# Effect of energy-enriched formula for catch-up growth in malnourished infants after congenital heart disease surgery

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Malnutrition and growth faltering are common in infants with congenital heart disease (CHD) with cyanosis, heart failure, recurrent infections, frequent hospitalizations and feeding difficulties impacting their nutritional status. Malnutrition in these infants not only delays growth and development, but also increases the risk of infection and affects clinical outcomes, rehabilitation, and recovery. This study aims to investigate the efficacy and safety of Energy Nutrient Dense Formula (ENDF) on postoperative catch-up growth in infants with CHD and malnutrition.

## METHODS

Subjects were included in this study with (1) a diagnosis of ventricular septal defect (VSD) requiring surgical treatment (2) age ≤ 6 months (3) requiring enteral feeding (4) a weight for age Z Score (WAZ) ≤-2 and (5) informed consent from parents or guardians. Infants were excluded if severe digestive tract malformation, inherited metabolic diseases, milk protein allergy or a postoperative chylothorax or chylous abdomen was present. All infants matching these criteria in a Chinese hospital (Guangzhou Women and Children's Medical Center) were randomly assigned to receive either the ENDF (100kcal/100ml; Infatrini) or a standard formula (66kcal/100ml) after surgery for a period of 3 months.

All infants were followed up until 6 months post-surgery. Measurements included body weight, length and upper arm circumference at 5 time points (preoperatively, upon discharge from ICU, upon discharge from hospital, 1 month after surgery and 3 months after surgery). Furthermore, prealbumin (PA), retinol-binding protein (RBP) and N-terminal pro-B-type natriuretic peptide (NT-proBNP) were compared between the two groups at these time points. Length-for-age Z-score (LAZ), weight-for-age Z-score (WAZ), and weight-for-length Z-score (WLZ) were assessed alongside adverse reactions and GI tolerance parameters (diarrhoea, constipation, vomiting and abdominal distention). Malnutrition was defined as having at least one of the three z-scores (WAZ, LAZ, WLZ) <-2.

## RESULTS

101 infants (60 male, 41 female) were included in the study, with 50 randomised to receive the ENDF and 51 infants randomised to receive the standard formula.

### Growth & Nutritional status

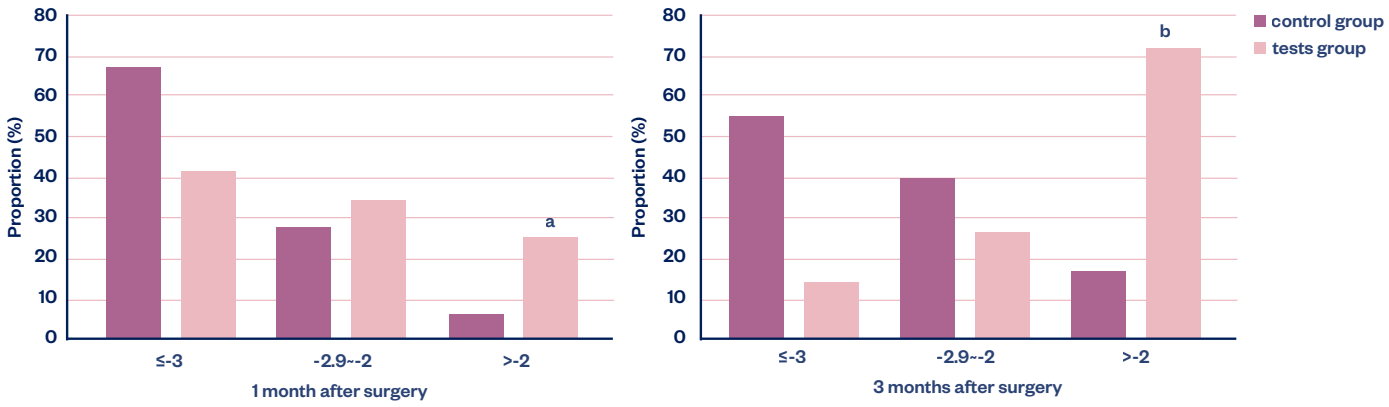
Mean fluid intake was not different between groups (P>0.05), however the group receiving ENDF achieved significantly higher energy intake compared to the control group (437.24 ± 6.68 KJ vs. 312.43 ± 86.22 KJ; P < 0.001).

Prior to hospital discharge, body weight of infants increased in the ENDF group (+0.067 ± 0.384 kg) but decreased in the control group (-0.125 ± 0.425 kg), the difference between groups being statistically significant (P=0.015).

A significantly higher proportion of the ENDF group demonstrated catch up growth with WAZ improvement over time compared to the control group. The proportion of infants with WAZ values > -2 was 25.0% (11/2) in the ENDF group vs. 4.9% (3/51) in controls (P=0.011) 1 month after surgery and 64.1% (25/39) vs. 15.7% (8/51) after 3 months (P<0.001) (Figure 1).

One month after surgery infants receiving ENDF demonstrated a significantly higher body weight (5.46 ± 1.36 kg vs. 4.80 ± 1.01 kg; P = 0.008) WAZ (-2.79 ± 1.28 vs. – 3.75 ± 1.27 P < 0.001) and WLZ (-2.47 ± 1.43 vs. - 3.62 ± 1.77; P = 0.001) than those in the control group.

**Figure 1:** Comparison of WAZ values at 1 and 3 months after surgery between the two groups




Note: WAZ: Z value of body weight for age compared with control group a) P=0.011 b) P <0.001

At 3 months post-surgery the group receiving ENDF had significantly higher body weights (6.78 ± 1.42 kg vs. 5.72 ± 1.01 kg); P<0.001, mid upper arm circumference (12.80 ± 1.17 cm vs. 12.00 ± 0.90 cm; P < 0.001], WAZ (-1.60 ± 1.17 vs. – 3.10 ± 1.40; P < 0.001], LAZ (- 1.41 ± 1.63 vs. -2.10 ± 1.41; P = 0.034) and WLZ (- 0.86 ± 1.31 vs. – 2.59 ± 2.13; P < 0.001) compared to the control group.

**Table 1:** Comparison of growth at 1 and 3 months after surgery between the two groups

| | 1 month after surgery | | | 3 months after surgery | | |
|---|---|---|---|---|---|---|
| | **ENDF group (n=50)** | **Control group (n=51)** | | **ENDF group (n=50)** | **Control group (n=51)** | |
| **Body mass** (kg) | 5.46 ± 1.36 | 4.80 ± 1.01 | p=0.008 | 6.78 ± 1.42 | 5.72 ± 1.01 | p=<0.001 |
| **WAZ** | -2.79 ± 1.28 | 5.46 ± 1.36 | p=<0.001 | -1.60 ± 1.17 | -3.10 ± 1.40 | p=<0.001 |
| **Proportion of WAZ >-2** (%) | 25.0% (11/2) | 4.9% (3/51) | p=0.0011 | 64.1% (25/39) | 15.7% (8/51) | p=<0.001 |
| **WHZ** | -2.47 ± 1.43 | -3.62 ± 1.77 | p=0.001 | -0.86 ± 1.31 | -2.59 ± 2.13 | p=<0.001 |

### Tolerance

There were no significant differences in tolerance or GI adverse events, demonstrating that both ENDF and the control formula were well tolerated. 4 infants in the ENDF group reported hard stools 3 months after surgery, however this was managed with appropriate fluid and probiotic intake without the need to change formula.

### Cardiac function

There was no significant difference in NT-proBNP between groups at different time points (P=0.119). NT- proBNP decreased to a low level in both groups 3 months after surgery (455.5 ± 589.6 ng/L in ENDF vs. 279.8 ± 114,5 ng/L in controls; P=0.0418), indicating that the cardiac function of the infants recovered well following surgery.

## CONCLUSIONS

Preoperative malnutrition and faltering growth are common in infants with congenital heart disease. This study demonstrates that ENDF is well tolerated and can subsequently improve nutritional intake and promote catch up growth in infants with congenital heart disease requiring surgery.