Real world evaluation of an oral treatment for infant colic

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A real world evaluation of a treatment for infant colic based on the experience and perceptions of 4004 parents

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Abstract

Infant colic (IC) is a common condition in young babies seen by primary care health professionals, especially health visitors. Nevertheless, the diagnostic criteria for IC are vague, which has resulted in a lack of clarity in published guidance on its causes and treatment. Credence has been given to alternative therapies, while health professionals are sceptical about the efficacy of over-the-counter treatments. Some 4004 parents of babies considered to have IC participated in this retrospective real world evidence study on the efficacy of a simeticone suspension in the treatment of IC. They were recruited via social media sources and were eligible for inclusion if their baby had received at least one dose of the simeticone suspension. Data were collected via an online questionnaire. The results showed that crying and discomfort-associated behaviour reduced and the babies' sleeping patterns improved following use of the suspension. More than two-thirds (69.7%) of respondents, who either used the suspension on its own or alongside another treatment, reported improvements in the signs of IC within one day. Almost all (93.2%) considered that its use was associated with either complete resolution of IC or had some effect on symptoms.

Keywords infact colic | simeticone | real world evidence | crying | Wessel criteria | trapped wind

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Infant colic (IC) is commonly observed in babies aged under 3 months, and is frequently encountered by primary care healthcare professionals, especially health visitors (HVs). There is uncertainty about its cause and no gold standard remedy or preventive action.

The common understanding is that IC is associated with what is perceived as excessive crying in infants who otherwise appear to be healthy. All infants cry more during the first 3 months of life than at any other time, whether or not they have colic. A meta-analysis of 24 studies of parental crying diaries found the mean duration of crying was 110–118 minutes per day during the first 6 weeks of life, decreasing to 72 minutes per day by 10–12 weeks, but this varied widely from infant to infant (Douglas, 2015).

Few people agree on how much crying is considered excessive. The average duration of crying during the first 3 months of life varies from 42 minutes to 2 hours per day (Lehtonen and Rautava, 1996). Barr argued that a cut-off point, based on duration, is wrong in principle and not helpful clinically because 'normal' and 'abnormal' crying depends on the context and quality of crying (Barr, 1993).

The situation is further confused by lack of consistency in the way that scientific studies of IC have been conducted and the inconsistency and contradictory nature of their conclusions. They have even differed in their definitions of IC. While a mother might say her baby has colic, the term might be used in a fluid way.

Current understanding of IC

Many studies have used the Wessel criteria to diagnose IC. The classic Wessel definition of IC is also called the 'rule of three': when a baby's crying lasts more than 3 hours a day for more than 3 days a week for at least 3 weeks (Wessel et al, 1954). This definition is taken from the Rome III criteria (Rome Foundation, 2006), which requires the presence of all the following signs in infants aged ≤4 months:

- Paroxysms of irritability, fussing or crying that starts and stops without an obvious cause
- Episodes lasting 3 or more hours/day for at least 3 days/week for at least one week
- No failure to thrive.

According to NHS Choices, IC is the name for excessive, frequent crying in a baby who otherwise appears to be healthy. It states that it affects up to one in five babies, and tends to begin when a baby is a few weeks old and normally stops by 4 months of age, or 6 months at the latest. NHS Choices is similarly vague about its treatment and does not endorse any medicines, focusing more on physical and environmental options, including how to hold or rock the baby, and the use of white noise (NHS Choices, 2015).

The National Institute for Health and Care Excellence (NICE) Clinical Knowledge Summary on IC recommends that parents should be given advice, reassurance and support, and suggests that medical treatments should be considered only if they feel unable to cope (NICE, 2014). Its two proposed treatment options are a one-week trial of simeticone drops or a one-week trial of lactase drops, with the recommendation to continue only if there is a response.

The predominant signs of IC in babies include persistent crying with no obvious cause, clenching of fists and drawing up of legs; there may also be trapped gastrointestinal wind (Sethi and Sethi, 1988; Zeifman, 2001). Diarrhoea, vomiting and failure are typically indicative of another diagnosis (NICE, 2014). In general, IC is a self-limiting condition as it usually resolves when the baby is 3–6 months old.

Roberts et al (2004) suggested three main possibilities for the origin of IC:

- Gastrointestinal, such as trapped wind or food allergy
- Psychosocial, such as a dysfunctional psychosocial relationship between infant and parent
- Neurodevelopmental, reflecting the expression of the neurological development of the newborn, which is resolved by about 12 weeks of age.

A review by *Drug and Therapeutics Bulletin* (2013) was just as uncertain:

> 'Another hypothesis is that inadequate amounts of lactobacilli and increased amounts of coliform bacteria in the intestinal microbiota influence gut motor function and gas production, which subsequently contributes to the condition. More controversially, behavioural issues such as family tension, parental anxiety, or inadequate parent-infant interaction have also been explored as causative factors for infantile colic. In addition, little is known about concomitant risk factors, however, maternal smoking, increased maternal age, and firstborn status are thought to be associated with the development of infantile colic. No association with feeding method has been noted.'

The article reviewed the evidence on various medical and non-medical options and concluded that all had shortcomings due to lack of evidence, pointedly stating that, based on the evidence from clinical trials, there were no safe, effective pharmacological treatments. It did not provide any clear guidance on treatment.

Issues with the evidence

What is needed is information, drawn from a substantial pool of babies, that relates to the parental perception of what happens in the uncontrolled situation of home life. Treatment of IC almost always happens at home, and therefore the conclusions of medically supervised studies may have limitations due to the narrowness of the populations studied.

In a review by Steutel et al (2014) on the outcome measures reported in 1702 studies on IC, 39 randomised controlled trials (RCTs), involving a total of 3295 patients, were identified. The RCTs used 20 different definitions of IC. As many as 35 (90%) used the Wessel or Rome III criteria, or a variation on them, with the remaining four trials (10%) using a different definition. Only 18 RCTs (46%) defined how symptoms improved following the intervention: of these, 11 trials (61%) said that the improvement was related to a reduction in crying time, six (33%) stated that it occurred when the infant no longer met the diagnostic criteria used and one (6%) used the effect of medication on symptoms of IC. Steutel et al also reported that the trials lacked input from parents and the results of their own work, indicating that the perceptions of parents and healthcare professionals differed markedly (Steutel et al, 2014).

The situation is not helped by the activities of alternative health practitioners capitalising on the lack of consensus among conventional health professionals. Klougart et al reported a prospective uncontrolled study involving 316 infants with IC, selected according to well-defined criteria, of whom 94% achieved a 'satisfactory result' with spinal manipulative therapy (Klougart et al, 1989). However, a systematic review subsequently found that the published evidence on chiropractic spinal manipulation did not support its efficacy (Ernst, 2009), while a Cochrane systematic review considered that the published literature on manipulative therapy, including chiropractic and cranial osteopathy for IC, lacked unbiased information, making it impossible to conclude that they have a positive benefit (Dobson et al, 2012).

The role of diet in the development of IC and of dietary manipulation as a treatment have also been considered. A Canadian committee report concluded that dietary modification is a treatment option for the management of some babies with IC (Leung and Sauve, 2003). Cow's milk proteins can elicit symptoms of IC in certain infants (Critch, 2011). Studies have shown that removing cow's milk from the diet might result in a significant reduction of symptoms of IC in a certain percentage of infants (evidence level A, where further evidence is unlikely to affect confidence in the estimate of effect). This was also demonstrated in smaller studies, such as that by Campbell (1989) involving 19 babies.

Real world evidence

An alternative to the traditional approach of RCTs into IC, whose results have caused confusion, is real world research, where information, gathered from people expressing their real world experience of healthcare interventions, comprises a structured collection of retrospective data. The strengths of this novel methodology relate to the fact that the participants are 'real' and not necessarily only those seeking a professional opinion, and a potentially large number can be recruited without using medical records.

Real world evidence studies examine how medicines and treatments work in the healthcare system. Unlike controlled clinical trials, they use observational data such as electronic medical records, insurance claims and patient surveys. The data can therefore provide a structured snapshot of the patient experience. However, the results cannot be used as the basis for clinical recommendations as the methodology falls short of the robust scientific analysis conventionally required (Annemans et al, 2007; Association of the British Pharmaceutical Industry (ABPI), 2011; Cziraky and Pollack, 2015).

This evidence represents the actuality of the experience of real users. It does not have the restrictions of a RCT, with its inclusion and exclusion criteria and limited number of selected patients. It is typically retrospective and, being based on experience, does not exclude patients, and therefore reflects the spectrum of ongoing variables such as use of different feeding methods, other medicines and alternative therapies. While real world evaluations cannot replace prospective controlled trials, their methodology permits the collection of additional data, which may form an adjunct to them. Well-known examples include the General Practice Research Database and patient registries, but these do not hold

information on conditions that are often managed without a consultation with a health professional.

Application to IC

A method has been devised to allow real world studies to be conducted in situations where health professionals might not be consulted or supervise treatment. It uses social media to recruit participants and internet-based questionnaires to collect the data, and has been used successfully to investigate the treatment of nappy rash (Goldman and Lodhi, 2016).

Simeticone oral suspension 40mg/ml (Infacol, Teva) is an antiflatulent medicine authorised for the relief of griping pain, colic and wind due to swallowed air—the signs of infant colic, based on a supposition that it is related to trapped wind in the intestine. Its efficacy was proven in a single double-blind crossover study (Sethi and Sethi, 1988). Despite these findings, which showed statistically significant efficacy, compared with placebo, in reducing the intensity and duration of crying, there has been scepticism about simeticone's efficacy and the results have not been reproduced in more recent clinical trials (Garrison and Christakis, 2000).

However, HVs and mothers appear to have confidence in the product: 19% of parents in the Infant Colic Real World Evidence (ICORE) evaluation described below stated that they bought Infacol on the recommendation of their HV. It was therefore considered that a re-evaluation using real world evidence was justified. The evaluation methodology and its results are described below.

Method

This was a retrospective non-interventional real world open evaluation that set out to ascertain parents' pragmatic experiences of using simeticone oral suspension (Infacol) to treat IC.

A review of the symptoms, signs and outcomes relating to IC was undertaken, based on the published literature. A protocol for the data collection was drawn up, and an independent group of experts advised on which outcomes would be credible to health professionals. The expert panel identified which questions should be included in the questionnaire to elicit data on these outcomes, and what level of outcome was needed to achieve credibility.

As this was an open and non-comparative study design, the expert group suggested an efficacy response rate that should be credible to other health professionals and the minimum sample size required to achieve this.

Parents were included if their baby had received at least one dose of Infacol (hereafter referred to as the oral suspension) for the treatment of IC. There was no specification as to who should have made the diagnosis of IC or how. As this was a retrospective, non-interventional trial, no randomisation or stratification was carried out. For the same reason, ethics committee approval was not required. Similarly, there were no regulatory implications as a marketed product was used that had been purchased or prescribed. The data were held anonymously by a third party compliant with data protection.

An English-language questionnaire, which used the SurveyGizmo platform, was developed. A pilot study, conducted on 50 parents of infants with IC, resulted in the fine-tuning of some of the questions. As the product is only authorised for use in the UK, and the instructions for use are solely available in English, it was not considered necessary to translate it into any other languages.

The questionnaire used multipoint rating scales, with no free-text questions. If an answer indicated that the product had not worked, the licence holder's drug safety department was notified. The SurveyGizmo application generates summary statistics and charts, with numbers rounded to the nearest whole digit.

Patients were recruited between 8 April and 8 May 2016. To avoid risk of bias from selecting respondents only from Infacol's website and social media channels, participants were also recruited from the Bounty Parenting Club database and other independent sources. It was recognised that, due to the length of the questionnaire, there was potential for a failure-to-complete issue. A random prize draw was therefore used to incentivise respondents to complete it.

Before completing the questionnaire, respondents gave their consent for their data to be used for discussion with competent authorities and promotional regulatory bodies. The questionnaire started by requesting demographic details, and then enquired about the diagnosis and treatment of IC and the infant's responses to treatment. No formal statistical analyses or comparisons were performed. However, a sub-analysis was undertaken to separate out parents who had used the oral suspension on its own to treat IC, rather than alongside any alternatives.

Results

During the data-collection period, there were 6300 attempts to participate in the evaluation, with 4004 parents providing data, of whom 4003 completed the questionnaire. (Data were therefore available for 4003 babies.)

Of the 4004 parents, 1995 were still using the product at the time of the evaluation, while 350 had used it more than 6 months previously. The oral suspension was used not only to treat IC, but also to prevent its return and the build-up of wind. *Table 1* lists the sources from which respondents were recruited.

Of the 4004 parents who participated, 3881 were female (96.9%). Just over half the babies (2092/4003, 52.3%) were male, which is consistent with the current national birth rate and indicates there is little, if any difference, in the incidence

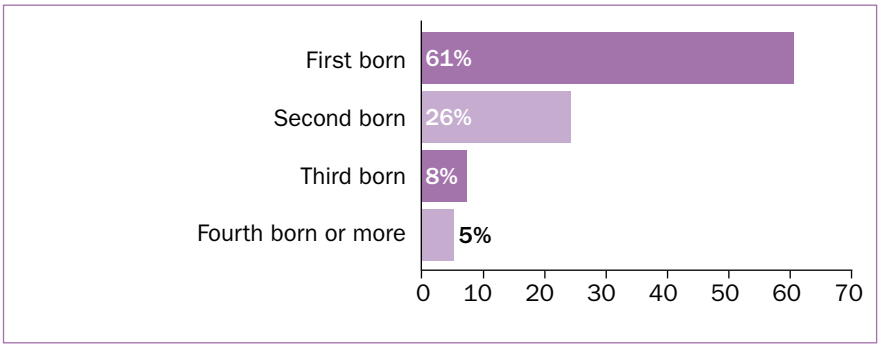

Fig 1. Birth order of babies with IC

Table 1. Sources of recruitment

	No.	%
Bounty website	1841	46.0%
Infacol website	375	9.4%
Infacol Facebook page	310	7.7%
Infacol Twitter feed	1	0.0%
Another website or social media page	171	4.3%
Somewhere else*	1306	32.6%
Total	**4004**	

*This was not defined but was likely to be other parenting and women's interest websites and social media channels with a link to the current evaluation

Table 2. Feeding methods

	No.	%
Breastfed	1279	32.0%
Bottle-fed	1590	39.7%
Both	1134	28.3%
Total	**4003**	

Table 3. Signs used to diagnose IC

	No.	%
1. Cried for more than 3 hours a day	1669	41.7%
2. Cried for more than 3 days a week	1060	26.5%
3. Cried for more than 3 weeks in a row	592	14.8%
4. Squirming in apparent pain or discomfort, clenched their fists, drew their knees up to the tummy or arched their back while crying	3651	91.2%
5. None of the above	88	2.2%
Total*	**4004**	

*Some parents identified more than one sign for their baby

Table 4. Who made the diagnosis of IC

	No.	%
The parent recognised the signs	1507	37.6%
The parent did after researching online and in books/leaflets	1086	27.1%
Family member	328	8.2%
Friend	46	1.2%
Health visitor	641	16.0%
Pharmacist	20	0.5%
GP	296	7.4%
Practice nurse	15	0.4%
Other	65	1.6%
Total	**4004**	

of IC between the sexes. The majority of babies were either a first (61.8%) or second (26%) child (*Fig 1*).

The feeding methods used are given in *Table 2*. Most cases of IC occurred in the first 3 months of life (3750/4003, 93.7%). There were no reports of IC in babies aged over 18 months.

The signs used to diagnose IC are listed in *Table 3*. The first three signs are the classic features, according to the Wessel criteria, and the third sign (squirming) is based on NHS Choices (2015). Clearly, for parents, crying and squirming in apparent discomfort were the most common presenting features of IC. A sub-analysis looking for just the Wessel criterion of crying for more than 3 hours a day for 3 days a week for 3 weeks in a row yielded only 13 respondents, indicating that parents do not use this as a diagnostic criterion.

Table 4 shows that IC was mostly diagnosed by parents, followed by HVs, who were the biggest external influencers for the selection of treatment, with 19% of purchases of the oral suspension resulting from an HV recommendation. Full details are given in *Fig 2*.

Almost all respondents (93.2%) considered that use of the oral suspension was associated with either complete resolution of IC or had some effect on the symptoms (*Table 5*). Only 1% said that it did not treat the IC. However, it is not clear from the information given about the diagnosis if these infants had IC, a different medical condition or if the product was being used for relief of crying.

Almost all parents (99%) indicated that they had used the oral suspension in accordance with the instructions. Forty-one (1%) reported that they had used less than the recommended dose, and only three stated that they had used more than the recommended dose. The most common pattern of use was 5–7 times daily, which is consistent with the fashion for demand feeding of babies aged <3 months; 36% parents were administering the product less frequently, which may reflect either a different feeding pattern or not feeling the need to administer for the indication at every feed. This might warrant further investigation.

It is noteworthy that 69.7% of respondents indicated that the symptoms improved within a day and only 2% reported no improvement (*Table 6*).

Tables 7 and 8 give the results for the duration and intensity of crying following administration of the oral suspension. *Table 9* gives results for the change in discomfort-associated behaviour. Some 81.2% (of 4002) respondents reported an improvement in the baby's sleeping patterns (*Fig 3*). Parents also reported an improvement in their own sleeping patterns and stress levels, which may have impacted on the parental bonding with the baby. *Table 10* gives the findings on how long parents continued using the oral suspension.

Choice of treatment

Of the 4004 respondents, 1891 (47%) indicated that they used the oral suspension alone to manage IC. The remainder therefore used additional treatments including medicines and physical/environmental interventions. A similar number (n=1895, 47%) indicated that they had previously tried another therapy, which had been ineffective.

A sub-analysis was attempted to determine whether the oral suspension alone resulted in a favourable outcome or if the data were confounded by use of more than one treatment. There did not appear to be any difference between the parents who had used the oral suspension on its own and those who had used additional treatments (*Table 11*).

Discussion

Crying in babies is so frequent that it might be thought to have a survival value. A thoughtful paper by Zeifman considered why babies cry and the cultural reactions to it (Zeifman, 2001). Most human infant crying is caused by hunger, pain or physical discomfort and by being left alone. IC, however, is regarded as excessive crying with no apparent underlying reason. One possible cause of IC is that the pattern of feeding and the habit of intermittent sizeable feeds might lead to trapped wind. The findings of a survey of infant care among non-human primate species and contemporary hunter-gatherer societies suggest that the amount and pattern of infant crying typical of modern Western societies might be, evolutionarily speaking, a fairly recent phenomenon resulting from modern caregiving practices that limit physical contact between infants and caregivers, inhibit prompt responses to fussing and

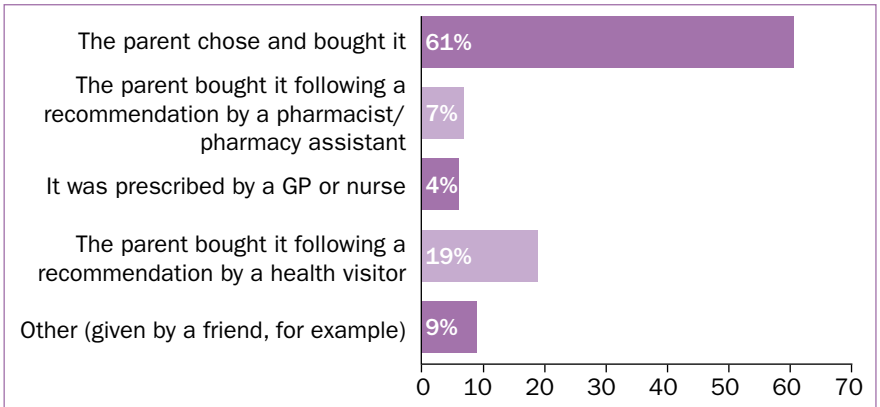

Fig 2. Sourcing patterns for the oral suspension

Table 5. Parents' answers to the question of whether or not the oral suspension successfully treated the IC

	No.	%
No, not at all	39	1.0%
Yes, it had some effect on the symptoms	2708	67.6%
Yes, it completely solved the problem	1026	25.6%
Not sure	231	5.8%
Total	**4004**	

Table 6. Speed with which signs of IC improved after administration of the first dose of the oral suspension

	No.	%
Immediately (within a minute)	194	4.9%
Within half an hour	1182	29.5%
In 1–2 hours	574	14.3%
The same day	841	21.0%
The next day	401	10.0%
In 2–3 days	561	14.0%
In >3 days	171	4.3%
The signs did not improve	79	2.0%
Total	**4003**	

Table 7. Duration of crying after first use of the oral suspension

	No.	%
No change/made crying worse	116	2.9%
A slight decrease	960	24.0%
More than a slight decrease	865	21.6%
Decreased significantly	970	24.2%
Decreased a great deal	415	10.4%
Dramatic decrease in duration of crying	276	6.9%
Crying linked to IC stopped altogether	402	10.0%
Total	**4004**	

Table 8. Intensity of crying after first use of the oral suspension

	No.	%
No change/made the intensity of the crying worse	211	5.3%
A slight decrease in the intensity of crying	1110	27.7%
More than a slight decrease	792	19.8%
Decreased significantly	857	21.4%
Decreased a great deal	378	9.4%
Dramatic decrease in the intensity of crying	242	6.1%
Any intense crying linked to IC stopped altogether	413	10.3%
Total	**4003**	

Table 9. Change in discomfort-associated behaviour following administration of the oral suspension

	No.	%
No decrease in discomfort of the baby/no difference	151	3.8%
A slight decrease	942	23.5%
More than a slight decrease	828	20.7%
Decreased significantly	902	22.5%
Decreased a great deal	451	11.3%
Dramatic decrease in discomfort	410	10.2%
Discomfort linked to IC disappeared altogether	318	8.0%
Total	**4002**	

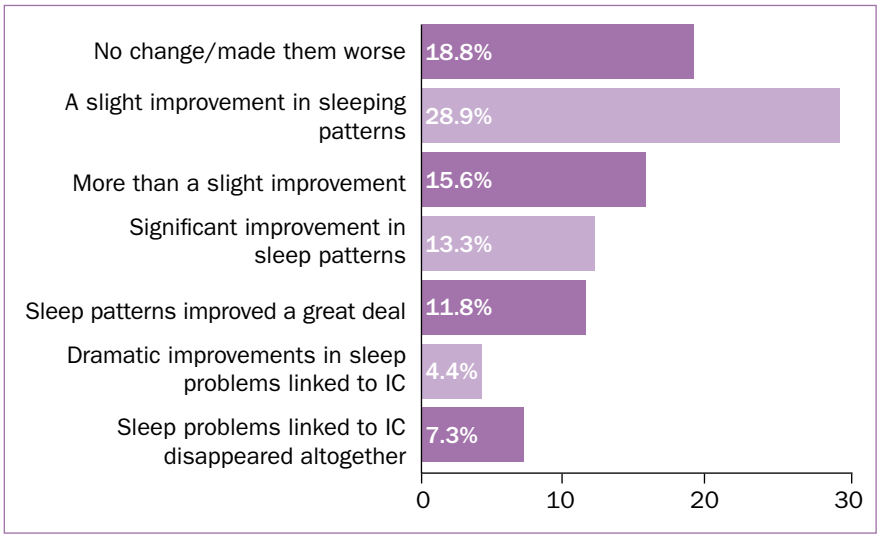

Fig 3. Babies' sleeping patterns after administration of the oral suspension

exacerbate crying (Zeifman, 2001).

Mothers frequently look to primary healthcare professionals for reliable advice on IC. The results of the present evaluation indicate that IC is predominantly a mother's problem, as only 3.1% of respondents were male, and is largely seen in first and second babies. It is not clear whether IC is not a problem in third and fourth babies, or simply less of a problem. It seems reasonable to propose that first-time mothers are more likely to need support and advice on IC. The results also show that parents rely heavily on their own judgement and research when diagnosing and treating IC. Community nurses, pharmacists and, in particular, HVs might therefore consider holding a pre-emptive evidence-based discussion on IC with new mothers.

The problem with IC is that it has defied attempts to identify a single or consistent cause, and there are several theories on its possible origin, as well as numerous approaches to its management, none of which has emerged as the gold standard.

As noted, the diagnostic criteria used to diagnose IC in controlled trials are inconsistent, with the Wessel and Rome III criteria being most commonly used. Clearly, this is not what parents perceive IC to be, with only a very small proportion of the babies in the present evaluation fitting the Wessel criteria. This might suggest that controlled studies are not addressing parents' concerns.

When diagnosing IC, it is easier to exclude what is not colic—failure to thrive, diarrhoea and vomiting, which would normally warrant a referral to a medical practitioner. However, these features can exist alongside IC. In this evaluation, parents were not given diagnostic criteria for IC, so clearly for them IC has a spectrum of features. Nevertheless, the data presented here show that babies who cry and squirm are considered to have IC and are treated as such.

The pragmatic evidence for the relief or cessation of IC is an improvement in its signs. In this evaluation, 67.6% of respondents thought that the oral suspension had some effect on IC, and 25.6% considered that it was associated with complete resolution. Most parents indicated that their experience of using the suspension was positive, but given the self-limiting nature of IC and that 69.7% considered that there was an improvement within one day, this raises the question of whether the intervention alone resulted in the improvements.

The oral suspension is thought to assist with the release of trapped wind in the gut. This theory is not accepted by all, and it is possible that IC is the final common pathway of several underlying dysfunctions that result in excessive crying. Nevertheless, the oral suspension is associated with positive outcomes when used on a crying, writhing baby, indicating that it might be a pragmatic solution that provides satisfaction for parents. While a double-blind crossover trial has demonstrated the efficacy of the oral suspension in reducing the frequency

Table 10. The length of time for which parents used the oral suspension to treat the episode of IC

	No.	%
1 day	118	3.0%
2-3 days	398	9.9%
Less than a week	318	7.9%
For 1-2 weeks	567	14.2%
2-4 weeks	500	12.5%
Over a month	926	23.1%
I am currently treating the episode of colic	1177	29.4%
Total	**4004**	

and intensity of crying when compared with placebo (Sethi and Sethi, 1988), these results have not been replicated in subsequent studies (Garrison and Christakis, 2000). Some of the studies used different dosing schedules (Lucassen et al, 1998), and the inclusion criteria were inconsistent. Therefore, the importance of the present data is that they demonstrate that the vast majority of users perceived the oral suspension to be associated with a positive outcome.

IC is sometimes called evening colic. The results indicate that the sleeping patterns of 81.2% of the babies improved. Anecdotally, it has often been reported to the licence holders that babies who are given the oral suspension seem to be sleepy, but it has never been clear if this is a response to a decrease in IC. It seems highly unlikely that this is a pharmacological effect, as the active agent in the suspension, simeticone, is not absorbed from the gut.

Almost 30% of the respondents were still using the oral suspension when the evaluation took place, although it is not evident if the intention was to prevent build-up of wind after the IC symptoms had subsided. Just over half the respondents (52.5%) had either used it for more than one month, suggesting they had continued to use it for prophylactic purposes, or were using it at the time of the survey. Recall bias is a potential weakness of retrospective real world evidence studies, but here it seems that, as so many participants were using the product at the time of the evaluation, recall is unlikely to be an issue. Traditional RCTs using diary cards would be subject to this also. A sub-analysis of those reporting an episode of IC they were treating or had treated in the past week (n=1956) showed no observable differences when compared with the total group (n=4004). While IC is potentially a self-limiting condition, parents were clearly reluctant to stop using the product, even though there may have been a rapid improvement in symptoms.

Limitations

Real world evidence studies have their shortcomings and the data from this evaluation should be interpreted accordingly. A review of real world evidence studies indicates that, without proper thought, data can be misinterpreted (Corrao, 2013). It should be remembered that this was not a clinical trial, so criteria for interpreting the results, such as that used by Hill (1965), might not apply in their strictest sense. Nevertheless, the weight of evidence presented supports the efficacy of the oral suspension in IC.

One possibility for the outcome, given the uncertain origins of IC and imprecision of its diagnosis, is that the suspension's treatment effects are those of a placebo, albeit a very powerful one.

The subjects were all English speakers who engage with social media, and therefore those who do not use social media were excluded. However, one of the biggest groups of social media users are mothers of young children. Also excluded were parents who are sceptical about the benefits of using a licensed treatment for IC or were unwilling to use a medicine on a young baby.

Table 11. Results of sub-analysis comparing outcomes for use of oral suspension alone versus use of the suspension along with other treatments

	Used the suspension with other therapies (n=2114) %	Used the suspension on its own (n=1892) %
Bottle-fed	37.2	42.6
Infants showing signs of discomfort including squirming	92.7	89.5
Parent bought the suspension following HV recommendation	19.8	17.3
The oral suspension was first used to treat IC and then to prevent wind	71.5	68.2
The oral suspension completely solved the problem of IC	16.6	35.8
The parent used the oral suspension 5–7 times daily	48.3	43.3
Results occurred within half an hour	31.0	31.4
No change in duration of crying	3.1	2.6
No change in intensity of crying	6.2	4.3
No change in discomfort	4.5	2.9

Some of the responses were observed very quickly, suggesting that the oral suspension might not have a pharmacological action. One of the models for the cause of IC is psychodynamic (Roberts et al, 2004), which focuses on the relationship between baby and mother: the very act of doing something produces a response. This must be balanced by the finding that 52% of the respondents had previously used another IC treatment that had not worked. On the other hand, as the condition is self-limiting, it might have been an intervention in a resolving situation. Only 79 respondents reported that the oral suspension had no effect.

The outcomes of this evaluation contradict most of the published RCTs and systematic reviews on simeticone in IC (Lucassen et al, 1998; Roberts et al, 2004). This evaluation shows that, in the real world, the experience of users is that the oral suspension successfully treats IC.

Another potential limitation is recall bias, which is discussed earlier.

Conclusion

In this real world evaluation, 24.3% of cases of IC were diagnosed by a health professional, most commonly HVs, although the great majority of diagnoses were made by a carer or family member. The results presented here indicate that diagnosis of IC was not necessarily based on the traditional triad of crying for 3 hours each day for more than 3 days a week for 3 weeks. These criteria are probably too strict for most carers, for whom excessive crying and squirming are likely triggers for treating IC.

A large majority of the 4004 respondents (93.2%) indicated that the oral suspension either completely resolved or had some effect on the signs of IC, with reported decreases in the duration and intensity of crying. More than two-thirds stated that the signs of IC were relieved within one day. A sub-analysis found there were no noticeable differences between participants who used the oral suspension on its own and those who used it in conjunction with other treatments (*Table 11*). This suggests that the positive results can be attributed to the suspension alone.

Social media appears to be an effective method for collecting real world evidence. The findings presented here show that Infacol is effective in reducing or eliminating what mothers consider to be the signs and symptoms of IC. In addition, almost 70% of participants reported an improvement or resolution within one day of starting the therapy.

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