

PROTOCOL

Title: Home Parenteral Nutrition and Cancer -
Selection Criteria for Patients with Advanced Cancer

Date Approved: October, 2002

Approved By: Clinical Practice Guidelines Committee

PURPOSE:

Provide selection criteria for referral of oncology patients for home parenteral nutrition. (see appendix 1, background information: home parenteral nutrition & cancer).

GENERAL INFORMATION:

NB: Prior to any referral being assessed for HTPN, the attending physician will be requested to review the following criteria as well as the “ Home Parenteral Nutrition and Cancer” document provided. If after review the physician wishes to pursue this course of treatment each patient will be considered on an individual basis

The HPN team reserves the option to call an interdisciplinary patient conference (including palliative care and oncology) to discuss the viability and appropriateness of proposed treatment. This may or may not include the patient and / or family members.

There is often an emotional nature, which surrounds the provision of nutrition (food) as opposed to basic hydration and other comfort measures. Due to this factor it is advisable that patients and families not be given any information that would lead them to believe they will be accepted on the program until the HPN team completes it's full assessment.

SELECTION CRITERIA**A. MEDICAL STABILITY**

Before a patient is discharged from hospital or enrolled in the Home Parenteral Nutrition (HPN) Program, their medical condition must be stabilized. This includes the following criteria:

1. The patient should have a clearly defined nutritional diagnosis in the setting of an oncology diagnosis that would benefit from the use of HPN i.e. obstructing tumor, short bowel. This would include non-treatable cancer, a non-functional gastrointestinal tract, a life expectancy in the order of months and a high quality of life.
2. If the patient has any additional problems, these should be manageable at home or in an outpatient setting with the full support of the appropriate outpatient program.

B. MEDICAL STABILITY...continued

3. Duration of treatment is expected to be at least 6 weeks. Any shorter time frame will be considered on an individual basis.
4. The patient is physically functional enough to be cared for at home, reflected by a Karnofsky score of >50. There is a family member/significant other who is willing and able to assist in care.
5. The patient can be easily monitored (i.e. Physician follow-ups, bloodwork, venous access site, etc.).

C. VENOUS ACCESS

A central venous catheter is necessary for ease of administration. This catheter must be one of the following – long-term tunneled catheter (i.e. Broviac), peripherally inserted central catheter (PICC) which requires 2 people to manage or implanted port (least preferred).

D. PSYCHOSOCIAL CONSIDERATIONS

1. The patient, a family member or significant other must be cognitively and psychologically capable of administering TPN at home.
2. There must be adequate family and community support for less functional individuals.
3. The home environment is safe, clean, and free of hazards.

E. COMPLIANCE

The patient, a family member or significant other must be willing to comply with the prescribed HPN procedure and follow-up blood work and clinic visits.

F. ABILITY TO LEARN

Patients and families should be aware that teaching all concepts and skills necessary to manage HPN will take a minimum of 3 days to complete. It is important to consider that this process may add unwelcome stress to an already difficult situation. The patient, a family member or significant other must be able to comprehend and reasonably manage:

1. Aseptic technique.
2. Central line maintenance.
3. Instructions regarding HPN.
4. Potential complications.
5. Who/where to call in case of emergency. The patient must have access to a telephone and transportation in case there is a need for an emergency visit to the hospital.

EXCLUSION CRITERIA

Factors that would exclude a patient from participating in the HPN program include:

1. Medical instability.
2. Patient is physically or cognitively impaired and no one else is available to be trained for HPN administration.
3. Home environment prohibits proper treatment (i.e. Lack of running water, electricity, refrigeration, or unclean surrounding).
4. Patient is able to tolerate enteral feeds.

APPENDIX 1

Background Information: Home Parenteral Nutrition and Cancer

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Home parenteral nutrition (HPN) is a life-saving therapy whereby patients with intestinal disorders in whom malnutrition would otherwise lead to death experience increased length of survival and quality of life (1). Although the benefits of HPN have been established for patients with stable intestinal disorders such as Crohn's disease, the benefits of HPN for patients with malignant disease are less clear. HPN does however, appear to offer certain oncology patients increased quality of life and/or increased survival (1). Logically, oncology patients most likely to benefit from HPN would be those with malnutrition due to gastrointestinal obstructive symptoms where mortality is influenced more by malnutrition than disease burden. For oncology patients with malnutrition due to cancer-anorexia or cachexia, disease burden may influence mortality more than malnutrition, rendering them less likely to benefit from HPN. Thus, it is crucial to identify which oncology patients would benefit from HPN over other less invasive forms of supportive care.

There is little published data regarding the prevalence and provision of HPN in Canada. However, a review of the first HPN program in existence in Canada at the Toronto General Hospital during the early 1980's showed that active malignancy was a relative exclusion criterion for admittance to the HPN program (2). More recent experience in Alberta has shown that active malignancy is not necessarily a contraindication to HPN and that utilization of HPN in oncology patients is on the rise (3). In the USA and parts of Europe, the oncology population is the largest growing component of existing HPN programs, comprising up to 40% of the new HPN admissions per year (4,5). Within Europe, the prevalence of oncology patients on HPN varies widely between countries: 0% in Poland; 67% in Italy (6). Observed inter-country variations have been attributed to differences in cultural, ethical, social and economic approaches to the provision of HPN to oncology patients, combined with a lack of scientific basis or literature (7). There is an inherent ethical difficulty in conducting prospective, randomized, comparative clinical trials of oncology patients treated with or without HPN.

A search for the years 1980-2001 affirmed the lack of existing scientific literature exploring the use of HPN in oncology patients. No clinical trials targeted to HPN in the oncology patient were found. However, case reports (8-12); HPN population surveys, the bulk of which were retrospective (7,13-18) versus prospective (19,20); reviews (21-24); a committee report (25) and practice guidelines (26) that make specific reference to HPN in oncology patients have been published. The general consensus of the literature is that:

- (a) Patients need not die of malnutrition, even if they have a terminal disease (23).
- (b) While each patient needs to be assessed individually, HPN should be reserved for patients in whom malignancy is incurable (21,22), the gastrointestinal tract is unusable (8,13,19,21,22,25,26), survival is expected to exceed months (7-9,16,19,25) and a high quality of life exists (4,7,9-12,16,17,20).

Some authors suggest that the criteria for the provision of HPN in oncology patients be equivalent to the criteria of other, non-oncology HPN candidates (13,21).

A non-functional gastrointestinal tract, not amenable to surgical or other treatment is likely the key factor determining appropriateness for HPN whether for oncology or non-oncology patients. Malnutrition in oncology patients resulting from a non-useable gastrointestinal tract must be differentiated from that resulting from anorexia or cancer cachexia (8). Anorexia-induced malnutrition secondary to cancer may be amenable to improved oral or enteral nutritional intake rather than parenteral nutrition support. Cachexia of cancer, on the other hand, even in the face of a functional gastrointestinal tract, is unlikely to respond significantly to any form of nutrition support (8).

Anticipated length of survival for oncology patients should be in the order of months to be considered for HPN. This differentiates those patients in whom death from cancer is imminent from those in whom death from malnutrition or starvation will occur (range of 60-70 days) long before death from the malignancy itself (7,9,19,25). Thus, for oncology patients otherwise destined to die from malnutrition, significant improvements in length of survival can be made (8,10,21). Oncology patients destined to succumb to their malignancy within a time frame of less than months may benefit as much from hydration therapy and symptom/pain management as from HPN (9,16,19,25). The imposition of a highly invasive, highly technical system of support such as HPN on an already stressed patient/family must also be weighed within the context of expected length of survival (12,14,19,25).

Quality of life (QOL) is a difficult measure to quantify. Few attempts have been made to measure the effect of HPN on quality of life of oncology patients (24). The subjective nature of QOL, the use of retrospective data and the variety of QOL assessment tools used make inter-study comparisons difficult (24). Improved (7,10,12,15,16,19), static (7,18,19) and decreased (18,19) QOL for oncology patients on HPN have been reported. Those patients with a pre-existing high level of QOL reap greater benefits from HPN than those whose initial QOL is poor (7,10). QOL was maintained or improved by HPN more often in oncology patients with a survival exceeding months compared to those with a shorter survival period (7,19). However, even failures of HPN to improve QOL in oncology patients as assessed by health care providers contradicted perceived improvements in QOL reported by patients and their families regardless of survival or pre-existing QOL (19).

In general, patients and their families perceived an improvement in QOL whether or not a measurable improvement existed (8,9,12,16,17,19). The ethics of providing HPN to oncology patients must take into account both the patient/family's perceptions of a meaningful QOL and the effect such a highly technical therapy has on QOL (10-12,14,17,19,27).

The cost-effectiveness of HPN in malignancy has also yet to be adequately addressed. A recent review of HPN practices noted a particular lack of economic appraisal of HPN for patients with malignant disease (24). The authors suggested that an analysis of the cost per quality-adjusted life year of HPN (requiring repeated measures of QOL before, during and after HPN) was required in order to evaluate this issue (24).

Oncology patients present a unique population for inclusion into HPN support programs in Canada that has been previously relatively untapped. However, not all oncology patients are appropriate candidates for HPN. Criteria that select only those oncology patients most likely to benefit from HPN are crucial to ensure adequate resource utilization and patient/program success. Oncology patients with treatable malignancy or with short life expectancy (i.e. death by cancer vs. malnutrition) and/or poor quality of life does not generally benefit from HPN. On the contrary, those with untreatable malignancy, a non-functional gastrointestinal tract, a life expectancy in the order of months and a reasonable (perceived or measurable) QOL are likely to derive benefit from admission to an HPN program.

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