

Should we change formula for a formula-fed infant with persistent spitting up, but with adequate weight gain?

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■ EVIDENCE-BASED ANSWER

We found no controlled trials evaluating the efficacy of changing formulas in the management of uncomplicated regurgitation. However, the evidence suggests that no benefit can be expected from changing formulas, including the discontinuation of iron-fortified formulas.^{1,2} Additionally, changing formulas leads many mothers to believe that their child has a disease or illness.³ Although controlled trials of infants with gastroesophageal reflux disease (GERD) show that formula thickening (eg, with rice cereal) decreases spitting-up,⁴ and expert consensus panels recommend formula thickening (along with parental reassurance) as first-line therapy in the management of uncomplicated regurgitation,⁵ one could question whether these outcomes in infants with GERD would hold for infants with uncomplicated regurgitation. Flat-prone positioning and avoiding the seated position is beneficial in infants with GERD, but the association of prone positioning with sudden infant death syndrome limits this intervention.⁵ (Grade of recommendation: D, based on a synthesis of information from controlled trials performed in other patient populations, retrospective surveys, physiologic evidence, and consensus expert opinion.)

■ EVIDENCE SUMMARY

Reflux of gastric contents into the esophagus (both regurgitant [into the mouth] and nonregurgitant) is a normal physiologic event. The incidence of regurgitation is similar in breast-fed and formula-fed infants, occurring in up to 67% of 4-month-olds. In the majority of infants, regurgitation is uncomplicated and self-limited, resolving spontaneously by 6 to 12 months of age,^{5,6} with 21% of 6- to 7-month-old infants and 5% of 10- to 12-month old infants experiencing regurgitant reflux.⁶ In less than 3% of infants, reflux is severe enough to result in clinically significant GERD.⁵ GERD is suggested by persistent irritability, sleep disturbance, abnormal posturing, hematemesis, excessive crying, respiratory symptoms, and failure to thrive.⁷

True allergy to cow's milk or soy-based formulas likely occurs in less than 2% of infants,⁸ but is unlikely to present with vomiting as the only symptom. Temporary carbohydrate intolerance may occur with gastroenteritis, malnutrition, or in preterm infants, but otherwise is rare in infancy.⁹ Controlled trials have demonstrated no

difference in colic, spitting-up, vomiting, fussiness, cramps, flatus, or stools frequency between iron-fortified and nonfortified formulas.^{1,2}

Retrospective surveys studying outcomes associated with formula change reveal that approximately one third of infants experience a formula change,³ but the retrospective nature of these studies, lack of blinding and control groups, and self-limiting nature of regurgitation makes interpretation of these studies difficult.

In infants with GERD, formula thickening has numerous benefits, including reductions in frequency of regurgitation, total volume of emesis, and time spent crying by one third, and an increase in time spent sleeping by 18% per 90-minute postprandial period. Formula thickening also increases the frequency of postprandial cough, but the clinical significance of this is unclear. Aspiration was not observed on scintigraphic examination following thickened feedings.⁴

Dry rice cereal (one tablespoon per ounce of formula) is a common thickener with excellent digestibility, but increases the caloric density of formula and can cause constipation. Thickened formulas also require enlarged nipple holes to feed, potentially resulting in greater ingestion of air or formula, which can favor regurgitation. Commercially available pre-thickened formulas are nutritionally balanced, convenient, well tolerated, and do not require enlarged nipple holes to feed.⁵

Increased frequency of feedings with smaller volumes has not been proved efficacious, is difficult to implement, and may create distress in a hungry infant. In overfed infants, or infants fed large volumes at infrequent intervals, feeding volume or feeding interval should be reduced. There is no benefit to head-elevated prone versus flat-prone positioning.

■ RECOMMENDATIONS FROM OTHERS

The European Society for Pediatric Gastroenterology, Hepatology and Nutrition recommend parental reassurance and formula thickening as first-line therapy for the management of infants with uncomplicated regurgitation.⁵ Flat-prone positioning, further evaluation, or a trial of H2 blockers may be considered in infants not responding to first-line therapy.

CLINICAL COMMENTARY

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Every family physician has his or her “top 10” when it comes to parental questions about an infant or child. My experience is that most parents appreciate knowing when a problem is nothing serious and can be managed with simple interventions. Infants with persistent spitting up who appear healthy and are gaining weight appropriately need parental reassurance and education, not a formula change.

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