Is there any Benefit of Short-Course Oral Nutrition Supplement on Surgical Outcomes in Mildly to Moderately Malnourished Patients Undergoing Colorectal Surgery Within an Enhanced Recovery after Surgery Protocol?

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Objective: *This study aimed to determine whether there is any clinical benefit of short-course oral nutrition supplement (ONS) on surgical outcomes in mildly to moderately malnourished patients undergoing colorectal surgery within an enhanced recovery after surgery (ERAS) protocol.*

Material and Method: *Patients with mild to moderate malnutrition (defined as those with subjective global assessment grade B) undergoing elective colorectal resection within an ERAS protocol from 2011 to 2015 were reviewed. Patients receiving perioperative ONS ≥600 calories per day (ONS group) were matched and compared with those with no supplement. Outcome measures included postoperative complication, gastrointestinal recovery and length of postoperative stay.*

Results: *There were 29 patients in each group. Patient's characteristics and operative details were comparable between the two groups. Median calories and protein intake from ONS were 800 kcal and 32 gram per day. Median time of ONS provided was 5 days. Patients receiving ONS had a non-significant shorter median time to resumption of solid diet (1 (IQR 1 to 3) vs. 2 (IQR 1 to 4) days; p = 0.27) and time to first defecation (2 (IQR 2 to 3) vs. 3 (IQR 2 to 4) days; p = 0.52). There was no significant difference in the rate of overall, minor and major postoperative complication between the two groups: 28% vs. 24% (p = 0.76), 21% vs. 7% (p = 0.25) and 7% vs. 17% (p = 0.42), respectively. Median length of postoperative stay was not different (5 (IQR 4 to 5) vs. 5 (IQR 4 to 7) days; p = 0.20).*

Conclusion: *Perioperative administration of ONS to non-severely malnourished patient fails to demonstrate any clinical benefits on surgical convalescence after colorectal surgery.*

Keywords: *Oral nutrition supplement, Enhanced recovery after surgery, Colon, Rectum, Surgery*

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The incidence of malnutrition in patients with colorectal diseases ranges between 4% and 57% due to the direct effect of poor intake, malabsorption, colonic obstruction and treatment intervention[1,2]. The prevalence of malnutrition is particularly high in elderly, those with advanced colorectal cancer and those in underdeveloped countries or developing countries[3,4]. Preoperative malnutrition increases the risk of postoperative complication, delayed gastrointestinal recovery and prolonged hospitalization[2,3]. Some studies have reported that malnourishment in colorectal cancer patients is associated with tumor recurrence and poor overall survival[5]. Perioperative assessment and proper nutrition support in such patients are therefore of great importance.

Cumulate evidence suggests that a 7 to 10 day period of preoperative and postoperative parenteral nutrition repletion in surgical patients with severe malnourishment, e.g. subjective global assessment (SGA) grade C, who cannot be adequately orally or enterally fed, will reduce the incidence of postoperative morbidity and mortality[6]. Conversely, nutrition intervention in well-nourished patients who can maintain adequate protein and calories by standard food intake has no clinical and functional benefit[6-9]. Meanwhile, perioperative nutrition support in patients

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with mild to moderate malnourishment remains an area of great interest especially in term of time and method of nutrition intervention as well as the choice of formula required e.g. standard whole protein formula and immune-modulating formula[7]. Regarding enteral nutrition, oral nutrition supplement (ONS) might be the most convenient way to improve protein and energy intake in patients undergoing colorectal surgery. Preoperative and postoperative intake of ONS in such patients was associated with a reduction in the degree of weight loss and the incidence of minor complications. It appeared to be cost-effective[10].

The European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines on enteral nutrition in surgical patients has recommended the administration of perioperative enteral nutrition-preferably with immunonutrition for 5 to 7 days before surgery and continue postoperatively for 5 to 7 days after surgery[7]. Also, the Enhanced Recovery After Surgery (ERAS) society has suggested perioperative ONS as a supplement to food intake in patients undergoing colorectal surgery[11,12]. However, most of health schemes in Thailand do not cover immune-modulating formulae and out-of-hospital ONS. Based on our daily practice and limitations of nutrition intervention in Thailand, the author hypothesized that, comparing with no nutrition support, a shorter period of ONS (only the period of hospitalization) would provide some clinical benefits in surgical patients with non-severe malnourishment. The objective of this study was therefore to determine whether there is any clinical benefit of short-course perioperative ONS on surgical outcomes in mildly to moderately malnourished patients undergoing colorectal surgery within an ERAS protocol.

Material and Method

After obtaining approval from the Siriraj Institutional Review Board, a prospectively collected database of patients undergoing elective colorectal resection under an ERAS protocol between January 2011 and October 2015 in the Division of General Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital, Bangkok, Thailand was reviewed. Only patients with mild to moderate malnutrition (defined as those with SGA grade B) were included[13,14]. Patient who receive perioperative oral nutrition supplement $\geq$600 calories per day (ONS group) were compared with those without ONS (non-ONS group). Patients with tube feeding or those receiving combined parenteral nutrition were excluded. Of note, there is good evidence to suggest that intake of ONS 600 kcal per day has positive influence on preservation of muscle mass[15], weight maintenance[16], handgrip strength[17], and quality of life[18]. If not contraindicated, a high-caloric protein-rich ONS (non-immune-modulating formulae) was provided in addition to the patients' usual food intake.

The eligible patients were matched for age, gender and type of surgical procedure. The ERAS protocol using in our institute has been previously described[3,19]. Basically, standard perioperative care included prophylaxis of postoperative nausea and vomiting, early feeding, preferential use of non-opioid analgesia and scheduled ambulation. The patients were discharged from the hospital when they had no fever, adequate pain control with oral analgesic, good ambulation and satisfactory recovery of gastrointestinal function. Notably, perioperative ONS was provided based on individual's healthcare coverage and a shared decision between surgeon and patient. All patients were operated on and taken care of by the author and his team.

All data were recorded including patient demographics (age, gender, actual weight, degree of unintentional weight loss, body mass index: BMI, American society of Anesthesiologists class: ASA, the ColoRectal Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity: CR-POSSUM)[20] and operative details (procedure type, operative time and blood loss). Primary outcomes were the incidence of postoperative complication (according to the Clavien-Dindo classification system)[21], gastrointestinal recovery (time to resumption of normal diet and time to first defecation) and length of postoperative hospital stay. All patients were scheduled for follow-up at 30 days postoperatively.

Sample size calculation for this study was based on the hypothesis that ONS would reduce postoperative complication. Twenty-nine patients per group were required to have an 80% chance of detecting, as significant at the 5% level, a decrease in minor complication from 68% in non-treatment group to 31% in perioperative ONS group[10]. Of note, minor complication was defined as the Clavien-Dindo complication grade I[21]. All data were prepared and compiled using Statistical Package for the Social Sciences program (SPSS®) version 18.0 for Windows (SPSS Inc., Chicago, IL). Values are expressed as median (interquartile range: IQR) or number (percentage). Continuous variables were compared using the t-test or Mann-Whitney U test. Categorical variables were

compared using the Pearson Chi-square test or Fisher's exact test. A *p*-value of less 0.05 was considered statistically significant.

Results

There were 29 patients in each group. There was no significant difference in patient's characteristics and operative details between the two groups except the ONS group had a lower BMI and a higher CR-POSSUM predicted mortality rate (Table 1). ONS provided was well tolerated with excellent patient adherence. Median calories and protein intake from prescribed ONS were 800 kcal (IQR 600-1,000) and 32 gram (IQR 24-40) per day. Median time of ONS provided was 5 days (IQR 4-5).

Patients receiving ONS had a non-significant shorter median time to resumption of solid diet (1 (IQR 1-3) vs. 2 (IQR 1-4) days; $p = 0.27$) and time to first defecation (2 (IQR 2-3) vs. 3 (IQR 2-4) days; $p = 0.52$). There was no significant difference in the rate of overall, minor and major postoperative complication between the two groups: 28% vs. 24% ($p = 0.76$), 21% vs. 7% ($p = 0.25$) and 7% vs. 17% ($p = 0.42$), respectively (Table 2). Median length of postoperative stay was also not different (5 (IQR 4-5) vs. 5 (IQR 4-7) days; $p = 0.20$). No 30-day readmission or death was observed in

Table 1. Patient characteristics and operative details

	Patients with ONS (n = 29)	Patients without ONS (n = 29)	*p*-value
Age (years)	73 (63-77)	68 (55-75)	0.11
Male	13 (45)	17 (59)	0.29
Weight (kg)	50 (43-60)	57 (51-66)	0.021
Body mass index	19.3 (17.9-22.9)	22.8 (21.1-25.5)	*0.006
Unintentional weight loss (kg)	3 (1-6)	2 (0-6)	*0.88
Percentage of unintentional weight loss	5.3 (0.8-12.7)	3.4 (0-8.9)	0.25
ASA class ≥3	13 (45)	8 (28)	0.17
CR-POSSUM predicted mortality rate	3.5 (1.8-6.5)	1.9 (1.1-3.0)	0.031
Hematocrit (%)	33 (29-35)	33 (30-35)	*0.29
Serum albumin (g/L)	3.2 (2.8-3.4)	3.2 (3.1-3.4)	0.73
Operative time (minutes)	180 (140-240)	180 (145-255)	0.79
Blood loss (mL)	150 (50-200)	200 (80-400)	0.93
Operation for malignancy	27 (93)	26 (90)	1.00
Rectal resection	15 (52)	13 (45)	0.60
Laparoscopic surgery	2 (7)	5 (17)	0.42

* *p*-value <0.05, values are expressed as median (interquartile range) or number (percentage).
ASA = American society of Anesthesiologists; CR-POSSUM = ColoRectal Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity; ONS = oral nutrition supplement

Table 2. Complication, gastrointestinal recovery and hospital stay

	Patients with ONS (n = 29)	Patients without ONS (n = 29)	*p*-value
Overall complication	8 (28)	7 (24)	0.76
Minor complication	6 (21)	2 (7)	0.25
Major complication	2 (7)	5 (17)	0.42
Time to tolerate solid diet (days)	1 (1-3)	2 (1-4)	0.27
Time to defecate (days)	2 (2-3)	3 (2-4)	0.52
Postoperative stay (days)			
Median (IQR)	5 (4-5)	5 (4-7)	0.20
Mean (SD)	5.0 (2.1)	6.4 (6.0)	0.24

Values are expressed as median (interquartile range: IQR), mean (standard deviation: SD), or number (percentage).
ONS = oral nutrition supplement

this study.

Discussion

The main findings of this comparative study are that the short-course perioperative administration of non-immunonutrition ONS in mildly to moderately malnourished patients undergoing colorectal surgery within an ERAS protocol does not have any significant clinical benefits on postoperative complication, gastrointestinal recovery and length of hospital stay. These results were contrary to some studies with a longer duration of perioperative ONS[10] and those with immune-modulating formulae[22-25].

In detail, the present findings are opposed to those reported from a large, multicenter, randomized control trial by Smedley et al in 2004, which examined the effect of preoperative and postoperative ONS in 179 patients undergoing elective moderate to major colorectal surgery[10]. Based on this randomized study, patients receiving ONS over an extended perioperative period (about 2 weeks before and after surgery) lost significantly less body weight and had the lowest rate of minor complications comparing with those receiving no supplements, or those receiving either preoperative ONS or postoperative ONS. It is conceivable that a relatively short duration of ONS has been insufficient for favorable clinical outcomes to be evident. However, there are some differences between the two studies. First, the rate of overall complication in non-ONS group of the randomized trial was about three times higher than those in our study (77% vs. 24%). Also, the duration of postoperative stay between the two studies was clearly different (12 to 14 days vs. 5 days). Hence, nutritional intervention in the present study may not lead to a further reduction in the incidence of complication and hospital stay. Second, by the study period of the randomized trial, an ERAS pathway may not be used or fully applied. It is possible that the benefit of ONS in our study is overwhelmed by an advantage of ERAS protocol, a multimodal perioperative program aiming to diminish stress response to surgery and support the recovery of organ function[19]. Consequently, the beneficial effect of a single intervention within an ERAS pathway, such as an ONS, may not be clearly seen[26]. Nevertheless, nutrition support is still considered as adjunctive care to every ERAS protocol.

Although there is growing evidence supporting the role of immunonutrition in patients undergoing elective surgery for gastrointestinal malignancies[24,25], high cost and limited availability of such formulae and its compliance are problematic in many countries including Thailand. Compliance to any ONS is a real challenge because the expected benefit depended on actual nutritional intake, with an assumption of dose-effect relationship for ONS[17]. A large study of preoperative ONS (immunonutrition) in Switzerland demonstrated that 42% of patients were considered non-compliant, mainly due to patient's willingness[27]. A recent collective review of ONS has suggested that standard ONS can be a good alternative to immunonutrition due to its inexpensive cost, better palatability and wide availability[28]. Interestingly, hospitalized patients receiving ONS had a higher total food, energy and protein intake than those without ONS[29,30]. It appears that ONS could stimulate appetite and food intake in both surgical patients and non-surgical patients. Similar to our finding, Sharma et al have demonstrated that patients receiving ONS after elective colorectal resection tended to have a quicker gastrointestinal recovery than those receiving no supplement[31].

The present study is limited by its retrospective nature and relatively small number of patients and events. Also, patients in the ONS group had a much lower BMI and a higher CR-POSSUM predicted mortality rate than the comparative group, where decreased BMI and elevated CR-POSSUM score clearly affected patients' recovery after colorectal surgery[32,33]. Moreover, no follow-up on laboratory parameter e.g. serum albumin or the measurement of other function outcomes such as handgrip strength and six-minute walking test were used in this study. These physical performances and biochemical parameters may help determining the functional and pre-clinical benefits of short-course nutrition support[31,34]. Finally, only non-severely malnourished patients were included. The present findings may be not generalizable to well-nourished or severely-malnourished individuals.

Although the present findings suggest that short-course ONS fails to show any significant clinical improvement on postoperative recovery after colorectal surgery in mildly to moderately malnourished patients, the author acknowledges that adequate intake of protein and calories is important for other metabolic, physiologic and biologic reasons. Several studies have suggested that protein-energy malnutrition impairs immune system and wound healing[35], alters normal gastrointestinal microflora and gut barrier function[36], promotes net protein and muscle loss[37], and leads to a higher morbidity and mortality[38].

Conclusion

In summary, due to the constraints of nutrition intervention in Thailand, perioperative short-course administration of standard formula ONS to non-severely malnourished patient fails to demonstrate any clinical benefits on surgical convalescence after colorectal surgery within an ERAS protocol. For maximal benefit and high cost-effectiveness, surgeons should tailor clinical guideline recommendations to individual patients, especially optimal time and choice of nutrition intervention, based on the presence of clinical evidence, their resource and the shared decision making among patients, relatives and surgeons.

What is already known on this topic?

Malnourishment in surgical patients adversely affects outcomes. Nutrition support is crucial in those with malnutrition or those with inadequate intake. Enteral nutrition, including oral nutrition support (ONS), is a popular choice of intervention in non-severely malnourished patients. Many international guidelines suggest the use of ONS about 5-7 days before and after surgery-with a preferential use of immunonutrition. However, the cost of immunonutrition is more expensive than standard formula.

What this study adds?

Perioperative short-course ONS (about 5 days) with standard formula did not result in a meaningful benefit after colorectal surgery in non-severely malnourished patients. It could imply that a sufficient duration of ONS (5 to 7 days before and after surgery) recommended by many guidelines should follow, and there is no 'short-cut' in nutrition intervention.

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Potential conflicts of interest

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การศึกษาประโยชน์ของการให้อาหารเสริมทางการแพทย์รับประทานระยะสั้นในผู้ป่วยที่เข้ารับการผ่าตัดลำไส้ใหญ่และไส้ตรงภายใต้โปรแกรมส่งเสริมการฟื้นตัวหลังผ่าตัด

วรุตม์ โล่ห์สิริวัฒน์

วัตถุประสงค์: *เพื่อประเมินประโยชน์ทางคลินิกของการให้อาหารเสริมทางการแพทย์รับประทานระยะสั้นในผู้ป่วยที่มีภาวะทุพโภชนาการเล็กน้อยถึงปานกลาง และเข้ารับการผ่าตัดลำไส้ใหญ่และไส้ตรงภายใต้โปรแกรมส่งเสริมการฟื้นตัวหลังผ่าตัด*

วัสดุและวิธีการ: *ผู้ป่วยที่มีภาวะทุพโภชนาการเล็กน้อยถึงปานกลางที่เข้ารับการผ่าตัดลำไส้ใหญ่และไส้ตรงภายใต้โปรแกรมส่งเสริมการฟื้นตัวหลังผ่าตัดในโรงพยาบาลศิริราชตั้งแต่ปี พ.ศ. 2554 ถึง พ.ศ. 2558 ถูกแบ่งออกเป็น 2 กลุ่ม (กลุ่มที่ได้รับและไม่ได้รับอาหารเสริมทางการแพทย์รับประทาน) เปรียบเทียบภาวะแทรกซ้อน การฟื้นตัวของระบบทางเดินอาหาร และระยะเวลารักษาตัวในโรงพยาบาลระหว่างผู้ป่วยทั้งสองกลุ่ม*

ผลการศึกษา: *การศึกษานี้มีผู้ป่วยกลุ่มละ 29 รายโดยไม่พบความแตกต่างอย่างมีนัยสำคัญของลักษณะของผู้ป่วย และรายละเอียดของการผ่าตัดระหว่างกลุ่ม อาหารเสริมทางการแพทย์ให้พลังงานเฉลี่ยวันละ 800 กิโลแคลลอรี่ เป็นระยะเวลา 5 วัน ผู้ป่วยที่ได้รับอาหารเสริมทางการแพทย์มีแนวโน้มในการรับประทานอาหารแข็ง และการขับถ่ายอุจจาระได้เร็วกว่าอีกกลุ่มประมาณ 1 วัน โดยไม่พบความแตกต่างอย่างมีนัยสำคัญของภาวะแทรกซ้อนและระยะเวลารักษาตัวในโรงพยาบาลระหว่างผู้ป่วยทั้งสองกลุ่ม*

สรุป: *การศึกษานี้ไม่พบประโยชน์ทางคลินิกอย่างมีนัยสำคัญของการให้อาหารเสริมทางการแพทย์รับประทานระยะสั้นในผู้ป่วยที่มีภาวะทุพโภชนาการเล็กน้อยถึงปานกลาง และเข้ารับการผ่าตัดลำไส้ใหญ่และไส้ตรงภายใต้โปรแกรมส่งเสริมการฟื้นตัวหลังผ่าตัด*