

Effect of Simplifying Protein Counting Tool and Educational Intervention on the Nutritional Status in Patient with Cirrhosis: A Randomized Clinical Trial

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Background: Protein-calorie malnutrition (PCM) is a common problem in cirrhotic patients and is associated with increased morbidity and mortality. Diet plays a key role as a nutritional therapy in chronic liver disease. However, most cirrhotic patients have not received adequate nutrition counseling from their physicians and very few patients have access to a registered dietician.

Objective: To study effect of simplifying protein counting tool and educational intervention on the nutritional status in patient with cirrhosis.

Materials and Methods: An open-label, randomized clinical trial was conducted at GI clinic from October 2018 to February 2020. After a short period of nutrition counseling, participants were randomly assigned to the intervention group who received simplifying protein counting tool and the control group. The outcomes were nutritional status at 3 and 6 months: serum albumin, transferrin, Child-Turcotte-Pugh (CTP) score, MELD score, Patient-Generated Subjective Global Assessment score (PG-SGA), and protein counting skill.

Results: A total of 57 patients were enrolled. Of these, 18/30 (60%) of intervention group and 13/27 (48.2%) of control group had serum albumin improvement at 3 months. Protein counting skill achieved in 15 (50%) in the intervention group compared with 10 (37.0%) in the control group ($p = 0.43$). Patients who had achieved protein counting skill had statistically significant improvements in serum albumin ($p < 0.01$), transferrin ($p < 0.01$), CTP score ($p < 0.01$) at 3 months and improvements in serum albumin ($p < 0.01$), PG-SGA ($p < 0.01$), CTP score ($p < 0.01$), and MELD score ($p < 0.01$) at 6 months.

Conclusion: Simplifying protein counting tool may improve protein counting skill. Nutrition advice may encourage the cirrhotic patient to have adequate protein intake to maintain a good nutritional status.

Keywords: Cirrhosis, Malnutrition, Protein counting tool

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Cirrhosis is the end stage of liver fibrosis caused by many forms of liver diseases and conditions, such as viral hepatitis, chronic alcoholism, nonalcoholic steatohepatitis (NASH) and drug-induced liver injury⁽¹⁾. As cirrhosis progresses, fibrosis causes liver dysfunction (decompensated cirrhosis) and portal hypertension leading to complications such as ascites, variceal bleeding, jaundice, hepatic encephalopathy and hepatocellular carcinoma⁽²⁾.

Protein-calorie malnutrition (PCM) is found up to

40 to 90% of cirrhotic patients⁽³⁾. The progression of PCM is associated with a higher rate of cirrhotic complications that increased morbidity and mortality⁽⁴⁾.

According to recent clinical practice guidelines on nutrition in chronic liver disease, nutritional counseling should be performed to achieve optimal daily energy and protein intake (total calories 35 to 40 kcal/kg, protein 1.2 to 1.5 g/kg)⁽⁵⁻⁷⁾. Late evening oral nutritional supplementation and breakfast in dietary regimen are recommended for decompensated cirrhotic patients^(8,9). Diet plays a key role as a nutritional therapy in chronic liver disease. However, most cirrhotic patients have not received adequate nutrition counseling from their physicians and very few patients have access to a registered dietician.

Therefore, we performed this randomized study to assess the effects of simplifying protein counting tool on nutritional status among cirrhotic patients with concurrent PCM.

Materials and Methods

Study design

This prospective, randomized, open-label clinical trial was conducted at gastroenterology outpatient

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clinic of Maharaj Nakhon Chiang Mai Hospital, Chiang Mai, Thailand between October 2018 and February 2020. The study protocol has been approved by the Institutional Research Ethics Committee at the Faculty of Medicine, Chiang Mai University (Reference No. 05764/2018, TCTR20190205006). Written informed consent was obtained from each patient before enrollment and randomization. Patients were followed-up 3 months and 6 months after randomization.

Patients and eligibility criteria

Adults, 20 to 75 years of age were eligible for participation if gastroenterologist made diagnosis cirrhosis defined by clinical of cirrhotic complication (varices, ascites, hepatic encephalopathy, and jaundice) or laboratory finding (hypoalbuminemia, hyperbilirubinemia, and coagulopathy) and imaging finding (surface nodularity, caudate width: right lobe width >0.65 or elastography >12.5 to 15 kPa according to causes of cirrhosis). Participant had one following of PCM risk; 1) serum albumin level <3.5 mg/dl, 2) body mass index ≤ 18.5 kg/m², 3) Scored Patient-Generated Subjective Global Assessment (PG-SGA) ≥ 4 , 4) mid-arm muscle circumference (MAMC) <23.4 cm in male and <21.3 cm in female patients⁽¹⁰⁻¹⁵⁾.

Key exclusion criteria were chronic heart failure, chronic kidney disease stage ≥ 3 , insulin-dependent diabetes mellitus, protein losing enteropathy, nephrotic syndrome, any exfoliative skin diseases, active malignancy, or had problem of enteral feeding (dysphagia, bowel obstruction). Patients were also excluded if they received intravenous albumin within 90 days before enrollment.

Data collection included 1) Patient's clinical data (age, sex, cause of cirrhosis, education, economic status, current alcohol consumption, current medication, cirrhosis complication, body mass index (BMI), Child-Turcotte-Pugh (CTP) score, MAMC, PG-SGA, current protein intake), 2) Laboratory data (complete blood count, coagulation profile, renal function tests, serum electrolytes, liver function tests, transferrin), model for end-stage liver disease (MELD) score, and MELD-Na score.

Randomization

Web-based randomization were used to assign patients to received simplifying protein counting tool and the control group after short period nutritional education in a 1: 1 ratio with a random block size of 4 and with stratification according to the CTP A and B/C.

Nutritional education

All participants were received nutritional recommendation book included with causes of malnutrition in cirrhotic patients, and a recommendation of calories (35 to 40 kcal/kg.BW/d.) and protein (1.2 to 1.5 g/kg.BW/d) intake according to recent clinical practice guidelines⁽⁹⁾.

Interventions

After short period nutritional education and

protein counting training, patients who were randomized to the intervention group were received simplifying protein counting tool comprised a total of adequate protein number per day as well as example of diets that provided one unit of protein (1 unit = 7 to 8 g of protein). Patients were also instructed to complete daily protein record form.

Outcomes

Primary outcomes were nutritional status after 3 months of intervention assessed by serum albumin, transferrin, CTP score, MELD score, MELD-Na score, PG-SGA, MAMC and protein counting skill (defined by patient knowing their adequate protein intake per day and can estimate 1 unit of protein diet). Secondary outcomes were nutritional status after 6 months of intervention.

Statistical analysis

Baseline characteristics of the participants were presented as mean, standard deviation, frequency and percentage. Baseline characteristics and outcomes were compared between the intervention group and control group using Fisher's exact test for categorical variables, and independent t-test or Wilcoxon rank-sum test for continuous variables depending on the distribution of the data. All statistical analyses were completed using Stata version 14 (StataCorp) with statistical significance indicated by a *p*-value of 0.05 and with the use of a 2-sided hypothesis test.

Sample size calculation was done based on previous study that nutritional support can improved serum albumin from 25.1 ± 4 to 28.1 ± 4 g/L⁽¹⁶⁾. The total sample size was estimated to be 68 patients, with 34 in each arm (5% probability of a type 1 error, 80% power, and assuming 10% loss to follow-up).

Results

Enrollment and patient characteristics

From October 2018 through February 2020, a total of 70 participants were enrolled, of whom 36 were randomly assigned to the intervention group and 34 were assigned to the control group. A total of 57 patients were complete the primary outcome and 47 patients were complete the secondary outcome (Figure 1). The mean age was 57.6 ± 8.5 years; 35 (61%) were male; 36 (63%) were the CTP B and C patients. The most common cause of cirrhosis was alcohol (49%).

Baseline characteristics were generally similar in intervention and controlled group except for lower economic status in the control group (*p* = 0.03) and hepatitis C viral infection with cirrhosis in the intervention group (*p* = 0.03) (Table 1).

Primary outcomes

A total of 18 of 30 patients (60%) in the intervention group and 13 of 27 patients (48.2%) in the control group had albumin improvement at 3 months (*p* = 0.43). Protein

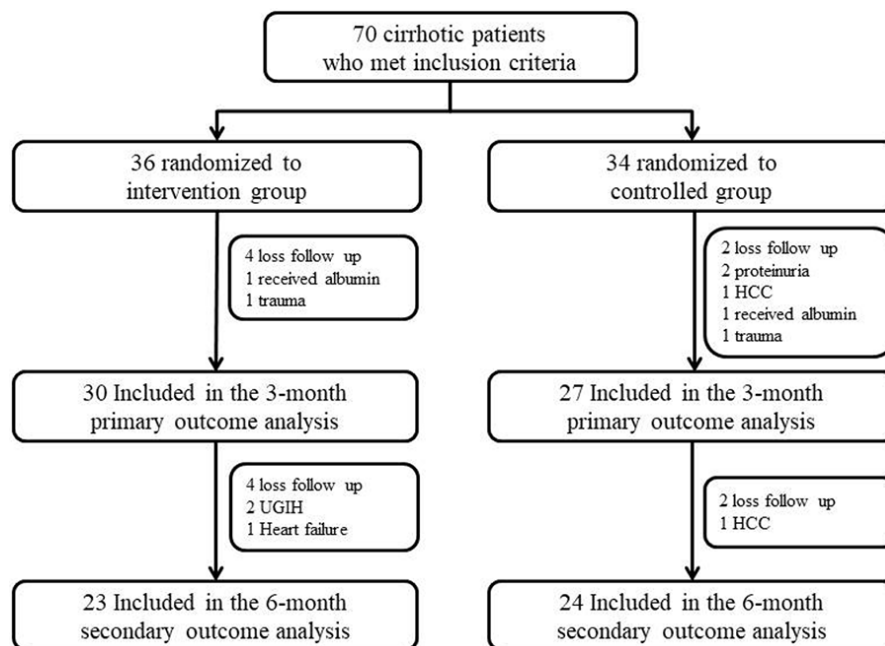


Figure 1. Enrollment, randomization, and follow-up of the patients.

counting skill archived in 15 of 30 patients in the intervention group compared with 10 of 27 patients in the control group (50% vs. 37%, $p = 0.43$) (Table 2).

Secondary outcomes

At 6 months, 15 of 23 patients (65.2%) in the intervention group and 12 of 24 patients (50%) in the control group had albumin improvement ($p = 0.22$). Protein counting skill archived in 13 of 23 patients (56.5%) in the intervention group compared with 9 of 24 patients (37.5%) in the control group ($p = 0.25$) (Table 2 and Figure 2).

Post hoc exploratory analyses

The authors compared nutritional status between patients who complete protein counting skill and non-skill group. Baseline characteristics were non-difference. Among 25 patients (43.8%) who achieved protein counting skill were statistically significant improvements of albumin ($p < 0.01$), transferrin ($p < 0.01$), CTP score ($p < 0.01$) at 3 months and improvements of albumin ($p < 0.01$), PG-SGA ($p < 0.01$), CTP score ($p < 0.01$), and MELD score ($p < 0.01$) at 6 months (Table 3 and Figure 3).

Discussion

In this randomized clinical trial that compared patients who received simplifying protein counting tool and control group resulted in non-statically significant in nutritional outcomes at 3 and 6 months. However, 57% of patients in both groups had albumin improvement at 6

months compared to baseline that could be the effect of nutritional education and cirrhosis treatment. Patients achieved protein counting skill were a tend to higher in the intervention group compared with control group (50% vs. 37% at 3 months and 56.5% vs. 37.5% at 6 months). In our study, patients who achieved protein counting skill were statistically significant improvements in nutritional status.

Maharshi et al reported that nutritional support, when compared with no nutritional therapy, did not improve clinical of hepatic encephalopathy in 6 months but shown significant improvement of albumin 0.13 ± 0.1 g/dl from baseline in a nutritional support group. Compared with our study, the intervention group had serum albumin improvement of 0.41 ± 0.39 g/dl from baseline. This result may be from advanced cirrhotic patients (minimal hepatic encephalopathy) in a prior study⁽¹⁶⁾.

The present study had some limitations. First, the sample size was limited because the complexity of the cases due to tertiary care hospital setting. After patients were diagnosed, most were referred to primary care and a number of non-complex cirrhotic patients were treated at local hospitals. Second, the authors found statically significant different of patient economic status in baseline characteristics that may be related to the adequate of protein intake. Third, the follow-up period was short. Six months nutritional evaluation may inadequate to assess nutritional outcomes.

This was randomized controlled trial of new

Table 1. Demographic and clinical characteristics of the patients

Characteristic	Intervention (n = 30)	Control (n = 27)	p-value
Age (years)	56.4 (8.9)	55.6 (9.2)	0.14
Male	18 (60)	17 (62.9)	1.00
BMI (kg/m ²)	24.3 (4.8)	24.1 (4.1)	0.83
Current alcohol intake	4 (13.3)	1 (3.7)	0.36
Education (primary school)	11 (36.7)	13 (48.6)	0.43
Low economic status	8 (26.7)	15 (55.6)	0.03
PG-SGA	6.5 (3.6)	6.74 (4.4)	0.97
PG-SGA >4	21 (70.0)	17 (62.9)	0.59
MAMC (cm)	26.6 (2.9)	27.3 (3.8)	0.57
Child-Turcotte-Pugh score	7.4 (1.7)	7.3 (1.4)	0.92
Class B or C	20 (66.7)	16 (59.3)	0.59
Cirrhotic etiology			
Alcoholic	14 (46.7)	14 (51.9)	0.79
Hepatitis B virus	4 (13.3)	7 (25.9)	0.32
Hepatitis C virus	11 (36.7)	3 (11.1)	0.03
NASH	2 (6.7)	1 (3.7)	1.00
Primary biliary cholangitis	0	3 (11.1)	0.10
Cardiac	1 (3.3)	0	1.00
Autoimmune hepatitis	1 (3.3)	0	1.00
Cryptogenic	0	2 (7.41)	0.22
Cirrhosis complications			
Varices	13 (43.3)	13 (48.2)	0.79
Ascites	10 (33.3)	8 (29.6)	0.78
Hepatic encephalopathy	0	1 (3.7)	0.47
Jaundice	7 (23.3)	9 (33.3)	0.56
Edema	3 (10.0)	3 (11.1)	1.00
Hepatocellular carcinoma	1 (3.3)	3 (11.1)	0.34
Medications			
Propranolol	12 (40)	12 (44.4)	0.79
Spironolactone	12 (40)	10 (37)	1.00
Furosemide	10 (33.3)	8 (29.6)	0.78
Lactulose	4 (13.3)	3 (11.1)	1.00
Vitamin B complex	28 (93.3)	22 (81.5)	0.28
Folic	28 (93.3)	19 (70.1)	0.04
Zinc	23 (76.7)	20 (74.1)	1.00
Silymarin	6 (20)	5 (18.5)	1.00
Ursodeoxycholic acid	2 (6.7)	5 (16.5)	0.24

Data are presented as number (%) or mean (standard deviation)

intervention after routine nutritional education and we collected both clinical and laboratory nutritional outcomes that were strength of our study.

Conclusion

Simplifying protein counting tool may improve

protein counting skill. Nutrition advice may encourage the cirrhotic patient to have adequate protein intake and maintain a good nutritional status.

What is already known on this topic?

Malnutrition is common problem in cirrhotic

Table 1. Cont

Characteristic	Intervention (n = 30)	Control (n = 27)	p-value
Laboratory data			
Albumin (g/dl)	2.9 (0.4)	3.0 (0.4)	0.85
Transferrin (mg/dl)	195.9 (51.1)	215.2 (52.8)	0.15
Hemoglobin (g/dl)	11.5 (2.6)	11.9 (2.4)	0.85
Platelet count (x10 ³)	102.1 (38.4)	110.3 (63.3)	0.97
PT (sec)	14.5 (3.2)	15.3 (3.4)	0.28
PTT (sec)	35.5 (7.5)	35.7 (5.7)	0.97
INR	1.3 (0.3)	1.4 (0.3)	0.24
Total protein (g/dl)	7.7 (0.7)	7.7 (0.7)	0.74
Globulin (g/dl)	4.7 (0.7)	4.6 (0.8)	0.29
ALT (U/L)	40.4 (29.5)	37.6 (20.2)	0.70
AST (U/L)	68.2 (34.9)	59.9 (23.1)	0.49
BUN, mg/dl	14.2 (6.6)	11.1 (3.3)	0.07
Creatinine (mg/dl)	0.9 (0.3)	0.9 (0.2)	0.86
MELD score	8.8 (1.7)	9.7 (2.6)	0.13
MELD-Na score	10.7 (2.5)	11.8 (3.5)	0.27

Data are presented as number (%) or mean (standard deviation)

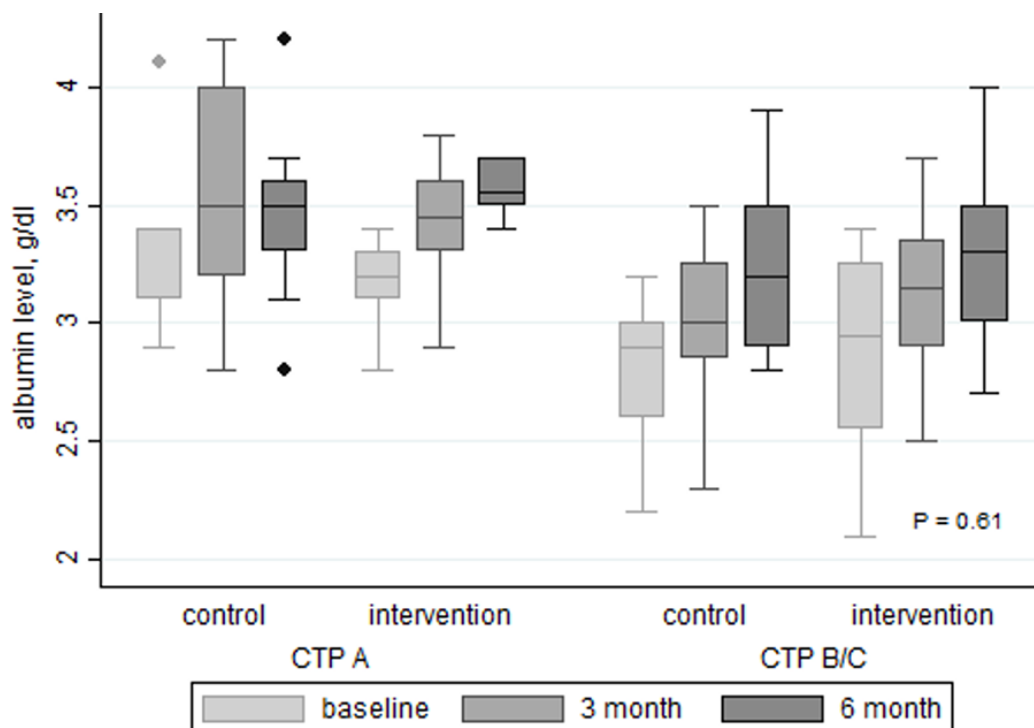


Figure 2. Box plot of serum albumin level by Child-Turcotte-Pugh (CTP) score in control and intervention group.

Table 2. Outcomes

Primary outcomes	Intervention (n = 30)	Control (n = 27)	p-value
Albumin, (g/dl)	3.2 (0.3)	3.2 (0.4)	0.61
Δ Albumin, (g/dl)	+0.2 (0.3)	+0.2 (0.4)	0.59
Transferrin (mg/dl)	206.9 (61.1)	215.5 (56.1)	0.42
Δ Transferrin (mg/dl)	+11.0 (31.7)	+0.3 (28.6)	0.43
PG-SGA	3.1 (3.6)	2.7 (3.8)	0.56
PG-SGA >4	9 (30)	5 (18.6)	0.24
Δ PG-SGA	-3.4 (3.3)	-4.0 (4.0)	0.86
CTP score	6.4 (1.4)	6.7 (1.5)	0.46
Δ CTP score	-1.0 (1.2)	-0.7 (1.0)	0.34
MAMC (cm)	27.5 (3.5)	27.3 (4.0)	0.86
Δ MAMC (cm)	+0.9 (1.7)	+0.01 (1.6)	0.05
MELD	8.4 (1.4)	9 (3.2)	0.64
Δ MELD	-0.4 (2.1)	-0.6 (3.6)	0.38
MELD-Na	10.9 (2.8)	11.1 (4.0)	0.96
Δ MELD-Na	+0.2 (2.3)	-0.6 (4.2)	0.30
Protein counting skill	15 (50)	10 (37)	0.43
Secondary outcomes	Intervention (n = 23)	Control (n = 24)	p-value
Albumin, (g/dl)	3.3 (0.3)	3.3 (0.4)	0.75
Δ Albumin, (g/dl)	+0.4 (0.4)	+0.3 (0.5)	0.51
Transferrin (mg/dl)	209.9 (53.6)	222.6 (56.3)	0.56
Δ Transferrin (mg/dl)	+22.3 (47.3)	+7.6 (44.4)	0.43
PG-SGA	1.0 (1.8)	1.2 (1.6)	0.77
PG-SGA >4	3 (13.0)	1 (4.2)	0.29
Δ PG-SGA	-5.8 (3)	-5.2 (4.6)	0.29
CTP score	6.0 (1.2)	6.3 (1.4)	0.37
Δ CTP score	-1.6 (1.5)	-1.0 (1.2)	0.11
MAMC (cm)	27.2 (3.6)	27.3 (4.2)	0.79
Δ MAMC (cm)	-0.2 (1.8)	-0.2 (1.2)	0.39
MELD	8.4 (1.3)	8.3 (3.2)	0.59
Δ MELD	-0.7 (1.6)	-1.6 (3.6)	0.37
MELD-Na	10.8 (2.7)	12.0 (4.5)	0.44
Δ MELD-Na	-0.1 (3.0)	-0.2 (4.9)	0.65
Protein counting skill	13 (56.5)	9 (37.5)	0.25
Cirrhosis complications			
Varices	1 (4.4)	0	0.49
Ascites	1 (4.4)	1 (4.2)	1.00
Hepatic encephalopathy	0	0	-
Jaundice	0	2 (8.3)	0.26
Edema	0	1 (4.2)	0.51
Hepatocellular carcinoma	1 (4.4)	2 (8.3)	0.52

Data are expressed as mean (standard deviation) or number (%)

Table 3. Outcomes of patients who achieved protein counting skill

3 months	Complete (n = 25)	Non-complete (n = 32)	p-value
Albumin (g/dl)	3.3 (0.3)	3.1 (0.4)	0.002
Δ Albumin (g/dl)	0.4 (0.3)	0.1 (0.3)	<0.001
Transferrin (mg/dl)	233.8 (60.4)	193.2 (50.9)	0.012
Δ Transferrin (mg/dl)	11.1 (32.7)	2.0 (28.4)	0.41
PG-SGA	2.1 (2.8)	3.5 (3.9)	0.22
Δ PG-SGA	-5.2 (3.6)	-2.5 (3.2)	0.003
CTP score	6.0 (1.2)	7.0 (1.5)	0.003
Δ CTP score	-1.4 (1.3)	-0.4 (0.8)	<0.001
MAMC (cm)	27.7 (3.9)	27.3 (4.2)	0.64
Δ MAMC (cm)	+0.9 (2.3)	+0.3 (2.3)	0.72
MELD	8.1 (2.0)	9.2 (2.6)	0.05
Δ MELD	-1.2 (2.8)	0.1 (2.2)	0.08
MELD-Na	10.9 (3.4)	11.1 (3.5)	0.71
Δ MELD-Na	-0.5 (3.8)	0.1 (2.9)	0.94
6 months	Complete (n = 22)	Non-complete (n = 25)	p-value
Albumin (g/dl)	3.5 (0.3)	3.2 (0.3)	<0.001
Δ Albumin (g/dl)	0.5 (0.5)	0.2 (0.4)	0.016
Transferrin (mg/dl)	229.6 (51.9)	204.8 (55.6)	0.12
Δ Transferrin (mg/dl)	21.3 (47.9)	9.1 (44.4)	0.70
PG-SGA	0.3 (0.5)	1.8 (2.1)	0.013
Δ PG-SGA	-6.7 (4.0)	-4.4 (3.5)	0.04
CTP score	5.5 (0.8)	6.8 (1.3)	0.003
Δ CTP score	-1.8 (1.4)	-0.9 (1.3)	0.007
MAMC (cm)	27.8 (3.9)	26.7 (3.9)	0.36
Δ MAMC (cm)	-0.2 (1.1)	-0.2 (1.7)	0.76
MELD	7.8 (2.6)	8.8 (2.3)	0.013
Δ MELD	-1.7 (3.4)	-0.7 (2.3)	0.26
MELD-Na	10.8 (3.7)	12.0 (3.7)	0.28
Δ MELD-Na	-0.9 (4.7)	+0.5 (3.5)	0.14

Data are expressed as mean (standard deviation) unless specified

patients. Specifics evaluation such as PG-SGA and MAMC should be evaluated in all patients. Nutrition intervention can decrease cirrhotic complication that leads to a better outcome.

What this study adds?

Simplifying protein counting tool may improve protein counting skill. Patients who achieved protein counting skill were statistically significant improvements in nutritional status.

Conflicts of interest

The authors declare no conflict of interest.

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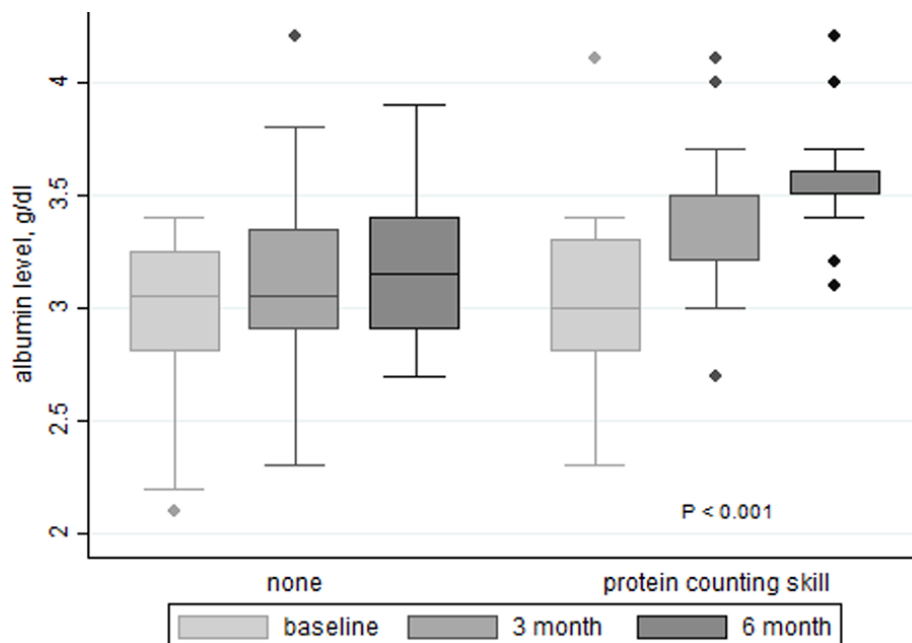


Figure 3. Effect of protein counting skill on serum albumin level

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ผลการใช้คู่มือกำหนดโปรตีนในอาหารอย่างง่ายและการให้คำแนะนำด้านโภชนาการต่อภาวะโภชนาการของผู้ป่วยตับแข็ง

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ภูมิหลัง: ภาวะทุพโภชนาการเป็นปัญหาที่พบบ่อยในผู้ป่วยโรคตับแข็ง และสัมพันธ์กับอัตราการเจ็บป่วยและการเสียชีวิตที่เพิ่มขึ้น การดูแลโภชนาการอย่างมีประสิทธิภาพจึงมีบทบาทสำคัญในผู้ป่วยโรคตับเรื้อรัง

วัตถุประสงค์: เพื่อศึกษาผลของคู่มือฉบับโปรตีนอย่างง่ายและการให้คำแนะนำด้านโภชนาการต่อภาวะโภชนาการในผู้ป่วยโรคตับแข็ง

วัสดุและวิธีการ: ผู้ป่วยโรคตับแข็งที่มีภาวะทุพโภชนาการระหว่างเดือนตุลาคม พ.ศ. 2561 ถึงเดือนกุมภาพันธ์ พ.ศ. 2563 หลังจากได้รับความรู้ทางโภชนาการเบื้องต้น ผู้ป่วยจะถูกสุ่มแบ่งเป็นกลุ่มที่ได้รับคู่มือการนับโปรตีนอย่างง่ายและกลุ่มควบคุม และติดตามภาวะทางโภชนาการ โดยอาศัยข้อมูลทางคลินิกและผลการตรวจทางห้องปฏิบัติการ รวมถึงความสามารถในการนับปริมาณโปรตีนที่ควรได้รับในแต่ละวันอย่างถูกต้องที่ระยะเวลา 3 และ 6 เดือน

ผลการศึกษา: ผู้ร่วมงานวิจัย 57 ราย พบว่าผู้ที่ได้รับคู่มือการนับโปรตีน 18 ราย (ร้อยละ 60) และกลุ่มควบคุม 13 ราย (ร้อยละ 48.2) มีระดับแอลบูมินสูงขึ้นที่ 3 เดือน ความสามารถในการนับปริมาณโปรตีนที่ควรได้รับในแต่ละวันอย่างถูกต้อง พบในกลุ่มที่ได้รับคู่มือการนับโปรตีน 15 ราย (ร้อยละ 50) เทียบกับกลุ่มควบคุม 10 ราย (ร้อยละ 37) (ค่าพีเท่ากับ 0.43) ผู้ป่วยทั้งหมด 25 ราย (ร้อยละ 43.8) ที่สามารถนับปริมาณโปรตีนได้ถูกต้อง พบว่ามีการเพิ่มขึ้นของระดับแอลบูมินและ transferrin การลดลงของคะแนน CTP อย่างมีนัยสำคัญทางสถิติที่ 3 เดือน (ค่าพีน้อยกว่า 0.01) และมีการเพิ่มขึ้นของระดับ albumin การลดลงของคะแนน PG-SGA, CTP และ MELD อย่างมีนัยสำคัญทางสถิติที่ 6 เดือน (ค่าพีน้อยกว่า 0.01)

สรุป: คู่มือการนับโปรตีนอย่างง่ายอาจเพิ่มความสามารถในการนับปริมาณโปรตีนที่ควรได้รับในแต่ละวัน ซึ่งผู้ป่วยโรคตับแข็งทุกรายควรได้รับคำแนะนำทางโภชนาการเพื่อให้ได้รับโปรตีนในปริมาณที่เหมาะสมและมีภาวะโภชนาการที่ดี
