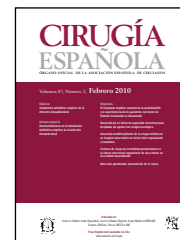




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Original article

Analysis of the quality of surgical treatment of colorectal cancer, in 2008. A national study

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A B S T R A C T

Objectives: A national study conducted for the Spanish Association of Surgeons with the aim of analysing the surgical treatment of colorectal cancer (CRC) in Spain and to compare it with scientific literature.

Material and methods: A multicentre, descriptive, prospective and longitudinal study of patients with CRC who were treated by elective surgery. A total of 50 hospitals in 15 Autonomous Regions took part, with 496 treated cases in 2008. A total of 88 variables were collected.

Results: The median age was 72 years, increase in ASA III patients; correct preoperative studies, 4% with no staging in the rectum. There was a tendency not to use the colon cleansing or to do it only one day. The percentage of complications is within the ranges in the literature, with the exception of surgical wound infections (19%). Mean of resected lymph nodes: 13.2; 4.3% no mesorectal resection. Mechanical anastomosis: 80.8%, 65.9% of the operations performed by a colorectal surgeon. Preoperative radiotherapy in 43.5% of rectal cancers. Chemotherapy: 32.9%. Laparoscopy: 35.1% of cases, conversion rate 13.8%. Use of antibiotics: 37.1%, blood transfusion: 20.6% and parenteral nutrition: 26.5%.

Conclusions: Surgical treatment of CRC in Spain has a level of quality and peri-operative results similar to the rest of Europe. Compared to previous studies, it was observed that there were advances in preparation of the patient, preoperative studies, imaging techniques, and improvements in surgical techniques with adoption of mesorectal excision, appropriate lymphadenectomies and preservation of sphincters.

There are areas for improvement, such as a reduction in surgical wound infections, increase use of protective stoma, appropriate use of antibiotics, parenteral nutrition or neoadjuvants and complete colonoscopies.

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Análisis de la calidad asistencial del tratamiento quirúrgico del cáncer colorrectal en 2008. Estudio de ámbito nacional

R E S U M E N

Palabras clave:
Cáncer de colon
Recto
Cirugía
Calidad

Objetivos: Estudio de ámbito nacional realizado por la Asociación Española de Cirujanos con el objetivo de analizar el tratamiento quirúrgico del cáncer colorrectal (CCR) en España y compararlo con la bibliografía.

Material y métodos: Estudio multicéntrico descriptivo, prospectivo y longitudinal de pacientes intervenidos quirúrgicamente de forma programada por CCR. Han participado 50 hospitales de 15 comunidades autónomas aportando 496 casos intervenidos en 2008. Se han recogido 88 variables.

Resultados: Mediana de edad 72 años, aumento de pacientes ASA III, preoperatorio correcto, en el recto un 4% sin estratificar. Tendencia a no realizar preparación del colon o a hacerlo únicamente un día. Los porcentajes de complicaciones están en rangos de la bibliografía excepto infección de herida quirúrgica (19%). Media de ganglios resecaados: 13,2; 4,3% no resección mesorrectal. Anastomosis mecánicas: 80,8%, 65,9% de las intervenciones realizadas por cirujano colorrectal, Radioterapia preoperatoria en cáncer de recto 43,5%. Quimioterapia 32,9%. Laparoscopia: 35,1% de los casos, índice de conversión 13,8%. Uso de antibióticos: 37,1%, transfusión sanguínea: 20,6% y nutrición parenteral: 26,5%.

Conclusiones: El tratamiento quirúrgico del CCR en España tiene un nivel de calidad y unos resultados perioperatorios similares al resto de Europa. Respecto a estudios previos, se observan avances en la preparación del paciente, estudio preoperatorio, técnicas de imagen y mejoras en técnica quirúrgica con adopción de escisión del mesorrecto, linfadenectomías adecuadas y preservación de esfínteres.

Existen áreas de mejora, como disminución de la infección de la herida quirúrgica, mayor uso de estomas de protección, uso adecuado de antibióticos, nutrición parenteral o neoadyuvancia y colonoscopias completas.

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Introduction

The *Asociación Española de Cirujanos* (Spanish Association of Surgeons) (AEC) quality management department has collaborated with other departments to develop a series of national studies designed to provide surgeons with information on various processes. These studies provide the basis to help improve these processes. One of these studies focused on colorectal cancer (CRC). In 2000, a national study was carried out,^{1–3} enabling quality of care to be analysed and a clinical pathway to be published.^{2,4}

CRC is one of the most prevalent cancers in our society, being the second most frequent for both sexes. In 2005, Spain's mortality rate for colon and rectal tumours was 29.63/100 000 inhabitants⁵ (34.77/100 000 for men and 24.62/100 000 for women). In 2006, 9912 patients died due to colon cancer and 3163 due to rectal cancer (RC).

As surgeons, we currently focus on the results obtained at the various stages in the care process, from diagnosis to follow-up and, in the case of CRC, adjuvant and neoadjuvant treatment. The aim of this study is to analyse the results of CRC surgical treatment a group of surgery departments.

Patients and methods

This was a prospective, multicentre, descriptive longitudinal study of patients that underwent CRC surgery in the general surgery and digestive system departments of public hospitals in 15 autonomous regions. Proposals for participation were sent to 70 departments. These departments were selected through AEC using three criteria: participation in a prior study by AEC,¹ special interest in the treatment of CRC and perception of the possibility of response (convenience sampling).

The sample size was calculated from information on CRC mortality from the *Instituto Nacional de Estadística* (National Institute of Statistics) (INE),⁶ for a 95% certainty and 4% accuracy and an expected probability of 0.5, with a sample size of 480 patients.

We included patients undergoing elective surgery for CRC with the exclusion criteria being emergency surgery, palliative surgery and cancers other than adenocarcinoma.

Eighty-eight variables were defined: clinical characteristics of patients (8 variables), scientific and technical quality (33 variables), in-hospital complications (12 variables), interval

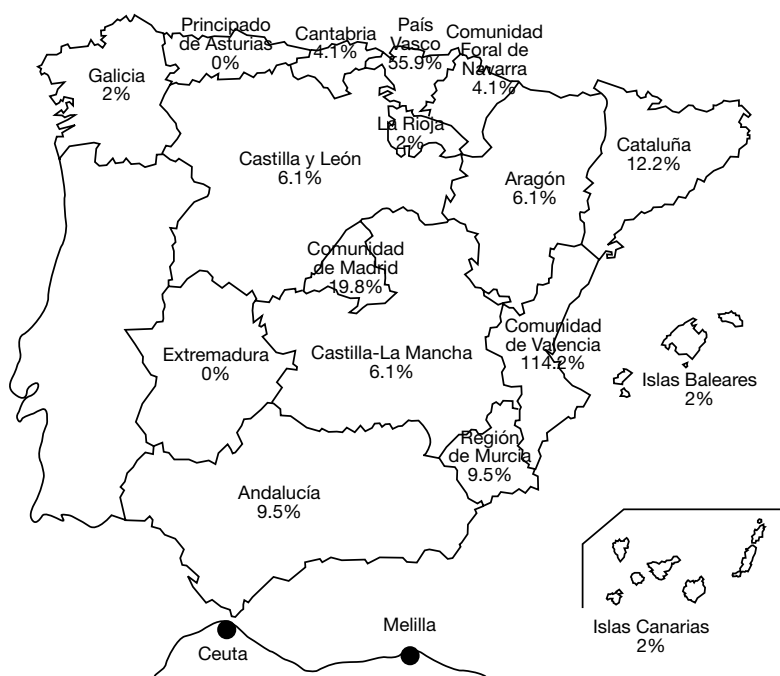


Figure 1 – Map showing distribution by autonomous region.

Table 1 – Distribution by hospital care level and ASA score

Hospital care level	Percentage
A (<300 beds)	13.5
B (300-800 beds)	51.8
C (>800 beds)	34.7
ASA	
I	6.6
II	48.8
III	39.3
IV	5.3

Table 3 – Preoperative mechanical preparation

Preoperative preparation	Percentage
No preparation	24
Oral solution+enemas	18.4
Enemas	13.9
Oral	67.7
One day preparation	86.8
Residue-free diet	73.8
ATB prophylaxis	99.2
Thromboembolic prophylaxis	92.9

Table 2 – Diagnostic and extension study

Diagnostic and extension study	Percentage
Abdominal ultrasound	31.9
Endorectal ultrasound (rectal cancer)	48.9
Colonoscopies	99.2
Complete colonoscopies	69.6
Opaque enema	17.5
Computed tomography	87.3
MRI (rectal cancer)	66.3
Endorectal ultrasound+MRI (rectal cancer)	40.2
MRI indicates magnetic resonance imaging.	

times used (8 variables), pathology report results (7 variables), complementary therapy (4 variables) and resources used (6 variables).

Data were collected consecutively from all patients undergoing surgery for CRC in participating hospitals until 10 patients per hospital had been found. Recruitment started in February 2008.

Results

Fifty hospitals in 15 autonomous regions participated (Figure 1) and provided 496 cases. Males made up 61.1% of the cases. The mean age was 70.16 years with a median of 72 years and standard deviation (SD) of 11.21, ranging from 28 to 96 years.

A total of 99.8% of patients provided informed consent and 38.6% followed a clinical pathway.

The hospital care level and ASA score are shown in (Table 1).

Diagnostic and extension studies on the patients were (Table 2):

Of the 184 patients with RC, 25% (46 patients) were studied with CAT scans and 4.35% were not studied using any type of imaging testing.

Table 4 – Tumour location

Tumour location	Frequency	Percentage
Rectal	184	37.1
Sigma	138	27.8
Right colon	115	23.2
Left colon	40	8.1
Transverse	2.4	2.4
More than one	7	1.4
Total	496	100.0

Table 5 – Type of surgery

Type of intervention	Cases	Percentage
Low anterior resection (LAR)	127	25.6
Right hemicolectomy	115	23.2
Sigmoidectomy	112	22.6
Abdominoperineal amputation	46	9.3
Left hemicolectomy	44	8.9
More than one of those above	13	2.6
Pancolectomy	8	1.6
Local Excision	5	1.0
Extended right hemicolectomy	5	1.0
Transversectomy	2	0.4
Other large intestine resections	19	3.8
Total	496	100.0

Table 6 – TNM

TNM classification	Percentage
Stage I	17.9
Stage II	42.9
Stage III	29.1
Stage IV	10.1

Table 7 – Complications

Complications	% Total	% Colon	% Rectum
Surgical wounds infection	19.3	14.7	27.1
Reintervention	9.1	7.7	11.6
Abdominal infection	7.1	5.5	9.9
Haemorrhage	6.1	6.1	6
Anastomotic fistulae	6.1	5.6	
Rectal anastomotic fistulae ≤8 cm			9.8
Rectal anastomotic fistulae >8 cm			4.7
Respiratory infection	5.7	6.2	4.9
Catheter infection	3.1	2.3	4.4
Ventral hernia	3.5	3.2	3.8
Thromboembolism	0.2	0	0.5
Death	3	3.9	1.6
Readmissions	4.9	4.5	5.5

Preoperative mechanical preparation is shown in (Table 3). The location of the tumours and the type of resection are shown in Table 4 and Table 5. Surgery on other organs was also performed on 16.5% of the patients (simultaneous resection of liver metastases for 1.2% of cases).

Mechanical anastomosis: 80.8%. For the right hemicolectomy, 36.5% required manual anastomosis, while 7 cases (5.8%) required manual anastomosis for the rectum. Forty-nine ileostomies were performed, 41 (32.3%) associated with anterior resection (AR).

Some 65.9% of interventions were performed by a surgeon specialised in colorectal surgery, and 9% of interventions were performed by a resident surgeon; 56.4% being right hemicolectomies and 1.4% AR or sigmoidectomies.

Some 35.1% of patients were operated on using laparoscopy with a conversion index of 13.8%. Intraoperative endoscopy was performed on 3.9% and 68.4% were operated on using laparoscopy.

A total mesorectal excision was performed on 88.6% of AR cases and 95.5% of abdominoperineal amputations (APA) (data taken from the pathology reports). Some 4.9% of surgeons performed an incomplete resection and no resection was performed on 4.3% of patients. Some 90.3% were considered R0 and 3.2% were considered R1.

The mean number of lymph nodes excised was 13.2 with a standard deviation (SD) of 7.6 and a median of 12 with a 95% CI: 12.6-13.9. Some 63.5% of patients did not have any tumours. The mean number of lymph nodes infiltrated was 1.6 with a 95% CI (1.27-1.87) and 3.37 SD.

Table 6 shows the stages of the tumours.

For colon cancer, 3.5% (11 patients) received radiotherapy, 3 before surgery. For rectal cancer, 80 patients (43.5%) received preoperative radiotherapy, 2 pre and 16 postoperatively. Chemotherapy was administered to 32.9% of patients: 7.1% before surgery, 9.1% before and after.

The average time between colonoscopy and surgery was 54.7 days, 95% CI (50.04-59.27) with SD 49.49 and a median of 35 days. Times between RC colonoscopy and surgery were: 44 days without neoadjuvant treatment and 135 days with it. Mean operative time was 163.9 min 95% CI (158.1-169.8) with SD 63.1 and a median of 150 min. Average preoperative hospital stay was 3.12 days, 95% CI (2.48-3.77) with SD

6.98, a median of 1 day and range of 0 to 110 days. Mean postoperative hospital stay was 12.36 days (14.6 for RC) with 95% CI (11.34-13.37) with SD 10.92 and a median of 9 days.

The time between neoadjuvant therapy and intervention was 47.28 days 95% CI (43.27-51.29) with SD 12.87 and a median of 47 days. The average interval between the intervention and chemotherapy was 40.7 days with 95% CI (35.1-46.35) with SD 18.1 and a median of 37 days. The interval between intervention and radiotherapy was 53.6 days.

Complications are shown in Table 7.

Total parenteral nutrition (TPN) was used in 26.5% of patients for an average of 12.76 days with 95% CI (9.5-15.97) with SD 7.94 and a median of 10 days. Excluding those patients with anastomotic fistulae who received TPN (19 cases), 23.5% of patients received TPN.

Some 37.1% received antibiotic treatment for an average of 13.5 days, 95% CI (9.67-17.33) and a median of 11 days. Excluding infectious complications (except for surgical wound infection) that constituted 74 (14.9%) of total cases, 28.7% received antibiotic treatment for an average of 7.4 days. Some 20.6% received transfusions and the mean number of units transfused was 3.7, 95% CI (2.75-4.7) with a median of 3.

Discussion

Several groups around the world are studying and publishing reports on the quality of surgical treatment of CRC. In Europe, this concern has led to studies in Norway,⁷ France,⁸ Germany,⁹ Sweden,¹⁰ Denmark,¹¹ and Holland,¹² among others. We have reviewed the European scientific literature. The results, especially for survival, have improved in the last 30 years¹³ due to improvements in surgical procedures and medical oncology treatments. Although we have attempted to reflect the current situation of CRC surgery in this study, there are unavoidable biases associated with using convenience sampling and not performing any external audits. However, we believe that these data provide a good approximation.

A total of 99.8% of patients provided informed consent, compared to 87.8% for 2000.^{1,14,15}

The demographics show an aging population, comparing the median of 61 years in the 2000 study¹ with 72 years in 2008. The risk of side effects is increased in patients older than 65 years. Patient comorbidity has increased as reflected in ASA III patients (30.2 vs 39.3%).

In preoperative studies, abdominal ultrasounds (68.6%¹ vs 31.9%) have been replaced by CAT scans (47.2%¹ vs 87.3%) as the better method for diagnosing extension.

Final diagnosis can not be drawn only from tumour markers. They are not suitable for screening and do not modify the choice of treatment¹⁶; however the use of the carcinoembryonic antigen (CEA) tumour marker is included in most clinical practice guidelines^{17,18} as it allows early detection of 25%¹⁹ of recurrences.

The percentage of complete colonoscopies has improved in comparison with 2000¹ (58.4% vs 69.6%) but is still far from the recommended 85%.²⁰ The use of opaque enema has declined to 17.5% of patients, and colonoscopy is the diagnostic test that is used first²¹ in 99.2% of cases.

Multiple tumours were found in 4.1% of patients and there was an increase in tumours in the right colon compared to data from 2000,¹ from 19.1% to 23.2%. This increase is attributed to the aging of the population and the distribution of polyps in the colon²² and demonstrates that the percentage of complete colonoscopies is an indicator of quality.

In RC, the extension study for correct preoperative staging should include magnetic resonance imaging (MRI) or endorectal ultrasound.²³ Some 4.35% of RC patients were not studied with imaging tests and for 25% CAT scan was used, therefore 30% were not studied properly. Determining tumour staging through imaging is essential when deciding whether neoadjuvant treatment should be used.³³ These data are consistent with those from the auditing project *Proyecto Vikingo*; MRIs were not conducted in 31.5% of cases and endorectal ultrasounds were not conducted in 34.4%.²⁴

Some 43.5% of RC patients received preoperative radiotherapy vs 33.3% in 2000. Patients who received preoperative radiotherapy were ten times more likely to suffer perineal wound complications.²⁵ This could explain the greater percentage of infections in RC; in APA, the infection of the surgical wound reached 50% (39% in 2000).

Preoperative preparation is adjusting to the scientific evidence that does not justify its use.²¹ Multimodal rehabilitation protocols (*Fast Track*)²⁶ include the use of two 200 ml enemas the day before surgery.

The use of thromboembolic prophylaxis has declined from 96.9%¹ to 92.9% despite the fact that the risk of pulmonary embolism²⁷ in colorectal surgery is high.

The rate of APA was 26.6%. We found values between 22% and 27% in the literature consulted,^{13,28} which is heavily influenced by the volume of the centre.²⁹ For tumours under 8cm, this percentage rises to 44.6%, which is very similar to the recently published 44.8%.²⁹ The appropriateness of using this as a criterion for technical suitability is debatable.²⁸

Mesorectal excision, which greatly influences the prognosis,³⁰⁻³² grew from 69%¹ in 2000 to 88.6% thanks to efforts made towards its implementation.³³ We found percentages higher than 95% from European literature.

The quality of lymphadenectomies was correct (average number of lymph nodes excised: 13.2). Since 1990,³⁴ the recommendation has been 12 lymph nodes for adequate staging of the cancer. In patients with negative lymph nodes, evaluation of 10 to 15 lymph nodes is recommended.³⁵

The mean number of lymph nodes affected (1.6) illustrates the importance of obtaining a minimum number of lymph nodes for study.³⁶ The percentage of interventions on other organs was low, with 6 cases of liver metastases resections. Between 13%-25% of CRC patients³⁷ had synchronous liver metastases. Advances in liver surgery have removed age, number of metastases or bilateral involvement of the liver or lung³⁸ from the list of contraindications for surgery.³⁹

The laparoscopic approach reaches one third of patients with evidence showing similar oncologic outcomes with lower morbidity.⁴⁰ The development of laparoscopy has influenced the increase in mechanical anastomosis (80.8% vs 62.2%), the reduction in manual anastomosis in right hemicolectomies (56%¹ vs 36.5%) and the reduction in resident junior doctors performing surgery.

Hospital mortality rates in the literature are around 3%-4% for colon cancer and below 3% for rectal cancer.²⁹ The figures obtained are within this range and are especially favourable for RC (1.6%).

Complications, except for wound infections, are within the range reported in the literature. The increase in the percentage of ASA III and elderly patients, would partially justify why it is difficult for perioperative morbidity to reduce.

Surgical wound infection, unrelated to the absence of antibiotic prophylaxis, was very high. This rate was higher than that recommended in the clinical practice guidelines.

RC has higher rates than colon cancer in all complications except for respiratory infection. However, it has lower hospital mortality.

The percentages of fistulae were lower than those found in the literature for AR (12%-15%).²⁹ Fistulae affect prognosis since they have higher rates of local recurrence and greater morbidity and mortality rates especially if they require reintervention.⁴¹ Protective stoma in the AR reach a third of patients and we find rates of 60% in European literature. Although using protective stoma has not changed the percentage of fistulae, it would be advisable to use them more often since they reduce the number of reinterventions.⁴²

The use of antibiotics and parenteral nutrition (TPN) is not consistent with the recommendations based on scientific evidence, with excessive use of antibiotics and TPN that are employed for excessive periods of time.

When compared to 2000,¹ the number of transfused patients has declined (27.1%). We can observe greater efficiency in preoperative and postoperative hospital stays.¹

The curative R0 resection rates (90.3%) are higher than those of studies conducted in Europe²⁹ (80%-85%), and are higher than the clinical guidelines (60%¹⁹) but similar to the rate published in other series (92%).^{8,19}

Some 39.2% of patients were diagnosed in stages III or IV. These data are similar (34.2%)⁸ or better than those published in Europe (45% stage III or IV in Germany where there is screening). This high percentage of patients with RC diagnosed in late stages (18% stage I) shows that the use of neoadjuvant treatment should be applied to a high percentage of patients. Our figures are not satisfactory but are higher than the 25% published in other countries.²⁹

To assess the impact of the structure, the hospital level has been included; however future studies should incorporate a more complex structural capacity index⁴³ to analyse the contribution of the structure to the quality of care (functional units, tumour registry, MRI, radiotherapy service, training). It is also important to add quality of life and satisfaction surveys so that patients perspective can be included.

In conclusion, the level of quality and perioperative results for surgical treatment of CRC in Spain are similar to the rest of Europe. Progress is being made in patient preparation, preoperative studies, use of MRI and endorectal ultrasound for staging, adoption of mesorectal excision, appropriate lymphadenectomies, laparoscopic approach and sphincter preservation.

There are areas for improvement such as surgical wound infection, accurate preoperative staging, neoadjuvant treatment, use of protective stoma and appropriate use of antibiotics and parenteral nutrition.

Conflict of interest

The authors affirm that they have no conflicts of interest.

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