

# Home enteral nutrition (HEN) – a complex cost-saving solution to long-term artificial nutrition



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## ABSTRACT

*Background:* Home enteral nutrition (HEN) was introduced in Poland several years ago. However, the benefits of such medical care have been questioned recently due to the growing costs in the health system. The purpose of this study was to examine the effect of a complex specialized home enteral nutrition on clinical outcome variables in HEN patients.

*Methods:* The observational study included 102 patients (51 women, 51 men, mean age 54.6 years) receiving HEN with homemade diets for at least 12 months before starting a specialized home nutrition program for another 12 months consisting of the provision of commercial enteral formulae and the guidance of a nutrition support team. Both study periods were compared in terms of the number of hospital admissions, length of hospital and intensive care unit stay, and costs of hospitalization.

*Results:* Implementation of the HEN program significantly reduced the number of hospital incidents and the length of hospital admissions and the duration

of ICU stay. The need for hospitalization and ICU admission was significantly reduced with odds ratios of 0.083 (95%CI 0.051 to 0.133,  $P < 0.001$ ) and 0.259 (95%CI 0.124 to 0.539,  $P < 0.001$ ) respectively. The specialized HEN was associated with a significant decrease in the prevalence of pneumonia (24.1% vs 14.2%), respiratory failure (7.3% vs 1.9%), urinary tract infection (11.3% vs 4.9%), and anemia (3.9% vs 0%) requiring hospitalization. The mean cost of hospital treatment decreased from 546.18 to 101.69 EURO/year/patient.

*Conclusions:* The specialized HEN care program reduces morbidity and costs related to long-term enteral feeding at home.

## INTRODUCTION

The recent epoch of tube feeding started at the beginning of the 20th century when gastric access was used for the provision of nutrients<sup>1,2</sup>. Consequently, enteral feeding became the preferred route of nutritional support due to its physiological advantages, low morbidity, and favorable costs compared to parenteral nutrition. One of the aspects of nutritional support, which was introduced in order to enable a patient's care

at home was home enteral nutrition (HEN) via either noninvasive (nasogastric or nasojejunal catheters) or invasive (gastro- or jejunostomy) accesses. Although home enteral nutrition, including HEN, has been used for many years, some recent reports have questioned the actual benefits of these interventions, mostly due to rapidly growing costs of HEN, which suggest that enteral nutrition may be susceptible to overuse, particularly in long-term care settings<sup>3,4,5,6,7,8</sup>.

The incidence of home enteral nutrition in the United States is four to ten times higher than in other western countries, and doubled between 1989 and 1992<sup>6,7,8,9,10,11,12,13,14</sup>. In the United States the annual prevalence of home enteral nutrition was approximately 175.0 per 100,000 population, while the incidence reported in a recent European survey was 16.3 patients per 100,000 inhabitants<sup>10,11,13</sup>. The increasing popularity of HEN is associated with significant annual costs to the health system. In the United States, HEN costs were estimated between 9,000 and 25,000 USD per patient in 2000, while in some European countries varied between 9,048 and 10,140 USD a year<sup>7,8</sup>. The widespread use of home enteral nutrition escalating the costs of home care has raised some concern about the cost-efficiency of the procedure for the National Health Systems<sup>6,7,8</sup>. However, data validating the benefits of home nutritional support by the enteral route are rare and very heterogeneous, as it is not feasible nowadays to carry out a clinical trial recruiting patients deprived of specialized home feeding.

The reimbursement of home enteral nutrition by the Polish National Health Service started in 2007. As no other form of financial support was available earlier for these patients, they were forced to prepare blenderized homemade diets for tube feeding using household products. This unique situation provided an exceptional opportunity to evaluate changes in clinical outcomes following the implementation of a specialized nutritional support program. The pur-

pose of this study was to examine the influence of commercial enteral diets combined with the guidance of specialized nutritional support team on clinical outcome variables in patients receiving nutrition support at home via the enteral route by tube.

## METHODS

An electronic database of 2114 patients treated between January 2008 and December 2010 at 12 centers of home enteral nutrition belonging to a home nutrition company and distributed in all regions of Poland was reviewed. All patients receiving HEN with homemade diets for 12 months before starting specialized nutritional support and continuing on HEN for the subsequent 12 months were selected as the study population. During the initial 12-month period, before home company could supervise the therapy, patients were fed at home with homemade diets consisting of regular meals prepared for the patient the same way as for other family members, but blenderized. The products were administered via feeding tubes (nasogastric or gastrostomy/jejunostomy) as a bolus of 50 to 100 milliliters 5 to 6 times daily. Patients were supervised by their general practitioner and no special nutritional care was provided. The assessment of this initial 12-month period was performed on a retrospective basis.

The second 12-month period was assessed prospectively; during this period patients received complex nutritional care by members of the home nutrition company's personnel: physicians (general surgeon, internal diseases specialist, anesthesiologist, gastroenterologist), qualified nurses, dietitian, physiotherapist, and psychologist. Initially, patients and their caregivers were visited at home by one or more of the team members and instructed regarding tube feeding regimes and care of the access. The nutritional status was assessed at the first home visit using clinical examination, NRS and SGA scales, laboratory tests, and anthropometry (triceps skinfold, midarm cir-

AN ELECTRONIC DATABASE OF 2114 PATIENTS TREATED BETWEEN JANUARY 2008 AND DECEMBER 2010 AT 12 CENTERS OF HOME ENTERAL NUTRITION BELONGING TO A HOME NUTRITION COMPANY AND DISTRIBUTED IN ALL REGIONS OF POLAND WAS REVIEWED.

cumference). Regular follow-up visits with laboratory tests were scheduled at the beginning of the treatment, in case of emergency and on the regular basis every 2 to 3 months. Laboratory test included: erythrocytes, leukocytes, hemoglobin, haematocrite, platelets, acid-base balance, serum sodium, potassium, calcium, magnesium, phosphate concentration, glucose, albumin, serum and urea amylase and lipase, blood urea, creatinine, cholesterol and triglycerides, bilirubin, aspartate aminotransferase (AST) alanine aminotransferase (ALT), gamma-glutamyl transpeptidase (GGT), alkalinephosphatase (ALP), International normalized ratio (INR), and C-reactive protein (CRP). Those visits also included nutritional assessment, nutritional access' check and the evaluation of a general status.

Additional visits depended on individual patient requirements. Enteral feeding was based on enteral iso- or hypercaloric, standard or fibre rich, iso- or protein rich diets provided by Nutricia Ltd. and Fresenius Kabi Poland. Diets were administered as boluses (150 – 300 milliliters), microboluses (50 – 100 milliliters/ dose) or continuous infusion (20 ml/ hour at the beginning up to 150 ml/ hour during normal treatment) to meet the caloric goal, which was estimated at 30-35 kcal/kg. The intake of the enteral feedings were supervised by nurses and physicians during home visits. At the same time, members of family or caregivers or patients themselves were asked to keep records on the patient's intake and, most of all, follow our recommendations. Gravitational infusion systems as well as pumps were used depending on the gastrointestinal access and treatment compliance. The type of diet was based on the following factors: the type of primary disease determining energy and protein requirements (i.e. higher energy amount required in cystic fibrosis patients, lower in neurological patients), presence of complications (i.e. specialized formula diets in stress ulcer patients), fluid restrictions (i.e. hypercaloric formula in cystic fibrosis children with overnight feeding) and



type of enteral access (i.e. oligopeptic diets in jejunostomy patients). In cases where nutritional needs could not be met due to enteral formula intolerance or treatment complications, diets were changed (i.e. in case of constipation the formula was changed from standard into fiber-rich) and administration regimen was modified (i.e. from boluses into continuous infusion).

Patients were informed about advantages of commercial diets and prospects of our home care prior to enrollment. Then they were informed about the regimen by physicians and the introduction of HEN was conducted gradually. At the end of this process an informed consent was signed and

patients or their families or legal caregivers agreed to the therapy and gave permission to use their medical history.

To evaluate the efficacy of specialized HEN, both study periods were compared in terms of the number of hospital admissions, length of hospital and intensive care unit (ICU) stay, and costs of hospitalization. Costs of hospital treatment were evaluated based on the diagnosis-related group (DRG) system adopted in 2007 by the Polish National Health Service and calculating the payments for hospitals based primarily on the diagnosis of discharged patients.

### *Statistical analysis*

The differences in proportions between groups were evaluated using the Chi-square test. The Wilcoxon signed ranks test was used to detect differences in quantitative parameters before and after implementation of HEN. Significance level ( $P$ )  $<0.05$  was considered statistically significant. Statistical analysis was performed using the SPSS v.16 (SPSS Inc., Chicago, Illinois, USA) software package.

## **RESULTS**

Detailed medical records were available for 102 patients (51 female, 51 male, mean age 54.6 years, range: 2 months – 89 years old). Enteral nutrition was initiated due to neuromuscular swallowing disorders ( $n=75$ ), cancer-related dysphagia ( $n=20$ ), cystic fibrosis ( $n=5$ ), and other causes ( $n=2$ ). The latter group included one case of chronic pancreatitis and one gastrointestinal motility disorder. Percutaneous endoscopic gastrostomy (PEG) was the most common gastrointestinal access (61%) followed by a nasogastric tube (21%). Surgical gastrostomy and jejunostomy were carried out in 15% and 3% patients, respectively. Iso-caloric and hypercaloric formulas were used in 87.7% and 12.3% of patients, respectively. 27.6% patients received fiber rich diets and hyperproteic formulae were used

in 4.9% patients. Enteral formulae covered 100% of daily protein and energy requirements (1.2 – 2.0 g/kg/day and 30 – 35 kcal/kg/day) and 85-100% of water requirement (30 – 40 ml/kg/day).

The implementation of a specialized HEN care program significantly reduced the number of hospital admissions, as well as the length of hospital and ICU stay (Table 1). The need for hospitalization and ICU admission was significantly reduced with odds ratios of 0.083 (95%CI 0.051 to 0.133,  $P<0.001$ ) and 0.259 (95%CI 0.124 to 0.539,  $P<0.001$ ), respectively. These changes significantly reduced mean annual costs of hospitalization from 546.18 EURO (95%CI 656.32 to 873.01) to 101.69 EURO (95%CI 85.02 to 199.72; 95%CI). An additional subgroup analysis by age groups (children, adults), type of enteral formula (isocaloric vs hypercaloric) and home nutrition centre failed to demonstrate any differences in outcome parameters.

Specialized HEN during the second 12-month period was associated with a significant decrease in the prevalence of pneumonia (24.1% vs 14.2%), respiratory failure (7.3% vs 1.9%), urinary tract infection (11.3% vs 4.9%), and anemia (3.9% vs 0%). Although nearly all other complications were more frequent during the first 12-month period, the differences compared to the specialized HEN were not statistically significant. The only complication more frequent in the HEN group was feeding tube occlusion, which was probably caused by the lack of experience of families, previously using home diets, during the initial period of HEN.

## **DISCUSSION**

In most European countries, reimbursement of diets for home enteral nutrition is covered by the National Health Systems, while in the United States costs are generally covered by private insurance companies<sup>12</sup>. In some cases this kind of reimbursement may increase the consumption



of health care resources and raises doubts about the cost-effectiveness of home enteral nutrition<sup>6,7,8</sup>. Therefore, changes in the reimbursement policy implemented since 2007 by the Polish National Health Service provided an exceptional opportunity to evaluate the actual benefits of a modern system of nutritional support at home consisting of commercial enteral formulae and the oversight of dedicated Nutrition Support Team. Between 2007 and 2009, our home nutrition company provided a complex nutritional solution, including the shipment of enteral diets and equipment, regular visits of physicians and nurses, laboratory tests, and transportation of patients to and from hospitals for 680 patients receiving home enteral nutrition. This group of patients corresponded to over a half of about 1300 patients treated in Poland. The selection of a homogenous population of patients fed only by tubes obviates the potential bias of many previous studies, where home enteral nutrition was defined as the provision of diets by tube or oral feedings and included subjects with disorders having the chance to improve over time<sup>12,16,17</sup>.

There are many potential advantages of using HEN and economic evaluations have demonstrated that home nutrition support is up to 75% more cost-effective than prolonged therapy in hospitals or nursing homes with savings of \$3100 to \$4200 per patient<sup>8,18,19,20</sup>. However, despite the high numbers of patients receiving enteral tube feeding, there is still insufficient evidence to clearly support its beneficial effects in various populations<sup>3,4,5</sup>. Some studies suggested that home enteral nutrition may even be associated with poorer survival rates or impaired quality of life of patients and their caregivers<sup>21,22,23,24,25,26,27</sup>.

Current practice recommendations for enteral nutrition formulated by ASPEN state that selection of the enteral formulation must rely on several parameters, such as nutritional and physical assessment, metabolic abnormalities, gastrointestinal function,

overall medical condition, and expected outcomes<sup>17</sup>. However, not only the superiority of specialized over standard enteral formulae remains insufficiently substantiated, but also there are no firm data supporting clinical benefits of commercial diets over blenderized food<sup>8,20,28</sup>. Nevertheless, it is generally believed that commercial enteral formulae are superior to homemade enteral diets<sup>2,9,10,29,30</sup>. These assumptions are based on previous observations demonstrating that blenderized enteral tube diets, even prepared in a hospital setting, contain unpredictable levels nutrients and their physical properties may be unsuitable for infusion through feeding tubes<sup>32,32</sup>. Moreover, marked bacterial contamination poses the risk of potentially serious complications in some patients<sup>33,34,35</sup>. Despite all those facts, no randomized controlled trials have been published comparing clinical outcomes of HEN in patients with either homemade or commercial diets, and blenderized food is still used due to economic reasons in cases when the reimbursement policy is inadequate<sup>11,36,37,38</sup>. The paucity of observational, retrospective studies, focused mainly on the nutritional and microbiological parameters of diets instead of clinical outcome criteria makes drawing of reliable conclusions even more difficult.

The concept of specialized nutritional support teams (NSTs) was initially developed for in-hospital patients and home parenteral nutrition, demonstrating significant reductions in metabolic and mechanical complications<sup>39</sup>. Such a team approach was subsequently implemented for hospital enteral nutrition, suggesting that greater numbers of patients attained appropriate energy and nitrogen balance, as well as reduced complication rates<sup>40</sup>. However, due to the paucity of adequate clinical trials evaluating the oversight of NSTs for home enteral nutrition, many physicians view this type of nutritional intervention as not routinely requiring monitoring or specialized interventions, compared to the parenteral route<sup>11,41,42,43</sup>. Although the first randomized clinical tri-

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al on NSTs for HEN failed to provide data demonstrating a significant reduction of the health care costs, the authors demonstrated a saving of 21% per patient<sup>44</sup>. Moreover, the supervised group had fewer and briefer episodes of readmissions and less demand for general practitioners and district nurse inputs.

Our study demonstrated that the change from poorly supervised HEN using homemade food to the specialized nutritional support with standard enteral formulae

of HEN, such as quality of life, could not be addressed. However, such a randomized study, involving a control group receiving only homemade food without appropriate medical supervision would hardly be justified ethically. In many cases withdrawal or limitations of reimbursement by the health care providers, such as the current recommendations implemented by the Polish National Health Service, forces some patients to use this old-fashioned type of feeding for economic reasons. Apparently, inappropriate restrictions not only increase the overall costs

Table 1. Number of hospital admissions, their length and cost

\*Wilcoxon Signed Ranks Test

PARAMETER	BEFORE HETF	AFTER HETF	P*
NUMBER OF HOSPITAL ADMISSIONS MEAN (95%CI) MEDIAN (INTERQUARTILE RANGE)	1.09 (0.96-1.22) 1 (2)	0.21 (0.14-0.28) 0 (0)	<0.001
DURATION OF HOSPITALIZATION, DAYS MEAN (95% CI) MEDIAN (INTERQUARTILE RANGE)	20.84 (17.29-24.39) 13 (30)	3.83 (2.13-5.53) 0 (0)	<0.001
DURATION OF ICU STAY, DAYS MEAN (95% CI) MEDIAN (INTERQUARTILE RANGE)	2.35 (1.32-3.37) 0 (0)	0.50 (0.09-0.92) 0 (0)	<0.001
COSTS OF HOSPITALIZATION, EURO MEAN (95%CI) MEDIAN (INTERQUARTILE RANGE)	546.18 (468.8 – 623.58) 471.00 (943)	101.69 (60.73 – 142.66) 0 (0)	<0.001

produced substantial improvements in clinical end-points such as the need and length of hospital admissions, as well as rates of several complications. Therefore, to our knowledge, this is the first large-scale report substantiating clinically and economically the benefits of such a complex solution to the health system. Reasons for this are various. In our opinion the reasons for the significant decrease of hospital admissions, ICU stay and the length of hospital stay were as follows: the use of commercial diets, which were nutritionally complete as opposed to blenderized meals, tight control of diet intake, and the monitoring of treatment results thanks to physicians' and nurses' visits as well as routine laboratory tests. Due to the observational design of this study some other important aspects

of health care, but also increase morbidity rates and potentially impair patients' quality of life.

In conclusion, this study demonstrated that management of HEN by a nutrition support team reduces morbidity and may reduce costs to the health system. Due to the rising costs of home enteral nutrition, these patients should be adequately supervised and provided with appropriate enteral diets to maximize the benefits of such a therapy.

#### Conflict of interest

All authors cooperate as lecturers with Nutricia Ltd, Fresenius Kabi, Baxter, B Braun and Nestle. ■

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