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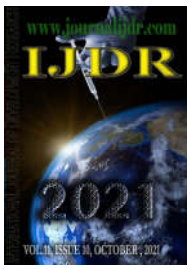

RESEARCH ARTICLE OPEN ACCESS

NUTRITIONAL COMPOSITION OF THE ENTERAL FORMULAS USED IN HOME ENTERAL NUTRITION

Caryna Eurich Mazur[1,*], Patrícia Audrey Reis Gonçalves Pinheiro[2], Marcia Maria Arenhart Soares[3], Rubia Daniela Thieme[4], Eliane Mara Cesário Pereira Maluf[5] and Maria Eliana Madalozzo Schieferdecker[6]

[1]Nutritionist, Midwest State University of Paraná, Brazil; [2]Nutritionist, Municipal Health Department, Curitiba, Brazil; [3]Nutritionist graduated by Federal University of Paraná, Brazil; [4]Nutritionist, Doctoral student of the Postgraduate Programme in Public Policy, Federal University of Paraná, Brazil; [5]PhD in Medicine, Professor of the Postgraduate Program in Intern Medicine in Federal University of Paraná, Brazil; [6]PhD in Medicine (Surgical Clinic), Professor of the Postgraduate Program in Food and Nutrition Security in Federal University of Paraná, Brazil

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***Corresponding author:**
Caryna Eurich Mazur

ABSTRACT

Introduction: In Home Enteral Nutrition (HEN), chemically defined formulas or handmade preparations composed of natural and/or processed foods may be used, two different categories of formulas. Both of them can beadministered to individuals with stroke in HEN. **Objectives:** To determine the energy and protein adequacy of enteral formulas to the nutritional needs of individuals with stroke and to compare the energy and nutritional value of different categories of formulas. **Methods:** Cross-sectional study with patients with stroke that are in HEN in Curitiba, Paraná, Brazil. The food intake by commercial formulas (CF), homemade diet (HD) and mixed formula (MF) was assessed by 24-hour recall and the nutritional compositions of the formulas were estimated. Patient's energy and protein requirements were calculated by Harris and Benedict equation, multiplying the disease injury factor and activity factor, and according to ASPEN, respectively. Statistical analysis was performed using the chi-square test, Kruskal-Wallis and Pearson correlation, at 95% confidence interval ($p<0.05$). **Results:** There were included 45 patients, 65% (n = 26) were female, age average of 74.25 ± 11.3 years, and 87.5% (n = 35) were elderly. The energy requirement was achieved by 88.9% (n = 40). The HD had higher protein content compared to CF and MF ($p<0.05$). The MF was used by 40% (n = 18), with the highest total fiber and B12 vitamin when compared to HD and CF ($p<0.05$). **Conclusions:** The protein and energy patient's requirements were achieved mostly by the different categories of formulas infused via tube in HEN.

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INTRODUCTION

Stroke affects the masticatory muscles, causing damage and decreasing swallowing ability, which is one of the most complex processes of the central nervous system. It consists in multiple voluntary and involuntary contractions of muscles coordinated by many areas of the brain. If one of these areas is damaged by a stroke, complications can be severe and the recovery slow. Dysphagia may be permanent or temporary. The multidisciplinary team should think of ways to prevent further aggravation of the person's nutritional status. In many cases, it becomes necessary the modification of the food consistency or the use of a catheter for enteral nutritional therapy (ENT) (Singh, 2006; Shaker, 2011). Food and nutrition are basic conditions for the promotion of health, allowing human growth and development with quality of life. The ENTis the recommended method for feeding patients who can't feed orally. The scientific and technological advances in ENT lead to improved food formulations as well as the tools associated with nutritional care (Sullivan, 2001; Dudrick, 2011). Home enteral nutrition (HEN), as a form of ENT, seeks the integration of the clinical stable patient to society and family. HENis indicated in patients who are unable to meet nutritional

requirements by the oral route, exhibit a functional gastrointestinal tract, and are at high nutritional risk or malnourished. HEN via feeding tubes may be nasogastric, percutaneous endoscopic gastrostomy and jejunostomy. Moreover, the reduction of the occupation of hospital beds, as well as improved prognosis and quality of life are associated with HEN (Bischoff, 2020; Ojo, 2019). The HEN can be consisted of formulas prepared with food (blended food or homemade), or produced industrially (Franca, 2017). Blended food is still used in chronic patients athome, but there isunclear benefit compared to commercial diet and could be less effectivethan commercial enteral formulas (Bischoff, 2020). But, the contribution of different categories of formulas applied in HEN is almost not discussed in the scientific literature. In Brazil, as in the other countries in development, the use of commercial enteral formulas is gradually increasing since the beginning of the last century. These diets are chemically defined and have a low risk of contamination. However, they are inaccessible to most of the population, legal measures may be taken to trial[8], especially when HEN is needed for prolonged periods. The use of formulas with food is inexpensive, therefore are suitable for individuals in HEN, for they meet the nutritional needs of most chronic and stable patients and are microbiologically safe when prepared properly (Pinheiro, 2014). Because of the diversity of enteral formulas, the growing number of individuals with stroke in HEN in the city of Curitiba, Brazil, and the importance of this therapy for health recovery or maintenance of life, it is necessary to compare the composition of different categories of formulas applied in HEN and their suitability to the nutritional needs of these individuals. The aim of the study was to determine the energy and protein adequacy of enteral formulas to the nutritional needs of individuals that had a cerebrovascular accident and compare the energy and nutritional value of different categories of formulas.

METHODS

It was a cross-sectional prospective study, conducted with patients enrolled in the Nutrition Care Program for People with Special Needs (PAN) of Curitiba, Brazil who had the diagnostic of cerebrovascular accident made by a medical team and registered in the clinical charts. Data were collected in the households of those users enrolled in primary health care in the period from may to december 2013. Patients were divided according to the category of enteral formula used. There were considered commercial formulas (CF) those which were composed of products with defined physical and chemical composition, having standardized nutrition label; homemade diet (HD) those that consisted of foods raw or cooked; and mixed formulas (MF) those which were made of CF and HD (food and industrialized). Dietetic assessment was performed by 24-hour recall (24HR), in which the patient's caregiver reported all components that were used: when food was used, the evaluation was performed by traditional measures with utensils used by the family; when formula / supplement was used, the evaluation was made by its label. There were analyzed the last 24 hours prior to the home visit, as well as quantities, time and amount of fluid infused. Most patients have been following the guidance of standardized prescriptions by the PAN and, thus, there was little variation. After collecting data with caregivers, we calculated the nutritional composition according to the category of formula that was used. Estimate of macro and micronutrients was carried out with the help of Diet Win Professional 2008® software, according to the following order of choice of food composition tables: Manufacturer information - labeling of enteral formulas - and Brazilian Food Composition Table[10]; and Philippi (Philippi, 2002). It was also evaluated the water intake of the patient (ml). Energy requirements were calculated individually by the formula of Harris and Benedict[12] and yet the result was multiplied by a factor of injury (FI) of the underlying disease (FI=1.1) and the activity factor (AF) (AF=1.2). The total amountofenergywasdividedbytheweight (currentorestimated) obtainingenergy per kilogramofweight (Kcal / Kg / day). The protein requirement was performed as recommended by ASPEN[13] of 0.8-1.0 g / kg / day and should not exceed 2.5 g / kg / day to minimize the risk of metabolic complications. The recommendation considered normal of lipids was 20-35% of the diet of total energy value (TEV). The study variables were expressed by descriptive statistics. The distribution of normality was determined using the Shapiro-Wilk test. For the evaluation of the variables according to what is considered normal, it was used analysis of variance (ANOVA) and Student's T-test for independent samples. For non-parametric data, we calculated the chi-square test, Kruskal-Wallis, besides the Post Hoc test to check the divergent. Associations between parametric variables were determined using Pearson correlation. The level of significance at 95% confidence interval ($p < 0.05$).

Table 1. Recommended energy comparison and administered in the tube of the sample patients

	Mean/SD	Median	Minimum	Maximum	p*
Recommended (Kcal)	1356.16±233.07	1339.03	1002.09	1845.82	0.0001
Infused (Kcal)	1712.78±622.25	1300.00	474.00	3311.00	

* Student's T test

Table 2. Comparison of average dietary variables with different formulations of the patients in home enteral nutrition therapy

	Total (n=45)	CF (n=17)	HD (n=10)	MF (n=18)	P value
TEV infused (Kcal)*	1712.78±622.25	1450.35±485.84£	1619.20±471.11	2012.61±702.35£	0.02[a]
Kcal/Kg/day**	42.80±21.22	31.09±13.21	42.82±18.03	53.85±23.72[c]	0.00[b]
CHO (%)**	52.71±7.39	54.41±4.30€	51.46±11.01	51.81±7.43€	0.49[a]
PTN (%)**	17.03±3.36	15.21±0.81€	19.20±4.28€	17.66±3.51€	0.05[b]
LIP (%)**	30.21±8.01	30.33±4.21	29.43±12.85	30.53±7.82	0.71[b]
PTN(g)/Kg**	1.88±1.07	1.19±0.51€	2.08±0.95	2.27±1.21€	0.00[b]
Fiber (g)**	8.71±9.11	4.39±8.19	12.09±6.50	10.91±9.93	0.00[b]
Calcium (mg)**	1258.15±677.54	960.75±316.07€	1153.07±522.66	1597.40±855.98€	0.09[b]
Iron (mg)**	15.59±8.31	17.47±6.16€	9.68±4.55€	17.10±10.28€	0.01[b]
Magnesium (mg) **	362.82±179.21	416.80±220.64	278.71±130.80	358.57±1148.65[c]	0.17[b]
Sodium (mg)**	1601.04±997.49	1373.26±684.39	1398.34±1086.75	1928.77±270.74	0.20[b]
Zinc (mcg)**	17.61±10.29	20.11±10.84	11.12±4.96	18.88±10.85	0.07[b]
Vitamin B12 (mg)**	4.95±3.56	3.11±1.14€	5.18±3.25	6.55±4.45€	0.01[b]
Vitamin A (mcg)**	1960.31±2426.67	1115.73±435.27	2054.56±1168.73	2705.61±3610.16	0.06[b]
Vitamin C (mg)**	157.52±112.21	159.09±88.27	111.13±81.92	181.81±140.74	0.31[b]
Vitamin E (mcg)**	21.20±13.59	18.45±7.84	20.87±16.45	23.98±16.14	0.57[b]

CF = commercial formula; MF = mixed formula; HD = homemade diet; TEV = Total energetic value obtained through the 24-hour recall; CHO = Carbohydrate; PTN= protein; LIP = Lipid. Analysis of Variance (ANOVA); b Kruskal-Wallis test £ statistically differ by post hoc test € statistically differ by Tukey test with 95% confidence

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS Inc, Chicago, IL, USA) version 19.0 for Windows. This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving

human subjects/patients were approved by the Research Ethics Committee of the Curitiba Municipal Health Department (protocol 09/2013 / CAAE: 11357712.5.0000.0102) and the Ethics Committee of the University (Opinion 197.447 / CAAE: 11357712.5.0000.0102). Written informed consent was obtained from all subjects.

RESULTS

The study sample consisted of 45 individuals, 65% (n = 26) were female, and 87.5% (n = 35) were elderly (mean age: 74.25 ± 11.3 years).The average Kcal / Kg / day estimated between patients was 42.8 ± 21.2 (min: 9.2; max: 112.5). Among the elderly, the average was 42.1 ± 22.2 Kcal / Kg / day (min: 9.2, max: 112.5) and among adults, it was 47.1 ± 13.3 Kcal / Kg / day (min: 26.5; max: 61.7). MF was observed to 40% of the patients (n = 18). Among the elderly, the most commonly used MF and CF (38.5%; n = 15, both) and among adults predominated the use of MF (50%; n = 3).Most patients (88.9%; n = 40) achieved its energy requirements; the recommended energy, when compared with infused by tube, are significantly different ($p<0.05$) (Table 1). Elderly received more Kcal / Kg / day and had the energy value of the diet measured and lower TEV when compared to adults ($p<0.05$). The MF presented a higher mean for total energy, Kcal / kg / day, protein (g) / kg / day, fiber and, vitamin B12 compared to other formulations. The MF had a higher mean for protein while the higher mean for iron was found in CF ($p<0.05$). There was no difference among the enteral nutrition formulas considering lipids, calcium, magnesium, sodium, zinc, and vitamins A, C and, E. The average number of daily infusions was higher, and with a shorter time interval during infusions in the administration of MF ($p<0.05$) (Table 2).

DISCUSSION

Most patients in the study were elderly. The epidemiological and demographic transition is increasingly present in population. Despite no categorization of the strokes was done (ischemic or hemorrhagic),it was observed that age may have been a factor in triggering the disease. In addition, females were predominant in this study. Stroke is also a disease that affects women more severely (Planas, 2005; Hebuterne, 2003; Brasil, 2013). It was noted that the formula energy value achieved the requirements of most of the sample patients. Although the most widely used formulation was MF (food and industrialized).

The energy intake may have been higher due to the mix of two formulas, as in MF. In addition, the range of hours was lower in MF compared to the others, which can induce satiety in the patient. In the assessment of the requirements of energy and offered macronutrient, it was observed that all patients receive adequate amounts or even above their requirements. It is known that in chronic malnutrition there is adaptation in energy demand. The energetic adjustment administered in relation to individual requirements is a quality tool for nutritional support. Among the factors related to adaptation, there is the acceptance degree of the patient, interruptions to perform diagnostic or therapeutic procedures, which can also occur at home, and possible failures in administration by the health team or caregiver (Gaino, 2007). It was noted that individuals who received guidance to prepare standardized recipes by the PAN Protocol (Curitiba, 2011) showed little variation in the reported preparations. CF mostly were reconstituted with water and there was also little variation. The category of formula most used by patients was MF. Most families bought the product to administrate through the tube. It is known that formulas categories are much discussed among health professionals. The argument is that in CF there is less handling, defined nutritional composition and thus, it would be sanitarily safe (Maloney, 2002; Freijer, 2014). It was not the objective of this study to evaluate the sanitary conditions of the formulations. For the choice of the feed formula, it should be considered the clinical condition of the patient, the characteristics of each formulas, the hygiene of the house, the place and the equipment necessary for the preparation, also the socioeconomic status of the family, considering that there are other costs associated such as bottle, equipment, diapers, medicines, etc. Therefore, the cost of formula may weigh on the budget, contributing to the choice of formulation with food. Industrialized diet has a higher cost compared to HD (Franca, 2017). MF may have been more used due to the municipal subsidy, which provides industrialized formulation to complement the HD. Thus, patients' families used at certain times HD, then at others CF or mix both formulations in meals throughout the day. Some studies suggested that industrialized diet is more suitable for patients using HEN (Bischoff, 2020; Franca, 2017), but other factors must be analyzed besides nutritional composition.

In terms of nutritional composition, to quantify in terms of macro and micronutrients, in the present study, the 24RH was performed due to low variability of feeding in this population. It is important to note that interpersonal evaluation was performed, but the intrapersonal was not. The higher fiber content and vitamin B12 in MF is because in the food routine there is infusion of meat, dark green vegetables, and whole grains such as oat flour and wheat bran. The MF showed higher levels of macro and micronutrients when compared to commercial formulations and food. Machado de Sousa et al., (2002) when evaluating the formulations in the laboratory, describe that the MF seems to provide part of the nutritional requirements of the patient, based on fruits and juices, and complemented with CF, which may be indicated as the best alternative to avoid damage to the health of individuals in HEN. However, the most fibers quantity must be revised from formulas, since they were not accounted for losses during preparation and handling, as the HD and MF must be liquid and not thicker to easily pass through the tube to prevent obstruction. This means that after preparation, the formula must be sifted (Machado de Sousa, 2014; Volkert, 2019; Jonkers-Schuitema, 2009). These studies differ from those showed in this research, because experimental data tend to be more reliable, since they use more accurate techniques than compared with food nutritional composition tables. The provision of appropriate nutritional formulas to the clinical status is part of the success of HEN. Monitoring HEN is an important feature for ensuring the achievement of the patient's requirements, it provides an opportunity to review the treatment plan and the early detection of complications (Jonkers-Schuitema, 2009; Elia, 2008).

This is central in HEN care because the significant variability in the nutritional value of homemadeenteral nutrition formula, prepared with foods, compared with commercial formulas. A systematic review and meta-analysis identified that the nutritional values of the homemade formulas do not meet the expected recommended levels and these may have implications for patient's nutritional status and health outcomes (Ojo, 2020). On the other hand, there is a growing preference for the use of homemade enteral nutrition formula, prepared with foods, in many countries globally (Ojo, 2020; Silva, 2019), and this is also observed in Brazil. It is important to analyze if the development of industrialized formulas for HEN aims real benefits to patients or profit. Its use is also associated with economic and financial interests. The food is a human right and the state must guarantee its access to individuals, HEN has been the subject of court proceedings to ensure this right (Thieme, 2019). Food Insecurity was already observed in of households, but with no association to enteral nutrition formula category. Food Insecurity in HEN occurs when the human right to adequate food intake is disrespected. To achieve this human right, some cities in Brazil are looking for regulate the supply of formulas and care in HEN through special programs for nutritional support (Thieme, 2019; Brasil, 2015).

CONCLUSION

In conclusion, the present study documented that the protein and energy patient's requirements were achieved mostly by the different categories of formulas infused via tube in HEN. At home, it is important to choose the formula that best suits the clinical stability and the socioeconomic status of the patient.

COMPLIANCE WITH ETHICAL STANDARDS

Conflict of Interest: The authors declare that they have no conflict of interest.

ABBREVIATIONS

24RH: 24-hour recall
AF: activity factor
ANOVA: analysis of variance
CF: commercial formulas
ENT: enteral nutritional therapy
FI: Factor of injury
HD: homemade diet
HEN: home enteral nutrition
MF: mixed formulas
PAN: Nutrition Care Program for People with Special Needs of Curitiba, Brazil
SPSS: Statistical Package for Social Sciences
TEV: total energy value

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