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COMPARATIVE STUDY TO EVALUATE THE EFFECT OF VACHADI ARKA AND SUPACHAYA ARKA IN THE MANAGEMENT OF UDARASHOOLA (INFANTILE COLIC) IN INFANTS

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Abstract : **Background:** *Shoola* is described in the Ayurvedic classics in the context of different disesases like *Shirashoola, Padashoola,*etc. *Vayu* is the main responsible factor in the origination of shoola. Aggravation of *vayu* is responsible for producing different varieties of pain like- cutting type, spasmodic type etc. The present study has been restricted to *udara shoola(*infantile colic) only. **Materials and methods:** Infants between 1to 4 months with clinical features of infantile colic were divided into 2 groups. 25 samples of each group were treated with *Vachadi arka* and *Supachaya arka* with dose of 10 drops (0.5ml) every 8th hourly for seven days and follow up on 8th day. Statistical analysis was done by using SPSS VER. 20, Wilcoxon signed rank test was done to interpret the time of significant change, Mann Whitney U test was done to compare the outcome between two groups, Paired t test was done to check the significance within the group. **Result:** The Study drug *Vachadi Arka* shown to be highly significant in reducing the clinical manifestation of infantile colic. Control drug *Supachaya Arka* was also having significant result in the management of infantile colic. *Vachadi Arka* had better edge over *Supachaya Arka* on symptoms such as frequency of pain, duration of cry, sleep duration, bowel frequency. **Conclusion:** There was significant change in weight increment during the treatment in *Vachadi Arka* and *Supachya Arka* group. *Vachadi Arka* shows better result in all parameters as compare to *Supachaya Arka* and no side effect observed during and after its clinical trial.

Keywords: *Vachadi Arka, Supachaya Arka, Udarashoola,* Infantile Colic.

I. INTRODUCTION

Ayurveda laid maximum emphasis about different varieties of shoola that is pain sensation. Shoola is described in the Ayurvedic classics in the context of different disesases like shirashoola, padashoola,etc. The present study has been restricted to udara shoola(infantile colic) only. In this regard sushruta samhita has described that vayu is the main responsible factorin the origination of shoola. Aggravation of vayu is responsible for producing different varieties of pain like- cutting type, spasmodic type etc. [i]

Infantile colic is a disease which exhibits a symptom complex of paroxysmal abdominal pain presumably of intestinal origin associated with severe crying. It usually occurs in infants one month to six month of age. It is considered to be the foremost complaint noticed in the infant which is expressed by incessant cry that disturb mother and whole family. If not attended to, it can impact on poor weight gain poor quality of life in

infants, thus the major issue to be focused on for proper management. The basic reason for all varieties of pain includes – nutritional causes, infective causes, congenital anomalies, psychological causes, traumatic causes, other like malignancy.[ii]

Infantile colic occurs at a very early phase of life and it is expressed by irritable incessant cry as infants are not able to express it in verbal form or other form. Excessive crying is the result of painful gut contractions caused by improper feeding technique, excess gas, allergy to cow's milk, lactose intolerance. It may also be a behavioral problem resulting from less than optimal parent-infant interaction, with difficult temperament of infant as a possible explanation for inadequate parental reaction. Colic is strongly associated with maternal depression and is the strongest risk factor for shaken baby syndrome. [iii]It is also a common cause of early breastfeeding cessation.[iv]

The important reason of this symptom is aerophagia, where burping after each feed for at least 10 minutes can reduce the colic illness but not completely relive the colic pain.[v] Improper knowledge of mother and negligence in following proper steps of feeding may lead to infantile colic and become a problem to the parents. All colicky infants should have a complete medical assessment in order to exclude underlying medical conditions that may require further evaluation and treatment.[vi]

Ayurveda, the traditional Indian system of medicine is the repository of time tested herbal formulation in the various forms that are effectively used in Indian society to combat many illnesses including infantile colic. Vachadi Arka and Supachaya Arka is an indigenous multi herbal distilled essence effectively practised against infantile colic in professional experience. Arka (distilled essences, of drug used in the preparation in a medium of water) are one such formulation easily adaptable in infants and children. The stability period of Arka Kalpana is comparatively more than Swarasa, Kalka, Kwatha, Hima, Phanta and Churna Kalpanas. Moreover, Arka possess good palatability and attractive color and hence its acceptance is more. This study aims to evaluate the effect of vachadi arka and supachya arka individually and in comparison in the management of udarashoola in infants.

2. Material & Methods

The materials and methods used for the study and the modifications made were based on easy availability of the drugs, feasibility of the methods, literature, traditional experiences and expert opinions. A special preform was designed to note the observations of the study. Informed consent was obtained from the parents before registering the child into the trial. Ethical clearance was obtained from the institutional ethics committee (IEC) of SDM College of Ayurveda and Hospital, Hassan, Karnataka (IEC No: SDM/IEC/28/2019) before initiating the clinical trial.

Method- Study type is interventional, Randomization was open labelled double armed, timing was perspective, end Point was effectiveness and comparison, sample size was 50, and allotted groups were two.

Source of data- Infants between 1to 4 months with clinical features of infantile colic from Kaumarbhrithya outpatient department and in patient department of S.D.M College of Ayurveda and Hospital Hassan, Karnataka.

Diagnostic Criteria and inclusion criteria- children's in age group between 1-4 months having complaints of Kosthavibandha (constipation), Chardi (vomiting), Sthanadamsha, Antrakunjana (gurgling sound). All babies who are no breast feeding. Childrens who fulfills diagnostic criteria and their parents are willing to give written consent for participation in the trial.

Exclusion criteria: All the cases of congenital anomalies, Infants with known cases of chromosomal, metabolic and hereditary disorder, Infant on formula and cow milk feeding, Infants with any other systemic disorder, Diarrhea and GIT condition.

Treatment Protocol: 25 samples of each group were treated with Vachadi arka and Supachaya arka with dose of 10 drops (0.5ml) every 8th hourly for seven days and follow up on 8th day.

Assessment criteria: Assessment was done be comparing to baseline score. The assessment was done on objective and subjective parameters. Objective parameters includes weight and abdominal girth, whereas subjective parameters include pan, vomiting, cry, sleep duration, per abdomen examination and bowel frequency.

Table 1: Quantitative scoring pattern of assessment parameters

Sr.No	Symptoms/ Gradings	1	2	3
1.	Pain A) Frequency in 3 Hours B)Duration of Pain	0-1 Time <1 Hour	1-2 Times 1hour – 2 Hour	3-5 Times >2 Hours
2.	Vomiting (In 24 Hours)	0-3 Times	3-6 Times	>6 Times
3.	Cry	Irritable	Relieved After Consoling (Rocking & Rolling)	Incessant
4.	Sleep Duration In 24 Hour	11-8 Hours	15-12 hours	<16 Hours
5.	Per Abdomen	Soft	Distended	Tense
6.	Bowel) Frequency In 1 Day	2 – 3 Times	3–4 times	>4 Times
7.	Gurgling Sound	5-6 Times	6-8 Times	>8 Times
8.	Body Movement	Transient Capitation	Frequent Agitation	Permanent Agitation
		Often calm	Can calm down	
9.	Skin	Warm without perspiration	Cold and clampy	Warm and weating
10.	Anthropometry A) Height B) HC C) CC D) Weight E) Abdominal Girth F) Mid Arm Circumference			

Statistical Analysis- Statistical analysis was done using SPSS VER. 20, Wilcoxon signed rank test was done to interpret the time of significant change, Mann Whitney U test was done to compare the outcome between two groups, Paired t test was done to check the significance within the group.

Observations: In the present study, 50 patients were enrolled, 25 patients in each group, among them 28 patients belonged to age group 1-2 months, 11 patients were of age group 2-3 month and 11patients belonged to the age group of 3-4 month.

Observation on complaints: Maximum numbers of patients i.e. 49 childrens had continuous cry, 26 patients had duration of cry <3 hours and 24 patients had duration of cry >3 hours, 41 patients had stiffness of body, 49 patients had complaints of abdominal bloating, 46 patients were observing sleep disturbances, 13 patients were rejecting breast feeding , 7 patients were having history of diarrhea, 49 were having history of vomiting. All patients were having history of abdominal distension.

In present study 22 mothers feed the baby in sitting position, 6 mothers breast feed in sleeping position and 22 mothers breast feed the baby in both position. Proper latching was seen in 45 patients. Burping after each feed was followed in 34 patients, whereas 16 children were not burped after each feed.

Result:

Result of Wilcoxons test of vachadi arka

Parameters	Negative Rank			Positive Ranks			Ties	Total	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR					
Frequency of pain in 3 hrsBT- Frequency of pain in 3 hrs AT-	24	13.10	314.50	1	10.50	10.50	0	25	-4.365	.000	S
Duration of pain BT- Duration of pain AT-	23	12.59	289.50	1	10.50	10.50	1	25	-4.290	.000	S
Vomiting in 24 hrs BT- Vomiting in 24 hrs AT-	21	12.10	254.00	2	11.00	22.00	2	25	-3.892	.000	S
Cry BT- Cry AT-	10	7.45	74.50	3	5.50	16.50	12	25	-1.140	.000	S
Sleep duration in 24 hrs BT- Sleep duration in 24 hrs AT-	1	9.00	9.00	16	9.00	144.00	8	25	-3.638	.000	S
Per abdomen BT- Per abdomen AT-	23	12.76	293.50	2	15.75	31.50	0	25	-3.701	.000	S
Bowel frequency in1 dayBT-Bowel frequency in 1 day AT-	3	5.00	15.00	7	5.71	40.00	15	25	-1.387	.166	NS
Gurgling sound BT-	9	5.00	45.00	0	.00	.00	16	25	-2.887	.004	S
Body movement BT Body Movement AT-	4	2.50	10.00	0	.00	.00	21	25	-2.000	.046	NS

Skin appearance BT- Skin appearance AT-	8	4.50	36.00	0	.00	.00	17	25	-2.640	.008	S

Wilcoxon signed rank test was applied to assess the effect of vachadi arka on subjective parameters, there was statistically significant reduction in the symptom of frequency of pain, duration of pain, vomiting, cry, sleep disturbances, per abdominal examination, gurgling sound, skin appearance with p value < 0.05, whereas non-significant result was found in bowel frequency and bowel movements.

Result of paired –T test of Vachadi arka

Parameter	**Mean**		**Paired Difference**					
	BT±SD	**AT±SD**	**Mean difference**	**SD**	**SE**	**'t' Value**	**'p' Value**	**Remark**
Weight BT- weight AT	1.05897	1.10007	-0.09280	0.17587	0.03517	-2.638	0.014	S
Abdominal girth BT- Abdominal girth AT	2.4.992	2.37606	2.15 000	0.70297	0.14059	15.292	.000	S

The weight and abdominal girth showed statically significant differnce when taken before the initial and after the final drug administration of vachadi arka with p value< 0.05.

Result of Wilcoxons test of Supachaya Arka

Parameters	**Negative Rank**			**Positive Ranks**			**Ties**	**total**	**Z Value**	**P Value**	**Remarks**
	N	**MR**	**SR**	**N**	**MR**	**SR**					
Frequency of pain in 3 hrs- BT Frequency of pain in 3 hrs- AT	25	13.00	325.00	0	.00	.00	0	25	-4.667	.000	S
Duration of pain- BT Duration of pain AT	25	13.00	325.00	0	.00	.00	0	25	-4.667	.000	S
Vomiting in 24 hrs BT- Vomiting in 24 hrsAT-	18	9.50	171.00	0	.00	.00	7	25	-4.001	.000	S
Cry- BT Cry- AT	13	7.65	99.50	1	5.50	5.50	11	25	-3.087	.000	S
Sleep duration in24 hrs- BTSleep duration in24 hrs -AT	0	.00	.00	20	10.50	210.00	5	25	-4.472	.000	S
Per abdomen- BT Per abdomen- AT	25	13.00	325.00	0	.00	.00	0	25	-4.716	.000	S

Bowel frequency in 1 day- BT Bowel frequency in 1 day- AT	3	5.00	15.00	9	7.00	63.00	13	25	-1.979	.048	NS
Gurgling sound- BT Gurgling sound – AT	7	4.00	28.00	0	.00	.00	18	25	-2.530	.011	NS
Body movement- BT Body movement- AT	5	3.00	15.00	0	.00	.00	20	25	-2.236	.025	NS
Skin appearance- BT skin appearance- AT	4	2.50	10.00	0	.00	.00	21	25	-1.857	.063	S

Wilcoxon signed rank test was applied to assess the effect of Supachya arka on subjective parameters, there was statistically significant reduction in the symptom of frequency of pain, duration of pain, vomiting, cry, sleep disturbances, per abdominal examination, skin appearance with p value < 0.05, whereas non-significant result was found in bowel frequency and bowel movements and gurgling sound

Result of paired –T test of supachaya arka on weight-

Parameter	**Mean**		**Paired Difference**					
	BT±SD	**AT±SD**	**Mean difference**	**SD**	**SE**	**'t' Value**	**'p' Value**	**Remark**
Weight BT-AT	1.05226	1.08240	.15000	.40680	.08136	-1.844	0.078	S
Abdominal girth BT-AT	1.87707	1.61139	2.18080	0.80615	0.16123	13.526	0.000	S

The weight and abdominal girth showed statically significant difference when taken before the initial and after the final drug administration of Supachya arka with p value< 0.05.

Table Comparison on the effect of Vachadi arka and Supachya Arka on sign and Symptoms of Udara Shoola (infantile colic) - Between the groups (Mann Whitney U test)

Parameters	**Mann-WhitneyU**	**Wilcoxon W**	**Z**	**Asymp. Sig. (2- tailed)**	**Remarks**
Pain frequency in 3 hours	275.000	600.000	-.887	.375	NS
Duration of pain	287.500	612.500	-.600	0.548	S
Vomiting in 3 hours	260.000	575.000	-2.017	.044	NS
Cry frequency	250.000	575.000	-1.442	0.004	S
Sleep duration in 24 hours	312.500	637.500	.000	1.000	NS
Per abdomen	311.500	636.500	-.041	0.967	S

Bowel frequency in 1 day	307.000	632.000	-.119	0.905	S
Gurgling sound	312.500	637.500	0.000	1.000	NS
Body movement	225.000	550.000	-1.986	.047	S
Skin appearance	312.500	637.500	0.000	1.000	NS
Weight	275.500	600.500	-0.718	0.473	NS
Abdominal girth	286.00 0	611.000	-0.523	0.601	S

Here, duration of pain, cry frequency per abdomen, bowel frequency, body movement, and abdominal girth shows significant difference between the group where as other symptoms i.e pain frequency, vomiting, , sleep duration, gurgling sound, skin appearance, weight did not showed any significant difference between the group.

Discussion

The word shoola has been originated from the mysterious story related to lord shiva and kamadev with the participation of lord Vishnu to protect kamadev from the attack of trishula. Here shoola was produced owing to the forceful syncope produced by the bombardment of trishula on the earth. Udara shoola is one of the most common manifestations of illness, which takes place repeatedly in infancy period. This can be attributed to the current environment changes lifestyle of mother and their improper food habits of indulging in faulty and unwholesome foods like bakeries, junk foods and chemical and preservative added eatables which are obstructer for channels (Abhishyandi), heavy to digest (Guru), slimy (Picchila), incompatible (virudha) in nature 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. Udara shoola which occurs repeatedly without any complications is most commonly seen in clinical practice in infants. As per the contemporary science also it is seen that there is more prevalence in infants due to their immature digestive and nervous system system , which can lead to various secondary complications if left untreated. Udara shoola explained by Acharya Kasyapa, was undertaken for this study as the characteristics said by Kasyapa can be closely parallel with those seen in clinical practice.[vii]

Sthana Vyudasyate: There will be aversion towards feeding due to pain and discomfort. Child will avoid sucking milk. Due to vitiated milk vata and kapha dusti occur which will induce aversion of intake resulting from strotorodha**. Rauti:** Due to accumulation of Vayu in Koshta distension and discomfort of abdomen there will be colicky pain due to which infant will be crying continuously. **Uttana Schaya bajyate:** Due to vitiation of Vata and Kapha will do Srotorodha due to which there will be difficulty in passing the flatulence easily ,therefore child will try to stiffened body and release the pressure of abdomen. **Mukaswedascha:** In Udarashoola, aggravated Vayu enters in Koshta and after that tremors and flatulence in Koshta causes Todavat Pida. Simultaneously infant feels anxiety that leads to sweating. As pain beyond the specific threshold of tolerance will cause horipillation and sweating as its feed back mechanism to nervous system changes. **Udara Sthabdhata:** Due to vitiation of Vata Dosha Udarastabdhata will be present. Ruksha and Sheeta are Gunas of Vata dosha . This vitiated dosha enters into koshta and affects Apana Vayu and reduces expulsion of vayu. Thus this accumulated Vayu of Koshta causes Udarasthabdhata. Here, Vyadhi can be managed easily by achieving Deepana ,Pachana of the Dosha in short duration. In this study it was seen that the patients were relieved from all the Laxanas of Udara Shoola i.e. Sthana Vyudasyate, Rauti, Uttana Schaya bajate, Mukhasweda, Udara sthabdheta, antrakunjana, and kosthavibandha.[viii]

Discussion on drug

Vachadi arka for management of infantile colic and Supachya arka is a proposed combination of Shada rasa arka. Vachadi arka and supachaya arka is been mentioned in Ravanakruta Arkaprakasha. Arka are distilled essences, which contain the volatile constituents of drug used in the preparation in a medium of water. The stability period of Arka Kalpana is comparatively more than Swarasa, Kalka, Kwatha, Hima, Phanta and Churna Kalpanas. Moreover Arka possess good palatability and attractive color and hence its acceptance is more.

Vachadi arka consist of vacha(acorus calamus), pudina leaf, ajamoda, and hingu are having katu tikta rasa, usna virya, katu vipaka and is vatakaphahara , agnijanaka, shoolahara, aadhamanhara dipana, hrdya,

vidhahi, vrsya, balya in action. It has **anti spasmodic, anti colic , anti flatunace activity. It is effective in soothing the smooth muscles, restors the gut flora, facilate the downward movement of Vata.** Owing to Pachana, Deepana, Vatanolomka and Vedana stapana property of drugs used in vachadi Arka it can be concluded that the infant had better digestion and clear bowel habits this added in less accumulation of gas which is the major culprit for Infantile colic its duration and increase in pain.

Supachya arka consist of *Ajamoda,Vibhitaki ,Chincha, Maricha, Punarnava, Sita, Saindhav Lavana*. As mentioned in Ayurvedic classics, it is necessary to administer Shad Rasatmak Dravyas to the infant to get accustomed to the digestion of other food items required for proper growth and nourishment. Anti-spasmodic activity of drugs present in *Supachya Arka* could be the reason for reduction of pain further owing to *Pachana, Deepana, Vatanolomka* and property of drugs used in *Supachya Arka*.

Though there was weight gain in within the groups analysis but on analysis between thegroup there was no statistically significant result obtained. But added weight gain was seen in infants treated with Vachadi Arka greater than the normal expected velocity may be attributed to the drug component present in Vachadi Arka. As we find reference in classis for because of its quality such as Balaya ,Trupitkar, vataanulomana ,dipaniya and dipaniya guna.

Conclusion:

Infantile colic mostly affects infants of 1 to 6 month of age but in this study age group was 1 to4 months. The infantile colic was more in evening hours. Burping should be done for at least 5-10 minutes after each feed in infants to escape from aerophagia. Mother should give her breast milk in comfortable position in timely without hurry schedule. Mother should take adequate nutritious and congenital diets during lactation.

The Study drug Vachadi Arka shown to be highly significant in reducing the clinical manifestation of infantile colic .Control drug Supachaya Arka was also having significant result in the management of infantile colic. Vachadi Arka had better edge over Supachaya Arka on symptoms such as frequency of pain, duration of cry, sleep duration, bowel frequency. Vachadi Arka shows antispasmodic effect and able to reduce frequency of pain , duration of pain and cry significantly . There was significant change in weight increment during the treatment in Vachadi Arka and Supachya Arka group. Vachadi Arka shows better result in all parameters as compare to Supachaya Arka and no side effect observed during and after its clinical trial.

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