EFFECTS AND TOLERANCE OF PROTEIN AND ENERGY-ENRICHED FORMULA IN INFANTS FOLLOWING CONGENITAL HEART SURGERY: A RANDOMIZED CONTROLLED TRIAL

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Cui Y, Li L, Hu C, Shi H, Li J, Gupta RK, Liang H, Chen X, Gong S. 2018

PURPOSE

For infants undergoing surgery for congenital heart defects (CHD), nutrition support is a critical component for positive outcomes. Energy- and nutrient-dense formula (ENDF) may help meet nutrient recommendations and support healing from surgery. However, tolerance and impacts of increased energy and protein delivery for this population has not been well researched. This trial aimed to study the tolerance and nutritional response to ENDF compared to a standard infant formula (SIF) in infants for 5 days following surgery for CHD.

DESIGN

Infants (n=50) were randomized to receive either a test formula (ENDF, Fortini™, n=26) or control formula (SIF, n=24). Tolerance and daily volume intakes were recorded. Plasma levels of amino acids were measured, and cumulative nitrogen balance (cNB) and cumulative energy balance (cEB) were calculated.

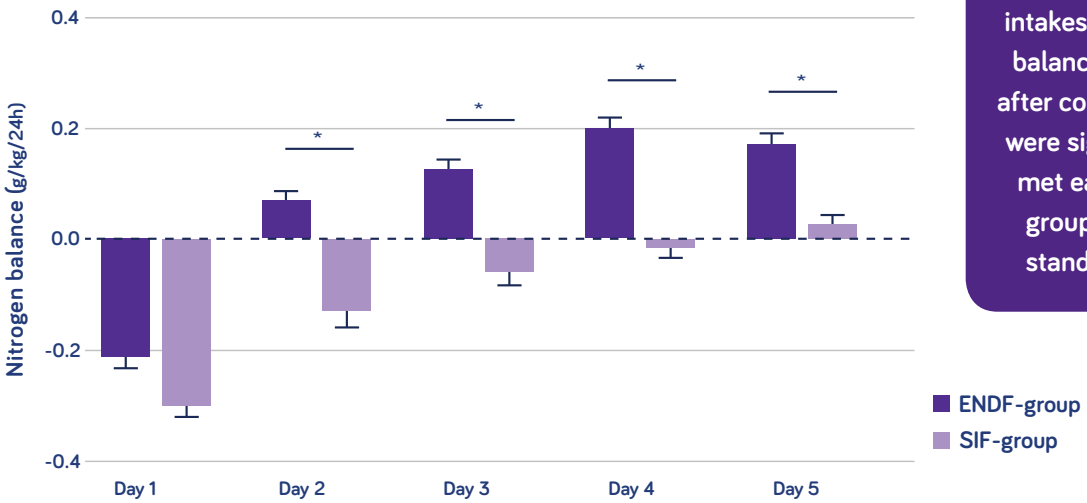
OUTCOMES

ENDF group had significantly higher intake of nutrients after day 1, with all subjects in this group meeting adequate nutrient intakes by day 2. Positive cNB was met in the ENDF group from day 2: the SIF group did not achieve this until day 5. Many essential amino acid concentrations increased significantly more in ENDF group. ENDF group did not experience significantly higher incidences of adverse events, with one exception for tolerable diarrhea (hazard ratio with multivariate adjustment, 3.16; 95% confidence interval, 1.24-8.01).

CONCLUSIONS

In the immediate days following surgery for CHD in infants, administering ENDF early was tolerated equally as well as SIF. Feeding an ENDF was also effective in meeting adequate nutrient intakes sooner, providing higher intake of nutrients, and achieving positive nitrogen balance sooner.

NITROGEN BALANCE ON DAYS 1–5 BETWEEN ENDF GROUP (N = 26) AND SIF GROUP (N = 24).



"We found that nutrient intakes and positive nitrogen balance... in the early stage after congenital heart surgery, were significantly higher and met earlier in the [Fortini™] group compared with the standard formula group."

Fortini is for the dietary management of term infants and young children from 0 to 18 months of age or up to 19.8 lbs (9 kg) with or at risk of growth failure, increased energy requirements, and/or fluid restrictions due to conditions such as: congenital heart disease, chronic lung disease, respiratory syncytial virus, neurological syndrome or neuro-disabilities, cystic fibrosis, non-organic failure to thrive. Fortini is known in other countries as Infatrini. For US healthcare professionals

NUTRICIA Fortini™