



Best Practice

Evidence based information sheets for health professionals

The effectiveness of interventions for infant colic

Recommendations

- An examination of the infant should be conducted to eliminate other possible physiological problems (**Grade A**)
- Simple causes of crying, such as hunger and cold, need to be excluded. This consultation should include questions concerning the infant's diet, indications of reflux, sleeping, bowel excretion and urination patterns, parents' general well being and social situation of the infant (**Grade A**)
- Affirm the parents' or care givers' efforts in caring for their distressed baby and acknowledge the sense of helplessness they may feel at seeing their baby so distressed (**Grade A**)
- Encourage parents to seek support from other family members to assist with care of the baby to allow parents to get some rest. Follow-up phone calls by the health professional to provide support and affirmation. Affirmation of parents and their efforts in caring for their baby is paramount (**Grade A**)
- Dietary interventions should aim to reduce or eliminate allergens that may be present in cow's milk from the infant's diet and egg, wheat and nut products from the mother's diet (**Grade B**)
- Behavioural interventions need to be considered at each step such as parents' responsiveness through application at comfort strategies, for example soothing, rocking, holding, massage of abdomen and gentle pushing of legs onto (**Grade B**)
- Encourage parents to seek support from family members to assist with care of the baby to allow parents some rest. (**Grade B**)

Information Source

The body of evidence related to interventions for infant colic has not significantly changed since the first BPI on this subject was published in 2004.¹ This information sheet includes data from one additional randomised controlled trial,² a systematic review³ and a clinical guideline for routine post-natal care.⁴

Background

Many parents, caregivers and health professionals are faced with caring for an unhappy infant displaying symptoms associated with colic. Food allergies, gastrointestinal and behavioural factors have been suggested as possible causes. Infantile colic usually affects infants in the first few weeks of life and resolves itself before six months of age.³ It has been estimated that colic is prevalent in 40% of male and female infants. In the United Kingdom alone, up to one in six families consult their doctor or community nurse about symptoms of colic in their child.⁴ Although transient, colic creates considerable distress in infants and caregivers. Inconsolable, unexplained and incessant crying in a seemingly healthy infant leads to exhausted, frustrated and concerned parents seeking to comfort their child. In many cases interventions make little impact and it is simply a matter of waiting for the infant to 'grow out' of colicky symptoms.^{2,4} The argument that colic does not exist suggests that it is normal for infants to have increasingly longer bouts of crying from birth to about six weeks, after which the crying decreases.² Others have suggested that many infants thought to have colic are in fact hungry.

Assessment of excessive and inconsolable crying

A baby crying excessively, drawing the knees up to the stomach, or arching the back should be reviewed for the presence of infant colic by assessing and documenting the following conditions:⁴

- general health of the baby
- antenatal and perinatal history
- onset and length of crying
- nature of the stools
- feeding assessment
- woman's diet if breastfeeding
- family history of allergy
- parent's response to the baby's crying

Note: The infant should be assessed by a qualified medical practitioner to rule out other diagnoses. Excessive and inconsolable crying may also mean an infant is presenting in pain, needing urgent investigation.

Grades of Recommendation

These Grades of Recommendation have been based on the JBI-developed 2006 *Grades of Effectiveness*⁵

- Grade A** Strong support that merits application
- Grade B** Moderate support that warrants consideration of application
- Grade C** Not supported

Definitions and Symptoms of Colic

Colic has been defined as an attack of crying and apparent abdominal pain in early infancy. It is a common condition characterised by extended and repeated periods of crying or fussing in an otherwise healthy infant. A commonly used criterion for defining colic is Wessel's 'rule of threes', which states that infantile colic involves crying lasting for at least 3 hours a day, for at least 3 days in any one week, for at least 3 weeks in the first 3 or 4 months of life. A colicky infant might exhibit symptoms including: excessive crying, high pitched screaming, paroxysms of irritability and fussing, flushed face, drawing up legs, arching the back, clenching fists, passing wind, the abdomen feeling rigid and difficulty settling. These episodes, while they can occur at any time of the day or night, typically begin during late afternoon or early evening. Overfeeding, undiluted juices, food allergies, and emotional stress can aggravate colic.⁴

Objectives

The purpose is to provide an overview of the effectiveness of pharmaceutical, dietary and behavioural interventions for infantile colic as reported in the systematic reviews identified.^{1,2}

Quality of research about interventions for colic

Much of the research conducted into effective interventions for colic has been criticised for lacking methodological rigor. The authors of one systematic review reported that a third of the studies identified in their review (27 studies) did not meet their quality criteria. The other systematic review identified 22 studies and reported that only 5 met their three main quality criteria: adequate case definitions, adequate double-blinding, and adequate randomisation. These comments indicate there is a need for more primary research of a high standard to identify effective interventions for colic.

Types of Interventions

Pharmaceutical interventions

The pharmaceutical interventions include drugs acting as a relaxant on the muscle of the gut to reduce spasms and others that assist in expelling gas.

Simethicone (e.g. Infacol®)

Simethicone reduces surface tension of bubbles in the intestinal tract, which enables gas to be expelled more easily. Of the three trials comparing simethicone with a placebo only one trial showed a positive effect in the symptoms of colic but this trial was of poor quality, providing no information about how colic was defined or determined. No benefit of using simethicone to treat infantile colic was evident in the other two trials. No adverse effects were reported in the trials.³

Anticholinergic drugs - dicyclomine/dicycloverine (e.g. Merbentyl®)

These drugs are used to relax the muscle in the wall of the gut to prevent spasms. Despite some findings of improvement in symptoms of colic, adverse effects were reported for a small number of infants treated with these drugs. Drowsiness, diarrhoea and constipation were the side effects most commonly reported, but severe adverse effects such as apnoea, seizures and coma have been published elsewhere in case reports. The manufacturers of dicyclomine have discontinued infant colic as an indication for treatment with dicyclomine and therefore this treatment is not recommended.³

Methylscopolamine

Methylscopolamine is a muscle relaxant that treats gastric or intestinal hypersensitivity or secretions. Symptoms of colic were reported as worse in 20% of infants who received the medication, while none of the infants who received the placebo were reported as worse. The drug was found not to be effective in treating colic and may in fact be unsafe to use as a treatment for colic.³

Dietary interventions

Many dietary interventions aim to reduce or eliminate cow's milk from the diet of the infant with colic or the infant's breastfeeding mother.^{2,3} In some diet interventions all major allergens, such as egg, wheat and nut products are eliminated from the mother's diet. For bottle fed babies, studies have substituted casein hydrolysate, whey hydrolysate, or soy milk for cow's milk in formula feeds to determine if a hypoallergenic diet is an effective treatment. Other interventions include lowering the amount of lactose in breast milk and formula milk by adding lactase, enriching formula milk with fibre, herbal tea and sucrose solutions.⁴

Elimination of cow's milk vs cow's milk in diet of breastfeeding mother

Cow's milk was eliminated from the diet of breastfeeding mothers in a small trial. Although eliminating cow's milk alone did not affect symptoms of colic, on the days the mothers ate fruit or chocolate the infants' symptoms of colic were more frequent. Breastfeeding mothers with atopic disorders (eczema, asthma, and allergic rhinitis) reported their infants had higher rates of colic on days when cow's milk was part of their diet. However, these results were not statistically significant and concerns about the case definition used in the trial means the findings cannot be regarded as conclusive.³

Lactase supplement vs placebo for breast-fed and formula-fed infants

Regardless of whether the infant is breast-fed or bottle-fed, there is no evidence that supplementing an infant's diet with lactase (to reduce the amount of lactose) is effective in treating colic. The three trials that examined the effects of lactase on symptoms of colic had small sample sizes, which make their results inconclusive.²

Low allergen diet vs normal diet in breast-feeding mothers

One previously included trial found a low allergen diet produced worse outcomes in terms of colic symptoms compared to a control diet when the results were stratified by age and method of feeding. However, a more recent trial suggests the overall effect of a one week, low allergen diet among exclusively breastfed infants who are 6 weeks old with colic will reduce the risk of colic symptoms by 37%. This indicates low allergen maternal diets may play a more significant role than previous trials have suggested.^{2,4}

Low allergen formula vs cow's milk formula, soy-based formula and fibre enriched formula for bottle-fed infants

One systematic review consisted of 27 controlled trials. Five trials studied the effect of eliminating cows' milk on colic. Three trials used soya milk substitutes and two used a hypoallergenic formula. Hypoallergenic formula had a significant and beneficial effect while the effect of soy was not significant. Lowering the lactose content of formula had no effect, nor did the enrichment of formula with fibre. Comparison of breast milk with standard cow's milk in infants who were weaned showed no significant difference.³

Summary of Treatment Effects⁴

Possibly useful interventions	No effect	Possibly harmful
Dietary interventions Low allergen diet for breastfeeding mother Low allergen formula milk Sucrose solution (short term) Behavioural interventions Reduced stimulation Improved parental responsiveness	Pharmaceutical interventions Simethicone Dietary interventions Soy substitute formula milk Elimination of cow's milk from breastfeeding mother's diet Lactase supplement/low lactose milk Fibre enriched diet Behavioural interventions Increased carrying Car ride simulators Focused parent counselling	Pharmaceutical interventions Anticholinergic drugs Methyloscopolamine Dietary interventions Herbal tea

Herbal tea vs placebo

Herbal tea containing chamomile, vervain, liquorice, fennel, balm-mint has been compared to a placebo tea as a treatment for colicky infants. Infants were given the tea, up to three times a day, on commencement of an episode of colic. The infants given the herbal tea showed marked improvements after 7 days. Colic was eliminated in 57% of the infants given the herbal tea compared to 26% of infants in the placebo group. While these results suggest that herbal tea may be an effective treatment, it is not a recommended treatment. Commentators have expressed concern that the intake of herbal tea may reduce the intake of milk and consequently compromise an infant's nutritional intake. There is inadequate evidence to conclude that herbal teas are harmful, but several case studies showed that high consumption of herbal tea mixtures can cause toxic effects in the breast-fed infant. Furthermore, herbal teas containing liquorice (*Glycyrrhiza glabra*) are not recommended for breast-feeding women.⁴

Sucrose vs placebo

There is evidence that a sucrose solution can effectively treat colic in breast-fed infants. In two trials, colicky infants responded positively to sucrose. The first trial found that positive effects were seen in 89% of infants receiving sucrose compared to 32% of infants receiving the placebo. In the second trial a controlled environment measured the effects of sucrose on colicky and non-colicky infants. This trial found that both groups responded positively to sucrose. However, sucrose appears to be effective for only a short time as the infants' response only lasted, on average, between 3 and 30 minutes.³

Behavioural interventions

Very few of the behavioural interventions were effective in reducing colic symptoms. The studies that have examined behaviour modification interventions as treatments for colic were of poor methodological quality and therefore the findings should be treated cautiously. There is a clear need for more primary research of a higher quality to be conducted in this area.

Increased carrying vs general advice

In a trial examining the treatment effect of increased carrying, mothers in the treatment group were advised to carry their infants at least 3 hours more each day, regardless of whether the infant was crying. The treatment showed no effect on frequency or duration of infants' crying when compared with infants who were carried, on average, about two and a half hours less each day.³

Car ride simulators vs reassurance and support

One trial examined car ride simulators as a treatment for colic. Parents in the treatment group were asked to use the car ride simulator during colic episodes (for up to one hour per day) and parents in both groups were given reassurance and support. Car ride simulators did not reduce the crying time of colicky infants, nor was it effective in reducing maternal anxiety.³

Focused parent counselling vs reassurance and support

Focused parent counselling was compared with reassurance for parents of a colicky infant. The focused parent counselling included advice about early response to crying, responding with a gentle, soothing motion, avoidance of over-stimulation, pacifier use, and carrying strategies. The results of this trial indicated that focused parent counselling is no more effective than providing general information and reassurance to parents.⁴ Another trial provided a group of parents with training in parent-infant communication skills and daily counselling, and compared this intervention with a control group to identify the effect on their infants' colic symptoms. While this trial showed marked improvements in the symptoms of colic in infants of treatment group parents (up to 2.67 hours less crying each day compared to 0.17 hours less crying), the quality of the trial was poor.³ Another criticism of this intervention is the time and commitment required of parents.

Reducing stimulation vs empathetic interview

Decreasing the amount of stimulation to which an infant is exposed was tested in one trial as a treatment for colic with advice to mothers to reduce patting, lifting, and jiggling their baby as well as to reduce the level of auditory stimulation. Although there were significant improvements seen in babies (under 12 weeks) in the reduced stimulation group the quality of the sampling and potential for bias is such that the findings must be treated with caution.³

Reducing stimulation and increased carrying vs general advice

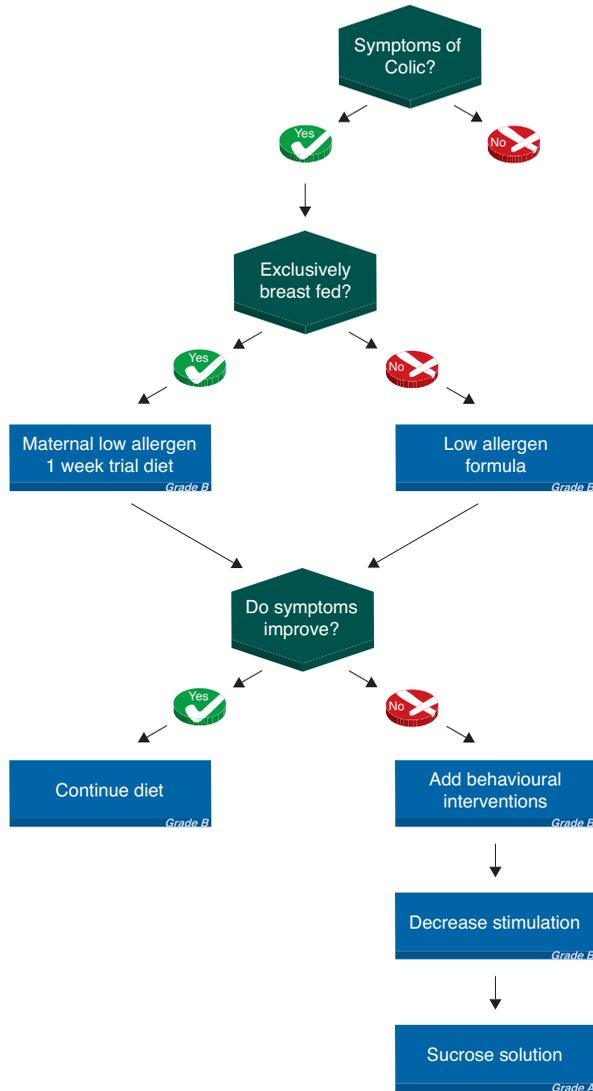
One trial tested whether reducing stimulation and increasing carrying of colicky babies would be an effective treatment compared to general advice provided to parents. No significant effects on symptoms of colic were found for the infants who were carried more and stimulated less.³

Diet vs behavioural treatment

Low hypoallergenic formula milk vs focused counselling to improve parent responsiveness

In a trial that compared two active interventions, one group of colicky infants was given hypoallergenic (casein hydrolysate) formula milk as a substitute for cow's milk or soy-based formula and the parents of another group of infants received focused counselling. This counselling included advice about responding to their baby's crying by feeding, holding, offering a 'dummy', stimulating, or putting the infant to bed. Results of this trial indicated that increasing parental responsiveness to their infants proved more effective in reducing symptoms of colic than the low hypoallergenic formula. On average, the infants of parents who received focused counselling cried 2.1 hours a day less compared with 1.2 hours a day less crying of infants receiving the dietary treatment.

Interventions for infant colic



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This Best Practice information sheet presents the best available evidence on this topic. Implications for practice are made with an expectation that health professionals will utilise this evidence with consideration of their context, their client's preference and their clinical judgement.⁶

References

1. The Joanna Briggs Institute. The Effectiveness of Interventions for Infant Colic. *Best Practice: evidence-based practice information sheets for health professionals* 2004; 8(2): 1-6.
2. Hill DJ, Roy N, Heine RG, Hosking CS, Francis DE, Brown J, Sperris B, Sadowsky J and Carlin JB (2005). Effect of a low-allergen maternal diet on colic among breastfed infants: A randomised, controlled trial. *Pediatrics*; 116(5): e709-715.
3. Garrison MM and Christakis DA (2000). Early childhood colic: Colic, child development, and poisoning prevention: A systematic review of interventions for infant colic. *Pediatrics*; 106(1): S184-190.
4. Demott K, Bick D, Norman R, Ritchie G, Turnbull N, Adams C, Barry C, Byrom S, Elliman D, Marchant S, Mccandlish R, Mellows H, Neale C, Parkar M, Tait P, Taylor C (2006). Clinical Guidelines And Evidence Review For Post Natal Care: *Routine Post Natal Care Of Recently Delivered Women And Their Babies*. London: National Collaborating Centre for Primary Care and Royal College of General Practitioners.
5. The Joanna Briggs Institute. Systematic reviews - the review process, *Levels of evidence*. Accessed on-line 2006 <http://www.joannabriggs.edu.au/pubs/approach.php>
6. Pearson A, Wiechula R, Court A, Lockwood C. The JBI Model of Evidence-Based Healthcare. *Int J of Evidence-Based Healthcare* 2005; 3(8):207-215.



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