COMPASS Therapeutic Notes on the Management of Infantile Colic

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Glossary of terms	
Foremilk	Breast milk released at the beginning of a feed. it is watery, low in fat and high in carbohydrates relative to the creamier hindmilk which is released as the feed progresses.
Intussusception	The slipping of a length of intestine into an adjacent portion usually producing obstruction
Volvulus	A twisting of the intestine upon itself that causes obstruction

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Introduction and Background

In the first few months of life babies cry for a variety of reasons including thirst, hunger, over stimulation, under stimulation and of course, when they are unwell or in pain. Sometimes babies cry persistently and excessively for no obvious reason – this may be a symptom of so-called "infantile colic".

Although there is no universally agreed definition of infantile colic, the term is usually used to describe repeated episodes of excessive and inconsolable crying in an infant that otherwise appears to be healthy and thriving.[1] Researchers use more specific definitions, often that of the "rule of threes" proposed by Wessel *et al* (1954)[2]: paroxysms of irritability, fussing or crying lasting for a total of three hours a day and occurring on more than three days in any one week for a period of three weeks in an infant who is otherwise healthy and well-fed.[2] The definition by Wessel has its limitations because it is arbitrary and few parents are willing to wait three weeks to see if the infant meets the criteria for colic! As a result, the third criterion is usually dropped in the clinical setting.

Colic is perceived by mothers to be one of the most common problems of infancy.[3] Although it is harmless, colic remains a frustrating and stressful problem for parents[4-6] and they may hope that medication will provide a simple cure.

What are the clinical features of infantile colic?

See **Box ONE**.

Box ONE: Features of infantile colic[1,7-13]

- Prolonged crying in an otherwise healthy, thriving baby. Rhythmical screaming attacks last a few minutes at a time, alternating with quiet periods in which the child almost goes to sleep, before another attack starts.
- Attacks appear to be more common in the afternoon or early evening, giving rise to the name "6.00pm colic".
- Other signs include a rigid abdomen, legs drawn up towards the chest, and clenched fists.
- The infant is inconsolable; crying does not abate when the child is picked up. The child cannot be soothed by feeding.
- Colic typically begins at two weeks of age. It is a self-limiting condition resolving in up to 90% of infants by the age of four months.[14] It is rare in babies older than six months.

How common is infantile colic?

Occurrence rates of infantile colic in community based samples vary greatly because of differences in study design, site of recruitment, definition, and method of data collection.[10] The two best prospective studies yielded occurrence rates of 5% and 19% respectively.[15,16] In the UK, up to one in six families consult their doctor or community nurse about symptoms of colic in their child.[17] There are no reported differences in prevalence between either boys and girls, or breast-fed and formula-fed infants.[18]

What causes infantile colic?

Despite over 50 years of research, the aetiology of infantile colic remains unclear. It is suggested that colic could be caused by interplay of the following factors (in no particular order of importance):[11,13,19,20]

Swallowing air

Pain and crying in an infant might be due to excessive wind caused by air swallowing during crying or feeding.[8] If the infant is bottle fed this is almost always due to the teat hole being too small. If the infant is breast fed then air swallowing can be due to sucking too long on the breast or sucking on an empty breast.

Intolerance of cow's milk protein

Excluding cow's milk from the mother's diet or switching to hypoallergenic infant formula may ease colic.[21,22] (See later for more information on hypoallergenic infant formulae).

Transient lactase deficiency

In recent decades, lactose intolerance due to a relative lactase deficiency has been identified as a possible causative factor in infant colic.[18] The resulting failure to breakdown all the lactose in the food allows significant amounts to enter the large bowel, where it becomes a substrate for lactobacilli and bifidobacteria in the colon. Fermentation by these bacteria leads to production of lactic acid and hydrogen. The rapid production of hydrogen in the lower bowel distends the colon, sometimes causing pain, whereas the osmotic pressures generated by the lactose and lactic acid in the colon cause an influx of water, leading to further distension of the bowel.[23]

Behavioural issues

Infantile colic may be a behavioural problem resulting from a less than optimal parent-infant interaction, with a difficult temperament of the infant as a possible explanation for inadequate parental reactions.[24,25] However, this is NOT supported by robust evidence.[26-28]

Developmental issues

Studies have suggested that colic may lie at the upper end of the normal distribution of crying in infants.[19,29]The crying patterns of colicky infants (i.e. peaking around six weeks of age with crying late in the afternoon and evening) are the same in normal infants. However, colicky infants cry longer and are more difficult to soothe once crying has begun. The fact that most infants outgrow colic lends support to a neurodevelopmental cause of colic.[29]

How is infantile colic diagnosed?

When parents seek advice about a baby who cries excessively, they may feel tired and inadequate, and may be worried that their child has a serious medical disorder. A careful history and physical examination are usually sufficient to determine if there is an organic cause for crying or to relieve parental fears and allow for a diagnosis of colic. The healthcare professional should ask about the infant's behaviour

and the time of day and length of the crying episodes.

The physical examination begins with careful observation while the infant is being held on the parent's lap. The infant is observed for lethargy, poor skin perfusion, and tachypnoea. High body temperature or poor weight gain suggests infection, gastrointestinal disorder, or nervous system disorder and requires further investigation. Next, a physical examination is required to check for evidence of skin trauma and palpation of the large bones for possible fractures. A gastrointestinal and neurological examination should follow. These examinations themselves may reassure parents. Further investigations are usually unnecessary if the child is gaining weight normally and has a normal physical examination.[13]

Which conditions is it important to eliminate?

Organic causes account for less than 5% of infants presenting with excessive crying.[29,30] If symptoms started suddenly and recently, consider:[1]

- Acute infection - Colic and acute infection of the ear or urinary tract can present with almost identical symptoms. However, in acute infection the child should have no previous history of excessive crying and have signs of systemic infection, such as fever.
- Intussusception, volvulus, strangulated hernia.
- Torsion of the testis.
- Corneal abrasion (i.e. scratch from the baby's nails).
- Non-accidental injury.

For more persistent crying, consider:[1]

- Discomfort (hunger, thirst, too hot, too cold, itch, nappy rash)
- Constipation
- Gastro-oesophageal reflux disease (demonstrated by daily regurgitation, crying, hiccups, refusal to feed, problems gaining weight)[9]
- Parental depression, anxiety, or inability to interact normally with the baby.
- Rare, serious causes (seizures, infantile spasms, cerebral palsy, chromosomal abnormalities).

Community Pharmacy trigger points for referral to General Practitioner:[8,31]

- Infants that are failing to put on weight
- Medication failure
- Over-anxious parents
- If the crying is accompanied by vomiting, sickness, or pallor or a rise in body temperature
- A baby aged over 4 months presenting with colic symptoms for the first time

Managing colic

Over the years, numerous behavioural and pharmacological remedies have been suggested as treatments for colic, although few have had rigorous scientific evaluation in the form of randomised controlled trials. The difficulties with definition, the transient nature of the condition, the undetermined aetiology, and the large placebo effect make evidence-based study of treatment difficult.

Step ONE: General advice and reassurance

This is the most important step in the management of infantile colic. If the infant is growing and developing appropriately, and has no other symptoms or signs to suggest an alternative diagnosis, reassurance and support are key.

Step One should include the information that infantile colic is a self-limiting condition, resolving by 3-4 months of age and is not due to a disease or to anything parents have or have not done to their infant. As well as providing reassurance, healthcare professionals should advise on:

Feeding technique

Feed the baby in a more upright position to reduce the chance of swallowing air. In a **bottle-fed baby,** underfeeding can result in excessive sucking resulting in air being swallowed leading to colic-like symptoms. Additionally, teat size should be checked. When the bottle is turned upside down the milk should drip continuously but slowly from the bottle. In a **breastfed baby**, certain foods can pass into breast milk and have been suggested to have a role in causing colic. Breastfeeding mothers should avoid peppers, onions, spices, caffeine and alcohol, which may aggravate colic in the baby. Colic may be a sign of too much foremilk. If the baby starts crying about half an hour after breastfeeding, advise the mother to return the baby to the same breast to complete the feed.

Soothing the infant

Holding the baby through the crying episode may be helpful. However, if there are times when the crying seems intolerable, it is best to put the baby down somewhere safe and take a few minutes "time out".

Other strategies

These include: gentle motion (pushing the pram, going out in the car), "white noise" (vacuum cleaner, hairdryer), and a warm bath.

Step TWO: Medication

Although there are many studies of interventions for infantile colic, **most are of poor methodological quality, making it difficult to evaluate the effectiveness of any treatment. No treatment has been shown to be of substantial benefit** (apart from antimuscarinics, which have serious adverse effects and are therefore not recommended. See Prescribing Note).

With the exception of antimuscarinics, none of the medications for colic are likely to cause harm.

Prescribing Note: Dicycloverine
(Formerly known as dicyclomine)

Dicycloverine (Merbentyl®) is an antimuscarinic antispasmodic.[32] It is licensed for the treatment of functional conditions involving smooth muscle spasm of the gastrointestinal tract (for example, mucous colitis, spastic colon).[32] In the past, it was widely used to treat infantile colic and whilst it was effective it is **not safe** and is **no longer licensed nor recommended in infants under six months of age**.[17,32,33] This is because of reports of respiratory symptoms (difficulty breathing, shortness of breath, respiratory collapse, apnoea), seizures, syncope, asphyxia, muscular hypotonia, and coma in infants given dicycloverine.[32]

When should treatment for infantile colic be considered?

Consider medical treatment if parents feel unable to cope despite advice and reassurance.[1] The options are a one-week trial of any of the following:

- Simeticone drops, or
- Gripe water, or
- Lactase drops.

The chosen treatment should only be continued if there is a response (e.g. the duration of crying shortens). If there is no response to one medical treatment, consider trying another.

Simeticone

(Also called "activated dimeticone") – For example Infacol®, Dentinox®

How does simeticone work?

Simeticone is reported to have anti-foaming properties. It acts by reducing the surface tension of small air bubbles, thus allowing them to coalesce to make larger bubbles that are easier to expel.[8,31,34] It can take 3-4 days to work and requires regular dosing.[31]

Is there evidence of efficacy?

Simeticone is widely used yet little evidence of its efficacy exists. Simeticone was compared with placebo for treating infantile colic in three trials.[35-37] In two of the studies,[35,36] simeticone was no better than placebo. In a third study,[37] infants had significantly fewer crying spells. However, in this study it is not clear how colic was defined or how cases were ascertained.

Is simeticone safe?

Simeticone is pharmacologically inert; it has no side-effects, drug interactions or precautions in its use and can therefore be safely prescribed to all children.[8,34]

Is there a place for simeticone in the management of infantile colic?

Although studies of simeticone have not demonstrated any benefit in infantile colic, it has been suggested that a one-week trial of simeticone may still be worth a try.[1] Simeticone is easily available, and is licensed for this

indication, it has no reported adverse effects, and the simple act of being able to give their baby something may help parents cope better with the crying.[1]

How should simeticone be used?

Simeticone is administered with or just after each feed. See **Table ONE**.

Gripe water

"Gripe water" is a collective term given to mixtures of aromatic oils, herbs, and sodium bicarbonate. The use of such mixtures for infantile colic dates back to the 1850s. The original formulations contained large amounts of alcohol but most contemporary commercially available gripe waters contain no alcohol.

Herbs commonly found in today's gripe water preparations include dill, fennel, ginger, and chamomile. The first three herbs contain volatile oils that produce smooth muscle relaxation and an antispasmodic effect. Chamomile contains multiple active compounds that are reputed to have anti-inflammatory and antispasmodic activity.[38] In addition, the soothing effect of gripe water is now thought to be in part due to its sweet taste.[39] It has been shown that infants with colic obtain relief from sugar solutions.[40,41] Artificial sweeteners such as aspartame are just as effective as sucrose.[42]

Is there evidence of efficacy?

There is no evidence from well-conducted trials to recommend the use of gripe water.[20] Despite this, gripe water is commonly used and there is much anecdotal evidence extolling the benefit of gripe water for infantile colic.

Lactase drops

(Colief®)

Is there any evidence of efficacy?

The available evidence suggests that lactase drops *may* help ease symptoms for *some* babies, providing that the lactase is added to the feed some time before it is given to the baby.[43,44] However, the studies are small and require confirmation by studies independent of industry.

How are lactase-containing drops used?

Lactase drops are safe to use from birth.[45] Their effectiveness depends on pre-incubation with milk (either formula or a small amount of expressed breast milk) – so education of the parent is essential. Lactase drops should only be added to the baby's feed – they should not be given directly to the baby. Because lactase is an enzyme, it works best in milk that is warm (not hot or cold).[45] See **Table ONE**.

Step THREE: Dietary Modification

Nutritional modulation is one of the options for infants with colic.

In breast-fed infants

It has been historically observed that certain foods ingested by breastfeeding mothers leads to fussy periods in infancy. We can therefore speculate that avoiding certain foods may prevent colic in at-risk infants. One study found that avoidance of cow's milk, soy, wheat, eggs, peanuts and fish by breastfeeding mothers was positively associated with a reduction in colic in breastfed infants.[46] Dietary interventions in mothers should be strictly monitored to ensure a well-balanced diet and an adequate calcium intake and continued only if they are effective.

In bottle-fed infants

In infants who are partially or fully formula-fed, the choice of formula may play a role in colic development. There is limited evidence that switching to a **hypoallergenic formula** for bottle-fed babies may ease the symptoms of colic.[14,19,22,47,48] Examples of hypoallergenic infant formulae include:

- Nutramigen® 1
- Pepdite®
- Cow & Gate Pepti® products
- Prejomin®

A full discussion of the use of these products is outside the remit of this review.

Note: any dietary modification in formula-fed infants should only be undertaken following advice from a specialist.

Useful Web sites:

- www.colichelp.com
- www.cry-sis.org.uk
- www.colief.com

Table ONE: Preparations available for the Management of Infantile Colic[31,33]

Product	Contents	Evidence	Side-effects	How to use
Dentinox® Infant Colic Drops	Simeticone 21mg per 2.5ml	Three trials, two of which showed simeticone was no better than placebo.[35,36] Third study was of poor methodological quality.[37]	No reported side-effects or drug interactions.	2.5ml to be given with or after each feed. May be added to baby's bottle or given direct by oral syringe. Maximum six doses a day.
Infacol®	Simeticone 40mg per 1ml			0.5ml to be given before each feed. If necessary this may be increased to 1ml.
Neo Gripe Mixture	Oil of dill 2.5mcl, strong tincture of ginger 10mcl and sodium bicarbonate 50mg per ml	No well-conducted trials. Evidence is anecdotal.	None reported.	Infants under one month: 2.5ml Infants one month to one year: 5ml Dose to be given up to three times a day.
Nurse Harvey's Gripe Mixture	Sodium bicarbonate 1.0% w/v, dill oil, caraway oil, sucrose and parabens			1-6 months: 5ml 6-12 months: 10ml Give one dose during or after a feed; extra doses as required. Do not exceed six doses in 24 hours.
Woodward's Gripe Water	Dill seed oil 2.3mg and sodium bicarbonate 52.5mg in 5ml			1-6 months:5ml 6-12 months: 10ml May be given during or after each feed or up to six times in 24 hours.
Colief®	Lactase drops (50,000 units per gram)	Small, industry-sponsored studies suggest lactase drops may help *some* babies.	None reported.	**Breast-feeding:** • Express a few tablespoons of breast milk into a small sterilised container. • Add four drops of Colief Infant Drops. • Give this to the baby on a sterilised plastic spoon. • Continue breastfeeding as normal.
				Bottle-feeding: • Make-up the infant formula according to manufacturer's instructions. • Add four drops of Colief Infant drops to formula that is WARM, not hot. • Shake the feed occasionally, and feed the baby after half an hour, having checked that the bottle is at the correct temperature. • Discard any unused feed.

Summary – Infantile colic

▶ Despite the differences used in definitions of infantile colic, it is generally agreed that infants with colic are healthy, thriving, and below six months.

▶ Crying is part of normal infant development.

▶ In most cases of colic, no underlying cause can be found.

▶ Addressing parental concerns is often the best way to cope with colic. Reassure parents that colic will resolve.

▶ A therapeutic trial of any of the colic remedies can be suggested. Any measure that parents perceive as helpful is worth continuing, provided it is harmless.

▶ Some infants will respond to a change in formula or exclusion of certain foods from their mother's diet.

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Infantile Colic

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1	**Features of Infantile colic:**			
	a	The most commonly described feature is prolonged crying in an otherwise healthy infant.	T	F
	b	Attacks of colic are most commonly reported when the infant first wakes in the morning.	T	F
	c	Infantile colic is a self-limiting condition which usually resolves around the age of twelve months.	T	F
2	**Managing colic:**			
	a	Reassurance and support are key to managing colic.	T	F
	b	One of the first steps in management of colic should be to review feeding technique.	T	F
	c	Holding the baby through the crying episode may be helpful.	T	F
3	**Medications used to manage colic:**			
	a	The pharmacological management of infantile colic is informed by a robust evidence base.	T	F
	b	It may be worth considering the use of a pharmaceutical product if parents feel unable to cope despite advice and reassurance.	T	F
	c	If one colic remedy fails, an alternative product is unlikely to be effective.	T	F
4	**Simeticone, gripe water and lactase drops.**			
	a	Simeticone can take 3-4 days to work and requires regular dosing.	T	F
	b	Modern formulations of gripe water usually contain alcohol.	T	F
	c	Lactase drops are administered directly into the infant's mouth just before a feed.	T	F