Review Paper

The Effect of High-density Versus Standard Formula on Weight Gain in Children Following Congenital Heart Surgery: A Systematic Review of Randomized Clinical Trials

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ABSTRACT

Background: Children with congenital heart disease (CHD) are prone to weakening and underweight.

Objectives: We aimed to evaluate the effect of high-density formula on weight gain and gastrointestinal intolerance in CHD children following heart surgery.

Methods: All randomized clinical trials (RCTs) on weight gain following heart surgery in CHD children were systematically searched on Web of Science, PubMed, and Scopus databases by related keywords from 1990/01/01:2022/12/30. Papers in languages other than English were excluded. Among 11 trials that evaluated the effect of a high-density formula on weight, 6 studies were excluded due to their study samples (older than 2 years) and using macronutrients to enrich the formula.

Results: Finally, 5 eligible trials with a total of 278 participants were included in this systematic review. The follow-up duration ranged from 5 to 30 days. Among 5 included studies, 4 indicated that feeding with high-density or concentrated formula can improve weight gain in children with CHD compared to the standard formula. Diarrhea was the most common gastrointestinal complication associated with the high-density formula, although its frequency was low.

Conclusions: Feeding with a high-density formula or concentrated standard formula could be an inexpensive and practical way to fulfill the nutritional requirements of CHD children following surgery, which can lead to more weight gain without any significant gastrointestinal side effects.

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Introduction

Congenital heart disease (CHD) refers to anomalies in the heart, its valves, and vessels. The worldwide prevalence of CHD has been reported to be 8 per 1000 live births [1].

Children with CHD are prone to wasting, underweight, and stunting [2-4]. According to some studies, 27% to 60% of children with CHD develop malnutrition [3, 5-8]. In infants with CHD, early surgical correction of the heart defect may be the optimal treatment. However, not all complex defects are fixed during the neonatal period, leading to infants undergoing palliative surgery and being managed with supportive therapy. Malnutrition in children with CHD could have a negative impact on their subsequent surgical outcomes. Malnutrition in these children increases the risk of infections and mortality [4], resulting in a longer duration of mechanical ventilation and intensive care unit (ICU) stay after surgery [9, 10]. In addition, malnutrition is related to delayed mental development, poor school performance, and decreased intellectual capacity in CHD children [11, 12].

Malnutrition in these patients is multifactorial; factors that reduce calorie intake and increase energy expenditure are involved in its mechanism. Anorexia, early satiety, fatigue on feeding, and fluid restriction are among the factors that lead to low total intake in patients with CHD [3, 11]. It has been reported that the intake of some nutrients in these patients is lower than the recommended values for their age [13]. CHD children may need to eat more frequently to compensate for the increased metabolic demands. However, despite a higher meal frequency, the intake may not meet the needs for growth [14], and the feeds may need to be enriched to increase the intake of nutrients in a tolerable fashion.

By definition, a high-density formula has a higher calorie content and more macronutrients and micronutrients than the standard formula [15]. However, increasing the density of the feed may have a negative effect on tolerance, which may ultimately lead to an insignificant difference in calorie intake compared to the standard feed.

To the best of our knowledge, no systematic review has been conducted to investigate the effect of high-density feeding on children's weight gain following heart surgery. Therefore, the present study systematically reviewed the impact of high-density formula on weight gain in infants with CHD.

Methods

Information sources and search strategy

This systematic review of studies was conducted based on the PRISMA (the preferred reporting items for systematic reviews and meta-analyses) guideline [16]. The comprehensive search strategies were used to identify reports of RCTs indexed in Web of Science, PubMed, and Scopus databases from January 1, 1990, to December 30, 2022. The following syntax was used to search studies: ((Heart [tiab] AND malformation [tiab]) OR (defect [tiab] AND congenital [tiab] AND heart [tiab]) OR (heart [tiab] AND abnormal*[tiab]) OR ("heart defect"[tiab] AND congenital [tiab]) OR (abnormal*[tiab] AND heart [tiab]) OR "heart abnormality"[tiab] OR (congenital [tiab] AND heart [tiab] AND defect [tiab])) AND (nutrition [tiab] OR feeding [tiab] OR "high calorie"[tiab] OR "high energy"[tiab] OR malnutrition[tiab] OR (nutrition*[tiab] AND deficienc*[tiab]) OR undernutrition [tiab] OR malnourish*[tiab]).

In addition, the reference lists of journal articles were checked to find additional studies. Also, manual searching of relevant journals and grey literature was performed.

Eligibility criteria and selection process

The RCTs with the following criteria were included: Nutritional interventions that compared high-density formula with standard formula, studies that assessed weight changes, and studies on CHD infants under 2 years. We excluded studies that assessed food fortification in infants older than 2 years. Also, we excluded books, reviews, editorials, letters, and articles that did not intend to assess the effects of high-density formula on weight gain. After excluding papers based on the titles and abstracts, the full texts of the remaining papers were read carefully.

Data extraction

Two independent reviewers (Maryam Aryafar and Zahra Irannejad Niri) screened titles, abstracts, and full texts of articles. We resolved any discrepancies through consensus with the chief investigator (Maryam Aryafar).

The following information was obtained from each study: First author's name, year of publication, study location, study duration, the calorie content of infant formula, the gender of subjects, trial design, number of participants in each group, and changes in outcome measures from baseline to the end of the trial.

Quality assessment

We assessed the quality of the included studies using the Cochrane scoring system [17]. Six criteria of this tool were used to determine the risk of bias: Random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and selective reporting. Three choices of "yes," "no," or "unclear" could be given to each item mentioned above. The resulting scores are interpreted as high risk, low risk, and unknown risk, respectively (Table 1).

Results

Our primary search detected 3817 records; 729 duplicates were identified and removed (Figure 1). After screening based on titles and abstracts, 11 articles remained for more evaluation. In the next phase, 6 articles were excluded after reading the full text. The exclusion was due to study samples (older than 2 years) and using macronutrients to enrich the formula. Finally, 5 studies were included in this systematic review.

Characteristics of the included studies

The characteristics of the included articles are outlined in Table 2. These studies were published from 2004 to 2022. Their follow-up was from 5 days [18] to 30 days [19]. The sample size in the included studies ranged from 23 [20] to 32 subjects [21].

Among the 278 children enrolled in these trials,140 subjects were allocated to the high-density formula and 138 to the standard formula. All studies were carried out on both genders. Participants in these studies were children with CHD.

Pillo-Blocka et al. [20] compared rapid advancement to higher concentration formula and standard advancement in infants after heart surgery. On days 1 or 2, infants in the control group initially received formula with an energy concentration of 67 kcal/100 mL, which increased to 79 kcal/100 mL on days 3 to 5 and 91 kcal/100 mL on day 6, when subjects were discharged from the hospital. In the intervention group, the concentration of formula was increased more rapidly to the higher concentration, such that on day 1, subjects received 79 kcal/100 mL formula, on day 2, 91 kcal/100 mL formula, and on day 3, 100 kcal/100 mL formula until their discharge from the hospital. The other aspects of the feeding process were similar between the two groups. Energy requirements for all subjects were determined based on the weight-for-length percentile. For

study subjects whose weight-for-length was 85% or more for the ideal percentile, energy values ranged from 95 to 120 kcal/kg/d. For subjects whose weight-for-length was less than 85%, energy requirements were defined as 150 kcal/kg/d. Three days before discharge from the hospital, the rate of weight gain was significantly higher for the intervention group (median gain=20 g/d) than the control group (median loss, 35 g/d). In the intervention group, only one patient had feeding intolerance (emesis) after receiving 100 kcal/100 mL formula for 3 days. This complication was resolved after changing the formula to 67 kcal/100 mL [15].

Cui et al. [18] compared protein and energy-enriched formula and the standard formula in 50 infants in the first 5 days after congenital heart surgery. Both groups received enteral feeding up to 130 mL/kg/day. Nutrient intakes were significantly higher in the enriched formula group after day one, and all met the adequate intakes as

Table 1. Risk of bias assessment for included studies using cochrane scoring system

Author (y)	Random Sequence Generation	Allocation Concealment	Blinding of Participants and Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Outcome Reporting	Other Sources of Bias
Aryafar et al. 2022 [21]	L	H	H	H	U	L	L
Scheefer et al. (2019) [19]	L	L	L	U	H	L	L
Zhang et al. 2018 [22]	L	U	L	L	U	L	L
Cui et al. 2018 [18]	L	H	L	L	L	L	L
Pillo-Blocka et al. 2004 [20]	L	U	H	H	L	L	L

Abbreviations: U: Unknown risk; L: Low risk; H: High risk.

Table 2. Summary of clinical trials included randomized control trials in the systematic review

First Author (y)	Location	Infants/Children Characteristics	Age (month) HDF/SF	Sex (F/M)	Sample Size HD HDF/SF	Duration, d	Group		
							Treatment	Control	Outcome
Aryafar et al. 2022, [21]	Iran	CHD	6 to 12	27/37	32/32	28	HDF 0.9 kcal/mL	S F 0.67 kcal/mL	Higher weight gain by HDF(P<0.05) No difference in tolerability
Scheefer et al. (2019) [19]	Brazil	21 Cyanotic/38 Acyanotic	7.28±6.4/ 6.25±7.08	35/24	29/30	30	HDF 1 kcal/mL	S F 0.67 kcal/mL	Higher weight gain by HDF (P=0.03) No difference in tolerability
Zhang et al. 2018, [22]	China	38 Cyanotic/21 Acyanotic	2/2	20/39	30/29	7	HDF 1 kcal/mL	S F 0.67 kcal/mL	Less weight loss by HDF (P=0.001) Tolerability of HDF lower than SF
Cui et al. 2017 [18]	China	CHD	4.69±3.54/ 5.23±2.49	14/38	26/24	5	HDF 1 kcal/mL Pro 2.6 g /100 mL	S F 0.67 kcal/mL pro 1.4g /100 mL	Higher weight gain by HDF (P=0.078) No difference in tolerability
Pillo-Blocka et al. 2004, [20]	Cana-da	18 cyanotic/28 Acyanotic	0.42±0.27 /0.56±0.25	Both	23/23	6	HDF 0.77-1 kcal/mL	S F 0.67 kcal/mL	Higher weight gain by HDF (P<0.05) No difference in tolerability

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Abbreviations: HDF: High-density formula; SF: Standard formula; CHD: Congenital heart disease.

early as day two. Nitrogen balance in the enriched-formula group met positive balance from day 2, compared to day 5 in the standard-formula group. However, no significant differences were observed in weight change between the high-density formula group and the standard-formula group (0.068±0.28 kg vs 0.067±0.25 kg; P=0.078). Regarding gastrointestinal tolerance parameters, there was a significantly higher stool volume on day 3 and significantly increased stool frequencies on both day 3 and day 4 in the enriched-formula compared to the standard-formula group [18].

Aryafar et al. [21] reported that the weight, height, and mid-arm circumference of infants (P=0.0001, P=0.001, and P=0.0001 for weight, length, and mid-arm circumference, respectively) and their z-scores at the end of the eighth week were higher in the high-density formula group than in the standard-formula group. However, the head circumference and its z-score improved in both groups after 8 weeks, but there was no significant difference between them. In both groups, serum albumin levels increased in the eighth week after surgery compared to the beginning of the study (before surgery), which was higher in the high-density formula group than the standard formula group (P=0.012). At the end of the eighth week after surgery, serum concentrations of iron and ferritin did not differ between the two groups.

Zhang et al. [22] compared the high-energy formula (100 kcal/100 mL) with the standard formula (67 kcal/100 mL) on weight gain and gastrointestinal tolerance in 64 postoperative infants with CHD for 7 days at the cardiac ICU. The mean weight gain in both groups was negative. However, infants who received high-energy formula showed less weight loss (-16 g) than those who received standard formula (-181 g). Gastrointestinal intolerance, including diarrhea (n=1), abdominal distension (n=1), and gastric residual volume of more than one-third of the previous feed (n=2), was more frequent in the intervention group. However, infants in the control group showed no gastrointestinal problems [22].

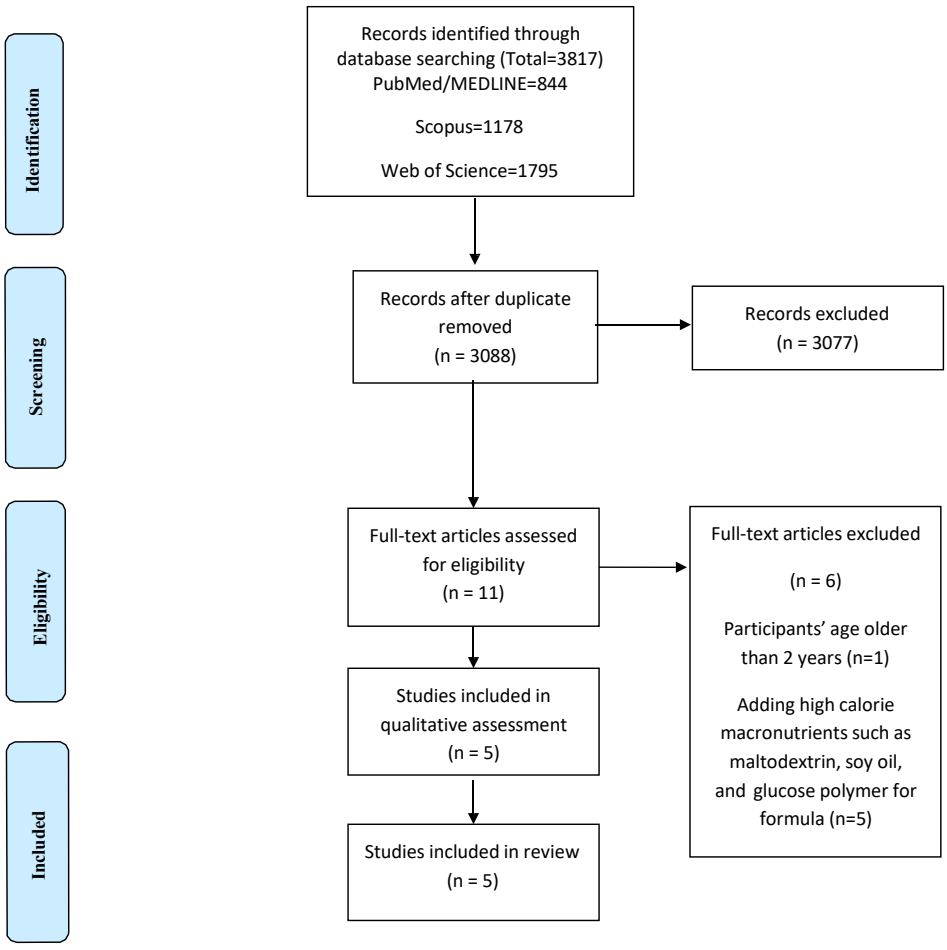

Figure 1. PRISMA flow diagram of the systematic review

Scheeffer et al. [19] compared the effect of the energy-enriched formula (1 kcal/mL) with the standard formula (0.67 kcal/mL) in 59 infants during 30 days after heart surgery. Diet volume was increased according to the specific condition of each infant, aiming to reach 120 kcal/kg for infants with appropriate weight-for-length and 150 kcal/kg for those with low weight-for-length. In both groups, patients received the formula along with complementary feeding. The mean daily weight gain was higher in the enriched formula group, with a mean of 16 g/d compared to 10 g/d in the control group. However, this difference was not statistically significant. The weight gain variation rate was significantly higher in the enriched-formula group, and there was a significant difference in weight-for-age z-score between groups. This difference was not observed before randomization. Gastrointestinal intolerance after starting enteral nutrition was not statistically significant between groups (11 patients in enriched formula and 8 patients in standard-formula group). Among the enriched-formula group with intolerance, 6 patients presented spontaneous resolutions of symptoms after 1 day (diarrhea=4 and emesis=2). Two patients with diarrhea had improvement after adjustment of enteral feeding rate, and two patients with emesis needed to change the formula.

Study quality and risk of bias findings

Quality score of the included clinical trials is presented in Table 1. All studies obtained low risk in randomization and selective reporting [18-22]. Blinding of participants was not reported in two studies [19, 21], and personnel blinding was reported in three studies [18, 20, 22]. All studies had a randomization design, so selection bias was not considerable. However, blinding was not performed for all studies to somewhat. Therefore, performance bias and detection bias existed. Of course, all participants in the included studies were children under 2 years, and blinding participants could not affect the results despite affecting adults.

Discussion

In the present systematic review, we summarized available reports from 4 RCTs that investigated the effect of high-density formula on the weight change of infants after congenital heart surgery. Most studies (4 out of 5) suggest that feeding with a high-density or concentrated formula can improve weight gain in pediatric patients following heart surgery compared to the standard formula. Of the 4 RCTs included in this review, only 1 study showed no significant effect of the enriched formula on weight gain; however, weight gain was still potentially higher in the enriched formula than in the standard formula group in the mentioned study. Besides, the infants of the formula-enriched group reached a positive nitrogen balance much faster during the study period [18].

The nutritional requirement of pediatric patients with CHD is high due to increased energy expenditure and low energy reserves. One nutritional measure that can increase calorie intake in these patients is an increased calorie density of infant formulas by adding extra energy in the form of macronutrients such as maltodextrin, soy oil [23], and glucose polymer [24]. However, this practice did not recognize that increased nutritional requirement for catch-up growth requires increased nutrients, not just energy and or protein [15].

Increasing the frequency of daily feedings will increase calorie intake and nutrients. However, it has been reported that despite a higher meal frequency and the higher fat content of the feeding to increase calorie density, pediatric patients with CHD appear to have a low intake of some micronutrients [14]. Increased calorie and nutrient intake can still be achieved by increasing the feed volume. However, restriction of fluid intake in the early stage after heart surgery, especially for complex cases, can cause further limitations in the intake of these patients with increased needs and low energy reserves. Preparing a formula using less water than the manufacturer's recommendation (concentrating the formula) and increasing the calorie content will proportionately increase all other macro and micronutrient content in the feed. However, increased density of the formula leads to elevated osmotic pressure that can increase gastrointestinal intolerance, such as diarrhea, emesis, and abdominal distention. In the reviewed studies, diarrhea was the most common intolerance observed with high-calorie density formulas. However, It has been suggested that gastrointestinal intolerance can be improved by gradually incrementing the formula density over 3-5 days [22].

To the best of our knowledge, this is the first systematic review of the effect of high-density formula on weight gain in infants with CHD. However, some limitations should be noted. First, there were very few studies that did a meta-analysis. Second, these studies were carried out

on different durations of formula administration, which might influence weight gain. Also, searching more databases such as Embase and Cochrane may add more studies for evaluation in this field. Finally, the included studies have used different formulas, which might have affected the findings.

Conclusion

Enriching the standard infant formula to achieve a high-density formula can be a practical, effective, and inexpensive method to increase calorie, macro, and micronutrients as a part of postoperative care management to meet the requirements in infants after cardiac surgery repair. Increased calorie density up to 1 kcal/mL has been associated with low and tolerable gastrointestinal side effects. Further research is needed to determine the longer-term effects of feeding CHD children with the high-density formula on promoting lean mass and linear growth after hospital discharge.

Ethical Considerations

Compliance with ethical guidelines

There were no ethical considerations to be considered in this research.

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Authors contributions

Study design, dtata interpretion and writing: Maryam Aryafar; Searching literature, data extraction and final approval: Both authors.

Conflicts of interest

The authors declared no conflict of interest.

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