

Evaluation of UNECE U-12 as nutritional supplementation for surgical patients with malnutrition

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Abstract: The study aims to investigate the effect of UNECE U-12 supplementation on the nutritional status of surgical patients. The study was conducted in the Linkou Chang Gung Memorial Hospital. Post-operative cancer patients with chronic diseases, cachexia, who met one or more of these criteria: underweight, abnormally low albumin levels, malnutrition, and insufficient dietary intake. 67 patients were originally recruited, but only 36 completed the study. UNECE U-12 was given to patients daily as a partial replacement of their usual diet. Anthropometric analysis, biochemical measurements, and clinical examinations were performed at the baseline, 4 weeks and 8 weeks later. 36 participants did not have any adverse reactions to the UNECE U-12 supplementation. Blood glucose levels, blood lipids levels, hepatic and renal function were all normal. Serum albumin levels were significantly increased after 8 weeks of UNECE U-12 supplementation. Increases in transferrin levels were also observed after 4 weeks and 8 weeks of supplementation. HDL concentrations were elevated both after 4 weeks and 8 weeks. Total lymphocyte counts were also increased after 4 weeks of supplementation. In summary, UNECE U-12, a nutritional supplement designed for surgical patients improved their post-operative nutritional status in this short term study.

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1. Introduction

A proper diet is essential for nutrient support and each nutrient plays an important role. For example, protein is the major building block of blood, muscle and other tissues. Maintaining an adequate protein level is critical for tissue repair. In burn and post-operative patients, pregnant and lactating women, teenagers, elderly and sportsman, increased uptake of albumin is required to replenish protein loss or insufficiency to sustain proper functioning of the body organs. Of course, carbohydrate and fat and other trace nutrients such as vitamins and minerals are also indispensable in sustaining life.

Butterworth et al (1974) first reported a high prevalence of malnutrition in hospitalized patients [1]. Since then, an increasing research found that malnutrition is particularly prevalent in hospitalized elderly and post-operative patients. It was found that 20-50% of hospitalized patients who had chronic disease and/or undergone surgeries were malnourished [2,3,4]. For such patients, the purpose of the surgery is to provide treatment, but post-operative complications are also linked with malnutrition.

Therefore, nutritional support in the post-operative care plays a determinant role for the patient's recovery. In the present study, UNECE U-12 nutritional supplement, specifically designed for post-operative patients. The formula uses soybean protein with high biological value it also contains immunity-enhanced components such as L-Glutamine and L-

Arginine. The hypothesis is that UNECE U-12 supplementation can promote their nutritional status thereby enhancing their recovery.

2. Material and Methods

Study subjects

The study was approved by the Institutional Review Board of Chang Gung Memorial Hospital and was conducted in the Linkou Chang Gung Memorial Hospital. Participants were first selected by screening the inpatient registry. These patients (mostly received gastrointestinal surgeries) had cancer, chronic diseases, or cachexia. They must meet either of the criteria: underweight, abnormally low albumin levels, malnutrition, and insufficient dietary intake.

Procedures

1) Anthropometric measurements: midarm circumference (MAC), midarm muscle circumference (MAMC), and triceps skin fold (TSF) were measured. Weight and height were used to calculate Body Mass Index (BMI) (weight/height in kg/m²). The same researcher took the measurements to minimize the variability. The measurements were taken at the baseline, 4 weeks and 8 weeks after UNECE U-12 supplementation.

2) Biochemical measurements: blood was sampled after an overnight fast. These included plasma levels of albumin, transferrin, blood glucose, blood urine nitrogen, plasma lipids (TG, HDL-C, LDL-C and VLDL), hemoglobin, uric acid, creatinine,

iron, calcium, sodium, potassium, magnesium, phosphorus and hepatic function measurements including glutamate oxaloacetate transaminase (GOT), glutamic pyruvic transaminase (GPT), C-reactive protein (CRP) and Glutathione peroxidase, (GPX). Whole blood cell count including red blood cells (RBC), white blood cell (WBC), total lymphocyte counts and platelet numbers was also performed.

3) Clinical examination: any gastrointestinal discomforts including nausea, vomiting, diarrhea, and constipation were documented. Other adverse effects were also recorded.

Prior to the study, the participants were given individual nutritional consultation and their daily energy requirement was calculated. The study spanned 8 weeks. Each pack of UNECE U-12 is 58g (257Kcal) and contains 8.0% of protein (11.6g), 29.7% of fat (8.5g), and 52.3% of carbohydrate (33.6 g). Participants consumed 2-3 packs of UNECE U-12 as a snack between two meals. Nutritional status was evaluated at the baseline, 4 and 8 weeks.

Statistical analysis

Statistical analysis was conducted using the SPSS statistics software. The results are expressed as mean \pm SD. Results were compared using paired t-test and considered statistically significant if $p < 0.05$.

3. Results

67 participants aged 21-89 (average age 60.9 \pm 14.6 with valid consent met the criteria of the study. The median age was 63. All participants had gastrointestinal surgeries prior to the study. During the study, 13 participants left the study as they were unwell due to their diseases, 2 had discomforts from chemotherapy, and 3 had transport issues. 1 participant left due to disapproval from the family. 8 participants did not like the flavor. 4 participants transferred to another hospital or did not return for follow-ups. In total, data from 36 patients were analyzed. Some participants had gastrointestinal symptoms (6 with constipation, 9 with diarrhea, 3 with nausea, and 3 with vomiting), but these symptoms existed before taking the UNECE U-12, or they are associated with adverse effects from chemotherapy.

Weight and BMI were calculated at the baseline and at week 4 and week 8 (Table 1). At week 0 (baseline), the mean of weight and BMI were 50.11 \pm 8.48 (kg) and 19.18 \pm 2.38 (kg/m²), respectively. After the 4-week supplementation, the mean of weight and BMI were 50.05 \pm 8.04 (kg) and 19.20 \pm 2.52 (kg/m²), respectively. At week 8 the mean of weight and BMI were 50.17 \pm 8.11 (kg) and 19.25 \pm 2.51 (kg/m²), respectively. No significant difference was found when values from three phases were compared. At the baseline, TSF, MAC, and MAMC were 8.68 \pm 4.48(mm), 23.76 \pm 3.08(cm), and

21.03 \pm 3.21(cm), respectively. After 8 weeks of the supplementation, TSF, MAC, and MAMC were 9.05 \pm 5.05 (mm), 23.90 \pm 3.18 (cm), and 20.92 \pm 2.83 (cm). No significant change in TSF, MAC and MAMC was found after the supplementation (Table 2).

Table 1. Change in weight, BMI

	Baseline	Week 4	Week 8
Weight(kg)	50.11 \pm 8.48	50.05 \pm 8.04	50.17 \pm 8.11
BMI(kg/m ²)	19.18 \pm 2.38	19.20 \pm 2.52	19.25 \pm 2.51

n=36, Data are expressed as means \pm SD

Table 2.

	Baseline	Week 8
TSF (mm)	8.68 \pm 4.48	9.05 \pm 5.05
MAC(cm)	23.76 \pm 3.08	23.90 \pm 3.18
MAMC(cm)	21.03 \pm 3.21	20.92 \pm 2.83

n=36, Data are expressed as means \pm SD

The results of biochemical measurements are described in Table 3. Mean albumin levels was increased from 3.76 \pm 0.74 mg/dL at the baseline to 4.09 \pm 0.64 mg/dL after the 8-week supplementation. Transferrin concentrations also showed an increase from 208.23 \pm 70.43 mg/dL to 229.92 \pm 74.88 at week 4 and 243.71 \pm 78.55 at week 8. There were increases in concentrations of HDL from 42.74 \pm 18.79 mg/dL to 51.68 \pm 17.61 mg/dL at week 4 and 53.06 \pm 21.07 mg/dL at week 8. Total lymphocyte count was significantly increased after 4 week supplementation. Platelet counts after 8-week supplementation were significantly lower than the baseline.

Uric acid concentration was higher at both 4 week (6.27 \pm 2.48 mg/dL) and 8 week (6.59 \pm 3.53 mg/dL) compared to the baseline 5.33 \pm 1.99 mg/dL. But the concentrations at three phases were within the normal range.

4. Discussions

Food is essential for nutritional support and every nutrient plays an important role. A high proportion (approximately 20-50%) of hospitalized patients had malnutrition [2,3,4]. Post-operative care such as nutritional support is one of the main determinants for the patient's recovery. Serious complications may be closely associated with malnutrition. Therefore, nutritional and calories insufficiency may have a detrimental impact on the patient's recovery. In this study, a nutritional supplement was given to post-operative participants and we hypothesized the patient's nutritional status can be improved. Participants experienced no adverse effects after 4-8 weeks of UNECE U-12

supplementation. Biochemical test results for blood glucose, lipids levels, renal and hepatic function were normal.

Table 3. Comparison of biochemical measurements at the baseline and after 4- or 8-week's intervention.

	Baseline	Week 4	Week 8
RBC (million/ μ L)	3.95 \pm 0.91	3.89 \pm 0.81	4.01 \pm 0.75
Hemoglobin (g/dL)	11.26 \pm 1.81	11.25 \pm 1.53	11.61 \pm 1.51
WBC(1000/ μ L)	8108 \pm 4137	7656 \pm 4157	7344 \pm 3138
Platelets(1000/ μ L)	277940 \pm 110840	253970 \pm 100771	239220 \pm 82036*
Total lymphocyte count (TLC) (1000/ μ L)	1763.09 \pm 1161.47	2023.11 \pm 1400.04*	1912.43 \pm 1135.28
Albumin(g/dL)	3.76 \pm 0.74	3.89 \pm 0.62	4.09 \pm 0.64**
Total protein (mg/L)	20.86 \pm 9.19	23.37 \pm 9.16	22.85 \pm 7.66
Transferrin (mg/L)	208.23 \pm 70.43	229.92 \pm 74.88*	243.71 \pm 78.55**
Blood glucose(mg/dL)	117.89 \pm 42.42	114.66 \pm 38.85	109.71 \pm 29.77
Blood urea nitrogen (mg/dL)	14.83 \pm 6.75	16.89 \pm 7.47	15.89 \pm 6.79
TG (mg/dL)	141.43 \pm 163.22	133.08 \pm 85.23	140.09 \pm 101.11
Cholesterol (mg/dL)	142.89 \pm 37.27	154.47 \pm 37.47	156.75 \pm 34.79
HDL-C (mg/dL)	42.74 \pm 18.79	51.68 \pm 17.61**	53.06 \pm 21.07**
LDL-C (mg/dL)	85.53 \pm 63.05	91.44 \pm 62.01	102.38 \pm 82.11
VLDL(mg/dL)	36.83 \pm 69.99	35.67 \pm 64.66	28.06 \pm 20.10
Uric acid(mg/dL)	5.33 \pm 1.99	6.27 \pm 2.48*	6.59 \pm 3.53*
Creatinine(mg/dL)	0.84 \pm 0.34	0.86 \pm 0.36	0.82 \pm 0.31
Iron(μ g/dL)	61.20 \pm 40.92	67.31 \pm 34.00	67.00 \pm 33.50
Calcium(mg/dL)	8.84 \pm 0.62	8.91 \pm 0.53	8.94 \pm 0.54
Sodium(mEq/L)	139.51 \pm 4.05	140.74 \pm 3.37	140.86 \pm 2.92
Potassium(mEq/L)	4.28 \pm 0.55	4.41 \pm 0.38	4.20 \pm 0.55
Magnesium(mEq/L)	1.74 \pm 0.25	1.79 \pm 0.16	1.77 \pm 0.15
Phosphorus(mg/dL)	3.71 \pm 0.77	3.53 \pm 0.63	3.60 \pm 0.72
GOT (U/L)	27.61 \pm 16.90	29.49 \pm 15.30	29.58 \pm 18.70
GPT (U/L)	23.53 \pm 18.31	25.11 \pm 15.53	26.36 \pm 21.00
CRP (mg/L)	21.53 \pm 41.58	10.98 \pm 18.55	9.28 \pm 11.28
GPX (U/g)	43.89 \pm 14.03	44.75 \pm 15.74	43.64 \pm 14.65

Data are expressed as mean \pm SD, * p <0.05 ** p <0.01

After 4 to 8 weeks of supplementation, body weight did not show any significant change. Possible increase in weight may be masked by the attenuated post-operative condition such as edema. Improved nutrition can lead to an increase in albumin levels. An increase in post-operative albumin levels can help ameliorate edema. In addition, most of participants were wither cancer or patients with gastrointestinal diseases. After surgery, weight loss is common. The fact that the weight was maintained at similar levels could provide an indirect proof for improved nutritional status is an indirect proof for improved. 4 to 8 week supplementation led to an increase in albumin levels. UNECE U-12 contains high quality whey protein, which quickly enters the gastrointestinal tract to be absorbed [5]. This may contribute to the increase in the serum albumin levels.

Significant increases in HDL concentrations were found both after 4 weeks and 8 weeks of supplementation. Chronic disease patients often high risks for various cardiovascular diseases. HDL, commonly known as "good lipoprotein", can scavenge excess cholesterol. The cholesterol/HDL emulsifies with bile acid and is excreted through the gastrointestinal tract [6]. Hence, higher levels of HDL could help clean up the blood vessels. Moreover, HDL can also exert anti-oxidant and anti-inflammatory effects to prevent plaque formation. So higher levels of HDL can prevent and lower the risks of cardiovascular diseases [7].

Total lymphocyte count was significantly increased after 4 weeks of supplementation of UNECE U-12, and this may indicate enhanced immunity. There was a trend of decrease in platelet

numbers. As most of participants were post-operative cancer patients, the reduction is likely attributed to the course of the treatment such as chemotherapy. An increase in uric acid concentration is likely due to the inter-personal difference in purine metabolism. This increase may also be associated with the surgery, radiotherapy or drugs. Other biochemical measurements such as blood glucose, lipids, hepatic and renal function were all normal and had no significance change.

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