are no reports in the literature which analyze the influence of the correlation between previous laparoscopic experience and the inclusion in a group of surgeons with robotic prior experience on both the learning curve and the short-term outcomes of rectal cancer surgery.

Prior laparoscopic experience has been analyzed by Kim et al. [16], who describe a one-step transition from open surgery to robotic surgery. They analyzed 100 consecutive cases performed by the two surgeons included in the study: surgeon A had no previous experience with laparoscopic rectal cancer surgery but he had some experience in open surgery and surgeon B had previous laparoscopic experience. Outcomes in relation to operative time and distal resection margins were more satisfactory in the cases performed by the surgeon without previous laparoscopic experience. However, the authors do not justify these results. They do not explain whether the surgeon was assisted by another surgeon or was part of a group of surgeons with previous robotic experience, which could justify the shorter operative time and the reduction in conversion rates.

Although some basic laparoscopic experience is necessary in order to place the trocar and to manage the patient when it is not possible to continue with the robotic procedure, no prior experience with laparoscopic surgery for rectal cancer is necessary, according to the results of our study. The results reported for the surgeon 1, who had not overcome the learning curve for laparoscopy, and for the other two surgeons showed no significant differences. As a result, intra-operative complications were not higher in the cases performed by surgeon 1. Also, he performed the same number of conservative surgeries of the sphincter as the other two surgeons but he did not perform more protective ileostomies.

Unlike to what we might expect from previous surgical experience, the longest operative time was observed in surgeon 1, whereas surgeons 2 and 3 obtained similar operative times. Probably, the inclusion in a group with prior robotic experience facilitated motion of the patient cart arms and the shortening of operative time. The surgeon with previous experience with laparoscopic surgery presented with a lower percentage of postoperative complications in comparison to surgeons 2 and 3. For surgeon 3, this could be justified by the lack of experience in rectal cancer surgery, but this is not applicable to surgeon 2.

In our study, the surgeon without previous laparoscopic experience performed a lower rate of conversions than the other two surgeons. Surgeon 1, who was not included in a group with previous robotic experience, showed the highest incidence of conversions. Although the results are not significant, in our opinion, these findings may show that the inclusion in a group of surgeons with previous robotic experience is important to overcome difficult situations, as was seen in the first cases of laparoscopic colorectal cancer surgery [17]. It is likely that the learning curves for success plotted for surgeons 2 and 3 were superior to that of surgeon 1, as the chances of conversion or intra-operative complications decreased with the help of a group of surgeons with robotic experience.

None of the three series of cases in our study showed differences in relation to the length of the surgical specimen or to the number of lymph nodes. The distance between the tumor and the distal margin was slightly longer in the group assigned to surgeon 1, although the differences were not significant.

Another variable that it is hard to analyze is the variability in the ability to perform surgery and mainly minimally invasive surgery. This has not been analyzed in this study due to the high level of subjectivity when making this analysis since it could include many other factors (age, place of previous training, etc) [18].

Although previous experience with laparoscopic surgery does not seem to be necessary to perform robotic rectal cancer surgery, oncologic outcomes in the mean and short term must be further analyzed in order to establish whether the learning curve affects patient's survival.

In addition, the use of robotic surgical simulators to provide surgeons with preclinical practice must also affect the learning curve. The design of charts to quantify the acquisition of basic skills and the progress in the use of different instruments on the part of trainees could lead to the necessity to establish some minimum requirements that should be attained before the preclinical training is completed.

Conclusion

The lack of previous experience with laparoscopy for the treatment of rectal cancer does not seem to affect the short-term outcomes of robotic surgery. Yet, being part of a group of surgeons who have overcome the learning curve for this technique reduces operative times and conversion rates but not the incidence of re-interventions in the immediate postoperative period.

Contribution

All authors were responsible for conceptualizing and designing the study; collecting, analyzing and interpreting the data and drafting the manuscript. All authors gave their approval on the final version for publication.

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