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## Original article

## Self-evaluation of a clinical pathway to improve the results of rectal cancer

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## A B S T R A C T

**Objectives:** To analyse whether the self-evaluation of a clinical pathway improves the results of rectal cancer (RC) treatment.

**Patients and method:** Patients operated on for RC were divided into 3 groups according to biannual modifications of a clinical pathway analysing several indicators.

**Results:** 166 patients: Group A: 2002–3 n=50, B: 2004–5 n=53 and C: 2006–7 n=63, without any differences in age, gender or comorbidity. Preoperative study improved with the introduction of CT scan: 76% in Group C vs 6% in Group A ( $P<.001$ ). All Group C tumours were staged using MR, rectal ultrasound or both, compared to 84% in Group A ( $P<.001$ ). The rate of abdominal-perineal resections was reduced from 42% (Group A) to 17% (Group C); ( $P=.007$ ) and about 48% of surgeons in Group A vs 94% in the C had a specific activity in coloproctology ( $P<.001$ ). The average lymph node count was: Group A=6.2  $\pm$  4.5 vs 13  $\pm$  6.5 in the C and circumferential margin analysis was reported in 24% of Group A vs 76% in Group C ( $P<.001$ ). Parameters such as perioperative blood transfusion, ICU admission, use of nasogastric tube, early feeding or epidural analgesia also improved progressively. Operative mortality decreased non-significantly to 4.7% and anastomotic leaks from 24% to 9.5% with a reduction in postoperative stay from 15 to 11 days during the period analysed ( $P=.029$ ).

**Conclusions:** Several indicators have significantly improved in a relatively short period of time due to self-evaluations of the process

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## Autoevaluación de una vía clínica para mejora del proceso quirúrgico carcinoma de recto

### R E S U M E N

#### Palabras clave:

Cáncer de recto

Vía clínica

Indicadores de calidad asistencial

**Objetivo:** Analizar si la autoevaluación de una vía clínica mejora los resultados del tratamiento del cáncer de recto (CR).

**Pacientes y método:** Pacientes intervenidos de CR divididos en 3 grupos según modificaciones bianuales de una vía clínica analizando diversos indicadores.

**Resultados:** Ciento sesenta y seis pacientes: grupo A: 2002–2003, n=50; B: 2004–2005, n=53 y C: 2006–2007, n=63; sin diferencias en edad, sexo o comorbilidad. El estudio preoperatorio mejoró con la introducción de TC toracoabdominopélvico: un 76% en el grupo C frente a un 6% del A ( $p < 0,001$ ). Todos los tumores del grupo C fueron estadificados mediante RM, ECO rectal o ambas, frente a un 84% del A ( $p < 0,001$ ). La tasa de amputaciones de recto pasó del 42% en el grupo A al 17% en el C ( $p = 0,007$ ). Un 48% de cirujanos del grupo A frente al 94% en el C ( $p < 0,001$ ) tenían dedicación específica a la coloproctología. La media de adenopatías analizadas fue: grupo A:  $6,2 \pm 4,5$  frente a  $13 \pm 6,5$  en el C ( $p < 0,001$ ) y se informó del margen circunferencial en un 24% del grupo A frente al 76% en el C ( $p < 0,001$ ). Parámetros como la transfusión perioperatoria de hemoderivados, ingreso en UCI, uso de sonda nasogástrica, tolerancia precoz o analgesia epidural también mejoraron progresivamente. La mortalidad operatoria descendió de forma no significativa hasta el 4,7% y las dehiscencias anastomóticas del 24% al 9,5%, reduciéndose la estancia postoperatoria de 15–11 días ( $p = 0,029$ ).

**Conclusiones:** Se han mejorado múltiples indicadores de forma significativa en un período relativamente corto al efectuar autoevaluaciones del proceso.

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## Introduction

Over the last few decades the culture of self-assessment of surgery results has spread, together with the need to establish minimum quality requirements.<sup>1</sup> Clinical pathways are useful tools for analysing the quality of care for common relevant processes with a predictable clinical course such as rectal cancer (RC). Its surgical treatment has traditionally been measured by indicators such as morbidity and mortality, hospital stay and recurrence rate. The quality of the surgical specimen, resources consumption, quality of life or the cost of the clinical process, among other factors, have been recently added to this list.<sup>2</sup>

Clinical practice guidelines set out the indicators and recommended standards for RC.<sup>3–8</sup> Some years ago, we designed a clinical pathway adapted to our hospital, which has been discussed and evaluated by a multidisciplinary group. The aim of this study is to analyse if self-assessment based on scientific evidence of posterior updates has improved the quality of care in rectal carcinoma.

## Patients and methods

We analysed all consecutive patients who underwent surgery for RC at our institution between January 2002 and December 2007. This followed a clinical pathway introduced in 2002, with subsequent biannual amendments by a multidisciplinary team to optimise the use of resources and

improve performance, depending on the available evidence (Table 1). This group has gradually expanded and, since 2005, it includes several specialist surgeons, an endoscopist, a radiologist, a pathologist, and medical and radiotherapy oncologists, all of whom meet on a weekly basis.

**Table 1 – Programmes to improve the colorectal carcinoma clinical pathway**

2002–2003
Initial development of the clinical pathway
Creation of a multidisciplinary group
Virtual colonoscopy
2004–2005
High resolution Magnetic Resonance Imaging
Fat clearance techniques to optimise lymph node count
Sedation assisted colonoscopy
2006–2007
Specially dedicated oncologist
Specially dedicated pathologist
Extension study protocol with thoracoabdominopelvic CT
Virtual colonoscopy (the same day, if the colonoscopy was incomplete)
Entry into the group of 2 colorectal surgeons accredited by the European Union
Surgery performed only by specially dedicated colorectal surgeons
Review criteria for admission to the Intensive Care Unit
Multimodal rehabilitation programmes ( <i>fast track</i> )
Analysis of the quality of the mesorectum

The patients were divided into 3 groups according to their date of surgery, which roughly corresponded to the dates of the clinical pathway updates (Group A: 2002–2003; Group B: 2004–2005, Group C: 2006–2007).

Cases of elective surgery by RC were included. Rectal tumours were considered to be those located within 15 cm of the anal margin by rigid sigmoidoscopy. Palliative colostomies and diffuse peritoneal carcinomatosis were excluded. The minimum postoperative follow-up was 18 months.

The variables analysed were, in addition to the clinical characteristics of patients and comorbidities, indicators of both technical and clinical quality, including imaging methods for staging, neoadjuvant therapy, surgical treatment and pathology, and use of resources. Data was collected prospectively in a clinical-administrative database (Microsoft® Office Access 2003), and was processed with SPSS 15 for Windows (SPSS Inc., Chicago IL, USA). Chi squared and Fisher exact tests were used for qualitative variables, and t-Student or Mann Whitney U tests for quantitative variables, depending on the distribution of data after an assessment using the Kolmogorov-Smirnov test. *P* value <.05 was considered statistically significant.

## Results

One-hundred and sixty-six patients (103 men and 63 women) with a mean age of  $71 \pm 11$  years were studied. Group A included 50 patients, Group B had 53, and Group C had 63. No differences of age, sex or severity of patients, as classified by the American Society of Anesthesiologists (ASA), were found (Table 2).

## Technical quality of the process

Regarding imaging techniques, the study ranged from the use of abdominal ultrasonography and plain chest radiographies, to thoracoabdominopelvic CT, which increased to 76.2% in group C (Table 3). Local staging by MRI and endorectal ultrasonography (EUS) also increased, and in group C either of these procedures was performed on 100% of patients. All patients underwent preoperative colonoscopy, which was incomplete in 80 (48.2%) and showed no differences between groups. In the case of a failed colonoscopy more virtual colonoscopies (CT colonography) were requested in each period for either the same or following day in order to complete the procedure as is protocol in group C. The overall rate of complete colonic evaluation between the preoperative period and the first 3 months of the postoperative period was 95.8%, without any difference between the groups.

There were no differences in the use of neoadjuvant therapy (chemoradiotherapy), with long and short cycles in 85 and 10 patients respectively. Thrombo- and antibiotic prophylaxis was applied in all cases. Mechanical colon preparation (MCP) was performed in 158 patients (95.2%). In groups B and C the colon was not prepared in 2 and 6 cases of high rectum cancer, respectively, due to a change in management protocol, which meant only those patients scheduled for a complete mesorectal excision with derivative ileostomy underwent MCP.

Regarding surgical treatment, the percentage of surgeons who specialise in colorectal surgery (i.e. it takes up at least 80% of their daily activity) has gradually increased, reaching 92% in group C. Non-palliative surgery was performed in 77.7% of cases, with no differences found between the groups.

**Table 2 – Patient characteristics**

	Group A	Group B	Group C	P
	n=50	n=53	n=63	
Age (SD)	72 (8.9)	69 (11)	70 (11.6)	.369
Sex (%)				.062
Men	31 (62)	39 (73.6)	33 (52.4)	
Women	19 (38)	14 (26.4)	30 (47.6)	
Tumour location (%)				.045
Upper third	11 (22)	8 (15.1)	25 (39.6)	
Mid third	23 (46)	28 (52.8)	23 (36.5)	
Lower third	16 (32)	17 (32)	15 (23.8)	
ASA classification,* %				.099
I	2 (4)	2 (3.8)	2 (3.2)	
II	20 (40)	20 (37.8)	38 (60.3)	
III	26 (52)	28 (52.8)	22 (34.9)	
IV	2 (4)	3 (5.6)	1 (1.6)	

ASA indicates American Association of Anesthesiologists; SD, standard deviation.

\*Surgical risk.

**Table 3 – Technical quality**

	Group A n=50	Group B n=53	Group C n=63
<i>Imaging techniques</i>			
Thoracoabdominopelvic CT (%)	3 (6)	5 (9.4)	48 (76.2)***,c
Pelvic MRI (%)	38 (76)	47 (88.7)*	59 (93.6)**
Endorectal ultrasonography (%)	8 (16)	0**	6 (11.3)a
Local staging (%) (MRI and/or EU)	42 (84)	47 (88.7)	63 (100)***,b
CT colonography, if incomplete colonoscopy	5/26 (19.2)	13/27 (48.1)*	16/27 (59.3)**
Neoadjuvant (%)	27 (54)	30 (56.6)	37 (58.7)
<i>Surgical treatment</i>			
Specialist surgeons (%)	24 (48)	40 (75.5)**	58 (92.1)***,a
Rectal amputations (%)	20 (40)	20 (37.7)	11 (17.4)*,a
Middle third amputations (%)	5/23 (21.7)	5/28 (17.8)	0/23*,a
Lower third amputations (%)	14/16 (87.5)	15/17 (88.2)	11/15 (73.3)
Laparoscopic approach (%)	0	0	7 (11.1)*,a
<i>Anatomical pathology study</i>			
Lymph nodes examined (SD)	6.2 (4.5)	8.2 (6)	13 (6.5)***,c
Circumferential margin analysis (%)	12 (24)	34 (64.1)***	48 (76.2)***
Circumferential margin involvement (%)	6 (50)	4 (11.8)*	7 (11.8)*
Satisfactory mesorectum (%)	NE	7/12 (58.3)	29/37 (78.4)
Correct response to neoadjuvant (%)	2/27 (7.4)	3/30 (10)	5/37 (13.5)
<i>Postoperative treatment</i>			
Postoperative radiotherapy (%)	9/47 (19.1)	5/48 (10.4)	5/60 (8.3)
Adjuvant chemotherapy (%)	29/47 (61.7)	21/48 (43.7)	29/60 (48.3)
Local recurrence (%)	5/47 (10.6)	8/48 (16.6)	5/60 (8.3)
Local recurrence in non-palliative surgery (%)	5/38 (13.1)	5/36 (13.8)	3/48 (6.2)
Local recurrence and colorectal surgeon (%)	1/23 (4.3)	5/38 (13.2)	3/56 (5.4)
Local recurrence and non specialist surgeon (%)	4/24 (16.6)	3/10 (30)	2/4 (50)

EU indicates endorectal ultrasonography; MRI, magnetic resonance imaging; NE, non evaluated; SD, standard deviation.

\*P<.05.

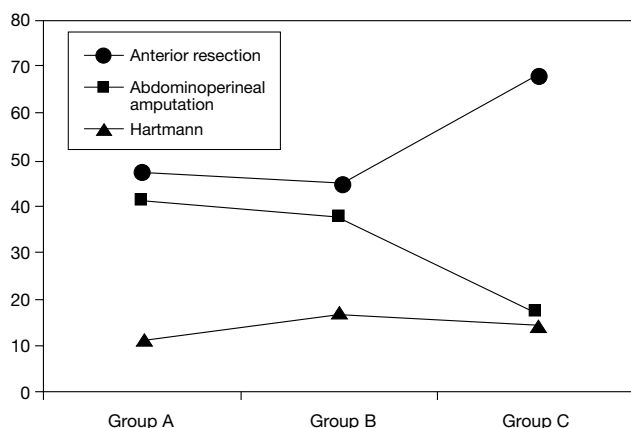
\*\*P<.01.

\*\*\*P<.001 versus group A.

<sup>a</sup>P<.05.

<sup>b</sup>P<.01.

<sup>c</sup>P<.001 versus group B.



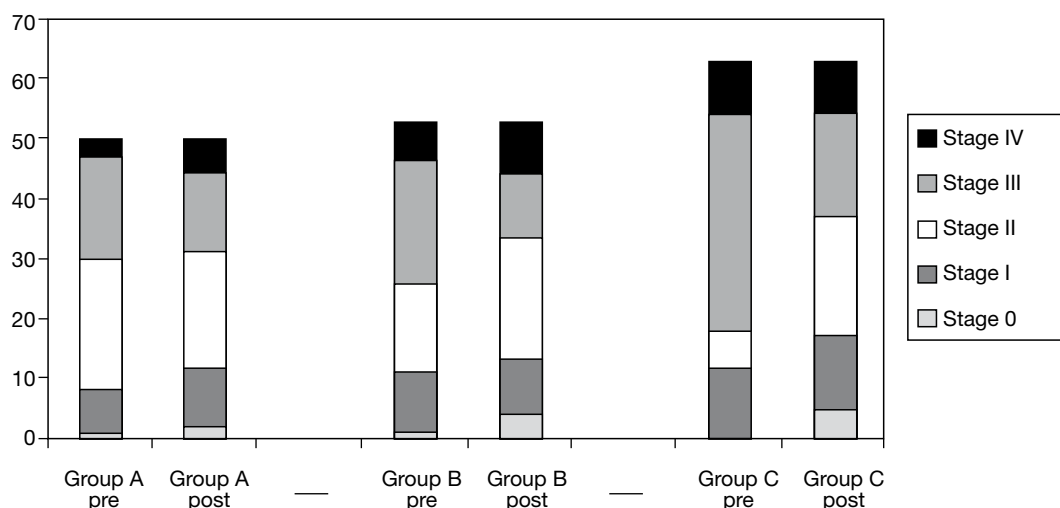
**Figure 1 – Percentage of each intervention by periods (%).** Anterior resection of the rectum: group C versus groups A and B, P<.001. Abdominoperineal amputation: group C versus groups A and B, P<.001.

The rate of abdominoperineal amputations (APA) was 17.4% in group C, which is significantly lower than in groups A and B (Table 3, Figure 1). The percentage of protective ileostomies in

previous resections was 35.2% and there were no differences between the groups. A laparoscopic approach began to be used in group C.

Both the number of nodes and the circumferential margin analysis, significantly improved statistically (Table 3) and the pathologist described the mesorectum as satisfactory in 78.4% of patients in group C. Preoperative staging was modified after surgery (Figure 2), improving tumour downstaging, with no significant increase in complete response in group C. Postoperative radiotherapy was used in a smaller percentage in group C, although this was not statistically significant. There were no differences among groups undergoing adjuvant chemotherapy.

Local recurrence occurred in 18/155 patients (11.6%), with a median follow up of 70, 45 and 30 months respectively. In non-palliative surgery the figure was 10.6%, improving progressively but without becoming statistically significant. Colorectal surgeons achieved a global series rate of 7.7%, without any difference between the groups, but this was significantly less than the 23.7% obtained by surgeons not specialised in any particular field, (P=.021; OR = 3.1, 95% = 1.1–8.3).



**Figure 2 – Tumour staging by imaging methods and changes in the postoperative period. Pre: preoperative evaluation. Post: Postoperative staging. Values are number of patients.**

**Table 4 – Resource consumption. Surgery**

	Group A	Group B	Group C
	n=50	n=53	n=63
Perioperative transfusion (%)	32 (64)	28 (52.8)	21 (33.3) <sup>***,a</sup>
Admission to ICU (%)	43 (86)	48 (90.6)	24 (38.1) <sup>***,c</sup>
Nasogastric tube use (%)	30 (60)	28 (52.8)	15 (23.8) <sup>***,b</sup>
Early oral tolerance (%) <sup>d</sup>	2 (4)	8 (15.1) <sup>*</sup>	37 (58.7) <sup>***,c</sup>
Average time in days of oral tolerance (SD)	4.9 (2.5)	4.8 (3.3)	2.5 (2.3) <sup>***,c</sup>
Epidural analgesia (%)	1 (2)	10 (18.8) <sup>**</sup>	19 (43.2) <sup>***</sup>
Global Stay (SD)	17.7 (18.1)	16 (8.9)	12.6 (7.7) <sup>***,b</sup>
Preoperative stay (SD)	2.6 (2.2)	2.1 (3.8) <sup>***</sup>	1.3 (1.6) <sup>***</sup>
Postoperative stay (SD)	15.1 (17.7)	13.9 (7.8)	11.2 (7.3) <sup>*,b</sup>

ICU indicates intensive care unit; SD: standard deviation.

<sup>\*</sup>P<.05.

<sup>\*\*</sup>P<.01.

<sup>\*\*\*</sup>P<.001 versus group A.

<sup>a</sup>P<.05.

<sup>b</sup>P<.01.

<sup>c</sup>P<.001 versus group B.

<sup>d</sup>Oral tolerance at 2nd day.

### Use of resources and clinical effectiveness

There was a progressive reduction in perioperative blood and haemoderivative transfusions (Table 4). Only 38% of patients in group C were admitted to the ICU, significantly less than in groups A and B, due to the creation of a postanesthesia care unit (PACU) for stays of up to 24 hours. A nasogastric probe (NG) was used significantly less in group C. In only 10 of the 93 patients who did not undergo this procedure, was it necessary to use it in their postoperative treatment. Early oral tolerance (days 0 to 2) continued increasing and reached almost 60% in group C.

The mean start time in this group was lower than in others. Epidural analgesia use increased significantly at each stage of assessment.

Total hospital stay was significantly lower in group C than in groups A and B, which was due both to a reduction in preoperative hospital stay (which had already improved in group B), and in postoperative stay.

A total of 69 patients (41.5%) showed complications initially during the postoperative stage. Mortality within 30 days after surgery was 6.6% in both cases, with no difference between the groups (Table 5). The rate of suture dehiscence was reduced to an insignificant 9.5% in group C.

**Table 4 – Postoperative complications**

	Group A	Group B	Group C
	n=50	n=53	n=63
Complications	22 (44)*	22 (41.5)	25 (39.6)
Operative mortality <sup>a</sup>	3 (6)	5 (9.4)	3 (4.7)
Reoperation	6 (12)	5 (9.4)	5 (7.9)
Tissue healing complications	7 (14)	6 (11.3)	5 (7.9)
Suture dehiscence	6/25 (24)	4/24 (16.6)	4/42 (9.5)
Evisceration	1 (2)	2 (3.8)	1 (1.6)
Infectious complications	7 (14)	12 (22.6)	8 (12.7)
Intraabdominal infection	4 (8)	5 (9.4)	2 (3.2)
Abdominal wound infection	3 (6)	7 (13.2)	6 (9.5)
Cardiorespiratory complications	7 (14)	10 (18.3)	6 (9.5)
Pneumonia/atelectasis	4 (8)	6 (11.3)	4 (6.3)
Heart failure	3 (6)	4 (7.5)	2 (3.2)
Other complications	7 (14)	11 (20.7)	12 (19.4)
Prolonged ileus	3 (6)	7 (13.2)	6 (9.5)
Urinary complications	2 (4)	3 (5.6)	5 (7.9)
Haemoperitoneum	2 (4)	1 (1.8)	1 (1.5)

\*Data is numbers with percentages in brackets.

<sup>a</sup>At 30 days.

## Discussion

The study attempts to show how the results of a relevant disease can be improved. The starting point was similar to that of many national centres.<sup>9</sup> While the Multidisciplinary Committee adopted successive amendments to the clinical pathway, not all changes were so static over time, as is shown by separating them into 3 groups, since some were gradual and were the result of weekly meetings and round tables.

Colonoscopy was the preferred preoperative diagnostic test, but could only be completed in half of the cases. To get around this problem, CT colonography was introduced on the same or following day after an unsuccessful examination, which was feasible in almost 60% of cases in group C. This is an improvement in the detection of occult lesions, with a sensitivity of 88% for polyps larger than 9 mm,<sup>10</sup> and also in patients' comfort because a preparation of the colon is only required. As a method of locoregional staging, high resolution pelvic MRI offers an assessment of circumferential margin of the mesorectum and prognostic variable of first magnitude<sup>11</sup> regardless of reliable T and N staging. It was performed significantly more in groups B and C, although 4 patients in Group C did not undergo MRI: in 2 cases because of benign biopsies and an absence of the invasion by endorectal ultrasonography, and because of metastasis in the 2 other patients. It is not necessary to stress the importance of neoadjuvant therapy in the RC, or the interest that the use of radiotherapy is preoperative. Our rates of neoadjuvant therapy did not differ in the periods analysed, but the indication of postoperative radiotherapy decreased significantly.

The need for MPC has never been demonstrated, and recent meta-analysis shows that it increases the risk of

dehiscence and infection. However, it remains particularly unclear if rectal surgery with anastomosis is safer in the absence of bowel preparation<sup>12</sup>, the concept is so deeply established that it is very difficult to change this.<sup>13</sup> Our policy is to perform the surgery when a loop ileostomy (low anastomosis) is expected, and to replace it with a saline enema in upper third tumours or amputations of the rectum. Therefore, CMP was not performed in groups B and C when a change in the management protocol took place, which only included those proposed for a complete mesorectal excision with derivative ileostomy.

The current trend is sphincter preservation, unless the sphincters are infiltrated. It is recommended that the percentage of rectal tumours treated by APA is less than 30–40%.<sup>3-5,14</sup> The APA results are worse in terms of local recurrence due to several factors, such as possible transanal leakage of tumour cells, perforation or the "cone" effect when performing the dissection.<sup>15,16</sup> Our APA rate has decreased significantly over time, not only in general but also in middle third tumours. This and other improvements are evidence of the multidisciplinary decision-making and the performance of this surgery by those professionals specialised in this field.<sup>17</sup> Undoubtedly both these factors are those which have contributed most positively to an improvement in performance.

At present there is considerable consensus in the implementation of protective stoma in low anastomoses and if there is risk of dehiscence,<sup>18</sup> then it was performed in almost all complete mesorectal excisions with anastomosis in group C.

In order to ensure with an accuracy more than 90% that there is no tumour lymph node involved, it is recommended to isolate a minimum of 12 negative lymph nodes.<sup>19</sup> Although the average of isolated nodes in our series was 13 in group C,



significantly higher than previous ones, the minimum of 12 was only achieved in 71% of patients. Therefore, we still need to improve these results.<sup>20</sup> Furthermore, the mesorectum with appropriate distal and circumferential margins must be properly removed. Thus, in recent years the number of circumferential margin (CM) analyses has increased, the rate of involvement of which varies widely in published papers, with figures between 2% and 28%.<sup>21</sup> In our case, this rate was 11.8% in Groups B and C, with a satisfactory 78.4% mesorectum in the latter, according to the pathologist. Finally, the rate of curative resections recommended should be above 60%<sup>14,21</sup> and, therefore, our 77.7% would be in an acceptable range.

Current evidence suggests that overall local recurrence below 10% can be achieved by means of optimal surgical techniques and preoperative radiotherapy for fixed or borderline tumours.<sup>2-5,9,14</sup> With this in mind, our overall results (11.6%) are not good, although they did decrease to 8.3% in the last period, where, if the surgery performed by specialist surgeons is analysed, the figure drops to 5.4%. Circumferential margin involvement of the mesorectum and local recurrences are very useful when evaluating the results,<sup>21</sup> in which both the experience of the surgeon<sup>22</sup> and the preservation of sphincter independent are prognostic factors.<sup>23</sup> In this sense, 2 surgeons with specific coloproctology accreditation (EBSQC) joined group C and helped to refine and standardise the surgical technique. Moreover, several surgeons involved attended training courses in order to create a colorectal surgery unit. It can be deduced that the tumour pathological features, neoadjuvant therapy, the attention to detail of surgery and the experience of the colorectal surgeon<sup>17</sup> all influence the outcome of surgical RC treatment.

One of the biggest advances for improving perioperative management after colorectal surgery is multimodal rehabilitation, which aims to speed up recovery by reducing morbidity and shortening hospital stays.<sup>24</sup> By applying these measures, we have significantly altered the use of nasogastric tubes, epidural analgesia, or early oral intake, although the latter is probably far more difficult to implement. ICU admissions, as a result of a change of attitude of the anaesthetic team,<sup>25</sup> have also been reduced, as well as the rate of perioperative transfusion.

The overall postoperative mortality (6.6%) was higher than the maximum of 5% recommended in the literature, which contains figures ranging from 0% to 8.6%,<sup>2,3,9</sup> with 4.7% being recorded in the last period. Suture dehiscence was a major cause of mortality. Currently, it is recommended<sup>3,5,26</sup> that the overall rate of clinically significant leakage is less than 8% for anterior resections. However, our figures are still 9.5% in Group C, despite its significant reduction. Regarding other complications, the results of surgical wound infection in group C are 16.3% including a perineal wound, and 9.6% excluding it. These figures are close to those recommended by the Clinical Management Care Project (*Proyecto de Gestión Clínica de Procesos Asistenciales*).<sup>5</sup> Cardio-respiratory complications were lower in the last period analysed, without reaching any statistical significance, possibly reduced to half through a more rational use of perioperative fluid therapy, which has

reduced the volume administered by 40%. Finally, the whole stay was reduced to 11.2 days in Group C, in a range similar to data published in our country.<sup>26,27</sup>

To conclude, according to the analysis of certain dimensions of care quality, we are still far from reaching 100% of published standards, even though some may be considered acceptable and are close to becoming the first to be taken from the audited syllabus of the Spanish Association of Surgeons (*Asociación Española de Cirujanos*) on the total excision of the mesorectum,<sup>8</sup> which aims to improve the national results of this important process. In a relatively short period of time, many indicators have improved significantly, and we believe the study highlights the importance of applying continuous constructive criticism to results.

## Conflict of interest

The authors state that they have no conflicts of interest.

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