ORIGINAL RESEARCH

Clinical profile of infantile colic:Descriptive clinical study

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ABSTRACT
Etiologically it may be due to painful gut contractions caused by allergy to cow's milk, hyper peristalsis due to increased motilin transient lactase deficiency or motility dysfunction, neutrophilicinfiltration, altered intestinal microflora, increased intra-abdominal gas, visceral pain, increased faecalCalpotectin levels as a possible role for gut inflammation. Informed consent was taken for those who fulfilled Modified Wessel's criteria of crying for more than 3 hours a day for at least 3 days in a week. Babies were randomized into 2 groups according to computer generated block randomization by an independent statistician. The components of PQAL score namely physical, emotional, functional and cognitive functioning were similar in both the groups (p>0.05). Also, components of family summary score namely daily activities and family relationships scores were similar in both the groups (p>0.05). The total PQAL and Family summary scores were similar in both groups at the start of the study. PQAL score was significantly higher in group A compared to group B at the end of study (p<0.05).
Key words: Infantile colic, modified wessel's criteria, PQAL

INTRODUCTION

Excessive crying in healthy, thriving infants for no apparent reason like hunger, soiled diaper, over clothing etc., usually in the late afternoon or evening is common due to infantile colic. It is defined by Modified Wessel's criteria as crying that lasts at least 3 hours a day and occurs at least 3 days in a week.[1]

Its incidence varies from 5% to 19% [2] and is a diagnosis of exclusion. Unexplained crying is the most common presentation to pediatricians in the first 16 weeks of life, with around one in six families seeking professional advice in Canada.

Pathogenesis is not available despite 40 years of research. Organic causes account for less than 5% of cases. At birth infant gut is sterile and colonization starts soon after birth and it depends on the mode of delivery. LSCS (Lower segment caesarian section) babies takes 40 days compared to NVD (normal vaginal delivery) babies to reach similar levels of Bifidobacterias and Lactobacillus like bacteria. NVD babies have bacteria similar to maternal vaginal canal. LSCS
babies similar to maternal skin.Lower counts of Lactobacilli have been observed in colickyinfants compared with healthy infants. Imbalance i.e. less Lactobacilli and relative high levels of Coliforms in gut, affect fermentation resulting in excessive intra intestinal gasproduction causing colic.[3]

Etiologically it may be due to painful gut contractions caused by allergy to cow's milk, hyper peristalsis due to increased motilin transient lactase deficiency or motility dysfunction,neutrophilic infiltration,altered intestinal microflora, increased intra-abdominal gas, visceral pain, increased faecalCalpotectin levels as a possible role for gut inflammation.Colic can be an infant's behavioral problem leading to inadequate parental reactions, or due to parental distress or depression leading to less-than-optimal interaction. There is no association between the mother's age, parity, or pregnancy history and colic.[4]

METHODOLOGY

STUDY POPULATION: Babies of 2 weeks to 5 months of age fulfilling the Modified Wessel'scriteria i.e. crying for more than 3 hours a day for more than 3 days a week.

INCLUSION CRITERIA

1. Term babies from 2 weeks-5months who fulfill (Modified Wessel's) criteria of crying for more than 3 hours a day for at least 3 days in a week.
2. Exclusively breastfeeding babies.

EXCLUSION CRITERIA

1. H/o birth asphyxia or abnormal neurological examination.
2. Organic cause for cry.
3. Abnormality preventing enteral feeding.
4. Easily consolable cries like hunger cries, nappy change cries.
5. On prolonged medication like Anticonvulsants, Levothyroxine etc.
6. Probiotic or antibiotic use within 7 days.

STUDY DESIGN: An open labeled randomized control study

- Informed consent was taken for those who fulfilled Modified Wessel's criteria of cryingfor more than 3 hours a day for at least 3 days in a week.
- Babies were randomized into 2 groups according to computer generated block randomization by an independent statistician:

We divided the study infants into group A (Probiotics and Prebiotics combination) and group B (Simethicone, Dill oil and Fennel oil combination). Number in each block (block size) was calculated using the formula-2n (where and is number of groups). So, we got block size-4. As the total sample size was 96(we recruited 76), number of total blocks-19 for the recruited sample. All possible allocation sequence were assigned to numbers 1 to 6 For ex, ABAB-1, AABB-2, ABBA-3.

Then computer generated random numbers were taken. The last digit of each number was taken to give the corresponding allocation sequence to the particular block. If last number was 0 or >6 then the previous number was took for the same. For ex 3292 last digit 2 was taken and the block was given the sequence AABB. 8018-as the last digit was >6, previous number was taken which is 1 here. So the block was given the sequence of ABAB.

This allocation sequence was kept hidden and according to the randomization separate chit is picked with each case and treatment was given. The primary investigator was not aware of the allocation sequence.

After randomization if the child gets group A, then child was given preparation A containing Probiotics and Prebiotics combination. If child belong to group B then was given preparation B containing Simethicone, Dill oil and Fennel oil combination.

- Preparation A, one tenth (1/10th) sachet per day for 10 days Each sachet contains

(Lactobacillus acidophilus in a dose of 1.25 x 109CFU, *B. longum*1.25 x108CFU, *B.bifidum*1.25 x108CFU, *B.lactis* 1x109CFU and Prebiotic Inulin 25mg, alsoCarbohydrate 0.791gm, Fat 0.008gm, Protein 0.005gm)

- Preparation B was given as 20mg twice a day (13drops/dose) for 10 days

(1ml ≈25 drops=40 mg Simethicone,
0.005ml Dill Oil B.P, 0.0007ml Fennel Oil USP-NF)

- Parents were told by the doctor to mix products immediately before administration to infant with 10ml of breast milk and to be given by spoon twice a day for preparation B, once daily for preparation A.
- It was explained to the parents that the questionnaire needs to be filled on particular days for the initial 10 days and the filled form returned.
- Questionnaire to parents included details of sleep, feeding and crying episodes of the baby. Parents were instructed to exclude easily consolable cries like hunger cries, nappy change cries.
- Normal sleep pattern was taken as.

Total-13 hr (till 2month), 12hr (2 to 5 month).
Night-8hr30min (till 2month), 9hr (2 to 5 month).
Daytime-5hr 45min (till 2month), 3 hr (2 to 5 month).

- Feeding pattern was considered adequate if infant feeds at least 8 times a day.
- Infants were clinically examined by doctor before and after treatment completion and in between if required. Birth history, anthropometry and detailed systemic and general examination were done on each visit. The parents were asked about adverse events during each visit.
- On days 1, 3, 7 and 10 the study doctor had send a mobile text message to families to remind them to fill the questionnaire about infants crying time and episodes.
- The doctor called families on day 11, to remind them to a) stop administration of the study product; b) to return the filled questionnaire.
- In addition to the questionarre for parents, the doctor assessed the quality of life using validated PedsQL™ Family Impact Moduleat the time of recruitment of the study and after 10 days.
- The study ended after 10 days.
- At the end of the study the following outcomes were analyzed in both groups Primary outcome

1. Mean and % reduction in crying time per day Secondary outcomes.

2. Decrease in number of crying episodes per day.
3. Scores on standardized measure of Parent quality of life.
4. Scores on standardized measure of family functioning.
5. Duration of sleep in each group.
6. Feeding pattern in each group.
7. Episodes of vomiting of feeds in both groups.
8. Number and nature of stools in each group.

RESULTS

Table 1: Sexdistribution in both the groups was as follows

Sex	Group A (N=36)		Group B (36)		Chi-square	P-Value
	Number	Percentage	Number	Percentage		
Male	23	60%	22	58%	0.054	0.815
Female	15	40%	16	42%		

The gender distribution was similar in both group A and B (p=0.815). In both groups, the proportions of boys (60% and 58%) were higher than girls (40% and 42%).

Table 2: Age distribution in both the groups was as follows

Group	Number	Mean(Days)	SD	tvalue	P value
A	38	48.42	29.038	1.24	0.219
B	38	57.00	30.841		

The mean age was slightly higher in group B than group A. However this was not statistically significant. (p>0.05).

Table 3: Distribution of Quantitative variables before the start of the study

Variable	Group	Mean	SD	t-value	p-value
Cry (Minutes)	A	264.11	55.945	0.313	0.755
	B	260.26	50.883		
Sleep in day time (Hours)	A	6.53	1.330	0.261	0.795
	B	6.61	1.306		
Sleep in night time (Hours)	A	5.63	1.683	0.401	0.690
	B	5.76	1.125		
Vomiting (Number)	A	0.89	0.981	1.278	0.205
	B	1.21	1.166		
No feeds (Number)	A	11.47	1.704	0.216	0.829
	B	11.58	2.467		
No motions (Number)	A	1.84	1.516	0.505	0.615
	B	1.68	1.188		

Before the start of the study, the crying time, sleep, feeds and frequency of vomiting and motion were similar in both the groups (p>0.05).

Table 4: Distribution of crying episodes between two groups before the start of the study

Crying episodes	Group A (No of infants)	Group B (No of infants)	Chi-square value	pvalue
6	1(2.6%)	5(13%)	4.5	0.373
7	9(23%)	9(23%)		
8	18(47%)	12(31.5%)		
9	9(23%)	10(26%)		
10	1(2.6)	2(5.2%)		

Before the start of the study, the crying episodes per day was similar in both the groups (p>0.05).

Table 5: Distribution of parameters of Parent quality adjusted life years (PQAL) and Family summary score before the start of the study

Variable	Group	Mean	SD	t-value	p-value
Physical functioning	A	353.29	52.688	0.124	0.902

	B	351.97	39.156		
Emotional functioning	A	340.13	41.728	0.142	0.887
	B	338.82	38.859		
Social functioning before	A	301.97	33.075	0.615	0.541
	B	297.37	32.252		
Cognitive functioning	A	385.53	29.995	0.104	0.918
	B	386.18	25.133		
PQAL	A	1383.42	127.312	0.351	0.726
	B	1373.82	110.524		
Daily activities	A	247.37	35.255	0.367	0.715
	B	250.00	26.636		
Family relationships	A	398.03	32.038	1.151	0.253
	B	390.13	27.595		
Family summary	A	645.39	53.856	0.164	0.870
	B	643.42	51.230		
Type of motion	LOOSE	1 (Group A)	2 (Group A)	0.347	0.556
	NORMAL	37 (Group A)	36 (Group B)		

The components of PQAL score namely physical, emotional, functional and cognitive functioning were similar in both the groups (p>0.05). Also components of family summary score namely daily activities and family relationships scores were similar in both the groups (p>0.05). The total PQAL and Family summary scores were similar in both groups at the start of the study.

Table 6: PQAL score between two groups after medical intervention

Variable	Group	Mean	Std.Deviation	t-value	p-value
PQAL before	A	1383.42	127.312	0.351	0.726
	B	1373.82	110.524		
PQAL after	A	1617.11	95.250	4.756	0.000
	B	1503.55	112.219		

PQAL score was significantly higher in group A compared to group B at the end of study (p<0.05).

DISCUSSION

In our study we observed greater improvement in the Probiotics, Prebiotics combination group over the Simethicone, Dill oil, Fennel oil combination group with respect to significant decrease in crying time and crying episodes from day 3 onwards (mean 202min/day versus mean 221min/day with p value of 0.025). Previous studies have not observed the crying time on day3 of intervention. In our study decrease in crying time and crying episode from day 3, may be due to use of both prebiotic and probiotic combination (in group A) which helps in early onset of beneficial effects.

In Probiotics, Prebiotics combination group 36% decrease and in Simethicone, dill oil, Fennel oil combination group 20% decrease in mean crying time from baseline is noted after 10 days of intervention.

A randomized controlled trial in 2007 done by Savino *et al*., comparing probiotic use versus simethicone in term infants with colic, 3wk-3 mo, using L reuteri ATCC55730 drops (10 8cfu/d) vs simethicone drops (60 mg/d)for 1 month concluded significant reduction in median daily crying time in probiotic compared with simethicone group from day 7.[5]

Szajewska*et al*., 2013 had done double blind randomized controlled trial using L reuteri DSM17938 drops (108cfu/d) vs placebo drops (21 d) in 80 term infants with colic, <5 month as inclusion criteria, but all enrolled infants were <3 months, breastfed only. Study concluded that there is significant reduction of crying time in probiotic compared with placebo group from day 7.[6]

Savino *et al*., had done double blind randomized controlled trial in 2010 comparing probiotic use versus placebo in term infants with colic, 2week-16week, using L reuteri DSM17938 drops (108cfu/d) vs placebo drops (21 d) and found significant reduction in median daily crying time in probiotic compared with placebo group at 21 d.[5]

A systematic review of probiotics for infantile colic is done by Anabrees J *et al*., in 2012.

Three trials that enrolled 220 breastfed infants met inclusion criteria, of which 209 infants were available for analysis. Probiotic supplementation compared to simethicone or placebo significantly and progressively shortened crying times to 7 days reaching a plateau at three weeks post initiation of therapy [mean difference −56.03 minutes; 95% CI (−59.92, -52.15)]. Similarly, probiotics compared to placebo significantly increased the treatment success of infantile colic with a relative risk (RR) of 0.06; 95% CI (0.01, 0.25) and a number needed to treat of 2. This review supports the beneficial effects of probiotic supplementation in infantile colic in predominantly breast-fed infants.[7,8]

In our study we found significant increase in score of all parameters of parent quality adjusted life years in Probiotics, Prebiotics combination group at the end of study.

physical functioning (mean 448.03 and 403.95 with p=0.0000), emotional functioning (mean 417.11 and 374.34 with p= 0.0000),social functioning (mean 335.53 and 312.50 with p= 0.001),cognitive functioning (mean 419.08 and 401.32 with p= 0.009), total PQAL score (mean 1617.11and 1503.55 with p= 0.000).

CONCLUSION

In our study we found significant improvement in parent quality adjusted life years at the end of study in Probiotics, Prebiotics combination group. This is due to significant decrease in mean crying time, crying episodes from day 3 onwards and also due to significant increase in night time sleep.

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