Management of infantile colic in practice

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Colic is common in the infant population but it can be challenging to diagnose and manage in the primary care setting. In this article, Dr Kanabar discusses how to reach a diagnosis of infantile colic and provides an overview of the current treatment options and their efficacy.

Babies who cry in the first few months of life may do so for a variety of reasons including thirst, hunger, overstimulation, under-stimulation and, of course, when they are ill or in pain. Sometimes babies cry with no obvious cause for their discomfort or unease, and this may indicate colic – suggesting that colic is something that babies ‘do’ rather than a condition that they ‘have’.

The prevalence of colic varies according to the definition used, but estimates range between 5% and 26% of the infant population.

Diagnosis
The diagnosis of infantile colic is not particularly difficult for experienced clinicians such as consultant paediatricians or gastroenterologists, but may prove challenging in primary care or community pharmacies. With no diagnostic test, colic is a diagnosis of exclusion. Once other causes such as cow’s milk protein intolerance (CMPI), infections, constipation and gastro-oesophageal reflux have been excluded, an infant in the first four months of life who is troubled by unexplained bouts of irritability or screaming, fussiness, facial redness, clenched fists, furrowed brow and a drawing up of the knees to the chest for a period of over a week (often in the evenings) can be diagnosed as suffering from colic.

A rare but potentially life-threatening differential diagnosis of a colicky baby is intestinal malrotation and therefore any infant who presents with fussiness, crying, tiredness, lethargy, fever, abdominal distension and bloody stools should be referred to hospital immediately.

Infantile colic is not considered to be a serious medical condition; however, it can occasionally lead to failure to thrive and, in extreme cases, to dehydration and electrolyte imbalance primarily due to inadequate (or inappropriate) fluid intake. More commonly, it contributes to impaired parent-child bonding and may increase the risk of non-accidental injury.

Current treatment options
The aetiology of infantile colic is unclear, but thought to be multifactorial. Immaturity of the infant’s nervous and digestive
systems are likely causes, but it is possible some infants have CMPI, altered gut microflora (low levels of bifidobacteria and lactobacilli) or increased levels of gut hormones such as ghrelin and motilin.\textsuperscript{7,9} As a result, several treatment strategies have been applied to treat colic, but only some have been successful. If CMPI or reflux oesophagitis is suspected, a time-limited therapeutic trial of a hydrolysed protein formula or anti-reflux medication is warranted.

Table 1 shows the current treatment options for infantile colic, including trial data and measured outcomes. However, there are few properly conducted randomised placebo-controlled trials, and those that exist have limited sample size.

Studies with simeticone (Infacol), one of the most commonly used colic treatments, have shown little or no effect

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Study outcomes</th>
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<tbody>
<tr>
<td><strong>Possible interventions that may cause harm to the infant</strong></td>
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<tr>
<td>Dicycloverine</td>
<td>Placebo-controlled trial showed significant benefit on symptoms of colic; however, some serious adverse effects (eg seizures, apnoea) were reported and so dicycloverine is contraindicated in infants under 6 months old</td>
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<tr>
<td>Herbal agents</td>
<td>Low-quality evidence from three studies suggests herbal agents reduce risk of crying compared with placebo; however, data on the side-effect profile is limited\textsuperscript{12}</td>
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<tr>
<td><strong>Interventions that have little or no effect</strong></td>
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<tr>
<td>Simeticone</td>
<td>Two randomised controlled studies showed little or no benefit of simeticone on crying time versus placebo, but a third randomised control trial in 26 infants found simeticone significantly reduced crying attacks on days 4 to 7 of treatment compared with placebo (effect size 0.54, 95% CI 0.21–0.87)\textsuperscript{13}</td>
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<tr>
<td>Lactase enzyme</td>
<td>Double-blind, randomised, placebo-controlled trial showed a reduction in crying time with lactase-treated milk (median 11.0 hours with lactase vs 14.1 hours with no lactase; median difference in crying time 23%; p=0.09) but sample size was small\textsuperscript{14}</td>
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<tr>
<td><strong>Interventions that may be useful</strong></td>
<td></td>
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<tr>
<td>Decreased stimulation, eg quiet room</td>
<td>Significant improvement in crying observed in one study, but biased as babies without true colic also included\textsuperscript{15}</td>
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<td>Low-allergen diet in breast-feeding mothers (exclusion of cow’s milk, eggs, peanuts, tree nuts, wheat, soy and fish)</td>
<td>Exclusion of allergenic foods from maternal diet for a week was associated with a reduction in distressed behaviour among breastfed infants with colic presenting in the first six weeks of life compared with control group whose mothers continued to consume these foods. In follow-up assessments on days 8 and 9, there were significantly more responders in the low-allergen group (74% vs 37% in controls), ie an absolute risk reduction of 37%. Cry/fuss duration per 48 hours was reduced by a substantially greater amount in the low-allergen group; the adjusted geometric mean ratio was 0.79, ie an average reduction of 21%. Mothers’ subjective assessments of the responses to diet indicated little difference between the groups\textsuperscript{16}</td>
</tr>
<tr>
<td>Probiotics</td>
<td><em>Lactobacillus reuteri</em> improved colicky symptoms in breastfed infants within one week of treatment compared with simeticone or placebo; 95% were responders in the probiotic group\textsuperscript{23}</td>
</tr>
<tr>
<td>Sucrose solution</td>
<td>Benefit reported in two trials. Sucrose effective for only a short period of time – effects lasting between 3 and 30 minutes\textsuperscript{13}</td>
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<tr>
<td>Hydrolysed whey formula versus standard cow’s milk formula</td>
<td>Double-blind, randomised placebo-controlled trial showed that hydrolysed whey formula reduced duration of crying by 63 minutes per day (95% CI: 1–127; p=0.05) compared with standard formula\textsuperscript{17}</td>
</tr>
<tr>
<td>Hydrolysed casein formula versus focused parental counselling</td>
<td>Randomised controlled trial of 20 infants. Infants of parents who received focused counselling (on feeding, holding, stimulating, offering a pacifier or putting to sleep), cried less compared with substitution of soya or cow’s milk with casein hydrolysate formula (mean decrease in crying 2.1 hours per day with counselling vs 1.2 hours per day with dietary change; p=0.05)\textsuperscript{20}</td>
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Table 1. Interventions for infantile colic and their reported effects
Infantile colic

Infant in the first four months of life troubled by unexplained bouts of irritability or screaming, fussiness, facial redness, clenched fists, furrowed brow and a drawing up of the knees to the chest for a period of over a week (often in the evenings)

Exclude cold, hunger, cow’s milk protein intolerance (CMPi), infections, constipation, gastro-oesophageal reflux and intestinal malrotation

If unsure of diagnosis, if any serious pathology suspected, or if there is faltering growth, refer to a paediatrician

Avoid dicycloverine and herbal agents

Remember simeticone (Infacol) and lactase enzyme (eg Colief) have little evidence of efficacy

Probiotics and sucrose solution have shown some benefit

Low-allergen diet and parental counselling have shown benefit

Decreased stimulation, eg quiet room, has shown some improvement

A study looking at the effect of either a hypoallergenic diet for mothers of breast-fed infants (free from milk, egg, wheat and nuts), or a casein hydrolysate milk in bottle-fed infants, was poorly designed and although pooled results of breast- and bottle-fed infants showed a significant reduction in infant distress in those on a low allergen diet compared with those on a control diet, the number of bottle-fed infants was too small to establish whether casein hydrolysate milks were of benefit compared with cow’s milk. A later randomised controlled trial by the same author in exclusively breastfed infants showed that a low-allergen maternal diet (excluding milk, eggs, nuts, wheat, soy and fish) significantly reduced infant crying compared with infants of mothers who continued to eat those foods.

In another randomised double-blind trial, a hydrolysed whey formula significantly reduced crying time by 58 minutes per day (p=0.03) compared with standard cow’s milk formula. The effect of physical interaction with infants on colic symptoms has also been investigated. In one study, advice to increase infant carrying showed no benefit compared with normal infant care; conversely, reduced stimulation has been shown to have a beneficial effect. Another study showed that counselling parents to respond to their babies’ cries by feeding, holding, offering a pacifier, stimulating or putting the baby down to sleep decreased the duration of crying by up to an hour per day (p=0.05) compared with milk substitution (soya or cow’s milk substituted with casein hydrolysate).

A study comparing infant massage (performed three times a day using olive oil) versus a crib vibrator device over a four-week period found no significant difference between the two interven-

Infantile colic

on reduction of colic symptoms. One brief communication did suggest a benefit; however, in that study, it was not clear how colic was defined or how cases were ascertained.

Because of its adverse side-effect profile (including apnoea, seizures and coma) the antispasmodic drug dicycloverine is contraindicated in infants under six months old.

Herbal therapies, such as using fennel seed oils, have proved beneficial in some instances. However, parents should be aware of a lack of standardisation of dosage and strength of herbal preparations (including herbal teas), and presently there are few studies of the effectiveness and safety of many herbal preparations in infants, including breast-feeding infants whose mothers take them. It is also important to remember that due to their small size and gastrointestinal immaturity, infants may respond abnormally to herbal treatments, and some treatments may even contain heavy metals such as lead, mercury or arsenic.

The idea that sugary fluids may ease infantile colic is not new either. A mixture of dill-flavoured sugar solution with alcohol is still sold as ‘gripe water’. It is slowly going out of fashion and, importantly, active ingredients such as sugar and alcohol are being removed from the formulation – perhaps making the compound less useful?

Lactase enzyme drops (eg Colief), which can be added to breast or formula milk, are also available to reduce lactose load, and the author’s own double-blind, randomised, placebo-controlled crossover trial to investigate the effect of lactase-treated milk on breath hydrogen excretion and crying time in infants showed some reduction in median crying time – but the study sample size was small.

A study looking at the effect of either a hypoallergenic diet for mothers of breast-fed infants (free from milk, egg, wheat and nuts), or a casein hydrolysate milk in bottle-fed infants, was poorly designed and although pooled results of breast- and bottle-fed infants showed a significant reduction in infant distress in those on a low allergen diet compared with those on a control diet, the number of bottle-fed infants was too small to establish whether casein hydrolysate milks were of benefit compared with cow’s milk. A later randomised controlled trial by the same author in exclusively breastfed infants showed that a low-allergen maternal diet (excluding milk, eggs, nuts, wheat, soy and fish) significantly reduced infant crying compared with infants of mothers who continued to eat those foods.

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tions, and it is also possible that massage may overstimulate a colicky infant.21 However, a randomised controlled Danish study did show benefit from spinal manipulation (chiropractic therapy for two weeks) versus two weeks of daily treatment with simeticone. This trial found that spinal manipulation significantly reduced crying time compared with simeticone (mean reduction in crying on days four to seven: 2.4 hours with spinal manipulation versus 1.0 hours with simeticone; p<0.04).22 However, the study was not blinded to treatment allocation, and a colic diary was kept.

Based upon the hypothesis that aberrant intestinal microflora may be responsible for intestinal dysfunction and excess gas production, the use of probiotics in infantile colic is gaining considerable interest. A randomised controlled trial showed that once-daily administration of Lactobacillus reuteri DSM 17938 oral drops to breastfed infants is well tolerated and improves symptoms of infantile colic compared with simeticone or placebo.23

**Conclusion**
Infantile colic is a common problem, and colicky crying babies can cause stress, frustration and anxiety for families. Many parents report how difficult it is to pacify their babies and this makes them feel helpless and guilty about their supposed lack of skill. Both casein and whey hydrolysed formulas have been used in infantile colic trials with limited success. If an infant is thriving on standard formula or breast milk, there is no need to change milks, unless of course there is strong evidence of CMPi, in which case the advice would be to change to a hypoallergenic formula, or for a breast-feeding mother to alter her diet. If the infant has faltering growth, then it is imperative to refer these babies for urgent investigation and not give them a ‘colic’ label without full investigation.

There is insufficient clinical evidence to advocate one particular treatment option over another and the management flowchart in Figure 1 should assist healthcare professionals in managing this complex condition, as many parents will have struggled between the various interventions.

Clinical trials are currently underway with a neurokinin 2-receptor antagonist, which reduces intestinal motility and may offer a new approach to therapy.

Support, encouragement and practical advice is important, as is asking, where possible, other family members or friends to take care of the child for brief periods to allow parents to refresh themselves.24 It is important to stress to families that colic is a temporary problem, that it is not their fault, and that it can generally be managed nonmedically, using manoeuvres such as gentle rhythmic rocking in a quiet environment, or even a car ride. Perhaps it is also worth suggesting to families that it is a sign that their baby is normal and vigorous and their infant’s crying may be due to underlying changes in the nervous system and how it modulates their baby’s behaviour.

The above strategies should help busy clinicians, nurses or health visitors to manage a stressful period of child development, as well as help prevent any serious outcomes of this generally benign and self-limiting condition. They should also help reduce the numbers of infants presenting to accident and emergency and other secondary care services.

**References**