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Letter to the Editor

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Optimising nutrition in infants with CHD: exploring the supplemental spoon-feeding strategy

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To
The Editor
Dear Sir,

We must congratulate and recognise the significant contribution made by Jangid et al.[1] The authors undertook an open label, pilot, randomised controlled trial, which offers valuable insights into addressing growth failure in infants with unoperated acyanotic CHD. The effort and dedication required to execute and complete such a study are indeed commendable. Our subsequent critiques are made with full appreciation of the challenges faced in conducting this clinical research. While the research presents a promising approach, several considerations emerge upon closer examination:

1. **Delayed enrollment age:** The enrollment of infants under 5 months old may be delayed, considering that many infants have already transitioned to complementary feeds by this age, potentially affecting the generalisability of the findings.
2. **Enrollment criteria:** The inclusion criteria, focusing on full breastfeeding, might inadvertently include infants already receiving supplemental expressed milk feeds due to attachment issues or illness severity. This could impact the randomisation process and introduce bias into the study.
3. **Outcome measures:** The authors have taken weight and weight gain velocity as the outcome measures to study the impact of the intervention; however, body composition measurement and dry weight assessment would have been a better parameter in these infants as they are predisposed to have excessive weight gain due to fluid retention and congestive cardiac failure.
4. **Allocation concealment was not done:** The authors have not mentioned the technique of allocation concealment. After going through the baseline parameters in both the groups, it appears that there was allocation bias and infants with more severe congestive heart failure were allocated to the control arm.
5. **Disease severity adjustments:** Given the differences in Ross scores and left ventricular internal dimension in diastole between the two groups, adjusting the primary outcome for disease severity would enhance the validity of the findings.
6. **Methodological clarifications:** Important methodological details, such as the method for determining milk volume ingested and ensuring compliance, are lacking. These omissions could introduce confounding variables and affect the reliability of the results.
7. **Excessive fluid justification:** Given the complexities of fluid management in moderate to severe CHF, it is essential to revisit the justification for administering additional expressed breast milk.[2,3] There is a compelling argument for implementing measured feeds to mitigate the risk of fluid overload in these infants.
8. **Short-term follow-up:** The short-term follow-up period of 2 and 4 weeks may not capture long-term effects adequately. Longer follow-up periods, especially with earlier recruitment, would provide a more comprehensive understanding of the intervention's impact.
9. **Study flow and exclusions:** Providing the total number of patients screened along with the reasons for exclusion, in accordance with the CONSORT 2010 updated guidelines,[4] is crucial for evaluating both the study's generalizability and the potential for selection bias.
10. **Baseline characteristics:** Baseline parameters such as weight, haemoglobin levels, and maternal factors could significantly influence outcomes and should be thoroughly documented and analysed.
11. **Hospitalisation rate:** The observed trend towards higher hospitalisation rates in the control group suggests a potentially more severe disease presentation, which could confound the results. Details on the duration and reasons for hospitalisation are essential for interpreting the outcomes accurately.
12. **Severity stratification:** Providing information on the distribution of infants with moderate and severe congestive heart failure in each group would offer insights into subgroup differences and treatment effects.

13. **Suboptimal weight gain:** The high proportion of infants with suboptimal weight gain in both groups underscores the urgency of addressing growth issues in this population, aligning with existing guidelines on early corrective surgery for CHDs.
14. **Effect of medication dosage:** Variations in diuretic dosage and their impact on growth outcomes should be explored further, particularly concerning potential confounding effects on weight gain.
15. **Sample size adequacy:** The study's sample size limits its statistical power (post hoc power being 58.6% in intention to treat analysis and 76.5% in per protocol analysis) to detect meaningful differences, highlighting the need for cautious interpretation and potential validation through larger studies.

In conclusion, though Jangid et al.'s[1] study offers valuable insights into supplemental spoon-feeding strategies for infants with CHD, careful consideration of methodological nuances and potential confounders is necessary to interpret the findings accurately and guide future research efforts effectively.

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