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Original

Trends in home enteral nutrition in Spain; analysis of the NADYA registry 1992-2007

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Abstract

Background: **There are few data on trends in home enteral nutrition (HEN) practice in different countries. NADYA is the Spanish home artificial nutrition (HAN) group, and is responsible for the Spanish HAN registry.**

Method: **We performed a 16-year retrospective study (1992-2007) of the Spanish HEN registry by retrieving data from the NADYA database and from publications of the working group. People receiving more than 1000 kcal/d with an enteral formula were included regardless of the access route (oral/tube feeding).**

Results: **The number of patients registered increased more than 8 times during the study period: the current prevalence is 113 patients/10^6 inhabitants (oral and tube feeding), or 41 patients/10^6 inhabitants (tube feeding). The distribution of the patients was not uniform, and most came from six autonomous communities (Catalonia, Galicia, Castilla-León, Madrid, Andalusia and Extremadura). Gender distribution was nearly 1:1. The number of paediatric patients was very low, representing less than 10% of the total. Mean age in adults was above 65 years in most of the reports. We observed an increase in the age of the patients over the years. The most common underlying diseases were neurological disorders, followed by cancer. We observed an increase in the use of the oral route, from 5.8% in 1992 to 64% in 2007, with a parallel decrease in the use of nasogastric tubes. Gastrostomy tubes were used in 15-20% of the patients. The number of complications was low (less than one complication/patient/year), the most frequent being change of tube, followed by gastrointestinal complications. The principal reasons for discontinuing treatment were death related to the underlying disease (40-50%) and switch to oral diet (30-40%). Most of the patients (75%) were followed by the hospital nutrition unit. Provision of the enteral formula and disposables varied according to the autonomous community. Most of the patients had limited physical activity or were chair- or bed-bound, requiring partial or total help in their daily life.**

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TENDENCIAS EN NUTRICIÓN ENTERAL DOMICILIARIA EN ESPAÑA; ANÁLISIS DEL REGISTRO NADYA 1992-2007

Resumen

Introducción: **Existen pocos datos sobre la evolución de la práctica de la nutrición enteral domiciliaria (NED) en diferentes países. NADYA es el grupo de trabajo español de nutrición artificial domiciliaria (NAD), y es responsable del registro español de estos pacientes.**

Métodos: **Realizamos un estudio retrospectivo de los últimos 16 años (1992-2007) del registro español de NED utilizando la base de datos de NADYA y las publicaciones del grupo de trabajo. Se incluyeron aquellos pacientes que recibieron más de 1000 kcal/d de una fórmula enteral, independientemente de la vía de acceso (oral/sonda).**

Resultados: **El número de pacientes registrados se multiplicó por ocho durante el periodo de estudio: prevalencia actual 113 pacientes/10^6 habitantes (oral y sonda), o 41 pacientes/10^6 habitantes (sonda). La distribución de los pacientes no fue uniforme, y la mayoría pertenecían a seis comunidades autónomas (Cataluña, Galicia, Castilla-León, Madrid, Andalucía y Extremadura). La distribución por sexo fue casi 1:1. El número de pacientes pediátricos fue muy bajo, representando menos del 10% del total. La edad media de los adultos fue superior a 65 años en la mayoría de los registros. Observamos un incremento en la edad de los pacientes a lo largo de los años de estudio. Las enfermedades más prevalentes fueron las neurológicas, seguidas del cáncer. Observamos un aumento del uso de la nutrición enteral oral, de 5,8% en 1992 a 64% en 2007, con un descenso paralelo del uso de las sondas nasogástricas. La gastrostomía se utilizó en el 15-20% de los pacientes. El número de complicaciones fue bajo (menos de una complicación/paciente/año), siendo la más frecuente el cambio de la sonda, seguida de las complicaciones gastrointestinales. Las principales razones de finalización del tratamiento fueron la muerte relacionada con la patología de base (40-50%) y el paso a la alimentación oral (30-40%). La mayoría de los pacientes (75%) fueron seguidos por las unidades de nutrición de los hospitales. El suministro de la fórmula de nutrición enteral y el material fungible varió dependiendo de las comunidades autónomas. La mayoría de los pacientes tenían limitada su actividad física o estaban confinados a cama/sillón, y requerían ayuda total o parcial para las actividades de la vida diaria.**

Conclusions: **The use of HEN has increased dramatically in the last 16 years in Spain. Most of the patients registered were elderly people with neurological disorders and limited physical activity. The oral route was the most frequently used. The number of complications was low. The mortality rate in these patients was highly related to the underlying disease.**

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Key words: *Home enteral nutrition. Registry. Complications.*

Conclusiones: **El uso de la NED ha aumentado mucho en los últimos 16 años en España. La mayoría de los pacientes registrados eran ancianos con enfermedades neurológicas y con una limitada actividad física. La vía oral fue la más empleada. El número de complicaciones fue bajo. La mortalidad de estos pacientes se relacionó principalmente con la enfermedad de base.**

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Palabras clave: *Nutrición enteral domiciliaria. Registro. Complicaciones.*

Introduction

Home enteral nutrition (HEN) is defined as the provision of enteral diets as the main source of daily intake at home. However, there is little agreement about what constitutes HEN. In one European survey, three countries (Italy, France, United Kingdom) considered only tube feedings covering > 75% of requirements as enteral nutrition, and six countries considered both tube and oral feedings covering > 75% requirements as enteral nutrition (Belgium, Czech Republic, Denmark, Israel, Poland, Spain). In two countries (Austria, Croatia), any kind of enteral diet or supplement was considered as enteral nutrition.[1]

The use of HEN has increased enormously in the last few decades,[2,3] triggering the development of specific legislation, guidelines and national registries in many countries.[1]

The Spanish home artificial nutrition (HAN) group, NADYA, was established in 1992 by health care professionals working with artificial nutrition.[4] One of the aims of the group has been the maintenance of a voluntary registry, which is accessible at www.nadya-senpe.com.

We now have an extensive database on the practice of HAN in Spain. Since 1994, the annual registries of patients on HAN have been published periodically (with the exception of 1997 and 1998), and we have observed an increase in the number of patients registered.[5-14] In 2006 we reviewed the progress of home parenteral nutrition (HPN) through this registry.[15] In this article, we present trends in HEN practice in Spain during this period.

Material and methods

We performed a 16-year retrospective study (1992-2007) evaluating the characteristics of patients receiving HEN in Spain. The data were extracted from the NADYA registry, and most are available in yearly publications.[5-14] The NADYA registry is voluntary and depends on the goodwill of reporters; therefore, real data may be underreported.

In1992, our group performed a national survey on HEN practice.[16] The first registry was conducted in 1994[5] and yearly thereafter, except for the years 1997-1998 (not available). Data from the years 2004 and 2005 are partial because of changes in the organization of the registry.[17] Data included personal information, underlying disease, type of enteral access, length of treatment, complications, outcome, HEN providers, physical activity, and patient autonomy. As the data from the previous year were filled out at the end of the current year, the prevalence was calculated annually.

Data recording in the initial registry was on paper until 1998, when an on-line reporting system was set up on the group's website, thus providing reporting physicians with direct individual access to the registry. The patients included in the registry were those receiving more than 1,000 kcal/d with an enteral formula regardless of the access route (oral/tube feeding).

In 2005, the registry was updated to meet the stipulations of Data Protection Law 15/1999, and changes were made: the number of items was reduced in order to increase the participation of the investigators.[17] Furthermore, in the updated version, data can be entered at any time, and are available until the investigator closes the enteral episode.

Results

Period prevalence 1992-2007

The number of patients registered increased more than 8 times during the study period (fig. 1). In 2007, the prevalence was 113 patients/10^6 inhabitants (including oral and tube feeding), or 41 patients/10^6 inhabitants (including only tube feeding).[14] The number of reporting centres during this period varied from 17 in 1994 to 28 in 2007.

In the period 2004-2005 there was a decrease in the number of patients registered due to the changes in the working of the registry.

Interestingly, the distribution of patients throughout Spain in not uniform (fig. 2). The available data from 10 of the 17 autonomous communities show that most patients were in six communities (Catalonia, Galicia, Castilla-León, Madrid, Andalusia, Extremadura).

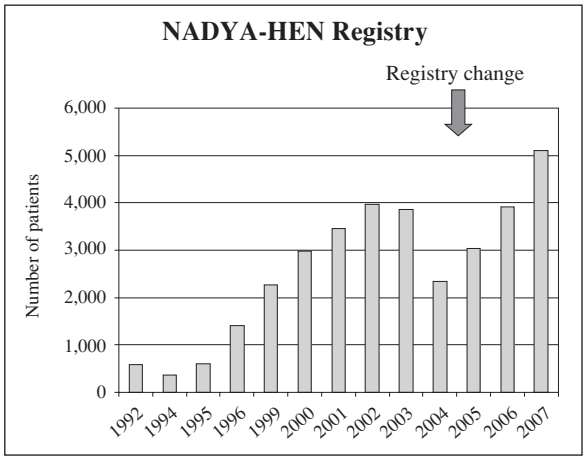

Fig. 1.—Evolution of the number of patients in the NADYA-HEN registry during the period 1992-2007.

Gender distribution was nearly 1:1, and the number of paediatric patients was very low (less than 10% of the registry). The mean age in adults is above 65 years in most reports (68 yrs in 2007); in children it is 4-6 years (4.2 yrs in 2007). Age tended to increase during the study period: people older than 74 years made up 26% of the study population in 1994, compared with 42% in 2007.

Underlying disease

Neurological disorders and cancer were the two most prevalent diagnoses, affecting nearly 70% of the patients (table I). In the last few years of the study period, we observed an increase in the number of patients with neurological diseases over cancer, probably as a result of the older age of the patients registered. Gastrointestinal diseases (eg, inflammatory bowel disease, motility disorders, malabsorption, ischemia, and radiation enteritis) represented less than 5%. During the last 5 years, HIV infection was present in very few patients.

Enteral access route

There was a large increase in the use of the oral route during the study period, from 5.8% in 1992 to 64% in 2007, with a parallel decrease in the use of nasogastric tubes, from 68.8% in 1992 to 26% in 2007. Gastrostomy tubes were used in 15-20% of patients, representing 25% of non-oral accesses. Jejunostomy tubes were used in 2% of patients.

Length of treatment

We observed an increase in the length of treatment from 6.3 months in 1994 to 9.4 months in 2007. Before the modification of the registry in 2005, the duration of treatment was < 3 months in ~30% of patients and between 3 and 5 months in 20%. This trend changed during the last few years of the study.

Complications

All the data on complications come from the old registry (table II). In general, patients had less than one HEN-related complication per year. The most frequent

Fig. 2.— Prevalence of HEN according to autonomous communities in 2007 (expressed per million inhabitants).

Table I
Diagnosis of patients requiring HEN in the NADYA registry (data are expressed as a percentage)

	Cancer	*Neurological disorders*	*Gastrointestinal diseases*	*AIDS*	*Other diagnosis*
1992	45	32	8		15
1994	36	35	7.6	1	21.4
1995	41	33.5	5.7	2.9	16.9
1996	39	33	5	3	20
1999	36.8	37.5	5.5	3.6	16.6
2000	32	41	4		23
2001	33.5	43.5	4	3	16
2002	35	39	3	3	20
2003	39	37.4			23.6
2004	29	40	4	–	27
2005	30	41	5	–	24
2006	28	42	4	–	26
2007	28	37	4	–	31

was the change of enteral tube, followed by gastrointestinal complications (diarrhoea, constipation).

Outcome

Until 2003, between 30% and 40% of patients were weaned from HEN during the year. This percentage fell towards the end of the study probably due to misreporting of data (ie, the investigators did not close the episodes). The principal reasons for discontinuing treatment were death related to the underlying disease (40-50%) and progress to oral diet (30-40%). Approximately 10-15% patients were lost to follow-up.

Follow-up and delivery of treatment

In 75% of patients, follow-up was performed by the hospital nutrition unit and in 10-15% by the home hospitalization units.

The enteral formula was provided by the hospital and private pharmacies, depending on the area. The type of formula was recorded until 2003, and polymeric formulas were the most commonly used (85%). The disposables were mainly provided by the hospitals. Enteral pumps were used in only 10% of patients.

Physical activity and autonomy

Most of the patients were limited in their physical activity (30%), or were chair- or bed-bound (40%). Very few patients were unconscious (1%). Most adult patients required partial (28%) or total help (39%) in their daily activities.

Discussion

We describe HEN practice in Spain over a 16-year period. The information we provide is useful, given

Table II
Complications of HEN (complications/patient/year)

	Total number	*Mechanic*	*Metabolic*	*Gastrointestinal*	*Tube change*
1992	0.18				
1994	0.07	0.04	0.005	0.002	
1995	0.5	0.09	0.003	0.17	0.23
1996	0.74	0.19	0.01	0.28	0.28
1999	0.62	0.12	0.01	0.26	0.25
2000	0.75	0.19	0.007	0.25	0.3
2001		0.15		0.16	
2002	0.85	0.19	0.078	0.25	0.32
2003	0.63	0.14	0.02	0.19	0.28

that HEN has received less attention in the literature than HPN.

We observed an enormous increase in HEN during the study period. This increase is the result of the development of the enteral industry (including new enteral formulas, many of them for oral use, and improvements in enteral access) and legislation on HEN, and a growing awareness of the importance of malnutrition in the prognosis of illness.

HEN was first approved in Spain in 1998 for people incapable of covering their daily requirements by oral diets.[18] Enteral feeding (generally by tube) is publicly financed for a long list of diseases. Legislation has recently been modified,[19] and in 1998, a group of experts on HEN and the Ministry of Health developed national guidelines,[20] which have recently been updated.[21]

As the NADYA registry is voluntary, we are aware that it could underestimate the number of patients on HEN in Spain. This is clearly visible from the map of the Spanish autonomous communities (fig. 2). The different systems for organizing HEN make follow-up easier to perform in some autonomous communities (for example Catalonia and Galicia).

Our data show that the prevalence of HEN is 113 patients/10^6 inhabitants (including oral and tube feeding), or 41 patients/10^6 inhabitants (including only tube feeding). Except for 5 autonomous communities (Catalonia, Galicia, Castilla-León, Madrid, Andalusia), this prevalence is lower than observed in other studies performed in different areas of Spain.

In Valladolid, de Luis et al[22] reported an incidence of 95-265 patients/10^6 inhabitants in the period 1999-2004. In Galicia, the prevalence found in a multicentre study in 1998-1999 was much higher (1,034 cases/10^6 inhabitants).[23] Although several studies have shown an increase in HEN in other areas of Spain, prevalence is unknown.[24-26]

In Europe, the prevalence of HEN is also unknown. One European survey in 1999, reported the median annual incidence to be 163 patients/10^6 inhabitants/year (range 62-457).[3] The British registry, which includes only people on tube feeding, reported 24,203 adult patients (prevalence 404 cases/million) and 5,831 children in 2007.[27] In Germany, the number of patients on HEN is unknown, but probably exceeds 100,000 cases.[28] An Italian survey in 2005 showed a prevalence of 128 cases/million.[29] In a recent report from Northeast Italy, the mean incidence and prevalence of HEN during 2001-2005 were 308.7 and 379.8 cases/million, respectively.[30] In the United States, there were 152,000 patients on HEN in 1992, with a prevalence of 415 cases/million during 1989-1992.[2]

Neurological disorders and cancer are the most frequent indications for HEN in our registry. The first has increased over the years, probably as a result of aging of the population. These data are similar to those from two studies performed in Galicia,[23,31] but differ from those reported in the study from Valladolid,[22] in which head and neck cancer was the most common underlying disease (43.8%), and neurological disorders represented only 9.6%, probably as a result of the younger age of the patients included (mean age 56.4 yrs).

In the European survey, the most frequent diagnoses were neurological disorders and head and neck cancer.[3] In the British registry, which includes patients with very similar characteristics to ours, neurological disorders were also the most frequent diseases.[27] In Italy, most patients on HEN had neurological disorders.[29,30] In the North American Home Parenteral and Enteral Nutrition Registry 1985-1992, the most frequent diagnosis was cancer (40%) followed by dysphagia (30%).[2] More recent data from Denver on 17,014 patients (mean age 46.6 years) followed from 1998 to 2002 showed that the most common indications were gastrointestinal diseases, malnutrition, and diseases of the esophagus.[32] The indication for HEN is clearly shown to depend on the characteristics of the patients (mainly age).

In our series, oral enteral feeding was the most frequently used approach, especially in the latter part of the study, as a result of the enormous increase in the availability of oral formulas during this period. This mirrors the results of the studies from Galicia[23,31] and Valladolid,[22] but differs from the practice in areas where oral enteral feeding is not reimbursed[28,32] and the patients are not included in the national registries.[2,27]

The use of gastrostomy tubes in our series was very low (15-20%) —25% of non-oral feedings— especially taking into account the age of the patients and the underlying disease. This percentage is similar to that observed in studies from other areas of Spain,[22,23,31] but differs from those reported in other countries (58.2% of gastrostomies in the European survey, 83% in the British registry).[3,27] However, in the study from Northeast Italy, most patients were fed by nasogastric tube.[30] In the United States, gastrostomies are probably overused because Medicare only finances HEN treatment lasting more than 3 months.[33] In addition, these tubes are currently very common in nursing homes.[32] In 1989, 15,000 percutaneous endoscopic gastrostomy (PEG) tubes were used; in 2000, this figure had risen to more than 216,000 tubes. Approximately 30% were used in patients with dementia.[34]

Although gastrostomy is indicated in long-term enteral feeding because of its safety and patient comfort,[35] there are many doubts over its benefits in some cases, especially in patients with advanced dementia.[36,37]

The number of complications in our registry was low, the most frequent being change of the feeding tube. This could be avoided by the use of gastrostomy in some cases. Our complication rate is similar to those of other studies performed in Spain[22,23,31,38] and elsewhere.[2,39,40]

The increase in the length of treatment over the years in our series is probably unreal and may reflect misreporting of the weaning process during follow-up in the

new registry. The most frequent reasons for discontinuing treatment were death and progress to oral diet, as occurred in other series.[2,22,27,30] It is important to note that mortality is very high (20% mortality 1 month after starting treatment) despite appropriate selection of patients,[41] and mostly depends on age and underlying disease.[22,42,43]

In our experience, HEN was used in elderly people (most of them chair- or bed-bound) who required partial or total help in their daily activities. These features are common in the British registry.[27]

The organization of HEN in Spain differs according to the autonomous community. While the enteral formula and disposables are provided by the hospital (or directly delivered to the patient's home through agreements with the enteral feeding industry) in Galicia and Catalonia, in the rest of the country the formula is provided by private pharmacies and the disposables by the hospital or primary care centers.

As this treatment is financed by the National Health Services in many countries, it is important to establish its cost-effectiveness. HEN costs about a tenth of HPN. In a recent report from Elia et al,[44] the cost per quality adjusted life years in patients receiving long-term enteral tube feeding in their own home was £ 12,817. This cost compares favourably with other forms of intervention, and is well within the typical range of the interventions recommended by the National Health Service in many countries.

We can conclude that HEN is a safe, cost-effective treatment, which has become increasingly used in the last 20 years in Spain and in other western countries.

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