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**Review Article**

# Standardization of parenteral nutrition – a review of protocol development in a tertiary neonatal setup

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## ABSTRACT

Infants, who are either born preterm or with a weakened gastrointestinal tract, cannot tolerate feeds immediately after their birth normally through enteral route. This is where parenteral nutrition (PN) comes in, which employs ways to maintain the child's nutrition through ways other than enteral route. PN can be of individualized type, one which is customized for each neonate, while the other is a standardized PN, which has some empirical components absolutely necessary for the infants. Both kinds help in maintaining the optimum nutritive requirements of the infants. However, there are some differences in their effects, which can be noteworthy.

**Keywords:** Standardized parenteral nutrition, Individualized parenteral nutrition, Neonates, Pakistan

## INTRODUCTION

Neonates who have premature gastrointestinal tract, which renders them incapable to digest the feed normally, are usually dependent on an outside source of nutrition. This source of nutrition can be parenteral nutrition (PN) that is given to maintain their nutritive requirements.

The solutions for PN are mainly composed of macronutrients like carbohydrates, amino acids, and lipids and micronutrients inclusive of electrolytes, vitamins and trace elements. The supplement also makes a point of maintaining the fluid requirements of the infant. All these nutrients are in perfect proportions to meet the requirements of the infant.[1]

### *Candidates for parenteral nutrition*

Infants who are unable to meet their caloric requirements through enteral route must be given these supplements. These include the neonates who cannot maintain their daily nutritional requirements through enteral means. These could be preterm infants with immature guts, the asphyxiated infants or the infants with congenital malformations that hinder early establishment of feeds.

According to several studies, premature infants have increased metabolic demands but insufficient energy stores to meet them, therefore, rapid establishment of postnatal nutrition is essential. The main aim of maintaining the postnatal diet is to make sure that the growth velocity of the infant remains similar to that of its intrauterine life.

### *When to start parenteral nutrition?*

After their birth there is a catabolic state that develops in preterm infants which is due to their low energy reserves.[2] To avoid this state, it is necessary that ample nutrients be available for the growth of the infant postnatally. Therefore, PN should begin soon after birth as it provides positive nitrogen balance, reduces the chances of postnatal weight loss, maintain the growth patterns and are associated with better neurodevelopmental outcomes.[3] The administration of PN within the required time after birth has proven to be beneficial in terms of a decrease in postnatal mortality and complications like broncho

pulmonary dysplasia (BPD) and necrotizing enterocolitis.[4,5]

***Route of administration***

PN is administered through IV lines, either peripheral or central venous line (umbilical/peripherally inserted central catheters). PN that is maintained through the central line must also have the recommended amount of heparin. Solution with glucose content higher than 12.5gm/100ml and hyperosmolar solutions should be preferably given through central line.[6]

***Volume***

For the infants with very low birth weight (VLBW) it is crucial to manage their fluid intake. Fluid overload is associated with respiratory morbidity in neonates therefore, it is imperative to closely monitor the fluid intake. It can also cause BPD and ductus arteriosus. The total body water and extracellular fluid should be inversely proportional to the gestational age. The fluid supplementation in such infants should be based on it to maintain the fluid balance. A total of 60-100 ml/kg/day is the recommended volume which can range up to 150-220 ml/kg/day by the first week of life depending on the gestational age. Daily fluid increments should not go north of 10-30 ml/kg/day for such neonates.[7]

***Energy requirements***

Growth requires energy mandatorily, VLBW infants require higher energy each day to compensate for their malnutrition. The following table illustrates how energy requirements are related to the growth of the infant in kcal/kg/d.

**Table 1: Energy requirement.**

| Basal body functions | Growth | Synthesis | Total requirement |
|---|---|---|---|
| **50-60 kcal/kg/d** | 20-30 kcal/kg/d | 15-20 kcal/kg/d | 90-120 kcal/kg/d |

***Carbohydrates***

Most of total parenteral nutrition (TPN) requirements are fulfilled via glucose in the supplementation formula. Dextrose provides 3.4-4 kcal/g which in TPN makes up about 30-35% of the total caloric daily requirement. Glucose infusions should be similar to those of the endogenous glucose production, which is 5.5 mg/kg/min in full term healthy newborns to 8 g/kg/min in VLBW infants. Ideally, 6-8 mg/kg/min glucose should be given to the newborns and should be adjusted to maintain 45-120 mg/dl of serum blood glucose. VLBW infants are at a higher risk of developing hyperglycemia in the initial days postnatal, hence, there should be slow increases in the glucose infusion rate (GFR).[8,9]

***Protein***

Preterm infants have very limited stores of energy at birth and must catabolize protein to meet their energy requirements. Protein provides 3.4 kcal/g and should provide between 10-15% of total energy intake. The predicted daily protein accretion of a fetus at ~28 weeks of gestation is ~2 g/kg. So, at least 3 - 3.5 g/kg (protein or amino acid) is needed to promote protein accretion, allowing for obligatory losses and preventing negative nitrogen balance. Studies have shown that amino acids started at 2 g/kg/d are safe shortly after birth and do not cause acidosis as feared by many.[10-12]

***Lipids***

Lipids are a major source of energy; one gram of fat provides 9 kcal. Lipids should provide 25-40% of non-protein parenteral nutritional calories. In VLBW infants, the initial dose of lipid emulsion is 2 g/kg/d.[13] Step-wise increments by 0.5-1 g/kg/d to a maximum of 3-4 g/kg/d should be followed. However, a lower initial dose and a maximum of 3 g/kg/d is also practiced widely.[14,15]

***Electrolytes***

Fluid and electrolyte balance is essential for survival of preterm infants. VLBW infants due to their large surface area and premature skin are more susceptible to insensible losses, often resulting in electrolyte imbalances such as hyper/hyponatremia and hyperkalemia. An individual infants' electrolyte requirement may vary keeping with clinical status and associated morbidities which makes the frequent monitoring of electrolytes essential. Studies reveal that a well-balanced PN containing balanced electrolytes commenced at birth is well tolerated with low rates of biochemical abnormalities.[16]

***Vitamin***

Vitamins and minerals should be provided with all parenteral nutrition regimens. Recommended daily intake of vitamin is mentioned below as per ESPHAGAN 2005 (Table 2).[13]

***Trace elements***

Trace elements play a vital role in numerous cell functions like enzyme activities, metabolism of proteins and lipids, endocrine functioning and immunomodulation. Recommended daily intake of trace elements is advised as follows (Table 3).[17]

***Heparin***

Heparin, as a continuous infusion, prolongs the duration of long line usability and reduces catheter obstruction without any increase in adverse effects. Heparin prevents bacteria to latch on to foreign surfaces, like catheters. The use of

heparin in TPN when infused through a long line reduces the incidence of central line related sepsis (CRS).[18-20]

**Table 2: Recommended daily intake of vitamins.**

| Vitamin | RDI |
|---|---|
| **Vit A, IU/kg/day** | 700-1500 |
| **Vit D, IU/kg/day** | 40-160 |
| **Vit E, IU/kg/day** | 2.8-3.5 |
| **Vit K, µg/kg/day** | 10 |
| **Ascorbate, mg/kg/day** | 15-25 |
| **Thiamine, µg/kg/day** | 200-500 |
| **Riboflavine, µg/kg/day** | 150-200 |
| **Pyridoxine, µg/kg/day** | 150-200 |
| **Nicotinamide, mg/kg/day** | 4-6 |
| **Pantothenate, mg/kg/day** | 1-2 |
| **Biotin, µg/kg/day** | 5-8 |
| **Folate, µg/kg/day** | 56 |
| **Vit B12, µg/kg/day** | 0.3 0.5 |
| **Vit A, IU/kg/day** | 700-1500 |
| **Vit D, IU/kg/day** | 40-160 |
| **Vit E, IU/kg/day** | 2.8-3.5 |

**Table 3: RDI for trace elements.**

| Element | Weight <1 kg (µg/kg/day) | Weight 1-1.5 kg (µg/kg/day) |
|---|---|---|
| **Zinc** | 400 | 400 |
| **Copper** | 20 | 20 |
| **Selenium** | 1.5-4.5 | 1.5-4.5 |
| **Chromium** | 0.05-0.3 | 0.05-0.3 |
| **Manganese** | 1 | 1 |
| **Molybdenum** | 0.25 | 0.25 |
| **Iodide** | 1 | 1 |
| **Iron** | 100-200 | 100-200 |

***Parenteral nutrition mixture***

PN can be delivered via three chambered bag, 2-in-1 system (one solution containing amino acids, dextrose, electrolytes, vitamins, minerals, and fluids and one solution containing fat emulsions (IVFEs) or via a 3-in-1 system (all nutrients mixed in one container).[18,20] Although the use of 3-in-1 PN solutions is not necessarily therapeutically advantageous, certain benefits may exist such as the potential to reduce the risk of contamination due to decreased manipulations, ease of administration, cost effectiveness and reduced IVFE wastage.[21] Both these types of infusion make sure that the contents of the bag remain separate and in their pure form till right before they are used. The literature suggests no superiority of one over the other.[22,23]

***Trends before standardization: individualized PN***

For the individualized PN, the physician formulates the concentrations of different components and the actual solution is prepared in the pharmacies. There all the calories are calculated and mixed together. These orders are reviewed each day for the patients so that the electrolytes can be adjusted to the bodily requirements, also to keep in mind the acid/base balance to be adjusted properly.[24]

PN utilization in developing countries is limited because of lack of basic requirements for compounding. In some lead local tertiary NICU setups have been using individualized parenteral nutrition which is formulated in hospital pharmacy. PN is usually started after 24-48 hours of life, each baby receiving customized PN as per their biochemical profile. Initial starting nutrients and electrolytes are as follows; proteins 0.5–1.5 gm, lipid 0.5–1.5 gm, glucose 4–6 mg/kg/min, sodium 1–2 mEq, potassium 0.5–1 mEq, and calcium 50–100 mg. No phosphorus or magnesium were added while total calories provided were below set standards.

***PN pharmacy review process***

Pharmacist receive PN requests on computerized software. They then countercheck by re calculating each individual component of the PN while reviewing the biochemical profile of the infant via patient profile viewer (PPV). If TPN pharmacist deems any necessary modifications they then approach the concerned physician on telephone to discuss. Finally, the request is forwarded to PN technician for formulation.

***Time required for prescription and formulating PN***

TPN requirement of NICU is around 12-15 prescriptions/day. Each physician writes around 4-5 prescriptions needing almost 30 minutes for the entire process of calculating, prescribing and placing request on the pharmacy software. Around the same time is required by TPN pharmacist to review and recalculate the requested PN. This takes up to ~3-4 hours after which TPN is begun to be formulated by PN technician. The entire process taking up to 6–8 hours altogether.

***Intervention: standardization of neonatal PN***

Standardized PN is the use of a preformed PN not based on individual needs of the neonate, rather a formula which can be used on all the neonates with the similar set of symptoms. This intervention saves time and extra cost that individualized PN might be consuming like physicians time to formulate the specific PN formula, and pharmacy to make that specific formula for each patient separately.

A study was conducted in tertiary care centers like Aga Khan University Hospital (AKUH) as well as The Indus Hospital (now Indus Hospital and health network). The study compared these two types of PN on neonates admitted to the hospitals due to VLBW or birth complications that made them dependent on PN in the first few days after birth.

The project was initially implemented at the AKUH which is JCIA accredited hospital at Karachi, Pakistan and has a 24 bedded level 3 neonatal intensive care unit (NICU). Annual birth rate is around 5000 out of which 16-17% are born premature. Annual NICU admissions are 1200-1300/year.

Specific type standard PN containing almost the same ingredients in fixed concentration. As the volume of infusion is increased in accordance with daily fluid requirement, the provided concentration of ingredients also increases accordingly. Concentration of different ingredient is the same in different categories that helps PN technician to remember easily. Biochemical status is monitored as clinically indicated.

Standard PN protocol was initially implemented at AKUH and later replicated with success at the Indus Hospital, Karachi which comprises of a 12 bedded level 3 tertiary care NICU with 700-800 births/year. The study finalized indications for PN in neonates as described in Table 4 and 5.

**Table 4: Indication for PN.**

| Preterm <32 weeks gestation | Gastrointestinal malformation |
|---|---|
| **Preterm baby with birth weight <1200 gm** | Malabsorption syndrome |
| **Having evidence of perinatal asphyxia** | Suspected/confirmed necrotizing enterocollitis |
| **Intrauterine growth retardation with absent or reversal of diastolic flow in umbilical artery** | Any clinical condition which cause delay in enteral feeding |

Any neonate unable to achieve full feed by fifth day of life

Also the specific standardized PN based on age and gestational age of the neonate as described in Table 6.

***Benefits***

Use of standardized PN has overall had a good impact on the standard of care provided. From observation we can say that we were able to reduce the unnecessary use of PN. There was a marked reduction in venipuncture associated complications as the need of frequent biochemical monitoring was decreased. Work load from physician and nurses' point of view decreased significantly. Overall the provision of both micro and macronutrients was significantly improved with better outcomes as compared to IPN (Table 7).

**Table 5: Consider individualized PN/fluid electrolytes mixture, if patient has.**

| Hypoglycemia despite of adequate GIR through standard PN |
|---|
| **Hypernatremia >150 mEq/dl despite of adequate fluids** |
| **BUN >50** |
| **Hypermagnesemia (> 2.5 mEq/dl)** |
| **PN associated liver disease (PNALD) (SBR >2 mg/dl, or direct bilirubin >20% of total, SGPT >50, gamma GT >100)** |
| **Hyperglycemia despite of low glucose parenteral nutrition** |
| **Needs fluids through TPN >160 ml/kg/day** |

***Monitoring and complications***

It is exceedingly complex to formulate PN perfectly as complications like septicemia as well as metabolic imbalances can arise from the improper use of the TPN. Glucose levels can frequently fluctuate more rapidly in neonates than in older children or even adults. These fluctuations can be devastating by resulting in neurological complications, therefore, the blood glucose of an infant should be closely monitored. In case the neonate goes into hyperglycemia, the condition can be corrected with proper dose of insulin, for glucose levels above 250 mg/dl it is recommended to restrict the glucose infusion rate to 4 to 6 mg/kg/min. Similarly, hyperglycemia should be addressed by the optimization of the glucose rate.[26] If the tests indicate increased blood urea nitrogen (BUN) twice the normal rage, it is advised to increase the fluid intake and the amounts of protein, reduced. Increase and decrease in lipid levels in blood of neonates can also result due to unmonitored lipid intake in PN. PN associated cholestasis can also result due to this condition therefore careful monitoring of the fluid loss is essential.

Standardized PN, therefore, is helpful in conserving that extra time spent, also, provides all the necessary nutrients for the infant to grow.[27]

**Table 6: Standard neonatal parenteral nutrition: volumes and concentration in different categories.**

| Ingredients with concentration | Age (yrs) | At birth | After 24 hours of life** | | Optional | |
|---|---|---|---|---|---|---|
| | Category | Starter# | Standard preterm | Standard term | Low glucose*** | High sodium**** |
| **Proteins (10% amino)** | | 25 ml=2.5 gram (gm)/100 ml | | | | |
| **Dextrose percentage** | | 8 gm/100 ml | ~8 gm/100 ml | ~10 gm/100 ml | ~7 gm/100 ml | 7.8 gm/100 ml |
| **25% dextrose** | | 6 ml | 12 ml | 25.3 ml | 6.3 ml | 12 ml |
| **10% D/W** | | 65 ml | 49.3 ml | 36 ml | 55 ml | 48 ml |

Continued.

| Ingredients with concentration | Age (yrs) | At birth | After 24 hours of life** | | Optional | |
|---|---|---|---|---|---|---|
| | Category | Starter# | Standard preterm | Standard term | Low glucose*** | High sodium**** |
| **Lipid (20% IVFE)** | | 0 | 9.5 ml (1.9 gm/100 ml) | | | |
| **$MgSO_4$ (8 mEq/2 ml)** | | 0.1 ml (0.4 miliequivalent/100 ml) | | | | |
| **Potassium phosphorus (KPO) - (hospital compounding); potassium (K) 1.5 mEq/0.35 ml; Phosphorus (Ph) 1 mmol per 0.35 ml[25]** | | **0** | 0.35 ml (K-1.5 mEq/100 ml, Ph-1 mmol/100 ml) | | | |
| **NaCl 2.5 mEq/ml** | | 1 ml (2.5 mEq) | 1.2 ml (NaCl-3 mEq/100 ml) | | | 2.4 ml (6 mEq/100 ml) |
| **Zinc (1 mg/ml)** | | 0.3 ml-300 mcg) per 100 ml | | | | |
| **Calcium gluconate (10%)** | | 1.25 ml (125 mg/100 ml) | | | | |
| **Multivitamin preferably both lipid and water soluble as per concentration** | | 1 ml | | | | |
| **Heparin* (0.5 IU/ml)** | | 0.1 ml (0.05 unit per 100 ml) | | | | |

*Only for central line, **if electrolytes and sugars are normal, ***consider if POCT blood sugar >200, 3-4 episodes, confirmed by RBS, ****consider serum sodium <135 ml, unable to receive oral sodium; hypertonic saline/normal saline boluses should be avoided during high sodium PN, #can be given to patients with hyperkalemia and renal failure

**Table 7: Nutrients and electrolytes provision (per kg/day) at 3rd day of life for an extremely preterm neonates.**

| Ingredients | IPN | SPN |
|---|---|---|
| **Sodium (mEq)** | 1 | 3.6 |
| **Potassium (mEq)** | 0.5-1 | 1.8 |
| **Calcium (mg)** | 501-00 | 150 |
| **Chloride (mEq)** | 1-2 | 3.6 |
| **Phosphorus** | 0 | 1.2 |
| **Magnesium** | 0 | 0.48 |
| **Proteins (gm)** | 0.5-1.5 | 3 |
| **Lipid (gm)** | 0.5-1.5 | 2.38 |
| **Zinc (mics)** | 250 | 360 |
| **Glucose** | 4-6 | 6.6 |
| **Calories (kcal)** | 35-50 | 70.92 |
| **Heparin (IU)*** | 0 | 60 |

**Table 8: Lab monitoring for biochemically and clinically stable babies.**

| Twice daily | Daily | Twice weekly (Monday, Thursday) | Weekly (Monday) |
|---|---|---|---|
| **If electrolytes imbalance<br>Negative fluids balance (50 ml/kg/day)<br>Anuria (>12 hours after first 24 hours)<br>Receiving high electrolytes fluids** | | | |
| **Electrolytes<br>BUN<br>Creatinine<br>And other biochemical profile** | Electrolytes first 72 hours | After first 72 hours of neonates on PN | Liver function test |
| | Calcium, if <6.5 mg/dl | BUN, Cr | Phosphorus, calcium |
| | Magnesium if <1.4 mg/dl | CBC for 1st week | Na, K once off TPN |
| | | | CBC after stabilization |
| | SBR if clinically icteric and/or required phototherapy | | |

## CONCLUSION

Early onset of TPN for the neonates suffering from nutrient deficiency helps in counteracting extra uterine growth restriction. Use of TPN while being a core necessity, however, individualized PN can be very time consuming and difficult for the physicians and pharmacy to manage.

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