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A clinical study on Infantile Colic with *Kuberaksha*

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ABSTRACT

Crying is one of the essential behaviors to communicate the demands of the baby so that it can be fulfilled by the parents. Prolonged crying is a source of anxiety and distress for the parents & challenge for the doctor. Infantile colic is a diagnosis of exclusion for prolonged cry in early infancy. It is described as paroxysmal crying. In the present clinical study total 100 patients were treated with 2 groups viz. treated group with *Kuberaksha Vati* (n=60) and Control group (n=40). By triturating *Beejamajja* (seed pulp powder) of *Kuberaksha* with honey, pills were prepared by an approximate weight of 125mg for treated group and for the purpose of controlled group study, placebo were prepared in similar way as that of *Kuberaksha Vati*. The disease infantile colic has compared with *Udarashoola* described in Ayurvedic classics. The history was noted by interviewing the parent/guardian. All Parents were advised to administer the drug 125mg twice daily for a period of 3 days. Follow up of study was done after 7 days for any reoccurrence of symptoms. Significant result was obtained after treatment and follow up in treated group; whereas the percentage of improvement was very low in control group. This randomized, placebo controlled clinical trial on infantile colic is found effective by administration of specially prepared *Kuberaksha Vati*. It has a positive short-term effect on infantile colic.

Key words: *Infantile colic, Udarashoola, Kuberaksha Beejamajja.*

INTRODUCTION

Infantile colic is a curious and mysterious condition. It is estimated that, on an average, 22.5% of all newborns suffer from colic every year. Infantile colic is defined as uncontrollable crying in babies from 0-3 months old, more than three hours a day, more than

three hours a day, more than three days a week for three weeks or more.^[1] It is usually seen in the afternoon and evening hours.^[2]

About 47 percent of infantile colic cases have disappeared by the age of three months, a further 41 percent disappeared before six months of age, and the remaining 12 percent of cases persevered until between the ages of 6 and 12 months.^[3]

Wiberg JMM and Nordsteen J, Nilsson N described in 1894, colic had no verified cause(s). Countless studies have, however, determined what it is not caused by: air or constrictions in the intestines; gastrointestinal transit time; intestinal hormones; intestinal micro flora; method of delivery (vaginal, cesarean section or vacuum extraction); use of pudendal block; epidural analgesia; general anesthesia; or intravenous oxytocin.^[4]

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Infantile Colic: Ayurvedic perspective

The disease infantile colic can be comparable with *Udarashoola* described in Ayurvedic classics with the features described as *Sthana Vyudasyate* (rejects breast), *Rauti* (cries), *Uttana Schava Bajyate* (sleeps in supine position), *Udara Stabdata* (stiffness of the abdomen), *Shaityam* (coldness), *Mukhasweda* (perspiration of the face).

Other texts described; the significant factor responsible for the genesis of *Shoola* is *Vata (Vayu)*. *Vayu* presents in the body gets aggravated because of different etiological factors produces a violent Cutting & Spasmodic pain in the abdominal cavity (*Kosta*). The patient complaints of pain as if he is being pierced with a pear (*Shanku*) inside, feeling of suffocation under the influence of that excruciating pain, which fact have determined the 4 nomenclatures of *Shoola*.^[6]

Where as an infant with colic pain only expresses continuous cry. Detailed etiopathogenesis about 8 types of *Shoola*,^[7] and the clue for the management of *Udarashoola* described in Ayurvedic classics, are referred to analyze the disease.^[8]

There is no similar type of *Shoola* found in classics to describe as per infantile colic, however some references of *Udarashoola* given here for easy understanding. The gross features of *Udara Shoola* is mentioned as *Koste Vibanda* (constipation), *Vamathu* (vomiting), *Sthana Damsha* (biting of the breast), *Antrakujana* (gurgling sound in the abdomen), *Adhmana* (flatulence), *Pristanamana* (bending back), and *Jathara Unnamana* (elevation of the abdomen).^[9]

The drug *Kuberaksha* popularised as *Kantakikaranja Beeja (Caesalpenia crista)* is emphasized for its multiple actions over different diseases like *Shothahara*, *Krimigna*, *Udarashoola*, *Agnimandya*^[10] etc. *Harita Samhita* described its definite action on *Udarashoola* i.e., *Kuberaksha* alone or along with *Haritaki*, *Sauvarchala Lavana* & *Hingu* can pacify all types of *Shoola*.^[11]

OBJECTIVE OF THE STUDY

To study the effect of *Kuberaksha Beeja Majja* in relieving infantile colic.

MATERIALS AND METHODS

Study design

Present study is a placebo controlled open clinical trial on infantile colic. Patients attending O.P.D and I.P.D of Kaumarbhritya, SDM College of Ayurveda and Hospital, Hassan, Karnataka in the year 2005 to 2007 diagnosed as infantile colic were taken for the study. All patients were measured with Paired “t” test for assessment of results.

Inclusion criteria

Patients in between the age group 1 month to 1 year, complaining of abdominal pain and vomiting, sleep disturbances, skin on touch, excessive crying were included.

Exclusion criteria

Congenital anomalies, Infants with known cases of chromosomal, metabolic and hereditary Disorders, Pain due to known organic causes such as urinary tract infections, Trauma, appendicitis, diarrhea, infection etc., were excluded.

Diagnostic criteria

The diagnosis was made on the basis of Wessel's criteria and the *Lakshanas* described in Ayurvedic texts such as; continuous cry, vomiting, sleep disturbances, gurgling sound in the abdomen with stiffness of abdomen, cold on touch and perspiration on face.

Grouping

All patients were selected irrespective of sex, caste, religion, socioeconomic status, geographical distribution etc. and divided in to 2 groups.

Group A (Treated group) contained 60 patients given *Kuberaksha Vati* in 2 divided doses for 3 days, Group B (Controlled group) contained 40 patients given fried rice powder 125mg in similar way as that of *Kuberaksha Vati*.

Preparation of *Kuberaksha Vati*

Well cleaned, dry fresh *Kuberaksha* seeds were taken from the market and cover is removed by sharp

instrument. Seed pulp was made in to fine powder was mixed with appropriate quantity of honey. By triturating the seed pulp powder with the honey pills were prepared by an approximate weight of 125mg. For the purpose of controlled group study, placebo was prepared with fried rice powder in similar way as that of *Kuberaksha Vati*.

Drug administration schedule

The history was noted by interviewing the guardian. After thorough clinical examination and symptomatic evaluation Parents of the patient were advised to administer the drug at a dose of 125 mg twice daily for a period of days.

Assessment criteria

Assessment was made on the basis of improvement in the clinical features through suitable gradations of both subjective and objective clinical features before & after the treatment.

Subjective criteria

- Pain-frequency of pain in 3 hrs duration, Duration of pain, Pain association and relief
- Sleep-Duration of sleep in 24hr period, Frequency of interruption in 24 hrs.
- Bloating of abdomen
- Excessive cry
- Vomiting

Objective criteria

- Skin - Warm, Cold/ Clammy, and Temperature with sweating.
- Gurgling sounds in abdomen by Stethoscope-Frequency, Duration, Intensity

Grading scale for assessment of Infantile Colic

Grading (0, 1, 2, 3) were made for easy assessment

Pain Symptoms

Frequency of pain in 3hours	Score
No pain	0

Occurrence 1-3times	1
Occurrence 3-5times	2
>5 times	3

Duration of Abdominal Spasm

Spasm	Score
No Spasm	0
Once in 15 seconds	1
Once in 30 second	2
> 45 second	3

Pain association & relief

Pain	Score
No Spasm	0
Association with Expulsion of gases (No stool & Urine)	1
Association with expulsion of stools & urine	2
Recurrent colicky pain without constipation	3

Vomiting in 24hrs period

Vomiting	Score
No Vomiting	0
Vomiting just after feed every time	1
Intermittent Vomiting	2
Frequent vomiting>8times	3

Duration of sleep in 24 hours period

Sleep	Score
>12 hours	0
10-12 hours	1

8-10 hours	2
<8 hours	3

Frequency of interruption in 24 hours period

Sleep interruption	Score
No interruption	0
4-6 times/day	1
6-10 times/day	2
>10 times/day	3

Skin on Touch

Skin on Touch	Score
Warm without perspiration	0
Cold/clammy	1
Warm with sweating	2
Severe perspiration	3

Gurgling sound in the abdomen frequency

Gurgling sound frequency	Score
5-10 times/minute	0
10-15 times/minute	1
15-20 times/day	2

Gurgling sound in the abdomen duration

Gurgling sound duration	Score
Mild & audible with stethoscope	0
High intensive audible with stethoscope	1
Audible without stethoscope	2
Audible nearby	3

OBSERVATION AND RESULTS

Percentage of Gross Improvements in Both the Groups:

SN	Clinical Features	% of improvement in Group-A patients		% of improvement in Group-B patients	
		AT-3days	AT-7days	AT-3days	AT-7days
1.	Frequency of pain in 3hr	61	88.83	20.25	33.52
2.	Duration of spasm	56.66	93.33	5	28.75
3.	Pain association and relief	85.83	93.33	10	33.75
4.	Vomiting	70.61	81.66	14.12	32
5.	Sleep duration in 24hr period	70	82.5	8.75	32.5
6.	Frequency of interruption in 24hr period	83.33	95	11.25	32.5
7.	Skin on Touch	90.83	97.5	7.5	25
8.	Frequency of Gurgling sound in the abdomen	52.5	94.16	10	25
9.	Duration of Gurgling sound in the abdomen	83.33	95.83	3.75	13.75

Overall Assessment: Group-A

Indication	Pre treatment (No. of patients)		Post treatment (No. of patients) A.T-3days		Post treatment (No. of patients) A.T-7days	
	Moderate	Reduced	Moderate	Reduced	Moderate	Reduced
Excessive crying	42	18	9	51	57	3
Abdominal	36	24	14	46	58	2

nal bloating						
Food intake	52	8	55	5	56	4
Abdominal Tenderness	4	56	2	58	0	60
Bowel sound	58	2	32	28	18	42

Overall Assessment: Group-B

Indication	Pre treatment (No. of patients)		Post treatment (No. of patients) A.T-3days		Post treatment (No. of patients) A.T-7days	
	Moderate	Reduced	Moderate	Reduced	Moderate	Reduced
Excessive crying	23	17	19	21	18	22
Abdominal bloating	25	15	8	32	10	30
Food intake	33	7	25	15	11	29
Abdominal Tenderness	4	36	2	38	1	39
Bowel sound	28	12	14	26	11	29

Note: In all the clinical features of Group-A like frequency of pain in three hours, duration of spasm, pain association and relief, skin on touch, gurgling sound frequency, gurgling sound durations, vomiting, sleep duration in 24 hours' period, frequency of interruption in 24 hours, highly significant results were found. This discloses that the drug *Kuberaksha Beeja Majja* is very effective to reduce colic symptom in the infants.

In Group B where placebo was administered there were very low percentage of improvement observed after 3rd day of treatment, and 7days of follow-up. But in multiple conditions there were highly significant results observed during the follow up may be because of the episodic problem occurs due to infantile colic and advice given them like burping after each feed, routine dietary advice to mother helps to reduce the illness.

DISCUSSION

There is conflicting evidence found regarding the etiological factors responsible for infantile colic. Mother's milk, cow's milk, formula feed, position during feeding, mothers' diet, mother's psychic condition, her busy schedule etc. are important points among them. As per the available data, all the factors are more or less may be a cause. Therefore, maternal health education probably helps to prevent this condition. Hill D J, Heine RG, Cameron DJ, et al. described that the child who is absolutely with mother's milk also sufferer with this problem. If the child is fed with formula the problem may be intolerance to milk proteins from cow's milk-based formula.^[12] A Santosh Kumar, 2001 described, if colic occurs due to either mother's milk or cow's milk, switching to a soy formula may decrease colic in such cases.^[13] However the recent study discloses that cessation of mother's milk for a period of two days is enough to normalize the condition and one can continue mother's milk later on could solve the problem.

Suraj Gupte, 2002 described Infants who are sensitive to both milk and soy may be given a hypoallergenic formula containing extensively hydrolyzed proteins.^[14] However, some children are sensitive even to that formula milk. But it is observed that change of state of mind or psychic condition of mother during feeding could solve the problem.

Recent study provides the information that colic is very common in all infants irrespective of their diet pattern viz. formula feed, Mother's milk, over feeding or lack of feed. However, those are absolutely with mother's milk where mother is healthy and absolutely

taking proportionate diet, the incidence of colic is comparatively less.

Harley L.M, 1969 described that the positioning during feeding and flexion of extremities during a crying episode helps to reduce colic determined as cry is reduced.^[15] It is observed that change of positioning could decrease the crying episodes of infants. Gupta SK, 2002 described that, GIT disorders have been implicated in colic because of the infant's leg position and grimace during a crying spell. In this research same thing is observed in many patients.

Excessive crying or increased gas production from colon function can result in intraluminal gas formation and aerophagia. However radiographic images taken during a crying episode have shown a normal gastric outline. It also has been speculated that abdominal cramping and colic may be a result of hyperperistalsis.

The later theory is supported by evidence that the use of Anti cholinergic agents decreases colic symptoms. Gut hormone such as Motilin also play a causative role in colic. Motilin is thought to cause hyper peristalsis, leading to abdominal pain and colic.^[16] In the present study it is seen that air in aerophagia during continuous crying in irritable infants, fast feeding when mother is hurry are found to be the aggravating factors for infantile colic.

Psychosocial causes: White BP *et al.* 2000, described that though studies have addressed possible psychosocial causes of colic, but no evidence has been found in support of this mechanism in the recent study. Even when colicky infants are cared for by trained occupational therapists, they cry twice as long as infants without colic.^[17] Same matters are observed in the recent study.

Barr RG, 2002, described Parents with colicky infants may think that they have poor parenting skills. However, there is no evidence that maternal personality or anxiety causes colic.^[18] In the recent study no such evidence found regarding poor parents' care.

Raiha H *et al.* 1996 described those families with colicky infants; there may be problems with

communications and family functioning as well as parental anxiety and fatigue.^[19] Recent study discloses that maternal psychic condition plays an important role for the aggravation of colic episodes, particularly when mother is derived from their family members, parental relationship is not so good, and mother is dissatisfied due to certain familial reasons the episodes of colic is more.

CONCLUSION

The study discloses that the drug *Kuberaksha* is safe and useful to administer in infantile colic condition for all infants. Parents are usually with stress due to continuous cry of the infants and often visited to doctors unknowingly to solve this problem. However, there is no single identifiable cause found for this. Different factors such as diet, positioning during feeding, maternal psychic condition, weaning problem, infection etc. plays important role to create the problem. *Kuberaksha* is found to be a better herbal remedy for infantile colic. Hence one can administer single drug *Kuberaksha* for the management of infantile colic.

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