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Preoperative Nutritional Risk and Postoperative Outcomes in Colorectal Cancer Surgery: Study Protocol of the FourColon-Factors Study

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Study protocol

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Abstract

Purpose: preoperative nutritional status may negatively influence the risk of anastomotic fistula (AF), a severe complication occurring after surgery for colorectal cancer (CRC). The FourColon-Factors study, approved by the Ethics Committee of the Istituto Nazionale Tumori IRCCS “Fondazione G. Pascale”, Naples (Prot. n. 70/24 OSS, November 27, 2024), aims to evaluate the prognostic role of malnutrition risk on AF in retrospective and prospective cohorts of patients with a primary diagnosis of CRC. Secondary outcomes include Health-Related Quality of Life (HRQoL) in the prospective cohort and overall survival (OS) in the retrospective cohort.

Methods: a total of 268 patients with a primary diagnosis of CRC eligible for surgery will be enrolled at the Istituto Nazionale Tumori IRCCS – Fondazione G. Pascale, Naples. In the prospective cohort, preoperative nutritional status will be assessed using validated screening tools, anthropometric measurements, handgrip strength test, and serum biomarkers. Body composition will be evaluated using bioelectrical impedance analysis, while HRQoL using a validated, cancer-specific questionnaire. Data on 60-day postoperative complications will be collected (T1). In the retrospective cohort, available data will be collected from a database of patients who underwent surgery for primary CRC between 2019 and 2024.

Results: We hypothesize that preoperative malnutrition risk is associated with an increased occurrence of AF.

Conclusion:
The FourColon-Factors study may improve the evidence regarding the prognostic role of nutritional risk on postoperative complications among patients with CRC. Furthermore, it may contribute to the identification of nutrition-related prognostic markers that could enhance clinical risk stratification and support tailored nutritional strategies.

1. Introduction

Colorectal cancer (CRC) is the third most diagnosed cancer and the second leading cause of cancer-related death worldwide in both sexes. In 2022, there were 1.9 million new cases and 904.000 deaths [1]. Currently, surgery remains the primary therapeutic approach for patients diagnosed with CRC. Unfortunately, postoperative complications can lead to short-term consequences (i.e. prolonged length of stay, readmission and mortality) and influence long-term outcomes (lower five-years survival and quality of life, QoL) [2]. The anastomotic fistula (AF), a severe complication of surgery, is associated with an increased risk of reintervention, permanent stoma formation, local recurrence, longer hospital stays, poorer Health-Related Quality of Life (HRQoL) and reduced overall survival (OS) [3]. According to evidence, advanced age, severe obesity, malnutrition, comorbidities, anemia, preoperative blood transfusions, and neoadjuvant chemoradiotherapy have been identified as potential risk factors for AF occurrence [4].

Malnutrition affects from 20 to 70% of cancer patients, depending on tumor type and stage, anticancer treatments, age and care setting [5]. In patients with CRC, the prevalence of preoperative malnutrition ranges from 23% to 38% according to the nutritional screening tool used [6]. This condition results from the activation of systemic inflammation induced by the underlying disease. The inflammatory response causes anorexia and tissue breakdown that can, in turn, result in significant loss of body weight, body composition impairment and declining physical function [7]. In patients diagnosed with CRC, malnutrition arises from a combination of factors, including increased nutritional needs due to cancer-related metabolic derangements, reduced food intake, loss of appetite and impaired nutrients absorption. These effects cumulatively led to a protein-calorie malnutrition phenotype, which affects postoperative outcomes by impairing the healing mechanisms necessary for wound-closure, hemostasis, proper coagulation, and other postoperative recovery processes [8].

While evidence indicates that nutritional problems often occur in advanced stage of disease, a growing number of studies suggest that patients with early-stage disease can also experience nutritional issues, including weight and muscle losses, which may negatively influence long-term outcomes [9]. In this regard, results of the PREMIO study indicate that 40% to 80% of patients had signs and indicators of nutritional impairment at their first oncological visit, particularly for gastro-esophageal, pancreatic, head and neck, and colon and rectal cancers [10].

The primary nutritional problem experienced by patients with cancer is muscle waste. In this regard, sarcopenia, the simultaneous loss of muscle mass and function is increasingly recognized as a significant prognostic factor of postoperative complications, poorer treatment tolerance and reduced OS [11]. Recent studies have demonstrated that sarcopenic patients with CRC have a two-fold increased risk of postoperative infections, AF and high-grade complications (grade 3-4) as defined by the Clavien-Dindo classification [12]. Similarly, patients with sarcopenic obesity, a condition characterized by the copresence of sarcopenia and excess adiposity, had longer hospital stays and a higher incidence of complications, including wound infections, AF, intestinal obstruction, and bleeding [13].

Given the role of malnutrition on clinical outcomes, the available evidence recommends an early assessment of patient's nutritional status followed by continuous monitoring [14]. This evaluation should involve the simultaneous use of clinical, anthropometric, and biochemical markers to enable a comprehensive diagnosis [15].

The analysis and monitoring of body composition should be an integral part of nutritional assessment as it allows for the estimation of various body compartments with particular attention to muscle mass, fat mass (FM), hydration status, and changes over time. This is especially relevant in cancer patients, where the early identification of reduced muscle mass can guide a personalized nutritional intervention also improving other clinical outcomes [11]. In the oncologic setting, body composition is commonly estimated through various techniques, including the computed tomography (CT) and magnetic resonance imaging (MRI), both providing accurate information on muscle quantity and quality. However,

they may not be routinely used in clinical practice except at certain time points of the patients' diagnostic path, and well-established age- and sex specific cut-offs are not yet available [16, 17].

Bioelectrical impedance analysis (BIA) is a widely used method to assess body composition in nutritional clinical practice due to its ease of use, portability, rapidity, relatively low cost and non-invasiveness for patients [16]. This method does not directly measure body composition, but instead electrical characteristics of human body, i.e. impedance (Z), through application of 4 electrodes and an applied alternate current, using single or multiple current frequencies [18]. BIA-derived raw measures include resistance (R), reactance (Xc) and phase angle (PhA). Through predictive equations, BIA provides information on hydration status, encompassing total body water (TBW), extracellular water (ECW) and intracellular water (ICW), fat-free mass (FFM), body cell mass (BCM), skeletal muscle mass (SMM), appendicular skeletal muscle mass (ASMM) and FM [19].

Although BIA is an alternative method to CT and MRI to assess body composition and clinical outcomes [20] [21], further prospective, clinical studies with larger cohorts are needed to evaluate its prognostic value, especially on postoperative complications and HRQoL in cancer patients. Moreover, the epidemiological study on preoperative malnutrition risk in relation to post-surgical complications (with particular attention to AF) may enhance and clarify the current knowledge available in the literature.

Given the above considerations, we present a clinical, observational cohort study, the FourColon-Factors with the primary purpose to evaluate the prognostic role of malnutrition risk on post-surgical complications, focusing on AF in prospective and retrospective groups of CRC patients.

2. Methods/design

Aim, design and setting of the study

The FourColon-Factors (*1: Body Composition 2: Malnutrition Risk 3: Post-Surgical Complications 4: Quality of life)* is a clinical, monocentric, observational cohort study that involves both prospective and retrospective groups of patients diagnosed with CRC. The primary objective of the prospective study is to evaluate the prognostic value of malnutrition risk and BIA-derived body composition parameters (both individually and in combination) on the occurrence of AF. As secondary objectives, the association between malnutrition risk and BIA-derived body composition parameters, other 60-days postoperative complications and HRQoL will be evaluated. As part of this observational investigation, the retrospective data collection will support the hypothesis developed in the prospective study and will contribute to the preliminary results. Accordingly, our primary objective will be to evaluate the prognostic value of malnutrition risk on the prevalence of AF while secondary objective will be to investigate the association between malnutrition risk and other 60-days postoperative complications. Finally, in the context of the retrospective study, the association between malnutrition risk and OS will be investigated.

Study population

For the prospective study, participants will be recruited among patients with a primary diagnosis of CRC, eligible for curative treatment with surgery at the Department of Colorectal Surgery and at the Abdominal Robotic Surgery Unit of the Istituto Nazionale Tumori “IRCCS Fondazione G. Pascale” of Naples. For the retrospective study, eligible participants will be selected from a database of patients with a primary diagnosis of CRC undergone surgery at our centre from 2019 to 2024. Based on the sample size calculation, a total of 268 patients, considering a percentage of drop-out equal to 10%, will be required to correctly estimate the primary outcome of the study. Figure 1 shows the study workflow.

Eligibility criteria

The prospective study will be open to patients aged 18 years or older, with a first diagnosis of CRC, eligible for surgery, presenting with good performance status (according to the Eastern Cooperative Oncology Group performance scale, ECOG PS<2 or Karnofksy PS>70%), able to feed orally and with primary tumor location within the colon. Conversely, patients with metastasis, previous diagnosis of cancer and/or cancer relapse, not eligible for surgery or undergoing emergency surgery, presenting with poor performance status (according to ECOG PS ≥ 2 o Karnofsky PS ≤ 70%), candidates to enteral or parenteral nutrition and with a primary tumor location within the rectum will be excluded.

For the retrospective study, patients aged 18 and older, with a primary diagnosis of CRC, treated with surgery at our cancer institute and with good performance status (according to ECOG PS<2 or Karnofsky PS>70%) will be included.

Conversely, patients with metastasis, previous diagnosis of cancer and/or cancer relapse, as well as patients treated with emergency surgery and with poor performance status (according ECOG PS≥2 o Karnofsky PS≤70%) will not be included in the retrospective study.

Methods of recruitment

For the prospective study, patients will be screened and assessed for eligibility after discussion of the cancer-specific Multidisciplinary Oncology Group (Gruppo Oncologico Multidisciplinare, GOM) at the Department of Colorectal Surgery and at the Abdominal Robotic Surgery Unit of the Istituto Nazionale Tumori “IRCCS Fondazione G. Pascale” of Naples. Before registration, eligible participants will receive complete information about the study. Only patients who provide informed consent form and the privacy disclosure will be enrolled. A progressive identification number with an anonymization procedure will guarantee participants’ data privacy. All data collected will be uploaded on a dedicated electronic database and will be stored anonymously. This study will be conducted in accordance with the ICH GCP guidelines, the Declaration of Helsinki, the Good Pharmacovigilance Practice and all current and relevant legislation. Ethical approval has been obtained from the Ethics Committee of the Istituto Nazionale Tumori IRCCS “Fondazione G. Pascale”, Naples (Prot. n.70/24 OSS on November 27, 2024).

Nutritional status assessment in the prospective group

At baseline visit (T0=before surgery and after the discussion of cancer-specific GOM), following the enrollment, data from nutritional assessment routinely performed for all patients referred to the Department of Colorectal Surgery and to the Abdominal Robotic Surgery Unit of our cancer center will be collected. Diagnostic criteria used for screening and assessment of malnutrition, sarcopenia and sarcopenic obesity [22-24] are summarized in Table 1.

Table 1. Diagnostic criteria for screening and assessment of malnutrition, sarcopenia and sarcopenic obesity

Nutrition-related condition	Diagnostic criteria	Reference
Malnutrition risk and assessment	Global Leadership Initiative on Malnutrition (GLIM)	[24]
Sarcopenia risk and assessment	European Working Group on Sarcopenia in Older People 2 (EWGSOP2)	[25]
Sarcopenic obesity risk and assessment	European Society for Clinical Nutrition and Metabolism and the European Association for the Study of Obesity (ESPEN-EASO)	[26]

Socio-demographic (i.e. age, sex, education level, employment status, marital status), clinical (particularly regarding the presence of intermediate risk factors and comorbidities, ongoing pharmacologic therapies, previous, ongoing or planned anticancer treatments) and lifestyle-related data (smoking status and alcohol consumption) will be collected using a case report form regarded by study staff.

After collecting general characteristics, patients will be screened for the risk of malnutrition and sarcopenia using two validated tools: the NRS-2002 [25], and the SARC-F [26], respectively. A detailed description of these nutritional and functional screening tools is provided in Table 2.

Table 2. Description of nutritional and functional screening tools

Tools	Description	Reference
NRS-2002	The NRS-2002 is a validated, rapidly administered tool for nutritional risk screening consisting of four initial screening questions: BMI, weight loss, reduced dietary intake, and illness severity. If the answer to at least one of the initial questions is “yes”, the final part of the screening will be performed. The final part includes two components: (1) impaired nutritional status (on a 4-step scale, scoring based on degree of weight loss, reduced food intake, or BMI) and (2) severity of disease (on a 4-step scale). The maximum score for each component is 3 points. For people aged ≥ 70 years, an additional point is added to the final score, resulting in a maximum total score of 7 points.	[22]
SARC-F	The SARC-F questionnaire consists of five questions assessing muscle strength, physical performance, and functional ability, each with three possible responses: “No difficulty”, “Some difficulty”, or “Severe difficulty or inability to perform the task”. For each of these responses, a score of 0, 1, or 2, will be assigned, respectively. The total score ranges from 0 to 10, with higher scores indicating a greater risk of sarcopenia.	[23]

According to the NRS-2002 screening system, patients with scores>=3 will be identified at risk of malnutrition. Similarly, following the SARC-F screening system, patients with scores>=4 will be identified as at risk of sarcopenia.

Anthropometric parameters (weight, height, waist and hip circumferences) will be collected following standardized conditions. Weight and height will be recorded without shoes to the nearest 0.5 kg and 0.1 cm, using a calibrated dedicated scale and a stadiometer, respectively. BMI (kg/m^2) will be calculated using the formula weight (kg)/height² (m^2) and compared to the World Health Organization (WHO) categories. Waist and hip circumferences will be collected using a flexible tap, following the standard procedures: waist circumference (WC) will be measured at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest, while hip circumference (HC) at the maximal circumference of the buttocks [27]. Waist-to-hip ratio (WHR) will be also calculated. Higher values of WC (>94 cm in men and >80 cm in women) and WHR (≥0.90 cm in men and ≥0.85 cm in women) will be considered indicators of increased metabolic risk according to the WHO criteria.

According to the European Working Group on Sarcopenia in Older People 2 (EWGSOP2), identification of sarcopenia requires the evaluation of muscle mass and physical function [23]. Assessment of muscle function is also recommended by the Global Leadership Initiative on Malnutrition (GLIM) consensus, as a supportive measure to evaluate reduced muscle mass [22]. For this purpose, muscle strength will be assessed measuring Grip strength by the Jamar hydraulic dynamometer, calibrated to the second handle position. The participants will perform the test seated in a chair without armrests, with their feet resting on the floor, their shoulders in adduction, their elbows flexed at 90° and without any support [28]. If the results of the handgrip strength test will be <27 kg for men and <16 kg for women, patients will be identified at high risk of sarcopenia (probable sarcopenia).

Body composition analysis will be performed using BIA with the patient in the supine position on a flat non-conductive surface and the limbs abducted at 30-45°. For each patient, R and Xc values will be

recorded using professional software. The following BIA-derived parameters and indices will be derived: PhA, TBW, EBW, IBW, FM, FFM, BCM, SMM, ASMM, and corresponding indices corrected for height squared: fat mass index (FMI), fat-free mass index (FFMI), body cell mass index (BCMI), skeletal muscle mass index (SMI), and appendicular skeletal muscle mass index (ASMI). The PhA will be calculated using the following equation: PhA = ¼ arctan (Xc/R) * (180/3.14).

HRQoL will be assessed using the European Organization for the Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Core 30 (QLQ-C30), a validated questionnaire tailored for cancer patients.

Blood pressure will be measured by medical staff.

Nutritional status assessment will be further integrated by the evaluation of certain serum biomarkers routinely collected during pre-admission, in accordance with standard clinical practice. Since fasting blood samples are regularly obtained from all patients referred to the Department of Colorectal Surgery and to the Abdominal Robotic Surgery Unit at pre-admission, no additional laboratory tests will be required for the purpose of our study. The panel of routinely assessed laboratory tests includes serum levels of albumin, glucose, total cholesterol, HDL, LDL, triglycerides, C-reactive protein, and complete blood count (particularly regarding total lymphocyte count, TLC).

Follow-up assessments

To assess over time the risk of malnutrition and sarcopenia and change in HRQoL, two follow-up remote interviews will be performed: within 60 days post-surgery (T1) and after 12 months (T2), respectively.

During these interviews, the following tools and questionnaires will be administered: the NRS-2002, the SARC-F and the EORTC-QLQ C30.

Additionally, further information on patients' health status and medical notes (focusing in particular on planned or ongoing anticancer treatments) will be collected.

The adoption of digital technologies will be useful to address issues related to incomplete or inaccurate data collection. Remote follow-ups will be conducted using dedicated conferencing platforms. For patients who demonstrated limited familiarity with the use of digital platforms, a caregiver will be identified at the baseline visit to provide support and assistance during the remote follow-ups. Table 3 reports assessment of the prospective study.

At 60 days from surgical intervention, data regarding surgery, histopathological tumor characteristics and any occurrence of postoperative complications, especially AF, will be prospectively collected. In particular, the following complications will be considered: pneumonia, intestinal obstruction/ileus, surgical site infection, postoperative bleeding and urinary tract infection.

Table 3. Assessment of prospective study

Assessment	Tools	Visits			
		T0[a]	Pre-admission	T1[b,c]	T2[c,d]
Collection of general, clinical and lifestyle-related data	Case Report Form (CRF)	x			
Malnutrition risk	Nutritional Risk Screening (NRS-2002)	x		x	x
Sarcopenia risk	Strength, Assistance with walking, Rising from a chair, Climbing stairs, and Falls (SARC-F)	x		x	x
Anthropometric measurements	Calibrated scales, stadiometer, tape measures	x			
Blood pressure measurement	Sphygmomanometer	x			
Handgrip strength test	Jamar hydraulic dynamometer	x			
Body composition analysis	Bioelectrical Impedance Analysis (BIA)	x			
Total cholesterol, HDL, LDL, triglycerides, glucose, albumin, C reactive protein (PCR) and complete blood count[e]	Blood samples collection		x		
Surgical data collection	CRF			x	x
Anticancer treatments	CRF			x	x
Health-Related Quality of Life (HRQoL)	European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30)	x		x	x

[a]Baseline visit (T0) will be performed in person; [b]Within 60 days from surgery; [c]T1 and T2 assessments will be performed through follow-ups remote interviews. [d]after 12 months. [e]From complete blood count, data on total lymphocyte count (TLC) will be collected.

Data collection for the retrospective group

Available data will be collected and analyzed from medical records of patients referred to the Colorectal Surgical Oncology Department from 2019 to 2024. Patients will be contacted to obtain authorization for the processing of their personal data. At least three attempts will be made to reach each patient before confirming that they are unreachable. In such cases, Article 110 of the Code concerning the processing

of personal data for medical and epidemiological research purposes will be apply. This provision also covers deceased patients or those who cannot be contacted, for whom a Data Protection Impact Assessment will be necessary.

For each participant, clinical (age at diagnosis, prior anticancer therapy, presence of intermediate risk factors and comorbidities) and socio-demographic information (age, marital status, education level, employment status), as well as lifestyle-related factors (smoking status) will be collected, where available. Moreover, the following data on preoperative patients' nutritional status and malnutrition risk will be collected: the NRS-2002 score, anthropometric measurements (including body weight, height, BMI), serum levels of albumin, glucose, total cholesterol, HDL, LDL, triglycerides, C-reactive protein, and complete blood count (from which TLC will be recorded).

Finally, clinical data regarding surgical intervention, tumor characteristics and 60-days postoperative complications (particularly concerning the occurrence of AF) will be collected and analyzed. To standardize data collection in the whole observational cohort, the same surgical complications previously reported for the prospective group will be evaluated.

Endpoints of the prospective study

The primary objective is to investigate the prognostic value of malnutrition risk and BIA-derived body composition parameters on the occurrence of AF.

The secondary objective is to evaluate the association between malnutrition risk and BIA-derived body composition parameters on the occurrence of 60-days postoperative complications and HRQoL.

In particular, the following parameters and indices related to malnutrition risk and patients' nutritional status (both individually and in combination) will be evaluated: the NRS-2002 and SARC-F scores, handgrip strength test, biochemical biomarkers levels (serum albumin, glucose, total cholesterol, HDL, LDL, triglycerides, C-reactive protein, and TLC), anthropometric measurements (focusing in particular on BMI, WC and WHR) and BIA-derived parameters.

The definition of post-surgical complication includes any deviation from the normal postoperative course occurring within 60 days from surgery. In particular, the following complications will be considered: pneumonia, intestinal obstruction/ileus, surgical site infection, postoperative bleeding and urinary tract infection. Complications will be graded according to the Clavien-Dindo Classification [29].

HRQoL is described by the EORTC as covering the subjective perceptions of the positive and negative aspects of cancer patients' symptoms, including physical, emotional, social, and cognitive functions and, importantly, disease symptoms and side effects of treatment [30, 31]. It will be assessed using the EORTC QlQ-C30 (version n. 3.0).

Within 60 days from surgical intervention (T1) and after 12 months (T2), changes over time in the risk of malnutrition, sarcopenia and HRQoL will be evaluated. For this purpose, the NRS-2002, SARC-F and

EORTC-QLQ C30 questionnaires will be administered through follow-up remote interviews.

Endpoints of the retrospective study

The primary objective is to evaluate the prognostic value of malnutrition risk on the prevalence of AF.

As secondary endpoints, the association between malnutrition risk, OS and other postoperative complications occurring within 60 days from surgery will be evaluated.

In particular, the following parameters and indices related to malnutrition risk and patients' nutritional status will be analyzed (both individually and in combination): the NRS-2002 score, anthropometric measurements (BMI) and biochemical biomarkers levels (serum albumin, glucose, total cholesterol, HDL, LDL, triglycerides, C-reactive protein, and TLC).

The OS is the time from surgical intervention and patient's death. Patients lost to follow-up or still alive at the time of evaluation will be censored. Table 4 summarizes the study endpoints.

Table 4. Study endpoints

Study endpoints	Retrospective group	Prospective group
Anastomotic fistula	x	x
Other 60-day postoperative complications[a]	x	x
Health-Related Quality of Life	-	x
Overall survival	x	

[a]Pneumonia, intestinal obstruction/ileus, surgical site infection, postoperative bleeding and urinary tract infection.

Sample size calculation

The sample size calculation for this study is based on the prospective investigation of Kwang et al [32]. In this study, malnutrition risk in patients diagnosed with CRC was 28.1%. In this group of patients, the occurrence of AF assessed within 60 days from surgery was 9% and 3% in patients at low malnutrition risk. However, based on our clinician's expertise, this prevalence is higher than that reported in this study, approximately double, reaching an estimated value of 18%. Using a two-tailed test for the difference between proportions, with a Type I error rate sets at 5% and a power of 95%, and adjusting the sample size for an allocation factor of 4 (the ratio of patients at high vs low risk of malnutrition is 1:4) and a patient dropout rate of 10%, a sample size of 268 patients is estimated. Regarding the retrospective group, number of participants will be identified from a database of patients with a first diagnosis of CRC who underwent surgery at the Department of Colorectal Surgical Oncology from 2019 to 2024.

Statistical plan

In order to describe patients enrolled in the study, descriptive statistics (mean (M), standard deviation (SD), median (Me), and interquartile range (IQR) for numerical variables, or absolute (N) and relative (%) frequencies for categorical variables) will be reported.

The main univariate analysis will focus on describing potential differences between patients experiencing an event of AF in relation to malnutrition risk and other confounding factors. This section will include tests for differences between means using Pearson's correlation and T-tests/Mann-Whitney tests for numerical variables, or Chi-square/Fisher tests for categorical variables. Additionally, the risk of malnutrition will be assessed concerning the clinical-pathological characteristics of the patients.

The multivariate analysis will involve the implementation of multivariate logistic models aimed at estimating the relationships between the risk of AF and malnutrition risk, adjusted for possible confounders, with particular attention to the possible differences induced by the application of the Enhanced Recover after Surgery (ERAS) nutritional protocol, as outlined in clinical practice. Furthermore, the prevalence of the primary outcome at 60 days will be evaluated using Kaplan-Meier curves, with the log-rank test employed to visualize and estimate the crude difference in trends between the two sub-samples. If necessary, Cox proportional hazard models will be adopted to estimate the time to event in the two sub-samples, adjusted for potential confounders. Tests and estimates will be calculated at a 95% confidence level. To correct the possible confounding effect caused by surgical team variations, a variable that assigns a code for each operator performing the surgical procedure will be created.

3. Ethical considerations

Ethical approval has been obtained from the Ethics Committee of the Istituto Nazionale Tumori IRCCS “Fondazione G. Pascale”, Naples (Prot. n.70/24 OSS on November 27, 2024).

The study will be conducted in accordance with the ICH GCP guidelines, the Declaration of Helsinki, the Good Pharmacovigilance Practice and all current and relevant legislation, and approved by the Ethics Committee of Istituto Nazionale Tumori IRCCS “Fondazione G. Pascale”, Naples (Prot. n.70/24 OSS on November 27, 2024).

4. Discussion

The FourColon-Factors study aims to investigate the prognostic value of malnutrition risk and BIA-derived body composition parameters on postoperative outcomes of patients with a primary diagnosis of CRC eligible for curative treatment with surgery. We expect that patients at nutritional risk, with impaired body composition, poor muscle mass and physical function had an increased risk of postoperative complications, especially AF.

In literature, the association between nutritional status and clinical outcomes of patients with CRC has been investigated in several studies. In the prospective study of Meissner et al., about 65.4% of patients with CRC were at nutritional risk (according to NRS-2002>=3) which was associated with an increased risk of complications and morbidity [33]. Similar results were found in the prospective, multicenter study of Duran Poveda et al. that involved a large sample of patients with a primary diagnosis of gastrointestinal cancer undergoing elective major abdominal surgery. In this analysis, the prevalence of nutritional risk at time of hospital admission (according to Malnutrition Universal Screening Tool score>=1) was 39%. Complications were more frequently observed in patients at risk of malnutrition both at hospital admission and discharge. Moreover, about 20% of patients not at nutritional risk on admission had moderate/severe risk at the discharge. Taken together, these results highlight an urgent need for improving nutritional risk screening before and after surgery in patients with gastrointestinal cancer, as well as nutritional therapy during hospitalization [34]. In the retrospective analysis of Hu et al. [35], the prevalence of preoperative malnutrition (defined by hypoalbuminemia, serum albumin levels<3.5 g/dl) was higher in patients with CRC compared to other cancer sites and was significantly associated with an increased risk of 30-day mortality, longer total hospital stays and postoperative complications, including pneumonia, re-intubation, transfusion, septic shock and return to operating room. Evidences regarding the role of body composition on postoperative outcomes of patients with CRC are sparse and conflicting. Almasoudi et al. found that male patients with high subcutaneous adiposity had an increased risk of surgical site and wound infections [36]. Weigl et al. did not observe statistically significant differences between patients with normal and impaired body composition parameters (including a lower SMM area and higher total fat area) concerning complication rate or anastomotic leakage. However, high visceral and subcutaneous fat areas were associated with longer length of hospital stay and duration of surgery, respectively [37]. Conversely, in the meta-analysis of van Helsdingen et al., higher visceral fat area was independently associated with a two-fold increased risk of overall complications and anastomotic leakage [38]. Importantly, both these studies used CT, one of the most accurate methods to study body composition [39].

Zojek et al. did not confirm the prognostic role of body composition on postoperative complications of patients with CRC. Of the numerous parameters determined in the study (including nutritional risk screening questionnaires, anthropometric measurements, handgrip strength test, laboratory biomarkers and BIA-derived parameters) only higher serum albumin levels and Onodera's (Preoperative) Prognostic Nutritional Index were significantly associated with the risk of postoperative complications. However, the authors observed that a significant number of patients undergoing surgery for CRC were overweight or obese and more than 20% of them had also sarcopenia. Consequentially, the results of the study highlights the importance of body composition analysis as integral part of patients' nutritional assessment, as it enables to discriminate FM and muscle mass, overcoming potential limitations associated to the simple use of BMI [40]. On the contrary, in the prospective observational study of Gulin et al., a lower preoperative PhA was associated with an increased risk of post-surgical complications in patients with gastrointestinal cancer. PhA represents an indicator of cell membrane integrity, cellular health and better cellular functions. Consequentially, lower value of PhA is indicative of higher risk of

malnutrition and sarcopenia, since it suggests a state of cellular stress, attributable to a decreased overall cell number, with consequent impairment of cellular membrane integrity and function [41]. Accordingly, in our study, we will evaluate the prognostic role of PhA, as well as other BIA parameters, on patients' postoperative complications, thereby improving evidence in the field.

As secondary outcomes, we will investigate the association between malnutrition risk and BIA-derived body composition parameters on HRQoL. Specifically, HRQoL will be evaluated in the prospective study at three points: baseline, T1 and T2. We hypothesized that patients at nutritional risk, with impaired body composition, lower muscle mass and physical function had poorer HRQoL. In this regard, in a retrospective analysis, Gupta et al. indicate that well-nourished patients had higher value of global, physical, and role function scales and lower values in fatigue, pain, insomnia, and appetite loss scales, suggesting diminished symptoms. At the same time, higher value of serum albumin level was independently associated with improved physical and role function scales [42]. Regarding body composition, the association between BIA-derived parameters and HRQoL in cancer patients was evaluated in the cross-sectional analysis of Porciello et al. [40]. In this study, cancer patients with higher muscle mass (ASMI, SMI, BCMI and FFMI) had better HRQoL, while patients with lower muscle profile (characterized mainly by FMI and SMI) exhibited the opposite trend [43].

5. Conclusion

Both malnutrition and over nutrition represent two modifiable risk factors for the occurrence of AF, one of the most severe postoperative complications in patients with CRC. However, the prognostic role of preoperative malnutrition risk and body composition assessed by BIA on surgical complications is not yet clearly understood, as well as its association with HRQoL. Furthermore, more scientific evidence is needed to evaluate changes over time in patients' nutritional risk and HRQoL. For this purpose, the FourColon-Factors will provide evidence through a prospective cohort study, a retrospective data collection and a comprehensive preoperative assessment of patients' nutritional status.

The analysis of these nutritional parameters, both individually and in combination, may offer the opportunity to identify nutrition-related prognostic markers that could be integrated into clinical practice to facilitate clinical management and nutritional treatment strategies. Body composition analysis performed through BIA will offer evidence and opportunity to clarify its prognostic value on patients' postoperative outcomes and HRQoL. The follow-up visits at T1 and T2 will be useful to investigate change over time in the risk of malnutrition and sarcopenia and HRQoL.

Finally, the results of this study will be helpful to identify patients' categories that may benefit from tailored multimodal intervention aiming at preventing malnutrition risk, improving body composition and HRQoL.

Declarations

Competing interest

LSAA is a founding member of the International Carbohydrate Quality Consortium (ICQC, www.carbquality.com), has received honoraria from the Nutrition Foundation of Italy (NFI, Milan), research grants for lifestyle studies from Lega Italiana per la Lotta contro i Tumori (LILT, Rome) a non-profit organization for the fight against cancer, and in-kind study support from Abiogen Pharma (Pisa, Italy), Barilla Spa (Parma, Italy), Roberto Alimentare (Treviso, Italy), Panificio Giacomo Luongo (Napoli, Italy), Consorzio Mandorle di Avola (Siracusa, Italy), SunRice (Australia) and Almond Board of California (USA). The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results. The other authors declare no competing interest.

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Ethical approval

This study will be conducted in accordance with the ICH GCP guidelines, the Declaration of Helsinki, the Good Pharmacovigilance Practice and all current and relevant legislation. Ethical approval has been obtained from the Ethics Committee of the Istituto Nazionale Tumori IRCCS “Fondazione G. Pascale”, Naples (Prot. n.70/24 OSS on November 27, 2024).

Consent to participate

Written informed consent will be obtained from all participants included in the prospective study.

Consent to publish

Not applicable

Data availability statement

No datasets were generated or analyzed during the current study. This article presents a study protocol.

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Author Contributions

Conceptualization, A.L., M.D., G.P., L.S.A.A., A.M., E.C., U.P., P.D., A.C.; methodology, A.L., M.G., M.P., F.N., N.R., G.D., L.P., E.R., R.P., A.C.; software, P.R., F.P.M.D.C., S.C., A.C.; validation, A.L., M.D., G.P. N.R., S.V., E.P., and A.C.; formal analysis, A.C.; investigation, A.L., M.D. G.P., M.P., F.N., N.R., G.D., L.S.A.A., A.M., L.P., U.P., P.D.; resources, M.D., A.M., P.R., F.P.M.D.C., E.C., U.P., P.D., A.C.; writing—original draft preparation, A.L. and A.C.; writing—review and editing, all the authors; supervision, G.P., L.S.A.A., E.C., U.P., P.D., A.C.; project

administration, M.G., F.N., E.R., R.P.; funding acquisition, A.C. All authors read and approved the final manuscript and have agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Figures

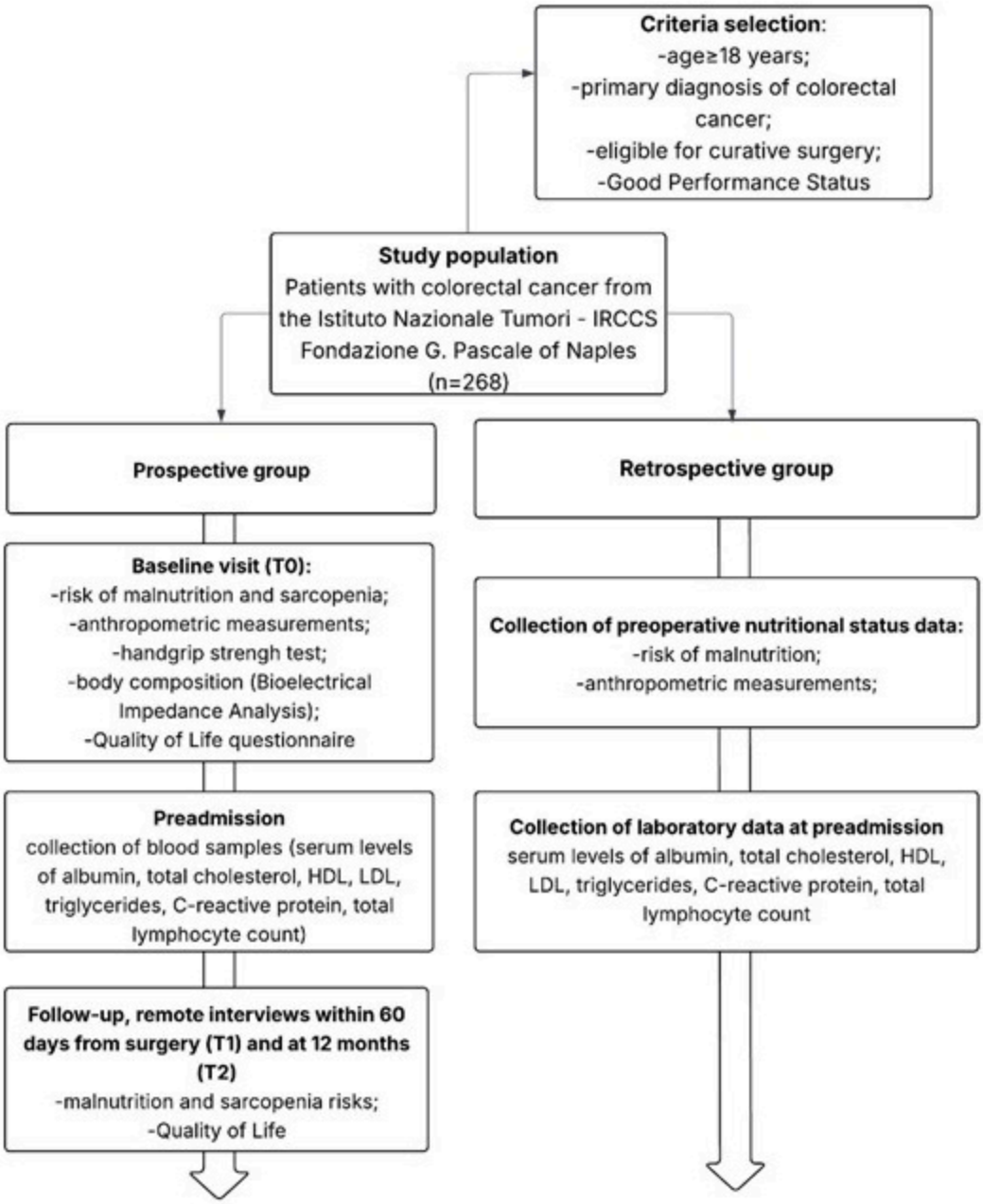


Figure 1

Study workflow