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Evolution of perioperative quality of life in patients under enhanced recovery after surgery care in colorectal cancer

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AUTHOR'S CONTRIBUTION

All authors critically revised the paper for important intellectual content. All authors have contributed to the work and agreed on the final version. This manuscript is not being considered by any other journal.

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ABSTRACT

Background: the Enhanced Recovery After Surgery (ERAS) protocols aim to improve postoperative outcomes by obtaining a functional rehabilitation after surgery. The purpose of this study was to evaluate the impact of ERAS on the quality of life (QOL) of patients undergoing colorectal cancer surgeries.

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Methods: a cohort observational study was designed of patients with colorectal cancer undergoing elective surgeries during a one-year period. Patients were included when the ERAS protocol was fully achieved for all the interventions, including the expected hospital discharge day. Patient reported outcomes (PROs) were evaluated by the EORTC QLQ-C30 and the QLQ-CR29 questionnaires on three different occasions: baseline before surgery and on postoperative days 7 and 30.

Results: the study included 40 patients who completed QOL evaluations with a mean age of 70 ± 11 years. There were no statistical differences between preoperative and postoperative QOL scores. By subgroups of QOL items, a significant decrease was observed in physical activity and role functioning when comparing preoperative *vs* postoperative status, whereas the cognitive, social and emotional functioning scales were similar or improved over time.

Conclusions: in our experience, surgery under ERAS protocols did not have an impact on decreasing global QOL in patients undergoing elective colorectal cancer surgery. The use of ERAS protocols in colorectal surgery achieves a positive influence, not only by decreasing surgical-related complications but also in terms of functional recovery, by decreasing the negative effects of surgery on patient QOL.

Keywords: Quality of life. Enhanced recovery after surgery. Colorectal surgery.

INTRODUCTION

Worldwide, colorectal cancer (CRC) is one of the most frequent gastrointestinal tumors (third in males and second in females) and almost the leading cause of deaths due to cancer (about 320,000 deaths per year in developed countries) (1). In our environment, the incidence of CRC is increasing over time, even in the young population (2). The standard potential curative treatment for CRC is surgery of the affected segment of the colon or rectum, followed by systemic chemotherapy based on the pathological status. As extensively described in the literature, any kind of surgery will induce surgical-stress and potential associated surgical complications for the patient and may have a negative impact on their condition. These effects may be transitory in the majority of cases. However, surgery will occasionally have permanent

consequences for our patients.

During the last decade, enhanced recovery after surgery (ERAS) has been established as a set of interventions in the perioperative setting, which aim to maintain the physiological function, optimize recovery and reduce the response to surgical stress. To date, ERAS protocols in colorectal surgery have been widely implemented and have been shown in clinical trials to reduce complications and the length of hospital stay (LOS) compared to traditional care (3,4). These outcomes have been used to measure short-term postoperative recovery.

The available literature has demonstrated the multiple advantages of ERAS in colorectal surgery in decreasing postoperative complications. However, there is a lack of evidence regarding the influence of ERAS in patient reported outcomes (PROs) on QOL after surgery (5). The QOL evaluation after colorectal surgery is based on two main questionnaires: the Global Quality of Life EORTC-QLQ-C30 and the EORTC-QLQ-CR29, established by the European Organization for Research and Treatment of Cancer (6,7). These previously validated patient-rated questionnaires are specifically designed to assess the QOL of patients with CRC.

Based on the previous background on ERAS and physical recovery after colorectal surgery, the present study aimed to evaluate the quality of recovery by assessing patient PRO.

METHODS

A prospective observational study was performed from a maintained database of patients who underwent elective surgery for CRC at a tertiary center in Madrid, Spain (Hospital Universitario Fundación Jiménez-Díaz). Inclusion criteria were: patients over 18 years of age, evaluated before and after surgery on postoperative day 7 (POD7) and postoperative day 30 (POD30). Exclusion criteria were: patients who suffered from any kind of mayor complication (Clavien-Dindo ≥ III). The study was started after obtaining approval by the local institutional review board committee.

Our ERAS program was based on the use of a set of ten interventions in the perioperative period, as shown in figure 1, and has been validated in two previously published studies (8,9). Patients received preadmission counseling and oral and

written information about the ERAS program before surgery and throughout their hospital stay.

All patients were requested to fill-in the QLQ-C30 (6) and the EORTC QLQ-CR29 (7) questionnaires on three different occasions: baseline health status (at day 1-2 before surgery), at POD7 and at POD30, both in the outpatient clinic. The QLQ-C30 is a core questionnaire that measures global quality of life perception. It is composed by the Global QOL score and five functional scales of physical activity, role, emotional, cognitive and social. The scales have different questions that are answered with four alternative responses: “very much” (four points), “quite a bit” (three points), “a little” (two points) and “not at all” (one point). The global QOL score ranges from 1 (“very poor”) to 7 (“excellent”) (6). The QLQ-CR29 is a colonic cancer-specific module that includes five functional scales: body image, anxiety, weight, sexual interest in men and women and symptom scales. These scales have the same answering system as the QLQ-C30. Linear transformation of raw scores were used to convert answers to a value between 0-100, as described by the standard EORTC scoring system (6). A higher functioning score implies a better level of functioning, whereas a higher symptom score implies greater severity of a symptom.

Additional data included in the analysis was recorded from the electronic medical records: patient characteristics (age, gender, associated comorbidities, preoperative anemia and nutritional status and neoadjuvant therapies), operative notes (type of intervention and stoma formation) and postoperative evolution (LOS, complications and 30-day readmissions).

Statistical analysis

A sample size calculation was estimated using the GRANMO® software, v. 7.12 (IMIM, Barcelona, Spain). Assuming an alpha risk of 0.05 and a beta risk of 0.20 in a two-sided test, 35 subjects are necessary to identify statistically significant difference greater than or equal to ten units. The standard deviation was assumed to be 20. The expected proportion of patients lost during the follow-up was 10%.

Descriptive statistics are presented as the mean and standard deviation (mean ± SD) for quantitative variables. The comparison of differences between groups was

performed using Chi-squared analysis with the Fisher's exact test when any value in the contingency table was less than 5, in order to compare proportion variables. The comparison of the differences between the mean values of the groups was performed using the Student's t-test. All statistical analyses were performed using SPSS® version 22 software (SPSS, Inc., Chicago, IL) and p-values of < 0.05 were considered as statistically significant.

RESULTS

Forty unselected patients who underwent surgery for CRC under ERAS were enrolled during a one-year study period. Demographics, patient baseline characteristics and surgical procedures are shown in table 1. Segmental colectomies were the most frequent procedure (60%), followed by rectal surgeries (35%) and subtotal colectomies (5%). With regard to the group of rectal cancer surgeries (14 cases), six were located in the upper rectum, four in the mid rectum and the remaining four in the lower rectum. All patients underwent a long course of neoadjuvant chemoradiotherapy and surgery was delayed for eight weeks after completion of the treatment. All patients had a temporary stoma.

The mean LOS as per the ERAS protocol was 5 ± 1.5 days. There was no mortality in the study group. Postoperative morbidity included two cases of acute urinary retention, two cases of rectal bleeding and one case of surgical site infection; all were Clavien-Dindo Score grade I-II. There were two cases (5%) that required hospital readmission; one patient suffered a minor complication (rectal bleeding) that was successfully treated with conservative management (Clavien-Dindo grade I) and the other patient developed an intraabdominal abscess that required a CT-guided drainage (Clavien-Dindo grade II).

The total response rate of the QOL questionnaires was 83.3% during the entire study. Specific missing data was observed in nine patients at POD 7 and seven patients at POD 30.

QLQ-C30

The results of the QLQ-C30 questionnaire are presented in table 2 and figures 2 and 3. PROs reported a Mean Global Health score at the preoperative evaluation of 68.5 ± 23 *vs* 67.2 ± 24 at POD30 ($p > 0.05$), as shown in figure 3. When analyzing the functional scales of the questionnaires, physical functioning was the most affected item, with a significant decrease in POD7 (from 79.6 ± 21 to 67.1 ± 26, $p = 0.000$) and a slight improvement in POD30 (70.1 ± 24, $p = 0.000$). Emotional and social functioning scores showed statistical improvements over time (Table 2).

Regarding the symptom scales, all remained stable during the postoperative period, except for fatigue and insomnia, which slightly increased in the comparison between the baseline *vs* POD30 (Table 2).

QLQ-CR29

The outcomes of the QLQ-CR29 questionnaire are summarized in table 3. Urinary symptoms (incontinence and dysuria) were the only aspects affected in the comparison between baseline and POD7, with a complete recovery at POD30. The rest of the symptoms analyzed in the questionnaire remained unchanged over time.

DISCUSSION

The present study shows that elective surgery in patients with CRC under ERAS protocols did have a negative influence on PROs reporting QOL perceptions. ERAS in colorectal surgery has been widely used during the last decade, showing repeatedly a reduction in morbidity rates, improvement in recovery and shortening of LOS (10). However, discharging patients from the hospital may not be synonymous with recovery and it should only be considered as complete when patients have reached their previous baseline status. Published data on ERAS programs have so far focused on LOS and surgical complications, and a few studies to date have investigated PROs on the QOL of patients undergoing colorectal surgery. In general, this shows positive but still weak conclusions regarding the effects of ERAS.

According to the previous literature, the median scores of Global Health in the QOL-C30 test are 62 for male patients and 60 for females, with a maximum of 100 (6). Based on our outcomes, the Global Health score was similar during the postoperative

period, with a slight decrease in POD7 that finally improved in POD30 (Fig. 3). When analyzing the functional scales, physical functioning showed a significant decrease between baseline and POD7, with a slight improvement at POD30. It is important to highlight that emotional and social functioning showed a constant improvement over time.

Our results are in line with other studies showing no differences on PROs in Global Health scores, before and after surgery under ERAS (5,11,12). The majority of previous studies were analyzed in a systematic review published in 2010 by Khan et al. (5). At that time, ten studies with only one randomized clinical trial were included, showing a reduction in pain and fatigue two weeks after surgery in two of the studies (13,14). The rest did not find any differences and only one found an increased emotional distress in the ERAS group. Of note, none of the studies were specifically designed to detect differences in PROs as the primary objective and QOL was reported as a secondary outcome. Moreover, the QOL tests used were different between studies, with a high heterogeneity. As a result, the authors concluded that there was no evidence that ERAS adversely affected QOL of patient satisfaction and that further research was required, especially in the early postoperative period. In addition, a recent study published by Partoune et al. (11) reported a complete recovery in 80% of patients 79 days after surgery with ERAS. Elderly patients, such as the cohort we have included in our study, showed similar benefits under ERAS when compared to younger patients. In contrast, a Japanese study reported worse outcomes in younger *vs* elderly patients and rectal *vs* colon cancer surgeries (15).

In our case, we believe that some aspects in the use of ERAS may have influenced a quick improvement in QOL after surgery. Firstly, the laparoscopic approach was the gold standard in our series. We consider that the use of a minimally invasive approach would be crucial to succeed in the implementation of ERAS and to decrease negative effects on PROs after surgery. Secondly, preoperative counseling for patients that needed a stoma was also important; nearly 38% of patients in the study required a stoma and required an extra educational effort from the caregiver team to succeed in the ERAS implementation. Furthermore, we should highlight that 35% of patients in the study had rectal cancer surgeries, which have been previously defined as a

negative compliance factor with ERAS protocols.

Concerning QLQ-CR29 questionnaire outcomes, body image, anxiety, weight, abdominal pain and sexual function remained unchanged throughout the study. On the other hand, urinary symptoms were the only factors significantly affected from baseline to POD7, showing a complete recovery at POD30. This is probably due to the fact that all patients in the study have had a perioperative urinary catheter. In addition, 35% of patients underwent rectal cancer surgery and preoperative chemoradiotherapy.

In summary, we believe that research on PROs is imperative to expand the benefits of ERAS in colorectal surgery and the recovery support after surgery must include not only a physical, but also a functional and emotional recovery. In addition, a new concept of prehabilitation has been recently introduced to maximize the positive effects of ERAS programs. A prehabilitation program will include an individualized preoperative counseling and a supervised functional schedule performed before surgery (16,17).

Limitations

This study has some limitations that should be mentioned. Our study is an observational study with a small sample size. However, a sample size calculation was performed to estimate the number of patients needed to detect statistical differences. In addition, three different time periods, prospective data collection and a primary objective design to measure QOL strengthen our conclusions. Based on our data, we have demonstrated the feasibility and safety of the ERAS program and early discharge of patients following surgery. There is a need for further research on this topic, especially using appropriate validated multidimensional QOL instruments

CONCLUSION

In our study, we have shown by comparing pre and postoperative status that elective colorectal cancer surgery under ERAS protocols did not have a significant impact on decreased global QOL. Treatment under ERAS protocols did not affect QOL patient perceptions. Further research on tools that measure recovery-specific QOL is needed

to move forward in the evaluation of the success of ERAS programs in colorectal surgery.

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Table 1. Patient baseline characteristics

	ERAS (n = 40)
Age (mean ± SD, years)	70 ± 11
Sex (F:M)	15:25
BMI (median, range, kg/m^2)	28.5 (24-36)
ASA score	I-II (22) II-III (18)
Preoperative albumin level (g/dl)	4
Preoperative hemoglobin level (g/dl)	13.7
Surgical technique (n, %)	
Subtotal colectomy	2 (5%)
Left colectomy	6 (15%)
Right colectomy	8 (20%)
Sigmoidectomy	10 (25%)
Anterior resection	14 (35%)
Neoadjuvant therapy (n, %)	15 (37.5%)
Laparoscopic surgery (n, %)	40 (100%)
Stoma (n, %)	15 (37.5%)
Drainage (n, %)	22 (55%)

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Table 2. Outcome summaries of QLQ-C30 scores, before and after surgery (p values were calculated using the Student's t-test)

Functional scales*	Baseline (mean ± SD)	POD 7 (mean ± SD)	p value Baseline *vs* POD7	POD 30 (mean ± SD)	p value Baseline *vs* POD30
Global health	68.5 ± 23	63.8 ± 21	*0.007*	67.2 ± 24	0.198
Physical functioning	79.6 ± 21	67.1 ± 26	*0.000*	70.1 ± 24	*0.000*
Role functioning	79.2 ± 32	41.9 ± 36	0.093	66.7 ± 32	*0.029*
Emotional functioning	71.1 ± 22	77.6 ± 25	*0.010*	76.8 ± 27	0.055
Cognitive functioning	88.4 ± 19	88.5 ± 17	*0.002*	85.8 ± 25	*0.000*
Social functioning	80.1 ± 27	79.9 ± 29	0.108	86.4 ± 21	*0.024*
Symptom scales†					
Fatigue	26.2 ± 26	41.4 ± 27	0.182	32.3 ± 31	*0.007*
Nausea and vomiting	6.0 ± 15	4.2 ± 16	0.769	5.5 ± 17	0.351
Pain	22.2 ± 31	37.4 ± 30	0.092	24.2 ± 27	0.977
Dyspnea	9.3 ± 19	13.8 ± 27	*0.033*	10.1 ± 17	0.052
Insomnia	23.1 ± 27	30.9 ± 31	0.325	30.3 ± 34	*0.002*
Appetite loss	25.9 ± 33	26.2 ± 32	*0.000*	24.2 ± 34	0.299
Constipation	9.3 ± 17	4.8 ± 15	0.309	5.1 ± 15	0.646
Diarrhea	17.6 ± 26	23.8 ± 32	*0.024*	16.7 ± 25	0.063
Financial difficulties	1.9 ± 8	4.6 ± 19	*0.000*	3.0 ± 17	0.245

*Functional scales range from 0 to 100, with 0 representing poorer QOL. †Symptoms scales range from 0 to 100, with 0 representing no symptoms.

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Table 3. Outcome summaries of symptom scores (QLQ-CR29), before and after surgery (p values were calculated using Student's t-test)

QLQ-CR29* (mean ± SD)	Baseline (mean ± SD)	POD 7 (mean ± SD)	p value Baseline *vs* POD7	POD 30 (mean ± SD)	p value Baseline *vs* POD30
Body image	94.4 ± 11	86.9 ± 22	0.249	89.2 ± 19	0.740
Anxiety	43.5 ± 33	51.7 ± 34	0.131	56.6 ± 33	0.158
Weight	80 ± 26	71.2 ± 29	0.183	81.8 ± 25	0.649
Men sexual function	56.7 ± 31	71.9 ± 25	0.053	63.1 ± 27	0.506
Women sexual function	75.75 ± 34	86.7 ± 18	0.095	84.8 ± 17	0.541
Urinary frequency	55.1 ± 20	65.5 ± 20	0.072	56.6 ± 27	0.723
Blood stool	15.3 ± 24	65.4 ± 20	0.236	56.7 ± 27	0.689
Urinary incontinence	12 ± 24	8.3 ± 23	*0.008*	13.1 ± 27	0.058
Dysuria	7.4 ± 24	14.3 ± 23	*0.011*	17.2 ± 25	0.378
Abdominal pain	15.7 ± 27	25 ± 28	0.304	18.2 ± 26	0.155
Buttock pain	18.5 ± 29	26.4 ± 33	0.136	26 ± 29	0.768
Bloating	39.8 ± 36	33.3 ± 35	0.435	32.3 ± 27	0.447

*Symptom scales range from 0 to 100, with 0 representing no symptoms.

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Preoperative period	Information of the complete process
	Nutritional optimization, anemia, and comorbidities
	Pre-assessment visit with the nurse in case stoma is necessary
	Bowel mechanical preparation (rectum surgery)
	Supplemental nutritional drinks throughout the day before
Intraoperative period	Thrombo-embolic deterrent stockings
	Antibiotic prophylaxis
	Epidural sited (if open surgery)
	Urinary catheter sited
	No nasogastric drainage
	Minimal perioperative IV fluid
	Normothermia
Postoperative period	IV fluids discontinued if patient drinking adequately
	Thrombo-embolic prophylaxis
	Enforced mobilization
	Urinary catheter removed
	Early intake
	Respiratory physiotherapy

Fig. 1. ERAS study protocol and interventions.

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Fig. 2. QLQ-C30 outcomes in functioning scores at three periods (*p < 0.05; **p < 0.001).

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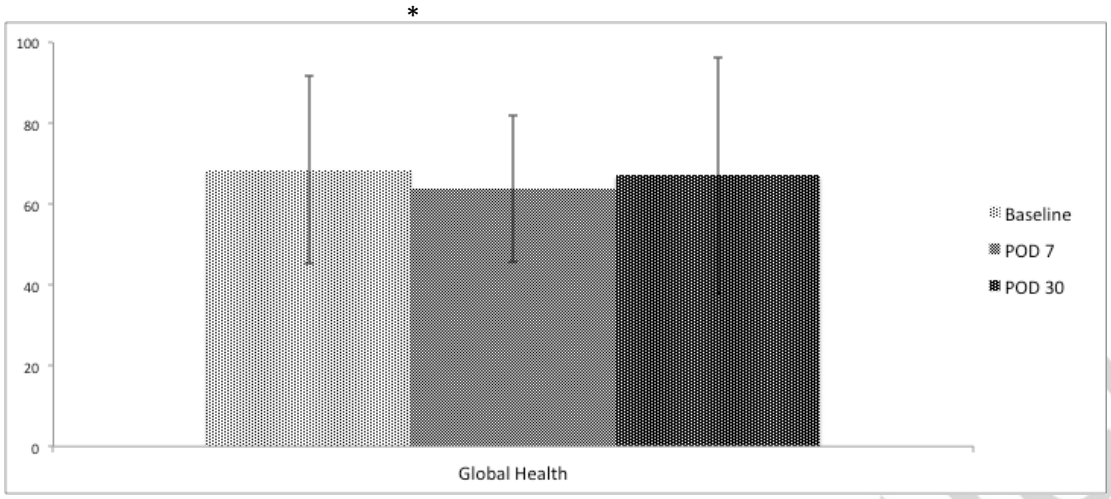

Fig. 3. QLQ-C30 outcomes of global health at three different periods.