Abstract

Objectives: Home artificial nutrition (HAN) is a technique in increasing use, but the available data about it is limited because record-keeping in most countries is voluntary. Our objective is to describe the characteristics of HAN in our setting and to design a future proposal that improves its coordination.

Subjects: Retrospective review of 237 clinical histories of the patients who began with HAN in 2006 in our unit. Variables: epidemiological information, indications, type of HAN, duration, complications and costs.

Results: Mean age: 75.4 years. Neurological and neoplastic diseases were the most frequent diagnoses (39.7% and 32.1%, respectively). Main indications were: reduction of ingestion (41.8%) and neurological dysphagia (27.8%). 48.1% presented an important functional impairment and 63.7% needed a caregiver. HAN duration was < 3 months in 43.9% and the principal cause of suspension was the lack of follow-up. Oral nutrition was the preferred route (70.9%), and gastrostomy was found in only 3.4%. High-energy formulas were mostly used in patients with supplements (53.3%) and standard formulas in those with complete diets (32.4%). Complications related to this therapy were low, mainly in the oral route. The most frequent were gastrointestinal (19.3%). Mean monthly cost: 159.3 euros/patient and an average travel distance of 26 km to pick up supplies.

Conclusion: HAN is a safe, short-term therapy, indicated in patients with diminished ingestion due to an acute situation. Our future proposal tries to improve the selection of patients, to facilitate the provision of materials and to customize follow-up to patient needs.

Key words: Nutritional support. Enteral nutrition. Home health aides. Health care costs.
**Background**

Home artificial nutrition (HAN) is defined as the enteral (HEN) or parenteral (HPN) administration of nutrients in the patient’s residence, with the purpose of improving or maintaining nutritional status. HAN provides nutritional support in their habitual surroundings, preserves their quality of life, and avoids the risks of hospitalization (i.e. nosocomial infections) with lower health care costs.

The success of a HAN program requires careful selection of the patients, who must have an appropriate residence and support. They or their caregivers must also be able to handle this technique correctly, so that complications will be rare.

In Spain, unlike HPN, HEN is legislated. According to the law, nutrition units are in charge of its coordination. The unequal distribution of equipment among these units explains the existing differences in handling of HEN between different areas and hospitals.

In Galicia, patients have to collect nutritional formulas and materials in the hospital pharmacy, and this can be problematic for those with limited mobility who are dependent on their relatives.

It is difficult to know the real prevalence of HAN due to the lack of obligatory records in most countries. In the case of HEP, the prevalence in the USA is about 120 patients/million, in Europe it varies between 0.3 and 12 patients/million and in Spain it is about 1.6 cases/million.

With regard to HEN, the prevalence in the USA is about 460 patients/million; in Europe, according to a recent multicentric study, it is approximately 163 patients/million, and in Spain the latest published data show a smaller prevalence of 74.6 cases/million, but this number is increasing.

In order to investigate the status of HAN in our area, we designed a study that included all our patients during a specific period, trying to obtain representative data describing the situation. We hope that this information will help to improve the selection of the patients and the provision of materials, as well as to develop educational programs and appropriate follow up. Thus we will improve our work as the unit responsible for the selection of patients and the coordination of the attention.

**Subjects and methods**

**Design**

We did a retrospective review of 237 clinical histories and a descriptive and analytical transversal study.

**Subjects**

All patients that began their treatment in our unit between the 1st of January 2006 and the 31st of December 2006 were included. We evaluated the data available until the 31st of July 2007.

**Variables**

- General characteristics of the sample: sex, age, medical antecedents, origin of the patient sent to our unit and indication for HAN. Functional situation: mobility, presence of pressure ulcers, necessity of caregiver and percentage of institutionalized patients (including only the patients who went to our unit but not those in institutions which we visited in other specific regular programs).
- Domiciliary treatment: number of daily medications, drugs that put patients at nutritional risk by influencing appetite, ingestion or metabolism (corticoids, digoxine, betablockers, antineoplastic or antiparkinsonian drugs).
- Follow-up data: number and frequency of visits to our unit, regularity of blood controls (hemogram and general biochemistry), total duration of the treatment, suspension of HAN and causes. The number of deaths was found out by consulting the Epidemiology Service of the Public Health System.
- Evaluation of nutritional status: weight and body mass index (BMI), visceral protein determination (albumin, prealbumin, transferrin and retinol-binding protein). We considered as malnutrition a mild depletion in two or more of those proteins or a moderate/severe depletion of at least one of them.
- Type of HAN: complete or supplemental, formula and diet, route of administration and energy provided.
- Complications: number of episodes, most frequent problems and hospitalizations.
- Economic data: calculation of the average monthly cost of this therapy, including diets and materials, and the travel distance in km for the monthly collection of the nutrition supplies in the hospital pharmacy.

**Data analysis**

For the statistical analysis we used the program SPSS version 12.0. For the comparison between qualitative variables the Chi Square test was used, whereas the Mann-Whitney test was used for quantitative variables without normal distribution. P values < 0.05 were considered to indicate statistical significance.

**Results**

**Epidemiological data and general characteristics**

We collected data from 237 patients, 133 (56.1%) men and 104 (43.9%) women, with a mean age of 75.4 years (SD 16.5 years). 187 patients (78.9%) were > 65 years old.
The most frequent diseases were neurological ones, in 94 patients (39.7%) and neoplasic ones in 75 (32.1%).

The main indication that motivated the HAN was the reduction in oral intake as a result of underlying disease; followed by neurological dysphagia and cancer (fig. 1).

The majority, 181 patients (76.4%), were sent to our unit from other services of the hospital system, whereas 52 (21.9%) came from their attending physician.

With regard to the functional situation of the patients, almost half had considerable impairment (bed-ridden or life bed-armchair), and only a few had mild or no impairment (fig. 2).

In our sample, 151 patients (63.7%) needed a caregiver for the basic activities of daily life, and 13 (5.5%) were institutionalized. In addition 56 (23.6%) had decubitus ulcers initially.

The mean number of drugs was 4.6 (DE 2.5 drugs) and 121 patients (51.1%) received ≥ 4 drugs. 91 patients (38.4%) received medications that put them at nutritional risk, mainly antineoplasic therapies (radio or chemotherapy), digoxine or corticoids (fig. 3).

The median duration of HAN was 4 months (amplitude 0.5-29.5 months), both in patients with supplemental nutrition as well as in those with complete diet replacement. 43.9% (104 patients) of the patients fell into the group of HAN duration of less than 3 months. Only 22 patients (9.3%) continued with the therapy more than 1 year.

The median number of visits was 2 visits by patient (amplitude 1-10 visits). We compared the neurological and oncological patients with the others, but we did not find differences in number of visits according to pathology (p = 0.4 and p = 0.8 respectively).

In most cases, the frequency of visits and blood tests was ≤ 6 months (fig. 4).

We determined serum levels of visceral proteins in 157 patients (66.3%) initially and after 3, 6 and 12 months (fig. 4). Weight was measured in 63 patients (26.6%), with mean BMI of 23.4 kg/m² (DE 4.6 kg/m²).

According to the evaluation of the visceral compartment there was undernourishment in 74 cases (31.2%), whereas only 7 patients (2.8%) had a BMI of < 18.5 kg/m².

In 150 patients (63.3%) the HAN was withdrawn. The main causes were lack of follow-up, death and cli-
nical improvement of the patient (table I).
Total deaths until the 31st of July of 2007 were 78 (32.9%).

Type of HAN

HAN was used as a complete diet in 71 patients (30%) and as a supplement in 152 (64.1%). 52/71 patients with complete diets had neurological diseases and 17/71 had neoplastic diseases (mainly ORL neoplasias). With regard to the group of patients with supplemental nutrition, the percentage of neurological and oncological patients was 57.9%.

Polymeric formulas were used in 172 cases (72.6%) and the most-used administration route was the oral one, in 168 patients (70.9%), followed by nasogastric tube in 59 (24.9%) and by gastrostomy in 8 (3.4%).

Globally, high-energy diets predominated, and the mean caloric supply was 3,876 kJ (926 kcal) (DE 2063 kJ) (DE 493 kcal). In the supplemental nutrition group, high-energy diets were also the most common, with a mean of 2,850 kJ (681 kcal) (DE 941 kJ) (DE 225 kcal). Nevertheless, in patients with complete diets, standard diets predominated and the average energy supply was 6,484 kJ (1549 kcal) (DE 1,142 kJ) (DE 273 kcal) (table II).

Complications

The mean number of complications was 0.04 episodes/patient in the period studied. There were no complications of any kind in 153 patients (64.3%). Of the rest, 46 patients (19.3%) had gastrointestinal complications, principally constipation or diarrhoea, 13 (5.5%) had infectious ones and metabolic or mechanical ones were less frequent.

The group of patients with oral administration presented fewer complications in comparison with the other routes (26.7% versus 45.3%, p = 0.007).

69 patients (29.1%) required hospitalization (0.38 hospitalizations/patient), nevertheless only in 17 cases (7.2%) was the hospitalization caused by complications related to HAN (9 bronchoaspiration, 5 diarrhea, 2 severe constipation and 1 reflux and pain after a surgical gastrostomy).

Economic data

Mean monthly costs of HAN were 151.2 euros (DE 75.1 euros); 127 euros (DE 60 euros) for those with supplemental nutrition and 216.2 euros (DE 58.2 euros) for those with complete diets. When we included necessary materials for administration, monthly costs increased to 159.3 euros (DE 87.5 euros).

The average costs per 1,000 kcal of nutritional formula was 5.6 euros (DE 1.9 euros) greater in supplements than in complete diets (6.1 euros versus 4.6 euros, p < 0.0001). The median travel distance to procure nutritional formulas and materials at the hospital pharmacy was 26 km (amplitude 2-188 km).

Discussion

In the last few years HAN has increased greatly in use because of the improvement in enteral formulas and systems, which are now easier to learn and handle. This has been followed by a great increase in the number of domiciliary patients who are controlled by nutrition units, requiring the creation of effective supply and control networks.

The analysis of our sample showed a high mean age, perhaps because of progressive aging of the population and because many diseases that require HAN are more frequent in older people.

Regarding pre-existing diagnoses, neurological and neoplastic diseases were predominant, like in the latest Spanish,4 European6 and North American records.5

The main indications were a reduction of oral intake due to underlying disease in the patient, or the presence of neurological dysphagia or cancer.

Our results differ from a European study,4 in which dysphagia, both neurological and mechanical, represented 80.8% of indications, followed by oral failure (not due to dysphagia or digestive problems) in 14.4%. This study included data from a wide variety of different countries.

Differences between our results and the ones from the European study may exist because some centers in the European study were specialized and not representative of the whole population. In addition medical practice is very different between countries, especially in reference to the use of HAN in cancer patients, the financing of nutritional supplements or the role of primary care in this therapy.

Two thirds of our patients needed a caregiver for basic daily activities, about half of them had an important functional impairment and almost 25% had pressure ulcers. These data are similar to those of the latest national records, in which the percentage of impaired patients (bedridden or bed-armchair) had increased to almost 50%.5,8-10

Polypharmacy and treatments that put patients at nutritional risk were frequent in our sample, with a mean number of medicines somewhat higher than in other studies.11

Table I

<table>
<thead>
<tr>
<th>Cause of suspension</th>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Withdrawal of the follow up</td>
<td>68</td>
<td>45.3%</td>
</tr>
<tr>
<td>Death</td>
<td>45</td>
<td>30%</td>
</tr>
<tr>
<td>Improvement</td>
<td>27</td>
<td>18%</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>7</td>
<td>4.6%</td>
</tr>
<tr>
<td>No data</td>
<td>3</td>
<td>2%</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
<td>100%</td>
</tr>
</tbody>
</table>
As in previous studies,\textsuperscript{1,11,12} only a small group of patients (9.3%) continued with HAN after a year. However, in the Spanish record of NADYA group 2006, \textgreater 50% of patients received HEN > 1 year. But this record excluded patients with a caloric supply \textgreater= 1,000 kcal, therefore increasing the percentage of chronic patients.

In our sample, the length of HAN was frequently short because many patients received supplemental nutrition after a surgical procedure or a hospital admission and the treatment was discontinued within a few months. Although the lack of follow-up may appear to be the main cause of termination of treatment, we think that in the majority of cases this is due to the resumption of sufficient natural oral intake after the resolution of the acute situation.

Unlike other European countries, the oral route was the most used, probably because of the differences in the financing of supplements and definition of enteral nutrition.\textsuperscript{6} Whereas some registries only include the administration by feeding tube or gastrostomy, others also include enteral diets by the oral route, when they constitute a certain percentage of calories of the total diet.

The frequency of gastrostomy was low in comparison with other records,\textsuperscript{7} partly because many relatives in our area still reject this technique. Probably the percentage would increase in our sample if we only included the patients with complete diets, or if we included more institutionalized patients.

The analysis of complications showed a low frequency of episodes (0.04 episodes/patient). The administration route is a determining factor, with the oral one being the safest. As in other publications, the most frequent complications were gastrointestinal (constipation and diarrhea) and infectious and few patients needed hospitalization. Therefore, HAN seems to be a safe therapy, with few complications, which are frequently mild.\textsuperscript{13}

With regard to the costs associated with HAN, although the total cost of a complete diet was higher than supplemental nutrition, supplemental nutrition was more expensive when we calculated costs per each 1,000 kcal of nutritional formula.

The economic study included the calculation of the distance between the patient’s address and the hospital pharmacy, because the greater the distance, the more likely it is to be an economic burden to the families.

In order to resolve this situation, in our community we have considered a project that brings nutrition supplies to health centers and residences, mainly for chronic patients.

One weakness of our study is the lack of data to evaluate the nutritional status in many patients, due to their frequent functional impairment. We could not collect weight and BMI data in some patients because they were unable to come to our unit or stand up.

Nevertheless, although we could not record weight, we almost always recorded a descriptive evaluation of weight status made by trained staff.

Another limitation was the inability to calculate the incidence of HAN in our area, because we could not include the institutionalized population in residences and the patients of the nutrition unit of the other hospital in the area, which is responsible for most of the oncological patients.

One of the strengths of this study is that, unlike the voluntary registries, we offer more representative data of the entire HAN population.

Our results may be different in comparison with other areas, because the situation varies between hospitals. For example, we have a great diversity of enteral diets and supplements, and a higher number of patients with supplements than in other nutrition units. But, although our data is specific to our region, we have included more of our patients and thus are likely to be accurately reflecting the population characteristics.

Furthermore, the inclusion of economic data in our study provides novel information and offers a more complete view of this treatment.

HAN is a relatively expensive therapy whose objective is not always to improve nutritional status, but rather the quality of life, while trying to avoid complications caused by the nutritional support.

Given the high percentage of deaths in the sample, one of our questions is: have we made a suitable selection of the patients?

In the last few years, there are studies that indicate that, in certain cases, HAN does not improve and even has a negative effect on the patient’s and caregiver’s quality of life.\textsuperscript{14} In the case of patients with dementia, nutritional support has not been demonstrated to
improve either the rate of survival or recovery. In terminal patients, diverse authors maintain that the administration of feeding and fluids beyond the patients’ requests is not beneficial. For this reason, individualized selection of patients is needed in order to design more suitable interventions and to revaluate periodically the need for HAN.

In conclusion, HAN is a continuously evolving technique that requires a greater knowledge and a better preparation of the unit responsible for prescription and control, in order to optimize its benefits.

Our future proposal to contribute to the development of HAN in our area must include:

1. To improve the selection of the patients: individualizing the indications according to the situation of the patient and considering ethical and educational aspects.
2. To make nutrition supplies available to the patients closer to home, especially for chronic and stable patients. This would not be beneficial in the case of oncological patients with active treatment, where it is preferable that they periodically go to the hospital for revisions and adjustments of their nutritional therapy, coinciding with their visits for antineoplastic treatment.
3. To adapt the follow-up to the pathology: increasing the frequency of visits in oncological patients when they need it or reducing the frequency in chronic or institutionalized patients, increasing the role of primary care in their follow-up.

References