

## Management of infantile colic

In England, Wales and Scotland, £250,088 is spent annually on preparations for the management of infantile colic, containing lactase, simeticone and gripe water (NHSBSA Feb - Apr 22, and Public Health Scotland Feb - Apr 22).

This bulletin aims to support the review of these treatments for infantile colic, reviewing the continued need for treatment and discontinuation of prescribing these preparations with insufficient good-quality evidence for their use.

### Recommendations

- Provide support to parents and reassurance that infantile colic is a common problem and should resolve by six months of age.
- Review patients prescribed lactase (Colief® Infant Drops), simeticone (Dentinox® Infant Colic Drops and Infacol® Colic Relief Drops) or gripe water for the management of infant colic and discontinue prescribing.
- Do not recommend maternal diet modification if breastfeeding, or changing the infant milk formula preparation, probiotic supplements, herbal supplements, and manipulative strategies such as spinal manipulation or cranial osteopathy.
- Give advice on appropriate sources of information and support and refer to the family's health visitor or nursery nurse to advise on strategies that may help to soothe a crying infant. In addition, parents / carers should be encouraged to look after their own wellbeing.
- Consider an underlying cause if symptoms are severe or persist after four months and consider seeking specialist advice or referral if necessary. A feeding assessment from an appropriate person may be useful.
- As with all changes, these should be tailored to the individual patient.

### Introduction

Infantile colic is a self-limiting condition which is defined clinically as repeated episodes of excessive and inconsolable crying in an infant that otherwise appears to be healthy and thriving <sup>1</sup> Typically, an infant with colic presents with: excessive, inconsolable crying which starts in the first weeks of life and resolves by around three to four months of age, crying which most often occurs in the late afternoon or evening and drawing its knees up to its abdomen or arching its back when crying.<sup>1</sup> It causes parental or carer stress, anxiety, depression and sleep deprivation.<sup>1</sup>

### National Guidance

The NICE Clinical Knowledge Summary on the management of infantile colic states that there is insufficient good-quality evidence to support the prescribing or recommendation of medication for infantile colic, including lactase drops (Colief® Infant Drops) and simeticone (Dentinox® Infant Colic Drops and Infacol® Colic Relief Drops).<sup>1</sup>

Maternal diet modification if breastfeeding, or changing the infant milk formula preparation, probiotic supplements, herbal supplements, and manipulative strategies such as spinal manipulation or cranial osteopathy are also not recommended for the treatment of colic.<sup>1</sup>

Instead, reassurance and advice should be given on sources of information and support and the family's health visitor or nursery nurse should advise on strategies that may help to soothe a crying infant. In addition, parents/carers should be encouraged to look after their own wellbeing.<sup>1</sup>

If the mother is breastfeeding, she should be encouraged to continue wherever possible and suspected breastfeeding issues should be addressed appropriately.<sup>1</sup>

If symptoms are severe or persist after four months, an alternative underlying cause for symptoms should be considered.<sup>1</sup>

A feeding assessment by someone with suitable training and expertise in breastfeeding should be considered, particularly if the parent/carer has experienced feeding difficulties including slow weight gain, pain or if there is parental concern, (including parental concern over tongue tie). If the baby is being fed by a bottle (expressed breastmilk or formula) the parent/carer should be supported to pace the bottle feed with a slow flow teat.

Specialist advice should be sought from a paediatrician or referral arranged, depending on clinical judgement, if:<sup>1</sup>

- Parents/carers feel unable to cope with the infant's symptoms despite reassurance and advice in primary care.
- The infant is not thriving, or symptoms are not starting to improve or are worsening after four months of age.
- There is a suspected underlying cause for symptoms which cannot be managed in primary care.

The NHS England Guidance for CCGs (the guidance will be amended to ICSs in the future) on which over the counter (OTC) items should not be routinely prescribed in primary care, includes treatments for infant colic.<sup>2</sup> This states that a prescription for treatment of infant colic should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment.<sup>2</sup>

In Scotland, infants with colic are potentially suitable for NHS Pharmacy First Scotland (NHS PFS), except for those who are unwell or failing to thrive. NHS PFS is a consultation service designed to encourage the public to visit their community pharmacy as the first port of call for all minor illnesses and common clinical conditions.<sup>3</sup>

A similar scheme in Wales, the Community Pharmacy Common Ailments Scheme, includes colic as an advice only condition with no treatment available on NHS, as there is insufficient evidence to support the use of medicines to treat colic on the NHS.<sup>4</sup>

Lactase enzyme (Colief® Colic Relief Drops) is classified as a borderline substance by the Department of Health and the Drug Tariff states that it is only permitted to be prescribed on the NHS for the specific indication of transient lactase deficiency.<sup>5</sup> Any patient without this specific diagnosis is not eligible to receive an NHS prescription for lactase (Colief® Colic Relief Drops).<sup>5</sup>

Woodward's gripe water is an over the counter (OTC) product containing terpeneless dill seed oil, sodium hydrogen carbonate, maltitol and propylene glycol. It is licensed for the symptomatic relief of distress associated with wind in infants up to one year old.<sup>6</sup> As a product containing herbal ingredients it is not recommended in the NICE CKS guidance.<sup>1</sup> Dinnefords Gripe Mixture is listed in part XVIII A of the Drug Tariff, - Drugs, Medicines and Other Substances not to be ordered under a General Medical Services Contract, commonly referred to as the "blacklist".<sup>5</sup> Therefore, this specific preparation cannot be prescribed on an NHS prescription, although it is no longer available.

## Clinical Effectiveness

There is currently insufficient evidence of effectiveness for treatments for infantile colic.<sup>1,2,7,8,9,10</sup>

A systematic review of medical therapies for infantile colic found little scientific evidence to support the use of these therapies including lactase and simethicone.<sup>8</sup> Two identified studies found no significant difference in crying duration between simethicone and placebo. Two studies comparing lactase to placebo, reported conflicting results, with one reporting a non-significant decrease in crying time and another reporting a reduction in crying/fussing duration with lactase compared to placebo 225±22min vs 185±25 respectively. A separate Cochrane review, also reported no difference in the duration of crying between simethicone and placebo. No studies investigating lactase were included.<sup>9</sup>

The Cochrane review authors concluded that evidence of the effectiveness of pain-relieving agents for the treatment of infantile colic is sparse and prone to bias.<sup>9</sup> The few available studies included small sample sizes, and most had serious limitations and benefits, which when reported, were inconsistent.<sup>9</sup>

There is very little evidence and no good, randomised control trial evidence assessing the use of gripe water for infantile colic.<sup>10</sup> The limited evidence available is mainly anecdotal, and any affect may be due to its sweet taste.<sup>7</sup>

A retrospective observational study by Jain et al, collected data on gripe water use and incidence of colic in all mother-baby dyads, aged one to six months, who attended an Indian hospital well baby paediatric clinic and consented to participate. Of the 335, mothers identified, 64.18% reported routinely administering gripe water to their baby. Out of 215 babies who received gripe water, acceptable weight gain was seen in only 121(56.27%). However, there was no observed difference to babies who did not receive gripe water and were exclusively breast fed. Persistent and prolonged crying diagnostic of infantile colic was seen in 29 babies on gripe water compared to only one in the non-gripe water group (OR 18.5538;95% CI:2.4941-138.0222; p=0.0001).

## Safety

There are concerns that some of these preparations can present a barrier to exclusive breast feeding (as they need to be mixed with breast milk or formula).<sup>11</sup>

In addition, gripe water may be associated with increased vomiting and constipation.<sup>11</sup> In the study by Jain et al, regurgitation of feeds was seen in 29 babies on gripe water compared to five babies in the no gripe water group, with vomiting observed in 12 babies in the gripe water group compared with 3 in the no gripe water group. (OR 2.3054; 95% CI:0.6375-8.337; p=0.0373.<sup>10</sup> The number of babies who had constipation was significantly more in the gripe water group compared to no gripe water; 19.53% vs 5.83% (OR 3.9191;95% CI 1.701-9.0287; p=0.0007).<sup>11</sup>

Lactase drops may be associated with looser and more frequent stools, when babies begin taking milk treated with Colief®. Stools may resemble those of a breastfed babies and be more frequent even if formula feeding. If the baby is otherwise well, gaining weight and urinating normally, there should be no cause for concern.<sup>12</sup>

Simeticone is not absorbed by the gastro intestinal tract and therefore is generally not known to cause any side effects. Allergic or hypersensitivity reactions are possible.<sup>13,14,15</sup>

## Patient factors

Infantile colic preparations are available to purchase over the counter (OTC) but in view of the lack of sufficient evidence to support their use, they should not be recommended.<sup>1</sup>

Treatment should instead consist of advice on sources of support and on strategies that may help to soothe a crying baby such as holding the baby through the crying episode, gentle motion such as pushing the pram or rocking the crib, white noise such as a vacuum cleaner or hairdryer, bathing the infant in a warm bath, ensuring an optimal winding technique is used during and after feeds, if needed.

Parents/carers should be reassured that infantile colic is a common problem that should resolve by six months of age.<sup>1</sup>

Top tips for effective parental reassurance include:<sup>7</sup>

- The conversational style should be collaborative, empathic and autonomy-respecting
- Listen to the parent more than you 'tell'. A useful guideline is that the parent does at least 50% of the talking.
- Agree an agenda.
- Take the time to listen to the parent's concerns, with the aim of understanding their dilemma.
- Avoid the 'expert trap' where advice/information is provided before understanding what the parent wants or needs.
- Ask permission before you share advice/information.
- Provide information/advice in small doses and avoid using jargon.
- Allow the parent time to process the information.
- Explore and build the parent's confidence to use the techniques/implement the advice.

Suspicion of food allergy, such as cow's milk allergy, should be investigated and managed appropriately.<sup>16,17</sup>

## Costs and savings

There is a significant difference in cost between infantile colic preparations. Table 1 below illustrates the cost differences.

**Table 1: Infantile colic product and price comparison**<sup>5,18,19</sup>

Product	Cost
Simeticone 42mg/5ml oral drops (Dentinox® Infant Colic Drops)	£2.13/100mL
Woodward's gripe water	£2.58/150mL
Simeticone 40mg/ml oral suspension sugar free (Infacol® Colic Relief Drops)	£3.20/55mL £4.66/85mL
Lactase (Colief® Colic Relief Drops)	£8.40/7mL
Gripe water	Retail approx. £4.00/150mL

## Switching options

Alternative treatment for infantile colic in primary care is centred around providing appropriate advice and reassurance (although clinicians may choose other options according to the clinical need of the patient):

- Review all patients prescribed lactase, simeticone or gripe water preparations for infantile colic and discontinue prescribing, with an explanation that there is insufficient evidence to support their use and provide advice and reassurance instead and further investigation, if warranted\*.

**\*Acid suppressing drugs such as proton pump inhibitors (PPIs) or H2 receptor antagonists (H2RAs), should not be prescribed unless indicated for gastro-oesophageal reflux disease, as outlined by NICE.**<sup>20-22</sup>

## Savings

In England, Scotland and Wales, £250,088 is spent annually (NHSBSA Feb - Apr 22, and Public Health Scotland Feb - Apr 22) on lactase (Colief® Infant Drops), simeticone (Dentinox® Infant Colic Drops and Infacol® Colic Relief Drops), and gripe water.

An 80% reduction in the prescribing of these products could release savings of approximately to £201,029 across England, Scotland and Wales. This equates to £284 per 100,000 population.

## Summary

There are no data to confirm that lactase, simeticone or gripe water are effective for the treatment of infantile colic. Lactase (Colief® Infant Drops), simeticone (Dentinox® Infant Colic Drops and Infacol® Colic Relief Drops) and gripe water represent a significant cost to the NHS and are not recommended for prescribing.

## Patient support resources:

Patient. Health information. Colic in Babies and Infants. Last edited October 2018 <https://patient.info/childrens-health/colic-in-babies-and-infants>

NCT. My baby won't stop crying - coping with colic symptoms <https://www.nct.org.uk/baby-toddler/crying/my-baby-wont-stop-crying-coping-colic-symptoms>

ICON website. Babies cry, you can cope. Various resources for parents and professionals <https://iconcope.org/>

Cry-sis®. Offers help and support to parents with babies who cry excessively or have sleeping problems. A telephone helpline is available seven days a week from 9am to 10pm. There is advice and information on how to cope with a crying and/or sleepless baby. <https://www.cry-sis.org.uk/>

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## Additional PrescQIPP resources

Briefing	<a href="https://www.prescqipp.info/our-resources/bulletins/bulletin-303-management-of-infantile-colic/">https://www.prescqipp.info/our-resources/bulletins/bulletin-303-management-of-infantile-colic/</a>
Implementation tools	
Data pack	<a href="https://data.prescqipp.info/views/B303_Managementofinfantilecolic/Front-Page?%3Aembed=y&amp;%3Aiid=1&amp;%3AisGuestRedirectFromVizportal=y">https://data.prescqipp.info/views/B303_Managementofinfantilecolic/Front-Page?%3Aembed=y&amp;%3Aiid=1&amp;%3AisGuestRedirectFromVizportal=y</a>

Information compiled by Gemma Dowell, PrescQIPP CIC, July 2022 and reviewed by Vicky Gibson, PrescQIPP CIC, July 2022. Non-subscriber publication July 2023.

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