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Orignial Study

THE EFFECT OF ORAL NUTRITIONAL SUPPLEMENTS ON NUTRITIONAL RISK IN POST-DISCHARGE PATIENTS AFTER COLORECTAL CANCER SURGERY: A RANDOMIZED CLINICAL TRIAL.

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ABSTRACT

Background
Colorectal cancer surgery often leaves patients at nutritional risk, impacting their recovery and quality of life. Oral nutritional supplements (ONS) may offer benefits in improving nutritional status and overall health outcomes in these patients. The study assessed the effects of ONS on individuals who were at nutritional risk after being operated on for colorectal cancer.

Methods
A total of 160 individuals with a Nutritional Risk Screening 2002 (NRS 2002) score of three or above were randomized into the ONS group (n = 80) and control group (n = 80) in a randomized clinical trial. For three months, the ONS group got both nutritional guidance and Nutren® Optimum, while the control group only received nutritional guidance. Quality of life (QoL), chemotherapeutic tolerance, nutritional outcomes, and readmission rates were evaluated.

Results
Out of the 160 enrolled patients, 148 completed the study. The ONS group showed significant improvements in weight (63.5 ± 10.2 kg vs. 61.0 ± 9.8 kg, p=0.048), BMI (23.4 ± 3.2 kg/m² vs. 22.0 ± 3.4 kg/m², p=0.018), serum albumin (3.8 ± 0.4 g/dL vs. 3.5 ± 0.5 g/dL, p<0.001), and hemoglobin levels (12.5 ± 1.1 g/dL vs. 11.8 ± 1.3 g/dL, p=0.002) compared to the control group. The ONS group also had lower readmission rates (10.8% vs. 24.3%, p=0.034) and higher chemotherapy tolerance (83.8% vs. 70.3%, p=0.047). QoL scores were substantially better in the ONS group across multiple domains.

Conclusion
After colon cancer surgery, the administration of ONS dramatically improves nutritional status, lowers readmission rates, increases chemotherapy tolerance, and promotes post-discharge patient quality of life.

Recommendations
For individuals with colorectal cancer who are at nutritional risk, including ONS in the post-discharge care plan is advised to promote healing and better health results.

Keywords: *Oral Nutritional Supplements, Colorectal Cancer Surgery, Nutritional risk, Quality of Life, Chemotherapy Tolerance*
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INTRODUCTION

One of the most prevalent cancers globally, colorectal cancer (CRC) has high rates of morbidity and death. Advances in surgical techniques and adjuvant therapies have improved survival rates, but the postoperative period remains critical for patient recovery and long-term outcomes. Nutritional status plays a vital role in postoperative recovery, particularly in colorectal cancer patients who often face malnutrition due to the disease and its treatments [1].

Malnutrition is prevalent among colorectal cancer patients, exacerbated by factors such as reduced oral intake, increased metabolic demands, and treatment side effects. Malnourished individuals are at higher risk for complications, prolonged hospital stays, and higher mortality rates [2]. Early nutritional intervention is crucial to mitigate these risks and support recovery. Oral

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nutritional supplements (ONS) have been widely recommended to address malnutrition in various clinical settings.

Recent studies have highlighted the advantages of ONS in improving nutritional status, enhancing immune function, and reducing postoperative complications. For instance, a study demonstrated that ONS effectively improved weight, body mass index (BMI), and muscle mass in malnourished cancer patients [3]. Another study found that ONS decreased the risk of hospital readmission and enhanced the quality of life (QoL) in older adults [4].

Despite these positive findings, there is limited research specifically addressing the effect of ONS on after-discharge CRC individuals at nutritional risk. Most existing studies focus on hospitalized patients or those undergoing active treatment. However, the post-discharge period is equally critical, as patients continue to recover and are at risk of nutritional decline once they return home. Addressing nutritional needs during this phase could potentially reduce readmissions and improve overall outcomes.

To enable prompt and focused interventions, individuals at nutritional risk are often identified using the Nutritional Risk Screening 2002 (NRS 2002) program [5]. Individuals who score three or higher on the NRS 2002 are deemed to be at high risk and may benefit from nutritional assistance.

The research assessed how oral nutritional supplements affect individuals who are at nutritional risk after being discharged from the hospital after CRC surgery.

METHODOLOGY

Study Design

A randomized clinical trial.

Study Setting

The study took place at Saheed Laxman Nayak (SLN) Medical College and Hospital, Koraput, Bhima Bhoi Medical College & Hospital, Balangir, and Nehru Satabdi Central Hospital, Talcher, Odisha, India, spanning 10 months (September 2023 to June 2024).

Participants

A total of 160 post-discharge individuals following CRC surgery were enrolled in this study.

Inclusion Criteria

- Patients with an NRS 2002 score of 3 or higher.
- Individuals aged 18 years or older.

Exclusion Criteria

- Patients already receiving other nutritional interventions.
- Patients unable to oral intake.
- Pregnant patients.

Sample size

A total of 160 patients were needed to detect an average variance in SMI between the ONS and control groups that were 2.17 cm^2/m^2 and 5.56 cm^2/m^2, respectively, for a two-sided type I error of 5% and a statistical power of 80%. The final sample size for each group was 116 patients, accounting for a 10% dropout rate.

Bias

Random assignment and blinding were used to minimize selection and performance bias. The randomization was done using a computer-generated list. Blinding was employed to minimize bias. Patients, healthcare providers, and outcome assessors were blinded to group assignments. Randomization was done using a computer-generated list, and Nutren® Optimum was identically packaged to maintain blinding. Group codes were held by an independent third party to ensure objectivity in outcome assessment.

Variables

The variables included weight, weight loss within three months after discharge, BMI, SMI, serum levels of albumin and hemoglobin, sarcopenia prevalence, 90-day re-admission rate, chemotherapy tolerance, and quality of life.

Data Collection

Baseline information, such as sex, age, blood levels of hemoglobin and albumin, weight, BMI, skeletal muscle index (SMI), comorbidities, tumor site, tumor stage, and NRS 2002 scores, were part of the baseline data at the time of hospital release.

Follow-up data collected three months after discharge included chemotherapy tolerance, 90-day readmission rate, nutritional outcomes, and QoL as measured by the EORTC QLQ-C30 questionnaire.

Treatment/Intervention

After submitting written informed consent, eligible subjects were randomized 1:1 into the ONS group (category 1) or the control group (category 2).

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- Category 1: For three months following their release, patients got nutritional guidance and Nutren® Optimum. A 500 mL dose was prescribed daily, with each 100 mL providing 100 kcal of energy, 11.7 gm of carbohydrates, 3.9 gm of fat, 4.1 gm of protein, 1.2 gm of fiber, and vitamins and minerals. Patients recorded in a notepad how much ONS they took each day, and during outpatient clinic visits, this information was confirmed. In the event of side effects, ONS treatment was modified.
- Category 2: Patients were given identical dietary recommendations as the ONS group. If, within a month of discharge, there was still a weight reduction of at least 5%, ONS treatment was started.

Every patient received telephone follow-ups twice a week to oversee and direct their care.

Statistical Analysis

STATA version 23 was employed for data analysis. The data were presented as mean ± SD. A P value of less than 0.05 was considered statistically significant.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULT

A total of 210 people had their eligibility checked. Eighty people were randomly assigned to Category 1 and eighty individuals to Category 2 out of the 160 patients who met the inclusion criteria. After 12 individuals (6 from each group) withdrew during the follow-up period, the final sample size consisted of 148 patients (74 in each category).

Table 1a: Demographic Characteristics

Characteristic	Category 1 (n = 74)	Category 2 (n = 74)	p-value
Age (years)	60.5 ± 8.4	61.2 ± 7.9	0.578
Gender, n (%)			
Male	38 (51.4%)	36 (48.6%)	0.715
Female	36 (48.6%)	38 (51.4%)	0.715
BMI (kg/m²)	22.8 ± 3.5	23.1 ± 3.7	0.685

Table 1b: Baseline Characteristics

Characteristic	Category 1 (n = 74)	Category 2 (n = 74)	p-value
Serum Albumin (g/dL)	3.4 ± 0.4	3.5 ± 0.5	0.234
Hemoglobin (g/dL)	11.8 ± 1.2	11.9 ± 1.3	0.642
NRS 2002 Score	3.5 ± 0.5	3.6 ± 0.6	0.483
Sarcopenia Prevalence, n (%)	22 (29.7%)	24 (32.4%)	0.716
Tumor Stage, n (%)			
Stage I	12 (16.2%)	14 (18.9%)	0.653
Stage II	36 (48.6%)	34 (45.9%)	0.742
Stage III	26 (35.1%)	26 (35.1%)	1.000

Three months after discharge, category 1 showed considerable improvements in nutritional outcomes compared to category 2.

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Table 2: Nutritional Outcomes After 3 Months

Outcome	Category 1	Category 2	p-value
Weight (kg)	63.5 ± 10.2	61.0 ± 9.8	0.048*
Weight Loss (%)	2.5 ± 1.1	4.2 ± 1.5	<0.001**
BMI (kg/m²)	23.4 ± 3.2	22.0 ± 3.4	0.018*
SMI (cm²/m²)	39.5 ± 4.3	37.2 ± 4.5	0.003**
Serum Albumin (g/dL)	3.8 ± 0.4	3.5 ± 0.5	<0.001**
Hemoglobin (g/dL)	12.5 ± 1.1	11.8 ± 1.3	0.002**
Sarcopenia Prevalence, n (%)	16 (21.6%)	28 (37.8%)	0.028*

*Statistically significant at P < 0.05, **Statistically significant at P < 0.01

Category 1 also demonstrated better outcomes in terms of readmission rates, chemotherapy tolerance, and QoL.

Table 3: Secondary Outcomes After 3 Months

Outcome	Category 1	Category 2	p-value
90-day Readmission Rate, n (%)	8 (10.8%)	18 (24.3%)	0.034*
Chemotherapy Tolerance, n (%)	62 (83.8%)	52 (70.3%)	0.047*
QoL (EORTC QLQ-C30)			
Global Health Status	75.4 ± 10.2	68.9 ± 12.3	<0.001**
Physical Functioning	78.3 ± 11.0	72.0 ± 11.8	0.003**
Role Functioning	74.6 ± 12.5	68.2 ± 13.4	0.004**
Emotional Functioning	80.2 ± 11.5	75.3 ± 12.6	0.012*
Cognitive Functioning	82.1 ± 10.4	78.0 ± 11.5	0.028*
Social Functioning	79.8 ± 11.3	74.5 ± 12.2	0.007**
Symptom Scales			
Fatigue	22.1 ± 10.5	27.8 ± 11.2	0.002**
Pain	18.4 ± 9.8	24.2 ± 10.6	0.001**
Nausea and Vomiting	15.2 ± 8.7	21.3 ± 9.4	<0.001**

*Statistically significant at P < 0.05, **Statistically significant at P < 0.01

DISCUSSION

The study included 160 participants, with 148 completing the trial, divided equally into the 2 categories. The baseline features between the 2 categories were comparable, ensuring a fair comparison of outcomes.

In contrast to category 2, category 1 demonstrated notable improvements in a range of nutritional outcomes following a three-month intervention. The Category 1 BMI was higher, SMI was higher, and there was less weight loss. Furthermore, the serum albumin and hemoglobin levels were considerably higher. Additionally, there was a substantial decrease in the prevalence of sarcopenia. These results imply that ONS helps post-discharge colorectal cancer patients' nutritional status.

Secondary outcomes further supported the benefits of ONS. Category 1 had a lower 90-day rate of re-admission-, higher chemotherapy tolerance, and better QoL scores. Global health status, role functioning, cognitive functioning, emotional functioning, physical functioning, and social functioning were considerably enhanced in category 1, according to the QoL assessment. Additionally, symptom scales revealed lower scores for pain, fatigue, nausea, and vomiting in category 1, indicating fewer reported symptoms and better overall well-being.

Overall, the trial demonstrated that oral nutritional supplements significantly enhance nutritional outcomes, reduce hospital readmissions, improve chemotherapy tolerance, and elevate QoL in post-discharge individuals following CRC surgery. These results underscore the importance of incorporating ONS into after-discharge care plans to facilitate better recovery and health outcomes for colorectal cancer patients.

A study found that employing ONS rather than only dietary guidelines improved chemotherapy tolerance and reduced the incidence of SML and sarcopenia in post-discharge individuals at nutritional risk following colon cancer surgery. QoL and the 90-day readmission rate were unaffected [6]. In people with colon cancer who were at nutritional risk and receiving postoperative adjuvant chemotherapy, ONS raised body weight and BMI, according to research. However, there were no discernible increases in quality of life, laboratory testing, or other anthropometric parameters [7].

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Another study showed that in patients after gastric cancer surgery, post-discharge ONS with dietary advice substantially lowered weight loss and improved BMI and SMI. When comparing the ONS group to the control group, there were fewer chemotherapeutic changes and a lower incidence of sarcopenia [8]. According to a study, ONS increased weight and BMI in patients with gastrointestinal cancer after discharge but had no discernible effect on QoL [9]. A study found that patients after colon surgery had an average 2-day shorter hospital stay while receiving nutritional prehabilitation, which included ONS. Multimodal prehabilitation may lead to better functional outcomes, according to some data [10].

GENERALIZABILITY

Since this trial was conducted at different institutions in Odisha, India, with a diverse patient population reflecting broader clinical circumstances, its findings have excellent external validity and relevance. Clear and inclusive inclusion criteria targeted nutritionally at-risk post-colorectal cancer surgery, a frequent clinical setting. The adoption of well-known dietary supplements and standardized nutritional risk screening techniques improves generalisability. These findings suggest that oral nutritional supplements (ONS) in post-discharge care plans can improve nutritional outcomes, reduce readmission rates, and improve quality of life for colorectal cancer patients, making them applicable globally.

CONCLUSION

The findings suggest that nutritional supplements taken orally after colon cancer surgery have a substantial positive impact on post-discharge patients. Comparing Category 1 to Category 2, the ONS group showed superior quality of life, stronger chemotherapy tolerance, lower readmission rates, and better nutritional status. These results imply that including ONS in the post-discharge care plan can improve the overall health and recuperation of individuals with colorectal cancer.

LIMITATIONS

The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

RECOMMENDATION

For individuals with colorectal cancer who are at nutritional risk, including ONS in the post-discharge care plan is advised to promote healing and better health results.

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LIST OF ABBREVIATIONS

ONS - Oral Nutritional Supplements
CRC - Colorectal Cancer
QoL - Quality of Life
NRS 2002 - Nutritional Risk Screening 2002
BMI - Body Mass Index
SMI - Skeletal Muscle Index
EORTC QLQ-C30 - European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30
SD - Standard Deviation

SOURCE OF FUNDING

No funding was received.

CONFLICT OF INTEREST

The authors have no conflicting interests to declare.

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