

PRACTICAL HANDLING, EASE OF USE, SAFETY AND EFFICACY OF A NEW PEDIATRIC TRIPLE-CHAMBER BAG FOR PARENTERAL NUTRITION IN PRETERM INFANTS

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Background: In adults, multi-chamber parenteral nutrition is commonly used. However, this has not historically been used for preterm infants.

Objective: To evaluate the efficacy, safety, flexibility, and ease of handling and use of the Ped3CB-A 300 mL, the first ready to use multi-chamber parenteral nutrition (PN) system, with optional lipid bag activation, specially designed for administration to preterm infants.

Methods: In this prospective, open-label, multicenter, noncomparative, Phase III clinical trial, preterm infants were treated with Ped3CB-A for 5-10 consecutive days.

Results: 113 preterm infants were enrolled in the study and 97 (BW:1382±520g, GA:31.2±2.5 weeks, PNA:5.6±6.1 d) were included in the per protocol analysis accounting for 854 perfusions days. Macronutrient, electrolyte, and mineral supplements were primarily administered through a Y-line or directly in the activated bag. In all, 199 additions (mainly sodium 95%) were made to the Ped3CB-A bags on 197 infusion days (23.1%) in 43 infants (44.3%). More than 1 of these nutrients was added to the bag on only 1 perfusion day. Mean±SD (standard deviation) of the averaged and maximum daily parenteral nutrient intakes were 2.8±0.7 and 3.6±0.8 g AA/kg*d and 80±20 and 104±22 kcal/Kg*d. Mean weight gain represented 10.0, 21.5 and 22.6 g/kg*d according to age at inclusion, 0-3,4-7 and >7 days of life. No adverse events were attributable to the design of the Ped3CB-A system.

Conclusion: Ped3CB-A provides ease of use, well balanced and safe nutritional support. Nutritional intakes and weight gain were within the more recent recommendations for preterm infants.