

## A CLINICAL STUDY ON THE MANAGEMENT OF BALATISARA WITH AN AYURVEDIC FORMULATION (SAMANGADI KWATHA) IN COMPARE TO HOMEMADE FLUID

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Received: 18-05-2015; Revised: 28-08-2015; Accepted: 30-08-2015

### Abstract

Diarrhea is a one of the common disease among the developing country and second common cause of death in children worldwide. The present study was conducted for clinical evaluation of (Samangadi Kwatha) in the management of children's diarrhea (Balatisara) on various scientific parameters to find out safe, cost effective and better treatment. The study was conducted in 60 patient of 0-16 years clinically diagnosed and confirmed patient of diarrhea in children. Patient having the history of loose motion in excessive frequency associated with bad smell, color, abdominal pain, abdominal distention and vomiting etc. were included; patient with severe dehydration and other metabolic disorder were excluded. The patient were randomly divided into two group A & B. Group A was treated with Samangadi Kwatha (in a syrup form) and group B managed by the home made fluid. During the course of therapy restriction regarding to diet were advised to all patient of both the groups as indicated in Ayurvedic classics. During the trial and follow up studies of all patients were assessed on various scientific parameter such as subjective (increase in frequency, consistency of stool etc.) clinical (various symptoms of atisara and laboratory parameter (stool microscopy and culture and sensitivity). On the basis of above findings results were drawn. It has been observed that there is statistically highly significant improvement in most of the symptoms of the Balatisara after the treatment with Samangadi Kwatha as a syrup form. Significant reduction was recorded in consistency, frequency, color, bad smell of stool along with abdominal pain, abdominal distention and loss of appetite) on third day of treatment. In homemade fluid treated (group B) was shown significant improvement in consistency, frequency and sign of dehydration only, on fifth day. Clinical and laboratory oriented studies on Samangadi Kwatha have revealed that Samangadi Kwatha has Antidiarrheal as well as health supporting syrup during diarrheal episode.

**Key word:** Atisara; Balatisara; samangadi kwatha.

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### Cite This Article

Neeraj Tripathi, Beena Tiwari, Krishnaiah N. A clinical study on the management of balatisara with an Ayurvedic formulation (Samangadi kwatha) in compare to homemade fluid. Ayurpharm Int J Ayur Alli Sci. 2015;4(8):145-151.

## INTRODUCTION

The man in this busy world, unable to concentrate on his regularities, proper and thus they are inviting many diseases especially of gastro-intestinal tract. The psychological factor has got an impact relation over the disorder of G.I. tract. However many unknown factor are also responsible.

Atisara (Diarrhea) a disease in infancy still constitutes one of the chief problems in pediatric practice, most of the developing countries of the world. The situation with regard to infantile gastroenteritis in this region is at present depressing because of excessive incidence of atisara in infant, lack of resistant power to fight against the causative pathogen, greater liability of the infant and the young children to develop to water and electrolyte disturbances, wide spread prevalence of malnutrition and under nutrition and their high mortality and morbidity rate.

According to WHO diarrhea was estimated to have caused 1.1 million deaths in people of age 5 year or more and 1.5 million deaths under the age of 5 years. There is by use of advance medical techniques as fluid replacement therapy mortality rate might have been declined but incidence of diarrhea remains unchanged at about 3.2 episodes per child per year.<sup>[1]</sup>

Diarrhea has been defined variously as an increase in stool weight, an increase in frequency 3 or more than 3 or an abnormal looseness of stool. It is a common cause of death in developing countries and second common cause of infant death, worldwide.<sup>[2]</sup>

Generally baby has more interest in Madhura (Sweet) Aahara, an early age also the Kapha predominant.<sup>[3]</sup>

These situation leads to Agnimandhya (decreased digestive power) which is basic cause for the derangement of GIT system and leads to common illness of pediatrics as

Balatisara. Samangadi Kwatha syrup prepared from the five herbal drugs which have the property of Deepana (digestive stimulant) Pachana (digestive) along with the Shoshanna (absorption). During diarrhea these three factors has major responsibility to cure atisara.<sup>[4]</sup>

The present study has been undertaken with objective of a clinical study on the management of Balatisara with an Ayurvedic formulation (Samangadi kwatha)<sup>[5]</sup> in compare to homemade fluid.

## MATERIAL AND METHODS

Total 60 children were selected from the OPD and IPD of the department of the Kaumarbhritya of SV Ayurvedic Hospital, Tirupati after proper screening on the predesigned proforma and also on the basis of inclusion and exclusion criteria. All the patients registered for the present clinical study were screened for Age, Sex, Socio-economic status, water supply, immunization, family history; past history along with general, physical and systemic examination and all the relevant information were noted.

### Drug formulation

In the clinical study, Samanga (*Mimosa pudica*), Dhataki (*Woodfordia fruticosa*), Lodhra (*Symplocos racemosa*), Sariba (*Hemidesmus indicus*) and Indrayava (*Holorrhina antidysentrica*) were selected in sum amount to prepare the syrup which made palatable to the babies.

In the case of control group B homemade fluid (Sugar + salt+ water) was given.<sup>[6]</sup>

### Assessment criteria

During the trial and follow up studies the patient were assessed on the parameters mentioned in Table 1 and 2.

**Table 1: Stool scoring criteria**

Sl.No.	Score of Stool characteristics	0	1	2
1	Frequency	< 3	3-10	>10
2	Color	Normal	Abnormal	
3	Consistency	Soft formed	Semisolid	Watery
4	Foul smell	Normal	Offensive	Highly offensive
5	Mucous	Absent	Occasionally	Frequent
6	Blood	Soft, formed	Semisolid	Watery

**Table 2: Scoring for sign and symptom**

Sl.No.	Sign and symptoms	0	1	2
1	Cough	Absent	Present	-
2	Fever	Absent	Mild	High
3	Abdominal distension	Absent	Present	-
4	Abdominal pain	Absent	Present	-
5	Appetite	Normal	Reduced	-
7	Vomiting	Absent	<3/day	>3/ day

**Laboratory parameter**

- a) Hb%, TLC, DLC, ESR
- b) Stool microscopy and culture and sensitivity

The trial drug Samangadi syrup was administered based on the age of the children and administered for five days thrice a day alone or along with water. (Table 3)

**Observation and result**

The major complication of diarrhea is dehydration and malnutrition. This dehydration leads to early collapse of baby due more water loss in compare to the adults. So the study had designed to find result on third and fifth day.

Improvement in signs and symptoms on third day is mentioned in Table 4, 5 and 6.

Table 7, 8, 9 and 10 shows that in Group A (Samangadi Kwatha treated) all symptoms score was highly significant at p value < 0.001 showing 90 – 100 % result except mucus in stool that shows statistical significant at p value < 0.005. In group A near about all the symptoms subsided by 5<sup>th</sup> day.

In group B patient shows relief but its significant level varies from p value < 0.005 to 0.05. The color of stool, Arochaka (anorexia), Avipaka (indigestion) and Anannabhilasa (loss of interest in food) shows mild improvement. Smell, mucus in stool and abdominal distention were not significant even at the level of p value < 0.05.

**Overall result of therapy on objective parameter**

In group A, 14 patients have positive stool pathology (ova and cyst) in out of 30. after treatment 10 patients (71 %) fully cured, 3 (21%) got moderate relief and 1 (7 %) patient found to be incurred.

In group B, 10 patient out of 30 shown positive stool pathology after treatment 3 patients (30%) cured, 3 (30%) got moderate relief and 4 (40%) incurred.

In diarrhea mostly children show loss of appetite fluid loss due to hyper responsive or secretory nature of intestine. The Ama formation works as allergen for enhancing this action of intestine. The drugs of Samangadi Kwatha have Deepana, Ama Pachana property which helps in vanishing Ama condition.<sup>[7]</sup>

**Table 3: Method of drug Administration and dosages**

Sl.No.	Age	Dose	Rout
1	0-6 month	8drops	Oral
2	6month -1 year	2.5 ml	Oral
3	1year -5year	5 ml	Oral
4	5year to 10 year	10ml	Oral
5	10- 16 year	15ml	Oral

**Table 4: Effect of therapy on Malavaha Srotasa on third Day**

Sl.No.	symptoms	Group	N	Mean		Mean Diff.	% relief	SD	SE	't' value	'p' value	Result
				BT	AT							
1	consistency	A	30	2	0.27	1.73	87	0.499	0.082	21.1	<0.01	S
		B	30	1.63	1.03	0.52	37	0.61	0.011	6.59	<0.01	S
2	Frequency	A	30	1.06	0.2	0.86	81	0.34	0.063	13.7	<0.01	S
		B	30	1.06	0.553	0.53	50	0.402	0.073	1.36	>0.05	IS
3	Color	A	15	0.5	0.1	0.4	80	0.498	0.091	4.39	<0.001	HS
		B	17	0.566	0.466	0.1	18	0.402	0.073	1.36	>0.05	IS
4	Mucus	A	7	0.233	0.1	0.133	57	0.345	0.063	2.11	<0.01	S
		B	2	0.066	0.233	-1.67	-250	0.379	0.069	-2.4	>0.05	IS
5	Bad smell	A	19	0.766	0.133	0.633	75	0.305	0.055	1.79	<0.05	S
		B	10	0.333	0.3	0.03	10	0.319	0.058	0.578	>0.05	IS

**Table 5: Effect of therapy on Annavaha Srotasa on third Day**

Sl.No.	Symptoms	Group	N	Mean		Mean Diff.	% relief	SD	SE	T value	P value	Result
				BT	AT							
1	Anannabhilasa	A	20	0.9	0.13	0.76	85	0.43	0.07	9.7	<0.001	HS
		B	20	0.66	0.46	0.3	45	0.30	0.05	16.1	<0.05	S
2	Arochaka	A	28	0.93	0.1	0.9	96	0.54	0.1	9	<0.001	HS
		B	20	0.66	0.5	0.16	25	0.53	0.09	1.72	<0.05	S
3	Avipaka	A	20	0.66	0.26	0.4	60	0.49	0.09	4.39	<0.001	HS
		B	16	0.53	0.4	0.17	25	0.57	0.01	0.18	>0.05	IS
4	Cchardi	A	4	0.13	0.03	0.1	75	0.30	0.05	1.79	<0.05	S
		B	8	0.26	0.1	0.16	-12.5	0.18	0.03	-1	>0.05	IS
5	Abdomen Pain	A	30	0.33	0.03	0.3	90	0.47	0.08	3.52	<0.001	HS
		B	8	0.26	0.2	0.66	25	0.36	0.58	0.57	>0.05	IS
6	Abdomen Distention	A	8	0.27	0	0.27	100	0.45	0.08	3.24	<0.05	S
		B	5	0.17	0.13	0.03	23.5	0.32	0.06	0.57	>0.05	IS

**Table 6: Effect of therapy on Udakavaha srotasa on third day**

Sl.No.	Symptoms	Group	N	Mean		Mean Diff.	% relief	SD	SE	T value	P value	Result
				BT	AT							
1	Jihwa talu kantha shosa	A	20	0.66	0	0.66	100	0.47	0.87	7.61	<0.001	HS
		B	20	0.66	0.16	0.5	47	0.50	0.09	5.38	<0.001	H
2	Pipasa	A	30	0.9	0	0.9	100	0.30	0.05	16.1	<0.001	HS
		B	20	0.66	0.06	0.06	36	0.49	0.091	6.59	<0.001	HS

**Table 7: Effect of therapy on malavaha Srotasa on fifth Day**

Sl.No.	symptoms	Group	N	Mean		Mean Diff.	% relief	SD	SE	t value	p value	Result
				BT	AT							
1	consistency	A	30	2	0.06	1.93	97	0.25	0.04	41.7	<0.01	S
		B	30	1.63	0.6	1.03	63.2	0.71	0.13	7.87	<0.01	S
2	Frequency	A	30	1.06	0.03	1.03	97	0.18	0.06	31	<0.01	S
		B	30	1.06	0.36	0.7	66	0.53	0.97	7.16	<0.01	S
3	Color	A	15	0.5	0.03	0.46	93	0.50	0.09	5.03	<0.001	HS
		B	17	0.56	0.36	0.26	47	0.58	0.01	2.50	<0.01	S
4	Mucus	A	7	0.23	0.03	0.2	86	0.40	0.08	2.69	<0.005	S
		B	2	0.06	0.16	-0.1	-1.50	0.48	0.08	-1.14	>0.05	IS
5	Bad smell	A	19	0.76	0.06	0.7	91	0.59	0.10	6.43	<0.01	S
		B	10	0.33	0.2	0.03	40	0.57	0.10	1.27	>0.05	IS

**Table 8: Effect of therapy on Annavaaha Srotasa on fifth Day**

Sl.No.	Symptoms	Group	N	Mean		Mean Diff.	% relief	SD	SE	t value	p value	Result
				BT	AT							
1	Anannabhilasa	A	27	0.9	0	0.9	100	0.30	0.07	9.76	<0.001	HS
		B	20	0.06	0.43	0.33	50	0.52	0.09	2.56	<0.01	S
2	Arochaka	A	28	0.93	0	0.9	100	0.25	0.04	20.1	<0.001	HS
		B	20	0.66	0.4	0.26	40	0.53	0.09	2.80	<0.005	S
3	Avipaka	A	20	0.66	0.03	0.63	95	0.49	0.08	7.07	<0.001	HS
		B	16	0.53	0.02	0.33	62	0.54	0.17	1.92	<0.05	S
4	Cchardi	A	4	0.13	0	0.13	100	0.03	0.05	1.78	<0.05	S
		B	8	0.26	0.1	0.16	62	0.37	0.06	2.4	<0.05	S
5	Abdomen Pain	A	10	0.33	0	0.33	100	0.48	0.09	3.52	<0.001	HS
		B	8	0.26	0.06	0.2	75	0.40	0.07	2.69	<0.01	S
6	Abdomen Distention	A	7	0.27	0	0.27	100	0.45	0.08	3.24	<0.01	S
		B	5	0.17	0.07	0.1	59	0.40	0.07	1.36	>0.05	IS

**Table 9: Effect of therapy on Uadakavaha srotasa on fifth day**

Sl.No.	Symptoms	Group	N	Mean		Mean Diff.	% relief	SD	SE	t value	p value	Result
				BT	AT							
1	Jihwatalukantha shosa	A	20	0.66	0	0.66	100	0.47	0.87	7.61	<0.001	HS
		B	20	0.66	0.06	0.6	90	0.49	0.09	6.59	<0.001	HS
2	Pipasa	A	27	0.9	0	0.9	100	0.30	0.05	16.1	<0.001	HS
		B	20	0.06	0.03	0.63	95	0.49	0.08	7.07	<0.001	HS

The shoshana property of drugs due to kashaya nature helps absorption of fluid and made early hydration.

This drug probably works on the concept of Prakriti vighata (Tikta kashaya rasa; Laghu Ruksha guna and Katu Vipaka) mentioned in Krimi chikitsa. The Prakriti vighata property of drugs, along with diarrheal flow (Virechana) may show the significant result on stool pathology.

This research had shown proper evidence towards the Krimihara (wormicidal) property of *Holorrhina antidysentrika* and *Woodfordia fruticosa* mentioned in Bhavaprakasa.<sup>[8]</sup>

## DISCUSSION

Diarrhea has been defined variously as an increase in stool weight, an increase in frequency three or more than three or an abnormal looseness of stool.

**Table 10: Overall improvement on fifth day**

Sl.No.	Symptoms	Group	% relief	Significance at			
				<0.001	<0.005	<0.01	0.05
1	Consistency	A	97	Yes	-	-	-
		B	63	Yes	-	-	-
2	Frequency	A	97	Yes	-	-	-
		B	66	Yes	-	-	-
3	Color	A	93	Yes	-	-	-
		B	47	No	No	Yes	-
4	Mucus	A	86	No	Yes	-	-
		B	-150	No	No	No	No
5	Atibahu	A	100	Yes	-	-	-
		B	69	Yes	-	-	-
6	Atidrava	A	100	Yes	-	-	-
		B	62	Yes	-	-	-
7	Jihwatalukantha shosa	A	100	Yes	-	-	-
		B	90	Yes	-	-	-
8	Pipasa	A	100	Yes	-	-	-
		B	95	Yes	-	-	-
9	Anannabhilasa	A	100	Yes	-	-	-
		B	50	No	Yes	-	-
10	Arochaka	A	100	Yes	-	-	-
		B	40	No	Yes	-	-
11	Avipaka	A	95	Yes	-	-	-
		B	62	No	No	No	Yes
12	Cchardi	A	100	No	Yes	-	-
		B	62	No	Yes	-	-
13	Samata	A	96	Yes	-	-	-
		B	46	Yes	-	-	-
14	Smell	A	91	Yes	-	-	-
		B	40	No	No	No	No
15	Abdominal Pain	A	100	Yes	-	-	-
		B	75	No	Yes	-	-
16	Abdominal Distention	A	100	Yes	-	-	-
		B	60	No	No	No	No

It is a common cause of death in developing countries and second common cause of infant death, worldwide. The incidence of atisara is high in children below 5 year.

Poor socioeconomic status, poor hygienic condition and consumption of unprotected water are precipitating factor of atisara.

Loose motion, frequency more than three times, impaired appetite, change in color of stool and bad smell etc common symptoms of Atisara. Feature of annavaha, udakavaha and malavaha srotasa, which are present in almost every patient initially, subsided in both group.

But in compare to group B, group A got more relief in every symptom. The relief observed in all symptom score of vitiation of srotus except mucus in stool was significant in Samangadi Kwatha treated group on third day. Samangadi Kwatha is effective in breaking of root cause of atisara as Agnimandhya, Ama.

Homemade fluid is effective in maintaining hydration of baby. It is life saving management in absence of medication. The major symptom of atisara as atidravata, atibahulata and sign of dehydration can easily manage by the homemade fluid. Children have immunity to combat infection of gastrointestinal tract, if maintenance of



hydration and proper hygienic condition followed. Homemade fluid was not effective in improving appetite, mucus, color and smell in stool.

Drugs of Samangadi kwath showed significant result on Anti-diarrheal, antiviral, antibacterial, gastric ulcer healing, antispasmodic etc in modern pharmacological researches.<sup>[9][10]</sup> *Hemidesmus indicus* especially adding Rasayana guna to the drugs, by which post complication of atisara as malnutrition was seen very minimal in compare to homemade fluid.

Sign of dehydration and mal-absorption was less seen in Samangadi Kwatha treated group due to Deepana Pachana property of active ingredient and early recovery from the Atisara. It converted the Sama mala into nirama mala due to their Deepana and amapachana effect, which help in correction of loose motions due to their Grahi karma. In the complication of diarrhea malnutrition is a major factor in disturbing the developmental delay in baby. In Samangadi yoga Sariba is added as Rasayana to combat the malnutrition and promote early recovery from the diarrhea. These drugs have been well documented by our acharyas in Ayurvedic literature. All these drugs have the property of Deepana, amapachana and Grahi. Due to these properties it may help in the correction of Agni and improve in the digestive power and finally correct the diarrhea. Most of the drug is contain active principle as alkaloids which may help in reducing the frequency of stool.

Treated group A, has shown 71 % which is statistical significant and homemade fluid group B shown only 30 % improvement in pathological investigation of stool. While comparing the Samangadi Kwatha syrup preparation with homemade fluid, Samangadi Kwatha seems to be more effective in atisara.

## CONCLUSION

Samangadi Kwatha may be used as main therapeutic agent in the cases of uncomplicated childrens diarrhea, with minimum risk of malnutrition because of early recovery and Rasayana property of Sariva (*Hemidesmus indicus*).

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