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Randomized Controlled Trial

Use of standard enteral formula versus enteric formula with prebiotic content in nutrition therapy: A randomized controlled study among neuro-critical care patients

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SUMMARY

Objective: To compare use of standard enteral formula versus enteric formula with prebiotic content in terms of nutrition therapy related outcomes among neurocritical care patients.
Methods: A total of 46 adult neurocritical care patients who received nutrition therapy with standard enteral formula (SEF group; n = 23) or enteral formula with prebiotic content (EFPC group; n = 23) during their hospitalization in intensive care unit (ICU) were included in this prospective randomized controlled study. Data on patient demographics (age, gender), diagnosis, co-morbid diseases, anthropometrics, length of stay (LOS) in hospital and ICU, Nutritional Risk Screening (NRS-2002) score, and Acute Physiology and Chronic Health (APACHE-II) score were recorded at enrollment. Data on daily nutritional intake [total energy (kcal/day), carbohydrate (g/day), protein (g/day), lipid (g/day), FOS (g/day), enteral volume (ml/day), fluid in enteral product (ml/day) and fluid intake (ml/day)], achievement of target dose [total fluid intake in enteral product (ml)/20 h], laboratory findings (blood biochemistry and complete blood count), complications and drug treatments were recorded on Day 1, Day 4, Day 7, Day 14 and Day 21 of nutrition therapy in SEF and EFPC groups.
Results: Use of EFPC compared to SEF was associated with significantly higher total energy, carbohydrate, protein, lipid, enteral volume and fluid intake (p values ranged from <0.05 to <0.001) on each day of nutrition therapy. Target dose was achieved by majority of patients (86.9%) and at day 4 of nutrition therapy in most of patients (71.7%) in the overall study population. Patients in the EFPC group had a non-significant tendency for higher rate (95.7% vs. 78.3%) and earlier (87.0% vs. 56.5% on day 4) achievement of target dose, lower rate (8.7% vs. 56.5%) and faster amelioration (none vs. 52.2% were diarrheic on day 7) of diarrhea and lesser need for insulin (56.5% vs. 13.0%, p = 0.002). Nutrition therapy was associated with significant decrease in prealbumin (Day 14 vs. Day 1, p < 0.05 for both), albumin (Day 14 vs. day 1, p < 0.01 for SEF, p < 0.05 for PEF), hemoglobin (Day 14 and Day 21 vs. Day 1and Day 14 vs. Day 4, p < 0.001 for each for SEF, Day 7, Day 14 and Day 21 vs. Day 1, p < 0.01 for each for PEF) and hematocrit (Day 14 and Day 21 vs. Day 1, p < 0.001 for each for both) levels in both SEF and EFPC groups.
Conclusions: In conclusion, our findings revealed achievement of target nutritional intake in majority of neurocritical care patients via nutrition therapy, whereas EFPC was associated with a non-significant tendency for more frequent and earlier achievement of target dose along with significantly lower rate and faster amelioration of diarrhea as compared with SEF group. Prealbumin and albumin levels remained below the normal range, whereas C reactive protein (CRP) and white blood cell (WBC) were over the normal range throughout the nutrition period in both groups, while creatinine and urea levels were higher in EFPC than in SEF group. Hence, our findings seem to emphasize the importance of avoiding protein debt in provision of nutrition therapy and the likelihood of deterioration of nutritional

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status in elderly neurocritical care patients despite provision of early enteral nutrition support due to complex and deleterious inflammatory and metabolic changes during critical illness.

1. Introduction

Critically ill patients have an increased risk of developing hospital acquired malnutrition due to complex and deleterious effects of illness on protein and energy metabolism resulting in metabolic dysregulation, hyper-catabolic state and depletion of energy stores [1–4].

Provision of adequate and timely nutritional support to critically ill patients is therefore considered crucial [2,3], given that protein/energy depletion in the critically ill has been associated with poor patient outcome nosocomial bloodstream infections and increased mortality as well as an increased intensive care unit (ICU) length of stay and cost increment [2,3,5–8].

Malnutrition incidence in stroke patients ranges from 6.1% to 62.0% depending on the method and timing of nutritional assessment [9,10], while dysphagia was evident in approximately 50% of patients in the early period [11–13]. Nutritional status has been suggested to be closely related to long term clinical outcome among stroke patients with an increased risk of post-stroke infection, recurrent stroke and mortality in case of malnutrition [10,14,15].

Early provision of enteral nutrition via the gastrointestinal tract is considered the first choice of nutritional support and a marker of quality of care for critically ill patients [16–20], as reported to be associated with protection of intestinal mucosal integrity, reduction of infection rates, morbidity and mortality [2,21–24].

However, provision of adequate nutritional support to critically ill patients still remains a challenge due to impact of underlying diagnosis and concomitant treatments on nutritional status, as well as difficulties in determining optimal caloric intake for a favorable clinical outcome and likelihood of failure to reach target intake alongside discrepancies between prescribed and provided nutritional intake in the setting of critical illness [20,25–28].

Fortification of enteral formulas with prebiotics serves the purpose of improving adequacy of nutrition therapy allowing specific alterations in the composition and/or function of the gastrointestinal microbiota in favor of host well-being [29–31].

Prebiotic fructo-oligosaccharides (FOS) selectively stimulate the proliferation of bifidobacteria and potentially lactobacilli and provide a substrate for fermentation and short chain fatty acid (SCFA) production [29,32–35].

Although the effect of FOS on the colonic microbiota have been extensively addressed in healthy populations consuming a normal diet, few clinical studies have investigated their use in enteral formulas and indicated potential benefit of FOS content to enable a stabilized intestinal barrier homeostasis and reduced infection rates [30,31,34–36].

The present study was therefore designed to evaluate provision of nutrition therapy via standard enteral formula (SEF) versus enteric formula with prebiotic content (EFPC) among neurocritical care patients in terms of achievement of target nutritional intake, complications and changes in blood biochemistry and hematologic parameters.

2. Materials and methods

2.1. Study population

A total of 46 adult neurocritical care patients who received nutrition therapy with standard enteral formula (SEF group; n = 23, mean ± SD age: 71.8 ± 20.0 years, 60.9% were males) or enteral formula with prebiotic content (EFPC group, n = 23, mean ± SD age: 73.9 ± 15.3 years, 60.9% were females) during their hospitalization in Ankara Numune Training and Research Hospital ICU between April 2014 and June 2015 were included in this prospective randomized controlled study. Of 68 patients initially enrolled, 22 patients were lost to follow up due to death (n = 12), transfer from ICU to another ward (n = 4) or hospital (n = 3) and switching to oral feeding (n = 3), and final study population was composed of 46 patients (23 patients in each group) (Fig. 1). Patients were randomized into SEF (Osmolite®, 1 kcal/1 ml) and EFPC (Jevity®, 1 kcal/1 ml) groups by the ICU nurse based on admission hour with consideration of admissions occurred at even hours in the SEF group and those at odd hours in the EFPC group. Patients aged 18–80 years, hospitalized at ICU with a neurological diagnosis and considered appropriate for provision of enteral nutrition based on presence of a functioning gastro intestinal (GI) tract and access via the gastric or jejunal route and/or the inability or unwillingness to meet oral nutrition were included in the study. ICU patients with non-neurological diagnoses, intubated patients, patients with multiple organ failure, immunosuppressive conditions (Acquired Immune Deficiency Syndrome, chronic corticoid usage, immunosuppressive therapy), lung damage, extremity fractures, thoracic and intraabdominal injuries, obesity (BMI>40 kg/m^2), cachexia (BMI<17 kg/m^2), malignancy, insulin dependent diabetes, chronic obstructive pulmonary disease, dialysis, liver dysfunction, cirrhosis, bilirubinemia (>3 mg/dl) past history (last 6 months) of chemotherapy or radiotherapy, previous transplantation, pregnancy and total parenteral nutrition were excluded from the study.

Written informed consent was obtained from each subject or his/her relative following a detailed explanation of the objectives and protocol of the study which was conducted in accordance with the ethical principles stated in the “Declaration of Helsinki” and approved by the Ankara Numune Training and Research Hospital Ethics Committee (Date of Approval: 18/09/2013; Reference number/Protocol No: 34/2013).

2.2. Data collection

Data on patient demographics (age, gender), underlying neurological diagnosis, co-morbid diseases, anthropometrics [body weight (kg), height (cm), body mass index (BMI; kg/m^2)], LOS in hospital and ICU, Nutritional Risk Screening (NRS-2002) score, enteral feeding route (oral, nasogastric, nasodeudonal, gastrostomy, jejunostomy) and Acute Physiology and Chronic Health (APACHE-II) score were recorded in each patient at study enrollment. Data on daily nutritional intake [total energy (kcal/day), carbohydrate (g/day), protein (g/day), lipid (g/day), FOS (g/day),

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