

The Amelioration of Nutritional Status and Phase Angle, Safety, and Satisfaction in Tube-Fed Patients With Ready-to-Use Blenderized Diet With Chicken and Pumpkin

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Background: The requirement of a hospital-made, blenderized diet, as a generally used and complete polymeric formula, is increasing beyond supply availability and accessibility. A ready-to-use blenderized diet with chicken and pumpkin in a retort pouch was developed from regular use formula by nutritionists and dietitians to solve these problems. However, its clinical outcomes should be evaluated.

Objectives: To assess the efficacy and safety of a ready-to-use blenderized diet, and to examine the satisfaction of patients and caregivers.

Methods: Thirty adult patients in Ramathibodi Hospital with absolute tube feeding were included in a pre-post treatment comparative study and fed with the study formula for 14 days. Body composition measurements, nutritional status, clinical parameters, and biochemical tests were collected at baseline and day 14 after feeding. Complications were monitored daily. Satisfaction was evaluated at day 14.

Results: This study reported statistically significant improvements in nutritional status ($P < .001$), albumin ($P = .003$), prealbumin ($P = .007$), total lymphocytic count ($P = .004$), and phase angle ($P = .02$) after 14-day feeding. No major complications were reported. Satisfaction of product use was evaluated in the level of satisfied (27%) and very satisfied (73%).

Conclusions: The present study revealed that a ready-to-use blenderized diet with chicken and pumpkin was efficacious in ameliorating nutritional status, nutrition-related blood tests, and phase angle without any major complications.

Keywords: Blenderized diet, Enteral nutrition, Nutritional status, Malnutrition, Phase angle

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Introduction

The prevalence of malnutrition is higher in hospitalized patients^{1,2} and those with a chronic illness³ comparing with the general population. Malnutrition, particularly in terms of protein malnutrition, is associated with worsening clinical outcomes, impairment of functional status, immune system, wound healing, and cognitive function, as well as increase in hospital readmission and mortality rate.⁴ Prolonged, inadequate dietary consumption can lead to malnourishment. Appropriate nutritional management plays an important role in prevention and improvement of this condition. Oral supplements or enteral feeding should be considered in patients eating less than daily dietary requirement.⁵

In patients with intact gastrointestinal function, enteral nutrition is a preferable method due to lower severe complications and better clinical outcomes such as reduced infections, hospital costs, and length of stay.⁶⁻⁸ Moreover, this feeding method can preserve healthy gut function such as minimized villi atrophy, endocrine organ function, barrier against bacteria, and immunological function.^{9,10} Because of these reasons, enteral feeding is increasingly used to ensure that patients receive their nutritional needs in both hospital and community setting.¹¹

Blenderized diet is a complete polymeric formula for tube feeding in patients with normal gastrointestinal function. This diet is produced from blended natural foods by dietitians or nutritionists with standardized control and served for hospital-based use. The advantages of this diet are the tailor-made formulas, natural sources of products, and lower costs.¹² However, it must be used within 24 hours of production.^{13,14}

Nowadays, the number of patients with chronic illness outside the hospital is continuously increasing and blenderized diet is prepared and used at home by patients or their caregivers, as well as during nursing home care by specialized health providers, particularly after hospital discharge. Previous studies^{15,16} showed that higher amounts of bacterial contamination and

increased osmolarity, viscosity, and physical and chemical instability were found in homemade blenderized enteral diets compared with standard blenderized diets.

Furthermore, the homemade blenderized diets contained less than half of the prescribed energy and macronutrients, and resulted in diarrhea, tube feeding obstruction, and inadequate nutrient intake.¹² Given these reasons and the inconvenience of self-preparation, many patients decide to order blenderized diets from hospitals. The higher blenderized diet requirement becomes a burden of hospital personnel to produce and wasting patients' time in daily transportation to the hospital.

Consequently, a ready-to-use blenderized diet with chicken and pumpkin in a retort pouch was created to address these problems. This product has a long shelf life (up to 3 months), which prevents microbial agents and preserves macronutrients. However, its efficacy and safety in patients must be confirmed.

This study aimed to assess the efficacy and safety of a ready-to-use blenderized diet with chicken and pumpkin in a retort pouch and to evaluate the satisfaction of patients and their caregivers with this product.

Methods

Study Population

The study was designed as a pretreatment and posttreatment comparative, open-label study conducted in the in-patient unit at Ramathibodi Hospital. Thirty adult patients who required tube feeding for total energy intake at least 14 days were included. Participants received other sources of calories (eg, oral diet or parenteral nutrition), had contraindication to enteral feeding (ie, gut obstruction, intestinal failure and malabsorption), and had the condition such as impaired renal function (estimated glomerular filtration rate [eGFR] less than 60 mL/min/1.73 m² or proteinuria more than 3.5 g/day), severe hepatic injury (Child-Pugh score class C), pregnancy, breast-feeding, severe sepsis, hemodynamic instability, abnormal metabolic diseases (ie, thyroid diseases), and allergy for study

formula composition were excluded. Baseline data of participants including age, sex, and medical history were recorded. Anthropometric measurements and physical examination were performed by the same physician in nutrition specialist. Nutritional information, including 24-hour dietary recall, was collected by the same well-trained dietitian from patients, caregivers, or nursing staffs. All clinical data, blood, and urine were also collected at baseline and 14 days postintervention.

All participants had been fed by the intermittent method with a ready-to-use blenderized diet with chicken and pumpkin via tube in 25 - 30 kcal/kg/day of energy for 14 days. All complications related to feeding, including nausea, vomiting, diarrhea, aspiration, clogged tubes, and allergies, were closely monitored daily. Diarrhea was defined as passage of loose stools often with more frequent bowel movements.¹⁷

Satisfaction in the feeding-formula product was anonymously assessed by patients and caregivers using a 1 (very dissatisfied) to 5 (very satisfied) rubric scale at the end of study. Sample size was strategic by comparing with the number of participants in the previous studies which were similar to this study in term of study design and intervention.^{18, 19}

Ethics Approval and Consent to Participate

The protocol was approved by the Ethics Committee on Researches Involving Human Subjects, Faculty of Medicine, Ramathibodi Hospital, Mahidol University (MURA2014/633 on December 18, 2014). Before participation in this study, written informed consent was obtained from each participant.

Study Formula

A ready-to-use blenderized diet with chicken and pumpkin in a retort pouch is a standard and complete enteral formula for patients with intact gastrointestinal function who require tube feeding, developed under cooperation between Faculty of Medicine Ramathibodi Hospital and Charoen Pokphand Foods Public Company, Ltd; and provided by Charoen Pokphand Foods Public Company, Ltd. The formula is composed of chicken breast, pumpkin, banana, egg, rice bran oil, soy lecithin, glucose syrup, iodine salt, calcium carbonate, and water. In terms of macronutrient composition, this formula contains moderately high protein (16.35% of total energy) (Table 1). This ready-to-use formula is prepared by sterilization method and preserved in a retort pouch. Each package contains 300 mL and has a shelf life of 90 days at room temperature (25°C). Measures of food quality and safety control including physical and chemical properties, microbiological tests, and heavy metal analysis were also evaluated as required by law.

Measurement and Laboratory Determinations

All measurements were performed on days 0 and 14 under fasting conditions for 8 hours. Anthropometric parameters including weight and height were measured with standard techniques by the same physician. Blood samples were obtained under aseptic conditions and analyzed by standard methods for complete blood count, serum albumin, prealbumin, lipid profile, creatinine, liver function tests and electrolytes, and plasma glucose.

Table 1. Macronutrient Composition in the Study Formula

Nutrient	Amount (per 100 g), g	Energy (per 100 g), kcal	Amount (per 1000 kcal), g	Distribution of Energy, %
Protein	4.50	18.00	40.87	16.35
Carbohydrate	14.32	57.28	130.05	52.02
Fat	3.87	34.83	35.15	31.63
Energy	-	110.11	-	100.00
Fiber	1.08	-	9.81	-

The nutritional screening was performed by the same well-trained dietitian using Nutrition Alert Form (NAF).²⁰ The NAF comprises simplified malnutrition screening tools modified from the original version of the Subjective Global Assessment (SGA)²¹ and validated in the Thai population. This tool is composed of 8 sections: height, weight and body mass index (BMI), body build, weight change, dietary intake change, gastrointestinal symptoms, functional capacity and patient's disease, and added serum albumin levels and total lymphocyte counts for patients whose weight could not be taken. NAF is calculated as a score and classified participants into 3 groups: NAF A or normal to mild malnutrition (score, 0 - 5); NAF B or moderate malnutrition (score, 6 - 10); and NAF C or severe malnutrition (score, ≥ 11).

Body compositions such as fat mass, skeletal muscle mass, extracellular and intracellular water, and phase angle were measured by the same physician in clinical nutrition, using bioelectrical impedance analysis (BIA).²² BIA machine was a multi-frequency impedance analyzer (model InBody S10, Biospace Co, Ltd, Seoul, Korea) providing 6 different frequency impedance measurements (1, 5, 50, 250, and 1000 kHz). Phase angle is the tan value of the ratio of reactance versus electric resistance, reported by BIA at 50 kHz. The low angle is associated with malnutrition and high mortality rate.²²⁻²⁴

Statistical Analysis

Means and standard deviation (SD) for continuous variables and frequencies (%) for binary or categorical variables were presented. Paired *t* test or Wilcoxon signed rank test and chi-square test were used to compare anthropometric measurements, nutritional status, and clinical parameters between baseline and after study formula feeding at 2 weeks. A *P* value less than .05 was considered statistically significant. The statistical analysis was conducted using SPSS version 24.0 (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp; 2016).

Results

A total of 30 patients were enrolled; 60% of those were male. The mean age was 57.91 years (SD, 17.22; range, 24.00 - 86.00). At baseline, the mean BMI was 19.23 kg/m² (SD, 3.65) and 43.33% of patients had BMI less than 18.5 kg/m². Regarding nutritional status, 63.33% of participants were severely malnourished as measured using NAF. The majority of participants were oncological patients (46.67%), followed by patients with cerebrovascular disease (33.33%) (Table 2).

Table 2. Baseline Characteristics of Participants (N = 30)

Characteristic	No. (%)
Gender	
Male	18 (60.00)
Female	12 (40.00)
Age, y	
≤ 60	14 (46.67)
> 60	16 (53.33)
BMI, kg/m ²	
< 18.5	13 (43.33)
18.5 - 22.9	14 (46.67)
≥ 23.0	3 (10.00)
NAF group	
A	2 (6.67)
B	9 (30.00)
C	19 (63.33)
Feeding route	
Nasogastric tube	26 (86.67)
Gastrostomy	4 (13.33)
Underlying disease	
Malignancy	14 (46.67)
Head and neck cancer	11 (36.67)
Brain cancer	2 (6.67)
Other cancers	1 (3.33)
Cerebrovascular disease	10 (33.33)
Others	6 (20.00)

Abbreviations: BMI, body mass index; NAF, nutrition alert form.

Each participant was provided the same amount of diet during 14 days of intervention. All participants were able to receive an adequate amount of energy and protein. The average energy and protein intakes during the study were 1386.42 ± 217.15 kcal/day (28.55 ± 6.87 kcal/kg/day) and 68.83 ± 10.8 g/day (1.42 ± 0.34 g/kg/day), respectively. The mean energy and protein intakes did not significantly differ to the dietary consumptions before receiving study formula.

To compare between pre and post 2-week feeding, nutritional status was significantly improved in median NAF score (from 12.50 to 8.00) and nutritional status level from NAF B to NAF C ($P < .001$). The percentage of severely malnourished patients (NAF C) was also reduced from 63.3% to 33.3%. Furthermore, biochemical tests related to nutritional status were improved. Means for serum albumin, pre-albumin, and total lymphocyte count were also significantly increased. In addition, the mean phase angle was increased from 4.59 to 6.74 degrees ($P = .02$). Nonetheless, no statistically significant changes were found in body composition and BMI. With regards to biochemical change, a statistically significant decline in mean plasma glucose levels from 6.01 to 5.57 mmol/L (118.4 to 100.4 mg/dL) was observed ($P = .002$). No significant difference in lipid profile,

liver function tests, and serum creatinine was observed between baseline and after 2 weeks of blenderized diet feeding (Table 3).

Regarding other adverse effects, 2 participants were reported having diarrhea from days 2 to 4 after feeding; however, the stool reports in both cases described only an increase of stool frequency without changes in consistency or evidence of infection, and the defecation became normal on day 5. Bloating and abdominal distention were presented in 2 cases by the same participants for 1 day (on day 2) in the first case and for 5 days (from day 2 to day 6) in the other. No vomiting, aspiration, allergies, nor clogging of tubes was detected (Table 4).

This study also evaluated the satisfaction of patients or their caregivers in study product use. All assessments indicated a score of 4 (satisfied) or 5 (very satisfied) and 73% were 5 points. Some favorable comments indicated that the product was convenient and easy use, the product can save time in purchase and preparation, and the care giver feel trust in the product since the product is prepared and controlled by hospital. Additionally, some suggestions for development opportunities were the bag should vary in size, and the packaging should be easy to storage after opening.

Table 3. Comparison of Dietary Intake, Anthropometric Measurements, Nutritional Status, and Clinical Parameters Between Baseline and 2 Weeks After Blenderized Diet Feeding (N = 30)

Between Baseline and 2 Weeks After Blended Diet Feeding (N = 56)			
Clinical Parameter	Mean ± SD		P Value**
	Baseline	Week 2	
Dietary data *			
Energy intake, kcal/day	1299.00 ± 368.24	1386.42 ± 217.15	.84
Protein intake, g/day	65.76 ± 15.30	68.83 ± 10.80	.65
BMI, kg/m ²	19.23 ± 3.65	19.37 ± 3.51	.39
Nutritional status			
NAF score, median [IQR]	12.50 [7.75 - 14.00]	8.00 [6.00 - 12.00]	< .001
NAF group, No. (%)			
A	2 (6.67)	3 (10.00)	.02
B	9 (30.00)	17 (56.67)	
C	19 (63.33)	10 (33.33)	

Table 3. Comparison of Dietary Intake, Anthropometric Measurements, Nutritional Status, and Clinical Parameters Between Baseline and 2 Weeks After Blenderized Diet Feeding (N = 30) (Continued)

Clinical Parameter	Mean \pm SD		P Value**
	Baseline	Week 2	
Body composition			
Skeleton muscle mass, kg	19.48 \pm 4.47	19.52 \pm 4.19	.90
Fat mass, kg	13.53 \pm 9.30	13.80 \pm 8.90	.63
Body fat, %	24.82 \pm 13.32	25.42 \pm 12.26	.62
ECW/TBW	0.40 \pm 0.01	0.40 \pm 0.01	.17
Albumin, g/L	26.66 \pm 4.78	28.63 \pm 4.65	.003
Prealbumin, g/L	19.25 \pm 9.38	22.18 \pm 9.20	.007
Total lymphocyte count, 10 ⁹ /L)	1.32 \pm 0.48	1.73 \pm 0.85	.004
Fasting plasma glucose (mmol/L)	6.01 \pm 1.07	5.57 \pm 1.19	.002
Lipid profile			
Triglycerides (mmol/L)	1.35 \pm 1.11	1.42 \pm 0.87	.61
Cholesterol (mmol/L)	4.49 \pm 1.05	4.33 \pm 0.97	.22
HDL-c (mmol/L)	1.09 \pm 0.30	1.10 \pm 0.27	.31
LDL-c (mmol/L)	2.71 \pm 0.77	2.55 \pm 0.76	.23
Creatinine (μ mol/L)	73.37 \pm 29.17	69.84 \pm 26.52	.15
Alkaline phosphatase (U/L)	111.37 \pm 43.51	101.23 \pm 32.53	.07
Aspartate aminotransferase (U/L)	33.47 \pm 18.42	28.57 \pm 12.91	.14
Hemoglobin (g/L)	111.00 \pm 13.31	113.67 \pm 15.12	.23
Phase angle, degree	4.59 \pm 2.72	6.74 \pm 4.60	.02

Abbreviations: BMI, body mass index; ECW, extracellular water; HDL-c, high-density lipoprotein cholesterol; IQR, interquartile range; LDL-c, low density lipid cholesterol; NAF, nutrition alert form; SD, standard deviation; TBW, total body water.

* Dietary intake before received the study formula at baseline.

** There were statistical significance between baseline and after 2-week fed with study formula when P value < 0.05.

Table 4. Number of Cases With Side Effects

Side Effect	No.								
	Day 0	Day 2	Day 4	Day 6	Day 8	Day 10	Day 12	Day 14	
Diarrhea	0	2	2	0	0	0	0	0	
Gastrointestinal side effects									
Vomiting	0	0	0	0	0	0	0	0	
Bloating	0	2	1	1	0	0	0	0	
Abdominal distention	0	2	1	1	0	0	0	0	
Aspiration	0	0	0	0	0	0	0	0	
Allergy	0	0	0	0	0	0	0	0	
Product physical change (color or consistency)	0	0	0	0	0	0	0	0	
Clog of tube feeding	0	0	0	0	0	0	0	0	

Discussion

Optimized nutritional management prevents and improves malnutrition and its related diseases. Owing that enteral feeding is efficacious, physiological and tolerated well in general patients, enteral nutrition via tube feeding is recommended in inadequate oral intake patients with intact gastrointestinal function⁵ for achieve feeding goals and resulting in improved malnutrition. The ready-to-use blenderized diet with chicken and pumpkin is a standard, complete enteral formula developed from a Ramathibodi Hospital blenderized diet, which has been made for feeding in hospitalized patients since 1972. The present study examined the efficacy and safety of a ready-to-use blenderized diet with chicken and pumpkin in a retort pouch and evaluated the satisfaction in this product. All participants tolerated the study diet and received an adequate energy and protein balance. The nutritional status was also significant improved after receiving the study diet for 2 weeks.

This study revealed feeding with ready-to-use formula improve nutritional status evaluated using NAF and nutrition-related biochemistry parameters such as serum albumin, serum prealbumin, and total lymphocyte count. This confirmed the efficacy of the formula in improving malnutrition. By 24-hour dietary recall, the amount of energy and protein intake did not differ between the previous and during the study periods. Before the study, the percentage of patients fed with home-made blenderized diet, prescribed commercial formula, and consuming per oral were 63.3, 13.3, and 23.3, respectively. The amelioration of nutritional status could be resulted from adequate macronutrient receive as prescription, good compliance, nutrient balance, and easy digestion and absorption.

This study found that participants improved in their phase angles. However, significant changes in other body compositions were not demonstrated during this 2-week study. Given that a significant increase in skeleton mass requires many factors, a longer duration of study and physical intervention may be required to

achieve this result. Some patients in this study were dependent and cannot perform active exercise, especially resistance exercise. Nevertheless, the ready-to-use formula could maintain body weight and skeletal muscle mass. Since phase angle is a parameter correlated with malnutrition and mortality of hospitalized patients,²³⁻²⁵ its alteration may reflect a good health signal in the participants.

In terms of safety, only minor side effects were reported in a few cases and all symptoms resolved spontaneously over a short period of time. No major events, including aspiration or food allergies, were reported during the 14 days of intervention. Because of the standardized preparation and sterilization process, no physical change of the blenderized diet was observed during the intervention within 3 months following production. Common pathogens could not be detected from microbiological tests. Nutritional status (using NAF) of patients fed with study formula stored less than 2 months and more than 2 months did not significantly differ at the end of study (data were not shown). Concerning metabolic complications, neither kidney nor liver abnormalities were observed in the participants during 2 weeks of study. This showed the safety of the ready-to-use formula.

In terms of satisfaction, both patients and their caregivers appreciated this diet compared with a traditional blenderized diet. Moreover, the study formula received additionally positive comments related its preparation, using and confidence.

This is the first study of ready-to-use, in a retort pouch, and hospital-based blenderized diet in Thailand. Comparing with other enteral formula, this blenderized diet is more advantageous that it is a moderately high-protein, low-carbohydrate, and well-tolerated formula and is previously prescribed in hospital for almost 5 decades. These properties benefit in positive protein-nitrogen balance, improved plasma glucose management, adequate intake and good compliance.^{18, 26}

However, the present study has some limitations should be concerned. The number of participants is modest but the sample size does not much differ comparing

with the previous studies with the same design and intervention in Thai population.^{18, 19} There was no control group owing that the study was designed as preintervention and postintervention. The majority of participants in this study were patients with oncological and cerebrovascular disease; nonetheless, the common diseases of patients requiring an enteral feeding in both hospital and homecare setting are stroke and cancer. Further studies in different settings and large population are warranted to confirm the efficacy of this dietary formula in long-term and real life use.

Conclusions

The enteral feeding with a ready-to-use blenderized diet with chicken and pumpkin ameliorated nutritional status, nutrition-related lab tests, and phase angle in

tube-fed patients without major complications. Moreover, this diet was the convenience and easy use confirmed by the satisfaction of the patients and their caregivers. Additionally, this enteral product could be practical to use in both hospital and community settings owing to containing complete nutrients, being prepared with a hospital-based composition, and possessing a long shelf life.

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การศึกษาการดีขึ้นของภาวะโภชนาการและมุมเฟส ความพึงพอใจ และความปลอดภัย ในผู้ป่วยที่ได้รับสารอาหารทางสายยางด้วยอาหารปั่นพร้อมใช้ผสมไก่และผักทอง

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บทนำ: ความต้องการอาหารปั่นครบสูตรที่ผลิตโดยโรงพยาบาลซึ่งเป็นอาหารครบสูตรและใช้กันทั่วไปกำลังเพิ่มขึ้นจนเกินความพร้อมและการเข้าถึงการให้บริการอาหารปั่นผสมไก่และผักทองในบรรจุกักตุนพร้อมใช้จึงถูกพัฒนาขึ้น โดยแพทย์ด้านโภชนาการและนักกำหนดอาหารเพื่อแก้ไขปัญหาอย่างไรก็ตาม จำเป็นต้องมีการประเมินผลลัพธ์ทางคลินิกของอาหารนี้

วัตถุประสงค์: เพื่อศึกษาประสิทธิภาพและความปลอดภัยของอาหารปั่นพร้อมใช้และความพึงพอใจของผู้ป่วยและผู้ดูแล

วิธีการศึกษา: การศึกษาเชิงทดลองเปรียบเทียบผลก่อนและหลังได้รับสารอาหารเป็นเวลา 14 วัน ในกลุ่มตัวอย่างผู้ป่วยผู้ใหญ่ที่ได้รับสารอาหารทางสายยางเท่านั้นจำนวน 30 คน ณ โรงพยาบาลรามาธิบดี โดยการวิเคราะห์องค์ประกอบของร่างกายภาวะทางโภชนาการ ตัวชี้วัดทางคลินิก และผลตรวจทางชีวเคมี เปรียบเทียบก่อนและหลังได้รับสูตรอาหารเป็นเวลา 14 วัน ติดตามภาวะแทรกซ้อนทุกวันและประเมินความพึงพอใจในวันที่ 14 ของการศึกษา

ผลการศึกษา: จากกลุ่มตัวอย่างผู้ป่วย จำนวน 30 คน พบว่า หลังได้รับสูตรอาหารเป็นเวลา 14 วัน ผู้ป่วยมีภาวะโภชนาการ ($P < .001$) ระดับอัลบูมิน ($P = .003$) ระดับพรีอัลบูมิน ($P = .007$) จำนวนเม็ดเลือดขาวชนิดลิมโฟไซต์ ($P = .004$) และมุมเฟส ($P = .02$) ดีขึ้นอย่างมีนัยสำคัญ ไม่พบภาวะแทรกซ้อนที่สำคัญ ความพึงพอใจต่อการใช้ผลิตภัณฑ์อยู่ในระดับน่าพอใจ (ร้อยละ 27) และระดับน่าพอใจมาก (ร้อยละ 73)

สรุป: การศึกษานี้แสดงให้เห็นว่าอาหารปั่นผสมไก่และผักทองในบรรจุกักตุนพร้อมใช้มีประสิทธิภาพทำให้ภาวะโภชนาการ ผลตรวจทางห้องปฏิบัติการ และมุมเฟสดีขึ้นโดยปราศจากภาวะแทรกซ้อนที่สำคัญ

คำสำคัญ: อาหารปั่น การให้อาหารเข้าทางเดินอาหาร ภาวะโภชนาการ ภาวะทุพโภชนาการ มุมเฟส

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