Abbreviated preoperative fasting favours postoperative oral intake at lower hospital admission costs for cancer patients.

Jejum pré-operatório abreviado favorece realimentação pós-operatória com menor custo de internação hospitalar em pacientes oncológicos.

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A B S T R A C T

Objective: to evaluate the feasibility of abbreviated fasting in oncologic colorectal surgeries, as well as the impact on the surgical outcome of the patients. **Methods:** prospective randomized comparative study with patients undergoing elective colorectal cancer surgeries from May to September 2017. Patients were randomized electronically into two groups according to the preoperative fast to be adopted: conventional or abbreviated. **Results:** of the 33 patients included, 15 followed the abbreviated fasting protocol and 18 the conventional fasting. Both groups had comparable profiles. No patient underwent mechanical preparation of the colon. In 69.7% of the cases, surgery involved low rectal dissection. The procedures were equivalent in relation to intraoperative variables and severe complications. The time to achieve complete oral intake was shorter for abbreviated fasting (10 *versus* 16 days, p=0.001), as well as the length of inhospital stay (2 *versus* 4 days, p=0.009). Hospital costs were lower in the abbreviated fasting (331 *versus* 682 reais, p<0.001). The univariable analysis revealed a correlation between complete oral intake and abbreviated fasting [HR 0.29 (IC95%: 0.12-0.68] and abdominal distension [HR 0.12 (IC95% 0.01-0.94)]. After multivariable analysis, abbreviated fasting presented a lower time for complete oral intake [HR 0.39 (IC95%: 0.16-0.92]. **Conclusion:** the abbreviated preoperative fasting favors the metabolic-nutritional recovery, reducing the time for complete oral intake. The implementation of the abbreviation protocol reduces hospital admission costs.

Keywords: Fasting. Cost Efficiency Analysis. Costs and Cost Analysis. Colorectal Neoplasms. Colorectal Surgery.

INTRODUCTION

There has been more and more discussion about perioperative handling of patients who undergo elective surgery. There has also been more demand for conduct based on evidence in services aiming at improving the quality of patient care[1-4]. New preoperative and perioperative protocols and strategies have been developed continuously aiming at a faster postoperative recovery and early hospital discharge, as well as reducing morbimortality and surgical complication rates[5-7].

ERAS (Enhanced Recovery After Surgery), the multicenter European group, proposes a multimodality approach protocol integrated to the perioperative care, which resulted in better recovery after colon surgery. Besides, randomized clinical studies comparing ERAS to traditional postoperative care showed a reduction in the length of hospital stay for the ERAS group[8-14].

Similarly, in 2005, project ACERTO (Aceleração da Recuperação Total - Total Recovery Acceleration) was started in Brazil, based on the concepts of the ERAS group[4,6]. A comparative study of patients who underwent elective surgery under ACERTO protocol and patients who received traditional care indicated that the ACERTO group showed a reduction in both the length of in-hospital stay and postoperative morbidity[5].

In colorectal surgery, the main points taken into account refer to the nutritional approach (perioperative nutritional support, reduction of preoperative fasting time and early release of dietary

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restrictions post surgery), the limitation of the use of drains and restriction in the use of nasogastric catheters, restriction of perioperative intravenous hydration and the systematic use of preoperative mechanical preparation of the colon in colorectal surgery[13,15]. Special attention has been given to the rational use of antibiotics, to pain control, to postoperative nausea to vomiting, to the emotional preparation of patients and to a physical therapy approach that promotes ultra-early mobilization and early return to activities[9,10,16].

The basis of this new multimodal approach lies in randomized studies which showed consistently that the use of the so-called "fast track" programs can promote an early return of the intestinal function and an improvement of patients' physiological functions, resulting in a reduction in the length of in-hospital stay and operative morbidity. The first rule of the program is: the day of surgery is the first day of patient recovery[2,4,17,18].

The protocols established so far, based on the perioperative handling of patients who underwent medium and major surgery, regardless of the segment of the gastrointestinal tract used, have been set up in general hospitals, with no selection of the base disease - with only the selection of the surgical procedure applied[10,19-21]. The medical literature shows but a few reports of similar protocols applied in leading cancer hospitals specialized in treating patients with more advanced stages of cancer who are, in the great majority, malnourished[9-11,20-22].

We carried out this study in order to evaluate the influence of the abbreviated preoperative fasting over the surgical outcomes in patients who underwent colorectal surgery due to cancer, as well as the impact over hospital stays costs.

METHODS

Single-blind, randomized, prospective, comparative study carried out between May and September 2017. Colorectal cancer patients referred to surgery at Erasto Gaertner Hospital (HEG) in the City of Curitiba, State of Paraná, were selected for the study. The project was approved by the hospital's Research Ethics Committee under number 2492/16 (CAAE 54503616.6.0000.0098).

Patients over 18 years old, with planned elective surgery, (ileocolectomy, left colectomy, abdominal rectosigmoidectomy or rectal dissection), diagnosed with colorectal cancer at any clinical stage and who agreed in taking part in the study were electronically randomized into two groups: abbreviated fasting and conventional fasting (control group). The abbreviated fasting group received one dose of Maltodextrin at 6am on the morning of surgery, and another dose at 10am - two hours before the time scheduled for the procedure. The control group remained in absolute fast since the night before surgery.

As per routine, all patients underwent outpatient nutritional assessment and preoperative follow-up, as well as postoperative fluid restriction. None of the patients underwent preoperative mechanical bowel preparation. It was not possible to administer placebo to the control group patients as it would interfere with the habitual fasting. The surgical team did not know to which group each patient belonged, which constituted the single-blind aspect.

All surgical technical aspects followed the usual Service routine, surgeon preference and availability of resources in the National Health System (SUS) - use of drains, suture wires, staplers, colostomy procedures, open or minimally invasive, etc.

Postoperative care in intensive care units was individualized according to the clinical laboratory and anesthesia parameters. Surgical complications were classified according to Clavien-Dindo[23].

Patients were followed daily by the team during in-hospital stay. After discharge, all patients were reassessed on the seventh, 14th and 28th days after surgery, and after that, they were reassessed quarterly for at least 12 months. Costs with medicines, nutrition and hospital supplies were assessed by balance sheet linked to permission granted by the SUS for in-hospital stay for each patient.

Data was exhibited as averaged and standard deviation and interquartilian range for non-normal data distribution. Students' t-test was applied for continuous numerical variables. Mann-Whitney's non-parametric test was used for independent numerical variables with non-normal distribution. The chi-squared test with Fisher's correction was used for categorical variables. Patients' survival rates were estimated by the Kaplan-Meier method and compared using the log-rank test. Outcome predictors were identified by Cox regression. The data collected was tabulated and analyzed by the systems SPSS v23.0 and STATA v15, in which $p<0.05$ was considered statistically significant.

RESULTS

For the study, 36 patients were randomized, and three were excluded because they did not take the product for logistic reasons. Of the 33 patients in the study, 15 followed the abbreviated fasting protocol and 18, the conventional 8-hour preoperative fasting protocol (control group), as shown on figure 1.

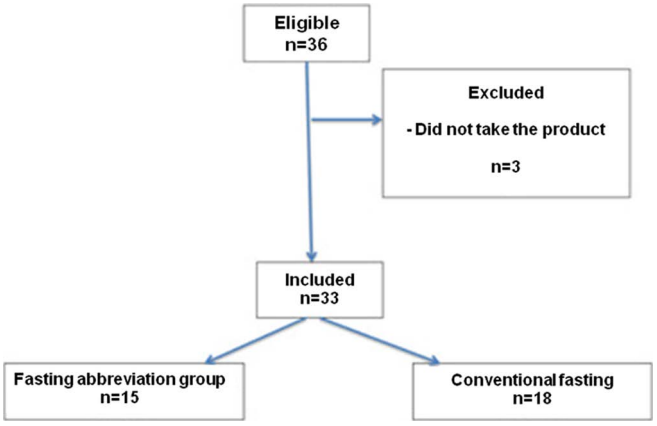

Figure 1. *Patient inclusion diagram.*

The profile of both groups was comparable in terms of average age, gender, body mass index, percentage of preoperative weight loss, preoperative immunonutrition, previous comorbidities (systemic hypertension, diabetes *mellitus*, acute myocardial infarction, chronic obstructive pulmonary disease), anesthetic risk (American Society of Anesthesiology - ASA), neoplasm staging and preoperative cancer treatment (preoperative radiotherapy and chemotherapy), as per table 1.

None of the patients underwent preoperative mechanical preparation of the colon, following Service routine. In 69.7% of the cases, the performed surgery involved rectal dissection in the pelvic cavity (rectosigmoidectomy and abdominoperineal resection). figure 2 shows the types of surgery performed.

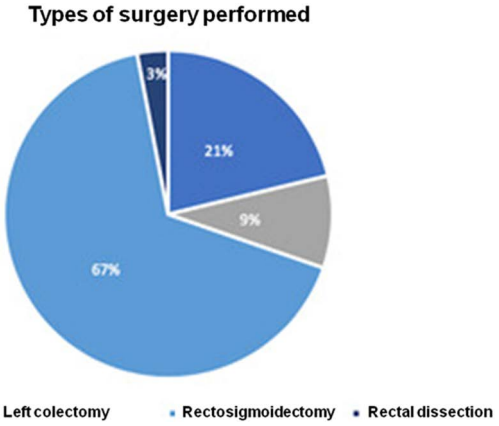

Figure 2. *Types of surgeries performed.*

Table 1. *Profile of patients in the study.*

Patient profile	Total (n=33)	Abbreviated fasting (n=15)	Control (n=18)	p
Age (years)	64 (56.50-72.50)	60 (56-72)	67 (56.70-75.00)	0.34
Gender, masculine	16 (48.50)	7 (46.70)	9 (50.00)	0.84
BMI* (Kg/m^2)	26 (22.20-29.20)	25 (20.80-27.90)	26.30 (22.60-30)	0.36
% PP**	10.80 (9.50-23.10)	10.70 (9.00-28.00)	17.60 (17.00-17.80)	0.37
Preoperative NT***	14 (42.40)	8 (53.30)	6 (33.30)	0.24
SAH[#]	18 (54.50)	8 (53.30)	10 (55.60)	0.89
DM[##]	7 (21.20)	2 (13.30)	5 (27.80)	0.31
Previous AMI[###]	3 (9.10)	2 (13.30)	1 (5.60)	0.43
COPD[¥]	1 (3.00)	0	1 (5.60)	0.35
ASA[¥¥]				0.49
I	1 (3.00)	1 (6.70)	0	
II	24 (72.70)	11 (73.30)	13 (72.20)	
III	8 (24.20)	3 (20.00)	5 (27.80)	
Clinical staging				0.51
I	10 (30.30)	6 (40.00)	4 (22.20)	
IIA	6 (18.20)	2 (13.30)	4 (22.20)	
IIB	2 6.10)	1 (6.70)	1 (5.60)	
IIIA	3 (9.10)	0	3 (16.70)	
IIIB	9 (27.30)	5 (33.30)	4 (22.20)	
IIIC	3 (9.10)	1 (6.70)	2 (11.10)	
Postoperative pelvic radiotherapy	10 (30.30)	4 (26.70)	6 (33.30)	0.67
Preoperative chemotherapy	10 (30.30)	5 (33.30)	5 (27.80)	0.73

**BMI: body mass index; **%PP: percentage of weight loss; ***NT: nutritional therapy; [#]SAH: systemic arterial hypertension; [##]DM: diabetes mellitus; [###]AMI: acute myocardial infarction; [¥]COPD: chronic obstructive pulmonary disease; [¥¥]ASA: American Society of Anesthesiology.*

The procedures were equivalent in both groups in terms of average length of surgery, colostomy procedure, surgical pathway of access, use of drain in the surgical bed, postoperative fluid restriction and use of antibiotics as a prophylactic measure. Besides, the outcomes were comparable in terms of length of ICU stay, diet acceptance on the first day after surgery, postoperative nausea and vomiting, abdominal distention, severe surgical complications (Clavien-Dindo 4 and 5), need for reoperation, post-surgery sepsis, intestinal fistula and surgical site infections. The length of average post-surgery follow-up was 14.8 months.

The time to achieve complete oral intake was significantly shorter in the group which underwent abbreviated fasting (10 *versus* 16 days, p=0.001), as well as the length of in-hospital stay (2 *versus* 4 days, p=0.009) and operative morbidity (up to 30 days).

As to hospital costs with medicines and hospital supplies used during in-hospital stay, the group which underwent abbreviated fasting showed significantly lower values in relation to the control group (R$ 331 *versus* R$ 682, p<0.001). Table 2 shows the comparative results of postoperative outcomes and of the characteristics of the procedures performed for the groups in the study.

Table 2. *Characteristics of procedures and outcomes in the groups.*

Postoperative evolution	Total	Abbreviated fasting	Control	P
Colostomy	16 (48.50)	5 (33.30)	11 (61.10)	0.11
Surgery length	180 (150-240)	184 (158-240)	180 (146-255)	0.68
Open access pathway	27 (81.80)	11 (73.30)	16 (88.90)	0.24
Drain surgical bed	23 (69.70)	11 (73.30)	12 (66.70)	0.67
Postoperative fluid restriction	29 (87.90)	13 (86.70)	16 (88.90)	0.84
Postoperative prolonged antibiotic use	9 (27.30)	2 (13.30)	7 (38.90)	0.10
Length of in-hospital stay	3 (2-5)	2 (2-3)	4 (3-9)	0.009
Prolonged ICU* stay	6 (18.20)	1 (6.7)	5 (27.80)	0.11
Diet acceptance on 1st postoperative day	28 (84.80)	13 (86.70)	15 (83.30)	0.79
Time to complete oral intake (days)	12 (10-16)	10 (8-12)	16 (10-16)	0.001
Nausea/Vomiting	5 (15.20)	2 (13.30)	3 (16.70)	0.79
Abdominal distension	6 (18.20)	1 (6.70)	5 (27.80)	0.11
Severe complication (Clavien Dindo 4/5)	8 (24.30)	2 (13.30)	6 (33.40)	0.18
Reoperation	5 (15.20)	2 (13.30)	3 (16.70)	0.79
Morbidity up to 30 days	4 (12.10)	0	4 (22.20)	0.05
Postoperative sepsis	3 (9.10)	0	3 (16.70)	0.09
Intestinal fistula	6 (18.20)	2 (13.30)	4 (22.20)	0.51
Surgical site infections	4 (12.10)	1 (6.70)	3 (16.70)	0.38
Average in-hospital stay cost (R$)	522.86	331.69	682.18	<0.001
Follow-up time (months)	14.80 (11.80-16.00)	15.20 (12.60-16.00)	13.9 (3.60-15.80)	0.16

**ICU: intensive care unit.*

The univariate analysis with Cox regression for the outcome regarding complete postoperative oral intake showed a significant correlation with abbreviated fasting and postoperative abdominal distention (HR 0.29 IC95%: 0.12-0.68 and HR 0.12 IC95%: 0.01-0.94, respectively). However, there was no association with preoperative immunonutrition, postoperative nausea and vomiting, preoperative radiotherapy, colostomy procedure, surgical access pathway, drainage in the surgical bed, post-operative fluid restriction, severe surgical complications and prolonged antibiotic use.

Additionally, after multivariate analysis with Cox regression, only abbreviated fasting showed statistically significant association with complete postoperative oral intake (HR 0.39 IC95%: 0.16-0.92). The results of the univariate and multivariate analysis are shown on table 3.

By analyzing the influence of abbreviated fasting over the time to complete postoperative oral intake, the group analyzed showed a much earlier progression in relation to the control group (10 *versus* 16 days, p=0.001), as shown on figure 3.

Table 3. *Univariate and multivariate analysis with Cox regression for complete postoperative food intake.*

Variable	Univariate analysis		Multivariate analysis	
	HR IC95%	p	HR IC95%	p
Abbreviated fasting	0.29 (0.12-0.68)	0.005	0.39 (0.16-0.92)	0.03
Preoperative NT*	1.23 (0.57-2.66)	0.58	-	-
Nausea/Vomiting	0.74 (0.22-2.49)	0.62	-	-
Abdominal distension	0.12 (0.01-0.94)	0.005	5.71 (0.74-43.90)	0.09
Preoperative radiotherapy	1.18 (0.53-2.66)	0.67	-	-
Colostomy	0.83 (0.39-1.78)	0.64	-	-
Open access pathway	0.55 (0.22-1.39)	0.23	-	-
Drain on surgical bed	1.17 (0.50-2.70)	0.70	-	-
Postoperative fluid restriction	1.25 (0.37-4.18)	0.70	-	-
Severe complication	0.52 (0.19-1.39)	0.16	-	-
Postoperative prolonged antibiotic use	0.51 (0.20-1.30)	0.14	-	-

**NT: nutritional therapy.*

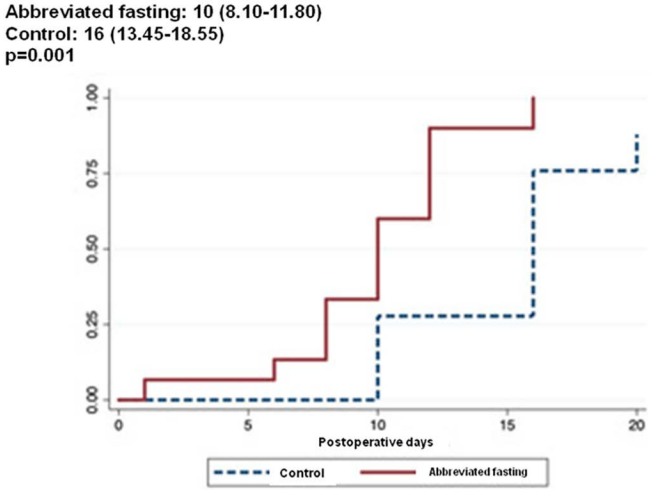

Figure 3. *Time to achieve full oral intake due to abbreviated fasting.*

DISCUSSION

The prospective, comparative and randomized character of the current study reinforces the validity of the data findings, since the sample was followed with scientific rigor and under controlled conditions for reliable data registration and control, despite the low number of patients included. A great portion of the studies already published on the same subject are retrospective, based on non-prospective international databases, or opinion polls with surgeons[10,24]. Electronic randomization was effective, seeing that the profile of the patients analyzed was homogeneous, showing clinical and epidemiological characteristic similarities within the compared groups.

The re-introduction of a complete postoperative food intake is a key factor for the immunophysiological recovery of the patients who underwent abdominal procedures[25,26]. The presence of intestinal transit assessed by peristaltic movement represents a predominant factor of the assessment of postoperative recovery in the majority of the surgical services, and allows for a safe diet progression[8,9,12,17].

Hospital costs are directly related to the length of the stay. Each in-hospital day reflects a rise in treatment cost, especially in prolonged stays due to severe surgical complications requiring the use of antibiotics and enteral/parenteral special diets[20,22].

In this study, we noticed that the abbreviated fasting for patients who underwent colorectal cancer surgery helped with physiological recovery and the early return to a full diet. Even after taking into account several factors corresponsible for this recovery through multivariate Cox regression for

confounding factors, abbreviated fasting revealed itself as the main statistically significant factor to support a return to full diet. A similar result was found by Li *et al*.[21].

Despite the fact that other factors leading to a prolonged in-hospital stay, such as complications, fistulae, etc., do not have statistical significance, the indirect indicator of such results (days of in-hospital stay) supports the use of abbreviated fasting in more patients. Possibly, the sample size limitation prevented the occurrence of more significant results, such as those presented by Seretis *et al.*[19].

One of the main analysis of this study is the assessment of intra-hospital stay costs. The difficulty to indicate a breakdown of the values in relation to the items used during in-hospital stay in most of the public services in the country prevents this assessment from being applied to other contexts. Thanks to the management model using electronic patient's medical charts and a reliable data collection regarding hospital admission cost, it was possible to assess rigorously all hospital supplies applied to each patient in this study. The savings in hospital admission costs for the abbreviated fasting group show that the full use of the industrialized product does not have a negative impact over the final cost. On the contrary, it revealed itself as very cost-efficient, and it should be encouraged in other cancer services in Brazil. Such saving supports the findings published by Nelson *et al*.[20].

We have come to the conclusion that abbreviated preoperative fasting favors the metabolic-nutritional recovery, contributing to the reduction of time to complete postoperative oral intake in patients who underwent surgery for treating colorectal cancer. The implementation of the fasting abbreviation protocol reduced hospital admission costs, and should be recommended.

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R E S U M O

Objetivo: *avaliar a viabilidade de abreviação do jejum em cirurgias colorretais oncológicas, bem como, o impacto no desfecho cirúrgico dos pacientes.* **Métodos:** *estudo prospectivo comparativo randomizado com pacientes submetidos à cirurgias eletivas colorretais, por câncer, no período de maio a setembro de 2017. Os pacientes foram randomizados eletronicamente em dois grupos de acordo com o jejum pré-operatório a ser adotado: convencional ou abreviado.* **Resultados:** *dos 33 pacientes incluídos, 15 seguiram o protocolo de jejum abreviado e 18 de jejum convencional. Ambos os grupos apresentaram perfis comparáveis. Nenhum paciente foi submetido a preparo mecânico do cólon. Em 69,7% dos casos, a cirurgia envolveu dissecção baixa do reto. Os procedimentos foram equivalentes em relação às variáveis intraoperatórias e complicações graves. O tempo para atingir realimentação plena foi menor para o jejum abreviado (10 versus 16 dias, p=0,001), assim como, o tempo de internação hospitalar (2 versus 4 dias, p=0,009). Os custos hospitalares foram menores no jejum abreviado (331 versus 682 reais, p<0,001). A análise univariável revelou correlação entre a realimentação plena e o jejum abreviado [HR 0,29 (IC95%: 0,12-0,68] e com a distensão abdominal [HR 0,12(IC95%: 0,01-0,94)]. Após análise multivariável, o jejum abreviado apresentou menor tempo para realimentação plena [HR 0,39(IC95%: 0,16-0,92].* **Conclusão:** *o jejum pré-operatório abreviado favorece a recuperação metabólico-nutricional, diminuindo o tempo para realimentação plena. A implantação do protocolo de abreviação do jejum reduz custos de internação hospitalar.*

Descritores: *Jejum. Análise Custo-Eficiência. Custos e Análise de Custo. Neoplasias Colorretais. Cirurgia Colorretal.*

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