



CLINICAL STUDY TO EVALUATE THE EFFECT OF SUKUMARA GRITA IN THE MANAGEMENT OF VIBANDHA (CONSTIPATION) IN CHILDREN.

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ABSTRACT

Background: *Vibandha*, frequently seen clinical condition which is usually compared to constipation. It presents with infrequent bowel movements, hard stool and difficulty in defecation. Its prevalence rate ranges from 0.3% to 28%, in which children aged between 2-6 years are mostly affected. Considering the pathology of *Vibandha*, main stay of treatment should be *Agnideepana*(appetizer) and *Vatanulomana* (carminative). *Sukumara Ghrita*, the major ingredients are Punarnava and Eranda which are best *Anulomaka* and *Agnideepaka*. Other ingredients of *Sukumara ghrita Mrudu*, *Agnideepaka* and *Vataanulomaka*, there by the usage of *Sukumara ghrita* may relieves *Vibandha*. Hence *Sukumara Ghrita* is the trial drug in the present study. **Objective:** To evaluate the effect of *Sukumara ghrita* in the management of *Vibandha* (Constipation) in children. **Material and Methods:** This study was Interventional, open labeled, single arm, prospective clinical study with pre and posttest design carried out at OPD and IPD level in a Ayurveda hospital attached to teaching institute. 20 children satisfying diagnostic criteria and of age 2-6 years were included. All the children enrolled in the study were given with *Sukumara Ghrita* in a dose of 5ml for 2-4 years and 10ml for 4-6 years BD with lukewarm milk, before food for 7 days and follow up was done on 8th day and 15th day.

Results: It was found that, there were significant changes on symptoms of *Vibandha* such as *Mala katinata*(hard stool), *Sa shoola mala pravarthana* (painfull defecation), *Kashta mala pravarthana*(straining) etc., with p value<0.05. There was relief from *Vibandha* at the end of the 7th day itself i.e AT.

Conclusion: Oral administration of *Sukumara Ghrita* was proved to be effective in the management of *Vibandha* (constipation) in children aged 2-6 years.

Key words: *Vibandha*, Constipation, Children, Ayurveda, *Sukumara ghrita*

INTRODUCTION

Vibandha is a common clinical presentation found in children, which is not explained as the separate disease in the Ayurveda classics. The term *Vibandha* is explained as a prodromal symptom, complication in many of the diseases such as *Arshas*, *Udara roga*, *Vata vyadhi* etc.

Direct and explicit description of *Vibandha* as a disease is not found in Ayurveda but different presentation of *Purisha* like *Baddha Purisha*, *Ghana Purisha*, *Sushka Purisha*(dried stool), *Mala avabaddhata*¹ are found in different contexts of Ayurveda, these can be taken as various manifestations of *Vibandha*. *Vibandha* occurs because of vitiation of *Apanavata* and it is considered as a prominent symptom in most of the *Annavaha and Purishavaha sroto vikaras* of children².

In contemporary sciences, Constipation it is explained as a separate disease of Gastro-intestinal system. In the present era constipation is the most common illness throughout the world not only in adults but in children too. Estimated prevalence of constipation is 4% among toddlers and pre-school children worldwide and 94% of them are considered functional. During the age group of the 3- 10 years³, children are mischievous and develop liking towards junk food, street food, and fast food, as it seems to be tasty and attractive even though it is unhealthy and unhygienic, which is found to be a major cause of Constipation⁴. Constipation is often associated from childhood to Adolescent and then to Adulthood. *Vibandha* leads to misery causing deprivation from routine activities of child, loss of interest, discomfort in abdomen, loss of appetite and fear of defecation which further causes depression and fear towards the act of defecation. Sometimes it may cause several other diseases too. So it is very much necessary to treat *Vibandha* in time and to prevent further complication occurring in children because of *Vibandha*⁵. The treatment principles adapted should target cause as well pathogenesis of the disease. Ayurvedic herbal laxatives are safe, time tested and harmless yet effective⁶. Being used for thousands of years they are without side effects. Hence the present study is to overcome such situation by offering good ayurvedic preparation with no side effect for re-establishing the natural and normal reflux action of evacuation without side effects.

As among such formulation *Sukumara ghrita* having the property of *deepana*, *pachana*, *vatanulomana* and *snigdha virechana*. In *Sukumara ghrita*, *punarnava* and *eranda* are the main ingredients. Both have the above said properties. Due to these properties, it relieves the *apana vaigunya* and soften the *mala* and pushes it out of the body hence clearing the obstruction of *srotas*⁷.

AIMS & OBJECTIVES: To clinically evaluate the effect of oral administration of *Sukumara Grita* in the management of *vibandha* (constipation) in children.

METHODOLOGY

Study design: Interventional, open labeled, single arm, prospective clinical Study

Ethical considerations: Ethical clearance was obtained from the institutional ethics committee (IEC) of the Institution. (IEC No: SDM/IEC/04/2024) .

CTRI REG NO-CTRI/25/03/082484

Method of collection of data:

Source of data: Children were selected from the Out Patient and In Patient Department of Kaumarabhritya of the institution.

Sample size: 20

Sampling method: Convenient sampling method.

Diagnostic criteria: Based on Pediatric Rome III Criteria for Constipation

Rome III criteria for neonates and toddlers

Must include 1 month of at least two of the following up to 4 yr of age:

1. Two or fewer defecations per week
2. At least 1 episode per week of incontinence after the acquisition of toileting skills
3. History of excessive stool retention and History of painful or hard bowel movements
4. Presence of a large fecal mass in the rectum
5. History of large-diameter stools that may obstruct the toilet.

For a child with a developmental age of above 4 years

Criteria fulfilled at least once per week for at least 2 months before diagnosis

1. 2 defecations in the toilet per week
2. At least 1 episode of fecal incontinence per week
3. History of retentive posturing or excessive volitional stool retention
4. History of painful or hard bowel movements
5. Presence of a large fecal mass in the rectum
6. History of large-diameter stools that may obstruct the toilet.

Inclusion criteria: • Children of either gender, • Children aged between 2 to 6 years • Fulfilling the diagnostic criteria of Constipation • Parents who are willing to give assent.

Exclusion criteria: • Children having constipation secondary to any of other disorders like hypothyroidism, hirschprung's disease. • Structural anomalies of anal canal.

Assessment criteria⁸

Children were assessed using a detailed case proforma and assessment was done based on Paediatric Rome III criteria for constipation (Rome III criteria: For neonates and toddlers and for a child with a developmental age of 4 years)

Dose & Route of administration: Age 2-4 years - 5ml, Age 4-6 years -10 ml,

Anupana- Luke Warm Milk through Oral route

Duration of study: 14 days (Intervention duration: 7 days, Follow up: 14th days)

Preparation of Ghrita :

Sukumara Ghrita Ingredients –

1.	Punarnava	<i>Boerhhaaviadiffusa</i>	Root	1 tula
2.	Dashamoola			10 pala each
3.	Shatavari	<i>Aspergusracemosus</i>	Root	10 Pala
4.	Bala	<i>Sidacordifolia</i>	Root	10 Pala
5.	Shalparni	<i>Desmodiumgangeticum</i>	Roots&Whole art	10Pala
6.	Nagbala	<i>Grewiahirsute</i>	Root	10 Pala
7.	Guduchi	<i>Tinosporacordifolia</i>	Root	10Pala
8.	Atibala	<i>Abutilon indicum</i>	Root	10 Pala
9.	Mulethi	<i>Glycyrrhizaglabra</i>	Stem &Root	2 Pala
10.	Ardarak	<i>Zingibarofficinalis</i>	Rhizome	2 Pala
11.	Draksha	<i>Vitisvinfera</i>	Fruit	2Pala
12.	Pippali	<i>Piper retrofractum</i>	Fruit	2 Pala
13.	Ajwaian	<i>Trachyspermumammi</i>	Fruit	2 Pala
14.	Saindhava			
15.	Jaggery			
16.	Castor oil			1 prastha

For the purpose of the study sukumara ghrita was prepared from GMP certified pharmacy.

OBSERVATIONS & RESULTS

Total 22 number of children were registered in present study, among 22 children, 13 children (59%) were of 2-4 years, 9 children (41%) were of 4-6years. The peak incidence of constipation is at 2–4 years of age, as they are very fussy eaters (junk foods) and intake no/less fiber diet, less water intake and is evident in the current study also. Gender wise distribution of children -showed that 56.7% were males while 43.3% were female gender. Socio-economic status wise distribution 20% were belonged to upper middle-class family, 26.7% were of lower middle class, 16.7% were of upper class, 36.7% were of upper-lower class and 0% from lower class. Which indicates constipation is almost equally distributed. Type of Diet - 36.7% of the children were on Vegetarian diet and 63.3% are on mixed diet. Regularity in Diet - 60 % were on regular diet time and 40 % were with irregular food time. Dietary Habits 25children (83.3%) had h/o junk foods intake among which 30.0% were had frequency of <1 per week, 30.0% with 1-2 per week, 23.3% with >2 per week and 16.4% were not on junk food. Street food -13 children (75%) had h/o junk foods intake among which 12(40%) were had frequency of <1 per week, 11(36.7%) with 1-2 per week and 7 (23.3%) were not on junk food. Predominance diet -Based on history, 90% children had rice as predominant food, 46.7% of children with legumes diet, 76.5% of children are with predominance of dairy products and 30% of children with predominance of Fruits and vegetables. Fluid intake Water intake 50% children were having less 250ml water intake in aday. Milk intake - Almost all the children had h/o milk intake, with quantity varying as 56.7% of children with the milk intake of 100-150ml/day, 16.7% of children with 200-250ml/day, 13.3% of children with 300-500ml of milk/day and 13.3 % of children with no intake of milk.

Observations Based on Rome III Criteria:

1. 2 or fewer defecations per week: 73.3% of the children had c/o 2 or fewer defecation per week and 26.7% of children were having irregular defecation with varying frequency in defecation. **2. Faecal incontinence:** 76.7% children were having c/o fecal incontinence and 23.3% weren't having any c/o fecal

incontinence. 3. **Retentive posturing:** Children with Vibandha were assessed for retentive posturing and 63.3 % of them were found to have retentive posturing while going for defecation. 4. **Volitional stool retention:** All 22 children (100%) children had c/o stool retention. 5. **Painful defecation:** 96.7% of children were having c/o painful bowel movements. 6. **Hard bowel movements** All 22 children have shown to be with hard bowel movements during defecation. 7. **Large fecal mass in the rectum:** All 22 (100%) children were having c/o presence of large fecal mass in rectum. 8. **Large-diameter stools:** 86.7% of children were having c/o presence of large diameter stool.

While chronicity of hard stool – 27 % of children had 2-3 months history, 34% had 4-5 months, 20% had more than 6months and 10% children had more than 1 year history of constipation. Co-existing complaints - 100% had difficulty and straining while defecation, 96.7% had irregular defecation, 90% of children had pain abdomen, 73.7% children had reduced appetite, 9 % of children had bleeding per rectum.

RESULTS

Total 22 children with Constipation were registered and 20 completed the study and 2 were dropped out due to irregular follow-up.

For ordinal data, with in the group Wilcoxon signed rank test was applied

TABLE No 2 - FRIEDMAN TEST EFFECTS ON MALAKATHINATA

PARAMETER	N	Mean Rank	X ²	P	Remark
BT	20	4.00	109.484	0.001	S
AT		2.28			
FU		1.86			

Friedman test was applied to assess the effect of Sukumara ghrita on Vibandha

On applying Friedman test on abdominal pain, there was reduction seen in the mean 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 is statistically significant reduction.

As Friedman test was significant, Post hoc Wilcoxon test was performed to interpret the time of significant change

Table : Effect of Sukumara Ghrita In Mala Katinata (Wilcoxon Signed Rank)

Parameters	Negative Ranks			Positive Ranks			Ties	Total	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR					
BT- AT	18	7.50	105.0	0	.00	.00	2	20	-3.742	.001	S
AT-FU	5	3.00	15.00	0	.00	.00	17		-2.236	.001	S
BT-FU	19	7.50	105.00	0	.00	.00	1		-3.416	.001	S

There was statistically significant difference in mala katinata with Z Value -2.232 and p value <0.05. Wilcoxon signed-rank test was applied resulting in a significance level set at p value <0.05. There was considerable change in mala Katinata between BT - AT and AT- Follow Up with mean rank 3.00, sum of rank 15.0.

Table : Effect Of Sukumara Ghrita In Alpamatra/ Muhurmuhu Mala Pravarthana (Wilcoxon Signed Rank)

Parameters	Negative Ranks			Positive Ranks			Ties	Total	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR					
BT –AT	18	7.50	105.0	0	.00	.00	2	20	-3.638	.001	S
AT-FU	16	6.50	78.00	0	.00	.00	4		-3.464	.001	S
FU-BT	20	88.00	120.00	0	.00	.00	0		-3.626	.002	S

There was statistically significant difference in alpamatra/Muhurmuhu Mala Pravarthana in children of Vibandha with Z Value -3.464 and p value <0.05 . Wilcoxon signed-rank test was applied resulting in a significance level set at p value <0.05. There was considerable change in Alpamatra/ Muhurmuhu mala Pravarthana between BT - AT and AT- Follow Up in 15 children , mean rank 6.50, sum of rank 78.0.

Table : Effect of Sukumara Ghrita in Kasta/ SA Shoola Mala Pravarthana (Wilcoxon Sign Rank)

Parameters	Negative Ranks			Positive Ranks			Ties	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR				
BT –AT	20	8.0	120.0	0	.00	.00	0	-3.873	.001	S
AT-FU	17	6.50	78.00	0	.00	.00	3	-3.464	.001	S
FU-BT	20	8.00	120.00	0	.00	.00	0	-3.626	.002	S

There was statistically significant difference in Kasta/Sa shoola Mala Pravarthana in children of Vibandha with Z Value -3.464 and p value <0.05 . Wilcoxon signed-rank test was applied resulting in a significance level set at p value <0.05. There was considerable change in Kasta/Sa Shoola mala Pravarthana between BT - AT and AT- Follow Up in 15 children , mean rank 6.50, sum of rank 78.0.

In the same statistical assessments was callculed for Aruchi, Ajeerna, Udarashoola, and Agni and found that statistical significant improvement were noted.

Table : Effect of sukumara Ghrita in Evacuation of stool (Wilcoxon Sign Rank)

Parameters	Negative Ranks			Positive Ranks			Ties	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR				
BT –AT	20	8.00	120.00	0	.00	.00	0	-3.520	.001	S
AT-FU	17	6.50	78.00	0	.00	.00	3	-3.276	.001	S
FU-BT	20	8.00	120.00	0	.00	.00	0	-3.493	.002	S

There was statistically significant difference in evacuation of stool in children of Vibandha with Z Value - 3.276 and p value <0.05 . Wilcoxon signed-rank test was applied resulting in a significance level set at p value <0.05. There was considerable change in nature of stool between BT - AT and AT- Follow Up in 15 children ,mean rank 6.50, sum of rank 78.0.

Table 86: Effect of Sukumara Ghrita in Nature Of Evacuation (Wilcoxon Sign Rank)

Parameters	Negative Ranks			Positive Ranks			Ties	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR				
BT –AT	20	8.00	120.00	0	.00	.00	0	-3.542	.005	S
AT-FU	16	7.00	77.00	2	7.00	14.0	4	-2.496	.013	S
FU-BT	18	7.00	91.00	0	.00	.00	2	-3.275	.001	S

There was statistically significant difference in nature of evacuation chart in children of Vibandha with Z Value -2.232 and p value <0.05 . Wilcoxon signed-rank test was applied resulting in a significance level set at p value <0.05. There was considerable change in nature of evacuation between BT - AT and AT- Follow Up in 15 children ,mean rank 7.00, sum of rank 77.0.

Table : Effect of Sukumara Ghrita in Bristol stool chart (Wilcoxon Sign Rank)

Parameters	Negative Ranks			Positive Ranks			Ties	Z Value	P Value	Remarks
	N	MR	SR	N	MR	SR				
BT –AT	20	8.00	120.00	0	.00	.00	0	-3.520	.001	S
AT-FU	20	8.00	120.00	0	.00	.00	0	-3.771	.002	S
FU-BT	20	8.00	120.00	0	.00	.00	0	-3.542	.005	S

There was statistically significant difference in Bristol stool chart in children of Vibandha with Z Value - 3771 and p value <0.05. Wilcoxon signed-rank test was applied resulting in a significance level set at p

value <0.05 . There was considerable change in Bristol stool chart between BT - AT and AT- Follow Up in 15 children, mean rank 8.00, sum of rank 120.0.

DISCUSSION:

Vibandha is the burning problem in pediatric age group, causing adverse impact on child's physical and mental health; hence it is an area of concern. It is considered as one among lifestyle disorder too. The word Vibandha in most of the context mentioned as one of the clinical presentations of many disorders in Ayurveda, but it can be considered as separate disease entity because of the availability of broad-spectrum information and explanation available in classical texts. Annavaha and Purishavaha srotas are mainly involved in the pathogenesis of Vibandha with Adhmana, katiprushta vedana, Varcho- Apravriti, Varcha-Kruchrata, Varcha-Chirata pravriti as cardinal features of Vibandha. . It was observed that Viruddha ahara krama, Visham-Aahara, Avyayama, Alpa jalapana and Vega Sandharana, Shoka, Bhaya, Chinta etc. were having more impact in the manifestation of Vibandha specially in children. Childhood constipation probably occurs much more commonly in males than in females. Nutritional adequacy especially in children is directly proportional to economic status. Poor economic status shows compromised nourishment, occurrence of Nutritional disorders, Constipation etc. and chance of related adverse conditions in a growing individual. Lack of knowledge and lack of proper diet increase the condition to further level. Incidence of Vibandha was higher in non-vegetarian as compared to those who are on vegetarian diet. Regular intake of meat will be the cause as it is high in fat, takes longer for the digestive tract to process it. Because of tough protein fibers it is difficult for digestion and it is rich in iron, which are constipating in nature. Children aged 2–5 years of age are very fussy eaters (junk foods) and all those and junk foods are high in fat and low in fiber. This contributes to constipation. Less fibre intake is also a major cause in the manifestation of constipation, it of prime importance. Common fibre-rich foods include cereals (rice, corn), bread, vegetables, fruits and whole grains. Less or no intake will result in decreased stool bulk, decrease osmotic load and de-accelerate colon transit (unable fermenting fibre produces short-chain fatty acids).

Optimal fluid intake is recommended by NICE as a necessary adjunct in the management of constipation. Children who are mainly on milk diet were with constipation. Cow milk protein allergy (CMPA) was proposed as one the common causes of constipation resulting in hard stools, painful defecation and anal fissures. Cow milk has high amount of calcium, which on digestion gets converted into calcium curds i.e. casein (protein which is not digested by human enzymes), it is constipatory and has high phosphate receptor binding agents, which lacks binding of iron resulting in Constipation. Less Water intake is the second major cause in functional constipation. Recommended water intake will result in softer, easier to pass stools.

Sukumara Grita regarded as sukhavirechaka (laxative action) which is considerably acts on fecal consistency, intestinal motility and entero-pooling. Cathartic activity and laxative action enhance the evacuation of unformed watery faeces from the entire colon. They act by, enhancing retention of intestinal fluid by hydrophilic or osmotic mechanism, decreasing net fluid absorption by effects on small- and large-intestinal fluid and electrolyte transport, and stimulation of intestinal motility. Active constituents of Eranda like Phospholipid pro-inflammatory mediator will stimulates colonic secretion and GI motility and Nitric

oxide also may stimulate intestinal secretion and inhibit segmenting contractions in the colon, thereby promoting laxative action. Other ingredients such as Dashamoola , Bala nagabala yashtimadhu , Ardraka draksha, Sharavari, Ajamoda, Pippali are regarded as Agni deepana, Vata anulomana, Mriduvirechana actions because of Snigdha and Ushna guna. Guda reduces the risk of digestive disorders because it maintains the proper functioning of the digestive system and improves digestion. Jaggery stimulates the secretion of digestive enzymes and it gets converted to acetic acid in the gut; thus reduces the overload of the digestive tract. Punarnava : It is having anti-inflammatory and expectorant properties. It also cure vata dosha . It has three distinct tastes mainly Madhura, Tikta, Kashaya, Ushna guna . The host of bioactive components in Punarnava balances the Tridoshas and helps to pacify the vata and kapha doshas and effectively removes the ama doshas which are toxins from the body. It is beneficial in reducing inflammation and treating irritable bowel movement. It stimulate the secretions of digestive juices. Eranda , shatavari, Nagabala, dashamoola Punarnava draksha ardraka Ajamoda and pippali acts as Deepana Amapachana Vatanuloamana thus leada tridosha shamana. Sukumara grita improves gastric motility, improves gastric secretions, promotes early gastric emptying thus relieves accumulated gases and feces. Increases distal colonic motility, helps in digestion , increases intestinal transit , enhances retention of intestinal fluid, easyevacualtion of stool. Over all the natural chemical constituents enable usage without any unwarranted side effects. It is a mild laxative that helps to cleanse the colon effectively without causing any harm to the body in the process. In addition to this, the antioxidant properties of Punarnava help to ensure a speedy recovery from constipation.

CONCLUSION

Oral administration of Sukumara Ghrita in a dose of 5ml for age of 2- 4 years and 10 ml for age group 4-6 years twice a day with warm milk before food has shown statistically significant improvement in the clinical features of vibandha. Therapy showed marked improvement in the symptoms of Vibandha such as Mala katinata, Sa shoola/ kashta mala pravarthana, alpamatra/ muhurmuha mala pravarthana, ajeerna, aruchi, Udarashoola, The palatability of the drug was good, all the children included in the study consumed the drug without much problem as the anupana was milk. The trial drug was well tolerated and no adverse drug reactions were noted. Hence it can be concluded from the study that oraladministration of Sukumara grita is effective in the management of Vibandha (Constipation) in children.

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