



Original/*Nutrición enteral*

The evolution of home enteral nutrition (HEN) in Poland during five years after implementation: a multicentre study

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Abstract

Background: home enteral nutrition (HEN) is the best option for chronic patients without the ability to swallow, but with intact digestive tract. Despite the increasing use of home enteral tube feeding (HETF), there is little published information about the types of patients receiving home enteral nutrition. The purpose of this paper to present the evolution of HETF.

Material and methods: the retrospective multicenter observational study was performed using questionnaires, which were distributed among the biggest Polish HEN centres. The study covered all patients treated between January, 2007 and January, 2014.

Results: in total 196 adult patients in 2008 (M:104, F: 92, mean age 58.1 [41-75]) and 2842 in 2013 (M: 1541, F: 1301, mean age 61.4 range: 1-91) were assessed. The number of patients grew significantly between 2008 and 2013 ($p<0.05$), rising from 196 up to 2842 (and 1716 at the moment of study). The predominant primary disease was neurology in both time periods, but the profile switched from neurovascular to neurodegenerative ($p>0.05$). Percutaneous endoscopic gastrostomy was the most common GI access ($>60\%$), its use and the use of gastrostomies increased significantly since 2008 ($p<0.05$). Although the reimbursement for HETF started in 2007, HEN centres expressed doubts about unclear rules for the qualification to HEN and its use.

Conclusions: HETF is a safe, well-tolerated and cost-effective procedure. The profile of patients and techniques may vary at the beginning, but becomes similar to other HETF countries relatively soon. The number of

EVOLUCIÓN DE LA NUTRICIÓN ENTERAL DOMICILIARIA (HEN) EN POLONIA DURANTE CINCO AÑOS DESPUÉS DE SU IMPLANTACIÓN: UN ESTUDIO MULTICÉNTRICO

Resumen

Antecedentes: el inicio con nutrición enteral (HEN) es la mejor opción para los pacientes crónicos sin capacidad de tragar, pero con el tracto digestivo intacto. A pesar del aumento en el uso de la alimentación por sonda enteral domiciliaria (HETF), hay poca información publicada sobre los tipos de pacientes que reciben nutrición enteral domiciliaria. El propósito de este trabajo es presentar la evolución de HETF.

Material y métodos: el estudio observacional multicéntrico retrospectivo se realizó mediante cuestionarios que se distribuyeron entre los mayores centros HEN polacos. El estudio abarcó a todos los pacientes tratados entre enero de 2007 y enero de 2014.

Resultados: en total fueron evaluados 196 pacientes adultos en 2008 (M: 104 F: 92, edad media 58,1 [41-75]) y 2.842 en 2013 (M: 1541, F: 1.301, con una edad media de 61,4 rango: 1-91). El número de pacientes aumentó significativamente entre 2008 y 2013 ($p<0,05$), al pasar de 196 hasta 2.842 (y 1.716 en el momento del estudio). La enfermedad primaria predominante fue la neurología en ambos períodos de tiempo, pero el perfil cambia de neurovascular a neurodegenerativa ($p>0,05$). La gastrostomía endoscópica percutánea fue el acceso GI más frecuentes ($>60\%$), su uso y el uso de gastrostomías aumentó significativamente desde 2008 ($p<0,05$). Aunque el reembolso de HETF comenzó en 2007, los centros de HEN expresaron dudas sobre las reglas poco claras para la calificación para HEN y su uso.

Conclusiones: HETF es un procedimiento seguro, bien tolerado y rentable. El perfil de los pacientes y las técnicas puede variar al principio, pero se vuelve similar a otros países HETF relativamente pronto. El número de

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patients grows quickly, and that fact suggests that the prevalence of HETF is similar in all countries.

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Introduction

Enteral nutrition (EN) represents unquestionably a method of choice for artificial feeding, because it is more physiological, safer and cheaper than the parenteral one¹. EN can be carried out with either oral route or tube feeding (naso-gastric or naso-jejunal catheters, gastro- or jejunostomy)² It can be performed at hospitals, long-term health care facilities, palliative care centres or at home. The latter is the best option for chronic patients without the ability to swallow, but with intact digestive tract. Guidelines of European Society for Clinical Nutrition and Metabolism (ESPEN) precisely describe indications and methods for home artificial nutrition².

Unfortunately, despite the increasing use of home enteral tube feeding (HETF), there is little published information from large scale studies or surveys about the types of patients receiving home enteral nutrition, their quality of life, dependency on others, and clinical outcome. As a matter of fact, only few analyses have been performed over last two decades: British, Spanish, French and Italian as well as a larger scale European survey^{3,4,5,6,7} The latter was coordinated by ESPEN Home Artificial Nutrition Special Interest Group⁷.

For many reasons, Polish situation in that matter differs from the rest of the world. Firstly, HETF in Poland can only be performed by dedicated medical centres, as it is fully reimbursed by the public insurance company. Secondly, the reimbursement for HETF started in 2007, which allowed the cost-effectiveness analyses, published in 2010 and 2014^{8,9}.

Thirdly, the first HEN year was well evaluated by a multicentre survey in 2008, which creates an opportunity to present the evolution of HETF patients' profile, indications and techniques used for home nutrition¹⁰. The manuscripts present the comparison of HETF at the beginning and its development after five consecutive years.

Subjects and methods

The retrospective multicenter observational study was performed using questionnaires, which were distributed among the biggest Polish HEN centres (< 50 patients at the moments of the study and more than 100 over previous years). Those centres included Warsaw, Rzeszow, Siedlce and Ostroleka's HEN units. The study covered all patients treated between January, 2007 and

pacientes crece rápidamente, y ese hecho sugiere que la prevalencia de HETF es similar en todos los países.

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January, 2014. All patients receiving HETF was included in the study. Exclusion criteria included: combined oral and tube feeding, enteral and perenteral nutrition, as well as the incomplete medical record.

As the reimbursement policy requires special attitude towards HEFT, in all centers home tube feeding was carried out on routine basis by family or care-givers, and supervised by nurses and physicians during regular home visits. Family members and/ or caregivers were keeping records on daily intake. The selection of artificial diet was based on type of primary disease determining energy and protein requirements, comorbidities, fluid restrictions and type of enteral access. Nutritional status was assessed at the first home visit using clinical examination, Nutritional Risk Screening 2002 (NRS) and Subjective Global Assessment (SGA), laboratory and anthropometry (triceps skinfold, mid-arm circumference) tests.

Regular follow-up home visits were performed every 2 to 3 months. They included nutritional re-assessment, enteral access site evaluation and laboratory tests (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), alkaline phosphatase (ALP), International normalized ratio (INR), and C-reactive protein (CRP)).

All patients and legal care-givers were informed about advantages of commercial diets and prospects of our home care prior to enrolment. An informed consent was signed in each case.

Statistical analysis

In order to provide descriptive statistics of the investigated groups means, standard deviations, and ranges were provided for continuous variables and percentages for categorical ones. As there were paired measurements, before variables were compared the normality of the distributions for differences had been tested by Shapiro-Wilk test, and the paired t-test for normally distributed differences and the Wilcoxon signed-rank test for not-normally distributed variables were used. For categorical variables the change of the proportion of patients presenting a condition of interest was tested by the McNemar test. Results with the p-value below 5% were

considered as statistically significant. The IBM SPSS Statistics version 21 software was used for calculations.

Results

In total 196 adult patients in 2008 (M:104, F: 92, mean age 58.1 [41-75]) and 2842 in 2013 (M: 1541, F: 1301, mean age 61.4 range: 1-91) were assessed. The Local Ethical Committee of Skawina Hospital approved the protocol.

The number of patients grew significantly between 2008 and 2013 ($p < 0.05$), rising from 196 up to 2842

(and 1716 at the moment of study), as presented in table I. Mean duration changed insignificantly, similar observation regarded the probability of being alive after 1-year (Table I). The predominant primary disease was neurology in both time periods, but the profile switched from neurovascular to neurodegenerative ($p > 0.05$). Also, among cancer patients, the percentage of head and neck cancer patients outran the gastrointestinal (GI) tract neoplasm ($p > 0.05$), insignificantly, though.

Percutaneous endoscopic gastrostomy was the most common GI access (>60%), its use and the use of gastrostomies increased significantly since 2008 ($p < 0.05$). Enteral diets changed from the simple ones into more

Table I
Patients' characteristics

	2008	2013
Mean time of HEFT (years) for all centres	n/a	5.5
Number of patients at the day of study	196	1716
All patients since 2007	196	2842
Prevalence per 1 mln inhabitants	5.4	47.6
Growth per year (no of pts)	n/a	93
Patients, overall	196	2842
Females	92 (46.9%)	1301 (45.8%)
Males	104 (53.1%)	1541 (54.2%)
Mean age [range]	58.1 [41-75]	61.4 [1-91]
Mean duration of HEFT (months)	8.5	9.9
% of patients treated:		
< 3 months	15	675
3-12 months	40	575
>12 months	45	466
Patients not treated (waiting list for HETF)	27	76
Probability of being alive after 1-year (%) for non-cancer patients	80	79
Probability of being alive after 1-year (%) for cancer patients	20	22
Primary disease		
Neurovascular	40	437
Neurodegenerative	33	496
Cerebral palsy	2	117
GI cancer	40	122
Head and neck cancer	21	128
Cancer of other location	0	148
Cystic fibrosis		15
Head trauma	10	71
Non-neoplastic GI tract disease	18	90
Inherited metabolic disease		40
Malnutrition	19	52

sophisticated and patient-dedicated ones over the years (Table II).

Although the reimbursement for HETF started in 2007, HEN centres has been complaining about unclear rules for the qualification to HEN and its use. Those aspects have remained unchanged for those five years.

Discussion

According to many authors, HETF represent an important and life-saving procedure⁴ Our previous studies showed reduction of hospital admission and the length of hospitalisation as well as its cost-effectiveness^{7,8}. HEFT is not, however, a homogenous procedure and its varies a lot among countries. Moreover, its evolves over years, even within one country and the same insurance company, along with the growing prevalence and awareness.

Only few analyses have been published on HEFT. It is probably due to the fact that in most countries this procedure is being performed by private units and pharmaceutical companies.

The fact is that only British, Spanish and French societies analysed HETF^{3,5,6}. Those studies were strongly enriched by the survey of ESPEN Home Artificial Nutrition Special Interest Group⁸

As mentioned before, Polish situation seemed to create a perfect opportunity to observe HTF's evolution. The following study shows the five-year perspective, describing Polish home enteral nutrition right from the beginning of the reimbursement over five consecutive years. Before the reimbursement started, patients had to prepare tube diets themselves using regular food and blenders, as they could not afford artificial admixtures.

The most important difference between Polish home nutrition and other countries' home EN is that Polish insurance company does not cover oral diets, it only covers tube-feeding. The other key difference is non-involvement of nurse in the process. The reimbursement does not cover that cost, so hardly anybody can afford it. Therefore, the typical care-giver is a family member or other relative, rarely patient himself, as presented in table II. That was different from French observations - the care-givers were a relative in 38% of cases and a nurse in 62% of cases⁶

The latter obstructions did not influence significantly the prevalence of HEFT. It increased from 5.4/ 1 million inhabitants up to 47.6 in only five years. The number of patients grew significantly between 2008 and 2013 ($p < 0.05$), rising from 196 up to 2842 (and 1716 at the moment of study), as presented in table I. Knowing that about 20% of patients have to wait for the enrolment, it is obvious that the only limit is that of the insurance company. Similar findings were presented by Santarpia et al in one Italian region¹¹.

The profile of Polish patients differed at the beginning, but it changed over the years. The proportion

Table II
Techniques used for HETF

GI tract access		
PEG	77 (39.2%)	1717 (60.4%)
Gastrostomy	35 (17.8%)	662 (23.2%)
Naso-gastric tube	48 (24.4%)	292 (10.2%)
Jejunostomy	34 (17.3%)	171 (6.2%)
Infusion technique (pts, %)	n=196	N=2842
Bolus technique	180 (91.8%)	2012 (70.8%)
Gravity set	14 (7.1%)	798 (28.1%)
Pump infusion	2 (1.1%)	32 (1.1%)
Person responsible for HETF		
Patient him/herself	1 (0.5%)	26 (0.9%)
Caregiver	195 (99.5%)	2816 (99.1%)
Enteral diet used (%):		
Standard	96	51,07
Fibre-rich	2	36,6
Protein-rich	0	12,9
Energy-dense	0	6,25
Diabetic	0	7,8
Oligopeptide	2	5,25
Enhancing wound healing	0	2,25

on neurology diseases switched from neurovascular into neurodegenerative disorders and among cancer patients the percentage of head and neck cancer patients outrun the gastrointestinal (GI) tract neoplasm ($p > 0.05$). The profile is nowadays similar to

Italian, Spanish and British^{3,5,12,13}

The choice of enteral access must take into consideration the expected duration of enteral feeding and the characteristics of the patient. The vast majority of EN patients have been fed using PEGs, as showed in the study of Gao et Sul and Gottrand et al as well as Schneider et al^{3,14}. PEG is a valid, safe and easy-to-perform GI access¹⁵. In our study PEG has also dominated among GI accesses, and its use significantly since 2008 from 39% to over 60%, while the use of nasogastric tube fell down ($p < 0.05$). Those findings were concordant with Spanish and British observations^{3,5}

French authors proved that polymeric diets were the most commonly used for HETF patients⁶. Polish patients did not differ at that point, but it was clear that with the growing awareness, the use of non-standard diets increased.

The reimbursement was one the major concerns for HETF's centres. It is worth mentioning that HEN is nowadays regulated in eight European countries⁷. Poland joined that group last, while Italy and France were the first to implement reimbursement policy in 1988.

Table III
Benefits and problems of HEFT

Benefits of HEFT		
Improvement of pressure ulcer healing	100%	100%
Improvement of pressure ulcer healing	0%	25%
Improvement of the general condition	100%	100%
Enabling the rehabilitation	50%	75%
Reduction of respiratory disorders	50%	75%
Reduction of urinary tract infections	0%	0%
Reduction of hospital admission	0%	75%
Reduction of the length of hospital stay	0%	50%
Prevention of malnutrition	100%	75%
Problems during HEFT		
Unclear qualification procedure	0%	50%
Low awareness among health professionals	100%	100%
Low awareness of payer	100%	100%
Unclear reimbursement procedure	0	25%

The importance of HEN regulations regarding reimbursement was quite high. Centres' coordinators emphasized the need for clear policy of insurance company. It was an interesting observation to find out that the longer HETF was, the more unclear it became (Table III).

Conclusion

HETF is a safe, well-tolerated and cost-effective procedure. Our study demonstrated that there is a potential for HETF in every country, and the reimbursement is the trigger point for its use. The profile of patients and techniques may vary at the beginning, but becomes similar to other HETF countries relatively soon.

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Stanislaw Klek was the coordinator and the supervisor of the study, responsible for the conception, and contributed to the design, data analysis, interpretation and writing of the manuscript. Other authors carried out the study and were responsible for the data collection and contributed to the writing of the manuscript.

Conflict of interest

Stanislaw Klek acts as a lecturer for Nutricia, Fresenius Kabi, B Braun, Baxter and Nestle. Dorota

Pawlowska is employed at Nutricia Ltd. Other authors declare no conflict of interest.

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