An Open Study of Efficacy, Safety and Body Weight Changing in the Blendera-Tube Fed Patients

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Objective: *To determine the efficacy and safety of Blendera in patients with tube feeding.*
Material and Method: *An open study with twenty-one subjects who required tube feeding in Bhumibol Adulyadej Hospital were fed with Blendera for seven days. Nutritional status, weight, laboratory values and complications were assessed on day 0 (baseline), day 3, and day 7.*
Results: *Tube-fed patients supported with commercial Blendera formula maintained nutritional status safely with the statistically significant improvement of potassium, calcium, magnesium, prealbumin, triglycerides, and HDL, p-value < 0.05. Especially patients with severe malnutrition status were getting better during the feeding period, p-value 0.028. In addition, there was no statistically significant difference in weight and nutritional status between genders.*
Conclusion: *Subjects supported with Blendera are effective in preventing significant weight loss and improves nutritional status without complications. The formula provides all the nutrients when administered daily.*

Keywords: *Bhumibol Adulyadej Hospital Nutrition Triage (BNT), Blendera, Blenderized diet, Commercial formula, Enteral tube feeding, Fiber, Hospital-prepared tube feeding, Intermittent tube feeding, Medium chain triglyceride*

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Nutrition plays an important role in the prevention and management of many diseases. People with illness may consume inadequately. The problems include anorexia, mouth, neck, or esophagus problems, and unconsciousness. To avoid prolonged starvation in patients, nutrition support is needed[1]. Patients with functional gut who are unable or not allowed to eat in general should receive enteral feeding, which is generally considered safer than parenteral feeding[2]. The physicians judge whether the patients receive enteral tube feeding based on serving sufficient nutrition to patients. Subsequently, this prevents malnutrition and shortens the duration of illness.

Blenderized diet is an enteral formula for patients with a functional gut who are unable or not allowed to eat. Hospital-prepared tube feeding is blended natural whole foods. This has some disadvantages of preparation process, sterilization, lactose intolerance from milk, storage, particle size, time consuming, and personnel. It was suggested that the tube feedings with blended natural whole foods were unacceptable from the perspective of bacterial contamination compared with a reconstituted commercial powdered nutrition[3]. To overcome these difficulties, commercial formula is designed for both oral intake and tube-feeding. The completed formula can be adjusted according to patient requirement. The benefits of commercially blenderized formula over hospital prepared tube-feeding are the uniformity of particle size that eliminates the tube obstruction and simple preparation by dissolving in water. Diarrhea is one of the problems found in hospital prepared formula. It may be caused by non-sterility, lactose, or osmolarity. Blendera, a commercial formula, used in the present study can calculate the required amount dissolved in water in a proper proportion and contains no lactose. These prevent diarrhea. Furthermore, the water-soluble fine particles lessen the incidence of tube obstruction, distention, flatulence, and reduce gastric residual volume[2]. Some source of fats, medium-chain triglyceride (MCT) has been included in this formula. Unlike long-chain fatty acids, MCT is reduced chain length also means that MCT is more rapidly absorbed by the body, more quickly metabolized and independent of carnitine transport into the mitochondria. This characteristic accelerates MCT metabolic conversion to energy instead of being stored as fat[4,5].

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Fiber, in additionally, is contained in the formula. When soluble fiber is fermented, short-chain fatty acids (SCFA) are produced. SCFAs are involved in numerous physiological processes promoting health, including stabilize blood glucose levels[6], regulating glucose absorption[7] provide nourishment of colonocytes, suppress cholesterol synthesis by the liver and reduce blood levels of LDL cholesterol and triglycerides responsible for atherosclerosis, improve barrier properties of the colonic mucosal layer and also soften the stool[8-11].

The present study aimed to determine the efficacy and safety of Blendera in patients with tube feeding.

Material and Method

Permission to conduct the present study was granted by the Ethic Committee for Researches Involving Human Subjects, Bhumibol Adulyadej Hospital, Royal Thai Air Force Bangkok, Thailand (March 15, 2010). Twenty-one subjects required tube feeding between June 9 and November 19, 2010 in Bhumibol Adulyadej Hospital were fed with Blendera for seven days. The informed consent forms were obtained from participants or legally representatives. Inclusion criteria were those who were at least 18 years of age and required tube feeding. Exclusion criteria were those who had gastrointestinal tract obstruction, severe diarrhea, severe hepatic impairment (Class C Child Pugh Classification), severe kidney impairment (stage 4 or higher) or the level of serum creatinine was at least more than three times of upper limit, severe septicemia, pregnancy or woman with breast-feeding, and allergy to any composition of Blendera such as soy protein. Subjects enrolled in the present study were physically examined and weighed with Oryza Model BFC 6[12]. Primary outcome was suggested by nutritional status on day 0, day 3, and day 7. Data collection included age, gender, height, weight, arm circumference, and vital sign. A complete blood profile, urinalysis including 24-hour urine urea nitrogen and urine creatinine was collected. Serum chemistry including albumin, prealbumin, total protein, and transferrin were also evaluated. The subjects received total energy 25 to 35 kcal/kg/day and protein 0.8 to 1 g/kg/day with the study formula, Blendera, 1 kcal/mL within 24 to 48 hours of stable hemodynamic status. The intermittent feeding was used as the prescribed nutrition delivery. Intermittent feeding is preferred for nasogastric feedings because the stomach can act as a reservoir, does not require a pump, and may be more physiological[13]. Nutrition parameter comprised energy requirement, energy concentration, nitrogen balance, gastric residue, and abdominal circumference. Nutritional status was measured as Bhumibol Adulyadej Hospital Nutrition Triage (BNT)[14]. BNT is a tool for evaluate malnutrition status developed by Bhumibol Adulyadej Hospital since the year of 2000. All data were collected every day except laboratory assessment was done on day 0, day 3, and day 7. Gastrointestinal complications were also evaluated as diarrhea, GI discomfort, and allergy. Diarrhea was defined as performing liquid stool more than three times a day[15,16] or based on the investigator's judgment. The quantity and frequency of stool affect the electrolytes, fluid or acid-base imbalance[17].

Statistical analysis

Continuous variables were presented as mean with standard deviation (SD) or mean with range and categorical variables as number with percentage. Statistical significance was tested by using repeated measure one way ANOVA for comparisons of all parameters in each patient between day 0 and day 1,

Blendera formula

Nutrients	Ingredients	Amount/100 g	Caloric distribution
Protein	Sodium caseinate (8%)-g Soy protein isolate (92%)-g	16.70	15%
Carbohydrate	Dextrin (68%)-g Sucrose (32%)-g	60.75	55%
Fat	Rice bran oil (92%)-g Medium chain triglyceride (8%)-g	15.00	30%
	Fructo-oligosaccharide (FOS)	2.25	
Others	Vitamins & Minerals Carrageenan Emulsifiers		

Table 1. Patient demographic data and vital signs (n = 21)

Variables	Statistic		
	Mean ± SD	Minimum	Maximum
Age (yr)	64.5 ± 16.8	18	91
Sex			
Male; n (%)	13 (61.9%)		
Female; n (%)	8 (38.1%)		
Height (cm)	161.7 ± 8.4	148	180
Weight (kg)	56.3 ± 16.8	32.4	95.4
Arm circumference (cm)	25.2 ± 4.4	18	32
Temperature (°C)	36.8 ± 0.6	36	37.8
Systolic (mmHg)	126.1 ± 18.7	98	160
Diastolic (mmHg)	71.8 ± 10.1	57	89
Pulse rate (beats/min)	93.6 ± 15.2	66	120
Respiratory rate (times/min)	21.7 ± 3.2	17	30

Table 2. Compare nitrogen balance of baseline, day3 and day 7

Variables	Day 0	Day 3	Day 7	p-value		
				3 times	D0 vs. D3	D0 vs. D7
Nitrogen balance: mean ± SD	-2.6 ± 5.2	-2.4 ± 3.1	-0.7 ± 3.4	0.21	0.83	0.19
Median+ (min, max)	-1.7 (-17.8, 3.6)	-1.7 (-10.2, 2.3)	-0.02 (-10.6, 6.9)	-	0.94	0.24

+ Standard deviation are much higher than mean, median and min, max value were used with Wilcoxon signed ranks test; significant at (*) p-value < 0.05 and (**) p-value < 0.01
3 times means the comparable of three values, day 0, day 3 and day 7

2, 3, 4, 5, 6, and 7. A within-subject comparison of post-treatment (day 7) and baseline values was analyzed by using paired t-test or Wilcoxon signed-rank test and Chi-square test or the Fisher's exact probability test for categorical variables. A p-value less than 0.05 were used throughout to connote statistical significance.

Results

Twenty-one patients were analyzed. Subjects were comprised of 13 males and eight females. The mean age of subjects was 64.5 ± 16.8 years with the minimum of 18 years and maximum of 91 years (Table 1). The authors did not find any statistically significant change of the normal value of weight and vital sign in the duration of seven days. When comparing the nitrogen balance, the values were getting positive but did not show statistical significance, as shown in Table 2. In point of BNT view, number of subjects with severe malnutrition, BNT-4, at the beginning of study was higher than those of day seven with statistically significance, 61.9%, and 23.8% respectively, p-value 0.03 (Table 3).

There was no difference ($p \geq 0.05$) in the values of hematology and urinalysis between day 0, day 3, and day 7, respectively. The values of serum

Table 3. Number of subjects in each BNT level on baseline and day 7

BNT level	Day 0	Day7	p-value
BNT-1	0 (0.0%)	1 (4.8%)	0.49
BNT-2	1 (4.8%)	5 (23.8%)	0.09
BNT-3	7 (33.3%)	9 (42.9%)	0.53
BNT-4	13 (61.9%)	5 (23.8%)	0.03*

* Number with percent showed with Chi-square test or Fisher's exact test at day 0 and day 7, statistical significance at (*) p-value < 0.05
BNT-1 no malnutrition/risk of malnutrition follow-up every 4-8 weeks
BNT-2 mild malnutrition follow-up every 2-6 weeks
BNT-3 moderate malnutrition start nutrition support and follow-up every 3-7 days
BNT-1 severe malnutrition consult nutrition department and follow-up every 3-7 days

chemistry did not show statistically significant difference when compared among the three periods of day 0, day 3, and day 7. Additionally, the values of potassium, calcium, magnesium, prealbumin, creatinine, blood urea nitrogen (BUN), and HDL demonstrated the statistically significant increment, in contrast to this of triglycerides when distinguishing two values of day 0 and day 3, and day 0 and day 7 (Table 4). Serum protein was increased after three days of feeding. There was also no difference in the values of weight change, nitrogen balance and BNT level between day 0 and day 7 among genders (Table 5).

For the gastrointestinal complication perspective, only one of 21 subjects with intermittent feeding got diarrhea on day 2 to day 5, three to six times a day without infection in liquid stool and was

Table 4. Values of serum chemistry

Variables	Day 0	Day 3	Day 7	p-value		
				3 times	D0 vs. D3	D0 vs. D7
Potassium	4.1 ± 0.9	4.4 ± 0.6	4.5 ± 0.5	0.09	0.01*	0.03*
Calcium	8.3 ± 1.2	8.5 ± 1.1	8.7 ± 1.2	0.68	0.32	0.01*
Magnesium	2.0 ± 0.3	2.1 ± 0.3	2.1 ± 0.3	0.19	0.03*	0.07
Prealbumin	14.3 ± 8.4	16.6 ± 9.5	17.3 ± 9.9	0.55	0.007**	0.02*
Creatinine	0.6 ± 0.3	0.7 ± 0.4	0.8 ± 0.6	0.57	0.04*	0.08
BUN	16.1 ± 13.1	17.9 ± 12.5	19.4 ± 13.7	0.71	0.07	0.01*
HDL	28.5 ± 13.1	30.4 ± 15.5	34.3 ± 9.8	0.36	0.46	0.02*
Triglycerides	110.1 ± 36.4	94.1 ± 27.1	92.7 ± 35.7	0.19	0.004**	0.04*

* Mean ± SD with F-test compare in three periods and paired t-test when compare to baseline, statistical significance at (*) p-value < 0.05 and (**) p-value < 0.01

3 times means the comparable of three values, day 0, day 3, and day 7

Sodium, chloride, phosphorous, bicarbonate, albumin, transferrin, liver function, total protein, total bilirubin, glucose, uric acid, total cholesterol and LDL show no statistical significance

Table 5. Compare weight, nitrogen balance and BNT level between genders

Variables	Baseline	Day 7	p-value
Male			
Weight (kg): (n = 11)	53.1 (35.5, 73.9)	51.1 (36.6, 71.6)	0.11
Nitrogen balance: (n = 11)	-1.8 (-17.8, 3.6)	0.1 (-10.6, 6.9)	0.13
BNT level: (n = 13)			
BNT-1	0	1 (7.7%)	1.00
BNT-2	1 (7.7%)	3 (23.1%)	0.59
BNT-3	5 (38.5%)	5 (38.5%)	1.00
BNT-4	7 (53.8%)	3 (23.1%)	0.23
ND	0	1 (7.7%)	1.00
Female			
Weight (kg): (n = 7)	57.1 (32.4, 95.4)	54.9 (33.8, 71.7)	0.25
Nitrogen balance: (n = 8)	-1.9 (-7.6, 2.9)	-1.3 (-4.6, 0.9)	1.00
BNT level: (n = 8)			
BNT-1	0	0	-
BNT-2	0	2 (25%)	0.47
BNT-3	2 (25%)	4 (50%)	0.61
BNT-4	6 (75%)	2 (25%)	0.13

Median, min and max with Wilcoxon signed ranks test; p-value < 0.05

ND = no data

Table 6. Number of subjects with diarrhea

Variables (n)	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
No diarrhea	21 (100%)	21 (100%)	20 (95%)	20 (95%)	20 (95%)	20 (95%)	21 (100%)	21 (100%)
Diarrhea (case)	0 (0%)	0 (0%)	1 (5%)	1 (5%)	1 (5%)	1 (5%)	0 (5%)	0 (5%)

Table 7. Number of subjects with GI discomfort on each day

Variables	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
No GI discomfort	19 (90.5%)	20 (95.2%)	19 (90.5%)	17 (81%)	16 (76.2%)	17 (81%)	18 (85.7%)	19 (90.5%)
GI discomfort	2 (9.5%)	1 (4.8%)	2 (9.5%)	4 (19%)	5 (23.8%)	4 (19%)	3 (14.3%)	2 (9.5%)
Bloating	1	1	2	3	4	2	2	1
Abdominal distention	0	0	1	2	3	2	3	1
Flatulence	0	0	1	1	1	2	0	0
Vomiting	0	0	0	0	0	0	0	1
Others	1	0	0	0	0	0	0	0
No allergy	21 (100%)	21 (100%)	21 (100%)	21 (100%)	21 (100%)	21 (100%)	21 (100%)	21 (100%)

not considered as osmotic diarrhea. The subject had been resolved on day 6 before the study ended. Ninety-five percent of subjects had no diarrhea (Table 6). Most of the subjects or 76.2 to 95.2% showed no GI discomfort in the entire period of feeding. However, the discomfort found in some subjects were bloating and distention. None was allergic to the study formula, as shown in Table 7.

Discussion

Enteral tube feeding is an acceptable technique to prevent nutrient bereavement and to keep the local defense barrier of the gut as well. The procedure is also less costly and more convenient to parenteral nutrition. Considering the effect of commercial medical food, Blendera, on nutritional status found the formula maintain the nutritional status without complications both in weight and laboratory values. In additional, some nutritional index from the laboratory data showed the improvement of minerals and visceral protein, prealbumin. Patients with severe malnutrition status were better at the end of the present study assessed by BNT. The study formula also refined the lipid profile by raising serum HDL and lowering serum triglyceride.

Blendera medical food is a lactose-free commercial medical food developed from Blendera beverage. It provides many benefits without complications including maintain nutritional status in the short period of feeding by providing complete nutrition requirement. This lactose-free mixture is the basic feeding formulations that generally provide 1 kcal/mL and are isotonic. They may be, although, concentrated to 1.5 to 2.0 kcal/mL. A standard formulation has 15% of its calories from protein, 55% of its calories from carbohydrates, and 30% of its calories from fats. They contain complex forms of carbohydrates, fats, and proteins and require some degree of digestion and absorption. The calories contained in MCT are very efficiently converted into fuel for immediate use by organs and muscles[4,5]. This source can be an advantage to the patient who shows fat malabsorption or bile salt deficiency[18].

The result of the present study concludes that subjects supported with Blendera are effective in preventing significant weight loss without complications. The formula provides complete nutrients when administered daily.

Potential conflicts of interest

None.

References

1. Kirby DF, Delegge MH, Richard FC. American Gastroenterological Association Medical Position Statement: Guidelines for the use of enteral nutrition [Internet]. November 11, 1994 [cited 2011 Aug 30]: Available from: http://www3.us.elsevierhealth.com/gastro/policy/v108n4p1280.html
2. American Society for Parenteral and Enteral Nutrition (ASPEN). Overview of enteral nutrition. In: Joseph B, Liesje NC, Peggi G, editors. The

ASPEN enteral nutrition handbook. Silver Spring, MD: ASPEN; 2010: 73-92.
3. Sullivan MM, Sorreda-Esguerra P, Santos EE, Platon BG, Castro CG, Idrisalman ER, et al. Bacterial contamination of blenderized whole food and commercial enteral tube feedings in the Philippines. J Hosp Infect 2001; 49: 268-73.
4. Wanke CA, Pleskow D, Degirolami PC, Lambl BB, Merkel K, Akrabawi S. A medium chain triglyceride-based diet in patients with HIV and chronic diarrhea reduces diarrhea and malabsorption: a prospective, controlled trial. Nutrition 1996; 12: 766-71.
5. Craig GB, Darnell BE, Weinsier RL, Saag MS, Epps L, Mullins L, et al. Decreased fat and nitrogen losses in patients with AIDS receiving medium-chain-triglyceride-enriched formula vs those receiving long-chain-triglyceride-containing formula. J Am Diet Assoc 1997; 97: 605-11.
6. Wong JM, de Souza R, Kendall CW, Emam A, Jenkins DJ. Colonic health: fermentation and short chain fatty acids. J Clin Gastroenterol 2006; 40: 235-43.
7. Drozdowski LA, Dixon WT, McBurney MI, Thomson AB. Short-chain fatty acids and total parenteral nutrition affect intestinal gene expression. JPEN J Parenter Enteral Nutr 2002; 26: 145-50.
8. The One Minute Counselor. A Pharmacist's guide to fiber and digestive health [Internet]. Washington, DC: The American Pharmacists Association; 2008 [cited 2011 Aug 30]. Available from: http://apha.imirus.com/Mpowered/book/vpt14/i8/p17
9. Anderson JW, Baird P, Davis RH, Jr., Ferreri S, Knudtson M, Koraym A, et al. Health benefits of dietary fiber. Nutr Rev 2009; 67: 188-205.
10. Kelly G. Inulin-type prebiotics—a review: part 1. Altern Med Rev 2008; 13: 315-29.
11. Kelly G. Inulin-type prebiotics: a review. (Part 2). Altern Med Rev 2009; 14: 36-55.
12. IND220, IND221, IND226 Industry terminal user/service manual. JiangSu, P.R.China; Mettler-Toledo (ChangZhou) Measurement Technology; 2006
13. Rombeau JL, Jacobs DO. Nasoenteric tube feeding. In: Rombeau JL, Caldwell MD, editors. Enteral and tube feeding. Philadelphia: W.B.Saunders; 1984: 228-39.
14. Guideline of BNT malnutrition assessment (Bhumibol Adulayadej Hospital Nutrition Triage) [Internet]. Version August 2009 [2011 Aug 30]. Available from: http://www.bhumibolhospital.rtaf.mi.th/
15. Kenler AS, Swails WS, Driscoll DF, DeMichele SJ, Daley B, Babineau TJ, et al. Early enteral feeding in postsurgical cancer patients. Fish oil structured lipid-based polymeric formula versus a standard polymeric formula. Ann Surg 1996; 223: 316-33.
16. Hu QG, Zheng QC. The influence of Enteral Nutrition in postoperative patients with poor liver function. World J Gastroenterol 2003; 9: 843-6.
17. Clohessy S, Roth JL. Administration of enteral nutrition: initiation, progression, and transition. In: Rolandelli RH, Bankhead R, Boullata JI, Compher CW, editors. Clinical nutrition enteral and tube feeding. 4th ed. Philadelphia: Elsevier Saunders; 2005: 243-7.
18. Caliari S, Benini L, Sembenini C, Gregori B, Carnielli V, Vantini I. Medium-chain triglyceride absorption in patients with pancreatic insufficiency. Scand J Gastroenterol 1996; 31: 90-4.

การศึกษาประสิทธิภาพและความปลอดภัยในการใช้สูตรอาหารเบลนเดอร่า (Blendera) แก่ผู้ป่วยที่จำเป็นต้องได้รับสารอาหารทางสายให้อาหาร

วิบูลย์ ตระกูลฮุน, บุชชา พราหมณสุทธิ์

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพและความปลอดภัยในการใช้เบลนเดอร่าในผู้ป่วยที่ต้องได้รับสารอาหารทางสายให้อาหาร*
วัสดุและวิธีการ: *การศึกษานี้เป็นการศึกษาแบบเปิด (open study) ในสถาบันเดียว ทำการศึกษาในผู้ป่วย 21 ราย ที่จำเป็นต้องได้รับสารอาหารทางสายให้อาหาร โดยให้อาหารทางการแพทย์เบลนเดอร่าเป็นเวลา 7 วัน โดยชั่งน้ำหนักด้วยเครื่องชั่ง Oryza Model BFC 6 เก็บปัสสาวะ และเจาะเลือดเพื่อตรวจวัดระดับค่าทางชีวเคมีต่าง ๆ จากนั้นติดตามผลอีกในวันที่ 3 และ 7*
ผลการศึกษา: *พบว่าการให้อาหารทางการแพทย์เบลนเดอร่าทางสายให้อาหารเป็นเวลา 7 วัน แก่ผู้ป่วยทั้งหมด 21 ราย สามารถช่วยให้น้ำหนักผู้ป่วยไม่ลดลง สามารถรักษาภาวะโภชนาการได้โดยเฉพาะอย่างยิ่งผู้ป่วยที่มีภาวะทุพโภชนาการขั้นรุนแรงมีภาวะโภชนาการดีขึ้นเป็นลำดับ ตลอดเวลาของการได้รับอาหารทางการแพทย์เบลนเดอร่า (p-value 0.03) นอกจากนี้ผู้ป่วยยังมีผลทางห้องปฏิบัติการของโพแทสเซียม แคลเซียม แมกนีเซียม ไขมัน HDL และมีระดับโปรตีนในเลือดอันได้แก่ prealbumin สูงขึ้น ส่วนระดับไขมันไตรกลีเซอไรด์ลดลงอย่างมีนัยสำคัญทางสถิติ ($p < 0.05$) และเมื่อได้วิเคราะห์ดูผลการเปลี่ยนแปลงที่เกิดขึ้นโดยแยกเพศพบว่า ไม่มีการเปลี่ยนแปลงอย่างมีนัยสำคัญทางสถิติทั้งในเรื่องน้ำหนักตัว และภาวะโภชนาการในเพศชายและหญิง*
สรุป: *ผู้ป่วยที่ได้รับพลังงานและโปรตีนอย่างพอเพียงจากอาหารทางการแพทย์เบลนเดอร่า จะช่วยป้องกันการเกิดภาวะน้ำหนักลดและช่วยรักษาภาวะโภชนาการได้อย่างปลอดภัยโดยไม่มีภาวะแทรกซ้อน สูตรอาหารทางการแพทย์เบลนเดอร่าเป็นสูตรที่ให้สารอาหารครบถ้วนโดยสามารถให้แก่ผู้ป่วยได้เป็นประจำโดยไม่มีข้อจำกัด*