EFFECT OF NUTRITIONAL SUPPORT, REGARDLESS OF NUTRITIONAL STATUS, ON POSTOPERATIVE COMPLICATIONS IN PATIENTS UNDERGOING ELECTIVE RECTAL RESECTION FOR CANCER

A PROSPECTIVE OBSERVATIONAL COHORT STUDY

Vplyv nutričnej podpory, bez rozdielu nutričného stavu, na pooperačné komplikácie u pacientov podstupujúcich elektívnu resekciu rekta pre karcinóm

Prospektívna observačná kohortová štúdia

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Abstract

Background. Preoperative oral nutrition supplementation has been shown to reduce postoperative complications. The European Society for Clinical Nutrition and Metabolism recommends providing patients with oral nutritional supplements when normal food does not meet patients' energy needs. Is nutrition intervention by itself - unrelated to the nutritional status - sufficient before minimally invasive rectal cancer resection?

Materials and methods. A prospective observational study assigned patients undergoing minimally invasive resection of rectum (either laparoscopic or robotic-assisted) for cancer, to receive 400 to 600 mL of milk-based oral nutritional supplements, along with the typical diet, 2 – 6 weeks before surgery. Between January 2020 and June 2022, 67 patients (25 in the intervention and 42 in the control group) met the inclusion criteria. This study evaluated the incidence of overall postoperative complications and anastomotic leak in a 30-day follow-up of patients undergoing elective laparoscopic or robotic rectal cancer resection, with or without receiving nutritional support unrelated to their nutritional status in the preoperative period.

Results. In the intervention group, 13 patients (52%) were discharged and monitored, with no complications, and postoperative complications occurred in 12 patients (48%). In the control group, 24 patients (57.1%) had no complications, and complications occurred in 18 patients (42.9%).

Conclusion. There is a trend for differences between patients with nutritional support having fewer postoperative complica-

Abstrakt

Úvod. Predoperačná perorálna výživa preukázateľne znižuje pooperačné komplikácie. Európska spoločnosť pre klinickú výživu a metabolizmus odporúča podávať pacientom perorálne výživové doplnky, keď bežná strava nespĺňa ich energetické potreby. Je nutričná intervencia sama osebe, nezávisle od nutričného stavu, postačujúca pred minimálne invazívnou resekciou rakoviny rekta pre karcinóm?

Materiál a metodika. V prospektívnej observačnej štúdii pacienti podstúpili miniinvazívnu resekciu konečníka (laparoskopickú alebo roboticky asistovanú) pre karcinóm rekta. Intervenčná skupina užívala 400 – 600 ml perorálnych výživových mliečnych doplnkov spolu s bežnou stravou, 2 – 6 týždňov pred operáciou. V období od januára 2020 do júna 2022 splnilo kritériá pre zaradenie 67 pacientov (25 v intervenčnej skupine a 42 v kontrolnej skupine). Táto štúdia hodnotila výskyt celkových pooperačných komplikácií a samotnej dehiscencie anastomózy v 30-dňovom pooperačnom sledovaní.

Výsledky. V intervenčnej skupine bolo 13 pacientov (52 %) prepustených a monitorovaných bez komplikácií a pooperačné komplikácie sa vyskytli u 12 pacientov (48 %). V kontrolnej skupine nemalo 24 pacientov (57, 1 %) žiadne komplikácie a komplikácie sa vyskytli u 18 pacientov (42, 9 %).

Záver. Štúdia preukázala, že trend rozdielov medzi skupinou pacientov s nutričnou podporou sú menej časté pooperačné komplikácie a že prínos predoperačného užívania orálnych nutričných suplementov na klinický výsledok sa prejavil nezávisle od stavu výživy. Napriek tomu, v prípade závažnosti dehiscencie anastomózy, ako aj iných celkových komplikácií, sú

tions, and that the benefit of preoperative oral nutritional supplementation on clinical outcome is independent of nutritional status. However, in the case of anastomotic dehiscence severity and other end-points, the rates are so small that the results are not significantly different (Tab. 3, Fig. 1, Ref. 27). *Text v PDF www.lekarsky.herba.sk.*
KEY WORDS: preoperative nutrition, oral nutritional supplements, prehabilitation, minimally invasive rectal cancer resection, anastomotic leak, complications after colorectal surgery.
Lek Obz 2025, 74 (10): 364-369

početnosti také malé, že sa výsledky signifikantne nelíšia (tab. 3, obr. 1, lit. 27). *Text v PDF www.lekarsky.herba.sk.*
KĽÚČOVÉ SLOVÁ: predoperačná výživa, perorálne výživové doplnky, prehabilitácia, miniinvazívna resekcia rekta pre karcinóm, dehiscencia anastomózy, komplikácie po kolorektálnej chirurgii.

Lek Obz 2025, 74 (10): 364-369

Introduction

There is strong evidence that malnutrition is associated with worse outcomes postoperatively (1). The high prevalence of obesity and sarcopenia may be one of the reasons malnutrition is often underestimated in surgical patients (2, 3, 4). Physiological fasting differs from starvation during metabolic stress caused by any type of injury (5). Surgery leads to a systemic inflammatory response that requires optimal nutritional status (6). The European Society for Clinical Nutrition and Metabolism (ESPEN) recommends giving oral nutritional supplements (ONS) during the preoperative period to all malnourished cancer and high-risk patients undergoing major abdominal surgery. Providing ONS is also recommended, unrelated to nutritional status, to patients, whose energy needs are not met from normal food (4), and to patients with unintentional weight loss of 5% to 10% or more (7). Nutrition is integral to Enhanced Recovery After Surgery (ERAS) protocols, and nutritional supplementation is strongly recommended because it is associated with fewer infectious complications and anastomotic leaks (8). Three randomized controlled trials (9, 10, 11) focused on providing perioperative ONS to patients not at nutritional risk. Two studies showed no significant impact on the clinical outcome, but one study (10) found a significant reduction in minor complications and confirmed cost-effectiveness.

Most case series analyses investigating postoperative complications included all types of colorectal resection. Anastomoses of <10 cm from the anal verge (12) are considered individual predictors of leaks (13, 14) that significantly impair short-term (15) and long-term oncologic outcomes and increase mortality (16). The incidence of leakage is 3-times higher at the distal extraperitoneal anastomosis (13, 14, 17). To date, no study has focused exclusively on minimally invasive rectal cancer resections in the context of routine preoperative nutritional support unrelated to the nutritional status. This study hypothesized that ONS may reduce the prevalence of overall postoperative complications and anastomotic leaks.

Patients and methods

Inclusion criteria were age >18 years and a planned laparoscopic or robotic intervention for rectal cancer. Patients with inoperable tumors, no malignancies, amputation of the rectum, or resection involving other parts of the colon were excluded. The clinical population was obtained from outpatient clinics throughout the country and was referred to 3 colorectal surgeons. Data from January 2020 to June 2022 were collected. After surgery, serum total protein, albumin, and C-reactive protein (CRP) levels were recorded. The date of admission, operation, and discharge were documented, and hospital length of stay after surgery was calculated. All patients met the criteria for the initial indication of ambulatory enteral nutrition for adult patients, due to increased nutritional requirements of malignancy and reduced food intake. The study included 67 patients. The main demographic, nutritional, and clinical characteristics of the intervention and control groups are listed in Table 1.

Table 1. Demographic and clinical characteristics in rectal cancer patients.

Characteristics	Intervention (n=25)	Control (n=42)	p*
Age, years	62.0 (11.4)	63.0 (13.6)	0.761
Sex, n (%)			0.317
Men	19 (76)	27 (64)	
Women	6 (24)	15 (36)	
Body mass index, kg/m^2	27.2 (4.2)	27.2 (4.4)	0.994
Early oral intake, mL	240 (92)	235 (69)	0.782
CRP, mg/L	49 (33)	44 (27)	0.296
CRP control, mg/L	119 (118)	110 (116)	0.579
Total protein, g/L	61.5 (6.1)	59.1 (4.4)	0.067
Albumin, g/L	35.1 (4.1)	36.0 (5.9)	0.502
Hospital stay, days	7.5 (4.9)	7.6 (5.8)	0.930
Neoadjuvant therapy, n (%)	5 (20.0)	3 (7.1)	0.116
30-day postoperative complications, n (%)			
None	13 (52.0)	24 (57.1)	0.878
Mild	6 (24.0)	10 (23.8)	
Severe	6 (24.0)	8 (19.1)	

Data are presented as mean (standard deviation) unless indicated otherwise as n (%). CRP=C-reactive protein; Early enteral intake=oral intake of clear liquids within hours after surgery. *Student *t* test for unrelated groups or $\chi 2$ test for categorical outcomes.

Patients were instructed to consume 2 to 3 cartons (400 to 600 mL) of ONS between meals for 2 to 6 weeks before surgery. Milk-based supplements (300 kcal/1255 kJ, 18 g protein/125 mL), either alone

or in combination with cream-consistency supplements (200 kcal/840 kJ, 10 g protein/100 g), were used. During the hospital stay, all patients followed a standardized nutrition protocol (including patients who did not receive ONS preoperatively) of consuming ONS together with the gradual reintroduction of regular diet. The intervention group also continued to receive ONS for at least 1 month after discharge.

The primary outcome measure was the total number of postoperative complications, recorded by applying European Perioperative Clinical Outcome (EPCO) definitions, a statement from the joint task force of the European Society of Anaesthesiology and the European Society of Intensive Care Medicine joint task force on perioperative outcome measures (18), and the Clavien-Dindo classification. Data were collected postoperatively from the hospital information system, and complications were clarified with the clinical team. The secondary outcome measure was an anastomotic leak (dehiscence of anastomosis), classified according to the International Study Group of Rectal Cancer definition and grading system (19).

The Shapiro-Wilk test was used to ensure the normality of data in each examined group. The Student´s *t* test for unrelated groups was used to examine the differences between the means of the intervention and control groups, and the χ^2 test was used to compare input differences between categorical characteristics. One-way analysis of variance, followed by Bonferroni pairwise comparisons, was used to evaluate differences between groups diagnosed with anastomotic leak. Differences at $p<0.05$ (2-tailed) were considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics, version 28.0 software (IBM Corp., Armonk, NY, USA).

Results

Of 385 colorectal procedures, 306 (79.5%) were performed minimally invasively, and 67 patients were selected due to localization of tumor (rectum), type of procedure, and highly skilled surgeons as operators (Fig. 1). The intervention group included 25 patients. Of these, 13 (52%) were discharged and monitored without complications. Postoperative complications occurred in 12 patients (48%). According to the Clavien-Dindo classification, complications were classified as grade I and II (any deviation from a normal postoperative course or requiring pharmacologic treatment) in 6 patients, grade IIIA (complications requiring endoscopic, radiologic, or surgical intervention without general anesthesia) in 4 patients, and grade IIIB (inter-vention under general anesthesia) 2 patients. In the control group, 24 patients (57.1%) had no complications, while 18 patients (42.9%) developed complications, classified as Clavien-Dindo grade I and II in 10 patients, IIIA in 2 patients, and IIIB in 6 patients. Overall, no significant differences were observed in outcomes between the intervention and control groups (p=0.878) (Tab. 1).

In the intervention group, an anastomotic leak occurred in 8 patients (32%). Anastomotic leak with no active therapeutic intervention (grade A) was recorded in 2 patients, 4 patients required endoscopic or radio-

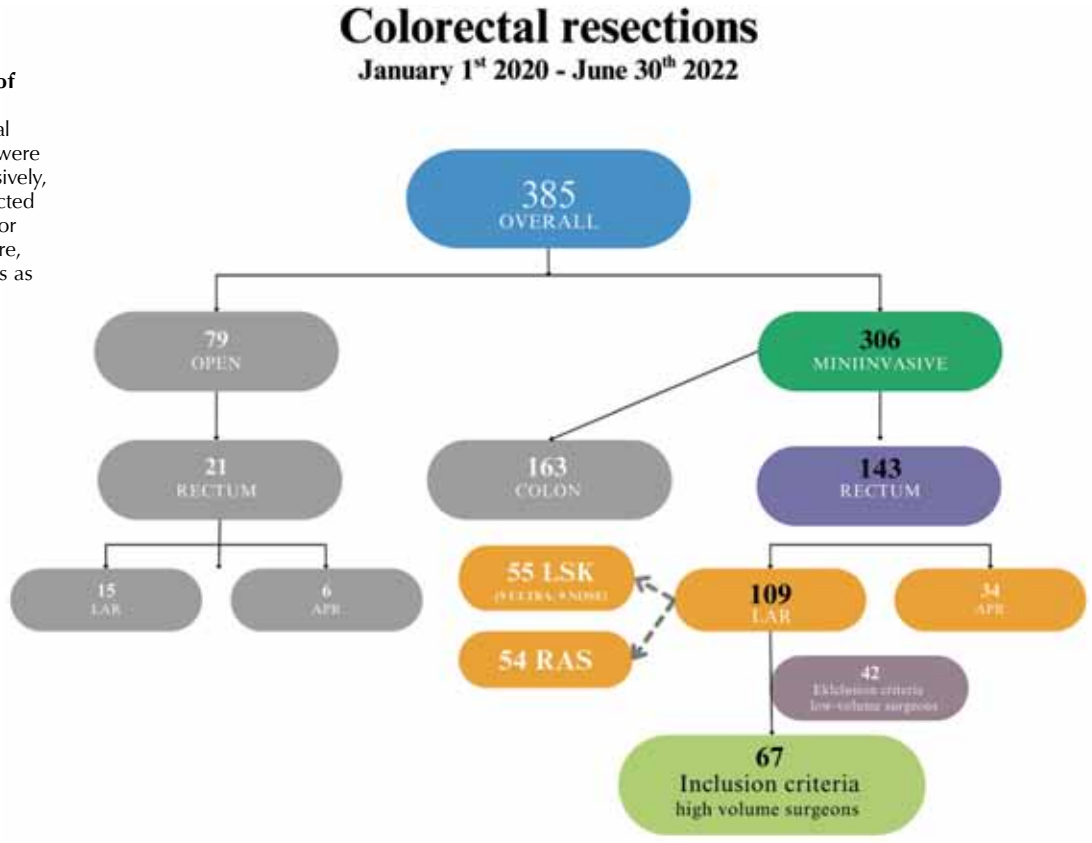

Figure 1. The flow chart of sample size calculation method. Of 385 colorectal procedures, 306 (79.5%) were performed minimally invasively, and 67 patients were selected due to localization of tumor (rectum), type of procedure, and highly skilled surgeons as operators.

logic intervention (grade B), and 2 patients underwent reoperation (grade C). In the control group, an anastomotic leak occurred in 7 patients (16.7%), 2 requiring endoscopic or radiologic intervention (grade B) and 5 requiring reoperation under general anesthesia (grade C) (Tab. 2). Patients receiving with nutritional support more often did not have any postoperative complications. The rates of the severity of anastomotic dehiscence (p=0.099) and other complications were comparable between the two groups (Tab. 2).

Table 2. Dehiscence in rectal cancer patients.

Characteristics	Intervention (n=25)	Control (n=42)	p*
None	17 (68.0)	35 (83.3)	0.099
A – Mild	2 (8.0)	0	
B – Endoscopy/radiology	4 (16.0)	2 (4.8)	
C – Reoperation	2 (8.0)	5 (11.9)	

Data are presented as n (%). *χ2 Test for categorical outcomes (contingency table 4×2).

Table 3 provides the demographic and clinical characteristics of rectal cancer patients according to postoperative complications. Statistical differences were found for age (p=0.019), serum CRP control levels (p<0.001), and hospital length of stay (p<0.001) between patients with none or various postoperative complications in the entire patient group. Patients requiring reoperation were younger, had higher serum CRP control levels, and had longer hospital length of stay (Tab. 3).

Table 3. Demographic, nutritional, and clinical characteristics in rectal cancer patients according to anastomotic leak graded groups.

Outcomes	Postoperative complications				p*
	None (n=52)	Mild (n=2)	Endoscopy (n=6)	Reoperation (n=7)	
Age, years	64.8 (8.9)	72.0 (14.1)	54.5 (10.8	50.3 (25.3)	0.006
Body mass index, kg/m^2	27.1 (4.0)	24.3 (4.7)	27.6 (2.9	30.0 (7.0)	0.538
Early orall intake, mL	241 (82)	200	233 (82)	214 (38)	0.755
CRP, mg/L	42 (25)	55 (60)	53 (46)	71 (32)	0.087
CRP control, mg/L	75 (70)	194 (88)	152 (103)	340 (141)	<0.001
Total protein, g/L	60.1 (5.5)	59.0 (8.5)	58.7 (2.9)	60.4 (4.2)	0.908
Albumin, g/L	35.2 (3.3)	34.0 (4.2)	35.5 (4.3)	40.1 (13.0)	0.125
Hospital stay, days	5.9 (1.0)	6.5 (0.7)	6.8 (2.2)	21.0 (9.0)	< 0.001

Data are presented as the mean (standard deviation). CRP=C-reactive protein; Early enteral intake=oral intake of clear liquids within hours after surgery. *One-way analysis of variance, followed by Bonferroni pairwise comparisons: Age, none vs reoperation, p=0.019; CRP control, none and endoscopy vs reoperation, p<0.001; Hospital stay, none, mild, and endoscopy vs reoperation, p<0.001.

Discussion

This case series analysis evaluated the use of preoperative ONS in an elective cohort of rectal cancer patients, unrelated to their nutritional status, using postoperative complications as the primary outcome and anastomotic leakage as the secondary outcome. Higher serum CRP levels on the first postoperative day correlated with the results of studies where significantly higher postoperative CRP was a marker of major complications (12, 17). Patients with complications had a longer hospital length of stay because they required acute intervention, reoperation, and/or control diagnostic methods. Minor and major complications are associated with prolonged postoperative length of stay (20). The findings that patients requiring reoperation were significantly younger requires further investigation.

The question remains: "Is nutrition alone enough?" According to the World Cancer Research Fund International, colorectal cancer is the third most common cancer worldwide, with >1.9 million new cases in 2020, and the burden of the disease is still high. Modifiable risk factors for colorectal cancer include high-fat and low-fiber diet, sedentary lifestyle, cigarette smoking, and heavy alcohol consumption. These risk factors lead to a high comorbidity rate in the population because of their impact on cardiorespiratory and metabolic systems (21). Given this knowledge, the value of preoperative nutrition in patients might increase even more in the context of prehabilitation. Prehabilitation has been recently recognized as a part of ERAS protocols (8). It is a multimodal approach consisting of equivalent pillars – exercise and physical activity, nutritional optimization, psychological well-being (especially stress and anxiety reduction), patient education, cessation of smoking (22), and others-representing a shift from the current health care paradigm (23). Most studies involving prehabilitation have focused on postoperative morbidity due to patient-related (older age, typically >65 years, and frail patients (24), and procedure-related (including major gastrointestinal (22) factors. However, some now centers offer prehabilitation programs for all surgical patients (22). Baseline values of functional walking capacity by 8 weeks were achieved by >80% of patients undergoing a multimodal prehabilitation program, in contrast with 40% of patients in the control group (25). A 4-week prehabilitation program showed a 51% reduction in postoperative medical complications (26). These results support the statement of the International Prehabilitation Society that claims the connection between increasing muscle mass alongside nutrition, better use of nutrition in combination with training, and a good mental state are mandatory for the ability to exercise. Conversely, the effort of training serves as a reward for the mental state, creating a reciprocal benefit (27). This may be the key to maximizing the benefits of preoperative nutritional supplementation and improving overall clinical outcomes, including a reduction of postoperative complications.

Limitations of this case series analysis include the unknown nutritional status of patients before surgery – since it was the primary purpose of the study as well as physical, psychological status, or frailty index, and compliance with using ONS. The control group included almost twice as many patients. The nonidentical duration of ONS intake may have contributed to the lack of statistically significant differences in the results.

Conclusion

In this case series analysis, patients with nutritional support more often did not have any postoperative complications. This occurred independently of their nutritional status. In the case of severity of anastomotic leak as well as other complications, the results were not significantly different, and those requiring revision under general anesthesia were considerably younger. Patients with no complications had significantly lower C-reactive protein levels on the first day after surgery and a shorter hospital length of stay.*

*__Ethics approval.__ Ethical approval No. 16/2021 was waived by the local Ethics Committee of the F. D. Roosevelt University Hospital in view of the retrospective nature of the study and all the procedures being performed were part of the routine care.

Declarations. The authors did not receive support from any organization for the submitted work. All authors certify that they have no affiliations with or involvement in any organization or entity with any financial or non-financial interest in the subject matter or materials discussed in this manuscript.

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Accepted for publication July 10, 2025.

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