



Original/*Nutrición enteral*

Economic burden of home artificial nutrition in the health area of Santiago de Compostela

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Abstract

Introduction: home artificial nutrition (HAN) is a growing therapy, but the absence of obligatory registries complicates the calculation of its real economic burden. The aim of this study was to assess the state and economic impact of HAN in our health area.

Methods: an observational, prospective study was designed to calculate the cost of nutritional formulas and materials in patients who initiated HAN in the nutrition unit during a year.

Results: we included 573 new patients with HAN during the study period, 60% of whom were treated with oral supplements. The median daily cost of oral HAN was 3.65 (IQR 18.63) euros compared to a cost of 8.86 (IQR 20.02) euros for enteral-access HAN. The daily expenditure per 1000 kcal of diet was higher for patients on oral HAN than for patients with tubes (5.13 vs. 4.52 euros, $p < 0.001$). The median cost of the complete HAN treatments during the study period was also calculated (186.60 euros and 531.99 euros for oral and tube HAN, respectively). The total estimated cost for all patients who initiated HAN in the study period was around one million euros.

Conclusions: HAN represented an important economic burden in our health area, but the estimated daily cost of HAN was moderate, probably because of the high frequency of oral HAN, the adjusted treatments, and the centralized dispensation by the hospital pharmacy.

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IMPACTO ECONÓMICO DE LA NUTRICIÓN ARTIFICIAL DOMICILIARIA EN EL ÁREA SANITARIA DE SANTIAGO DE COMPOSTELA

Resumen

Introducción: la nutrición artificial domiciliaria (NAD) es una terapia en creciente desarrollo, pero la ausencia de registros obligatorios hace difícil calcular la carga económica que implica. Nuestro objetivo es evaluar el estado y el impacto económico de la NAD en nuestra área sanitaria.

Métodos: estudio observacional y prospectivo diseñado para estimar el gasto en fórmulas y materiales nutricionales en los pacientes que iniciaron NAD durante 1 año.

Resultados: se incluyeron 573 pacientes que iniciaron NAD en el período de estudio. El 60% recibieron suplementos orales. La mediana de gasto diario fue de 3,65 (RIC 18,63) euros en la NAD oral y de 8,86 (RIC 20,02) euros en la NAD por acceso enteral. El gasto por 1.000 kcal de dieta fue superior en los pacientes con NAD oral respecto a los pacientes con NAD enteral (5,13 vs. 4,52 euros, $p < 0.001$). Asimismo se calculó la mediana de gasto completo de los tratamientos durante todo el período de estudio (186,60 euros y 531,99 euros en NAD oral y enteral, respectivamente). Considerando el gasto conjunto de todos los pacientes que iniciaron NAD en el período de estudio, el gasto estimado estaría en torno a un millón de euros.

Conclusiones: la NAD representa una importante carga económica en nuestra área sanitaria. Sin embargo, el gasto diario estimado fue moderado, probablemente por la elevada proporción de NAD oral en nuestra muestra, la revisión frecuente de la indicación y la centralización de la dispensación desde el servicio de Farmacia Hospitalaria.

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Palabras clave: *Malnutrición. Soporte nutricional. Nutrición enteral domiciliaria. Costes. Economía.*

Abbreviations

HAN: Home artificial nutrition.
HEN: Home enteral nutrition.
IQR: interquartile range.
KCAL: calories.
SD: standard deviation.
SERGAS: Galician Health Service.
TNF: tumor necrosis factor.

Introduction

Malnutrition is currently a serious problem, both in hospitals and for outpatients^{1,2}, and it is particularly associated with the aging population and the growth of chronic diseases. Studies of different countries revealed not only malnutrition's clinical consequences but its economic burden. Malnutrition increases the frequency of hospital admissions, the length of stay and costs during hospitalization, and the frequency of patient monitoring in specialty and primary care practice^{3,4}.

In order to address this problem, nutritional support therapies have developed greatly. Home artificial nutrition (HAN) is a growing technique that allows for the nutritional treatment of stable patients in a more comfortable and familiar environment, avoiding hospitalization.

In 2010 in the US, approximately 12 million patients required some form of home care, and malnutrition was described as one of the 10 most common diagnoses in these patients⁵. Therefore, the expansion of home nutrition therapy could be related to the increase in the detection of malnutrition and the awareness of the need to treat it.

Mandatory HAN epidemiological registries would be essential to estimate HAN's real frequency and economic burden. However, the current scenario is far from ideal. HAN records are rare and usually voluntary, offering only a partial view of the situation and depending on the degree of individual participation.

In 2009, a systematic review was conducted using major scientific databases. Only 11 HAN registries (in 8 countries: Australia, Germany, Italy, Spain, Sweden, the UK, the US, and Japan) were founded and published between 1987 and 2007. They all had limitations and heterogeneity in data collection. This suggests that the observed increase in HAN therapy is not accompanied by a parallel increase in HAN registries, making it difficult to obtain representative information⁶.

In Spain, the NADYA-SENPE registry started in 1992, and it publishes annual HAN data⁷⁻²⁰. Other international HAN registries exist, and though they all offer valuable information, they probably underestimate the prevalence of HAN because participation is voluntary. Due to the health care professionals' limited time, HAN registries are usually focused on collecting data only about patients who receive over 75% of their

requirements from enteral nutrition. Therefore, those patients with supplements, nutritional thickeners, or modules are normally excluded, which again would underestimate the actual frequency of HAN.

Since the National Health System funds HAN treatments, it must obtain more realistic data on the frequency of this therapy and make an estimate about the economic burden it causes.

In Spain, home enteral nutrition (HEN) has been legally regulated since 1997. It is considered a necessary therapy for patients who cannot meet their nutritional needs with ordinary foods. HEN is funded only if certain conditions are satisfied (e.g., for patients with swallowing problems due to mechanical alterations or neuromotor disorders, those with severe malnutrition, or those with special energy or nutrient requirements).

Regarding prescription and dispensation of HEN, Galicia presents a different model from the rest of the country. The Galician Health Service (SERGAS) established that the prescription should come from a doctor in a hospital's nutrition unit, or in certain exceptional cases from another hospital specialist who diagnosed the patient. Although in most regions of Spain any formula funded by the National Health System can be prescribed, Galicia has established its own catalog of enteral formulas, restricting the number of formulas approved for funding. Dispensation, both of the formulas and expendable materials, should be made from the hospital pharmacy and should follow official approval recipes.

This centralization of the HEN dispensation in the hospital pharmacy is presented as an opportunity to estimate the economic burden of this therapy and to reveal more about a subject for which only scarce information is available in national and international studies.

Objectives

Our aim was to estimate the economic impact of HAN by creating an obligatory HAN registry, including all patients who receive nutritional support at home, in the health area of Santiago de Compostela.

Methods

This prospective observational study included all patients who started HAN as prescribed by the Department of Endocrinology and Nutrition of the Complejo Hospitalario Universitario of Santiago de Compostela (CHUS) in the period from October 15, 2009, to October 14, 2010. Patients with HAN that was prescribed and monitored by other hospital services were excluded because of the difficulties in proper data collection. However, these patients were considered for the calculation of all patients who started HAN in the study period.

At the inclusion, baseline characteristics of the patients were registered. The patients were followed until October 15, 2011, to evaluate their evolution and changes in nutritional support.

From the list of diets and material prices provided by the hospital pharmacy, HAN spending for each patient was calculated, taking into account the type of prescribed diet, the daily amount, the total duration of treatment, and changes during follow-up. The cost of materials was estimated based on the type of administration, by gravity or pump. The difference in costs between oral and enteral methods was also evaluated. Finally, the total HAN expenditure for all patients enrolled in the study was estimated; this total considered patients who started HAN during a period of one year at the Department of Endocrinology and Nutrition, considering the months of treatment registered for each patient.

Statistical analysis

Statistical analysis was performed with SPSS 19.0 (SPSS Inc., Chicago, IL, USA). The normal distribution of quantitative variables was examined by the Kolmogorov-Smirnov test. Variables matching normal distribution were presented in terms of mean and standard deviation (SD), and those without normal distribution were presented in terms of median and interquartile range (IQR). Quantitative variables were compared with T Student for normal variables and Mann-Whitney tests for other variables. Categorical variables

were expressed as percentages. A p value lower than 0.05 was considered statistically significant.

Ethical issues

The study was conducted in accordance with the standards of Good Clinical Practice (GCP) and according to ethical principles grounded in the latest update of the Declaration of Helsinki. The Ethics and Clinical Research Committee of Lugo-Santiago approved the study protocol, and patient anonymity was preserved.

Results

During the study period, 788 patients started home nutritional support in the health area of Santiago de Compostela. However, only 573 patients were finally included in the study. The main reason for exclusion was the lack of prospective data among patients whose HAN was prescribed and monitored by other hospital services and those who were not captured in the recruitment period because although HAN was prescribed in the Department of Endocrinology and Nutrition (Fig. 1).

Baseline characteristics of patients

Of the patients included in the registry, 59.7% were women. The median age was 79 (IQR 87) years, with 78.6% of patients over 65 years. We found high le-

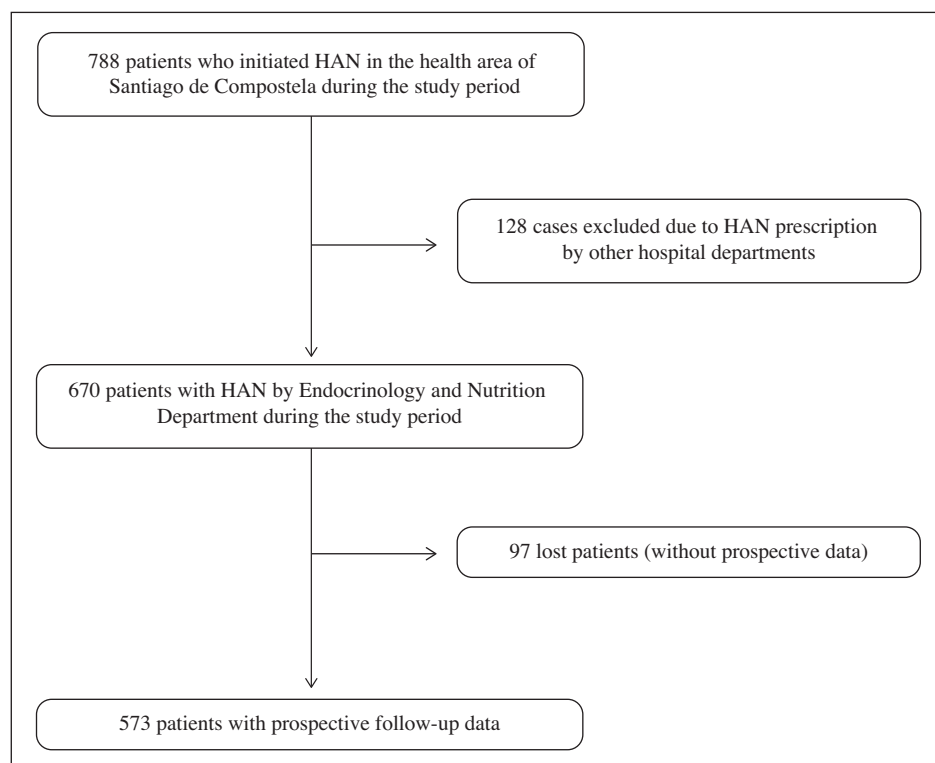


Fig. 1.—Flowchart of study patients.

vels of comorbidity: 51.7% had neurological diseases, 32.1% had digestive problems, 30.2% had cardiac pathology, 28.8% had respiratory diseases, 28.4% had a history of neoplasia, and 19.7% had diabetes. The median number of home treatments was 6 (IQR 19) drugs. About 80% of the patients reported mobility limitations and 33.4% needed a caregiver.

Neurological and oncological diseases, which are the most common indications of HAN, accounted for 50% of indications in the registry. At baseline, 75% of patients had malnutrition, mainly protein or mixed malnutrition. At the end of the study period, home nutritional support was active in 24.4% of patients; the rest had already discontinued it. The median duration of HAN was 8.5 months, and the death rate was 42.9%.

HAN characteristics

Table I summarizes the type of nutritional support at both the beginning and the end of the study. Oral supplements were the most frequent type of HAN (60% of patients). Among patients with HAN by enteral access, nasogastric tubes and bolus administration by gravity systems were predominant. Standard and high-calorie formulas were the most reported in the present study. No home parenteral nutrition was started in the study period.

With regard to energy intake, 38.8% of patients received more than 1,000 kcal/day, and their median

intake was 1,500 (IQR 1560) kcal/day. The remaining 61.2%, of patients received less than 1,000 kcal/day, with a median intake of 600 (IQR 827) kcal/day.

Formula and material costs

The daily and monthly expense of HAN, including both the formulas and the materials needed for administration (syringes, containers, systems, and adapters) are summarized in table II. Results are also presented according to the route of administration (oral or enteral access).

Caloric intake also affected HAN cost, as shown in table III. The daily expenditure per 1,000 kcal of diet was higher in patients with oral HAN (median 5.13 [IQR 17.97] euros), compared to patients with HAN by enteral access (median 4.52 [IQR 10.41] euros), with a significant difference ($p < 0.001$).

Complete treatment costs

The total cost of HAN during the period of study, including the year of inclusion and the year of follow-up, was estimated. For every patient, we considered the length of time that HAN was maintained and the supplies that were collected at the pharmacy department. All the treatment changes were registered as well. Table IV shows the differences between oral and enteral complete treatment costs. We also calculated the cost of finalized treatments, excluding patients who still had active treatment.

After calculating individual HAN costs, we estimated the total cost for the 573 patients during the period of the registry at 659,385.49 euros. Knowing that our sample represented 72.7% of patients who started HAN during one year (573 of 788 total incident patients), a total HAN expenditure of 906,995.17 euros can be estimated.

Discussion

Home nutritional support has great economic impact on health systems because of its high consump-

Type of nutritional support	Initial (%)	Final (%)
Oral supplements (<1000 kcal)	59.3	56.5
Oral enteral nutrition (>1000 kcal)	5.4	8.6
Nutrition by enteral access	31.1	29.5
Thickener	3.4	3.6
No data	0.5	1.6

	Total population	Oral HAN	HAN by enteral access
Formulas	4.62 (IQR 18.63) euros/patient/day	3.65 (IQR 18.63) euros/patient/day	7.38 (IQR 15.70) euros/patient/day
Materials	1.29 (IQR 4.32) euros/patient/day	0	1.29 (IQR 4.32) euros/patient/day
Total daily cost	4.62 (IQR 22.86) euros/patient/day	3.65 (IQR 18.63) euros/patient/day	8.86 (IQR 20.02) euros/patient/day
Total monthly cost	138.6 (IQR 685.8) euros/patient/month	109.5 (IQR 558.90) euros/patient/month	265.80 (IQR 600.60) euros/patient/month

Table III
Cost estimation by caloric intake

	<i>Caloric intake <1000 kcal</i>	<i>Caloric intake >1000 kcal</i>
Formulas	3.56 (IQR 12.43) euros/day	7.38 (IQR 15.41) euros/day
Materials	0	1.29 (IQR 5.61) euros/day
Total daily cost	3.56 (IQR 12.64) euros/day	8.85 (IQR 20.36) euros/day
Total monthly cost	106.8 (IQR 379.20) euros/month	265.65 (IQR 610.80) euros/month

Table IV
Complete treatments costs

Complete treatments (total population)	415.80 (IQR 9,057.60) euros
Complete treatments (oral HAN)	186.60 (IQR 4,395.60) euros
Complete treatments (enteral access HAN)	531.99 (IQR 6,040.80) euros
Finalized treatments	306.90 (IQR 6,249.60) euros

tion of resources. In countries with public health care, such as Spain, it is essential to ensure a rational distribution of resources. This is especially true considering that a progressive increase in expenditure, related to an aging population and its increasing healthcare demands, is observed²¹ and that budget cuts motivated by the financial crisis have affected Spain's health system. In the field of HAN, economic studies are critical to provide realistic information for rational and responsible pharmaceutical expenditure planning. However, only scarce national or international economic data are available about HAN.

Economic impact of HAN in health systems

In recent years, several records from different countries have found that HAN, and more specifically HEN, is a growing economic burden on health systems. In the early 90s, a study was conducted in the US to estimate HEN costs for beneficiaries of Medicare, which was the principal HEN funding program at the time. Between 1989 and 1992, the number of HEN patients increased from 34,000 to 73,000, and this meant an increase in spending from 47 to 137 million dollars. Assuming Medicare financed 46% of those listed in the National Register of HEN, it was estimated that in 1992, the total number of patients with HEN in the US reached 152,000 patients, with a cost of 357 million dollars²².

In Germany, HEN cost was calculated at 600 million euros/year: 200 million euros for HEN materials (e.g., tubes and pumps) and 400 million euros for nutritional formulas²³.

This increasing HAN spending has also been observed in other countries, such as Ireland and Spain²⁴. In the Community of Madrid, a rise in HEN prescription was detected between 1998 and 2001, with an incremental cost that rose from 57,956,347 to 121,607,693 euros in that period²⁵.

In Andalusia, between 2000 and 2007, trends in HEN consumption and cost were evaluated. During that period, a cost increase of 2800% was detected (from 1.3 to 37 million euros); this related to HEN's increasing prevalence, especially in the prescription of oral supplements. Enteral nutrition by tube represented the 81.7% of total HEN costs in 2000 but diminished to 41.4% in 2007, while the cost of supplements increased from 17.6% to 54.2%. Increased spending on supplements was not only due to increases in prescriptions but also to the higher use of more expensive special formulas (for diabetes and cancer cachexia, mainly)²⁶.

In the Community of Galicia, the SERGAS 2009 report included HEN as one of the most expensive hospital-dispensed drugs in the outpatient setting. HEN was placed in fifth position, behind antiretroviral drugs, tumor necrosis factor (TNF) antagonists, tyrosine kinase inhibitors, and drugs for multiple sclerosis. In the context of total health expenditures, in that year, more than 4 billion euros were spent on HEN drugs, with an average cost per patient of 1,457 euros; the total estimated HEN expenditure was 5,651,843.60 euros²⁷.

Considering our results, in just this study's health area, the estimated HAN cost would approach one million euros in a year, counting incident patients but not prevalent cases. Therefore, our data would be similar to the data in other countries' published records, corroborating the importance of HEN's economic burden on the public health system.

Daily/monthly cost per patient with HEN

One of the first studies found in the literature about the daily cost of HEN is a survey performed by Hebuterne and colleagues in several European countries in 1998. In this paper, HEN's average cost ranged between 7 and 25 euros per patient and day, with significant differences between surveyed countries (12.4 euros in Belgium, 10 euros in France, 23.3 euros in Germany, 24.2 euros in Italy, 12 euros in Portugal, and 16.7 euros in Spain). These costs included the formula, infusion pumps, micronutrients, and equipment, but not the cost of caregivers, readmissions or medical monitoring²⁸.

In Spain, studies have estimated the daily cost per HEN patient. Thus, we have data from the area of Valladolid, where the average HEN daily cost per patient was 17.8 (SD 35.6) euros/day²⁹.

Comparing the European and Spanish data with our registry, our cost estimations were significantly lower (4.62 euros/patient/day). The explanation may lie in the fact that Hebuterne's European survey only took into account enteral nutrition by tubes and not oral supplements.

Dividing our results based on the route of administration, we found that daily spending was 3.65 euros for oral HAN and 8.86 euros for HAN by tube, which resembled the European data. Within this expenditure, the material represented 14.5% of the total cost, and formulas accounted for 85.5%.

We highlight in our data that the daily expenditure per 1,000 kcal of diet was higher for oral HAN patients than for those with enteral access (5.13 vs. 4.52 euros, $p < 0.001$). The increased use of special formulas in patients with oral supplements could explain this phenomenon.

In our registry, both the monthly cost per HEN patient (estimated at 138.6 euros/month) and the cost per complete treatment (186.60 euros in patients with oral support and 531.99 euros in patients with enteral support), were lower than the costs calculated in other studies. In Germany, several studies found a monthly average expenditure per HEN patient between 580 and 650 euros²³. The Valladolid study also presented a higher cost per complete treatment than our estimations (1,803 [SD 3,601] euros)²⁹. Moreover, in a study conducted in the area of Santiago de Compostela in 2007, the monthly HEN cost was slightly higher than that calculated in our present work (159.3 euros/month, including formulas and materials)³⁰. One possible explanation would be that, in our sample, a high percentage of patients received short periods of treatment, for example, a temporary HAN indication after a hip fracture or hospitalization in malnourished elderly. Adjusting the treatment periods could reduce total treatment costs.

Perhaps having a centralized dispensing hospital contributed by allowing the negotiation of lower prices with pharmaceutical companies. This could also optimize treatment, as the patients could receive just the amount of nutritional supplies they need, the flavors they prefer, etc. In short, centralization of dispensation may contribute to better monitoring and adjusted treatment.

One of the considerations to make regarding our economic calculation is that it is a theoretical calculation that assumes 100% compliance with prescriptions. We actually know that compliance in HAN treatments, especially in oral HAN, is difficult to maintain, and adherence is not always adequate.

Thus, we can guess that the theoretical cost of the prescribed treatment may be somewhat higher than the real cost because patients often collect less packaging than prescribed if they do not comply with the entire treatment regimen, and thus they often have a surplus at home. Furthermore, families often return these surpluses when a patient discontinues nutritional support, allowing other patients to use the surpluses and providing savings for the system.

Another limitation of our study is that its design has only allowed us to calculate the cost of formulas and materials; we could not include other important aspects for planning the economic impact of HAN, such as outpatient visits or hospitalizations.

In conclusion, HAN represented a significant economic burden on the health area of Santiago de Compostela. However, the estimations of daily costs and complete treatment costs in our area were moderate. The high proportion of oral HAN in our sample, the frequent review of the need for nutritional support, and the centralization of the dispensation at the hospital pharmacy justify these results.

Conflict of interest

The authors declare no conflict of interest.

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