Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic

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Aim and objective. The aim of the study was to evaluate the effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula, each used individually in the treatment of infantile colic.

Background. The term colic describes a group of symptoms that occur frequently in infants, consisting of paroxysmal abdominal pain and severe crying. Infant colic is of importance for both parents and the community health services that provide families with care, and is therefore an important clinical problem that is amenable to nursing interventions.

Design. This prospective and randomised-controlled study involved 175 infants in Turkey.

Methods. Data were gathered by using Wessel criteria; parents wrote a daily structured diary, recording the onset and duration of crying. Patients were assigned randomly into four different intervention groups (massage, sucrose solution, herbal tea and hydrolysed formula) and control group. Duration of crying following each intervention was recorded in the diary by parents for a one week period.

Results. There was a significant reduction in crying hours per day in all intervention groups. The difference between mean duration of total crying (hours/day) before and after the intervention infants in hydrolysed formula group was found higher

than massage, sucrose and herbal tea group. The difference between mean duration of total crying(hours/day) before and after the intervention infants in massage group was found lower than other intervention groups and all groups.

Conclusion. Our findings demonstrated that varied interventions such as administration of massage, sucrose solution, herbal tea and hydrolysed formula are effective in the treatment of colic. The difference between mean duration of total crying (hours/day) before and after the intervention in hydrolysed formula group was found higher than other intervention groups. Hydrolysed formula was the most effective in reducing the duration of crying (hours/day) when compared with the other intervention groups. Massage intervention yielded the least symptomatic improvement among all the interventions.

Relevance to clinical practice. Colic treatment models used in this study can be used by nurses in neonatal and primary healthcare settings as an aid to families for the treatment of infantile colic.

Key words: colic, herbal tea, hydrolysed formula, massage, nursing, sucrose

Introduction

Infantile colic is a syndrome characterised by paroxysmal, excessive and inconsolable crying without identifiable cause in an otherwise healthy infant during the first four months of life and can be alarming and stressful for parents. According to various published studies, the prevalence of colic ranges from 3%–40% of infants, depending on the study design, the definition of colic used and methods of data collection (Helseth & Begnum 2002, Roberts *et al.* 2004). Also, estimates of cumulative incidence have varied too, depending on the case definition and the period of follow-up, from 10% to 40% (Hide & Guyer 1982, St James-Roberts 1991).

If health workers were able to diagnose infant crying as colic, they would also be able to alleviate many parents' worries about their children's crying (Helseth & Begnum 2002).Community surveys in Denmark (Alvarez & James-Roberts 1996), England (St James-Roberts & Halil 1991) and the USA (Forsyth *et al.* 1985) have found that 12–20% of mothers are upset by such crying and/or seek the help of a clinician because of it. A better understanding of this phenomenon, often referred to as 'infant colic', is therefore of importance both for parents and for community health services providers (St James-Roberts 1999).

The aetiology of infantile colic remains unclear and, to date, no effective intervention exists for its treatment (Boychuk 2003). Careful physical examination is important to eliminate disease or other causes of the crying. To understand the underlying causes better, we need to know what exactly is reliably distinct about such crying (Reust & Blake 2000). Most studies on infantile colic use the diagnostic criteria of Wessel *et al.*, which define infantile colic as paroxysms of

uncontrollable crying or fussing in healthy infants less than three months of age, with duration of crying greater than three hours per day and more than three days per week for more than three weeks (Wessel *et al.* 1954).

Many theories have been advanced concerning the cause of colic. The cause of colic can be summed up as organic and behavioural. The behavioural hypothesis includes inadequate and inappropriate maternal–infant interaction, mother's anxiety (Lucas & James-Roberts1998, Leung & Lemay 2004). The organic hypotheses cite causes such as abnormal gastrointestinal function and allergic disorder and have led to such intervention as substituting cow's milk, soya milk or hydrolysed protein milk (hypoallergenic milk) or using herbal tea or pharmacotherapy (Lucassen *et al.* 1998, Olafsdottir *et al.* 2001, Wade & Kilgour 2001, Boychuk 2003, Roberts *et al.* 2004). Literature reviews have concluded that organic disturbances including cow's milk intolerance do indeed cause prolonged crying (Garrison & Christakis 2000). Clinically, cow's milk protein sensitive enteropathy usually presents with symptoms such as vomiting, chronic diarrhoea, mucous bloody diarrhoea and haematemesis. Infantile colic is considered to be a very unusual presentation associated with cow's milk protein sensitive enteropathy (Yimyaem *et al.* 2003).

To date, there are no consistently effective yet safe methods of managing colic. Changing babies and feeding rarely help and effective pharmacologic remedies are, as yet, unavailable. Several behavioural and complementary therapies have been suggested (Huhtala *et al.* 2000, Wade & Kilgour 2001, Rogovik & Goldman 2005).

Although, typically, infant massage does not significantly improve colic symptoms, it has been recommended in many

studies (Huhtala *et al.* 2000, Hughes & Bolton 2002, Roberts *et al.* 2004). Olafsdottir *et al.* (2001) showed that chiropractic spinal manipulation is no more effective than placebo in the treatment of infantile colic. Other researchers found no difference in the reduction of colicky crying between infants receiving massage and those with a crib vibrator over the course of a three week intervention (Huhtala *et al.* 2000).

The administration of sucrose herbal tea have also been shown to decrease crying in colicky infants (Weizman *et al.* 1993, Allen *et al.* 1996, Ramenghi *et al.* 1999, Garrison & Christakis 2000, Roberts *et al.* 2004). A randomised-controlled trial found that, at seven days, herbal tea eliminated colic in more infants than did sucrose (Wade & Kilgour 2001). However, Markestad (1997) found that sucrose does indeed have a significant ameliorating effect on infant colic. In another study, it was reported that fennel seed oil emulsion decreased colic crying (Alexandrovich *et al.* 2003). In other studies, herbal teas containing mixtures of chamomile, vervain, licorice, fennel and lemon balm, used up to three times a day have been shown to decrease crying in colicky infants (Weizman *et al.* 1993).

Hill *et al.*'s (1995) study demonstrated that the use of hypoallergenic formula led to significant improvements in clinical scores when compared with infants in the placebo group. The findings of Forsyth (1989) confirmed the results of the Hill's study. Swadling and Griffiths (2003) also found that hydrolysed formulae have a positive effect reducing the symptoms of infant colic although sample sizes were small, so the statistical significance of these studies is not clear. The relative success of hypoallergenic formula and behavioural intervention could depend on whether there are atopic features in the infant, positive family history of atopy or a more typical clinical picture of infantile colic (Lucassen *et al.* 1998).

Determining the most probable explanation for each infant and then selecting interventions based on this explanation is likely to be more successful in preventing or decreasing the length or frequency of episodes than the various trial and error approaches to treatment currently recommended by healthcare providers. Infant colic is an important clinical problem that is amenable to nursing interventions (Ellett 2003). Such intervention should have three foci: (1) emotional support for family members, (2) effort to maintain healthcare relationship and (3) effort to reduce or prevent colic episodes (Foster *et al.* 1989). Serious somatic problems are absent in most cases, but nevertheless doctors and nurses believe that they have to do something because of the distressed parents are experiencing (Treem 1994).

It is possible to be systematic by offering a list of interventions to be tried in consecutive order and to further evaluate progress by keeping in contact with the families (Dihigo 1998). Therefore, the purpose of the present study was to evaluate the effectiveness of massage, sucrose solution, herbal tea and hydrolysed formula in the treatment of infantile colic in a randomised-controlled trial, so that a series of interventions can be suggested for use in consecutive order to treat colic symptoms

Methods

This prospective and randomised-controlled study was conducted on 175 infants recruited consecutively from January 2005 to June 2005 among patients seen at the public healthcare clinics and Department of Pediatrics of the Yakutiye Research Hospital, Atatürk University in Western Turkey. In the study, four different intervention groups and one control group were formed randomly. As some scholars believe that colic as a behavioural disturbance can be related to a mother's anxiety (Treem 1994, Lucas & St James-Roberts 1998, Leung & Lemay 2004), face-to-face interviews were conducted with the mothers either before or during the intervention, to evaluate their anxiety levels, the compatibility of the interventions and reliability of the information collected. To decrease anxiety of mothers, the researchers discussed the baby's colic with the mothers in a convenient and comfortable room. Researchers explained that infantile colic is not a serious problem and that it is temporary and benign. It was determined that all parents followed the recommended treatment regime. Inclusion criteria were:

1 Typical infantile colic as defined by Wessel *et al.* (minimum of three hours of crying per day, three days per week for the last three weeks) (Wessel *et al.* 1954). Those who were diagnosed with infantile colic according the Wessel rule of threes were included in this study;
2 Infant, age between 4–12 weeks;
3 Born at term or preterm (gestational age 37–42 weeks) with a birth weight between 2·5 and 4 kg;
4 Appropriate gain in weight, length and head circumference and normal psychomotor development on paediatric physical examination;
5 Written informed consent from the parents before participation in the study.
   Exclusion criteria were:
1 Previous colic treatment;
2 Clinical evidence of gastroenterological disease;
3 Mothers who were defined as having anxiety (by means of observation);

4 Infant previously treated with medication that affects abdominal symptoms, such as antibiotic or probiotic medications.

Before starting the study, parents were given a structured questionnaire about their infants' behaviour, temperament, sleeping and eating habits and history of colic symptoms. Parent participants were then given a one-week diary to recording crying times and durations. Study subjects were then assigned randomly into four intervention groups (massage, sucrose solution, herbal tea and hydrolysed formula). Then, parents were then educated about their assigned regime by the researchers. Mothers were trained in massage technique and given brochures with written illustrated instruction. Parents wrote a daily structured diary, recording the onset of crying time, when the intervention was administered, the end of crying time, as well as any side effects observed during the week of therapy. Crying was quantified by length of crying in hours per day for one week before and one week during the intervention.

Interventions

Massage (chiropractic spinal manipulation) (n = 35)

Parents were advised to administer massage twice a day for 25 minutes duration during symptoms of colic. This time period and method were used successfully in a previous study (Huhtala *et al.* 2000).

Sucrose (n = 35)

Sucrose was administered at a dose of 2 ml of 12% solution twice a day at 5 PM and 8 PM. This concentration and volume were chosen because it had been used successfully in a previous study on pain in newborn infants (Haourai *et al.* 1995).

Herbal tea (n = 35)

Herbal tea (fennel tea) was administered at a dose of 35 ml (maximum dose of 150 ml) three times a day (Weizman *et al.* 1993).

Formula (n = 35)

In the group receiving breast feeding, it was thought that it would be wrong to discontinue breast feeding. Therefore, only the infants who were fed with standard formula were assigned to the group to receive hydrolysed formula.

Control group (n = 35)

There was no nursing intervention administered to the control group. The same paediatrician and nurse were in contact with all study parents, each of whom was visited and trained in the scoring system.

Statistical analysis

All statistical calculations were analysed by using the statistical software program, SPSS 10·0 for Windows (SPSS Inc., Chicago, IL, USA). Statistical significance was defined as $p < 0.05$. Variance analysis and chi-squared test were used to analyse the characteristics of the study population (intervention groups and control group). Paired samples *t*-test was performed to compare the variances in crying time before and after intervention. To compare the control group with the four intervention groups fairly, the Dunnet's *t*-test (Dunnet's *t*-multiple comparison test) was applied. The comparisons of all groups were made by using Duncan's test (Duncan's multiple comparison test).

Ethical consideration

The study protocol was approved by the ethical committee of our medicine faculty. Written informed consent was obtained from parents before they participated in this study.

Results

Between January 2005–June 2005, families with colicky infants (187) were enrolled in this study. Of these, 12 (6·4%) did not participate for various reasons: eight mothers did not complete the qualification period, four mothers disapproved of the interventions. Therefore, 175 participating infants were randomised into four intervention groups (35 for each group, namely: massage, sucrose solution, herbal tea, hydrolysed formula and control group). The study population characteristics are described in Table 1. Intervention groups and the control group did not differ significantly in maternal instruction, gestational age, gender, birth weight, feeding type, delivery type or maturity of infants ($p > 0.05$).

After one week of intervention, the mean amount of total crying (hours/day) decreased significantly ($p < 0.001$) in the massage groups, sucrose solution, herbal tea and hydrolysed formula, but not ($p > 0.05$) in the control group (Table 2).

There was a significant reduction in crying hours per day in intervention groups when compared with the control group when the Dunnet's *t*-multiple comparison test was applied (Table 3). The difference between mean duration of total crying (hours/day) before and after the intervention infants in hydrolysed formula group was found higher than massage, sucrose and herbal tea group. The difference between mean duration of total crying(hours/day) before and after the intervention infants in massage group was found lower than other intervention groups and all groups (Tables 2 and 3). There was resemblance in the difference between

Table 1 Characteristics of infants in the four different interventions and control groups

	Massage	Sucrose solution	Herbal tea	Hydrolysed formula	Control	Significance
Girls/boys	16/19	18/17	18/17	14/21	12/23	$\chi^2 = 3{\cdot}15$, $p > 0{\cdot}05$
Age (month)	2·29 ± 0·75	1·97 ± 0·75	2·24 ± 0·69	1·97 ± 0·71	2·28 ± 0·61	$F = 1{\cdot}39$, $p > 0{\cdot}05$
Birth weight (g)	3274·2 ± 489·6	2958·5 ± 324·6	3173·5 ± 488·8	3110·0 ± 425·6	3052·7 ± 736·2	$F = 1{\cdot}227$, $p > 0{\cdot}05$
Weight at study (g)	5840·0 ± 1052·5	4705·7 ± 883·1	5250·0 ± 1048·0	4982·8 ± 1032·5	5477·7 ± 1180·5	$F = 1{\cdot}223$, $p > 0{\cdot}05$
*Feeding type**						
Breast fed	35 (100·0)	35 (100·0)	35 (100·0)	–	35 (100·0)	
Bottle fed	–	–	–	35 (100·0)	–	
Delivery type						
Normal delivery	25 (71·4)	26 (74·3)	31 (88·6)	28 (80·0)	30 (83·3)	$\chi^2 = 5{\cdot}357$, $p > 0{\cdot}05$
Caesarean section	10 (28·6)	9 (25·7)	4 (11·4)	7 (20·0)	6 (16·7)	
Mother's education						
Illiterate	1 (2·9)	2 (5·7)	4 (11·4)	3 (8·6)	–	
Primary school (5 years)	19 (54·3)	15 (42·9)	20 (57·1)	18 (51·4)	19 (54·3)	
Secondary school and over	15 (42·8)	18 (51·4)	11 (31·5)	14 (40·0)	16 (45·7)	$\chi^2 = 7{\cdot}62$, $p > 0{\cdot}05$
Father's educations						
Illiterate*	2 (5·7)	1 (2·9)	–	1 (2·9)	–	
Primary school (5 years)	7 (20·0)	6 (17·1)	8 (22·9)	5 (14·3)	8 (22·9)	
Secondary school and over	26 (74·3)	28 (80·0)	27 (77·1)	29 (82·8)	27 (77·1)	
Mother age	28·02 ± 4·79	28·49 ± 4·67	28·86 ± 4·89	27·83 ± 5·09	27·11 ± 5·43	$F = 1{\cdot}06$, $p > 0{\cdot}05$
Father age	30·80 ± 5·37	32·14 ± 5·13	31·29 ± 4·67	30·66 ± 5·39	30·61 ± 5·06	$F = 0{\cdot}568$, $p > 0{\cdot}05$
Preterm						
Yes	5 (14·3)	6 (17·1)	4 (11·4)	8 (22·9)	9 (25·7)	
No	30 (85·7)	29 (82·9)	31 (88·6)	27 (77·1)	26 (74·3)	$\chi^2 = 3{\cdot}28$, $p > 0{\cdot}05$

*This group is not included for statistic.
±, SD

Table 2 Mean duration of total crying (hours/day) before and after the interventions

Groups	n	Crying before intervention mean ± SD	Crying after intervention mean ± SD	Significance (paired sample t-test)	(Duncan's test**) difference
Massage	35	5·34 ± 1·75	4·37 ± 1·82	$t = 7·69, p < 0·001$	0·97
Sucrose	35	5·71 ± 1·71	3·94 ± 1·51	$t = 7·51, p < 0·001$	1·77
Herbal tea	35	5·11 ± 1·43	3·20 ± 1·23	$t = 8·76, p < 0·001$	1·91
Hydrolysed formula*	35	4·91 ± 1·52	2·69 ± 1·08	$t = 7·60, p < 0·001$	2·22
Control	35	4·60 ± 1·40	4·51 ± 1·50	$t = 1·78, p > 0·05$	0·09
Total	175	5·14 ± 1·59	3·74 ± 1·59		

*Bottle-fed infant only.

**The comparisons of all groups.

Table 3 Difference mean duration of total crying (hours/day) before and after the four different interventions

Groups	n	Dunnet's t-test mean difference ± SE**	(Dunnet's t-test)* significance
Massage (1)	35	0·88 ± 0·28	(1 and 5 compare) $p = 0·009$***
Sucrose (2)	35	1·68 ± 0·28	(2 and 5 compare) $p = 0·0004$****
Herbal tea (3)	35	1·82 ± 0·28	(3 and 5 compare) $p = 0·0003$****
Hydrolysed formula (4)	35	2·14 ± 0·28	(4 and 5 compare) $p = 0·000007$****
Control (5)	35		
Total	175		

*Compares the control group with each intervention group (95% confidence interval).

**SE, standard error.

***$p < 0·01$.

****$p < 0·001$.

mean duration of total crying(hours/day) before and after the intervention in sucrose and herbal tea groups (Tables 2 and 3).

Discussion

In considering the findings, we note that this study has three limitations. Firstly, the fact that mother kept crying records of the infants can be thought as a limitation regarding the reliability. On the other hand, a recent study showed an infantile colic occurrence rate of 5·3% when registered with a diary, as opposed to 12·1% rely on parents' memory (Canivet *et al.* 1996). Therefore, it appears that diaries kept by the mothers are fairly reliable. Secondly, as treatment was only of one week long, it is probable that possible side effect would not be observed in this time period. The researchers determined that as the interventions were administered by the mothers, their observations regarding possible side-effect were reliable. Mothers were specifically asked if they noted any side effects following intervention. Lastly, another limitation of this study is the fact that posttest was administered only one week after the four interventions were initiated. Therefore, these before mentioned limitations must be considered when the study findings are interpreted.

Infantile colic, defined as excessive crying in an otherwise healthy baby, is a significant problem in infants and remains frustrating for both parents and other caregivers (Garrison & Christakis 2000). Despite the favourable clinical course of infantile colic in that most infants are free of symptoms by the age of 4–5 months, many parents seek medical help for treatment. Moreover, although serious somatic problems are absent in most cases, doctors and nurses believe that they should offer interventions, to alleviate the anxiety and stress, to those parents who are experiencing. Over the years, numerous remedies ranging from behavioural to pharmacological have been studied as treatments for colic. However, to date, no specific treatment has been found to be more effective than others (Lucassen *et al.* 1998, Garrison & Christakis 2000, Ellett 2005).

In contrast, results of the current study revealed that after one week of intervention, the mean duration of crying (hours/day) decreased significantly ($p < 0·001$) in the massage, sucrose solution, herbal tea and hydrolysed formula groups, but not in the ($p > 0·05$) control group. Additionally, the added psychological comfort (for the parents) of doing something for their children should be factored into the degree of improvement of symptoms.

Massage, sucrose solution, herbal tea and hydrolysed formula should therefore be recognised as effective in the treatment of infantile colic. For this study, infant massage was shown to be the least effective in reducing the duration of crying. The reason that massage had less effect when compared with the other interventions may result from the fact that greater comfort is derived from (the three) internal (oral) interventions (sucrose, herbal tea and hydrolysed formula) than from external intervention (massage). Previous studies also demonstrate that infant massage does not significantly improve colic symptoms (Huhtala *et al.* 2000, Olafsdottir *et al.* 2001, Roberts *et al.* 2004).

The analgesic effect of sucrose solution has been demonstrated in previous studies by reduced crying in both term and premature babies (Allen *et al.* 1996, Ramenghi *et al.* 1999). Additionally, there is some evidence for the effectiveness of sucrose solution in the relief of colic symptoms (Markestad 1997, Garrison & Christakis 2000). It has not yet been investigated, whether sucrose will be effective for the treatment of chronic pain other than that noted for colic. Massage techniques were also considered by parents to be too complex or time-consuming to be carried out effectively whereas administering 2 ml of sucrose was not at all burdensome. The fact that the duration of massage intervention was longer than that of administering sucrose solution seemed to be influential on this result.

Herbal tea has been shown to decrease crying in colicky infants (Weizman *et al.* 1993, Garrison & Christakis 2000, Roberts *et al.* 2004), but the mean tea consumption of 32 ml/kg/day used in these previously published studies raises concerns about the potential nutritional effect if prolonged treatment leads to decreased intake of milk.

The difference between mean duration of total crying (hours/day) before and after the intervention in hydrolysed formula group was found higher than other intervention groups. Hydrolysed formula is the most effective in reducing the duration of crying (hours/day) when compared with other intervention groups. In two previously published studies, the duration of crying of the babies was also reduced considerably when hydrolysed formula (hypoallergenic formula) was used; in these same studies, when standard formula was administered again, the duration of crying increased (Garrison & Christakis 2000, Lucassen *et al.* 2000). Infantile colic has been previously reported to be related to allergic disorders and thus might be (Yimyaem *et al.* 2003, Ewing & Allen 2005) the reason that hydrolysed formula was demonstrated to be the most effective intervention in this and other studies. Hydrolysed formula should therefore be the first choice in bottle-fed infants, as it had a beneficial effect on infantile colic in several studies (Hill *et al.* 1995, Allen *et al.* 1996, Garrison & Christakis 2000, Lucassen *et al.* 2000, Roberts *et al.* 2004, Rogovik & Goldman 2005).

Conclusion and clinical implications

Our findings indicate that certain interventions proved to be effective in the treatment of infantile colic. Hydrolysed formula should be the first choice. However, we must note that, because of the design of the study, blinding was not possible. Even if it is thought that this is a significant bias, this is an objectively measurable bias because duration of crying is a measurable phenomenon. However, the study emphasises the need to investigate these and similar alternative methods of treatment used controlled and blinded studies to further document whether these treatment regimens are effective or not. This is important to establish appropriate advice that can be offered to parents of colicky infants.

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Contributions

Study design: DA, HA; data analysis: DA, HA, SG, EKÇ and manuscript preparation: DA, HA, ZO, SG.

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