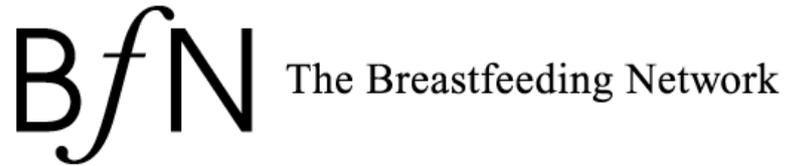


To find your nearest Breastfeeding Supporter call the **Supporterline 0844 412 4664**



Assessing the evidence:

Treatments for Colic

£2

© The Breastfeeding Network, March 2002

The Breastfeeding Network, PO Box 11126, Paisley PA2 8YB

Tel/Fax: 0844 412 0995

e-mail: admin@breastfeedingnetwork.org.uk

www.breastfeedingnetwork.org.uk

Calls provided by BT will be charged at 5 pence per minute.

A call set-up fee of 3 pence per call applies to calls from BT residential lines. Mobile and other providers' charges may vary.

The Breastfeeding Network is a recognised Scottish Charity No SC027007

Treatments for Colic

This paper considers the strength of evidence for different treatments for colic, but first it is worth considering what is meant by colic.

What is the difference between crying and colic?

When colic is talked about in babies it means they are showing a combination of unexplainable irritability, fussing and crying over a prolonged period often at the same time each day, often in the evening, but even this description is vague, if familiar. The baby usually starts feeding then pulls off as if in pain, he might draw his legs up as if in pain. He can be soothed for a while if carried, or rocked but if put down the screaming starts again. There is evidence of evening crying from as far back as ancient Egyptian times. Translation of Egyptian hieroglyphics about family life records babies crying from dusk until dead of night.ⁱ

The internationally used definition of infantile colic is generally considered to be the Wesselⁱⁱ definition, which was first published in 1954. This allows both the symptoms, frequency and duration of colic to be included. It is sometimes written as Wessel's rule of threes, and is defined as:

"unexplained paroxysmal bouts of fussing and crying that lasted >3 hours a day, for >3 days a week, for >3 weeks of duration."

Colic is not uncommon, and the search for effective treatments has led to 3 different systematic reviews within the last 2 years: Lucassenⁱⁱⁱ, Garrison^{iv}, Wade and Kilgour^v. The incidence is said variously to affect 5-19% (Lucassen), 16-26% (Garrison), 3.3-17% (Wade and Kilgour) of infants during the first months of life, this variation depending on the methods and definition used. One study suggested that all babies no matter how they were fed were as likely to become colicky (Lucassen), though the Stahlberg^{vi} study ('86) showed more colic in babies (already troubled with colic) when they were bottle-fed infant formula than pooled breast milk (89% v 71%). Lawrence states that colicky breastfed infants who switch to formula usually become much worse, though no reference is given. Lucas^{vii} found babies fed infant formula cried more at week 2 than breastfed babies (43%v16%) though by week 6 the breastfed babies had overtaken the formula fed babies in time spent crying and being awake (crying >3hrs 31%v12%). These results came from diaries kept by parents so without an independent observer the results are open to many factors affecting reliability. We also don't know if the breastfed babies were exclusively breastfed, or if breastfeeding was baby led.

What causes it?

Colic is described as 'spasmodic contraction of smooth muscle causing pain and discomfort'^{viii} (Lawrence p 286). Though Barr^{ix} has an alternative theory, taking the focus away from within the gastrointestinal tract, suggesting that for some infants the origin may lie in the central nervous system relating to the responsivity, reactivity and regulation of the infant to his environment (Barr p61). All agree it is likely to have a variety of causes, but is still poorly understood. Crying levels are said to peak at around 6-8 weeks, and have subsided by 3 months.

Treatments

A quick look in any parenting magazine will show a number of suggested treatments for colic. However we need information on the strength of the evidence for these treatments. Of the three systematic reviews available I have taken most of the information from the Garrison paper, with some additional detail from Wade and Kilgour. The other review by Lucassen has been criticised by Garrison for its design, for not including all possible colic treatments, and for including trials that failed to meet Garrison's inclusion criteria. I too consider the Lucassen paper to have methodological problems that affect its reliability – several letters^x were published in response criticising the article. However in a letter to Pediatrics, Lucassen^{xi} defends his paper and criticises Garrison in return, which Garrison refutes.

Garrison's systematic review describes the search strategy and the standard databases used. Known authors were contacted for additional information including unpublished trials which in this context is especially important as studies showing no effect are harder to publish, this can lead to the true effect of an intervention being overestimated^{xii}. Each trial was assessed for quality, how the groups were divided and whether the parents or researchers knew whether the baby was having the treatment or acting as the control. They explain how this double blinding was crucial as colic has such a high placebo response rate where any

improvement in crying is often an impression rather than a definite measure. They agree with others in this field that the ideal definition of colic is the Wessel definition, and this is used throughout.

Their search revealed a total of 53 articles, only 22 randomised controlled trials met their criteria, of these 9 defined colic adequately and 12 had parents and health workers unaware of which treatment they were taking. Only 5 trials were considered adequate in all these areas to meet the basic screening test.

The most commonly used colic treatment offered to parents contains **simethicone** (infacol) and this was shown to have no effect on reducing symptoms of colic. The other widely advertised treatment using **lactase enzymes** for suggested lactose intolerance (eg Colief) also showed no effect. The only drug treatment that showed any effect, Dicyclomine (merbentyl) is now considered unsafe for babies under the age of 6 months and therefore is not available for babies with infantile colic. The trial testing a **hypoallergenic diet** is best seen as two separate trials. The breastfeeding mothers were all given a diet free of food dyes, additives and preservatives and were also randomised to an active diet that was also free from dairy, eggs, wheat and nut products or a control diet. The babies being artificially fed were randomised to receive hypoallergenic milk or a standard cow's milk based formula. Unfortunately the results from both these groups are combined and only just reach significance. Cates and Buchanan questioned this in response to the Lucassen study and despite Garrison noting our concerns the results remain pooled. Looking at the Hill^{xiii} study in more detail still doesn't help. There was no significant difference between the improvements noted by the mothers of babies in the active diet group compared to the control group. Interestingly the babies trying the hypoallergenic milk instead of standard formula didn't seem to like the taste as there was a 47% drop-out rate in this section of the trial.

Increased carrying for at least 3 hours per day, whether or not the baby was crying was not found to reduce symptoms (as described in Wade and Kilgour) but no record is given of the parents' views on whether it helped them or their babies cope with the colic, as Lawrence says 'No type of crying should go untended in a young infant. Holding and rocking do not spoil infants.'(p288)

The trial on **herbal teas** was found to help reduce colic but no mention is made to the potential harm it might have on the breastfeeding relationship. It could also have metabolic consequences, affect the infant's gut and Garrison raises concerns about potential nutritional effects of prolonged treatment leading to a decreased intake of milk. Bandolier's view is stronger '*May be slight effect in single study, but sensible parents unlikely to try this in small infants.*'

So despite all the available research as Bandolier puts it '*the simple fact is that there is no evidence that any intervention is effective. For today's mums and dads all we can offer is the knowledge that their screaming infant will grow out of it.*'

Garrison recommends future studies to look at specific groups of babies or with suspected causes before testing treatments. Studies also need to be larger to have any reliability.

Specific Breastfeeding options

Although this review considers the evidence for various ways of treating colic it doesn't mean that these are the only options. The main focus of these treatments is on finding something that can be used for formula fed and breastfed babies alike. Yet there are ways of managing colic that apply specifically to breastfed babies and this is usually missing from any review of treatments. For example, there is some evidence that making sure the baby is well positioned may lead to a reduction in colic^{xiv}. The importance of finishing the first side first is also helpful in reducing colic^{xv xvii}. So for breastfed babies, managing colic might start with watching the baby during a whole breastfeeding episode looking at positioning and attachment until the feed is finished.

Maternal diet

There may be a family history of allergies and an association with dairy products in the mother's diet has been investigated, though as Garrison reports results are not conclusive. Within the Hill study (see above) those mothers on the hypoallergenic diet noticed a greater improvement in colic with babies younger than 6 weeks, though numbers were too small to be of significance.

According to Lawrence 'acute 24 hr colic in a breastfed baby may result from a particular item in the maternal diet. Colic inducing foods are different for different infants, the most likely foods to cause colic are given as: cruciferous vegetable (such as cauliflower), onions, cow's milk and chocolate and less likely with beans, legumes, spicy foods and caffeine'. An association with diet drinks have also been found^{xvii}.

Although the evidence is limited about avoiding particular foods it is worth noting that some, especially dairy products need to be excluded for about 2 weeks to see an effect. This means reading the small print on all food to look for traces of the suspected food. Milk can be included as an ingredient in the most unexpected foods including sausages and biscuits.

New research however suggests another mechanism to explain the allergic response in babies which may be associated with some causes of colic. Hoppu^{xviii} suggests that the presence of dietary antigens in breastmilk having been modified by the mother's gut may be ideal for the maturation of the baby's immune system. He highlights the role of growth factor present in breastmilk in stimulating intestinal growth and development, so interruption of exclusive breastfeeding may affect the maturation of the infant's gut. So although his paper focuses on reducing allergies the suggestions about altering diet may be an idea worth trying as a means of reducing colic. This involves reducing the saturated fat content of the mother's diet and increase the amount of fresh fruits and vegetables and fat from vegetable origin (though current concerns about peanut allergies might make these worth avoiding).

Colic and Chiropractic Treatment

There have been two randomised trials looking at the effect of chiropractic treatment on colic. The first a Danish study^{xix}, looked at the effects of chiropractic on colicky babies. Babies joined the study if the assessment by health visitor nurses showed they met the Wessel criteria for colic (arguably modified). One group of 25 babies received spinal manipulation for two weeks. The other group of 25 was treated with dimethicone (also known as simethicone) for two weeks. Effect on crying measured by daily hours of crying in a colic diary. From day 5 the manipulation group did significantly better than the dimethicone group. (one hour reduction of crying with dimethicone v 2.7 hours with manipulation). This study would have been excluded by the Garrison review as there is no control group. Some of the benefit is likely to be the placebo effect, though it is arguable that as dimethicone has been shown to have no conclusive benefit, this could give a base line for a placebo effect. However coupled with the absence of double blinding (the mothers knew which treatment group their baby was in) it could have affected the results and with a drop out of 9/25 babies in the dimethicone group including 5 within the first week caution should be used when looking at this study. The study did ensure the interpretation of the colic diaries was carried out by an observer who was unaware of the treatment group. The chiropractic intervention looks like it had a positive effect but further studies are needed.

The second study from Norway^{xx} is larger with 100 babies with colic being recruited. The selection criteria was thorough – they met the Wessel's definition, the mothers had tried a cow's milk free diet for 4 days, or babies had hypoallergenic formula if artificially fed, they tested negatively for lactose intolerance and were otherwise well. However despite the detail given in this study it fails to consider the impact of age variation across the two groups and there are some signs that the control group may have been older, as they had a slightly longer duration of colic [3.6 v 4.3 weeks, p=0.062]. Colic decreases with age so it is possible that the control group was resolving at a faster rate. More babies were breastfed in the treatment group but again this did not reach significance [93.5%v80%, p=0.073]. This study was double blinded, the nurse took the baby away from the mother before treatment so she didn't know whether the baby had spinal manipulation or not. The results showed an improvement in both groups, 69.9% treatment v 60% in the control group [p=0.374]. So in this study chiropractic treatment was no more effective than the placebo in reducing colic, though as one reviewer (Midirs abstract) has pointed out effective spinal manipulation may have been difficult when a baby is removed from his mother.

Smoking

In a national sample of 3345 Dutch babies^{xxi} aged 1-6 months the incidence of colic was doubled if the baby was formula fed and the mother smoked, adjusted OR 1.81 (1.21 to 2.72). The risk of colic was lowered if the mother who smoked also breastfed her baby, partial breastfeeding OR 1.18 (0.60 to 2.32). It is suggested that exposure to the products of smoking during pregnancy may affect the infant in some way.

Managing Colic

- Ask a Breastfeeding Supporter to watch a whole breastfeed, until the baby comes off the breast - even good positioning might be made better.
- If there seems to be plenty of milk with both breasts being used at each feed gradually changing over several days to using one breast per feed will help decrease the volume of milk. "Finishing the first breast first," anecdotally this can be extended for varying lengths of time till an effect is found, for some keeping to one side for an hour helps, for others 3 hours at a time is needed^{xxii}, longer times

have been noted too. This is thought to help by giving the baby a lower-volume, higher-fat feed. Discuss this with a Registered Breastfeeding Supporter.

- If you feel milk is coming too fast so that the baby comes off crying or pulling off the breast it sometimes helps to feed with the baby sitting upright or the mum lying on her on her back, with the baby on top of her – so the milk 'goes uphill'.
- Consider baby led feeding v restricted feeds. Some parenting books offer a rigid style of breastfeeding, resulting in feeds being restricted - colic can be improved by feeding to the baby's needs.
- If none of the above helps, you may want to consider temporarily eliminating certain foods which may be linked with colic from your diet (see above) to see whether this makes any difference – particularly if you suffer from asthma or eczema yourself. As already mentioned, if using this method dairy products in particular may need to be excluded for about 2 weeks to see an effect. Alternatively the diet suggested by Hoppu could be tried, increasing the amount of fruit and vegetables in the diet, and reducing the amount of saturated fat and replacing this with fat from vegetable origin.

Phyll Buchanan, BfN Breastfeeding Supporter

with thanks to Carolanne Lamont, Jane Britten, Wendy Jones and Magda Sachs .

Further reading

Bestfeeding: Getting breastfeeding right for you. Renfrew, Fisher and Arms. 2nd edition
Colic case study on p184-185. smoking and colic is discussed on p94

The Breastfeeding Answer Book. LLLI Revised Ed Mohrbacher N and Stock J. p38-39, 89-90

Breast is Best. Stanway P&A. 3rd Ed Pan books ISBN 0330347535 p196-202

The Ultimate Book of Breastfeeding Answers. Newman J, Pitman T. ISBN 0761529969 Prima Publishing
Chapt 9 p175-199

The Breastfeeding Atlas. 1999, B Wilson-Clay, K Hoover p37,38

Resources online from the Australian breastfeeding association - *Lactose intolerance and the breastfed baby.* Anderson J www.breastfeeding.asn.au/bfinfo/lactose.html

Why is my baby crying? www.breastfeeding.asn.au/bfinfo/whycry.html

Colic Treatments

Interventions that showed some effect

Intervention	Outcome measured	Resolution rate		Comment
		Infants (% placebo)	(no treated)	
Dicyclomine (e.g. merbentyl)	Elimination of colic	25% 49	63% 49	RR= 0.5, 95%CI= 0.28-0.88. p= < .01 n = 134 Adverse effects, some serious reported in infants and drug contraindicated in infants less than 6 months
Hypo-allergenic diet	Daily reduction of symptoms	43% 54	61% 61	RR = 1.43; 95%CI = 1.00-2.06. p= .047 n=38 artificially fed, n= 77 breastfed Poor study design in the Hill study mixes results from breastfeeding mothers comparing a diet avoiding milk, wheat, egg and nuts with normal food and babies comparing hypoallergenic milks with standard formula. Misleading study, results should have been considered as two different trials looking separately at breastfed and artificially fed babies. Trial of hypoallergenic milk v standard formula had a 47% drop-out rate
Soy formula	Elimination of colic	5% 19	68% 19	RR = 0.33;95%CI = .017- .65. p < .001 n = 158 One study showed improvement, while larger of the two did not. The results of second study are not given in a useful way. Neither study made any attempt to disguise the soy formula so it would have been obvious who was getting the new treatment. May have an effect on artificially fed babies but needs further research – no discussion on known harms.
Decreased stimulation	Improvement observed	50% 22	93% 20	RR = 1.87; 95% CI = 1.04-3.34. p = < .01 n = 42 Babies without colic may have been included in this trial. Likely to show bias.
Herbal tea	Elimination of colic	26% 33	57% 35	RR 0.57;95% CI 0.37-0.89, p = < .01 n = 68 Said to have a control group but both groups got bottles of tea, one with herbs, the other without. No discussion on possible harms this could cause – too much fluid replaces milk and can have metabolic consequences.

Interventions that showed no effect

Intervention	No of trials	No of infants	Comment
Simethicone (e.g. infacol)	3	272	The largest and most reliable of these trials showed no effect, even for those babies considered 'gassy' by parents. The other 2 had design flaws, one showed no effect, the other an effect on days 4-7. Existing data does not show conclusive benefit of simethicone as a treatment for infant colic.
Increased carrying	2	94	No effect on crying but no information about the parent's views.
Sucrose	2	72	Minimal effect (less than 3 minutes)
Lactase enzymes (e.g. colief)	1	20	Bottle fed only – babies given cows milk some days and pooled breast milk on other days – no effect (see commentary)
Fibre enriched formula	1	24	Breastfed only – no effect on sleeping, crying or feeding.
Fibre enriched formula	1	54	No effect on average time spent crying.
Methyl-scopolamine (eg hyoscine)	1	40	Not effective or safe for babies
Car ride simulator	1	32	No effect on crying or maternal anxiety
Parent training	1	14	Some effect but trial small and likely to show bias.

- i¹ Cox S. *Breastfeeding -- I can do that*. 1997 P 15
- ii Wessel MA, Cobb JC, Jackson EB, Harris GS, Detwiler AC. 'Paroxysmal fussing in infancy, sometimes called "colic."' (1954) *Pediatrics* 14:421-434
- iii Lucassen PLBJ et al. *Effectiveness of treatments for infantile colic: systematic review*. *Br Med J* 1998; 316:1563-1569
- iv Garrison M Christakis D. *A systematic review of treatments for infantile colic*. *Pediatrics* Vol.106 No1 July 2000. p 184-190
Abstracted as Treatments for infant colic, Bandolier Sep 2000; 79-4
<http://www.jr2.ox.ac.uk/bandolier/band79/b79-4.html>
- v Wade S, Kilgour T. *Infantile colic*. *BMJ* 2001;323:437-440
- vi Stahlberg MR Savilahti E. *Infantile colic and feeding*. *Arch Dis Child*. 1986;61:1232-1233
- vii Lucas A, St James-Roberts I. *Crying, fussing and colic behaviour in breast- and bottle-fed infants*. *Early human Development* 1998; 53: p9-19
- viii Lawrence RA, Lawrence RM. *Breastfeeding; a guide for the medical profession*. 5th Edition. Mosby ISBN: 0815126158
- ix Barr RG, Hopkins B, James A. Green JA *Crying as a Sign, a Symptom and a Signal*. MacKeith Press; ISBN: 1898683212
- x Letters in response to Effectiveness of treatments for infantile colic:
Cates C. *Dietary interventions in breast fed and bottle fed infants should not be pooled*.
Buchanan P. *Trial of hypoallergenic milk is not supported by strong enough evidence*.
BMJ 1998;317:1451 plus several more letters with other comments.
- xi Lucassen PLBJ, Assendelft WJJ. In reply Garrison MM, Christakis D. *Systematic Review of Treatments for Infant Colic*. *Pediatrics* Vol 108 No4, Oct 2001 p1047
- xii *The Cochrane Reviewers' Handbook Glossary*. Version 4.1.4 Updated March 2001
- xiii Hill D et al. *A low allergen diet is a significant intervention in infantile colic: Results of a community based study*. *J Allergy and Clin Immunol*. Dec 1995;96:886-892
- xiv Righard L, Alade M. *Sucking Technique and its effect on success of breastfeeding*, *Birth* 19:4 Dec 1992, p185-188
- xv Woolridge M, Fisher C. *Colic, overfeeding, and symptoms of lactose malabsorption in the breastfed baby: a possible artifact of feed management?* *Lancet* 2, no.8607 (1988): 382-384
- xvi Evans K. *Effect of the method of breastfeeding on breast engorgement, mastitis and infantile colic*. *Acta Paed* 84: 849-52, 1995
- xvii Personal communication, Lorna Hartwell
- xviii Hoppu U et al. *Breast milk – immunomodulatory signals against allergic diseases*. *Allergy* 2001; 56: Suppl. 67: p23-26
- xix Wiberg JM, Nordsteen J, Nilsson N. The short-term effect of spinal manipulation in the treatment of infantile colic: a randomized controlled clinical trial with a blinded observer. *Journal of Manipulative and Physiological Therapeutics*, vol 22, no 8, Oct 1999, pp 517-522
- Reviewed in *Midirs* Dec 2000, Vol 10:4
- Comment from Volkening D in: *J Manipulative Physiol Ther*. 2000 Jun;23(5):365.
- xx Olafsdottir E et al. Randomised controlled trial of infantile colic treated with chiropractic spinal manipulation. *Archives of Disease in Childhood*, Vol 84, no2, Feb 2001, p 138-141
- Reviewed in *Midirs*, June 2001, Vol 11, no2, p259-260
- xxi Reijneveld S et al. *Infantile colic: maternal smoking as potential risk factor*. *Arch Dis Child* 2000;83:302-303
- xxii *Lactose intolerance and the breastfed baby*. Anderson J www.breastfeeding.asn.au/bfinfo/lactose.html