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Impact of the implementation of a preoperative nutritional program for colorectal surgery patients

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ABSTRACT

Introduction: generalized hypermetabolism is common in cancer patients and increases the risk of complications when combined with the systemic effects of surgery.

Objective: the aim of this study was to clinically assess the implementation of a Nutritional Assessment and Support Program for patients undergoing colorectal surgery with a diagnosed neoplasia.

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Material and methods: a quasi-experimental study was performed with analyses before and after the implementation of the Nutritional Assessment and Support Program. Patients who underwent surgery for colon or rectal neoplasia were included. The incidence of complications and the average hospital stay were studied. The effect of the intervention was evaluated using a logistic regression analysis to yield adjusted odds ratios (OR).

Results: a total of 130 patients were included in the study, 65 from 2016-2017 (pre-program) and 65 in 2018 (post-program). The incidence of surgical site infection decreased from 18.5 % to 6.2 % (OR = 0.29; 95 % CI: 0.09-0.95) (p = 0.033). Postoperative fevers were also reduced by 50 % (OR = 0.41; 95 % CI: 0.17-0.96) (p = 0.037). Average hospital stay was reduced from 11.3 days (DE = 8) to 7.18 days (DE = 2.5) (p = 0.02). More clinical and analytical information was logged about the patients' nutritional status and risk.

Conclusion: the implementation of a Nutritional Assessment and Support Program for patients undergoing colorectal surgery has shown statistically significant differences in the reduction of surgical site infection, postoperative fever and the length of hospital stay.

Keywords: Colorectal cancer. Colorectal neoplasms. Surgical wound infection. Enteral nutrition. Quasi-experimental study.

INTRODUCTION

Malnutrition and weight loss are common in patients with cancer and are issues that affect disease prognosis (1). However, there is a lack of scientific evidence on the prevalence or incidence of malnutrition during the course of neoplastic disease (2,3). Generalized hypermetabolism is common in cancer patients, which increases the risk of complications (5,6) when combined with the systemic effects of surgery and the patient's age (4). According to some studies, the prevalence of malnutrition in these patients can reach 50 % at the time of diagnosis and 80 % in patients with advanced disease (7). In recent decades, the comprehensive care of patients undergoing colon or rectal cancer surgery has seen significant advances, with the aim of reducing post-operative complications (8-10). These advances have culminated in recent Multimodal

Enhanced Recovery After Surgery (ERAS) programs, a set of perioperative care protocols designed to reduce the physiological stress response following surgery and improve recovery via a multidisciplinary approach (11,12). There is no single parameter for nutritional screening and assessment that is sufficiently sensitive and specific (13). Thus, a combined interpretation of the patient's dietary, biochemical, anthropometric and clinical tests is required (14,15). A preoperative nutritional program was implemented in our hospital for patients where surgery for colorectal neoplasia was indicated during 2017 and 2018. The aim of the study was to clinically assess the program's effect on the incidence of surgical site infection (SSI) and other postoperative complications.

MATERIAL AND METHODS

A quasi-experimental study was performed with analyses before and after the introduction of a Nutrition Management Program for patients diagnosed with colorectal neoplasia who underwent surgery at the Hospital Univeritario de Móstoles. The study included patients who had undergone colorectal surgery for colon or rectal neoplasia and were at risk of malnutrition, treated at the General and Digestive Surgery Department at the Hospital Univeritario de Móstoles (HUM) in 2017 (pre-program, control group) and 2018 (post-program, group with intervention). Patients were selected by sampling of consecutive cases.

The sample size was calculated based on a confidence level of 80 %, a power of 80 %, an incidence of infection in the non-intervention group of 10 % and 5 % in the intervention group, with a 5 % loss during follow-up. Therefore, a sample of 130 patients was required. The study was approved by the HUM Ethics and Research Committee.

The Malnutrition Universal Screening Tool (MUST) was used as a nutritional screening tool, which was developed by the British Association for Parenteral and Enteral Nutrition (BAPEN). Albumin, transferrin, prealbumin, retinol-binding protein, cholesterol, creatinine and lymphocytes were measured to analyze biochemical indicators. The Fanbal method was used to interpret the analytical results (16). The selection criteria for patients at moderate- or high-nutritional risk were: age ≥ 70 years

and/or MUST ≥ 1 (intermediate-high) and/or change in ≥ 2 analytical parameters (Fanbal ≥ 2) and/or complex surgical intervention (left colon or rectal surgery). The historical group consisted of patients who were not told about the program's measures, even though they were eligible. The prospective group was made up of recruited patients who were told about the measures. The Nutritional Program's measures are detailed in table 1.

Patient evolution from the time of surgery to the end of the maximum 30-day incubation period was studied. Centers for Disease and Prevention Control (CDC) standards were used for the diagnosis of SSI and the Clavien-Dindo classification for all other surgical complications.

The variables included in the study were: age, sex, weight, height, ASA (American Society of Anesthesiologists) risk, high blood pressure (HBP), diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), heart disease, use of antiplatelet drugs, antihypertensives or blood thinners, weight loss, body mass index (BMI), MUST score, analytical parameters and degree of their alteration, surgery duration, type of surgical intervention, presence of incision infection, organ/space surgical site infection, SSI, respiratory infection, urinary tract infection, sepsis, anastomotic dehiscence, abdominal dehiscence and hernia.

Patients were interviewed by telephone one week before surgery and again one day prior to surgery to assess their adherence to the dietary-nutritional measures provided.

A specific data collection sheet and a relational and standardized Microsoft Access® database were designed to record the information. A descriptive study of the sample was performed. Quantitative variables were described as the mean and standard deviation (SD) or median and interquartile range (IQR) if they did not follow a normal distribution. Parameters were compared with the Student's t test and the Mann-Whitney U test was used if they did not follow normal distribution. Quantitative variables with more than two categories were compared using an analysis of variance (ANOVA) and the non-parametric Kruskal-Wallis test was used if their application conditions were not met. Qualitative variables were described by their frequency distribution and compared with the Pearson's X^2 test or Fisher's exact test if the

application criteria were not met. The cumulative incidence of SSI and the influence on its appearance as risk factors of the different variables under study were evaluated. The statistical and epidemiological analyses were performed using the SPSS v.22 and Epidat v.4.2 programs. Statistical significance was set at $p < 0.05$ and all estimates were described with the 95 % confidence interval (CI).

RESULTS

A total of 130 patients were included, 65 in 2017 (prior to the implementation of the program) and 65 in 2018 (during the implementation of the program). The average age was 70.9 (SD = 8) in the group without an implemented program and 66.9 (SD = 10) in the group with an implemented program. The most common concurrent disorders in patients were HBP (53.3 %), dyslipidemia (DL) (38.7 %) and type I diabetes mellitus (17 %). A total of 12.6 % of patients had heart disease (heart failure, atrial fibrillation or coronary disease) and 13.3 % had COPD.

A right hemicolectomy was performed to treat ascending or transverse colon cancer in 38.5 % of patients (n = 50) and a left hemicolectomy was performed to treat descending colon, sigmoid colon or rectal cancer in 61.5 % (n = 80). No statistically significant differences (p = 0.72) were observed when the tumor location was compared between intervention groups. The characteristics of patients and the main study variables are shown in table 2.

The average BMI in the group without an implemented program was 27.1 (DE = 3) and 27.5 (DE = 4) in the implemented program group. Weight loss in the 3-6 months prior to diagnosis was more frequently recorded in the intervention group, in 65 patients (100 %) *versus* 38 patients (58.5 %), which was statistically significant ($p < 0.001$). No differences were observed in the distribution of overall weight loss by intervention group (p = 0.39).

However, a statistically significant difference was found in the distribution of overall weight loss according to the symptomatic state at diagnosis. Weight loss was reported in 30 % (n = 9) of asymptomatic patients in a screening program and 71.2 % (n = 52) in the group of patients diagnosed with symptomatic colorectal cancer (CRC) (p = 0.016).

A total of 80 % of the patients studied (n = 104) had ≥ 2 altered nutritional parameters, which was not statistically significant between the groups. Sixteen of 130 patients had SSI, nine had a superficial incision infection, five had organ/space infection and two patients had combined incision and organ/space infection. This resulted in an overall SSI incidence of 12.3 %. According to the univariate study, the incidence of SSIs decreased after the implementation of the Nutritional Program from 18.5 % (n = 12) to 6.2 % (n = 4) (OR = 0.29; 95 % CI: 0.09-0.95) (p = 0.033). Thus, we could confirm that nutritional therapy was a statistically significant protective factor in the development of SSIs. A reduction in the rates of postoperative fever from 30 % to 10 % was also observed (OR = 0.41; 95 % CI: 0.17-0.96) (p = 0.037). No differences were found with regard to hematoma or seroma formation in surgical wounds, rectal bleeding, bleeding, urological infection, renal failure, respiratory infection, hemodynamic failure and anastomotic fistula. The application of the Nutritional Program was associated with a reduction in hospital stay from 11.3 ± 8 days to 7.2 ± 2.5 days (p = 0.02).

According to the univariate analysis, the risk factors associated with SSIs were (Table 3) non-application of the Nutritional Assessment and Support Plan, DM, heart disease, symptoms at the time of diagnosis, ≥ 2 altered nutritional biochemical parameters and laparoscopic surgery.

The risk factors for SSI, which were statistically significant according to the univariate analysis, and those considered as relevant due to their clinical and prognostic significance (age, weight loss, albumin deficit and total protein deficit) with a significance of p ≤ 0.2 were analyzed in the multivariate analysis (Table 4). The following parameters were statistically significant: the administration of the Nutritional Program (OR = 0.27; 95 % CI: 0.07-1.0), DM (OR = 3.0; 95 % CI: 0.9-9.9), underlying heart disease (OR = 4.6; 95 % CI: 1.1-18.6) and laparoscopic surgery (OR = 0.28; 95 % CI: 0.08-0.97).

DISCUSSION

The association between malnutrition in surgical patients and increased postoperative morbidity and mortality is a hypothesis widely supported by several studies (13,15,18-20). The PREDyCES© study published in 2012 by Álvarez Hernández et al. reported a

prevalence of malnutrition in 23.7 % of hospitalized patients and more specifically, 10 % of patients who undergo surgery (17).

Surgery, like any other uncontrolled physical trauma, triggers a "systemic inflammatory response syndrome" which can contribute to *metabolic risk,* along with other factors typical of the underlying disease (18). The European Society for Clinical Nutrition and Metabolism (ESPEN) sets out recommendations for nutritional management and support for patients. This includes those who are malnourished (a condition that is difficult to interpret in Western countries) and those with a high metabolic risk. This need is particularly relevant to elderly cancer patients (18).

In our study, the average BMI of the population was 27 and 27.7 % of patients had a BMI ≥ 30. However, involuntary weight loss was recorded in 46.9 % of patients. A total of 20 % of patients lost less than 5 kg, 24.6 % lost between 5 and 10 kg and 2.3 % lost more than 10 kg. According to the MUST nutritional risk assessment tool, a loss of 3.5-7 kg in the last 3-6 months in an individual weighing 70 kg is associated to a medium nutritional risk. However, the loss of ≥ 7 kg of weight for the same individual is associated with a high nutritional risk. Therefore, we could conclude that 26.9 % of patients in this study had a high nutritional risk when taking weight loss into account in isolation and without considering other factors. The recorded weight loss was different ($p = 0.016$) among symptomatic and asymptomatic patients. In our study sample, 71.2 % of the patients diagnosed with symptomatic CRC had some degree of weight loss, indicating the need to take extreme nutritional screening measures in this group.

Of all patient postoperative complications, SSI is of particular relevance (19,20). SSI rates are proportional to the adequacy of the surgical practice and represent a good indicator of the improvement in the quality and safety of care provided at each facility (21,22).

According to the INCLIMECC study, the incidence of SSI in Spain is 5.9 % (23), reaching rates of up to 26 % for colorectal surgery (24). SSI contributes to increased morbidity and mortality rates and represents a significant economic burden (25-27), which has driven the promotion of programs to implement "bundles" of preventive measures for SSI (Surgical Infection Zero project) (28). The implementation of a perioperative Nutritional Assessment and Support Program associated with these bundles of

measures could contribute to the improvement of the quality of care.

The overall incidence of SSI during the study period was 12.3 %, falling from 18.5 % to 6.2 % after program implementation, a relatively low figure when compared to other SSI series in colorectal surgery (24,29). Patients were monitored for 30 days post-op. Some studies limit the monitoring of SSI to the period of hospital admission and not to 30 days after surgery, which may underestimate its incidence. With this result, we could confirm that the application of the Nutritional Program is related to a statistically significant lower frequency of SSIs. However, after controlling for other variables that significantly influence SSIs, the effect of the Nutritional Program was less significant. A larger group of patients in both groups is likely required in order to obtain more definitive results. The hospital stay was reduced from 11.3 to 7.2 days with the implementation of the program. However, despite such a statistically significant and striking improvement (as detailed in the results section), we cannot rule out the influence of other factors that were not evaluated in our study which may have contributed to such a dramatic improvement.

The Nutrition Assessment and Support Program improved the recording of clinical data in terms of nutritional clinical information and parameters. BMI, weight loss in the last 3-6 months, dietary habits and nutritional analytical parameters were tracked for all patients.

According to the multivariate analysis, laparoscopic surgery protects against the development of SSI with an OR of 0.28. There are many studies in which short-term clinical advantages, including reducing SSIs, were observed in laparoscopic surgery over open surgery in the treatment of CRC (30-33). The documentation and information provided to patients improved patient engagement and collaboration. Patients demonstrated a greater confidence and satisfaction throughout the surgical process and compliance with the program was 100 %.

Due to the quasi-experimental study design, it could be limited by the fact that participating patients were not randomized in the study. However, the distribution of patients was similar in the two groups and possible biases were balanced, both before and after the intervention. In order to prevent loss biases in monitoring, a percentage of possible losses were estimated during the period studied when the sample size was

calculated. Our center has electronic medical applications. This allowed patients to be monitored in the outpatient clinic during the 30 days post-op and at the Primary Care centers through the Horus® computer application after hospital discharge. Thus, information biases have also been controlled.

CONCLUSIONS

The implementation of a nutritional assessment and support program for patients undergoing colorectal surgery has shown statistically significant differences in the reduction of the incidence of surgical site infection, postoperative fever and hospital stay. We cannot rule out the possibility that there are other factors that were not evaluated in our study that may have influenced these results.

As the Nutritional Assessment and Support Program was implemented, surgeons focus more on recording and interpreting preoperative clinical and analytical information related to nutritional status. The adoption rate of early improvement measures has improved as a result of the program. Actions aimed at identifying surgical patients with some degree of nutritional or metabolic risk can help prevent postoperative complications and improve treatment outcomes.

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Table 1. Preoperative Nutritional Assessment and Support Program

1. Training for the General and Digestive Surgery Department medical staff, explaining the program
2. Introduction of a nutritional assessment protocol in the surgery consultation for all patients who come to their first appointment with a colon or rectal neoplasia diagnosis
3. Request for complete nutritional analysis, measurement of anthropometric parameters (size and BMI), daily dietary habits questionnaire in the last week, weight loss assessment
4. Completion of the MUST nutritional assessment scale
5. Detailed documentation to improve the nutritional quality of the patient's diet. Information brochure on the recommended and non-recommended food provided during the consultation
6. Protocol-based care for patients that require oral nutritional support
7. Protein nutritional support prescription, Fortimel Extra®, during the ten days prior to surgery
8. Fiber restriction during the four days prior to surgery. Hodernal® to avoid constipation
9. Complete nutritional analytical tests in outpatient centers, upon admission, 3rd day post-op and 5th day post-op

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Table 2. Characteristics of the patients and principal variables of the study

	Before the program n (%)	*After the program n (%)*	*p-value*
Gender (male)	43 (66.2)	42 (64.6)	0.85
*Average age **	70.9 (8)	66.9 (10)	0.17
Comorbidities			
HBP	38 (58.5)	34 (52.3)	0.48
DM	21 (32.3)	12 (18.5)	< 0.001
Dyslipidemia	29 (44.6)	23 (35.4)	0.28
Heart disease	9 (13.8)	8 (12.3)	0.80
COPD	6 (9.2)	12 (18.5)	0.13
ASA			
ASA I	0 (0)	5 (7.7)	0.21
ASA II	39 (60)	39 (60)	
ASA III	26 (40)	10 (29.2)	
ASA IV	0 (0)	2 (3.1)	
*BMI**	27.1 (3)	27.5 (4)	0.65
Weight loss record	38 (58.5)	65 (100)	< 0.001
Weight loss			
No weight loss	15 (23.1)	27 (41.5)	0.39
Weight loss ≤ 5kg	13 (20)	13 (20)	
Weight loss 5-10 kg	9 (13.8)	23 (35.4)	
Weight loss ≥ 10 kg	1 (1.5)	2 (3.1)	
Symptomatic status at diagnosis			
Asymptomatic patients (CRC screening)	13 (20)	24 (36.9)	0.46
Surgery			
Open	26 (40)	21 (32.3)	0.64
Laparoscopy	32 (49.2)	37 (56.9)	
Reconverted	7 (10.8)	7 (10.8)	
Tumor location			

Left colon, sigma y rectum	41 (63.1)	39 (60)	
*Surgery duration**	233.9 (DE = 63)	222 (DE = 56)	0.287

HBP: high blood pressure; DM: diabetes mellitus; COPD: chronic obstructive pulmonary disease; ASA: American Society of Anesthesiologists; CRC: colorectal cancer. *Media (standard deviation).

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Table 3. SSI according to the considered risk factor. Univariate analysis

Risk factor	*Yes*	*No*	*p-value*
Nutritional Assessment and Support Program	4 (6.2 %)	12 (18.5 %)	0.033
DM	8 (24.2 %)	8 (8.2 %)	0.016
Heart disease	5 (29.4 %)	11 (9.7 %)	0.02
Albumin deficit	2 (28.6 %)	14 (12.1 %)	0.21
Prealbumin deficit	1 (8.3 %)	6 (9.5 %)	0.90
Total protein deficit	6 (20 %)	10 (10.6 %)	0.18
≥ 2 altered nutritional biochemical parameters	16 (15.4 %)	2 (7.14 %)	0.04
Symptomatic at diagnosis	16 (17.2 %)	0 (0 %)	0.007
Age ≥ 70 (years)	11 (16.2 %)	5 (8.1 %)	0.16
Male sex	9 (10.9 %)	7 (15.6 %)	0.4
HBP	10 (13.9 %)	6 (10.3 %)	0.54
Pulmonary disease	2 (11.1 %)	14 (12.5 %)	0.87
Weight loss	13 (14.8 %)	3 (7.1 %)	0.22
ASA ≥ III	7 (14.9 %)	9 (10.8 %)	0.5
BMI ≥ 30	13 (12.4 %)	13 (12.4 %)	0.96
Surgical technique (right hemicolectomy)	10 (12.5 %)	6 (12 %) (left hemicolectomy/sigma/rectum)	0.93
Laparoscopy surgery	11 (18 %)	5 (7.2 %)	0.06
Surgery duration ≥ 150 minutes	15 (12.8 %)	1 (7.7 %)	0.28

HBP: high blood pressure; DM: diabetes mellitus; ASA: American Society of Anesthesiologists; BMI: body mass index. *Media (standard deviation). *The biochemical parameters studied were: albumin, transferrin, prealbumin, retinol-binding protein, cholesterol, total proteins and lymphocytes.

Table 4. Multivariate analysis of SSI risk factors

Multivariate analysis	*OR*	*95 % CI*	*p-value*
Nutritional Assessment and Support Program	0.27	0.07-1.01	0.05
DM	2.99	0.91-9.87	0.07
Heart disease	4.57	1.12-18.64	0.03
Laparoscopic surgery	0.28	0.08-0.97	0.04

DM: diabetes mellitus.