TOLERABILITY AND EFFECTS OF THE USE OF ENERGY-ENRICHED INFANT FORMULA AFTER CONGENITAL HEART SURGERY: A RANDOMIZED CONTROLLED TRIAL

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PURPOSE

Children with congenital heart disease (CHD) frequently experience undernutrition, which can negatively impact outcomes after surgery. Increased energy intake following CHD surgery has been linked with improved outcomes. This trial evaluated the impacts of using an energy- and nutrient-dense formula (ENDF) compared to standard infant formulas (SIFs) during the 30 days following surgery for CHD.

DESIGN

Children undergoing surgery for CHD in a tertiary care hospital in southern Brazil between March 2017 and December 2017 were eligible for this randomized controlled trial. Subjects in the test group were fed with ENDF (Fortini™, 1 kcal/mL), and those in the control group were fed with an SIF at the standard energy density (0.67 kcal/mL). The individual responsible for anthropometric measurements was blind to each subject's random group assignment.

OUTCOMES

Fifty-nine patients were randomized: 29 to the test group (ENDF) and 30 to control (SIF). No statistically significant differences were seen between groups following randomization regarding gender, age, anthropometry or surgical risk classification. After intervention, the ENDF group demonstrated significantly higher weight-for-age *z*-score and weight gain variation rate compared to the SIF group. Similar frequency of general GI side effects was seen between groups, although diarrhea was more frequent in the ENDF group. Findings for the ENDF group included less frequent use of antibiotics (p=0.047) and a trend toward shorter hospital length of stay vs. the SIF group.

CONCLUSIONS

This trial found that use of ENDF is well tolerated by children following surgery for CHD while also supporting weight gain. Potential impacts seen on reducing length of hospital stay and use of antibiotics in this trial could be confirmed in future trials with larger sample sizes.

OUTCOMES AND FINDINGS BY GROUP AFTER COMPLETION

	ENDF	SIF	p Value
WFA z-score	–1.57 ± 0.2	–2.69 ± 0.2	**0.042***
Length of stay, days	14.4 ± 1.84	20.19 ± 2.56	0.057*
Mechanical ventilation duration	90.3 ± 23.5	108.4 ± 26.3	0.65*
Oxygen at day 30, n (%)	0	5 (31.2)	**0.01**†
Diuretics at day 30, n (%)	11 (55)	16 (100)	**<0.01**†
Antibiotic use among intent-to-treat, n (%)	16/29 (55.2)	24/39 (80)	**0.047**†
% kcal formula at day 30	92.27 ± 2.5	73.25 ± 3.4	0.14‡

*Mean ± SEM; Student *t*-test
†Fisher's exact test
‡Wald's χ^2

Fortini™ is well tolerated and supports positive weight gain in patients for 30 days after CHD surgery.

Other findings from this trial - less frequent use of antibiotics and a trend toward shorter hospital length of stay for the Fortini™ group - suggest further potential benefits.

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

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