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Original Article

Mixed fibers diet in surgical ICU septic patients

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Diarrhea commonly occurs in surgical critically ill patients, especially septic patients and fiber formulas have been reported to improve diarrhea. Most reports have used soluble or insoluble fiber exclusively, while the effects of a mixed fiber diet remain unclear. This study compares diarrhea scores between mixed-fiber and non-fiber diets in surgical septic patients receiving broad spectrum antibiotics. We conducted a prospective randomized control double blind study in a general surgical ICU. Patients who received broad spectrum antibiotics and no contraindication to enteral feeding were randomly allocated to a fiber or non-fiber diet for up to 14 days. Nutritional delivery and diarrhea scores were recorded daily. Intention to treat analysis was performed. Thirty-four patients were enrolled in the study, 17 in the fiber group and 17 in non-fiber group. These two patients groups were similar in demographics, disease severity, nutritional status, cause of sepsis and total feeding per day. The proportion of patients with diarrhea score ≥12 was higher in the non-fiber group than in the fiber group, but the difference was not statistically significant [8/17 (47.06%) vs. 4/17(23.53%); p=0.15]. However, the fiber group had a lower mean diarrhea score (fiber vs. non-fiber = 3.6 ± 2.3 vs. 6.3 ± 3.6; p=0.005), as well as a lower global diarrhea score from the generalized estimation equation model for repeated measurement [Coefficient -3.03 (95%CI= -5.03 to -0.92); p=0.005]. In summary, a mixed fiber diet formula can reduce the diarrhea score in surgical critically ill septic patients who received broad spectrum antibiotics.

Key Words: mixed fiber, soluble fiber, insoluble fiber, diarrhea, surgical critically ill

INTRODUCTION

Diarrhea commonly occurs in critically ill septic patients who receive broad spectrum antibiotics. About 70-80% of surgical patients admitted to the surgical-ICU in our institute need broad spectrum antibiotics due to sepsis.[1] Fiber-enriched enteral formulas can stimulate the growth of beneficial normal flora bacteria which inhibit harmful bacteria, and there is ample evidence of their beneficial effects. Soluble fiber pectin can prevent diarrhea related to enteral-feeding.[2] Some cereal fibers could be fermented by colonic bacteria and produce short chain fatty acids (SCFAs).[3] SCFAs are rapidly cleared from the colon and increase sodium absorption which promote trans-mucosal water transportation and diminish diarrhea.[4-5]

Homann *et al.* performed a study on soluble fiber diet (10 g/L of hydrolyzed guar gum) in total or supplemental enteral nutrition and found that it reduced the incidence of diarrhea but the authors excluded patients who received broad spectrum antibiotics.[5] In septic patients, Spapen *et al.* investigated the effects of soluble fiber (22 g/L of partially hydrolyzed guar gum) and also found favorable outcomes.[6] However, their study population was limited to those with severe sepsis, and septic shock, most of whom were patients from medical unit who received a concentrated soluble fiber guar diet. Although diet containing insoluble fibers increase intestinal motion and bulk up stool quantity, most purely insoluble fiber (soy polysaccharide) feeds have demonstrated negligible effects on diarrhea in the critically ill.[7-9] Even though previous studies have investigated fiber's effects in mixed critically ill populations, they have used single fiber diets. Thus, the results of mixed fiber formulas remain unclear, especially in surgical patients who are predisposed to intestinal intolerance. Therefore, the aims of this study are to demonstrate the effects of an enteral formula containing mixed soluble and insoluble fiber in a single population of surgical critically ill septic patients who needed broad spectrum antibiotics.

MATERIALS AND METHODS

We conducted a prospective randomized control double blind study in a six-beds general intensive care unit (ICU) of a university hospital from February 2007 through November 2008. Patients who were admitted to surgical ICU were classified into those with sepsis and those without according to consensus guideline.[10] Septic patients who received broad spectrum antibiotics and total enteral feeding were eligible for enrollment. Exclusion criteria were

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1) hemodynamic instability; 2) bowel obstruction, hemorrhage, ileus; 3) acute pancreatitis; 4) post-endoscopy <24 hours; 5) bowel resection and anastomosis <24 hours; 6) ischemic bowel; 7) inflammatory bowel, ulcerative colitis, Crohn's disease; 8) enteric fistula and; 9) gut malabsorptive syndrome. Eligible patients who did not sign informed consent were also excluded. We recorded the patients' demographic data, admission disease, type of procedure, type of antibiotics, APACHE II score, SAPS II score, weight, height and albumin level. Nutritional requirements were calculated using the Harris Benedict equation. The main outcome assessment was a diarrhea score according to Hart and Dobb as shown in Table 1.[11] After patients were randomized, they received assigned diets for at least 5 days. Diarrhea scores were followed for up to 14 days or until changing from enteral nutrition to normal oral diet. A daily score was obtained by summing the scores for each stool over a 24-hour period. Diarrhea was defined as a daily accumulation score more than or equal 12.[6] Scores were collected by the same investigator who was blinded to the study. In this study, the length of ICU and hospital stay (ICU and hospital LOS) started at the intervention assignment date until ICU and hospital discharge respectively.

We randomly assigned two diets to patients. The intervention group received a mixed fiber formula [Nutren Fibre®, Nestlé Suisse S.A. (Switzerland)] and the control group received a standard formula without combined fiber [Nutren Optimum®, Nestlé Suisse S.A. (Switzerland)]. The nutritional composition of fat: protein: carbohydrates of the mixed fiber and standard formula were 38: 40.1: 126.5 and 38: 40: 126.3 kcal/L respectively. Both diets had the same osmolarity 360 mOsm/L after brewing according to standard recommendation. The fiber formula contained 15.1 g/L of dietary fiber which was produced by yellow pea fiber mixed with fructo-oligosaccharide, which is not present in the standard formula. The formula had an approximately one to one ratio of soluble and insoluble fiber. Soluble fiber was 35% FOS and 15% pectin. Insoluble fiber was approximately 30% cellulose 5% lignin and 15% hemicelluloses. Both diet formulas were prepared and packaged by dietary unit in our hospital by randomized assignment then delivered to the surgical ICU and handled by a nurse who was unaware of the study allocation. All eligible patients strictly followed the feeding guidelines of the surgical critical care unit protocol. Medications that directly cause diarrhea such as metoclopramide, quinidine, xylitol, magnesium, erythromycin, aminophylline, sorbitol and phosphorus were prohibited. This study was approved by the Committee for Ethics in Human Research of Faculty of Medicine, Chiang Mai University. Informed consent was obtained from all cases.

All data were analyzed by STATA 11 software. These are presented as mean with standard deviation in normal distribution continuous data. All categorical variables were analyzed by chi-square tests, except when small size required the use of Fisher's exact test. Comparison of continuous variables among groups was performed using Student's t test for variables with normal distribution and the Mann-Whitney U test for variables with non-normal distribution. All patients who were allocated to a treatment group were included in analytic processes regardless

Table 1. Diarrhea score proposed by Hart and Dobb

Consistency	Estimated volume (mL)		
	<200	200-250	>250
Formed	1	2	3
Semi-solid	3	6	9
Liquid	5	10	15

of whether or not they completed the intervention protocol (Intention to treat analysis). The main outcomes of repeated measurement diarrhea scores were analyzed by repeated measurement model. Incidence density of diarrhea ≥12 was analyzed by Poisson's distribution, while diarrhea score was analyzed by Gaussian distribution. Hazard ratio of time to start of first diarrhea was performed by Cox regression. Differences were considered to be statistically significant when $p<0.05$.

RESULTS

During of the 19-month study period, 189 septic patients who received broad spectrum antibiotics were eligible. Only 34 consenting septic patients with no contraindication for enteral feeding and consent were randomized and allocated to this study (Figure 1). The 17 patients in the intervention group were fed with mixed fiber supplement formula (fiber group). The other 17 patients, the control group, were fed with standard formula (non-fiber group). The baseline characteristics and severity of disease at admission for both groups were comparable as shown in Table 2. The most common sites for infection were pulmonary system and urinary system. The frequently prescribed antibiotics were beta-lactam and carbapenem for gram negative sepsis, glycopeptides for gram positive infection and clindamycin for anaerobic infection.

After randomized allocation, all patients received enteral diet for at least five days. Only 10 patients in the

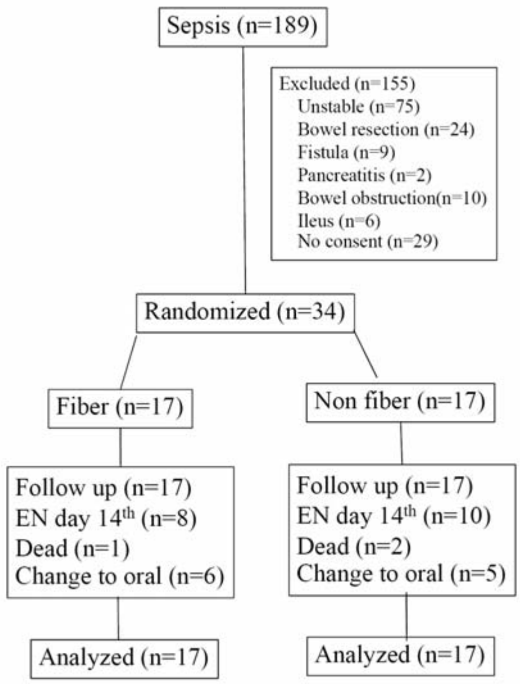

Figure 1. Flow chart of study.

Table 2. Baselines characteristic of both groups patients

Parameters	Fiber(n=17)	Non fiber(n=17)	*p* value
Age in years, (Mean±SD; 95%/CI)	49.2±20.5 (38.7-59.8)	51.9±17.4 (43.0-60.9)	0.68
Gender (F:M)	11:6(64.7:35.3)	11:6(64.7:35.3)	1.00
APACHE II, (Mean±SD; 95%/CI)	19.8±4.2 (17.6-22.0)	20.2±6.6 (16.8-23.6)	0.83
SAP II, (Mean±SD; 95%/CI)	39.9±8.5 (35.5-44.2)	40.1±8.6 (35.6-44.5)	0.95
Body weight, (Mean±SD; 95%/CI)	55.1±9.5 (50.3-60.0)	56.9±15.3 (49.0-64.8)	0.69
Height, (Mean±SD; 95%/CI)	160.9±8.3 (156.7-165.2)	161.8±8.9 (157.2-166.4)	0.78
Albumin, (Mean±SD; 95%/CI)	3.1±0.8 (2.7-3.5)	2.9±0.9 (2.4-3.3)	0.37
Organ infection			
Gastrointestinal	1(5.9)	2(11.8)	1.00
Hepatobiliary	2(11.8)	0(0)	0.49
Pulmonary	12(70.6)	12(70.6)	1.00
Urologic	13(76.5)	11(64.7)	0.71
Soft tissue	1(5.9)	3(17.7)	0.60
Trauma	2(11.8)	1(5.9)	1.00
Antibiotics			
Beta lactam	8(47.1)	10(58.8)	0.49
Carbapenem	5(29.41)	9(52.9)	0.16
Aminoglycoside	2(11.8)	2(11.8)	1.00
Fluoroquinolone	3(17.7)	6(35.3)	0.44
Metronidazole	4(23.5)	3(17.7)	0.67
Clindamycin	8(47.1)	8(47.1)	1.00
Glycopeptides	7(41.2)	8(47.1)	0.73

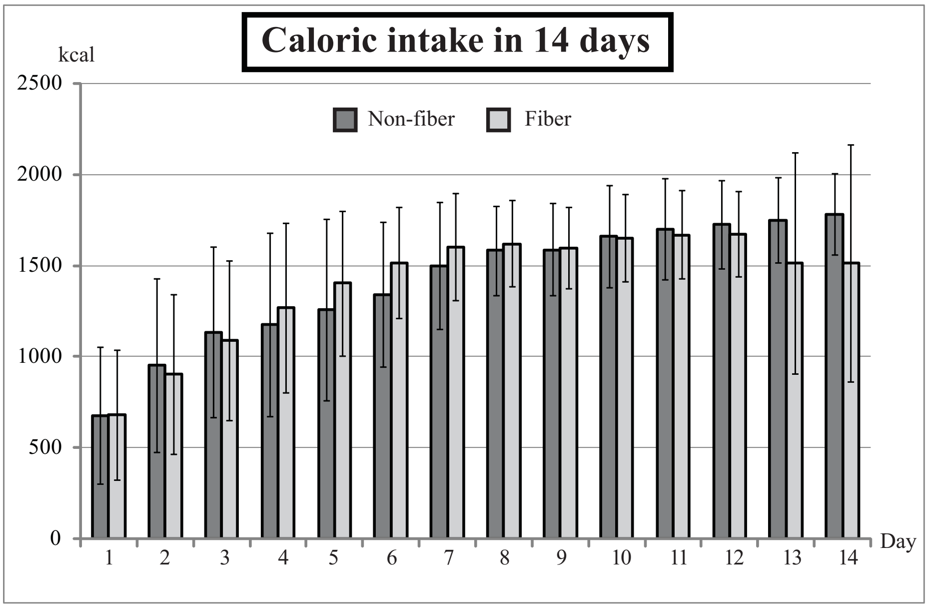

Figure 2. Daily caloric intake for 14 days of the cohort period.

non-fiber group and eight patients in the fiber group received enteral feeding until day 14th. The fiber group achieved mean caloric delivery of 1500 kcal earlier (at day 6th) than those in non-fiber group (at day 8th). However; there was no statistically significant difference in mean caloric intake when comparing daily delivery between groups (Figure 2). At the end of cohort, 14 days after the start of enteral feeding, we found that the accumulation and mean diarrhea score in the fiber group was significantly lower than in that found in the non-fiber group (50.8±32.0 vs. 87.7±50.7; p<0.01 and 3.6±2.3 vs. 6.3±3.6; p <0.01 respectively). Although the incidence of patients with at least one day of diarrhea, defined by diarrheal score ≥12 in this study, had a lower trend in the fiber receiving group (4/17 (23.5%) vs. 8/17 (47.1%); p=0.14), the overall incidence of diarrhea density per 100 patient-fed days in the mixed model was significantly lower in the fiber group (6.7 vs. 14.8; IRR=0.45; 95% Confidence interval; CI, 0.2-0.9; *p*=0.01). Repeated measurement of incidence rate ratio of diarrhea (IRR) had also significantly lowered in the fiber group when enteral nutrition started after receiving broad spectrum antibiotics (IRR 0.44; 95% CI, 0.2-0.9; *p*=0.04). Daily mean and standard deviation of diarrhea scores after 14 days of random assignment are shown in Figure 3. Diarrhea scores were statistically different from day 3 through day 11 except for day 8. Those differences were confirmed by the repeated measurement model, in which the coefficient of the fiber group was -3.03 (95%CI= -5.0 to -0.9; *p*<0.01). Although data cannot show the median time of the start of diarrhea's due to the lower incidence of diarrhea in the follow-up period but it is probable that the fiber group had a lower trend of first diarrhea beginning at day 14th (Table 3) with a hazard ratio of 0.45 (95% CI, 0.13-1.49; *p*=0.19).

Surviving patients in the fiber supplement and control groups had mean durations of ICU stay of 16.8 days (6-37 days) and 25.5 days (11-50 days) respectively (*p*=0.06). Mean hospital LOS of the fiber and non-fiber groups were 30.9 days (6-120 days) and 36.1 days (15-61 days) (*p*=0.07). No adverse outcomes due to either type of diet (such as allergy, aspiration pneumonia, sinusitis, tube displacement and tube obstruction) were observed during the study period. Three patients died, one in the fiber group and two in the control group. The remaining 31 patients survived to hospital discharge. Cause of death of the participant in the fiber group was ARDS. In the non-fiber group, patients died from severe sepsis and acute myocardial infarction. No deaths were associated with our intervention.

DISCUSSION

Sepsis-induced diarrhea may have many causes such as *Clostidium difficile* infection, gut ischemia, hypoalbuminemia and cellular derangement associated with shock. In addition, prolonged total parenteral nutrition impairs gut tolerance to enteral feeding by enhancing mucosal atrophy and reducing enzyme activity, which precipitates diarrhea in critically ill patients.[12] The interventions which can prevent or intercept those mechanisms might minimize the occurrence of diarrhea. Of those interventions, satisfactory results have been reported for diets containing fiber.

Dietary fibers have been divided into two groups, insoluble and soluble fibers. Insoluble fiber in a blended enteral diet, such as lignin cellulose and hemicelluloses, cannot hold water and has little effect on viscosity. The natural source of these fibers is soy bean or soy polysaccharide. These types of fibers increase colonic transit time due to bulking action.[13-14] Studies of soy polysaccharide

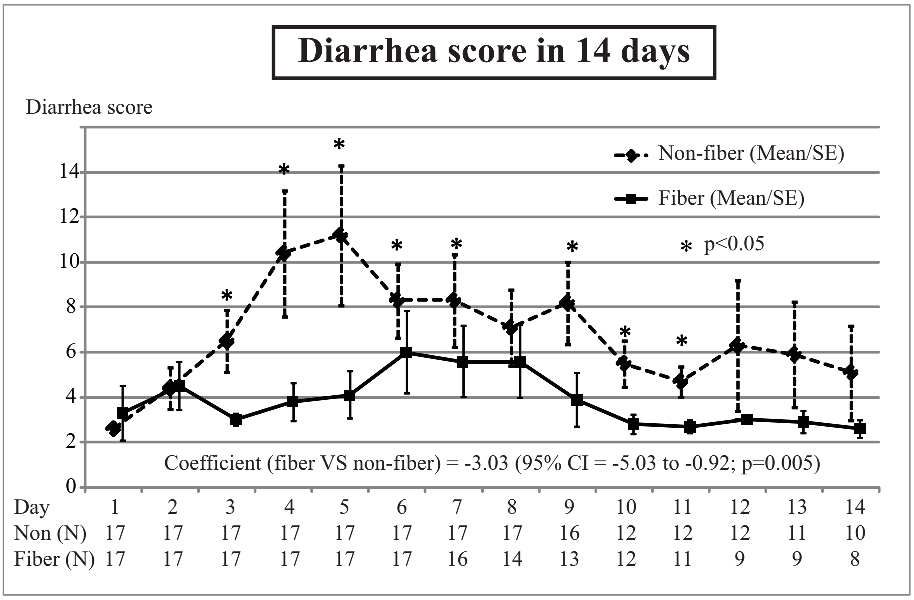

Figure 3. Diarrhea score (mean/standard error) in 14 days of follow up.

Table 3. Outcomes of study

Main outcomes	Fiber (n=17)	Non fiber (n=17)	*p* value
Accumulation diarrhea score	50.8±32.0	87.7±50.7	<0.01*
Mean diarrhea score	3.6±2.3	6.3±3.6	<0.01*
Number of patients with at least 1 day of diarrhea (%)	4 (23.5)	8 (47.1)	0.14
Incidence rate of diarrhea (100 patient-fed day)	6.7	14.8	0.01
Probability of first diarrhea beginning at day 14th (95% CI)	0.24 (0.1-0.5)	0.47 (0.3-0.7)	0.19**
Hospital LOS	30.9±28.0	36.1±14.8	0.07*
ICU LOS	16.8±8.0	25.5±13.0	0.06*

*Mann-Whitney U test
**Cox regression of fiber with hazard ratio 0.45 (95% Confidence interval; 0.13-1.5)

(insoluble fiber) in critically ill patients did not show diarrhea incidence alternation.[7-9] However; it has been found that a diet which contains a mixture of insoluble and soluble fibers is associated with significantly greater proximal antral motility than an insoluble-fiber diet in healthy volunteers.[15] This effect might benefit critically ill patients with gastroduodenal paresis and ultimately improve gut intolerance.

Soluble fiber and fiber-like substance (e.g. pectin, guar gum, inulin and FOS) have gelling properties and increase viscosity. Many studies have demonstrated that a combination of these fibers can reduce diarrhea.[2,5-6,16] Most of those could be fermented by intestinal bacteria and result in short chain fatty acids (SCFAs).[2-3,14] These final products have an important role in gut function. Firstly, SCFAs are rapidly cleared from the colon and are associated with the activity of the sodium – hydrogen exchanger system which facilitate water absorption.[17] Secondly, SCFAs have ancillary benefits in reversing toxin induced secretion in cholera and other diarrheas, as well as decrease the *Clostidium difficile* toxin uptake to cells and reducing the cytopathic effect to colonic cells.[18-19] Finally, SCFAs have the anti-inflammatory effects via molecular mechanism such as NFκB inhibition and reduction of proinflammatory cytokines.[20-21] However, no hypotheses regarding these mechanisms could be confirmed in this study because it did not investigate the differences in intestinal flora and fecal SCFAs concentration between the two groups.

Using these background hypotheses, the authors investigated the effects of a mixture of insoluble and soluble fiber on clinical outcomes (Table 3). After randomization, the patient background in each group was comparable (Table 1) Accumulation diarrhea scores, daily mean scores and incidence density of score per 100 patient–fed days revealed statistical differences between the groups. However, there were only lower trends of at least one day diarrhea incidence, hazard ratio of diarrhea beginning, ICU length of stay and hospital length of stay in the fiber group. It is possible this could occur due to the small sample size and that results would be different in larger trials. The authors analyzed both mixed model and repeated model of individual patient of diarrhea scores and diarrhea occurrences, and both analyses demonstrated statistically significant differences (Table 3 and figure 3).

This study demonstrates the clinical outcomes of diarrhea but not the underlying mechanism. The important one is *Clostidium difficile* toxins. They are routinely investigated in clinical practice in developed countries, but laboratory settings are not commonly available in most of government public hospital in Thailand because they are not as cost effectiveness as therapeutic diagnosis with metronidazole. Therefore, the authors cannot conclude that *Clostidium difficile* inhibition or toxin neutralization was improved by soluble fiber.

Although previous studies have preferred soluble fiber to insoluble fiber for diminishing diarrhea in critically ill patients, the authors' results have demonstrated better outcome using mixed formula.[6-9,16] There are two possible explanations: 1) only the soluble fibers play an important role and; 2) soluble and insoluble fibers have a synergistic interaction which enhances each other's effects in mixed formula while there are fewer effects when separately administered. The authors prefers the second hypothesis for the following reasons. Despite different types of soluble fiber between studies, previous studies achieved favorable results by adding 10-22 g/L of soluble fiber to their trial formulas whereas this study obtained similar results by adding only 7.5 g/L.[5-6] Accurate causal association needs further investigation, either by factorial two by two designs of soluble and insoluble fiber or by three-armed randomization of soluble, insoluble and mixed fiber fibers.

Even though mean caloric intake was not different between the two groups, the fiber group reached its caloric target earlier than the non-fiber group. This phenomenon might be explained by fecal content in each group's patients. In common practice, when diarrhea occurs, most physicians prefer to discontinue enteral feeding and observe until the problem is resolved before then resuming feeding. As previously explained, there was less enteral interruption and more enteral administration in the fiber group.

Finally, there were many limitations to this study. The first is the small number of patients, so that some results were only demonstrated tendencies. Larger populations are needed to confirm these tendencies. Second, the study could only demonstrate global clinical outcomes but could not explain the underlying mechanisms. Detailed investigation in future trials could explain pathophysiological responses of intervention such as fecal intestinal flora difference, fecal SCFAs and *Clostidium difficile* toxin. Third, heterogeneous fiber composition in each study might have different results despite the similar physical characters.[6,16] Therefore; this study can postulate and reveal the global effects of mixed fibers but it cannot accurately summarize which favorable results occur from which types of fiber in the formula. In addition, various methods were used to measure diarrhea in the different studies with no standard consensus, so that it might be difficult to compare results among different studies. Lastly, the primary endpoint in this study focused on occurrence of diarrhea. Further studies should concentrate on other important clinical endpoints such as severity of disease improvement, mortality and weight change or alteration of nutritional parameters such as albumin, prealbumin (transthyretin) or thyroglobulin between groups.

In conclusion, formula containing mixed fiber is safe and can reduced diarrhea scores in surgical critically ill septic patients who need broad spectrum antibiotics.

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AUTHOR DISCLOSURES

The authors have no conflict of interest. Nestlé Ltd. only provided both enteral diet formulas to the patients free of charge, without providing financial support to the study and with no intervention in any of the trial processes and reports. The medical faculty of Chiang Mai University allowed basic laboratory investigation free of charge in every patient in this study.

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Original Article

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外科加護病房敗血症患者之混合纖維飲食

外科重症病患經常會發生腹瀉現象，特別是敗血症患者，而含纖配方已被報告可改善腹瀉症狀。大部分的報告僅使用可溶性纖維或是不可溶性纖維兩者之一，而混合纖維飲食的效果尚不清楚。本研究是比較混合纖維飲食及不含纖維飲食，兩者在接受廣效性抗生素的外科敗血症患者的腹瀉分數。我們在一個一般外科加護病房進行一項前瞻性雙盲隨機對照研究。接受廣效性抗生素及對腸道營養無禁忌症的病患被隨機分派至含纖飲食與不含纖飲食組進行達 14 天的研究。每天記錄營養給予及腹瀉分數。以及進行治療意圖分析。一共有 34 位病患被納入研究，其中 17 位為含纖飲食組，另外 17 位為不含纖飲食組。這兩組病患的人口學分布、疾病嚴重度、營養狀況、敗血症的導因以及每日的總攝食量是相似的。不含纖飲食組中，腹瀉分數≥12 分的病患比例高於含纖飲食組，但是兩者的差異未達統計上顯著。含纖飲食組有較低的平均腹瀉分數，以及較低的來自廣義估計方程式模式重複測量所得的總腹瀉分數(係數為-3.03，95% CI: -5.03 至-0.92，*p*=0.005)。總體而言，混合纖維飲食配方可以降低那些接受廣效性抗生素的外科術後嚴重敗血症病患的腹瀉程度。

關鍵字：混合纖維、可溶性纖維、不可溶性纖維、腹瀉、外科重症