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Original article

Nutritional and microbiological quality of commercial and homemade blenderized whole food enteral diets for home-based enteral nutritional therapy in adults☆

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SUMMARY

Background & aims: Serious nutritional and contamination risks may be involved in the preparation of blenderized tube-feeding diets and in the handling of commercial diets. Their nutritional and microbiological quality in home settings is unknown. The objective of this study was to assess the nutritional and microbiological quality of commercial enteral and homemade blenderized whole foods diets intended to adult patients in home nutritional therapy.

Methods: In a cross sectional study, 66 samples of commercial (CD) and noncommercial (NCD) enteral diets were collected at the homes of patients in home enteral nutritional therapy, 33 of each type. Commercial diets were either powder (PCD; n = 13) or liquid (LCD; n = 20). The samples were analyzed in laboratory to assess their nutritional and microbiological quality. Anthropometric data of mid upper arm circumference (MUAC) and triceps skinfold (TST) thickness were obtained from the patients' medical records.

Results: NCD presented significantly lower values for protein, fat, fiber, carbohydrate and energy while water content was significantly higher. PCD and LCD did not show any statistically significant differences between them. In the NCD, the values measured for macronutrients and energy corresponded to less than 50% of the prescribed values (except for fat). In CD, protein value was about 20% more than the prescribed value; fat and energy values corresponded to approximately 100% of the prescription, while carbohydrate corresponded to 92%. Regardless the type of the diet, prevalence of undernutrition was high in both groups though patients of the NCD presented a higher percentage. Samples of NCD complied significantly less with the microbiological standards; only 6.0% complied with the standard for coliform bacteria. *Escherichia coli* was detected in 10, 2, and 2 samples of NCD, PCD and LCD, respectively.

Conclusions: Homemade blenderized enteral diets showed low values of energy and macronutrients, delivered less than 50% of the prescribed values and had high levels of bacterial contamination.

1. Introduction

Among chronic diseases, stroke and other neurological conditions are the main indications for home care, and such patients also frequently require enteral tube feeding [1]. Tube feeding should be used if patients are not able to maintain adequate oral intake in order to fulfill their energy and substrate needs. In many developed countries, commercial enteral formulas are supported by the National Health Systems [2,3]. In 2011, the Brazilian government established a public-sector health program for the elderly population called "Better in home" [4]. However, this service currently has a limited reach; most of the estimated 310,000 patients in home care are covered by the private sector. Only the more affluent socioeconomic classes can afford private health insurance to cover these services. Different types of health insurance coverage exist; however, only the most expensive cover commercial enteral formula. Commercial enteral feeding is too expensive for patients for whom health insurance does not offer full coverage. In these cases, families must rely on blended whole food as an alternative.

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These homemade blended diets are often described as nutritionally unbalanced, have an increased risk for food contamination, and may compromise enteral access devices [5]. Even when prepared in hospital environments, blenderized enteral tube feeding diets using common foodstuffs have rendered unpredictable and inconsistent micronutrient and macronutrient levels despite the use of standardized recipes [6,7] and have presented a high degree of contamination [7,8]. Commercial diets for their part are not without risk of contamination [8–10].

Taking into account that most of the studies evaluated the nutritional and microbiological quality of enteral diets in hospital settings and the serious nutritional and contamination risks involved in the preparation of blenderized tube-feeding diets and the handling of commercial diets, this study aimed to evaluate the nutritional and microbiological quality of homemade blenderized whole foods and commercial enteral diets intended to adult patients in home nutritional therapy. The study also evaluated the percentage ratios of expected values/measured values of macronutrients and energy of the diets. The nutritional status of the patients was assessed through the mid-upper arm circumference and triceps skinfold thickness anthropometric indicators. To our knowledge, this is the first study to assess the quality, both nutritional and microbiological, of enteral diets in home settings [11].

2. Methods

2.1. Study design and population

This study was approved by the Ethics Committee of the Universidade Federal de São Paulo and consisted of a collection of samples of commercial and noncommercial enteral diets at the homes of patients in home enteral therapy located in the urban area of the city of São Paulo, Brazil. The samples were analyzed in laboratory to assess their nutritional and microbiological quality. Anthropometric data of mid upper arm circumference (MUAC) and triceps skinfold (TST) thickness were provided by the dietitians of the home care companies from the patients' medical records. Stroke sequels and neurological diseases were the main medical conditions of the patients ($n = 66$). Thirty-four were males and thirty-two, females, with a median age of 73 years (ranging from 20 to 100 years).

In this study, all patients were covered by private health insurance, which paid the home care companies for their services. Health care coverage included a multiprofessional team of physicians, nurses, speech therapists, physical therapists, social workers, and dietitians who visited the patients at least once a month. For enteral nutrition therapy, most health insurance companies covered only the administration set and the feeding containers. Because of the cost of the enteral diets themselves was not reimbursed by the insurance companies, the families were responsible for this purchase. Due the high cost of commercially manufactured enteral feeding diets, families chose to use homemade enteral diets. Less comprehensive coverage usually was related to health insurance paid by employers. For some patients, health insurance companies covered the commercial diet itself in addition to the administration sets and feeding containers.

Consent was obtained from clinical directors of home care service companies that agreed to participate to participate in the study. Terms of consent were also obtained from patients' families. The first author (MMCV) telephoned the family of each potential patient to ask whether they would like to take part in the study. In the case of a positive answer, a home-visit was scheduled. Inclusion criteria were adult patients with neurological baseline disease, of both genders, clinically stable, without fever, under home nutritional therapy and that received nutrition solely by the enteral route for at least 3 months. The enteral feeding was prescribed by nutritionists of the home care companies without interference from the authors. Samples of diet of patients who had been receiving homemade blenderized whole foods enteral tube feeding consisted of the noncommercial diet group (NCD) while samples of the diets of patients receiving the commercial diet group consisted of the commercial diet (CD) group. The study consisted of 66 samples, 33 in each group. Commercial diets were either powder (PCD) or liquid (LCD). Noncommercial diets consisted of the following food groups: lean meat, poultry, eggs, milk, grain, vegetables, legumes, beans, cooking oil and salt. Energy and macronutrients were calculated for each day according to the requirements of each patient. Though caregivers could choose the ingredients from a list of interchangeable items, the nutritional composition was every day the same. Fruit was not served because difficulties related to the passage through the administration set. Fish was considered unsuitable out of the concern about its freshness. All ingredients were cooked together, pureed in a food blender and then passed through sieves in order to remove large food particles. Powder commercial diets were reconstituted with filtered or bottled water in a bowl. Liquid commercial diets in cans were transferred directly into the feeding containers. The daily costs of the diets (1500 ml) were estimated at US$ 5.0 and US$ 14.0 for the NCD and CD groups, respectively.

Samples were collected at the patients' home before the diets were to be delivered. Samples for microbiological analyses were kept at <10 °C until they reached the laboratory, which was within 2 h of sampling. The samples were analyzed for the presence and concentration of indicator microorganisms, i.e., mesophilic and coliform bacteria and *Escherichia coli*, which have long been used as indicators of bacterial quality. All samples were processed in conformity with standard microbiological methods [12]. The results were compared to the Brazilian microbiological standards for enteral diets [13]: mesophilic bacteria <1000 organisms/ml, and coliform and *E. coli* < 3 organisms/ml.

The samples were also analyzed in duplicate for moisture, protein, fat, dietary fiber and ash [14]. The moisture content was obtained by heating the samples to 102 °C until a constant weight was attained. The protein level was obtained by determination of total nitrogen by Kjeldahl method, whereas the fat was extracted by using the Soxhlet equipment. Dietary fiber was analyzed with an enzymatic-gravimetric method. Ash was obtained by incineration at 500 °C − 550 °C until the ash was carbon-free. Carbohydrate content was determined by difference. The energy density was calculated using Atwater's factors, specifically by multiplying the protein and total carbohydrate content by 4 Kcal and adding the result to the fat content multiplied by 9 Kcal. Percentage ratios of expected values/measured values were calculated for macronutrients and energy. The expected nutrient content of noncommercial diets was calculated from food composition tables. For commercial diets, the expected values were those showed in the nutritional labels information.

Statistical analyses were performed using Sigma Stat 2.0 software for Windows (SPSS Inc.). Sample size was calculated considering a water content proportion of 85% and 75% in samples of NCD and CD, respectively, a power of 0.90 and $p < 0.05$. The result was a sample size of at least 30 samples. Tests to compare multiple groups were used to compare the macronutrients content, energy, and the microbiological counts of the noncommercial, powder and liquid enteral diets samples. One Way Analysis of Variance and Kruskal–Wallis test were used depending on whether the variables presented or not normal distribution. The level of significance was 5%, corrected for multiple comparisons. The association between the energy content and mesophilic counts of the samples, and the results of the patients' anthropometry of MUAC and TST was

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investigated using the Pearson Product Moment Correlation. The anthropometric data were transformed to Z-score through the following equations: a. Standard deviation (SD) = Standard Error x $\sqrt{n}$; b. Z-score = score minus the mean divided by standard deviation. Standard error, 'n' and mean were taken from the tables of the reference population [15]. Paired tests were used to compare the Z-scores of the NCD and CD groups. T-test and Mann–Whitney test were used depending on whether the variables presented or not normal distribution. The chi-square test was used to compare the proportions of complying samples with microbiological standards of the noncommercial, powder and liquid enteral diets. Fisher's exact test was used when over 20% of the expected values in the contingency table were less than 5. A partition of the chi-square test was used after a significant ($p < 0.05$) overall test. There were no missing data. The results in the tables are presented with their respective statistical tests.

3. Results

Table 1 shows the analytical results of the macronutrient and energy contents of the noncommercial, and powder and liquid commercial enteral diets. Noncommercial enteral diets presented significantly lower values for protein, fat, fiber, carbohydrate and energy when compared to powder and liquid commercial diets while water content was significantly higher. No differences were seen with regard to minerals content. Powder and liquid commercial enteral diets did not show any statistically significant differences between them, except for fat which was lower in LCD samples.

In Fig. 1 are the mean percentage ratios of the measured values/prescribed values for macronutrients and energy in noncommercial and commercial enteral diets. In the noncommercial enteral diets, the values measured for macronutrients and energy corresponded to less than 50% of the prescribed values, except for the fat content. In the commercial enteral diets, protein value was about 20% more than the prescribed value; fat and energy values corresponded to approximately 100% of the prescription, while carbohydrate corresponded to 92%.

In Table 2 are the Z-scores of MUAC and TST in the NCD and CD groups. The median of MUAC in the NCD group was lower when compared to the CD group though no statistically significant difference was reached. The values of TST were similar in both groups.

The counts of mesophilic, coliform and *E. coli* bacteria and the compliance with microbiological standards are presented in Tables 3 and 4. The counts of mesophilic and coliform bacteria were significantly higher in noncommercial enteral diet. They showed the lowest compliance with the microbiological standards. Only 6.0% of the samples complied with the standard for coliform bacteria. Samples of powder commercial enteral diets complied less when compared to liquid commercial enteral diet. Presence of *E. coli* was detected in 10, 2, and 2 samples, respectively, of noncommercial, powder commercial and liquid commercial enteral diets. No association between the energy content and mesophilic counts of the samples, and the results of the patients' anthropometry of MUAC and TST was observed.

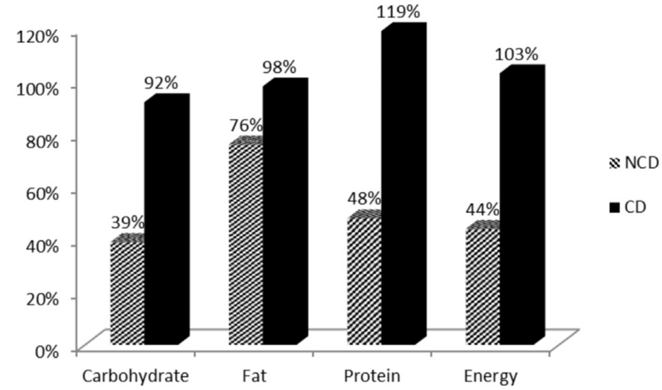

Fig. 1. Percentages ratios of expected values/measured values for macronutrients and energy in non-commercial and commercial diets.

Table 2
Z-scores of MUAC and TST in the NCD and CD groups.

	NCD (n = 33)	CD (n = 33)	Statistical analysis
MUAC	−1.8 (−2.1/−1.1)	−1.3 (−1.9/−0.9)	p = 0.087[a]
TST	−1.1 ± 0.9	−0.9 ± 0.8	p = 0.293[b]

[a] Mann–Whitney test: median and P25/P75.
[b] T-test: mean ± SD.

4. Discussion

The results of this study showed that noncommercial enteral diets presented significantly lower values for protein, fat, fiber,

Table 1
Macronutrients and energy according to the type of the enteral diet.

	NCD n = 33	PCC n = 13	LCD n = 20	Statistical Analysis
Water (g/100 g)	91.1 88.2/93.2	75.7 71.0/82.6	79.2 75.5/80.2	p < 0.001[a] PCD = LCD < NCD[c]
Protein (g/100 g)	2.1 1.4/3.4	4.1 3.2/5.0	4.1 3.8/4.4	p < 0.001[a] NCD < PCD = LCD[c]
Fat (g/100 g)	1.9 ± 1.2	4.3 ± 1.8	3.0 ± 1.2	p < 0.001[b] NCD < LCD < PCD[c]
Minerals (g/100 g)	0.7 0.4/0.8	0.7 0.6/0.8	0.6 0.6/0.7	p = 0.702[a]
Dietetic Fiber (g/100 g)	0.8 0.6/1.6	1.2 0.4/1.4	1.9 1.5/2.4	p = 0.025[a] NCD < LCD; NCD = PCD; PCD = LCD
Carbohydrate (g/100 g)	3.4 2.4/5.6	13.2 11.0/15.6	11.6 10.2/15.6	p < 0.001[a] NCD < PCD = LCD[c]
Energy (Kcal/100 g)	40.5 26.0/49.4	113.5 75.0/124.0	110.0 98.0/120.0	p < 0.001[a] NCD < PCD = LCD[c]

[a] Kruskal–Wallis, median and percentiles 25 and 75.
[b] One Way Analysis of Variance, mean and SD.
[c] Multiple comparisons analysis.

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Table 3
Counts of mesophilic, coliform and *Escherichia coli* bacteria according to the type of diet.

Colony-forming unit/mL	NCD (n = 33)	PCD (n = 13)	LCD (n = 20)	Statistical analyses
Mesophilic	40,000 3000–2,400,000	360 5–15,000	0 0–0	$p < 0{,}001$[a] LCD < PCD < NCD[b]
Coliform	14,000 330–100,000	180 0–1400	0 0–0	$p < 0{,}001$[a] PCD = LCD < NCD[b]
Escherichia coli	0 0–5	0 0–0	0 0–0	$p = 0{,}062$[a]

[a] Kruskal–Wallis, median and percentiles 25 and 75.
[b] Multiple comparisons analysis.

Table 4
Number of samples complying with microbiological standards, according to the type of diets.

Colony-forming units/mL)	NCD (n = 33)	PCD (n = 13)	LCD (n = 20)	Statistical analyses
Mesophilic	7 (21%)	8 (62%)	20 (100%)	$p < 0{,}001$[a] NCD < PCD = LCD[c]
Coliform	2 (6%)	4 (31%)	17 (85%)	$p < 0{,}001$[a] NCD = PCD < LCD[c]
Escherichia coli	23 (70%)	11 (85%)	18 (90%)	$p = 0{,}18$[b]

[a] Chi-square test.
[b] Fisher exact test.
[c] Partition.

carbohydrate and energy when compared to powder and liquid commercial diets while water content was significantly higher. Blenderized tube-feeding diets typically contain common foodstuffs such as milk, eggs, meat, soft fruits, and vegetables that are cooked and then pureed in a food blender or mixer. These blenderized foods frequently must be sieved to remove large food particles, and even after this procedure, their viscosity may be unsuitable for infusion through a feeding tube, requiring the addition of more liquids to reduce their thickness. These procedures may explain the variable and low nutrient content of the noncommercial diets. In consequence, their actual concentrations of nutrients were substantially different from the expected concentrations. The values measured for macronutrients and energy corresponded to less than 50% of the prescribed values resulting in inaccurate nutrient administration and potentially jeopardizing the nutritional status of the patients. Indeed, patients that received noncommercial diets presented a higher prevalence of undernutrition, 64% and 45%, for MUAC and TST anthropometric indicators, respectively. Commercial diets, though accurately delivering the expected macronutrients and energy, have a non-negligible prevalence of 48% and 24% of undernourished patients, respectively. These are worrisome findings since there is excellent evidence that undernutrition is an independent risk factor for higher morbidity, increased length of hospital stay, higher readmission rates, delayed recovery, lower quality of life as well as higher hospital costs and higher mortality [16]. The possible reasons underlying the undernutrition in the patients using commercial diets should be better investigated.

In addition of having a low nutrient content, noncommercial diets presented a higher microbiological contamination and a lower compliance with the microbiological standards. Only 6% of the samples complied with coliform bacteria standard. Mesophilic bacteria, coliforms and *E. coli* are indicators microorganisms largely used in assessing the microbiological quality of food because they have ecological characteristics that are similar to those of pathogenic microorganisms. The presence of indicators at certain levels suggests that the foods have been exposed to conditions that would also allow the presence of pathogenic microorganisms. Therefore, they reveal the potential risk for the presence of such agents. Indicators are also used to verify if treatments meant to ensure the safety of a food product, such as heat treatment, were effective [17].

The more the need of handling, the greater the degree of microbial contamination. Noncommercial and powdered commercial diets showed higher bacteria counts and lesser compliance with standards when compared to liquid commercial diet. The same pattern was found in hospital environments [8]. The many procedures used in the preparation of noncommercial diets provided many potential sources of contamination. Inadequate cooking of contaminated raw foods and cross-contamination from food handlers, equipment, utensils and surfaces may explain the high level of bacterial contamination found in this study. Sieves, surfaces and, particularly, blenders proved to be sources of contamination in hospital environments [8]. For powder diets, the handling consisted of hydration with either filtered or bottled water. Contamination of both types of water have been reported in hospitals [8,18]. On the other hand, liquid commercial diets only require transferring of the cans' content into the feeding container.

Selecting and adapting the nutrient sources in blenderized diets are difficult and complex tasks for nutritionists. In addition to requiring adequate nutritional composition and microbiological quality, these formulations must be stable and have appropriate viscosity and osmolar concentration. Furthermore, guiding and training caregivers in the preparation of these formulations in the patients' homes represent additional challenges. A recently proposed modular homemade standardized formulation, for another set of patients, overcame many of these obstacles [19]. The formulation proved to be adequate in their nutritional and physicochemical properties. The microbiological quality of the formulation, however, remains a matter of concern [19]. A significant proportion of samples (approximately 40%) of the diets prepared at the patients' homes did not comply with the Brazilian standards for mesophilic bacteria, though this is a far more better result when compared to 79% found in this study. These results indicate that more attention should be paid by health professionals to good handling practices in non-commercial diets preparation. It is also possible that not all households have the proper conditions to safely prepare the diets. In such cases, health professionals should perform a careful on-site evaluation [19].

Patients of the NCD group presented a lower Z-scores of MUAC and TST when compared to the CD group probably due the low nutrient content of the enteral diets in this group. More likely, statistically significant differences were not reached due the low sample size. However, the CD group also presented negative Z-scores though they were receiving the well-established treatment for enteral nutrition. Though the quality and adequacy of the diet may be the most important factor in the maintenance of the nutritional status, others variables, such as infections, age, basal disease and physical inactivity may have an influence too.

No association between the energy content and mesophilic counts of the samples, and the results of the patients' anthropometry of MUAC and TST was observed. This finding probably may be explained by the fact that the study design does not allow investigating multifactorial outcome such as nutritional status. A larger sample would be required to perform a statistical analysis such as multiple logistic regression.

In this study the authors were allowed only the collection of samples. This situation led to the main limitation of this study that is the limited access to the patients and to some related information such as social economic and demographic variables, complications of the use of enteral nutrition, and caretakers compliance with health professionals' guidance. The lack of association between the diets contamination and energy levels and patients' nutritional status found in this study could be attributed to the small sample of patients. Further studies with larger number of patients and designed to address this issue could provide a better understanding of this question. Another limitation includes the use of a convenience sample of patients of home care companies located in one Metropolitan area and its results may not reflect the situation in other locations. Replication of these findings in other jurisdictions and with a larger sampling frame would strengthen the generalizability of the study findings to other regions and countries.

The strength of this study include the use microbiological and chemical analyses of the samples. Therefore, the results expressed the actual condition of the enteral diets consumed by the patients. As a renewed interest in returning to more whole foods for the nutrition of tube-fed patients has been reported [20], the results of this study highlights the shortcomings, both in the nutritional and microbiological quality, found in noncommercial enteral diets.

In conclusion, homemade blenderized enteral diets showed low values of energy and macronutrients, delivered less than 50% of the prescribed values and had high levels of bacterial contamination.

Conflict of interest

None of the authors reported a conflict of interest related to the study.

Authors' contributions

MMCV designed and conducted the research, analyzed the data, performed statistical analysis and wrote the paper; VFNS and AB designed the research and analyzed the data; TBM designed and oversaw the research, analyzed the data, performed statistical analysis, wrote the paper and had primary responsibility for final content.

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