Bone mineralization in the first year of life in infants fed human milk, cow-milk formula, or soy-based formula


Introduction

In several reports, soy-based infant formulas have been shown to support adequate growth in term infants, but concerns have been raised about the adequacy of bone mineralization. Manufacturers have since improved the suspensibility of minerals in these formulas (especially calcium and phosphorus) in order to improve their delivery and absorption by the infant.

Study Purpose

This study sought to further the understanding of growth and bone mineralization patterns during the first year of life for infants fed human milk, cow milk-based infant formula, or soy protein-based infant formula.

Study Design

The study had a single-blind, prospective design, with randomization to three formula groups. The three formula groups were compared with a concurrently recruited human milk-fed group. For ethical reasons, the human milk-fed group was self-selected by parental preference (n=10). For formula-fed groups, parents were aware of the specific formula assignment, but investigators measuring outcome variables were not. A total of 107 infants were enrolled in the study. Seventy-two infants continued in the study until at least the 16-week follow-up visit; this group of 72 infants was included in the analysis.

Study subjects were assigned to one of three groups:

1) Cow milk-based formula (Similac, Abbott Nutrition) (n=20)
2) Soy protein-based formula (Isomil, Abbott Nutrition) (n=21)
3) Soy protein-based formula (Prosobee, Mead Johnson) (n=21)
Subjects were examined at baseline (2-7 days old) and at 8, 16, 26, and 52 weeks of age. Three days prior to each follow-up visit, parents completed dietary records of the amounts of formula consumed and indices of formula tolerance. Measures of growth (e.g. weight, length, head circumference), bone mineral content (BMC) and selected blood chemistry values (e.g. serum ionized and total calcium, phosphorus, magnesium, alkaline phosphatase, and 1,25-(OH)$_2$D) were made at entry and at each follow-up visit.

Study Results

There were no significant differences in growth and bone mineralization during the first year of life in infants fed soy protein-based formula compared with infants fed cow milk-based formula. However, the rate of length gain was higher in formula-fed infants (all 3 groups) than in the human milk-fed group in the first 6 months of life ($p<0.01$), though this distinction did not persist at 1 year.

Serum phosphorus concentrations were higher in formula-fed than human milk-fed infants, but there were no differences in BMC between human milk-fed and formula-fed infants. Serum 1,25-(OH)$_2$D levels were elevated at 8, 16, and 26 weeks ($P<0.05, 0.01$ and 0.01 respectively) in those infants fed Prosobee.

Discussion

The results of this study support the theory that increased concentration and enhanced suspensibility of minerals in two commercially-available soy-based formulas appear to promote adequate growth and bone mineralization. Regardless of the mechanism for bone mineralization, it may be concluded that currently-available, soy-based formulas are an acceptable alternative for term, non-human milk-fed infants with lactose sensitivity or cow milk protein allergy and without allergy to soy.

While elevated 1,25-(OH)$_2$D concentrations are usually perceived as a physiologic adaptation to inadequate mineral intake or high mineral need, the elevated level of serum vitamin D in the Prosobee group was apparently sufficient to increase calcium absorption efficiency, leading to adequate BMC.

Study Conclusions

There appear to be no significant differences—either statistically or biologically—in growth and bone mineralization in the first year of life between infants fed cow milk-based formula and infants fed soy protein-based formula. Though the rate of length gain was higher in formula-fed infants in the first six months of life and there were some differences in blood chemistry values between the formula-fed infants and the human milk-fed infants, there were no differences in BMC.
References


