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ORIGINAL ARTICLE

Adult Home Parenteral Nutrition: a clinical evaluation after a 3-year experience in a Southern European centre

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Aim: To evaluate the current use of Home Parenteral Nutrition (HPN) in a Southern European region.
Subjects and methods: A total of 159 (86 m, 73 f) HPN patients, mean age 60.1±14.2 years, BMI 18.8±3.3 kg/m^2, consecutively referred to the Artificial Nutrition outpatient Unit of the Federico II University Hospital in Naples (Italy), from January 2000 to December 2002 and treated for at least 4 weeks. Retrospective evaluation of baseline disease, indications and duration of HPN treatment, type of venous access, complications.
Results: In all, 140 (88%) were cancer and 19 (12%) noncancer patients. Main indications were carcinosis in 68 for total, and hypophagia/dysphagia in 62 patients for partial/integrative (to oral-enteral nutrition) HPN; mean duration of HPN was 81.45±110.86 days of treatment and infection rate 2.89‰ in the whole population and 2.66‰ in the 36 patients treated for more than 3 months. No other major complications have been observed.
Conclusion: HPN is confirmed to be a safe and effective treatment when prescribed and administered by a trained team.
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Keywords: Home Parenteral Nutrition (HPN); indications; complications; safety

Introduction

Nowadays, total or partial/integrative Home Parenteral Nutrition (HPN) is an established treatment in patients presenting severe, definitive or transient, gut failure secondary to malignant or nonmalignant diseases.

HPN may reduce health care costs related to these patients' management, and allows improvement in their quality of life. Nevertheless, increased use in clinical practice has led to controversies on the clinical indications, management, costs, also for the ethical implications involved (Mac Fie, 1996; Howard and Hassan, 1998; Contaldo and Pasanisi, 2001; Balzola *et al*., 2002; Planas and Camilo, 2002; SINPE Executive Committee, 2002a).

HPN patients' outcome is in fact the result of several factors such as underlying disease, general clinical conditions, level of health care professionals, family and social support, education, facilities, etc. (Bozzetti, 2003).

One of the main concerns is its fluctuating identification as treatment or just basic care, in particular for individuals with intractable malignant disease whose survival may depend mostly on nutritional support (August *et al*., 1991; Buchman, 2002). It is clear from the available literature on national registries that HPN in some countries is currently prescribed in terminal cancer patients while this is not the rule in others (Mughal and Irving, 1986; Howard *et al*., 1991, 1995; Van Gossum *et al*., 1996, 1999). Furthermore, the appropriateness of indications remains a clinical challenge to improve its application, besides other already referred factors, such as local economic, social and cultural influences.

The aim of this study was to evaluate, mostly in clinical terms, the current use of HPN in a Southern European region, with particular reference to safety and indications.

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Subjects and methods

A total of 159 (86 m, 73 f) adult patients consecutively referred from in- or outpatient oncology, neurology or surgery units to the outpatient Clinical Nutrition Unit for Home Parenteral Nutrition of the Federico II University Hospital in Naples, Italy, from January 2000 to December 2002 and treated for more than 4 weeks, have been recruited for the study.

Indications to PN were classified according to ASPEN and SINPE guidelines (SINPE Executive Committee, 2002a; ASPEN Board of Directors and the Clinical Guidelines Task Force, 2002).

Before starting HPN all patients and/or their relatives were carefully informed on the procedures for HPN, gave their informed written consensus and participated at an individual training course, held in the hospital and including written instructions, for CVC handling. Parenteral Nutrition (PN), given as all in one galenic personalized or prepacked industrial preparations, has been mostly furnished by the Artificial Nutrition laboratory of the Hospital and in a minority of cases by the Pharmacy of the local Health Districts of the patient. Safety was evaluated recording the rate of mechanical, metabolic and in particular infectious complications.

HPN was withdrawn because of death in the largest number of the cancer patients, or after conversion to enteral/oral nutrition in neurological and in other nononcological patients.

Peripheral vein HPN has been prescribed in 18 patients, as partial integrative PN: these patients were excluded from the evaluation of the risk of CVC infections.

All patients were classified according to age, underlying disease, Karnofsky Index (KI), indication for HPN, type of venous access, complications, duration of HPN, and need for home care through the National Health Service. In detail, KI is a graded scale at 10 as intervals, with a score 0–100 with intervals of 10, used to evaluate a patient's autonomy to work and to self care. These abilities are assessed by using a standard questionnaire filled in by patients or their caregivers and then verified by the clinician. KI score $\leqslant 40$ indicates patients requiring constant assistance and medical care.

Data were presented as mean $\pm$ s.d., minimal and maximal values; when possible they were compared with the national HPN registry.

Results

The whole patient population had a mean age of 60.1 ± 14.2 years (min 21, max 93; median value: 63), initial BMI $18.8 \pm 3.3\,kg/m^2$ (min 12.5, max 28.7; median value: 18) and KI between 30 and 80 (median value: 50). When divided in the different KI scores, 64 patients (40.2%) had KI $\leqslant 40$, 69 (43.4%) had 50, 19 (11.9%) had 60, 6 (3.7%) had 70, 1 (0.6%) had 80.

In all, 140 (88%) were cancer patients and 19 (12%) were affected by non-neoplastic disease; in the former, the affected organ/system was esophageal–gastric in 56, gut in 25, pancreas and biliary tract in 12, ovaries and/or uterus in 20, head and/or neck in 14, other sites in 13 (Table 1). To make a local comparison the data presented in the table refer also to those available from the Italian HPN registry (De Francesco *et al*., 1995). It is worth noting that the higher proportion of uterine and ovarian cancer with peritoneal involvement in our population in comparison with the national data. Non-neoplastic diseases were short bowel syndrome (SBS) in nine patients, vascular and nonvascular cerebral disease in five; other conditions in five. The main indications for total and partial/integrative HPN are reported in Table 2 (and compared with those of the Italian registry): there were 67 carcinosis, 61 dysphagia/hypophagia, 21 malabsorption/SBS, three high output enteric fistulas, and others in seven; with a higher frequency of indications for SBS and malabsorption and no indication for bowel rest as

Table 1 Neoplastic location in patients on HPN: data from the national SINPE registry vs the local registry

Neoplastic location	*Study population Pts. 2000/2002*	*SINPE registry Pts. 2000/2001*
	n (%)	n (%)
Esophageal–gastric system	56 (40)	353 (32)
Gut	25 (17.8)	243 (22)
Head–neck	14 (10)	209 (19)
Pancreas	12 (8.5)	66 (6)
Uterus–ovaries	20 (14.3)	44 (4)
Other	13 (9.4)	188 (17)
Total	140 (100)	1103 (100)

SINPE: Società Italiana di Nutrizione Parenterale ed Enterale (Italian Society of Parenteral and Enteral Nutrition).

Table 2 Indications for HPN: data from the national SINPE registry vs local registry

Type of HPN	*Study population Pts. 2000/2002*	*SINPE registry Pts. 2000/2001*
	n (%)	n (%)
Total		
Neoplastic occlusion/subocclusion	67 (42.2)	375 (34)
Bowel rest	—	33 (3)
Malabsorption/SBS	21 (13.2)	77 (7)
Fistulas	3 (1.9)	33 (3)
Other	7 (4.4)	188 (17)
Partial		
Dysphagia/hypophagia	61 (38.3)	397 (36)
Total	159 (100)	1103 (100)

SINPE: Società Italiana di Nutrizione Parenterale ed Enterale (Italian Society of Parenteral and Enteral Nutrition).

compared to national data. PN was delivered by implanted central venous catheters in 105 patients (74 port-a-cath, 31 tunnelled). Certofix CVC was used in 36 and peripheral vein catheters in 18. Mean duration of HPN (through pheripheral and central vein) was 81.5 ± 110.9 days of treatment, min: 28, max: 1050 (SINPE registry 63.5 days; min: 3, max: 534) corresponding to 13 226 days of treatment. It was delivered in 36 patients (22.6%) for more than 3 months.

HPN complications consisted only of CVC infections: 32 in 24 patients (18 of whom neoplastic), that is, 15% of the whole population of 159 patients, corresponding to 11 069 days of treatment performed through CVC: the infection rate resulted of 2.89‰ days of treatment. If we consider only those treated for more than three months, that is, 36 patients for 7496 days of treatment, we found 20 infections in 13 patients with an infection rate of 2.66‰. The infection rate for patients treated for less than 3 months was 3.35‰.

Removal of totally implanted CVC, requiring a short hospital stay, was necessary in eight patients. In all other cases home care with systemic and lock antibiotic therapy was successful. No other hospitalization related to HPN was recorded whilst it was necessary for the underlying disease in 19 patients who required 30 hospitalizations for active chemotherapy or complications not related to PN. Home emergency treatment for PN support was never required or necessary.

Discussion

HPN is known to play a key role for survival in non-neoplastic gut failure and in palliative care for terminal cancer patients. Nevertheless HPN still remains, in some circumstances, a questionable therapy especially for terminal cancer patients (Bozzetti *et al*., 1996; Faisinger and Gramlich, 1997; Contaldo and Pasanisi, 2001). In fact survival in starved cancer patients is expected to be 4–6 weeks (Bozzetti, 2003) and for these reasons PN support is suggested when life expectancy is of at least 1–2 months. The Italian Society of Parenteral and Enteral Nutrition has provided a set of recommendations (SINPE Executive Committee, 2002b) but unfortunately they have not produced specific national regulations. On the other hand, the SINPE national HPN registry collects a large number of patients under this treatment thus representing an useful national referral (SINPE Executive Committee, 2002a, b).

In clinical practice, SINPE (Italian Society of Parenteral and Enteral Nutrition) and other National Scientific Society guidelines are considered only suggestions but not strong referral criteria. As a matter of fact, many advanced terminal cancer patients, already on parenteral therapy based on hydration and other types of support (CHO, lipids and proteins given in separate bottles) are referred to our Clinical Nutrition team. In these circumstances our policy is to rationalize the intervention without any drastic interruption of the therapy. We excluded patients surviving <4 weeks because in these patients there is no a definite agreement for Artificial Nutrition. However, in our patients treated for <4 weeks, HPN was provided only as compassionate therapy and mostly for hydrating, more than full PN therapy. HPN registries available from various countries as well as international reports display a quite large difference in terms of patient selection (Mughal and Irving, 1986; Howard *et al*., 1991, 1995; De Francesco *et al*., 1995; Takagi *et al*., 1995; Bozzetti *et al*., 1996; Van Gossum *et al*., 1996, 1999; Faisinger and Gramlich, 1997; Guidelines for the use of parenteral and enteral nutrition in adult and pediatric patients, 2002; SINPE Executive Committee, 2002b). In particular, cancer cases may represent the largest percentage of HPN patients in some (for example 57% in Italy or 60% in The Netherlands) and the lowest in other countries, that is, 8% in Denmark and 5% in the United Kingdom.

Indications to PN are reported in Table 2; their frequencies did not differ from those reported in the Italian National Registry. In our sample, only five patients were affected by vascular and not vascular neurological disease with secondary severe dysphagia and short life expectancy: as they already had an implanted catheter, they were given Parenteral instead of Enteral Nutrition, although not appropriately.

Here, we describe our 3 years experience (patients recruited from January 2000 to December 2002) with HPN in the Naples district. Our center covers a large part of HPN in the Campania region and in particular in the whole Naples district. The sample studied refers to a 3-year follow-up experience of a Clinical Nutrition Centre covering a geographical area with a population of more than 3.0 million people.

Many patients have been referred from Oncology units, already with an implanted port-a-cath catheter. That is why, a port-a-cath was used, instead of other catheters.

Based on our experience HPN request regards mostly terminal cancer patients, representing the highest percentage of HPN patients since now described in the literature, and it is often considered a palliative type of medical intervention. Nevertheless in these difficult clinical circumstances HPN appears to be a reasonable safe intervention, provided that it is followed by a trained team (Santarpia *et al*., 2002).

Extensive data on HPN in Europe and Italy have been already published but, in both circumstances, data specifically referring to Southern Italy, even in the Italian National Survey, are scant. This paper describes a quite large number of patients on HPN, coming from a large health district in Southern Italy, giving additional information that we consider of some interest. In our view, specific of the study are the large number of cancer patients under treatment, evidence of the safety of this nutritional procedure, provided that the team has reached good experience, the necessity/urgency of an earlier referral to a specialized team.

Actually the rate of complications and hospitalizations due to PN is reasonably low and caused only by CVC infection,

eventually CVC removal if necessary. Moreover, there were no specific requests by the patients and families for home care support.

On the other hand, some major concern regards the indications for HPN. In our experience patients are still referred late to the Clinical Nutrition Team. This delay in referring terminal cancer patients seems also to be the main reason for the lack of proper indications found in a subgroup of patients, that is, those with dysphagia/hypophagia, and treated with partial/integrative PN despite total enteral nutrition should be the rule. In these patients, at this terminal stage of the disease, we prefer to use an already available central venous access rather than to add another tube for enteral nutrition. It is appropriate to remember that in terminal cancer patients HPN has been always associated with all other palliative treatments (pain therapy, etc.) if necessary and not yet prescribed.

In conclusion, our experience in a Southern European region supports the view that HPN represents, also in difficult clinical conditions such as terminal cancer patients, a safe and effective therapeutic procedure if provided by an experienced Clinical Nutrition Team. At least in our area referral for Home Artificial Nutrition, even for palliative – the most frequent – indication, should be more timely, thus increasing the prescription of enteral nutrition.

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