

**Charles A. Crotteau, MD**  
University of Illinois at Chicago

**Sarah Towner Wright, MLS**  
University of North Carolina at  
Chapel Hill

## What is the best treatment for infants with colic?

### EVIDENCE-BASED ANSWER

Infantile colic, defined as excessive crying in an otherwise healthy baby, is a distressing phenomenon, but there is little evidence to support the many treatments offered. Several small studies report some benefit from use of a hypoallergenic (protein hydrolysate) formula, maternal diet adjustment (focusing on a low-allergen diet), and reduced stimulation of the infant. While dicyclomine has been shown to be effective for colic, there are significant concerns

about its safety, and the manufacturer has contraindicated its use in this population. An herbal tea containing chamomile, vervain, licorice, fennel, and balm-mint was also effective in a small RCT, but the volume necessary for treatment limits its usefulness (strength of recommendation: **B**, inconsistent or limited-quality patient-oriented evidence). The one proven treatment is time, as this behavior tends to dissipate by 6 months of age.

### CLINICAL COMMENTARY

#### For pure colic, only time will help

A broad definition for colic may capture infants who cry for a variety of reasons. I consider pure colic to be a patterned daily behavior of crying that a parent can predict will occur and stop at certain times, and the baby is fine at other times of day. For these babies, I wouldn't expect a change in formula or maternal diet to help; they greatly improve by about age 3 months.

However, for babies who are fussy and difficult to console throughout day and night, further evaluation and dietary

changes are worth trying. For breastfeeding mothers, I usually start with dairy avoidance and test the baby's stools for microscopic blood to be sure there is no colitis related to maternal diet. Only if there is evidence of infant colitis or allergy should a more restrictive maternal diet be prescribed. For formula-fed infants, a change to a protein-hydrolysate formula is worth a try, the main risk being the cost of the formula.

**Anne Eglash, MD**  
Department of Family Medicine, University of Wisconsin  
Medical School, Madison

### ■ Evidence summary

Colic has been described using the "rule of 3": crying for at least 3 hours per day on at least 3 days per week for at least 3 weeks.<sup>1</sup> The distinction can be subtle; a normal infant can cry more than 2 hours

per day. This syndrome has its onset typically in the first few weeks of life. It spontaneously resolves by age 4 to 6 months. Prevalence depends on the definition used for colic; approximately 5% to 25% of infants meet some reasonable definition of

colic.<sup>2</sup> The cause of infantile colic is poorly understood. Although clinicians tend to focus on a likely gastrointestinal cause, neuropsychological issues, food allergy, and parenting misadventures are also potential contributing factors.

There are myriad strategies—ranging from craniosacral osteopathic manipulation to car ride simulation—offered for dealing with infantile colic. Although none of these treatments has been validated in rigorous studies, the available evidence offers tentative support for 3 strategies: (1) a trial of a hypoallergenic (protein hydrolysate) formula (for formula fed infants), (2) a low-allergen maternal diet (for breastfeeding mothers), and (3) reduced stimulation of the infant.

A systematic review analyzed controlled clinical trials lasting at least 3 days involving infants less than 6 months of age who cried excessively.<sup>3</sup> Twenty-seven studies were included; the outcome measure was colic symptoms, typically reported as duration of crying. Two reports studying hypoallergenic (protein hydrolysate) formula in nearly 130 infants found an effect size of 0.22 (95% confidence interval [CI], 0.10–0.34) for the hypoallergenic formula. Additionally, 3 behavioral trials (involving nearly 200 infants) revealed the benefits of reduced stimulation of the colicky infant (effect size of 0.48; 95% CI, 0.23–0.74).

A more recent systematic review<sup>4</sup> followed a similar high-quality search strategy and identified 22 articles, and reported a number needed to treat (NNT) of 6 for the 2 hypoallergenic formula studies identified in the previous review.<sup>4</sup> Because of concern regarding the quality of the behavioral studies involving infants with colic, the authors of this second review only included 1 small (42 patients) trial of decreased stimulation, which resulted in a relative risk (RR) of 1.87 (95% CI, 1.04–3.34) and a NNT of 2. There was some inconclusive evidence to suggest benefit to dietary adjustment for breastfeeding mothers (specifically, the avoidance of cow's milk and other potential allergens like nuts, eggs, and wheat).

A recent randomized controlled trial confirmed the value of this approach by showing significant improvement in distress scores of infants whose mothers followed a low-allergen diet (excluding dairy, soy, wheat, eggs, peanuts, tree nuts, and fish) for 7 days.<sup>5</sup> This well-designed study included 107 patients (a relatively large sample in the published research about colic), and showed an absolute risk reduction of 37% (NNT=3) for those mothers following the challenge.

A small RCT (43 patients) suggested efficacy in the substitution of a whey hydrolysate formula in place of cow's milk-based formula for infants with colic (casein hydrolysate formula has been more widely studied), but there continues to be controversy regarding the preferred protein hydrolysate formula (whey vs casein) in the treatment of colic.<sup>3</sup>

Several medications have been tested in RCTs; only dicyclomine has shown an effect in a few small RCTs.<sup>3,4</sup> However, there have been reports of apnea and other serious, although infrequent, adverse effects. For that reason, the manufacturer has contraindicated the use of this medication in infants aged <6 months.

A small (n=68) study of an herbal tea showed reduced symptoms (RR=0.57 favoring the active tea), although the mean volume of tea consumption (32 mL/kg/d) is a nutritional concern in this age group.<sup>6</sup> No adverse events were noted, but the small sample size limits the ability to detect any but the most common events.

### Recommendations from others

The American Gastroenterological Association recommends a hypoallergenic, protein hydrolysate formula for formula fed infants or a maternal low-allergen diet as an initial strategy for infant struggling with colic symptoms if the clinician is considering a diagnosis of (cow's milk) allergy.<sup>7</sup>

The American Academy of Family Physicians on their familydoctor.org web site makes no specific formula or diet adjustment recommendations.<sup>8</sup> The web site does list some techniques (eg, massage

### FAST TRACK

**There may be some benefit in hypoallergenic baby formula or adjusting the mother's diet, but the only proven treatment is time**

or warm compress of abdomen, swing or car rides) not supported by the available evidence. The National Library of Medicine and the National Institutes of Health web site Medline Plus presents similar information.<sup>9</sup> The American Academy of Pediatrics does not address the topic on its public web site.

#### REFERENCES

1. Wessel MA, Cobb JC, Jackson EB, Harris GS Jr, Detwiler AC. Paroxysmal fussing in infancy, sometimes called colic. *Pediatrics* 1954; 14:421–435.
2. Kilgour T, Wade S. Infantile colic. *Clin Evid* 2005; 13:362–372.
3. Lucassen PL, Assendelft WJ, Gubbels JW, van Eijk, JT, van Geldrop WJ, Neven AK. Effectiveness of treatments for infantile colic: systematic review. *BMJ* 1998; 316:1563–1569.
4. Garrison MM, Christakis DA. A systematic review of treatments for infant colic. *Pediatrics* 2000; 106:184–190.
5. Hill DJ, Roy N, Heine RG, et al. Effect of a low-allergen maternal diet on colic among breastfed infants: a randomized, controlled trial. *Pediatrics* 2005; 116:e709–e715.
6. Lucassen PLBJ, Assendelft WJJ, Gubbels JW, van Eijk JT, Douwes AC. Infantile colic: crying time reduction with a whey hydrolysate: a double-blind, randomized, placebo-controlled trial. *Pediatrics* 2000; 106:1349–1354.
7. Sampson HA, Sicherer SH, Birnbaum AH. AGA technical review on the evaluation of food allergy in gastrointestinal disorders. *Gastroenterology* 2001; 120:1026–1040.
8. Familydoctor.org [web site]. Colic: Learning how to deal with your baby's crying. Last updated April 2005. Available at: [familydoctor.org/036.xml](http://familydoctor.org/036.xml). Accessed on June 12, 2006.
9. Colic and crying. Medline Plus, last updated August 23, 2005. Available at: [www.nlm.nih.gov/medlineplus/ency/article/000978.htm#Treatment](http://www.nlm.nih.gov/medlineplus/ency/article/000978.htm#Treatment). Accessed on June 12, 2006.