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CLINICAL TRIAL ON EFFECTIVENESS OF HINGWASHTAKA ARKA DROPS IN THE MANAGEMENT OF INFANTILE COLIC

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ABSTRACT:

Background: Infantile colic is a typical pediatric disorder in which persistent or excessive crying is one of the most distressing problems of infancy. Infantile abdominal colic is episodes of crying for more than three hours a day or more than three days in a week. Colic begins at about 2 to 3 weeks of age and ends anywhere between 3 to 24 months of age. As per Ayurveda, it is correlated to the udarashoola (colicky pain) which is considered to be foremost complaints noticed in infants, which is expressed by increased cry that disturbs the mother, care taker and whole family. Hingwasthaka choorna is having Deepana (increases the digestive power), pachana (digestive), rochana (appetizer), vata kapha prasamana, vataanulomna, shoolaghna (relives pain) and vibandhara (relieves constipation)properties which may be helpful to reduce the infantile colic. **Objective:** To evaluate the effect of Hingwasthaka Arka Drops administered per orally for 7 days in infants between the age group of 2-6 months suffering from Infantile colic **Method:** This study is open labelled single arm prospective clinical trial. Hingwasthaka Arka (a liquid preparation obtained through distillation) drops 1ml thrice a day before feeding for 7 days orally. Methodology: it was a single group clinical study with pre and post design. Pretest assessment of subjective parameters was done using FLACC scale and other associated features on day 1 day 4 and day 7 of the treatment. **Results and conclusion:** The study has shown statistically significant reduction in the subjective parameters with the P value 0.005. hence it was inferred that the intervention selected for the present study Hingwashtaka arka drops is effective in the management of infantile colic in 2-6 months.

Key words: Infantile Colic, Udara Shoola, *Hinwasthaka Arka*, FLACC Scale

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INTRODUCTION:

Persistent or excessive crying (colic) is one of the most distressing problems of infancy [1]. Infantile abdominal colic is defined as episodes of crying for more than three hours a day or more than three days in a week. Colic begins at about 2 to 3 weeks of age and ends anywhere between 3 to 24 months of age. Up to 20% of infants are affected by infantile colic and is one of the most common presentations to the primary health sector in early life [2]. Clinical Features includes Intense crying seems more like screaming, Fussiness is seen, Facial discoloration such as skin flushing, Body tension, stiffened arms, clenched fist, having a tight belly [3]. In modern science, for infantile colic dicyclomine content medicines are administered, these mainly cause dizziness, dryness of mouth and loose motion in some infants.

As per Ayurveda it is mainly correlated to the *udarashoola. Udarashoola* [4] (colicky pain) in infancy occurs due to various reasons, which are unknown. *Udarashoola* is considered to be foremost complaints noticed in infants, which is expressed by increased cry that disturbs the mother, care taker and whole family and the most commonly encountered pain in infants which makes the baby irritable and uncomfortable if not attended it can impact on weight gain and quality of life. Thus, the major issue needs to be focused on its proper management.

Drugs with *Deepana* (increases digestive power)*, Pachana* (Digestive) and *Anulomana* (eliminates flatus and feces) property are to be mainly chosen for management in *udarashoola. Ajamoda, Shunti, Jeeraka, Vacha, Shatapushpa[5], Hingu* which are having *Deepana, Pachana* and *Anulomana* properties can be used in this condition. *Hingwashtaka churna* is one such drugs indicated for *udarashoola* as it is having *Deepana, Pachana, Rochana, Vatakaphaprashamana, Vataanulomna, Shoolaghna, Vibandhahara [6,7]* properties.

Hingwashtaka churna: It is a combination of 8 ingredients. *Hingwashtaka churna[8]* is used as a digestive aid as it helps in the removal of all digestive disorder as it is acting as a carminative and antispasmodic. It is considered as strong appetizer and is indicated in *agnimandya* (Reduced digestive power). It is also used in the treatment of anorexia, indigestion. It is a strong vermifuge as well as best *vata Anulomana*. Hence *Hingwashtaka churna* is selected for the present study in the management of *udarashoola* (infantile colic). Whenever we are treating children, especially infants, the form of the drug and dosage are to

be considered. Hence using *Hingwashtaka churna, arka* was prepared for this clinical study.

OBJECTIVE:

To evaluate the effect of *Hingwasthaka Arka* Drops administered per orally for 7 days in infants between the age group of 2-6 months suffering from Infantile colic

METHODOLOGY:

Research Design: Open labelled single arm prospective clinical trial.

Source of Data: Diagnosed subjects of *Udarashoola* (Infantile colic) attending Kaumarabhritya out-patient department of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan were included.

Method of collection of Data: In this study, minimum of 20 infants fulfilling diagnostic criteria were selected. A special case proforma was designed to collect the information which includes history taking and clinical examination.

Sampling Technique: Convenience sampling

Sample Size:20

Diagnostic Criteria:

Diagnosis was made on the basis of Lakshana of Udarashoola (infantile colic). *Rodana* (cry) and *Adhmana* (Flatulence) along with any one or more symptoms

1.*Vibandha* (Constipation)

2.*Chardi* (Regurgitation)

3.*Antrakujana* (Gurgling sound in the abdomen)

4.*Uttanaschaavabhajyate* (Lies in supine position)

Inclusion Criteria:

Diagnosed cases of infantile colic of age group 2-6 months, irrespective of gender, socioeconomic status was included in the study.

Infants whose parents are willing to participate in the study and ready to sign the informed consent form.

Exclusion Criteria:

Known cases of congenital anomalies.

Infants with known cases of chromosomal, metabolic and hereditary disorder.

Infants with any other systemic disorder.

Fever, diarrhea and vomiting or GIT infection to be excluded.

Assessment Criteria: Assessment will be done based on FLACC SCALE 21 and other criteria as mentioned below on Day 0- Before treatment (BT), Day 4-During Treatment, Day 7- After Treatment (AT)

SUBJECTIVE PARAMETERS

- FLACC SCALE
- *Stanamvyudasyte* (Rejects breast)
- *Chardi* (regurgitation)
- *Nidra* (Sleep)
- *Antrakujana* (Gurgling sound in the abdomen)

OBJECTIVE PARAMETERS

- Abdominal girth

Intervention: *Hingwashtaka Drops*

Duration of Treatment: 7 days, ***Anupana***: - Nil, **Dose**: - 1ml 3 times a day

Method of preparation of study drug:

Source of Authentication of raw drug: The authentication of drug was done at the department of Dravyaguna, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. Collection of raw drugs was done from pharmacy SDMCAH Hassan

Method of preparation of Arka: The preparation of was done under the supervision of teaching pharmacy of the department of Rasashastra and Bhaishajya kalpana,Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

Preparation of Drops:

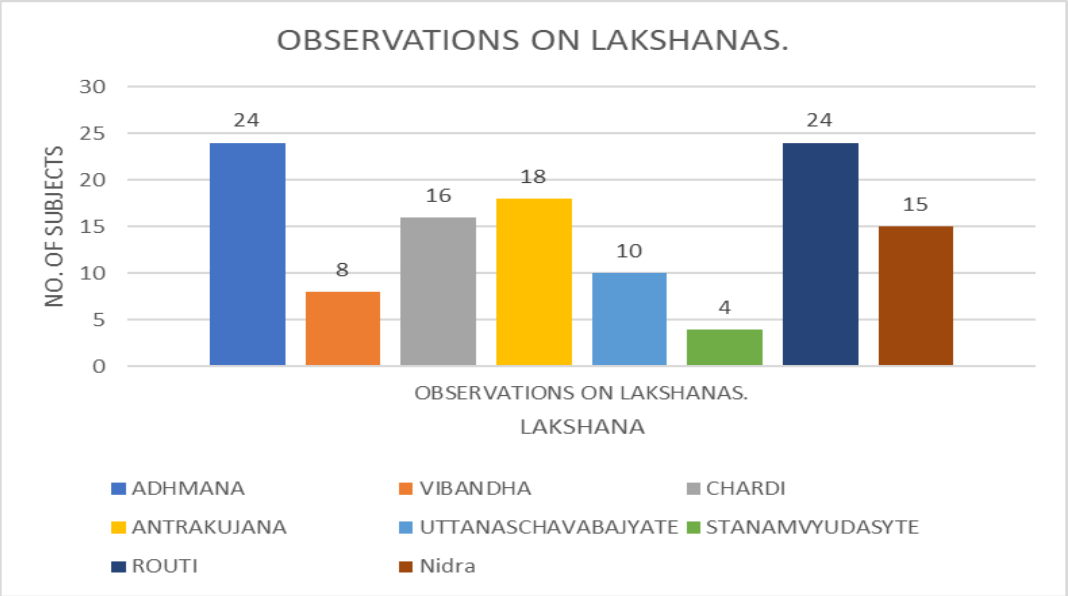
Preparation of *Hingwasthaka Arka* was done based on the method of *Arka* preparation. Simple distillation apparatus was used for the preparation.

TABLE No. 1: Ingredients
1.Shudha Hingu
2.Pippali
3.Marich
4.Shunti
5.Ajamoda
6.Shweta jeeraka
7.Krishna jeeraka
8.Saindhava lavana

The above-mentioned drugs are taken 1part each and triturated separately in *Khalva yantra* to obtain a coarse powder. Later 1 Part of *Hingwashtaka* coarse powder and 3 parts of water is added to the drug for soaking and kept overnight. On the next day the mixture was transferred to a distillation apparatus having a capacity of 1liter. The temperature was set up to 50^0C and maintained the same till the water started boiling later reduced to 10^0C. During distillation the continuous water supply was provided to condense the *arka* properly. In the beginning, the vapors consist of only streams and may not contain the essential principles of the drug and it should be discarded. The end portions may not contain therapeutically essential substance and should be discarded. Later the distillate *Hingwasthaka Arka* was collected up to 60% volume of water and stored in the air tight container.

Observations and Results

36 subjects were screened for the study, in which 24 subjects were included and 20 completed the full course of treatment. The observation & statistics were done for 20 patients who have successfully completed the study.



Graph 1- Lakshanas of udarashoola

In this present study, 18 (75.0%) subjects belonged to the age group of 2-4 Months and 6 (25%) subjects belonged to the age group of 4-6 Months.10 (42.0%) subjects were females and 14 (58.0%) subjects were males and 31(77.5%) subjects were consuming breast feeding, 9(22.5%) subjects were consuming both (breast feeding and artificial milk). In this present study 21(52.5%) subjects were adopted sitting posture while feeding, 13(32.5%) subjects were adopted lying posture while feeding and 6(15%) subjects were adopted both (sitting and lying) posture while feeding. 28(70%) subjects were having rarely habit of burping after each feed, 11(27.5%) subjects were having no habit of burping after each feed and 1(2.5%) subject was having properly habit of burping after each feed

Effect Of Treatment on Abdominal Pain (FLACC Scale)

TABLE No 2 - FRIEDMAN TEST EFFECTS ON ABDOMINAL PAIN: FLACC SCALE					
PARAMETER	**N**	**Mean Rank**	**X2**	***P***	**Remark**
FLACC Scale BT	20	4.00	109.484	0.001	S
FLACC Scale 3 RD Day		2.28			
FLACC Scale 5 TH Day		1.86			
FLACC Scale AT		1.86			

Friedman test was applied to assess the effect of *Hingwasthaka Arka* drops on

Udarashoola (abdominal pain). On applying Friedman test on abdominal pain, there was reduction seen in themean rank (MR) from 4.00 (before treatment) to 1.86 (AT) with a X2 value =109.484, p value = 0.001. This shows that there was statistically significant improvement in *udarashoola* (*abdominal pain) in infants*. As Friedman test was significant, Post hoc Wilcoxon test was performed to interpret the time of significant change.

TABLE No. 3 - WILCOXON SIGNED RANK TEST EFFECTSON ABDOMINAL PAIN (FLACC SCALE).

Parameter	Negative ranks			Positive ranks			Ties	Total	Z-value	P value	R
	N	MR	SR	N	MR	SR					
3RD Day – BT	20	20.50	820.00	0	0.00	0.00	0	20	-5.690	0.000	S
5TH D-3RD Day	11	6.00	66.00	0	0.00	0.00	09	20	-3.071	0.002	S
AT –5TH Day	0	0.00	0.00	0	0.00	0.00	20	20	0.000	1.000	NS
AT – BT	20	20.50	820.00	0	0.00	0.00	0	20	-5.650	.0005	S

During BT to 3rd day, it was found that 20 subjects had reduction in symptoms, which was statistically significant with z value= -5.690, p value=0.001. From 3rd to 5th day, it was found that 11 subjects had decrease in theirsymptoms, whereas there was no further improvement in 09 subject which is evident with tie value at 09. This was statistically significant at z value = - 3.o71, p value =0.002. From 5th to 7th day, it was found that 20 subjects had no further improvement (no further aggravation and decrease) in their symptoms, which is evident with tie value at 20. this was statistically non-significant at z value = 0.000, p value= 1.000. By the end of the treatment, it was found that 20 subjects had reduction in symptoms, which was statistically significant at z value = -5.690, p value =0.001.

On applying Friedman test to the statistical effect of treatment on *adhmana, rodana, chardi, nidra* and *antrakoojana* there was reduction seen in the mean rank (MR) and statistical improvements were observed. As Friedman test was significant, Post hoc Wilcoxon test was performed to interpret the time of significant change. It was observed that statistically significant improvement was observed during the first 3 to 5 days of treatment.

DISCUSSION:

Udarashoola (Infantile colic) is considered to be the foremost complaint noticed in infants, which is expressed by incessant cry that

disturb mother and whole family. This can be attributed to the current environmental changes such as lifestyle of mother and their improper food habits which leading to vitiation of Agni and produces *Ama* (toxins) thereby causing *Rasavaha Sroto dushti* in mother and resulting in similar pathological condition in infants. *Udarashoola* is mentioned as *Koste Vibhanda* (Constipation), *Vamathu* (Vomiting), *Sthana Damsha* (Biting of breast), *Antrakujana* (Gurgling sound in the abdomen), *Admana* (Flatulence), *Pristanamana* (Bending back) and *Jataraunnamana* (Elevation of the abdomen). As per the contemporary science also it is seen that there is more prevalence in infants due to immature digestive and nervous system, which leads to various secondary complications if left untreated.

Faulty feeding techniques and not following burping after each feed are found to be important causative factors. Appreciable amount of air, which is swallowed by infant's during suckling, collects within bulge of the infant's stomach was predominantly associated with causing infantile colic. Burping is the method which is done to help a baby let out air from stomach, especially by patting or rubbing the baby's back. Other relieving factors like - Prone lie position, abhyanga followed by hot fomentation will also help the baby. Pressure present over the abdomen during prone lie helps to relieve uncomfortable gas, *Abhynaga (* soft touch and massage) given to the infant especially on the abdomen and back with luke warm oils which reduced *Vata*, because *Vata* is the most common predisposing factor for *udarashoola* (infantile colic). Hot fomentation performed on an infant by cloth sudation and through hands rubbing sudation which is indicated in colic because *swedana* is having *shoolaghana* properties.

Drugs with *Deepana*, *Pachana* and *Anulomana* qualities are to be mainly selected for internal administration in the management of *Udarashoola* (Infantile colic). which may be helpful in reducing the infantile colic. *Ajamoda, Shunti, Jeeraka, Vacha, Shatapushpa, Pippali Hingu* which are having *Deepana, Pachana and Anulomana* properties can be used in this condition. *Hingwashtaka churna* is one such drugs indicated for Udarashoola as it is having *Deepana, Pachana, Rochana, Vatakaphaprashamana, Vataanulomna, Shoolaghna, Vibandhahara* properties. *Hingwashtaka churna*: It is a combination of 8 ingredients used as a digestive aid as it helps in the removal of all digestive disorder as it is acting as a carminative and antispasmodic. It is considered as strong appetizer and is indicated in agnimandya. It is also used in the treatment

of anorexia, indigestion, It is a strong vermifuge as well as best *vata Anulomana*. Here the form of the trial drug was modified into *Arka* form, considering the administration of the drug in infants, has helped in easy administration in infants. The ingredients in *Hingwasthaka choorna* are having volatile oils which is very essential while preparing arka. Hence using *Hingwathaka choorna, hingwasthaka Arka* was prepared. Hingwasthaka *Arka* having increased potency, more shelf life and easily absorbable, better palatable and also has instant action, has helped in relieving *udarashoola, adhmana rodana chard*i etc which are the cardinal features of *Udarashoola* (Infantile Colic).

CONCLUSION:

After a thorough study of the observations and results, the following conclusions can be drawn: *Samprathi Vighatana* in *Udarashoola* can be achieved by administering drugs of having *Gunas* like *Teekshna, Laghu, Snigdha, and Sara* with *Pachana, Deepana*, *Rocana, Anulomana and Shoolprasamana* properties. In the present study 24 infants of either sex diagnosed with *Udarashoola* (infantile Colic) were assigned by Convenient sampling method. The overall observation in the study revealed that, the maximum number of infants in the present study were within the age group of 2 – 4 months. Faulty posture of mother while feeding and not following burping after each feed triggered infantile colic. No adverse reactions were noted during study period. The effect of treatment has shown statistically significant improvements with *p* value <0.001 in all assessment parameters on 4th day of treatment. All infants included in the study got relief on 7th day. The Arka was palatable and no adverse reactions were noted during the study period.

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