

Prehabilitation with Whey Protein Supplementation on Perioperative Functional Exercise Capacity in Patients Undergoing Colorectal Resection for Cancer: A Pilot Double-Blinded Randomized Placebo-Controlled Trial



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ABSTRACT

Background A previous comprehensive prehabilitation program, providing nutrition counseling with whey protein supplementation, exercise, and psychological care, initiated 4 weeks before colorectal surgery for cancer, improved functional capacity before surgery and accelerated functional recovery. Those receiving standard of care deteriorated. The specific role of nutritional prehabilitation alone on functional recovery is unknown.

Objective This study was undertaken to estimate the impact of nutrition counseling with whey protein on preoperative functional walking capacity and recovery in patients undergoing colorectal resection for cancer.

Design We conducted a double-blinded randomized controlled trial at a single university-affiliated tertiary center located in Montreal, Quebec, Canada. Colon cancer patients (n=48) awaiting elective surgery for nonmetastatic disease were randomized to receive either individualized nutrition counseling with whey protein supplementation to meet protein needs or individualized nutrition counseling with a nonnutritive placebo. Counseling and supplementation began 4 weeks before surgery and continued for 4 weeks after surgery.

Main Outcome Measure The primary outcome was change in functional walking capacity as measured with the 6-minute walk test. The distance was recorded at baseline, the day of surgery, and 4 weeks after surgery. A change of 20 m was considered clinically meaningful.

Results The whey group experienced a mean improvement in functional walking capacity before surgery of +20.8 m, with a standard deviation of 42.6 m, and the placebo group improved by +1.2 (65.5) m ($P=0.27$). Four weeks after surgery, recovery rates were similar between groups ($P=0.81$).

Conclusion Clinically meaningful improvements in functional walking capacity were achieved before surgery with whey protein supplementation. These pilot results are encouraging and justify larger-scale trials to define the specific role of nutrition prehabilitation on functional recovery after surgery.

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COLORECTAL CANCER IS THE THIRD MOST commonly diagnosed cancer in North America, and it is primarily treated with surgery.¹ Traditionally, surgical “recovery” has been defined by using outcome measures such as length of hospital stay and rates of morbidity; however, these measures are confounded by socioeconomic, cultural, and institutional factors.² From a patient’s perspective, return to baseline function can mean

restoration of activities of daily living, resolution of clinical symptoms, return to work, and improvement in quality of life. A shift from these traditional measures to a more patient-centered outcome measure of recovery, such as function, is required.²

The process of enhancing an individual’s functional capacity to optimize physiologic reserves before an operation to withstand the stress of surgery has been coined

prehabilitation.^{3,4} A pilot prehabilitation program providing physical exercise, psychological, and nutrition care with whey protein supplementation, initiated 4 weeks before colorectal surgery, produced a mean improvement in walking distance of 40 m, as measured by a 6-minute walk test (6MWT), before surgery and accelerated functional recovery after surgery.⁵ Eight weeks postoperatively, 81% of the prehabilitated patients had recovered functional walking capacity, compared with 40% of the control group receiving standard care, independent of traditional outcome measures.⁵

To uncover and target the specific roles of diet and exercise in improving the functional walking capacity of the surgical patient, a similar study was conducted with an exercise-only intervention.³ One-third of patients deteriorated preoperatively despite participating in an intense exercise regimen, suggesting that exercise alone is insufficient to prepare patients for surgical insult.³ A limitation of this study was that a nutrition assessment was not conducted. Indeed, exercise is generally accepted to be the main anabolic stimulus, but optimal gains in protein accretion cannot be achieved without adequate substrates.⁶ Whey protein substrates have great potential to be used effectively to support postsurgery anabolism. Whey proteins are of high quality,⁷ have proved to be effective in modulating postexercise muscle protein synthesis, and are a convenient way to supplement protein needs.^{8,9} Whey proteins also have immunomodulating properties,¹⁰ including biosynthesis of antioxidant glutathione,¹¹ which could attenuate the catabolic effects of surgery and spare protein.

The specific role that nutrition plays in functional capacity before surgery is unclear. Previous studies and systematic reviews evaluating the effect of preoperative nutritional status or nutrition interventions on surgical recovery are limited by the use of traditional measurements of recovery only (eg, length of stay).¹²⁻¹⁴ Furthermore, validated functional measures of colorectal surgical recovery have rarely been used in nutrition-focused studies within hospitals currently using enhanced recovery protocols.

The objective of the current study was to provide insight into the role of nutritional prehabilitation on function, a patient-relevant outcome measure of recovery, and more specifically, the role of whey protein supplementation on functional exercise capacity and recovery. A pilot randomized, double-blinded, placebo-controlled trial was conducted in patients undergoing elective resection of colorectal cancer. The study estimated the extent to which a prehabilitation program involving nutrition counseling and whey protein supplementation impacted preoperative functional walking capacity, compared with nutrition counseling alone. The impact was measured by the 6-minute walking test (6MWT), before and after surgery.

MATERIALS AND METHODS

Patients

The study was approved by the McGill University Health Centre Research Ethics Board, Montreal, Quebec, Canada, and the protocol was registered at <http://clinicaltrials.gov> (NCT 01727570). Consecutive adult patients scheduled for elective resection of nonmetastatic colorectal cancer were approached at their first appointment with their surgeon at a

single university-affiliated tertiary center located in Montreal, and written informed consent was obtained in eligible patients. Patients with poor English or French comprehension, milk allergy, or premorbid conditions that contraindicated exercise were deemed ineligible.⁵ All patients received standardized perioperative care based on the enhanced recovery after surgery guidelines implemented in the institution in 2010.¹⁵

Study Design

This study was initially designed as a randomized controlled trial (RCT) with 60 patients; however, reorganizational issues required a change in the original protocol as registered at <http://clinicaltrials.gov> (NCT 01727570). Due to the lack of personnel to conduct the original postoperative follow-up at 4 and 8 weeks after surgery, patients only received one postoperative follow-up at 4 weeks. Recruitment ended when 48 patients were enrolled. Because of the smaller sample size, fewer follow-up interviews, and decreased power, the original trial became a pilot study to collect supportive data for a future trial with sufficient power, sample size, and staff support.

At the time of consent, patients were instructed by a registered dietitian to complete a 3-day estimated food record of 2 weekdays and 1 weekend day.¹⁶ Participants were required to measure and record the quantity of all foods and beverages consumed, using standard household measures. Approximately 4 weeks before each patient's scheduled operation, medical examinations and nutritional risk screenings were conducted. Baseline questionnaires, biochemical, functional, and anthropometric measurements were also obtained at this time. All measurements were collected again preoperatively (day of surgery) and 4 weeks after the operation by a research assistant who was blinded to group assignment. Patients were randomly assigned on a 1:1 ratio by computer-generated random numbers to receive either individualized nutrition counseling with whey protein supplementation or individualized nutrition counseling with placebo supplementation. No group stratifications were performed. Group allocation was concealed by using sequentially numbered sealed envelopes. The scheduling of surgery was not affected by study group.

Compliance was measured by using a diary to document the quantity of the nutritional supplement taken each day. Patients were contacted weekly by the research assistant and queried with a standardized set of open-ended questions designed to identify problems with compliance to the supplement regimen.

Nutrition Intervention

Both study groups participated in identical nutrition assessment and counseling sessions (90 minutes total) provided by a registered dietitian at their baseline appointment. During this session, each patient was provided with a personalized nutrition care plan based on their dietary needs as determined through analysis of food records and estimated requirements.

Dietary protein and energy intake were estimated from the food records provided by using food exchange lists and a food composition database.¹⁷ Dietary intake was then evaluated based on individually calculated energy and protein

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