Soy-based formulae and infant growth and development: a review

Mendez M A, Anthony M S, Arab L

Authors' objectives
To evaluate various measures of infant health and development in clinical studies comparing modern soy-based formulae (SBF) with other diets.

Searching
MEDLINE and ISI databases were searched using the search terms listed in the review; the search dates were not stated. Citations were checked for additional papers.

Study selection
Study designs of evaluations included in the review
The inclusion criteria for the study design were not stated a priori in the review. The included designs were clinical trials and observational studies.

Specific interventions included in the review
The inclusion criteria specified interventions of modern SBF compared with cow's milk-based formulae (CMF) and human milk (HM). Earlier formulations were also included so as to view longer-term endocrine effects for which data on modern SBF are not yet available. Follow-up studies on chloride-deficient soy formulas were excluded.

Participants included in the review
The inclusion criteria for the participants were not specified a priori and were not reported in the review.

Outcomes assessed in the review
The inclusion criteria for the outcomes were not specified a priori. Since the long-term follow-up of modern SBF is not yet possible, studies of early SBF were reviewed to assess adolescent and adult outcomes. The outcomes assessed in the review included nutritional status, reproductive or sexual development, and other outcomes (visual acuity, cognitive development, hypothyroidism, immune function, the use of asthma or allergy medication, and the incidence of asthma and eczema.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. The results of studies using modern SBF were presented only for short-term outcomes.

Methods of synthesis
How were the studies combined?
The reports were summarised in tabular format and were discussed in a narrative review.

How were differences between studies investigated?
The authors did not report a method for assessing any differences between the studies.
Results of the review

Five clinical trials (n=1,001) and one observational study (n=31) were reported in the tables of the review. However, additional studies were discussed; these included one large trial of young adults, which was a prospective cohort study, and another case study.

Nutritional status (5 studies).

The sample sizes were small. Each of the included studies reported comparable growth among infants fed SBF versus CMF or HM. Infants fed SBF had energy or fluid intake volumes similar to those fed CMF. Markers such as serum albumin and blood urea nitrogen suggested no differences in protein metabolism in children fed SBF versus CMF. Other measures were similarly equivalent, or higher, for children fed SBF than those consuming CMF or HM.

Reproductive or sexual development (2 studies).

The cohort study found that SBF and CMF feeding groups were similar with respect to multiple outcomes, including timing of pubertal maturation, menstrual cycle length, heaviness of menstrual bleeding, fertility, pregnancy outcomes, hormonal disorders and sexual orientation. The duration of menstrual bleeding was slightly longer and menstrual discomfort slightly more common among SBF-fed women. In the case-control study, there were positive associations between premature thelarche (breast development) and the consumption of early SBF and various meats. SBF alone could not explain the results.

The data for other outcomes were limited, but generally they suggested that modern SBF support healthy development.

Authors’ conclusions

The results suggested that SBF support normal growth and nutritional status in healthy term infants in the first year of life. However, the data for other outcomes were limited. The available data did not provide evidence of meaningful differences in timing of maturation, sexual development, or fertility in adolescents or adults.

CRD commentary

This systematic review barely met the inclusion criteria for abstracting and is of questionable benefit. Both the quality of the systematic review and the quality of the included studies was very poor. The research question was stated, but the inclusion criteria and review process were poorly reported. There was no attempt to assess the validity of the included studies and the nature of the data prevented a statistical analysis.

The results were not conclusive. The authors’ conclusions were correct in that additional research is needed in this area.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that, given the lack of evidence in this review, further research following infants fed SBF into adulthood is warranted.

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