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Implementing and Promoting the Improvement of a Colorectal Surgery Unit: A Comparative Study

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ABSRACT

AIM

Specialized coloproctology units were created with the aim of promoting excellence in the treatment of colorectal conditions. Aim: evaluate the 10-years evolution of the colorectal surgery unit in our centre, comparing the results obtained with established quality indicators.

METHODS

Retrospective observational study at Malaga Regional Hospital, for patients who underwent programmed surgery for colorectal neoplasm from 2009 to 2018, divided into two five-year groups.

RESULTS

1353 patients were included, both study groups are demographically similar, except for ASA score, which was higher in the second period (SP). Surgical site infection (SSI) rate in the first period (FP) for colon cancer was 11.8% *vs.* 11.7% in SP (Spanish Association of Coloproctology(AECP) indicator) <23%). SSI rate in rectum neoplasm was 15.7% *vs.* 10.5% (AECP indicator <25%). Our anastomotic leakage rate in colon cancer was 6.9% *vs.* 8.9% (quality indicator <5%, threshold: <10%), and in rectal cancer 7.5% *vs.* 8.8% (AECP indicator <10%). Mortality rate in our study was 4.3% *vs.* 3% (quality indicators <7%). Re-entry rate was 1.8% *vs.* 5.4% according with AECP indicators. We showed that our eventration rate was 3.6%, meeting the quality indicators. Our reintervention rate was 6.1% *vs.* 6.6% (AECP indicator <6%, threshold <9%). The average postoperative hospital stay was 9 ± 12.9 days *vs* 9 ± 12.2 days (AECP indicator <7 days, threshold <11 days).

CONCLUSION

Our coloproctology unit has promoted its improvement and currently meets the quality standards set by the AECP, although there is still much room for improvement in terms of reducing hospital length of stay and the rate of anastomotic leakage.

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KEYWORDS

Colorectal surgery; Coloproctology; Anastomotic leakage

WHAT DOES THIS PAPER ADD TO THE LITERATURE?

After 10 years, the establishment of our colorectal unit, the following question arises: Have we improved our results? Are our results similar to the standards published in the scientific literature?

This study aims to highlight the importance of studying our own results to identify and implement areas for improvement.

INTRODUCTION

The need to provide excellence in the treatment of colorectal conditions promoted the creation of specialized units for them. Specifically in Spain, the Spanish Association of Coloproctology (AECP) developed a certification programme for coloproctology units in 2010, with the aim to recognize excellence and drive their improvement efforts [1].

Given the high prevalence of this condition, scientific societies establish a series of quality indicators for these colorectal surgery specialized units, with the aim to provide ongoing evaluation of the results obtained, in order to promote the necessary changes to reach the goal of therapeutic excellence [1-4].

The aim of this article is to analyze the evolution of the 10 years of experience of the coloproctology unit in our centre by conducting a comparative study between a first period and a second period (5 years long each), taking as a reference AECP indicators [2], which evaluate the results of surgical therapy in colorectal cancer (Table 1).

Name	Definition	Standard	Threshold
SSI indicator for rectal cancer	Rate of patients included in the assessment presenting with SSI (superficial, deep and organ space) after rectal cancer surgery.	<23%	<25%
SSI indicator for colon cancer	Rate of patients included in the assessment presenting with SSI (superficial, deep and organ space) after colon cancer surgery	<25%	<27%
Anastomotic leakage indicator	Rate of patients included in the assessment showing infection or anastomotic leak (clinical or radiological)	<5% (<10% low rectum)	<10% (<15% low rectum)
Mortality indicator	Rate of patients included in the assessment who die during hospital admission, due to problems related to the surgery performed.	<7%	<10%
Re-entry indicator	Percentage of patients readmitted to hospital within 30 days of discharge from hospital.	<5%	<10%
Eventration	Evisceration is considered only during hospital admission.	<3%	<5%
Reintervention		<6%	<9%
Post-surgical hospital stay		<7 días	<11 días

Table 1: AECP indicators for colorectal cancer surgery. SSI: Surgical site infection.

MATERIALS AND METHODS

Single-centre retrospective observational study conducted at Malaga Regional Hospital, comparing the results obtained in a first period with those obtained in a second period.

The established inclusion criteria were the following: Age ≥18 years old, having accepted the informed consent according to Helsinki declaration, with neoplasms diagnosed either at our centre or at regional hospitals attached to our centre, without any general or anaesthetic contraindications for colorectal surgery.

Those patients under the following conditions were excluded: Patient's rejection of informed consent, disseminated disease, or vital urgency and emergency situations.

The patients included in the study were those who underwent programmed surgery for neoplastic disease by the coloproctology unit in our centre, distributed in two groups: the first period, from 2009 to 2013, and the second period, from 2014 to 2018. All the procedures in both periods were performed by the same 5 surgeons from our centre, specialized in colorectal surgery. The follow-up period was at least 2 years for all patients and finished in December 2020.

The variables analyzed in this study were divided into 4 groups:

- Demographic variables: Age, sex, body mass index (BMI) and previous abdominal surgery rate.
- Perioperative variables: Location, approach, minimally invasive surgery rate (MIS, understood as laparoscopic and robotic approaches), procedure performed, stoma rate, sphincter preservation rate, mesorectal excision, total lymph node count (as long as it was ≥12), affected lymph nodes, lymph node ratio, average surgical time, average estimated blood loss, distal and circumferential margin, conversion rate, type of resection, and staging.
- Postoperative variables: Morbidity rate, Clavien classification [5], surgical site infection (SSI), intra-abdominal abscess rate, eventration, anastomotic leakage, postoperative ileus, postoperative hospital stay, reintervention and readmission.
- Survival variables: Exitus at the end of follow-up, cause of exitus, and overall survival.

The quality indicators established by AECP for the treatment of colorectal cancer were taken as a reference [2,6,7].

Statistical Analysis

The mean and the standard deviation (SD) are included for continuous variables, as well as the number of lost cases, if any. Quantitative variables are expressed as number of cases and percentage.

The non-parametric Mann-Whitney U-test was used as a contrast method in the comparative analysis of quantitative variables (given that no continuous variables were found to be normal according to the Kolmogorov Smirnov test previously conducted). This test is used to verify the hypothesis of equality of medians between the groups to be compared. The chi-squared ($\chi2$) test or Fisher's exact test were used for qualitative variables. The chi-squared ($\chi2$) test is aimed at verifying the hypothesis of equality of distributions between the two treatments to be compared. The statistical significance threshold was set at $P < 0.05$.

The analysis of the overall survival data is presented with an associated Kaplan-Meier plot, and a log-rank test evaluating the hypothesis of whether both risk functions are equal or show any differences over time. The statistical significance threshold was set at $P < 0.05$.

The analysis of the data was performed using SPSS 15.0 software (IBM Statistics, Chicago, IL).

RESULTS

The study was conducted on a total of 1353 patients who underwent surgery for colorectal neoplasm from 2009 to

2018, divided into two groups: 571 patients operated on during the first period (2009-2013) and 782 patients during the second period (2014-2018).

Table 2 shows the patients' demographic characteristics.

		FIRST PERIOD	SECOND PERIOD	p
Age (years)		65.9 ±15.8	66.8± 14.8	0.382
Sex (%)				0.31
	Male	324 (57.9)	474 (60.6)	
	Female	236 (42.1)	308 (39.4)	
BMI		27.4 ± 16.5	27.5 ± 5.3	0.308
ASA (%)				0.001
	I	56 (10)	26 (3.3)	
	II	268 (47.9)	346 (44.2)	
	III	230 (41.1)	407 (52)	
	IV	6 (1.1)	3 (0.4)	
Previous surgery (%)		329 (58.7)	453 (57.9)	0.784

Table 2: Demographic characteristics of the patients in the study, categorized by surgery period.

There were no significant differences between groups in terms of age, sex, BMI and previous history of abdominal surgery. Therefore, we can conclude that both study groups are demographically similar, except for their ASA score.

Surgery for colon cancer (54.6%) was predominant over that for rectal cancer (45.4%) in the first period, and the other way round in the second period (49.1% colon *vs.* 50.9% rectum), with no statistically significant differences (p = 0.045). The minimal invasive surgery (MIS) rate was statistically significant (p = 0.011) due to the increase in the cases treated with a minimally invasive approach in the second period in relation to the first period (57.5% *vs.* 64.3%).

Table 3 shows the perioperative variables of the patients included in the study. The predominantly performed procedures in both periods were right hemicolectomy and sigmoidectomy (21.6% and 16.8% respectively in the first group, *vs.* 23.9% and 14.5% in the second group). The number of low anterior resection (LAR) and ultralow anterior resection (ULAR) procedures increased in the second period, whereas abdominoperineal resection (APR) decreased in the second period in comparison with the first period.

The rate of patients with ≥12 lymph nodes obtained in colon neoplasms was 61.3% in the first group, versus 79.9% in the second group, with statistical differences (p = 0.001). The rate of patients with ≥12 lymph nodes obtained in rectal neoplasms was 61% in the first period versus 76.7% in the second period, also with statistically significant differences (p = 0.001) (Table 2). The average number of lymph nodes obtained in colon neoplasms was 13 ± 6.4 in the first period versus 15.3 ± 6.2 in the second period, with a statistically significant difference (p = 0.001). In rectal neoplasms, the average number of lymph nodes obtained was 12.9 ± 5.9 in the first period, versus 14.4 ± 6 in the second period, being the difference statistically significant (p = 0.003).

Both the average surgical time and the estimated blood loss decreased gradually between the first and the second period, being the average time 152.8 ± 63.1 minutes in the first group, versus 138 ± 57.9 minutes in the second group, with statistically significant differences (p = 0.001).

Regarding estimated blood loss, the average was 144.1 ± 274.4 ml in the first period versus 81.7 ± 219.8 ml in the second period, being the difference equally significant (p = 0.001).

		FIRST PERIOD	SECOND PERIOD	p
Approach (%)				**0.001**
	Open	238 (42.5)	279 (35.7)	
	Laparoscopy	166 (29.6)	333 (42.6)	
	Da Vinci®	156 (27.9)	170 (21.7)	
Procedure (%)				**0.001**
	Right hemi	121 (21.6)	187 (23.9)	
	Left hemi	24 (4.3)	25 (3.2)	
	Sigmoidectomy	94 (16.8)	113 (14.5)	
	Total colectomy	18 (3.2)	13 (1.7)	
	Subtotal colectomy	15 (2.7)	5 (0.6)	
	AR	56 (10)	69 (8.8)	
	LAR	42 (7.5)	102 (13)	
	ULAR	18 (3.2)	29 (3.7)	
	APR	74 (13.2)	88 (11.3)	
	Other	98 (17.5)	151 (19.3)	
Stoma (%)				**0.033**
	No	404 (72.1)	520 (66.5)	
	Temporary	45 (8)	93 (11.9)	
	Permanent	111 (19.8)	169 (21.6)	
Sphincter preservation (%)				0.093
	No	74 (38.9)	88 (30.5)	
	Yes	116 (61.1)	200 (69.5)	
Mesorectal excision (%)				**0.007**
	Partial	47 (22.5)	110 (33.2)	
	Total	162 (77.5)	221 (66.8)	
Lymph node colon (mean ± SD (range))		13 ± 6.4	15.3 ± 6.2	**0.001**
Lymph node rectum (mean ± SD (range))		12.9 ± 5.9	14.4 ±6	**0.003**
Neoplastic lymph nodes colon		1.7 ± 4.2	1.3 ± 2.9	0.479
Lymph node ratio colon (%)		0.1 ± 0,2	0.1 ± 0.5	0.076
Neoplastic lymph nodes rectum		1.4 ± 2.8	1.1 ± 2.9	0.007
Lymph node ratio rectum (%)		0.1 ± 0.2	0.1 ± 0.5	0.446
Distal margin (%)				0.308
	Affected	6 (1.1)	18 (2.3)	
	Free	478 (85.4)	647 (82.7)	
	Unspecified	3 (0.5)	2 (0.3)	
	Not applicable	71 (12.7)	115 (14.7)	
Circumferential margin (%)				**0.001**
	Affected	39 (7)	45 (5.8)	
	Free	128 (22.9)	365 (46.7)	
	Unspecified	63 (11.3)	55 (7)	
	Not applicable	73 (13.1)	308 (39.4)	
Resection (%)				**0.047**

	R0	527 (94.1)	746 (95.4)	
	R1	12 (2.1)	23 (2.9)	
	R2	21 (3.8)	13 (1.7)	
Staging				0.265
	Stage 0	120 (21.4)	165 (21.1)	
	Stage I	111 (19.8)	189 (24.2)	
	Stage II	143 (25.5)	191 (24.4)	
	Stage III	118 (21.1)	155 (19.8)	
	Stage IV	68 (12.1)	82 (10.5)	

Table 3: Perioperative variables of the study subjects. Right hemi: Right hemicolectomy. Left hemi: Left hemicolectomy. R0: No microscopic or macroscopic disease. R1: Microscopic disease. R2: Macroscopic disease.

		First Period	**Second Period**	**P**
Clavien classification (%)				0.125
	0	322 (57.5)	514 (65.7)	
	I	62 (11.1)	74 (9.5)	
	II	107 (19.4)	115 (14.7)	
	III	38 (6.8)	46 (5.9)	
	IV	6 (1.1)	8 (1.2)	
	V	24 (4.3)	24 (3.1)	
SSI colon (%)				0.983
	Sí	36 (11.8)	45 (11.7)	
	No	269 (88.2)	338 (88.3)	
SSI rectum (%)				0.051
	Sí	40 (15.7)	42 (10.5)	
	No	214 (84.3)	356 (89.5)	
Intra-abdominal abscess (%)				**0.04**
	Sí	17 (3)	42 (5.4)	
	No	542 (96.8)	739 (94.5)	
Eventration (%)				0.994
	Sí	20 (3.6)	28 (3.6)	
	No	539 (96.3)	753 (96.3)	
Anastomotic leakage colon (%)				0.339
	Sí	21 (6.9)	34 (8.9)	
	No	284 (93.1)	349 (91.1)	
Anastomotic leakage rectum (%)				0.553
	Sí	19 (7.5)	35 (8.8)	
	No	235 (95.5)	363 (91.2)	
Postoperative ileus (%)				0.938
	Sí	104 (18.6)	144 (18.4)	
	No	455 (81.3)	637 (81.5)	
Reintervention (%)				0.740
	Sí	34 (6.1)	51 (6.6)	
	No	525 (93.9)	730 (93.4)	
Readmission (%)				**0.001**
	Sí	10 (1.8)	42 (5.4)	
	No	548 (97.9)	737 (94.6)	
Exitus 30 days (%)				0.237
	Sí	24 (4.3)	24 (3)	
	No	536 (95.7)	758 (97)	

Table 4: Postoperative variables of the patients in the first period versus those in the second period.

The rate of conversion to open surgery was similar in both periods (7% *vs.* 7.1% respectively), without statistically significant differences (p = 0.561).

Statistically significant differences were found in:

- Approach: Conventional laparoscopic approach is more frequent in the second period than in the first period (29.6% *vs.* 42.6%).
- Permanent stoma rates: Lower in the first period than in the second period (16.8% *vs.* 21.6%).
- Total mesorectal excision (Table 2).
- Free circumferential margin (Table 2).
- Type of resection performed (Table 2).

Regarding postoperative variables, morbidity rate in the first period was significantly higher (p = 0.014) than in the second period, being 41.6% in the first period and 35% in the second period. The average postoperative hospital stay was 9 ± 12.9 days in the first period and 9 ± 12.2 days in the second period, with no statistically significant differences (p = 0.743). Table 3 shows the surgical variables obtained in the study.

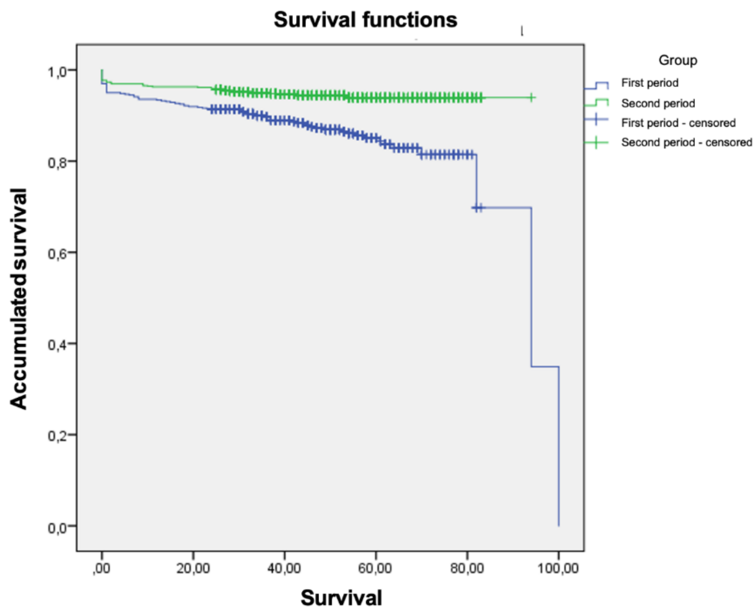

Figure 1: Kaplan-Meier plot for the survival of the patients included in the study, stratified by periods.

A statistically significant difference between groups (p = 0.001) was found in the analysis of survival, given that there were 77 deaths in the first period (13.8%) versus 44 in the second period (5.6%). The causes of death were the following:

- Neoplastic causes: 32 cases in the first period versus 13 cases in the second period.
- Sepsis of abdominal origin: 10 patients in the first group versus 4 patients in the second group.
- Cardiopathy: 9 cases in the first period versus 2 cases in the second period.
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- Pneumopathy: 6 cases in the first group versus 7 cases in the second group.
- Multiorgan failure: 3 cases during the first period versus 2 cases during the second period.
- Pulmonary thromboembolism: It caused the death of only one patient in the first group.
- Stroke: One patient in each group died of it.
- Sepsis of unknown origin: 3 cases in the first group versus 1 case in the second group.
- Nephrouropathy: It caused the death of one patient in the first group.
- Other causes: 11 patients in the first period versus 7 patients in the second period.

The patients' overall survival was 89.4 ± 1.6 months. When the patients' average survival was stratified according to each period, a statistically significant difference was found ($p = 0.001$), being 82.8 ± 2.6 months in the first period versus 89.2 ± 0.7 months in the second period. Figure 1 represents the survival curve of the study population.

DISCUSSION

The results presented in our study reflect both the implementation and the continuous improvement effort of the colorectal surgery unit in our centre during a 10-years period. Throughout this time, laparoscopic approach has gradually become the most frequently used with our patients. The robotic Da Vinci system (Abex, Madrid, Spain) was incorporated in 2009, as well as the fast-track protocol, and patients with higher surgical risk (older age, higher ASA score, previous abdominal surgery, lower rectal anastomosis) have progressively been assumed.

The limitation of this study is its retrospecddtive character, which could reduce internal validity, given that it includes possible confusion factors in relation to the time in which patient evaluation is done. With the purpose of trying to correct these factors, the follow-up period was the same for all the study subjects, thus generating different cut-off points in their follow-up processes

The MIS rate was significantly higher in the second period than in the first period, which is justified by the increased rate of minimally invasive transanal surgery (TAMIS), as well as the increased learning curve of our surgeons, which facilitates a change of mentality and a higher level of confidence.

The number of APRs decreased progressively from the first to the second period, being the APR rate in patients with rectal neoplasms 38.9% in the first group, versus 30.5% in the second group. APR rates below 40% are considered as a quality criterion, which has therefore been met in both periods, with significant improvement in the second one.

The SSI rate in colon cancer in our centre was 11.8% in the first period and 11.7% in the second period, being both results within the AECP [2] standards for this type of complication (Table 1). SSI rates in rectal cancer were also within the Spanish standards, having obtained a rate of 15.7% in the first period and an important decrease in the second period, tending towards statistical significance (10.7%). This fact is probably related to the implementation of the programme "Infección quirúrgica zero" [8] in 2018, established by the Ministry of Health, Social Services and Equality. The minimally invasive approach also became more frequent due to the increase in the number of procedures done by conventional and robotic laparoscopy.

Anastomotic leakage is one of the surgeons' most dreaded complications, because it increases perioperative morbimortality and the length of hospital stays. In our study, the rate of anastomotic leakage in colon surgery during the first period was 6.9%, *vs.* 8.9% in the second period. The incidence of anastomotic leakage in rectal cancer surgery was 7.5% in the first group, *vs.* 8.8% in the second. The standard set by AECP is <5% of anastomotic leakage, with a <10% threshold in colon surgery and a <15% threshold in rectal surgery. Our results in terms of anastomotic leakage are within the thresholds set by AECP, although the incidence of anastomotic dehiscence increased in the second period. We associate this increase in the leakage rate with higher patients' ASA scores, as well as with an increased number of LAR and ULAR procedures performed in the second period, given that they entail anastomoses with higher risk of dehiscence. Rates of anastomotic leakage between 6.4% and 8.7% have been published in literature [9-11], which coincide with the results obtained in our large series of patients.

A total of 48 patients died within the first 30 postoperative days: 24 patients (4.3%) in the first period versus 24 patients (3%) in the second period. The standard by the AECP is a rate below 7%. Therefore, our perioperative mortality rate is much lower than the rate established for the accreditation of a colorectal unit.

The average hospital stay of our patients was similar in both periods. The fast-track programme implemented in our unit from the beginning of the study was strongly influenced by the high percentage of minimally invasive surgery, given that it implies less surgical aggressiveness for patients and less bowel manipulation, which reduces morbidity and hospital stays in most cases [12]. However, as we have observed, the average length of our patients' hospital stays has not decreased over time, probably because more complex surgeries have been assumed, which implies higher morbidity risk and longer hospital stays.

As it has been published in numerous series in scientific literature [13-17], surgical time and estimated intraoperative blood loss decrease as the surgeon's learning curve rises. In our study, surgical time decreased from 152.8 ± 63.1 minutes in the first period to 138.7 ± 57.9 minutes in the second, being this time reduction statistically significant. Regarding intraoperative blood loss, a dramatic decreased was also observed from the first period (144.1 ± 274.4 ml) to the second (81.7 ± 219.8 ml).

The survival analysis showed a higher rate of exitus in the first period than in the second period (13.8% *vs.* 5.6%), with highly varied causes, as presented in Figure 1. The average overall survival of the patients included in the study was 89.4 ± 1.6 months, with some differences if we stratify it by groups, being higher in the patients from the second period.

In conclusion, more complex surgeries were assumed during the second period of the study, due to higher ASA scores and higher LAR and ULAR rates. There was also an increase in the MIS rate, as well as a decrease in surgical time and the average intraoperative blood loss. Therefore, we can affirm that our coloproctology unit has promoted its improvement and currently meets the quality standards set by the AECP, although there is still much room for improvement in terms of reducing hospital length of stay and the rate of anastomotic leakage.

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