Microbial, nutritional and physical quality of commercial and hospital prepared tube feedings in Saudi Arabia

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ABSTRACT

Objective: Blenderized tube feedings (BTF) may present disadvantages over commercially prepared formulas (CPF). This study compares the microbial safety, nutritional content, and physical properties of BTF versus CPF.

Methods: A total of 18 samples of BTF were collected from 3 hospitals in the Kingdom of Saudi Arabia from August 1999 through to November 1999. Samples of a CPF were collected for comparison. All samples were analyzed for nutritional content, microbial quality (aerobic plate counts, coliform counts, microorganism growth) and physical characteristics (viscosity, osmolality).

Results: The nutrient content of BTF varied significantly within and between sites. The average intra site variability for all sites ranged from 16-50%. The average variability of the CPF was 4-7%. Between sites, the mean concentration of most nutrients varied by 2-3 fold. The BTF had considerable differences between actual and expected nutrient concentrations, reaching statistical significance in 12 nutrients. The measured concentration of most nutrients in the CPF was within 10% of expected values. The BTF samples had higher viscosity and osmolality than the CPF. All samples of BTF had detectable aerobic plate counts that increased significantly over 4 hours ($p<0.0005$). Coliform contamination varied between sites, with 100% contamination at one site. No aerobic plate counts or coliform counts were detected in the CPF samples.

Conclusions: There is a high degree of variability in nutrient content and physical properties with BTF. Furthermore, BTF are highly contaminated, increasing the risk of nosocomial infections. For these reasons, CPF should replace BTF.

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Following the Turnlund and Tannous[1] publication in 1983 on the status of hospital dietetic and food services in the Middle East, very little has been published on dietetic practices in the region. A noteworthy study by Chang et al[2] in 1985, reported approximately 40% of surgical patients as suffering from malnutrition in the Riyadh Military Hospital, Riyadh, Kingdom of Saudi Arabia, (KSA). It became well known to health care professionals that malnutrition was prevalent to a high degree among hospitalized patients throughout the world.[3-5] It is also documented that patients with good nutritional status have fewer complications, lower morbidity and mortality rates, and shorter hospital stays than malnourished patients.[6-9]

Providing nutritional intervention when it is indicated is clearly advantageous and selecting the appropriate method of nutrition support is necessary

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in order for it to be effective. The nutritional intervention strategies from which to choose include, ordinary food, nutritional supplements, enteral tube feeding (commercially prepared formula or hospital prepared feed) and partial or total parenteral nutrition. These are only a few of the many options which are available to health care practitioners. This investigation focuses on enteral tube feeding choices, specifically the selection of blenderized tube feedings (BTF) or commercially prepared formulas (CPF).

Enteral tube feedings are commonly used in hospital settings as a means of nutritional support. While commercial, ready-to-use formulas have been available for over 20 years, some institutions prefer the use of "homemade" BTF. Blenderized tube feeding typically contain normal or "natural" foodstuffs, such as milk, eggs, meat, soft fruits, and vegetables, that are pureed in a food blender or mixer. Institutions may prefer BTF for economic or cultural reasons, or for the flexibility they afford with regard to ingredients and nutritional content.

Since BTF are composed of foods that are eaten daily they are presumed to be safe and appropriate for use in hospital patients requiring enteral tube feedings. However, disadvantages relating to nutrient content, microbial safety with risk of nosocomial infection, and physical property limitations, have been reported with the use of BTF. Gallagher-Allred[10] compared 2 commercial liquid formulas to 3 hospital prepared BTF with respect to bacterial contamination, nutritional content and osmolality. Microbial analyses revealed standard plate coliform counts of between 11,000 and 108,000/mL for institutionally prepared formulas, compared with less than 10/mL for commercial formulas. One of the institutionally prepared formulas had a coliform count of 325/mL, compared with 0/mL for the commercial formulas, with a desired count of less than 10/mL as recommended for raw milk by the United States and British Dietetic Association.[11-13] In comparison to commercial formulas, the institutionally prepared formulas were found to have lower nutritional quality, higher osmolality and substantial discrepancies between actual and expected values for specific nutrients. In addition, the institutionally prepared formulas required a larger bore feeding tube for adequate flow. Additional studies have reported considerable microbial contamination of hospital prepared enteral feedings. Thurn et al[14] found that enteral feeds mixed on site were more highly contaminated and resulted in increased colonization compared with premixed feeds. Anderson et al[15] reported that locally prepared and manipulated formulas contained a significantly greater number of organisms when compared to non manipulated formulas. Freedland et al[16] found that undiluted, canned feedings were significantly less contaminated at 24 hours than those requiring mixing of powder ($p<0.0001$). These investigators stressed the need for procedures that minimize contamination of enteral feedings. Contamination of enteral feedings has been implicated in the development of serious nosocomial infections including diarrhea, salmonella infection, enterocolitis, pneumonia, and sepsis.[17] Nosocomial infections result in substantial morbidity and mortality and tremendous costs to both patients and health care institutions.[18] The development of a food borne illness is particularly dangerous in hospitalized patients who are immunocompromised or who are receiving immunosuppressive therapy.[19,20] Food-borne pathogens can cause symptoms such as nausea, vomiting, diarrhea, fever and abdominal cramps, and may be responsible for chronic diseases such as hepatitis, septic and aseptic arthritis, and Guillain-Barré syndrome.[18]

This study was conducted to assess and compare the microbial safety, nutritional quality and physical properties of hospital prepared BTF from 3 hospitals in KSA versus a commercially available liquid formula.

Methods.

Study design. Six samples of BTF were collected from 3 hospitals in KSA. Each hospital provided 2 BTF, one standard diet and one therapeutic diet. All of the therapeutic diets in this study were diabetic diets. Samples of both the standard and therapeutic feedings were collected from each hospital on 3 separate days, for a total of 18 BTF samples for nutritional analysis and assessment of physical properties (viscosity and osmolality). From these samples, aliquots were collected at 0, 1, 2 and 4 hours after preparation for a total of 72 samples for microbial analysis. Aliquots of a CPF were collected at the same time as the samples of BTF from one of the hospitals.

Study materials. All tube feeding ingredients and recipes were provided by the respective hospitals. The ingredients used for the BTF varied between sites and included fresh fruits and vegetables, meat, eggs, milk, and fruit juices. The CPF was Jevity® 500 mL ready-to-hang (RTH) closed feeding system (Abbott Laboratories, Abbott Park, Illinois, United States of America, (USA)). Ready-to-hang foil cutters were supplied by Abbott Laboratories, Sligo, Ireland. Nalgene bottles for the collection of samples were supplied by Covance Laboratories, Indianapolis, Indiana, USA.

Procedures. Feedings used for this study were prepared by the same food service employees who regularly prepared the feedings for hospital patients. All tube feedings were prepared using the techniques established by the respective hospitals. The laboratory technician scheduled 3 separate sample collection dates at each hospital. These

visits were coordinated so that the collector was present when the tube feedings were prepared. Hospital personnel were asked to make one standard and one therapeutic preparation of BTF according to their own recipes and procedures. Each recipe was to yield approximately one liter of feeding and was to be poured into the same type of container as used to deliver feedings to the patient floors. The container was labeled for identification as a study product, stating that the feeding was a clinical product and not for patient use. Samples of the product were collected by the laboratory technician as follows: 1. Time 0 collection: upon completion of the BTF preparation, approximately 200 mL of BTF was poured into each of 3 sterile containers for nutritional analysis; a further 10 mL aliquot was poured into a sterile bottle for microbial analysis. All specimens were labeled and immediately placed on dry ice. 2. One hour, 2 hour, and 4 hour collections: 10 mL aliquots of BTF were collected into sterile bottles at one hour, 2 hours, and 4 hours after BTF preparation and placed on dry ice. All samples were kept on dry ice until transferred to a -70°C freezer within 10 hours of collection. A total of 18 samples (3 hospitals, 2 feedings per hospital, 3 separate days) were collected for nutritional analysis and 72 samples (3 hospitals, 2 feedings per hospital, 3 separate days, 4 time points) were collected for microbial analysis. One of the 3 hospitals providing samples of BTF (site 1) was selected as a site for the collection of samples of the CPF. These samples were collected immediately prior to the samples of BTF on the same days as the samples of BTF. The laboratory technician opened the Jevity® container with a RTH® foil cutter; samples of the feeding were collected as follows: 1. Time 0 collection: approximately 150 mL of the CPF was poured into each of 3 sterile containers for nutritional analysis; a further 10 mL aliquot was poured into a sterile bottle for microbial analysis. All specimens were labeled and immediately placed on dry ice. 2. One hour, 2 hour, and 4 hour collections: 10 mL aliquots of the CPF were collected into sterile bottles at one hour, 2 hours, and 4 hours and placed on dry ice. All samples were kept on dry ice until transferred to a -70°C freezer within 10 hours of collection. A total of 12 aliquots (3 days, 4 time points) were collected for microbial analysis. The 72 aliquots of BTF were analyzed for aerobic plate counts (APC), coliform counts and the presence of *Escherichia coli (E. coli), Staphylococcus aureus, and Salmonella*. In addition, isolated microorganisms were identified when possible. The recipes were analyzed to determine expected nutrient content using nutritional computer software (Nutritionist V, First Data Bank, San Bruno, CA) and dietary manuals.

Blenderized tube feedings and CPF samples (time 0 collections) were analyzed for actual nutrient content. The following nutritional components were recorded: calories, carbohydrate nonferrous extract (NFE), total fat, saturated fat, unsaturated fat, protein, cholesterol, dietary fiber, vitamins (vitamins A, B_1, B_2, B_3, C, D, E, pantothenic acid, pyridoxine [vitamin B_6], and cyanocobalamin [vitamin B_{12}]) and minerals (calcium, magnesium, phosphorus, sodium, iron, potassium, zinc, copper, and selenium). In addition, the samples were analyzed for the physical properties of viscosity and osmolality. All microbial, nutritional, and physical analyses were performed by the University of Jordan, Amman, Jordan.

Statistical methods. All statistical tests were 2-sided with a 0.05 significance level. Tests were performed based on the means of triplicate samples. Statistical analyses were performed separately for each hospital and for the combined data from all hospitals. Power values were based on the analyses for the combined data and were obtained from Query Advisor (version 2.0) and Cohen.[21]

For each recipe, descriptive statistics were calculated for nutritional parameters, viscosity and osmolality. Paired statistical tests were used to determine whether the actual nutrient levels differed from the expected levels. Paired t-tests were used to compare results when the differences showed a normal or approximately normal distribution and the nonparametric paired sign test was used when the differences showed an extremely non-normal distribution. The paired t-test had an 80% power for detecting a difference between the actual and expected mean nutrient levels when the population difference was fairly large (effect size=0.6). The paired sign test had a 91% power for detecting a difference when 80% of the actual values were less than the expected values or 80% of the actual values were greater than the expected values.

Scatter plots and correlation coefficients were obtained for actual versus expected nutrient concentrations to determine how close the actual and expected nutrient levels were. Pearson correlation coefficient was used to test the hypothesis of zero correlation when the actual nutrient levels had a normal or approximately normal distribution. Spearman correlation coefficients were used when the actual nutrient levels had an extremely non normal distribution. The Pearson hypothesis test had an 80% power when the population coefficient was 0.55. In order to obtain an estimate of the within site variability for the concentrations of nutrients, the percent coefficient of variation (% CV), the standard deviation divided by the mean and expressed as a percentage, was calculated for every nutrient in each feeding.

Since bacterial and coliform counts typically have an extremely right skewed distribution, the nonparametric Friedman test was performed for

Table 1 - Coefficient of variation (% CV), BTF and CPF.

Diet	Site	Coefficient of variation (range) Macro nutrients	Minerals	Vitamins
Standard BTF	1	21 (8-47)	19 (5-33)	20 (8-38)
	2	16 (4-25)	18 (2-33)	21 (8-38)
	3	40 (3-79)	27 (5-60)	25 (11-44)
Therapeutic BTF	1	24 (13-32)	20 (6-44)	25 (6-100)
	2	29 (9-39)	22 (9-47)	21 (1-60)
	3	50 (11-89)	19 (4-40)	21 (1-48)
Commercial formula (CPF)		<7*	4 (2-9)	6 (2-13)

*Except cholesterol
BTF - blenderized tube feeding
CPF - commercially prepared formulas

microbial analysis results. Counts were compared for all time points (0, 1, 2 and 4 hours). If a statistically significant result was obtained paired sign tests were performed to determine which time points had different counts. The paired sign test had 91% power for detecting a difference between the counts for 2 time points, when 80% of the population for one time point was less than the counts for the other time point.

Results. ***Nutritional analyses. Intra and inter-site variability (% CV).*** Intra-site variability of nutrient concentrations was determined by calculating the % CV. (**Table 1**) For macronutrients, the average intra-site % CV ranged from 16-40% in the BTF standard diets and 24-50% in the BTF therapeutic diets. The % CV for macronutrients in the commercial formula was less than 7% for all macronutrients except cholesterol. The greatest intra-site variability for BTF standard diets was observed for cholesterol and for BTF therapeutic diets, saturated fat and dietary fiber. (**Table 2 & 3**)

The average intra-site variability for mineral concentrations ranged from 18-27% in the standard BTF diets and 19-22% in the therapeutic BTF diets. The greatest intra-site variability was noted for copper concentrations (standard and therapeutic diets), iron and selenium (therapeutic diets). The average variability in the commercial feedings for mineral concentrations was 4%. The average intra site variability for vitamin concentrations ranged from 20-25% in the standard BTF diets and 21-25% in the therapeutic BTF diets. The greatest intra-site variability was for vitamin B_2 and vitamin D concentrations (standard BTF diets) and B_1, B_2 and B_6 (therapeutic BTF diets). The average variability for the vitamin concentration in the commercial feedings was 6%.

Between sites, the mean concentration of most macronutrients, minerals and vitamins varied by approximately 2-3 fold in both the standard BTF and therapeutic BTF diets. The greatest variability between sites was observed for saturated fat and cholesterol, sodium and iron, and vitamins B_2 and B_3.

Actual versus expected nutrients. Both standard BTF and therapeutic BTF diets from all 3 sites had similar discrepancies between measured and expected nutrient content. Although the nutrients that did not meet expectations varied somewhat between diet type and site, all preparations had multiple nutrients that were either higher or lower than expected values. When all BTF preparations from the 3 sites (total 18) were examined together to determine the correlation between the expected and measured values of all nutrients, only 4 nutrients, were found to have a positive correlation coefficient: 0.69 for vitamin A, 0.50 for vitamin E, 0.61 for vitamin B_6, and 0.71 for vitamin C. Negative correlation coefficients were observed for vitamin B_{12} with -0.65 and pantothenic acid with -0.54. Furthermore, there were statistically significant differences between actual and expected concentrations for vitamins A, D, E, B_1, B_6, C, pantothenic acid, phosphorus, iron, cholesterol, carbohydrates and calories. (**Table 4**)

In the comparison analyses for BTF versus CPF (**Table 5**), the mean concentrations of cholesterol, sodium, vitamin A and vitamin B_6 for all BTF were notably higher than in the CPF. However, the mean concentrations of unsaturated fat, nonferrous extract (NFE), calories, calcium, phosphorus, magnesium, zinc, iron, copper and vitamins D, E, B_3 and C were notably lower for all BTF than for the CPF.

Microbial analyses. Aerobic plate counts. All samples of BTF tested had detectable (≥10 colony forming unit (CFU)/gram) APC. (**Table 6**) For the standard BTF feedings, 31/36 (86%) of samples had $>10^4$ CFU/gram. For the therapeutic BTF feedings, again 31/36 (86%) of samples had counts $>10^4$ CFU/gram. There were significant differences between sites for aerobic counts at 0 hours (p=0.002), 1 hour (p=0.004), 2 hours (p=0.003) and 4 hours (p=0.019). There were also significant increases over time in APC at each site (site 1, p=0.023; site 2, p=0.006; site 3, p=0.042). For all BTF combined, there were significant increases in APC over time (p<0.0005), with a significant increase from 0 hour to 1 hour (p=0.029), and from 0 (p<0.0005), 1 (p=0.018), 2 (p<0.0005) hours to 4 hours. For these combined data, the median exceeded 10^4 CFU/gram at the time of preparation and nearly exceeded 10^5 at 4 hours. Aerobic plate counts for all CPF samples were non detectable (<10 CFU/gram) at all times.

Coliform counts. The maximum coliform count for any BTF sample from sites 1 and 2 was 50

Table 2 - Measured nutrient concentrations of standard BTF and CPF.

Nutrients	Site 1		Site 2		Site 3		CPF	
	Mean ± SD	(Range)	Mean ± SD	(Range)	Mean ± SD	(Range)	Mean ± SD	(Range)
Macronutrients (per 100 ml)								
Cholesterol (mg)	5.31 ± 2.49	(2.55-7.38)	9.54 ± 2.41	(7.87-12.30)	14.58 ± 11.51	(6.49-27.75)	0.23 ± 0.12	(0.10-0.33)
Fat (g)	2.94 ± 0.58	(2.44-3.58)	1.67 ± 0.29	(1.38-1.97)	3.72 ± 1.82	(2.00-5.63)	3.37 ± 0.11	(3.25-3.46)
% saturated fatty acids	34.8 ± 3.4	(31.0-37.7)	35.0 ± 0.7	(34.5-35.8)	49.1 ± 9.9	(37.9-56.6)	28.2 ± 1.1	(27.0-29.2)
% unsaturated fatty acids	65.2 ± 3.4	(62.3-69.0)	64.9 ± 0.65	(64.2-65.3)	50.9 ± 9.9	(43.4-62.1)	71.8 ± 1.11	(70.8-73.0)
Saturated fat (g)	1.03 ± 0.26	(0.76-1.28)	0.59 ± 0.11	(0.48-0.71)	1.93 ± 1.07	(0.82-2.97)	0.95 ± 0.06	(0.88-0.99)
Unsaturated fat (g)	1.91 ± 0.34	(1.68-2.30)	1.08 ± 0.18	(0.90-1.26)	1.79 ± 0.77	(1.17-2.66)	2.42 ± 0.06	(2.37-2.48)
Protein (g)	2.63± 0.29	(2.42-2.96)	3.82 ± 0.93	(2.83-4.69)	6.31 ± 2.44	(3.51-7.87)	3.87 ± 0.06	(3.83-3.94)
NFE (g) (Carbohydrate)	6.36 ± 0.53	(6.01-6.97)	6.49 ± 0.61	(5.78-6.88)	10.79 ± 0.34	(10.48-11.15)	15.13 ± 0.12	(15.05-15.28)
Calories (cal)	62.6 ± 5.8	(56.7-68.3)	56.4 ± 2.0	(54.3-58.3)	102.0 ± 25.4	(74.0-123.7)	106.7 ± 0.7	(106.0-107.3)
Dietary fiber (g)	0.59 ± 0.18	(0.46-0.80)	0.96 ± 0.16	(0.86-1.14)	1.22 ± 0.32	(0.87-1.51)	1.10 ± 0.05	(1.07-1.16)
Minerals (per 100 ml)								
Sodium (mg)	94.1 ± 4.4	(90.3-98.9)	29.0 ± 0.7	(28.2-29.5)	354.1 ± 101.1	(272.8-467.3)	93.1 ± 1.9	(92.0-95.3)
Potassium (mg)	120.6 ± 16.7	(104.9-138.1)	112.4 ± 17.9	(98.4-132.5)	274.2 ± 34.9	(234.0-294.8)	168.7 ± 4.4	(165.5-173.7)
Calcium (mg)	46.4 ± 11.3	(33.3-52.9)	41.1 ± 5.7	(36.2-47.3)	80.5 ± 33.5	(42.0-103.4)	94.9 ± 6.1	(88.6-100.7)
Phosphorus (mg)	38.7 ± 7.6	(30.4-45.2)	36.2 ± 5.9	(29.7-41.1)	64.7 ± 25.7	(35.2-82.2)	90.4 ± 1.3	(89.0-91.7)
Minerals (per 100 ml)								
Magnesium (mg)	8.56 ± 0.76	(7.87-9.37)	9.99 ± 0.69	(9.23-10.60)	19.89 ± 1.03	(18.70-20.50)	28.6 ± 0.42	(28.20-29.00)
Zinc (mg)	0.32 ± 0.08	(0.26-0.40)	0.32 ± 0.06	(0.26-0.39)	0.56 ± 0.15	(0.40-0.68)	1.84 ± 0.16	(1.67-1.97)
Iron (mg)	0.15 ± 0.04	(0.12-0.19)	0.22 ± 0.06	(0.16-0.27)	0.65 ± 0.09	(0.54-0.72)	1.33 ± 0.07	(1.26-1.40)
Copper (mg)	0.03 ± 0.01	(0.02-0.04)	0.06 ± 0.02	(0.04-0.08)	0.05 ± 0.03	(0.02-0.08)	0.16 ± 0.01	(0.15-0.17)
Selenium (mcg)	5.00 ± 0.55	(4.53-5.60)	6.67 ± 1.96	(4.53-8.40)	4.88 ± 0.89	(4.07-5.83)	4.99 ± 0.10	(4.90-5.10)
Vitamins (per 100 ml)								
Vitamin A (mcg RE)	59.8 ± 11.3	(47.0-68.3)	61.8 ± 8.4	(54.0-70.7)	111.7 ± 23.3	(90.7-136.7)	50.3 ± 3.3	(47.7-54.0)
Vitamin D (mcg cholecalciferol)	0.35 ± 0.10	(0.27-0.46)	0.24 ± 0.09	(0.14-0.29)	0.40 ± 0.15	(0.29-0.57)	0.68 ± 0.01	(0.66-0.69)
Vitamin E (mg)	0.59 ± 0.11	(0.46-0.67)	0.44 ± 0.06	(0.38-0.50)	0.68 ± 0.16	(0.49-0.81)	2.25 ± 0.29	(1.93-2.50)
Pantothenic acid (mg)	0.47 ± 0.16	(0.34-0.65)	0.73 ± 0.16	(0.57-0.89)	1.02 ± 0.11	(0.94-1.15)	1.16 ± 0.06	(1.0 9-1.21)
VitaminB_1 (mg)	0.11 ± 0.01	(0.10-0.12)	0.12 ± 0.01	(0.12-0.13)	0.27 ± 0.11	(0.15-0.38)	0.21 ± 0.01	(0.20-0.21)
Vitamin B_2 (mg)	0.08 ± 0.03	(0.06-0.12)	0.20 ± 0.07	(0.12-0.25)	0.25 ± 0.11	(0.13-0.35)	0.17 ± 0.01	(0.16-0.18)
Vitamin B_3 (mg)	0.60 ± 0.05	(0.55-0.65)	0.63 ± 0.16	(0.51-0.81)	1.71 ± 0.22	(1.50-1.93)	2.37 ± 0.09	(2.30-2.47)
Vitamin B_6 (mg)	0.65 ± 0.09	(0.58-0.75)	0.27 ± 0.07	(0.22-0.35)	0.44 ± 0.07	(0.38-0.52)	0.21 ± 0.01	(0.20-0.22)
Vitamin B_{12} (mcg)	0.47 ± 0.09	(0.38-0.56)	0.76 ± 0.15	(0.63-0.93)	0.84 ± 0.20	(0.65-1.04)	0.63 ± 0.04	(0.59-0.66)
Vitamin C (mg)	0.89 ± 0.09	(0.78-0.94)	0.91 ± 0.11	(0.80-1.01)	2.09 ± 0.40	(1.83-2.55)	13.45 ± 0.60	(12.85-14.05)

NFE - nonferrous extract, BTF - blenderized tube feeding, CPF - commercially prepared formulas, % - percentage, SD - standard deviation

CFU/gram. (**Table 7**) Coliform contamination was observed in all samples from site 3. Coliform counts for all CPF samples were non detectable (<10 CFU/gram).

Other bacterial contamination. All BTF and CPF samples were free of *E. coli* (<10 CFU/gram), except for one aliquot of the therapeutic BTF from site 1, which had an *E. coli* count of 10 at 4 hours. (**Table 8**) All BTF and CPF samples were negative for *Salmonella* and *Staphylococcus aureus* (<10 CFU/gram). Sixteen different organisms were identified in the BTF samples. Some of these organisms are pathogens commonly associated with clinical disease. No microorganisms were isolated from the CPF samples.

Physical properties. Osmolality and viscosity. Compared to the CPF, the BTF had a higher viscosity (200-fold) and higher osmolality (2-fold). (**Table 9**) Furthermore, there was an extremely wide range of results and great inter site variability for both viscosity and osmolality of the BTF formulas. Viscosity ranged from 4.99-16,897.8 cP and osmolality ranged from 306.7-912.0 mOsm/kg H_2O.

Discussion. Commercial, ready to use formulas have been available for over 20 years. Nevertheless, many institutions prefer to use hospital prepared blenderized tube feedings for tube fed patients because of perceived economic advantages or cultural preferences. Theoretically, hospital staff members may feel that BTF permit the tailoring of recipes to suit dietary needs of different patient populations. In practice however, the individualizing of recipes is time consuming, labor intensive and may not actually occur. In this study, the primary difference between standard and diabetic diets prepared at each site was omission of sugar from the diabetic feedings. In contrast, ready to use, commercially prepared formulas are

Table 3 - Measured nutrient concentrations of therapeutic BTF.

Nutrient	Site 1		Site 2		Site 3	
	Diabetic diet		Diabetic diet		Diabetic diet	
	Mean ± SD	(Range)	Mean ± SD	(Range)	Mean ± SD	(Range)
Macronutrients (per 100 ml)						
Cholesterol (mg)	4.67 ± 1.24	(3.44-5.92)	5.33 ± 2.02	(3.15-7.14)	12.24 ± 7.21	(5.82-20.04)
Fat (g)	2.03 ± 0.61	(1.47-2.69)	1.88 ± 0.63	(1.44-2.60)	3.60 ± 2.38	(1.84-6.31)
% saturated fatty acids	13.6 ± 0.4	(13.2-14.0)	29.8 ± 2.7	(27.4-32.7)	49.9 ± 2.9	(48.0-53.3)
% unsaturated fatty acids	86.4 ± 0.4	(86.0-86.8)	70.2 ± 2.7	(67.3-72.6)	50.1 ± 2.9	(46.7-52.0)
Saturated fat (g)	0.28 ± 0.09	(0.19-0.38)	0.55 ± 0.14	(0.47-0.71)	1.77 ± 1.13	(0.98-3.06)
Unsaturated fat (g)	1.76 ± 0.52	(1.27-2.31)	1.33 ± 0.49	(0.97-1.89)	1.83 ± 1.26	(0.86-3.26)
Protein (g)	2.17 ± 0.49	(1.61-2.51)	3.42 ± 0.95	(2.42-4.31)	6.32 ± 1.31	(5.40-7.82)
NFE (g) (carbohydrate)	5.41 ± 1.11	(4.52-6.66)	7.53 ± 1.56	(6.11-9.19)	9.75 ± 1.06	(8.93-10.95)
Calories (cal)	48.3 ± 10.4	(40.0-60.0)	60.8 ± 5.7	(55.0-66.3)	96.8 ± 17.0	(83.7-116.0)
Dietary fiber (g)	0.84 ± 0.10	(0.73-0.93)	0.85 ± 0.33	(0.48-1.10)	1.96 ± 1.75	(0.89-3.98)
Minerals (per 100 ml)						
Sodium (mg)	92.3 ± 9.6	(82.2-101.4)	32.0 ± 7.9	(25.5-40.9)	375.2 ± 96.5	(263.9-435.3)
Potassium (mg)	137.1 ± 29.3	(105.4-163.2)	138.5 ± 30.0	(116.4-172.6)	274.7 ± 15.3	(262.0-291.7)
Calcium (mg)	48.7 ± 3.2	(45.0-50.8)	47.0 ± 6.5	(39.5-51.5)	82.2 ± 15.2	(66.1-96.2)
Phosphorus (mg)	37.0 ± 9.3	(26.3-42.4)	36.3 ± 3.5	(32.9-39.9)	75.5 ± 7.3	(69.1-83.4)
Minerals (per 100 ml)						
Magnesium (mg)	9.09 ± 1.40	(7.57-10.33)	11.97 ± 2.80	(10.23-15.20)	20.14 ± 0.85	(19.20-20.83)
Zinc (mg)	0.31 ± 0.04	(0.28-0.35)	0.32 ± 0.03	(0.29-0.34)	0.67 ± 0.06	(0.60-0.70)
Iron (mg)	0.16 ± 0.07	(0.09-0.22)	0.21 ± 0.06	(0.16-0.27)	0.78 ± 0.29	(0.60-1.11)
Copper (mg)	0.03 ± 0.01	(0.02-0.04)	0.05 ± 0.01	(0.04-0.06)	0.05 ± 0.02	(0.03-0.07)
Selenium (mcg)	4.29 ± 0.27	(4.00-4.53)	6.00 ± 2.80	(3.13-8.73)	4.17 ± 0.76	(3.33-4.83)
Vitamins (per 100 ml)						
Vitamin A (mcg RE)	63.0 ± 4.0	(59.0-67.0)	64.5 ± 10.1	(57.7-76.0)	117.2 ± 38.9	(84.0-160.0)
Vitamin D (mcg cholecalciferol)	0.32 ± 0.07	(0.27-0.40)	0.23 ± 0.06	(0.17-0.29)	0.40 ± 0.12	(0.29-0.53)
Vitamin E (mg)	0.57 ± 0.07	(0.49-0.63)	0.42 ± 0.03	(0.38-0.44)	0.83 ± 0.03	(0.80-0.86)
Pantothenic acid (mg)	0.49 ± 0.05	(0.44-0.53)	0.66 ± 0.13	(0.54-0.80)	1.22 ± 0.01	(1.20-1.23)
Vitamin B_1 (mg)	0.10 ± 0.01	(0.09-0.10)	0.12 ± 0.01	(0.11-0.13)	0.24 ± 0.11	(0.12-0.33)
Vitamin B_2 (mg)	0.08 ± 0.01	(0.07-0.09)	0.10 ± 0.02	(0.08-0.12)	0.21 ± 0.10	(0.09-0.28)
Vitamin B_3 (mg)	0.55 ± 0.20	(0.42-0.79)	0.69 ± 0.13	(0.57-0.82)	2.11 ± 0.07	(2.03-2.17)
Vitamin B_6 (mg)	0.68 ± 0.10	(0.62-0.80)	0.35 ± 0.21	(0.22-0.60)	0.50 ± 0.06	(0.45-0.56)
Vitamin B_{12} (mcg)	0.68 ± 0.09	(0.61-0.78)	0.72 ± 0.01	(0.70-0.73)	0.80 ± 0.08	(0.71-0.87)
Vitamin C (mg)	0.97 ± 0.24	(0.74-1.22)	1.34 ± 0.46	(0.82-1.70)	2.20 ± 0.59	(1.67-2.84)

NFE - nonferrous extract, BTF - blenderized tube feeding,
% - percentage, SD - standard deviation

available in a wide variety of disease specific formulations. Any initial economic advantage of preparing BTF (based only on cost of ingredients) may be considerably offset by the increased medical costs resulting from their use. A future consideration would be to conduct a detailed cost-benefit analysis of blenderized versus commercial tube feedings.

The results of this study highlight some of the problems that have been previously reported for homemade enteral feedings.[10,14] The blenderized diets did not provide the predicted nutrient content. There was a high degree of variability within and between sites for the concentrations of many of the nutrients measured; viscosity and osmolality were high and had a large degree of variability. There was significant bacterial and coliform contamination of many of the feedings. This compares unfavorably with the CPF which displayed a high degree of accuracy in the provision of expected nutrients, low variability in nutrient concentrations and physical properties, and no bacterial or coliform contamination.

Variations in the nutrient compositions of blenderized enteral feedings have been observed in other studies.[10,22] There are several likely sources for the variability, including human error and inconsistencies in measuring, as well as loss of nutrients in cooking and processing foods, which, again, will vary depending on the personnel preparing the food. In addition, this variability has been partly attributed to the nutrient compositions of the fresh foodstuffs used, which can vary according to the geographical source of the food, the season and stage of maturity when the food was harvested and storage conditions.[22] All the feedings prepared

Table 4 - Nutrients with significant differences between expected and actual concentrations (BTF), N=18.

Nutrient	n	%	*p* value
	n ≥ expected concentrations		
Vitamin A	16	(89)	0.001
Vitamin D	15	(83)	0.008
Vitamin E	18	(100)	< 0.0005
Pantothenic acid	17	(94)	< 0.0005
Vitamin B_1	18	(100)	< 0.0005
VitaminB_6	18	(100)	< 0.0005
	n ≤ expected concentrations		
Vitamin C	18	(100)	< 0.0005
Phosphorus	14	(78)	0.031
Cholesterol	17	(94)	< 0.0005
Iron	14	(78)	0.031
Carbohydrate	14	(78)	0.031
Calories	15	(83)	0.008

p values from nonparametric sign test,
BTF - blenderized tube feeding

in this study contained fresh foodstuffs. Although similar types of ingredients (example, meat, fruit, vegetables) were used at all sites, differences in the actual ingredients and amounts used contributed to the wide range of nutrient concentrations in the feedings between sites.

In addition to inter and intra-site variability in nutrient concentrations, we found that the actual concentrations of nutrients were substantially different from the expected concentrations for many of the feedings. For all feedings, positive correlations between actual and expected concentrations were only observed for vitamins A, E, B_6 and C. The concentrations of many of the vitamins measured were greater than expected, while the concentrations of carbohydrate, calories and many of the minerals were lower than expected. Specifically, the caloric content was less than expected in 15 of the 18 samples (p=0.008). Enteral feedings usually contain approximately 1000 calories per liter of formula. The expected caloric content per liter (as estimated from the recipe ingredients) was within acceptable range at sites 1 and 3. However, for feedings prepared at site 2, the expected energy value was only 700 calories. Of particular concern is the actual energy levels in both standard and therapeutic preparations were only 400 - 683 calories (site 1) and 543-663 calories (site 2).

This variability in nutrient concentrations can have a significant impact on the patient. Patients may require tube feedings for a number of reasons including trauma, surgery, cancer, and anorexia. Many of the diseases or conditions necessitating enteral feedings also produce alterations, both increases and decreases, in the need for specific nutrients. Inadequacies or excesses can have serious detrimental effects over time. Therefore, the tube fed patient requires a high degree of specificity and accuracy in an enteral formulation, which is unavailable in a BTF product. Hence, the purported benefit of using blenderized feedings to suit the needs of different patient populations is not supported by this study.

In addition to having altered nutrient requirements, patients who require tube feedings may be immunologically stressed as a result of the disease process or malnutrition. Malnutrition in hospitalized patients resulting from inadequate nutrient prescriptions or incomplete delivery of formula is common.[23,24] Food-borne illness can be particularly devastating to hospitalized patients who are immunocompromised or receiving immunosuppressive therapy.[20] In our study, we found that nearly all BTF analyzed had APC greater than 10,000 CFU/gram, compared with counts of less than 10 CFU/gram (the detection limit) for all samples of the commercial feeding. At the time of preparation, 86% of both standard BTF and therapeutic BTF diets had APC $>10^4$/gram and 36% of the feedings at all time points had counts $>10^5$ CFU/gram. Indeed, some of the samples of the therapeutic BTF feeding prepared at site 3 had APC greater than 1,000,000 CFU/g. Similarly, there was significant coliform contamination of many of the feeding samples prepared at site 3. Guidelines for manufactured formulas place a limit of 10,000 (10^4) organisms/mL for total plate count at the time of manufacture[11] and the suggested maximum coliform count for raw milk is 10/mL.[12,13] The quantity and variety of organisms present in BTF is representative of colonic or fecal flora. In comparison to the standards, the BTF preparations were highly contaminated and posed a substantial risk for developing a food-borne illness.

There are many potential sources for contamination of blenderized feedings, which is why contamination is so prevalent and difficult to control. The high levels of bacterial contamination observed in some of the BTF are likely due to the use of food products such as meat, fresh fruits, vegetables and eggs. Contamination, therefore, is apt to be from microorganisms inherent in the ingredients of feedings. The hospitals participating in this study are in major cities where the water source is well controlled. Thus, water is unlikely to

Table 5 - Nutrient comparison of BTF and CPF.

Nutrient	All BTF N=18		All CPF N=3	
	Mean ± SD	(Range)	Mean ± SD	(Range)
Macronutrients (per 100 ml)				
Cholesterol (mg)	8.61 ± 6.25	(2.55-27.75)	0.23 ± 0.12	(0.10-0.33)
Fat (g)	2.64 ± 1.38	(1.38-6.31)	3.37 ± 0.11	(3.25-3.46)
Saturated fat (g)	1.02 ± 0.84	(0.19-3.06)	0.95 ± 0.06	(0.88-0.99)
Unsaturated fat (g)	1.62 ± 0.66	(0.86-3.26)	2.42 ± 0.06	(2.37-2.48)
Protein (g)	4.11 ± 2.00	(1.61-7.87)	3.87 ± 0.06	(3.83-3.94)
NFE (g) (carbohydrate)	7.72 ± 2.15	(4.52-11.15)	15.13 ± 0.12	(15.05-15.28)
Calories (cal)	71.2 ± 24.0	(40.0-123.7)	106.7 ± 0.7	(106.0-107.3)
Dietary fiber (g)	1.07 ± 0.77	(0.46-3.98)	1.10 ± 0.05	(1.07-1.16)
Minerals (per 100 ml)				
Sodium (mg)	162.8 ± 156.9	(25.5-467.3)	93.1 ± 1.88	(92.0-95.3)
Potassium (mg)	176.3 ± 75.0	(98.4-294.8)	168.7 ± 4.4	(165.5-173.7)
Calcium (mg)	57.7 ± 22.1	(33.3-103.4)	94.9 ± 6.1	(88.6-100.7)
Phosphorus (mg)	48.1 ± 19.4	(26.3-83.4)	90.4 ± 1.3	(89.0-91.7)
Magnesium (mg)	13.3 ± 5.2	(7.6-20.8)	28.7 ± 0.4	(28.2-29.0)
Zinc (mg)	0.41 ± 0.16	(0.26-0.70)	1.84 ± 0.16	(1.67-1.97)
Minerals (per 100 ml)				
Iron (mg)	0.36 ± 0.28	(0.09-1.11)	1.33 ± 0.07	(1.26-1.40)
Copper (mg)	0.04 ± 0.02	(0.02-0.08)	0.16 ± 0.01	(0.15-0.17)
Selenium (mcg)	5.17 ± 1.56	(3.13-8.73)	4.99 ± 0.10	(4.90-5.10)
Vitamins (per 100 ml)				
Vitamin A (mcg RE)	79.7 ± 30.4	(47.0-160.0)	50.3 ± 3.3	(47.7-54.0)
Vitamin D (mcg cholecalciferol)	0.32 ± 0.11	(0.14-0.57)	0.68 ± 0.01	(0.66-0.69)
Vitamin E (mg)	0.59 ± 0.16	(0.38-0.86)	2.25 ± 0.29	(1.93-2.50)
Pantothenic acid (mg)	0.76 ± 0.30	(0.34-1.23)	1.16 ± 0.06	(1.09-1.21)
Vitamin B_1 (mg)	0.16 ± 0.09	(0.09-0.38)	0.21 ± 0.01	(0.20-0.21)
Vitamin B_2 (mg)	0.15 ± 0.09	(0.06-0.35)	0.17 ± 0.01	(0.16-0.18)
Vitamin B_3 (mg)	1.05 ± 0.65	(0.42-2.17)	2.37 ± 0.09	(2.30-2.47)
Vitamin B_6 (mg)	0.48 ± 0.18	(0.22-0.80)	0.21 ± 0.01	(0.20-0.22)
Vitamin B_{12} (mcg)	0.71 ± 0.16	(0.38-1.04)	0.63 ± 0.04	(0.59-0.66)
Vitamin C (mg)	1.40 ± 0.64	(0.74-2.84)	13.5 ± 0.6	(12.9-14.1)

SD - standard deviation, BTF - blenderized tube feeding,
CPF - commercially prepared formulas, NFE - nonferrous extract

Table 6 - Aerobic plate counts (CFU/gram) of BTF and CPF.

	Site 1		Site 2		Site 3		CPF	
	Median	Range	Median	Range	Median	Range	Median	Range
Standard feedings								
0 hours (n=3)	54,000	(38,000-620,000)	2,000	(800-17,000)	130,000	(66,000-360,000)	<10	-
1 hour (n=3)	57,000	(19,000-960,000)	2,200	(800-12,000)	160,000	(70,000-450,000)	<10	-
2 hours (n=3)	95,000	(19,000-150,000)	4,500	(1,300-10,000)	170,000	(75,000-450,000)	<10	-
4 hours (n=3)	240,000	(40,000-700,000)	17,000	(14,000-20,000)	310,000	(67,000-480,000)	<10	-
Therapeutic feedings								
0 hours (n=3)	19,000	(3,000-45,000)	6,000	(1,900-8,600)	240,000	(120,000-1,800,000)		
1 hour (n=3)	16,000	(16,000-49,000)	12,000	(7,100-58,000)	390,000	(140,000-7,500,000		
2 hours (n=3)	24,000	(13,000-50,000)	25,000	(8,500-60,000)	260,000	(220,000-1,300,000		
4 hours (n=3)	49,000	(46,000-95,000)	85,000	(13,000-270,000)	290,000	(270,000-2,100,000)		

	All BTF combined	
	Median	Range
All feedings		
0 hour (n=18)	41,500	(800-1,800,000)
1 hour (n=18)	53,000	(800-7,500,000)
2 hours (n=18)	55,000	(1,300-1,300,000)
4 hours (n=18)	90,000	(13,000-2,100,000)

BTF - blenderized tube feeding,
CPF - commercially prepared formulas

Table 7 - Coliform counts (CFU/gram).

Site	Diet	Median coliform counts (range) over time (hours)							
		Hour=0		Hours=1		Hours=2		Hours=4	
		Median	Range	Median	Range	Median	Range	Median	Range
1	Standard (n=3)	10	(<10-30)	10	(<10-30)	20	(<10-30)	40	(28-50)
	Therapeutic (n=3)	<10		<10		<10		<10	
2	Standard (n=3)	<10		<10		<10		<10	
	Therapeutic (n=3)	<10	(<10-30)	<10	(<10-40)	<10	(<10-10)	<10	(<10-20)
3	Standard (n=3)	170	(19-340)	100	(10-290)	130	(40-260)	120	(30-280)
	Therapeutic (n=3)	20	(10-440)	7,100	(10-45,000)	33,000	(10-42,000)	19,000	(10-54,000)

Table 8 - Types of organisms detected in BTF.

Pathogenic Species (18)	Sites	Other bacterial species	Sites
Enterobacter cloacae	1,3	*Chromobacterium violaceum*	1
Enterococcus faecalis	2	*Enterococcus durans*	3
Escherichia coli	1	*Enterococcus hirae*	1
Klebsiella oxytoca	2,3	*Lactococcus lactis*	1,2,3
Klebsiella pneumoniae	1,2,3	*Leuconostoc amelibiosum*	2
		Leuconostoc carnosum	1
		Leuconostoc mesenteroides	2
		Micrococcus sedentarius	1,2,3
		Micrococcus varians	1,3
		Pantoea species	1
		Streptococcus thermophilus	1,2,3

BTF - blenderized tube feeding

Table 9 - Physical properties of BTF and CPF.

Site	Viscosity (cP)		Osmolality (mOsm/kg H_20)	
	Standard feedings	Therapeutic feedings	Standard feedings	Therapeutic feedings
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)
Site 1 (n=3)	6.74 ± 2.01 (4.99-8.93)	8.30 ± 0.95 (7.31-9.21)	578.9 ± 38.0 (541.7-617.7)	614.7 ± 112.8 (515.3-737.3)
Site 2 (n=3)	362.7 ± 230.5 (105.3-550.2)	606.9 ± 446.3 (181.5-1071.4)	383.0 ± 104.9 (306.7-502.7)	400.1 ± 146.2 (307.7-568.7)
Site 3 (n=3)	4232.1 ± 2731.1 (1232.7-6575.2)	8444.9 ± 7810.8 (1494.7-16897.8)	830.7 ± 25.7 (805.3-856.7)	832.4 ± 118.7 (696.0-912.0)
All BTF (n=18)	2276.9 ± 4292.9 (4.99-16897.8)		606.6 ± 203.9 (306.7-912.0)	
Commercial feeding (CPF)	10.84 ± 0.87 (10.20-11.83)		277.9 ± 3.1 (274.3-280.0)	

SD - standard deviation, BTF - blenderized tube feeding
CPF - commercially prepared formulas

be a source of microbial contamination. In addition to food, utensils and personnel are likely sources of contamination. Microorganisms can reside in utensils and blenders, as well as on counters and hands, resulting in bacterial contamination during the preparation and mixing of ingredients, the dilution or decanting of feedings into the nutrient container or the assembly and handling of the feeding system.[17] In general, the more a product is handled or manipulated, the more opportunities for contamination arise. Hence, the level of microbial contamination decreases with the progression from BTF, which are highly manipulated, through commercial powders, commercial liquids in cans, to commercial closed enteral feeding systems, which require virtually no manipulation.[10,15-17]

Hang time is an additional factor to consider in the risk of bacterial contamination and development of food-borne illness. As we demonstrated in our study, there is a significant increase in microorganism concentrations with time, which poses an additional problem with BTF. The preparation of the feeding may typically take 30 minutes to one hour, followed by 30 minutes to one hour to deliver the product to the patient.[22] Additional hang time is then required to actually feed the product to the patient. During this time period, the degree of microbial contamination may increase.

In addition to disadvantages relating to nutrient content and microbiological contamination, we found several problems in the physical properties of BTF. Commercial feedings that are known to flow unaided through small bore (8 French) feeding tubes typically have a viscosity of less than 60 cP.[25] We found the mean viscosity of the BTF to be 2276.9 cP, compared to 10.84 cP for the commercial formula. Furthermore, feedings prepared at sites 2 and 3 had viscosities that were highly variable, approximately 10-1,000 fold higher than the commercial feeding. Feedings with such high viscosity would likely clog a small bore feeding tube. Placing a large bore feeding tube to enable the flow of a highly viscous product has several disadvantages. Larger feeding tubes are less comfortable for the patient and may result in the patient's refusal to initiate or continue a tube feeding. In addition, large bore feeding tubes have been implicated in the development of aspiration pneumonia by facilitating the transmission of gastric contents to the trachea.[26-28] Furthermore, the bolus method of feeding, which is typically how BTF are administered[22] also increases the risk for aspiration pneumonia.[26] Hence, the risk of aspiration pneumonia from BTF results from: 1. The use of a large bore feeding tube that is necessitated by the high viscosity of BTF. 2. Feeding via the bolus method, which is typical with blenderized foods. 3. Microbial colonization of the stomach from highly manipulated, contaminated feedings results in those pathogenic bacteria entering the airway when stomach contents are aspirated.

Similar to viscosity, we found the results for osmolality to be suboptimal. The osmolality for the BTF was much higher than the commercial formula, approximately double at 606.6 mOsm/kg H_2O versus 277.9 mOsm/kg H_2O. In addition, the range of results was much wider, at 306.7-912.0 mOsm/kg H_2O versus 274.3-280.0 mOsm/kg H_2O. The commercial formula varied by approximately 2%, while the BTF varied almost 200%. Both the higher osmolality and high degree of variability between feedings exposes the patient to an increased risk of gastrointestinal complications. In a poorly functioning gut, hypertonic solutions may cause abdominal distention, vomiting and diarrhea, which could lead to electrolyte depletion and dehydration.

In summary, we found that blenderized tube feedings: 1. Did not provide their expected nutrient content, and nutrient analyses of the samples showed high variability within and between sites. 2. Contained a high prevalence and degree of microbial contamination, with APC and coliform levels exceeding acceptable limits and pathogenic microorganisms present in some cases. 3. Displayed high values for viscosity and osmolality, rendering them impractical for use in tube fed patients.

In order for nutrition support with an enteral feeding to be effective, the appropriate formula must be provided. An appropriate formula should provide consistent, adequate nutrients according to the diet prescription and have a low risk for complications to the patient. In our study, we confirmed some of the previously reported complications with BTF (microbial contamination, poor nutritional quality, suboptimal physical properties) and established that commercially prepared enteral formulas in a closed system is the preferred method for enteral tube feeding.

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