



Best Practice

Evidence Based Practice Information Sheets for Health Professionals

The Effectiveness of Interventions for Infant Colic

Information Source

This *Best Practice* Information Sheet has been derived from two systematic reviews^{1,2} and an extract from *Clinical Evidence*.³ The studies included in the systematic reviews are listed in the full articles referred to on the back of this information sheet.

Background

There is no known cause of colic and it has been suggested by some that colic does not exist. Whether this is true or not, many parents, caregivers and health professionals are faced with caring for an unhappy infant displaying symptoms associated with colic. Infantile colic usually affects infants in the first few weeks of life and resolves itself before six months of age. The prevalence of colic has been estimated as high as 40% of male and female infants. In the United Kingdom, up to one in six families consult their doctor or community nurse about symptoms of colic in their child. Although transient, colic creates considerable distress in infants and caregivers. Inconsolable, unexplained, and incessant crying in a seemingly healthy infant gives rise to tired, frustrated and concerned parents seeking a way to comfort their child. In many cases interventions for colic

This Information Sheet Covers the Following:

- Symptoms of colic
- Pharmaceutical interventions
- Dietary interventions
- Behavioural interventions
- Implications for practice
- Recommendations

have little effect and it is simply a matter of waiting for the infant to 'grow out' of the colicky symptoms.

Although the cause of colic is not known, food allergies, gastrointestinal problems, environmental and behavioral factors have all been suggested as possible causes. 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. Others have suggested that many of the infants thought to have colic are in fact hungry.

Grade of Recommendation

These Grades of Recommendation have been based upon the JBI developed Grades of *Effectiveness*:

Grade A: Effectiveness established to a degree that merits application

Grade B: Effectiveness established to a degree that suggests application

Grade C: Effectiveness established to a degree that warrants consideration of applying the findings

Grade D: Effectiveness established to a limited degree

Grade E: Effectiveness not established

Definitions and symptoms of colic

Colic is 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' that 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 that include: excessive crying, high pitched screaming, paroxysms of irritability and fussing, flushed face, drawing up legs, arching the back, clenching fists, passing wind and difficulty settling.

Objectives

The purpose of this *Best Practice Information Sheet* 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}

The quality of research about interventions for colic

Much of the research conducted into effective interventions for colic has been criticised for its lack of methodological rigour. The authors of one of the systematic reviews 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.

Pharmaceutical interventions

The pharmaceutical interventions studied include drugs that act 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 the surface tension of bubbles in the intestinal tract, which enables gas to be expelled more easily. Of the three trials that compared 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. There were no adverse effects reported in the trials.

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

These drugs are used to relax the muscle in the wall of the gut to prevent spasms occurring. 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.

Methylscopolamine

Methylscopolamine is a muscle relaxant which can be used to treat gastric or intestinal hypersensitivity or secretions. Symptoms of colic were reported as worse in 20% of the 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.

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. In some diet interventions all major allergens, such as egg, wheat and nut products are also 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 for colicky infants. 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.

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. These researchers also noted that 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 can not be regarded as conclusive.

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 identified that have examined the effects of lactase on symptoms of colic had small sample sizes which render their results inconclusive.

Low allergen diet vs normal diet of breastfeeding mothers

The effect of a low allergen maternal diet (i.e. eliminating milk, egg, wheat and nut products) on colic in breast-fed infants is yet to be clearly demonstrated. One trial examined the effect of the low allergen diet on colic symptoms - comparing the findings with those of breast-fed infants of mothers whose diet included these products. This trial also compared low allergen formula with cow's milk formula for bottle-fed infants (see below). The daily duration of symptoms of colic in infants of mothers on the hypoallergenic diet (and infants fed with low allergen formula) were reduced by $\geq 25\%$ over a period of 8 days for 61% of these infants compared with 43% of the infants of mothers in the control diet group. These findings should be weighed against additional trial data supplied by the author, stratified by age and feeding method. This showed that the reverse occurred. That is, breast-fed infants of mothers in the control group had significantly better outcomes.

Low allergen formula vs cow's milk formula for bottle-fed infants

Mixed findings have been reported in trials of low allergen formula milk, in which casein hydrolysate or whey hydrolysate was substituted for cow's milk. One trial comparing low allergen formula milk (casein hydrolysate substitute) with a cow's milk formula showed marked improvements in the daily duration of symptoms of colic in infants fed with the low allergen formula when compared with the infants in the control diet group. The substitution of casein hydrolysate for cow's milk in formula milk was tested in a second trial that also reported significant improvements in colic symptoms of infants fed with the formula. However, the lack of rigour of both trials suggests that the findings should be treated with caution.

A third trial compared the effect of a low allergen formula (using whey hydrolysate as a substitute for cow's milk) against cow's milk formula. Babies fed with the low allergen formula cried, on average, 63 minutes less each day compared with the babies fed with cow's milk formula.

Soy-based formula vs cow's milk formula for bottle-fed infants

In a study that tested the effectiveness of soy formula in place of cow's milk formula, the soy replacement was found to reduce the crying time of infants with colic. A second trial provided insufficient details about the treatment effects to establish if the treatment was effective. Furthermore the sample was selected from infants who had

been admitted to hospital for colic symptoms. Although the findings of the first trial suggest that soy-based formula is an effective treatment for colic, further research is required to confirm these findings. There is some debate about substituting soy milk because it is thought that infants with an allergy to cow's milk are more likely to develop an allergy to soy protein products.

Fibre-enriched formula vs placebo for bottle-fed infants

The logic behind testing whether fibre-enriched formulas are an effective treatment for colic is based on the theory that the pathology of colic bears a resemblance to irritable bowel syndrome. One trial examined this treatment and found no difference in crying time between the group receiving the fibre enriched formula and the group receiving the placebo.

Herbal tea vs placebo

Herbal tea containing chamomile, vervain, liquorice, fennel, balm-mint has been compared with a placebo tea as a treatment for colicky infants. The 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 with 26% of infants in the placebo group. While these results suggest that herbal tea may be an effective treatment for colic, it is not a recommended treatment. Commentators have expressed concern that the intake of herbal tea may reduce the intake of milk and consequently negatively affect the nutrition received by an infant.

Although there is inadequate evidence to conclude that herbal teas are harmful, a number of case studies have shown that high consumption of herbal tea mixtures can cause toxic effects in the breast-fed infant. Furthermore, consumption of herbal teas containing liquorice (*Glycyrrhiza glabra*) is not recommended for breast-feeding women.

Sucrose vs placebo

There is some evidence that a sucrose solution can be an effective treatment for 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 with 32% of infants receiving the placebo. In the second trial a controlled environment was used to measure 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 a short time as the infants' response only lasted, on average, between 3 and 30 minutes.

Behavioural interventions

Very few of the behavioural interventions were found to be effective in reducing symptoms of colic. In general, the research studies that have examined behaviour modification interventions as treatments for colic have been of poor methodological quality and therefore the findings should be treated very 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.

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.

Focused parent counselling vs reassurance and support

Focused parent counselling was compared with general information and 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 of an infant with colic. 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 colic symptoms of their infants. 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 with 0.17 hours less crying), in many respects the quality of the trial was poor. A further 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.

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 when compared with general advice provided to parents. No significant effects on symptoms of colic were found for the infants who were carried more and stimulated less.

Summary of treatment effects

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

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 were 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. The focused 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 was more effective in reducing the symptoms of colic than the low

hypoallergenic formula. On average, the infants of parents who had 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.

Implications for Practice

Caregivers of infants with colic require reassurance that their child is healthy. An examination and thorough history of the infant should be conducted to eliminate other possible physiological problems. Simple causes of crying, such as hunger and cold, also need to be excluded. This consultation should include questions relating to the infant's diet, indications of reflux, sleeping, bowel excretion and urination patterns, the general well being of the parents and social situation of the infant. The caregivers should be asked about their response to their infant's crying.

In many cases interventions aimed at treating colic are not effective and the only course of action for caregivers is to wait until the symptoms of colic cease, usually when the infant reaches three or four months of age. This advice should be weighed up against the disruption that a colicky baby can create in a household. Caregivers have reported feelings of depression, worthlessness, inadequacy and incompetence, anger, anxiety, fear, loneliness and social isolation, exhaustion, marital conflict, and, in extreme cases, thoughts of infanticide. These reports demonstrate that caregivers expressing frustration and concern about their colicky infant should not be dismissed lightly, but rather given reassurance, support and advice to enable them to cope during this period.



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Recommendations

Based on the findings of the two systematic reviews and one additional RCT referred to in the extract from *Clinical Evidence* the following recommendations to reduce infant colic are proposed:

- Mothers of breastfeeding babies might consider a trial diet in which major allergens such as milk, egg, wheat, and nut products are eliminated. (Grade C)
- Eliminate cow's milk protein from bottle-fed infants' diet by substituting a hypoallergenic formula. (Grade C)

Other options based on studies of lower quality

- Eliminate cow's milk protein from bottle-fed infants' diet by substituting soy based formula. (Grade D)
- Provide parent training to improve their response to a crying infant. (Grade D)
- Reduce the amount of stimulation - such as jiggling, and auditory stimulation of infants. (Grade D)

References

1. Garrison, Michelle M. & Christakis, Dimitri A. (2000). Early childhood: Colic, child development, and poisoning prevention: A systematic review of interventions for infant colic. *Pediatrics* 106(1): S184-190
2. Lucassen, P.L., Assendelft, W.J., Gubbels, J.W., van Eijk, J.T., van Geldrop, W.J., Knuistingh Neven (1998). Effectiveness of interventions for infantile colic: systematic review. *BMJ* 316(23 May): 1563-1569
3. Wade, Sally & Kilgour, Teresa (2001). Infantile colic. *BMJ* 323(25 August): 437-440



THE JOANNA BRIGGS INSTITUTE

Margaret Graham Building,
Royal Adelaide Hospital, North Terrace,
Adelaide, South Australia 5000
<http://www.joannabriggs.edu.au>
ph: (+61 8) 8303 4880 fax: (+61 8) 8303 4881
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