

Organisation, regulations, preparation and logistics of parenteral nutrition in hospitals and homes; the role of the nutrition support team – Guidelines on Parenteral Nutrition, Chapter 8

Organisation, Verordnung, Zubereitung und Logistik der parenteralen Ernährung im Krankenhaus und zu Hause; die Rolle von Ernährungsteams – Leitlinie Parenterale Ernährung, Kapitel 8

Abstract

PN (parenteral nutrition) should be standardised to ensure quality and to reduce complications, and it should be carried out in consultation with a specialised nutrition support team whenever possible. Interdisciplinary nutrition support teams should be established in all hospitals because effectiveness and efficiency in the implementation of PN are increased. The tasks of the team include improvements of quality of care as well as enhancing the benefit to cost ratio. Therapeutic decisions must be taken by attending physicians, who should collaborate with the nutrition support team. “All-in-One” bags are generally preferred for PN in hospitals and may be industrially manufactured, industrially manufactured with the necessity to add micronutrients, or be prepared “on-demand” within or outside the hospital according to a standardised or individual composition and under consideration of sterile and aseptic conditions. A standardised procedure should be established for introduction and advancement of enteral or oral nutrition. Home PN may be indicated if the expected duration of when PN exceeds 4 weeks. Home PN is a well established method for providing long-term PN, which should be indicated by the attending physician and be reviewed by the nutrition support team. The care of home PN patients should be standardised whenever possible. The indication for home PN should be regularly reviewed during the course of PN.

Keywords: nutrition support team, organisation of PN, compounding, multi-chamber bags, home parenteral nutrition

Zusammenfassung

Die parenterale Ernährung (PE) im Krankenhaus sollte standardisiert werden um die Qualität zu erhöhen und die Komplikationsraten zu reduzieren. PN sollte soweit möglich in Konsultation mit einem spezialisierten Ernährungsteam durchgeführt werden. Ein interdisziplinär arbeitendes Ernährungsteam sollte in allen Krankenhäusern etabliert werden, um die Effektivität und die Effizienz der Durchführung der Ernährungstherapie zu verbessern. Die Aufgaben des Teams sind vielseitig und beinhalten u.a. die Verbesserung der ernährungsmedizinischen Qualität sowie der Wirtschaftlichkeit. Die Indikation zu medizinischen Maßnahmen einschließlich der PE muss durch den behandelten Arzt gestellt werden und sollte unter Einbezug des Ernährungsteams erfolgen. „All-in-One“-Beutel werden generell für die PE im Krankenhaus bevorzugt und können entweder vollständig industriell hergestellt, industriell hergestellt mit der Notwendigkeit individueller Zugaben von Mikrosubstraten, oder innerhalb bzw. außerhalb des Krankenhauses nach

S. C. Bischoff¹

L. Kester²

R. Meier³

R. Radziwill⁴

D. Schwab⁵

P. Thul⁶

Working group for developing the guidelines for parenteral nutrition of The German Association for Nutritional Medicine

1 Dept. Nutritional Medicine and Prevention, University Stuttgart-Hohenheim, Germany

2 Dept. of Gastroenterology, Hepatology and Endocrinology, Medical University of Hannover, Germany

3 Dept. of Gastroenterology, Hepatology and Nutrition, University of Basel, Switzerland

4 Pharmacy und Patient Advice Centre, Clinic Fulda, Germany

5 Dept. Medicine II, Martha-Maria Hospital, Nuremberg, Germany

6 Dept. of General, Visceral, Vascular and Thorax Surgery, Humboldt University of Berlin, Germany

standardisierter bzw. individueller Rezeptur „on demand“ unter Berücksichtigung von sterilen und aseptischen Bedingungen zubereitet werden. Im Laufe einer PE sollte generell ein enteraler oder oraler Kostaufbau nach standardisiertem Schema angestrebt werden. Eine Indikation für eine Heim-PE kann gestellt werden wenn eine PE-Dauer von mindestens vier Wochen erwartet wird. Heim-PE ist ein medizinisch etabliertes Verfahren zur langfristigen PE, die durch den behandelnden Arzt indiziert wird und durch ein Ernährungsteam begleitet werden sollte. Die Betreuung des heimparenteralen Patienten sollte möglichst standardisiert erfolgen. Die Indikation zur Heim-PE ist im Verlauf regelmäßig zu überprüfen.

Schlüsselwörter: Ernährungsteam, individuelle Rezeptur, Compounding, Mehrkammerbeutel, heimparenterale Ernährung

Nutrition support team

Organisation of parenteral nutrition in hospitals

- PN in hospitals should be standardised and carried out in consultation with a specialised nutrition support team whenever possible (C).
- Nutrition support teams should be established in hospitals, because effectiveness and efficiency in the implementation of PN are increased (A).
- The nutrition support team should work in close consultation with the medical and nursing staff (C).

Commentary

The practical implementation of artificial nutrition often does not correspond with current scientific evidence, mainly due to a lack of specialist knowledge and insufficient organisation. This particularly applies to the intensive care sector where nutrition support is often required [1]. Less than 5% of hospitals in Germany have established nutrition support teams, which is a far lower rate than in some other European countries such as the UK [2], [3]. The impact of nutrition support teams has been evaluated in various studies. With nutrition support teams, patients' energy requirements are more likely to be met and mechanical as well as metabolic complications of nutritional therapy are reduced [4], [5], [6], [7], [8], [9]. The authors of a meta-analysis of all studies published between 1970 and 1993 [10] concluded that nutrition support teams reduce the rate of catheter sepsis and metabolic complications, improve documentation, and probably also lower costs, although the personnel costs of the team were not taken into consideration in all studies. The economic benefits of setting up a nutrition support team, and even of only a dedicated nutrition nurse, have been extensively documented [11], [12], [13], [14]. Standardisation of product selection and of prescribing can result in significant savings [15].

If it is not possible to establish a nutrition support team, then at least a physician dedicated to nutrition support

should be available, with support by other staff such as nursing staff and dieticians, wherever possible.

Establishing a nutrition support team

- A nutrition support team should be established in all hospitals and should include physicians, nurses and dieticians and/or nutritionists trained in clinical nutrition; pharmacists, technical assistants and administrative assistants should also be available if possible (C).
- The appropriate size of the team depends on the size of the hospital, the scope of the hospital, the number of patients cared for, the budget and other activities of the team (C).
- The tasks of the team include reviewing the indications for PN, documenting the patient's nutritional state and metabolic situation both at the beginning and during PN, developing and adapting the PN composition or selecting the commercially available bags as well as monitoring sterility, compatibility and stability of the nutrition bag. The team should also be involved in helping to identify when PN is no longer required, in collaboration with the attending physician, in planning the introduction and advancement of enteral or oral nutrition, and in helping organising home PN when necessary. The team should pay particular attention to implementing PN according to current scientific knowledge and guidelines. The tasks of the team also include training personnel, patients and their relatives (C).

Commentary

The nutrition support team should advise the ward on the choice of standard or individual PN solutions, how they should be prepared in individual cases, which hygiene and compatibility aspects must be observed, how PN should be administered (e.g. selection of access, tubes, pumps) and how possible complications may be prevented (cf. chapter "Access technique and its problems in parenteral nutrition" <http://www.egms.de/en/gms/2009-7/000078.shtml>). The monitoring of PN comprises laboratory, clinical and anthropometrical

parameters (cf. chapter "Complications and monitoring" <http://www.egms.de/en/gms/2009-7/000074.shtml>). The team's task is to improve the medical quality and at the same time optimise the benefit to cost ratio of this expensive form of nutrition. This can be achieved by monitoring indication and composition of PN, by providing suitable quantities and selection of substrates, as well as suggesting alternatives as appropriate.

Indication for PN

- Therapeutic decisions, including those on using PN, must be taken by the attending physicians. The nutrition support team should be involved in decisions on PN (C).

Commentary

Legal regulations indicate the physician's responsibility for decisions on PN, whereas the role of the nutrition support team is based on expert opinion because there is no published data. Involving a nutrition support team's expertise can provide benefits, e.g. if it results in an increase in efficacy of PN [1], [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15].

Preparation of PN solutions

- "All-in-One" bags are generally preferred for PN in hospitals (B).
- "All-in-One" bags may be industrially manufactured, industrially manufactured with the necessity to add micronutrients, or be prepared "on-demand" within or outside the hospital according to a standardised or individual composition. There is no general preference for any one of these three concepts (C). Industrially manufactured multi-chamber bags may be more economical than the preparation of a bag in hospital, if one considers the added personnel cost for the later choice (B).
- In hospitals PN bags should be prepared at the hospital pharmacy under sterile conditions according to agreed quality assurance guidelines (B).
- Additions of micronutrients or other components to PN bags must be performed under aseptic conditions, and they should preferably be added under a Lamina Airflow according to good manufacturing practice (GMP) standards (C).

Commentary

Providing PN from multiple bottles should be avoided because it is often more expensive than the multi-chamber bag and it carries a higher risk for error [16], [17]. The choice between commercial multi-chamber bags and individually prepared PN bags depends on the type and structural conditions of the hospital as well as patient needs. Individual PN compositions are usually preferred

for long-term and home PN, as well as for a number of paediatric patients [18].

Prerequisites for preparing individually composed PN solution include the need for a sterile workplace, regular microbiological checks, and monitoring of compatibility and stability [19], [20]. Further details are laid down in guidelines of the Federal Chamber of Pharmacists [21]. In Germany PN solutions used in hospitals must be prepared under the responsibility of a pharmacist [22]. Manufacture is defined in the German Drug Law: manufacture is the extraction, production, preparation, processing, working, filling, packing and labelling of drugs which includes PN [22]. Manufacturing permits, know-how and authorisation with exceptions particularly regarding the pharmacy are regulated in the German Drug Law. PN can only be manufactured in pharmacies and without a special license. The preparation of nutrition bags for immediate use (within no more than 24 h) may be carried out by a physician or assistant staff.

The nutrition support team should advise the pharmacy on the completion of its tasks, since otherwise recommendations are not met to a satisfactory extent [23], [24].

Sterility of PN bags aseptically prepared in the hospital pharmacy may be guaranteed for up to 7 days at room temperature [25]. However, this expert group recommends that such solutions should be used within 24 h after preparation if stored at room temperature, or within 7 days if stored at 4 °C. This recommendation is based on the known risk of microbiological contamination and physicochemical changes, which are expected to increase with storage time. Industrially-manufactured multi-chamber bags can be stored for periods of months to years as specified by the manufacturer. Attention should be paid to the preparation of the multi-chamber bag for use, since the stability of added components such as vitamins is limited and often does not exceed 24 h at room temperature [26].

In hospitals pumps should always be used for PN administration to ensure a controlled flow rate and to help prevent metabolic and osmotic complications.

Advancement of enteral and oral nutrition

- A standardised schedule should be established for introduction and advancement of enteral or oral nutrition (C).
- Individual advancement of enteral and oral nutrition may be necessary in patients with gastroenterological diseases such as pancreatitis, Crohn's disease, Colitis Ulcerosa, hepatic cirrhosis, or after long-term PN for more than 14 days (C).
- The advancement of oral nutrition results in a progressive supply of both macro- and micronutrients (C).

Commentary

Some studies have associated PN with altered morphology and intestinal function, for example with reduced mucosa thickness, a reduced number of villi in the small intestine and increased intestinal permeability [27], [28], [29], [30], while other trials do not show such alterations [31], [32]. If such effects occur, they depend on the duration of PN and are usually reversible.

In general a standardised advancement of enteral and oral nutrition is recommended after PN, because clinical practice has shown that incompatibilities may occur, particularly in the adaptation phase, regardless of whether enteral or oral nutrition. A standardised schedule should be established for the advancement of enteral and oral nutrition in the hospital. The speed of PN reduction depends on the tolerance of enteral or oral nutrition. Based on expert opinion, nutrition consultation during the phase of advancing enteral and oral nutrition is useful, particularly in patients who received PN for more than 14 days and in patients with gastroenterological disease. Advancement of enteral and oral nutrition must be adapted to the patient's tolerance, particularly in pancreatitis, where nutrition-related pain is well documented. Consideration should also be dedicated to the type and amount of protein given to patients with liver cirrhotic patients and imminent encephalopathy. Small meals and the use of medium chain triglycerides may be useful after gastrointestinal operations and in patients with dumping syndrome.

Supplying PN

Standardisation of procedures

- Standardisation of procedures for supplying PN is recommended to ensure quality and to reduce complications (B).

Commentary

Standardisation includes a clear process for defining PN indications, which is provided by the attending physician and preferably checked by a nutrition support team (or a physician dedicated to nutrition support). PN is only indicated when sufficient oral or enteral nutrition is not achievable. Criteria for the choice of central venous catheters (individual or tunnelled catheters or PORT systems) should be laid down. The choice of macro- and micronutrient intakes depends on energy requirements, the patient's metabolic situation, illness and other aspects of therapeutic strategies. Energy requirements can be estimated with the help of established formulas (i.e. Harris-Benedict formula). A limited number of products should be selected for PN, which can be decided on by the nutrition support team jointly with the drugs committee and the hospital pharmacy. If individually prescribed PN solutions are considered necessary the attending

physician and the nutrition support team, these should be prepared by trained personnel under the guidance of a pharmacist following standardised procedures under sterile conditions. The application of PN must be monitored and documented, for example by the nutrition support team. The roles of the nutrition support team contribute greatly to establishing standardised implementation of PN, because the team is involved in most steps and hence can take over main coordination tasks. Documented reductions of medical complications and of unnecessary costs by inadequate PN are arguably the result of the work of nutrition support teams [33], [34], [35], [36], [37], [38].

Cost aspects of PN

- The adequate calculation of PN costs in hospital requires internal accounting (C). Home PN is usually available on prescription and is financed by health insurance funds, although additional payments by the patient may be necessary.

Commentary

Hospital accounting is needed to secure funding for central hospital services such as PN services [39], [40], [41], and the multidisciplinary nutrition support team jointly with the hospital pharmacy should aim at being involved in the evaluation of cost aspects of PN. The nutrition support team should be funded by the health care funds and not by industrial sponsorship to avoid potential conflicts of interests.

Home PN

- Home PN is a well established method for providing long-term PN (A).
- Home PN is indicated if
 - (I) the patient cannot obtain adequate oral or enteral feeding
 - (II) there are no other reasons for not discharging the patient from hospital,
 - (III) home PN is expected to last for a period of at least 4 weeks,
 - (IV) the patient requests or is (presumably) in agreement with home PN, and
 - (V) it is expected that disease state or quality of life remains stable or is improved with home PN (C).
- The attending physician should decide on the indication for home PN, which should also be reviewed by the nutrition support team (B).
- The patient or its legal representative should receive extensive information on home PN and the need for providing a suitable catheter system (tunnelled central venous catheter or PORT). The nutrition support team should be involved in all aspects of comprehensive planning and organisation of home PN

- Home PN must be monitored considering complications (i.e. catheter complications, metabolic complications, organisational deficiencies) and success rate (i.e. improvement in nutritional status and quality of life); and the nutrient supply must be adapted if necessary, which can be done either by a dedicated nutrition support team or by an outpatient physician experienced in this area. The care of home PN patients should be standardised whenever possible. The indication for home PN should be regularly reviewed during the course of PN.

Commentary

Complication rates during home PN are generally low. The most frequently occurring complications are catheter sepsis (0.34 occurrences per year), catheter occlusions (0.071/year), catheter-associated central venous thromboses (0.027/year), fluid and electrolyte disturbances (0.12–0.61/year), liver and bile duct problems (0.42/year) and other metabolic complications (osteopeny, hyperglycaemia, hypertriglyceridemia etc.) [42], [43], [44]. According to a European study, catheter complications occur in approx. 0.25% of patients over the course of home PN, 50% of these complications being infections (equals 0.37/year) [45]. Comparable results have been reported for children [46]. Validated methods for reducing complications such as catheter infections or thrombosis have not been reported [42]. For patients with short bowel syndrome or other forms of intestinal failure, the only alternative to long term PN is intestinal transplantation, which is still associated with high rates of complication despite impressive progress in this area [47].

Home PN is carried out in tumour patients with peritoneal carcinosis or (sub)ileus, in patients with intestinal failure, such as short bowel due to Crohn's disease, after intestinal ischaemia with short gut infarction (e.g. superior mesenteric artery or venous thromboses), radioenteritis and in severe colonic motility disorders [42]. Tumour patients receiving home PN contribute a smaller number to the home PN population in some other countries (e.g. Denmark, UK) [48].

Many of the underlying principles for supplying PN also apply to home PN and depend on general or organ-related considerations (see appropriate chapters). Some additional aspects must be considered with home PN. For example, it is important to estimation the patient's prognosis and possible duration of home PN. Although there is no scientifically agreed lower limit of duration, a minimal duration of home PN of at least one month is consistently recommended. In adult patients the duration of home PN is usually shorter than one year, because patients either die (99% of tumour patients) or oral or enteral nutrition can be established [49], [50]. There is expert consensus that patients bound to die usually benefit do not from (home) PN, which should be checked even more critically in the case of home PN than in hospital where there is usually a defined therapy objective. This question

is difficult since definitions are imprecise and decisions often need to be taken on an individual basis, taking into account the (presumed) wishes of the patient and effects on quality of life, which should be given high priority. Home PN can positively influence in tumour patients if patients survive at least three months after commencing home PN [51]. However, quality of life of patients on home PN was lower than in patients without home PN, which may in part be due to a more severe underlying illness in patients who require home PN [52], [53]. The quality of life after small intestinal transplants is comparably higher in patients without rejection [54], [55].

Which catheter system is optimal for home PN remains controversial. Based on comparative studies we assume that tunnelled central venous catheter (i.e. Broviac® catheter) may present slight advantages over port systems with respect to infections and catheter sepsis [45], [56]. Conventional non-tunnelled central venous catheters should not be used outside the hospital [57]. The costs and particularly the long-term costs of consumables are significantly lower with the use of Broviac®-catheters than with implanted port systems, which require special needles for injection. Individual factors such as daily infusions or infusions with larger time intervals and cosmetic aspects should also to be considered selecting access catheters. Hence, the choice of catheter is influenced by many factors which have not been fully explored in comparative studies.

Preparation and organisation of Home PN is usually carried out prior to patient discharge from hospital and requires approx. 2–3 working days by the nutrition support team and other hospital departments. Tasks include:

- (I) review of indication,
- (II) detailed information, clarification and consent of patient and their relatives,
- (III) preparation of individual composition,
- (IV) authorisation of a qualified pharmacy, or a specialised home care company, for preparation of PN solutions, home delivery of the materials, and implementation of home PN, potentially in collaboration with a home care nursing service,
- (V) individual instruction of the patient and its relatives – depending on the wishes and degree of independence of the patient – by the nutrition support team or the home care service organisation.
- (VI) setting up a plan for monitoring, which may be implemented by a general practitioner and/or a specialised clinic.

These standards have generally been developed empirically, but have also been tried-and-tested in various practical settings [33], [58], [59]. There is no standard strategy to document complications and monitor home PN. We recommend controls of clinical and laboratory parameters every one to two weeks in the first three months, followed by monthly checks over the next three months, as recommended also in the Mayo Clinic schedule (cf. chapter "Complications and monitoring" <http://www.egms.de/en/gms/2009-7/000076.shtml>).

Assuring stability and compatibility of the PN solutions is extremely important in Home PN, because the bags are often delivered only once a week or so to the patient and then are stored in the refrigerator at 4 °C until utilised after hours of being warmed up to room temperature. The micronutrients (vitamins, trace elements) show a particularly limited storage time and should be added just prior to using the PN bag [60]. The electrolyte and mineral concentrations should be taken into consideration in bags containing lipids, because they may result in the emulsion breaking (i.e. a separation of lipid and water components) (cf. chapter "Practical handling of AIO admixtures" <http://www.egms.de/en/gms/2009-7/000077.shtml>) [61]. The stability should be checked with the manufacturer whenever the composition is modified.

The administration of home PN should be employed by specially trained carers, or in individual cases by the patient, if the patient requests this and has been appropriately trained [59]. It is important that measures associated with home PN are standardised by means of a suitable standard of care. The contents of these standards of care are usually established by empirical measures rather than hard scientific data, but they have been tried and tested and should form the basis of standard operating procedures until scientifically accountable guidance is available.

In conclusion, home PN is an area for which many standards have been established, but which have rarely been backed up by controlled, randomised trials. Thus, there is a great need for studies in this area which might contribute to improved quality of care and reducing the burdening of in-patient departments.

Notes

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