

Open versus closed enteral nutrition systems for critically ill adults: is there a difference?

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SUMMARY

Objective: To compare the volume, total calories, and protein received by critically ill patients between open and closed enteral nutrition (EN) systems and identify the main reasons for EN discontinuation. **Methods:** A cohort study in which adult patients admitted to the intensive care unit (ICU) were followed-up in two periods: throughout November 2009 with all patients (n = 85) receiving EN using the open system (OS group); and from October 2010 to April 2011 with patients (n = 170) receiving EN using the closed system (CS group). Parametric and nonparametric tests were used to compare the variables, taking into account their distribution. **Results:** Demographic and clinical characteristics were similar in both groups. There were minor differences with no statistical significance between groups: more calories/kg were prescribed to the OS group (p < 0.001), and a higher volume (mL/kg, p = 0.002) and protein (g/kg, p = 0.001) were prescribed to the CS group. Fasting, enteral feeding or gastrointestinal problems, and performance of procedures and ICU routines in different frequencies between groups (p = 0.001) led to the discontinuation of EN. **Conclusion:** There was no clinically relevant difference between the volume, energy, and protein intake of EN prescribed and administered in OS and CS groups. Clinical instability, procedures, and ICU routines led to EN discontinuation in both groups.

Keywords: Enteral nutrition; nursing care; intensive care unit; nutritional therapy.

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INTRODUCTION

Although enteral nutrition therapy (ENT) is a widely adopted treatment option for patients with intact gastrointestinal tracts and partially or fully compromised oral intake^{1,2}, the appropriate prescription and administration still represent a challenge³. Hospitalized patients receive less enteral nutrition (EN) than the prescribed volume⁴, increasing the risk of malnutrition, thus contributing to negative in-hospital outcomes^{5,6}.

In Brazil, all stages of ENT are regulated by specific legislation², which establishes minimum requirements for the prescription, formulation, and administration of the diet, and specifies assignments to healthcare institutions and each member of the multidisciplinary team (physician, nurse, nutritionist, and pharmacist). Currently, there are two types of ENT administration systems available: 1) open system (OS) and 2) closed system (CS). OS is characterized by being produced in a restricted and specific area in which powder or liquid industrialized nutrients are mixed, in accordance with Good Handling Practices², in order to obtain the desired composition. OS appears to have less direct costs, although costs related to implementation, maintenance, physical space and equipment depreciation, human resources, and manipulation process validation should be considered⁷. However, OS allows the specification of EN in terms of diet composition (volume, calories, macronutrients, and micronutrients). CS, also called ready-to-use, consists of industrialized, sterile, liquid diets packed in bags ready to be administered^{8,9}. It is industrially manipulated, eliminating critical stages of the preparation process in health facilities, which reduces the risk of contamination and, therefore, infection—if properly used¹⁰⁻¹². However, the CS diets have standardized composition and volume, making it difficult to meet the specific dietary requirements of each patient. Countries like the USA, UK, and Australia, based on studies evaluating safety and cost, adopted the CS formulations as routine^{13,14}, but stressed the need for additional studies assessing the environmental impact of ENT presentation¹⁵. It is worth noting that the CS diet presentations in these countries are not as costly as in Brazil because, within the Brazilian Unified Health System (SUS), purchases are conducted by bidding in order to purchase products at the lowest price, regardless of indirect costs (e.g., handling process, physical area, and professionals).

Due to the lack of additional studies comparing these systems and evaluating the nutritional needs adjusted to the patient's condition, particularly those critically ill, this study compared volume, total calories, and proteins of the EN received by critically ill adults using OS and CS. It also identified the reasons leading to EN discontinuation in both systems.

METHODS

This was a cohort study in which groups were formed in two different periods. The study was approved by the Research Ethics Committee and the Research Council of the institution.

On the occasion of the annual audit of institutional routines, adult patients in the intensive care unit (ICU) receiving EN using OS (November 2009) or CS (October 2010 to April 2011) were followed-up daily from the first day of EN prescription to the end of the audit period, diet suspension, or transfer. Two of the authors, using a standardized form, prospectively evaluated the clinical characteristics of patients and characteristics related to EN (volume, composition, mode of diet administration). The patient's medical records (electronic and paper) were also reviewed by the authors in search of additional information, when necessary. Patients with prescription of a sucrose- and lactose-free polymeric diet were monitored in both groups.

SAMPLE CALCULATION

The need for inclusion of 90 patients in the OS group and 270 patients in the CS group was estimated using PEPI software, based on audit findings of 2009 (OS) when patients received 692 ± 314 mL of diet, and considering a confidence interval (CI) of 95%, with 80% power, a ratio of three patients in the CS group to each patient in the OS group, and an expected increase of 104 mL (15%) in the volume administered within CS period. In the present study there was no increase in the estimated volume of the administered diet, and 170 patients were included in the CS group, which changed the ratio from 3:1 to 2:1. The same CI was maintained and, with the results obtained, sample power was calculated for the values of EN administered: 98% for the volume, 21% for the calories, and 90% for the proteins.

DATA ANALYSIS

OS and CS groups were compared using parametric and nonparametric tests for independent samples, taking into account the characteristics and distribution of variables. Statistical analysis was performed using PASW Statistics v. 18 software. Calorie and protein intakes were adjusted for body weight and compared using the *t*-test for independent samples. Volumes adjusted for body weight were compared using the Mann-Whitney U test. Comparison of categorical variables was performed using the chi-square test. The reasons for EN discontinuation were described in proportions between the two systems due to the difference in number of patients in both groups (2:1). Frequencies and proportions of days of EN discontinuation and/or suspension were analyzed using chi-square test, with Monte Carlo exact test, 99% confidence interval, and compared with Fisher's exact test.

RESULTS

OS and CS groups had similar demographic and clinical characteristics for age, sex, APACHE II score, Glasgow scale, use of vasoactive drugs, abdominal surgery performed, mechanical ventilation, length of ICU stay, days of EN use, presence of infection, and hospital mortality ($p > 0.05$ for all comparisons). There was little difference in the Charlson Comorbidity Index (OS: 2; IQ: 1-4 *versus* CS: 1.9; IQ: 0-3, $p = 0.001$), although this finding has no clinical relevance (Table 1).

Figure 1A shows the analysis of prescribed volume, calories, and proteins, with a trend towards lower volume/kg/day of diet prescribed for patients in the OS group (16.3; IQ: 13.7-19) than for patients in the CS group (17.9; IQ: 13.4-21.5) ($p = 0.06$). Figure 1B shows the same trend towards proteins (OS = 1.05 ± 0.3 *versus* CS = 1.13 ± 0.3 , $p = 0.07$). In contrast, Figure 1C shows that the values of prescribed calories/kg/day were higher in the OS group (22.6 ± 6.5) than in the CS group (19.6 ± 6.1 , $p < 0.001$).

Comparison of the administered volumes, calories, and proteins showed statistical difference between groups: higher volume (mL/kg/day) in the CS group (11.8, IQ: 7.6-17) than in the OS group (10.2, IQ: 7-13.5, $p = 0.002$), and more protein/kg/day in the CS group ($0.63 \text{ g} \pm 0.3 \text{ g}$ *versus* $0.8 \pm 0.3 \text{ g}$, $p = 0.001$) (Figure 1D and 1E). There was no significant difference between both systems regarding calorie administration (13 ± 6.6 *versus* 14 ± 6.4 , $p = 0.4$) (Figure 1F). Despite any observed statistical difference, it is noteworthy that, in clinical terms, the magnitude appears to be statistically irrelevant.

There were different reasons for EN discontinuation. 219 days of discontinuation for 699 days of EN use (31.3%) in the OS group were identified, and 522 days of discontinuation for 1539 days of EN use (33.9%) in the CS group. Discontinuation of EN to perform tests and procedures, including preparation for surgery and/or by medical advice, was the most prevalent justification in both groups (OS = 57%, CS = 65.1%). Other reasons for EN discontinuation were: opening the feeding container tube due to nausea/vomiting, transition to oral diet, transfer to inpatient unit, accidental removal and/or tube repositioning, and death. Differences in reasons for diet discontinuation are shown in Table 2 for both groups ($p = 0.001$).

DISCUSSION

The present study found that although patients in the CS group received more volume of EN and proteins than patients in the OS group, the magnitude of these differences did not represent any clinical benefit to the CS group. Corroborating our data, a recent Brazilian study³ comparing the adequacy of ENT energy intake between hospital 1 (closed system) and hospital 2 (open system) found no significant difference in the prescription and administration of calories (adjusted for weight/day) between both institutions³. In a previous Canadian study¹⁶ of patients from two long-stay clinics (clinic A and clinic B), the results were also similar to the present study (1,347 mL for OS *versus* 1,358 mL for CS, $p = \text{NS}$)¹⁶. A study conducted in Ribeirão Preto¹⁷, which assessed energy needs and complications associated with EN in both OS and CS

Table 1 – Comparison of clinical and demographic characteristics of patients enrolled in both periods

	OS group (n = 85)	CS group (n = 170)	p
Age	63 (45.5-71)	57.5 (40-68)	0.18*
Male	34 (40)	82 (48.2)	0.2 [§]
Apache II score	23 (16-30)	21 (15-28)	0.13*
Glasgow score	11(7-14)	11.5 (7-15)	0.2*
Use of vasoactive drugs	66 (77.6)	132 (77.6)	1 [§]
Use of mechanical ventilation	81 (95.3)	144 (84.7)	0.1 [§]
Abdominal surgery	7 (8.2)	14 (8.2)	1 [§]
Charlson comorbidity index	2 (1-4)	1.9 (0-3)	0.001*
Duration of ICU stay (days)	12 (6.5-22.5)	11 (6-18)	0.6*
Time on enteral nutrition (days)	6 (4-11)	7 (4-13)	0.5*
Hospital infection	35 (41.2)	50 (29.4)	0.7 [§]
Death	39 (45.9)	52 (30.6)	0.2 [§]

APACHE: Acute Physiology and Chronic Health Evaluation. Numbers are expressed as mean \pm SD, n (%), or median (IQ: 25th and 75th percentiles). EN, enteral nutrition; ICU, intensive care unit; *Mann-Whitney U-test; [§]Pearson's chi-squared test.

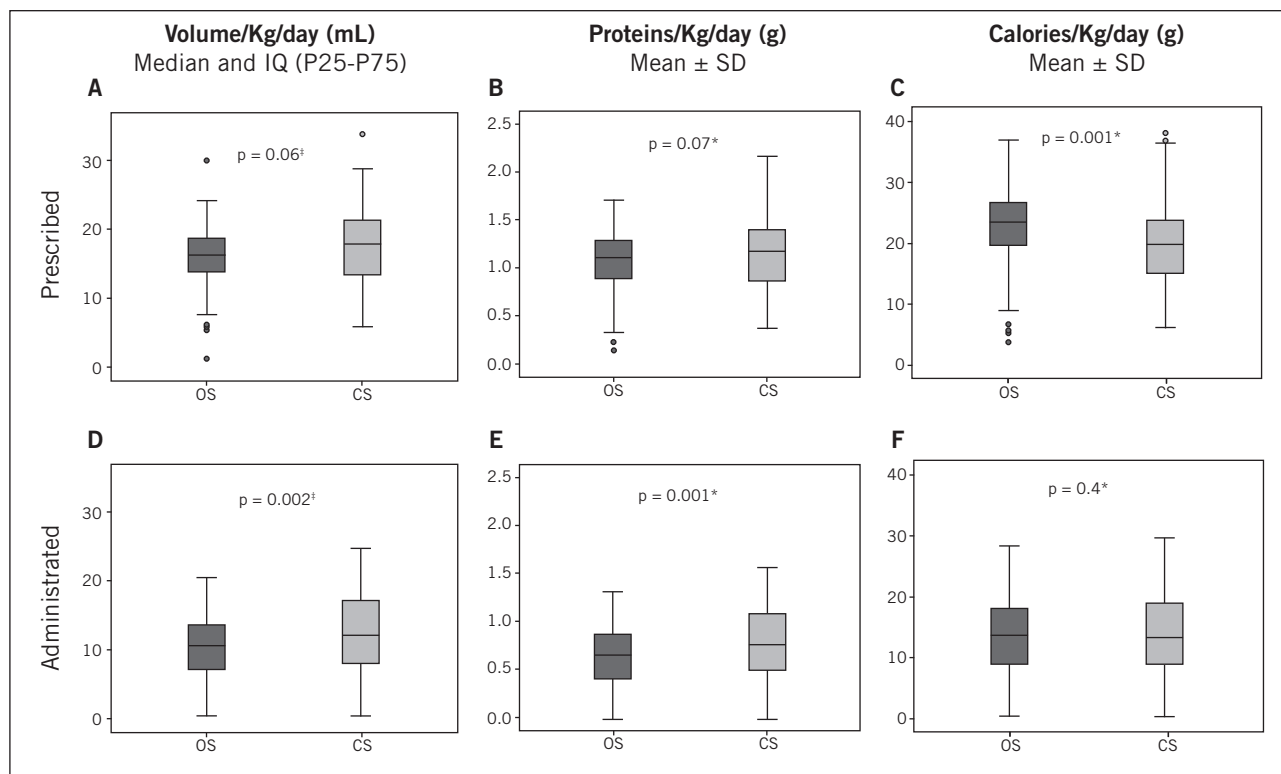


Figure 1 – Table of comparison between open system (OS) and closed system (CS) groups for volume, protein, and calories of enteral nutrition (EN), adjusted for kg/day, prescribed and administered to patients#. IQ, interquartile range; #, p-values between groups (OS vs. CS), *Student's t-test; #Mann-Whitney U test.

Table 2 – Proportion of reasons of EN discontinuation during follow-up

Reasons of EN discontinuation during follow-up	OS = 219 d	CS = 522 d	p*
EN discontinuation	125 (57%)	340 (65.1%)	0.001
NET in open container	24 (10.9%)	82 (15.7%)	
Start VO/ICU transfer	28 (12.8%)	49 (9.4%)	
NET removed and/or re-passed	31 (14.1%)	30 (5.7%)	
Death	11 (5%)	16 (3%)	
NDS did not distribute diet	–	1(0.2%)	
Prescription for drip reduction	–	4 (0.7%)	

*p-value equal for all reasons by chi-square test and compared with Fisher's exact test. Proportion of discontinuation days of the total days of EN use: OS group = 219/699 (31.3%) and CS group = 522/1539 (33.9%). OS, open system; CS, close system; EN, enteral nutrition; NET, nasoenteric tube; ICU, intensive care unit; PO, per mouth; NDS, nutrition and dietetics service.

groups, found that patients who had complications related to the OS received more calories/day than those in CS group ($p < 0.001$). However, after adjusting these calories to meet patient's needs by body weight (using the Harris-Benedict equation), these differences were not significant ($p = 0.18$).

Regardless of the system used, critically ill patients do not receive the recommended energy and protein intakes, which is associated with worse clinical outcomes^{4,5}.

This picture can be prevented through the actions of multidisciplinary teams¹⁸. Heyland et al.¹⁹, for example, adopted a protocol for EN in which, at the beginning of the EN, the nurse administered 25 mL/h, assessing the volume of gastric residuals, and increased the diet's volume every 4 hours or asked the doctor to order prokinetic agents. The nurse also controlled the volume and calories administered, compensating for breaks. With this protocol, patients received a higher caloric ($p = 0.015$) and

protein intake ($p = 0.002$) in the first 7 days of EN use, compared to those not using this protocol¹⁹.

In a study conducted in Spain²⁰, regardless of EN system, critically ill patients had shorter period of discontinuation (24.4%) than patients in our study (about 30%). The reasons for discontinuation were also similar to those reported by this study: diagnostic procedures or treatment inside/outside the ICU (53%), gastrointestinal manifestations (35%), and problems with feeding tubes (12%)²⁰. In contrast, in a study by O'Meara et al.²¹, problems with gastrointestinal or nasogastric tubes occurred in 25.6% of total discontinuations, a percentage nearly twice that of the present study. However, 32.3% of those patients had their diet discontinued to undergo procedures, with 2.3% undergoing nursing procedures²¹, almost half the percentage found in this study. The percentage of discontinuation for nursing care and physiotherapy was not assessed in the present study, as prescription diet is calculated for 22 hours, providing a 2 hour break for such procedures. However, in a research conducted in an ICU by O'Leary-Kelley et al.⁴, the percentage of EN discontinuation was associated with specific intensive care routines (70%)⁴, surpassing the data presented in this study.

It is worth noting that the reasons for EN discontinuation do not follow a single pattern in all studies, making comparisons between the frequencies of the reasons difficult^{4,20,21}. Most of these discontinuations occur due to the intensive care routines, norms, and standards of patient's safety and protection established by each institution^{4,20,21}. The multidisciplinary team should evaluate each case to avoid unnecessary and prolonged discontinuations that compromise the adequate daily intake.

In this study, the impact of changing the type of EN systems on the work process at the Department of Nutrition and the nursing staff was not evaluated. This point should be studied in order to investigate differences in cost-effectiveness and work process management.

CONCLUSION

Changing the type of EN system did not affect the ENT of critically ill adults, as there was no clinically relevant difference in protein and energy intake using OS or CS. EN discontinuations in critically ill patients are motivated by clinical instability; performance of diagnostic, therapeutic, and nursing procedures; besides routines of intensive care.

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