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A THREE-CHAMBER PARENTERAL NUTRITION SOLUTION WAS ASSOCIATED WITH IMPROVED PROTEIN INTAKE IN VERY LOW BIRTHWEIGHT (VLBW) INFANTS

A study to evaluate the actual parenteral nutrition of VLBW infants admitted to the Helsinki Children's Hospital NICU during 2005–2013 and to compare the nutritional intakes with current recommendations.

Immeli L, et al. *Acta Paediatr.* 2020

OVERVIEW

STUDY AIM

To test the hypothesis that using a commercial, three chamber PN solution (Numeta G13E) would improve protein intake in very low birth weight (VLBW) infants (less than 1500g) admitted to the neonatal intensive care unit (NICU) by comparing actual nutritional intakes during 2005-2013 with 2018 ESPGHAN/ESPEN/ESPR/CSPEN guidelines.

STUDY METHOD

A retrospective cohort study comprised of 953 VLBW infants born between 2005-2013 and admitted to the NICU at a gestational age (GA) of less than 32+0/7 weeks or with a birthweight less than 1501g and admitted to the neonatal care unit according to their year of birth at Helsinki Children's Hospital, Finland. The infants were divided into four subgroups according their birth year and PN regime. Parenteral nutrition was started immediately after birth. Nutrient intakes were obtained from computerised medication administration records.

FLOWCHART OF THE STUDY COHORT

1227 INFANTS

- Registered birthweight of <1500g
- Admitted to the Neonatal Intensive Care Unit of the Helsinki University Children's Hospital in years 2005-2013

EXCLUDED

- **72 infants** admitted after the first 24h of life
- **148 infants** with gestational age > 31+6/7
- **30 infants** with major congenital malformations or chromosomal anomalies
- **24 infants** with a duration of stay < 24h

953 INFANTS

TOTAL COHORT (n=953)	2005-2007 (n=278)	2008-2009 (n=246)	2010-2011 (n=239)	2012-2013 (n=190)
PARENTERAL NUTRITION (PN) REGIME	Individual PN solution	2-in-1 PN solutions + lipids	2-in-1 PN solutions + lipids	Numeta G13E

STUDY RESULTS

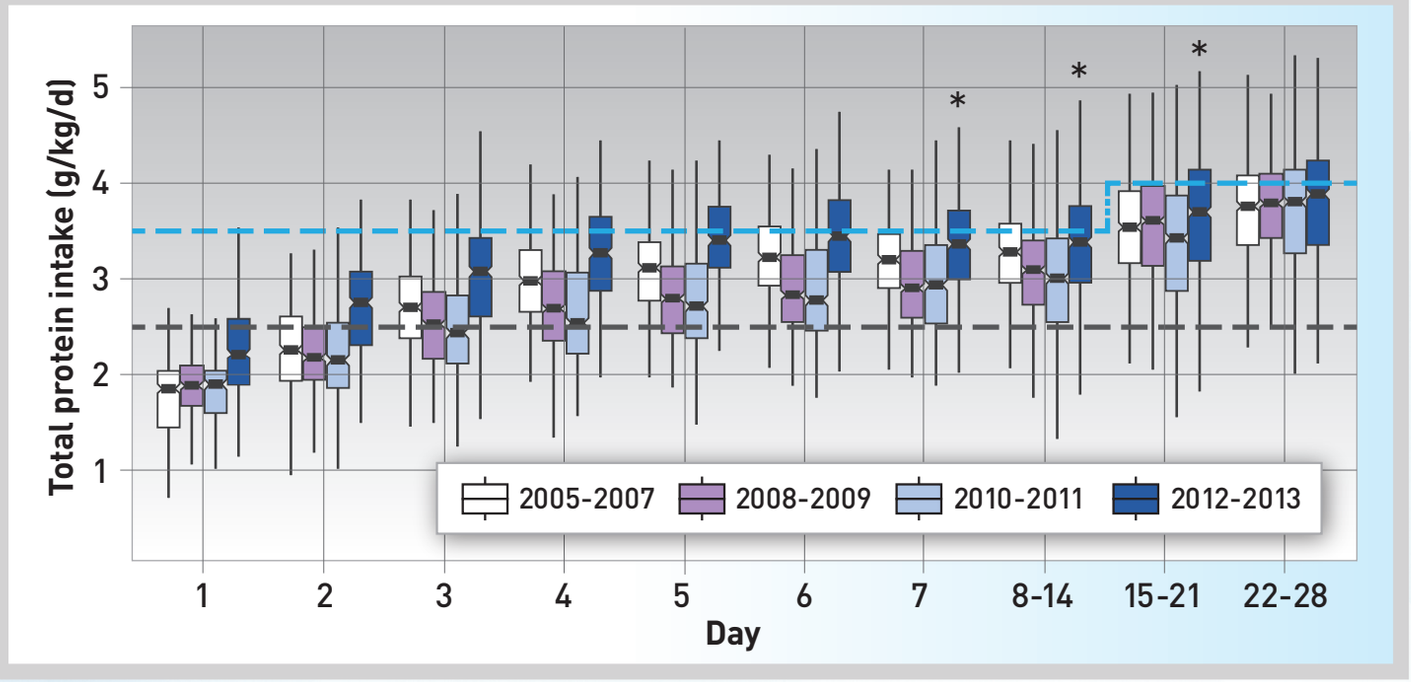
Infants in the **Numeta G13E group** had the **highest median energy intake** (90kcal/kg/d) during the **first week**. They also had **higher median protein intakes** in weeks one, two and three (3.1, 3.4 and 3.7g/kg/d) than infants born in 2005-2011 ($p<0.05$). See Figure 1.

In 2012-2013, when **Numeta G13E** was used, infants were **more likely to reach the target parenteral protein intake of 3.5g/kg/d**, and reach it **3-7 days earlier**, compared with infants who received individual PN or standard two-in-one PN solutions in 2005-2011 ($p<0.0001$). See Figure 2.

STUDY RESULTS

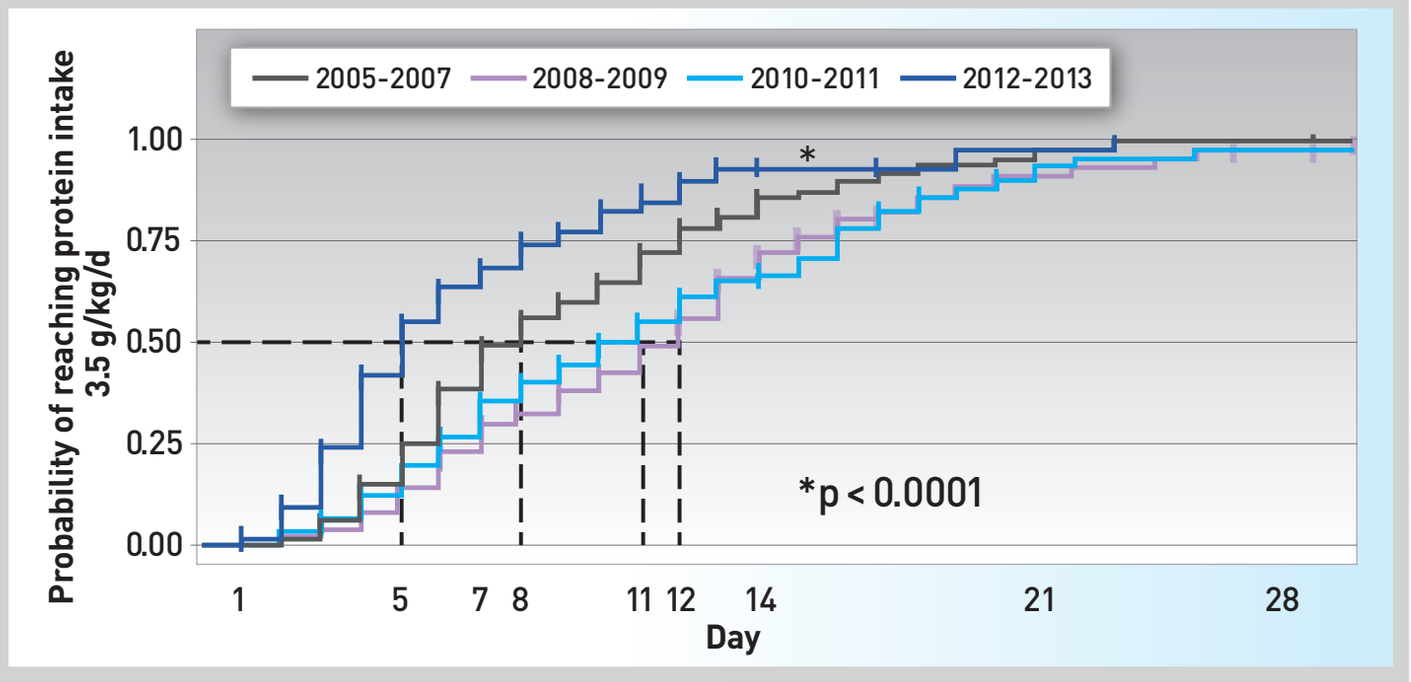
Only infants born in 2012-2013 subgroup (Numeta G13E) reached 2018 ESPGHAN/ESPEN/ESPR/CSPEN guidelines protein target on day two, whereas infants born in 2005–2011 reached protein target on either day three or day four.

FIGURE 1.



Infants born in 2012-2013 subgroup (Numeta G13E) reached the target parenteral protein intake on the fifth day of life (median), which was three to seven days earlier than infants born in 2005–2011.

FIGURE 2.



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STUDY CONCLUSIONS

- The **median protein** intake of VLBW infants **improved** during the time when commercially available three-chamber PN solutions (**Numeta G13E**) were used instead of standard two-in-one PN solutions or individual PN solutions.
- The **recommended nutrient intakes for VLBW infants could be achieved** by combining computerised PN prescriptions and the use of multi-chamber PN solutions.

STUDY POINTS TO CONSIDER

- The early protein intake of 953 VLBW infants improved during the period when a three-chamber parenteral nutrition (Numeta G13E) was used.
- Infants that received Numeta G13E (2012-2013 subgroup) had a higher median protein intake during the first three postnatal weeks compared with infants born in 2005–2011.
- The target parenteral protein intake of 3.5g/kg/d was more likely to be reached when using Numeta G13E (2012-2013 subgroup) and 3-7 days earlier than in individual and two-in-one PN solutions (2005-2011 subgroups).

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Numeta G13E emulsion for infusion COMPOSITION Three-chamber bag. Each bag contains a sterile nonpyrogenic combination of a glucose solution, a pediatric amino acids solution, with electrolytes, and a lipid emulsion. Container size 300 ml, 50% glucose solution: 80 ml, 5,9% amino acid solution with electrolytes: 160 ml, 12,5% lipid emulsion: 60 ml. If lipid administration is undesirable, the design of the bag allows the possibility to activate only the peel seal between the amino acids/electrolytes and glucose chambers, leaving the peel seal between the amino acids and lipid chambers intact. The content of the bag can subsequently be infused with or without lipids. **THERAPEUTICAL INDICATIONS** Numeta G13E is indicated for parenteral nutrition in preterm newborn infants when oral or enteral nutrition is not possible, insufficient or contraindicated. **POSOLOGY** The dosage depends on energy expenditure, the patient's weight, age, clinical status, and on the ability to metabolize the constituents of Numeta G13E, as well as on additional energy or proteins given orally/enterally. Total electrolyte and macronutrient composition is dependent on the number of activated chambers. The maximum daily dose should not be exceeded. Due to the static composition of the multi-chamber bag, the ability to simultaneously meet all nutrient needs of the patient may not be possible. Clinical situations may exist where patients require amounts of nutrients varying from the from the static composition. The maximal recommended hourly rate of infusion and volume per day depend on the constituent. The first of these limits to be reached sets the maximum daily dose. The guidelines for maximal recommended hourly rate of infusion and volume per day are: Maximal volume/kg/day of Numeta G13E with lipids 127,9 ml/kg and Numeta G13E without lipids 102,3 ml/kg. Max infusion rate (ml/kg/h) of Numeta G13E with lipids 6,4 ml/kg/h and of Numeta G13E without lipids 5,1 ml/kg/h. **ADMINISTRATION** Administered through a central vein. However, sufficient dilution of Numeta G13E with water for injection lowers the osmolarity and allows peripheral infusion. **CONTRAINDICATIONS** Numeta G13E without lipids: Hypersensitivity to egg, soy or peanut proteins, or to any of the active substances, excipients, or components of the container. Congenital abnormality of the amino acid metabolism. Pathologically elevated plasma concentrations of sodium, potassium, magnesium, calcium and/or phosphorus. Concomitant treatment with ceftriaxoneeven if separate infusion lines are used. Severe hyperglycaemia. Numeta G13E with lipids: Severe hyperlipidaemia, or severe disorders of lipid metabolism characterized by hypertriglyceridaemia. **UNDESIRABLE EFFECTS** Clinical Trial and Post-marketing experience Adverse Reactions Metabolism and nutrition disorders. Common: Hypophosphataemia, Hyperglycaemia, Hypercalcaemia, Hypertriglyceridaemia, Hyponatraemia. Uncommon: Hyperlipidaemia. Hepatobiliary disorders Uncommon: Cholestasis. Skin and subcutaneous tissue disorder Not known: Skin necrosis, Soft tissue injury. General disorders and administration site condition Not known: Extravasation. Fat overload syndrome: may be caused by inappropriate administration (e.g. overdose and/or infusion rate higher than recommended); however the signs and symptoms of this syndrome may also occur when the product is administered according to instructions. The reduced or limited ability to metabolize the lipids contained in Numeta G13E accompanied by prolonged plasma clearance may result in a "fat overload syndrome". This syndrome is associated with a sudden deterioration in the patient's clinical condition and is characterized by findings such as hyperlipidemia, fever, liver fatty infiltration (hepatomegaly), deteriorating liver function, anemia, leukopenia, thrombocytopenia, coagulation disorders and central nervous system manifestations (e.g. coma). The syndrome is usually reversible when the infusion of the lipid emulsion is stopped. Pulmonary vascular precipitates (pulmonary vascular embolism and respiratory distress). **PRECAUTIONS** Cardiovascular: Use with caution in patients with pulmonary edema or heart failure. Fluid status should be closely monitored. Renal: Use with caution in patients with renal insufficiency. Fluid and electrolyte status, including magnesium, should be closely monitored in these patients. Severe water and electrolyte equilibration disorders, severe fluid overload states, and severe metabolic disorders should be corrected before starting the infusion. Hepatic/Gastrointestinal: Use with caution in patients with severe liver insufficiency, including cholestasis, or elevated liver enzymes. Liver function parameters should be closely monitored. Endocrine and Metabolism: Metabolic complications may occur if the nutrient intake is not adapted to the patient's requirements, or the metabolic capacity of any given dietary component is not accurately assessed. Adverse metabolic effects may arise from administration of inadequate or excessive nutrients or from inappropriate composition of an admixture for a particular patient's needs. Hematologic: Use with caution in patients with severe blood coagulation disorders. Blood count and coagulation parameters should be closely monitored.

COUNTRY SPECIFIC INFORMATION:
Denmark: Udlevering: B, Tilskud: Ikke tilskudsberettiget, For prices see: www.medicinpriser.dk. Norway: Reseptgruppe: C, Blå resept: Nei, For prices, see: www.legemiddelsok.no. ATC code: B05BA10.

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