



CLINICAL RESEARCH ON “*LAVANGA CHATUSAM CHURNA* IN *BALATISARA*”

Dr. Jyoti Devi¹, Prof - Dr. Keerti Verma² & Prof. Dr. Sanjay Kumar Singh³

1. Author and MD final year, PG Department of Kaumarbhritya, Rishikul Campus Haridwar UAU Dehradun.
2. Co-author and Head of Department, Kaumarbhritya, Rishikul Campus Haridwar UAU Dehradun.
3. Co-author and Prof, Department of Roga Nidana and Vikriti Vigyan, Rishikul Campus Haridwar UAU Dehradun.

ABSTRACT- Diarrhea is a common disorder amongst children especially 5-12 years of age. School going children consume more of outside food/packet food/junk food frequently and lack of hygiene and contaminated water, leads to gastric upset. Dietary habits, stomach infections and unhygienic conditions are major causes of diarrhea, Ayurveda described diarrhea as *Atisara* which means *ati* (excess in consistency, frequency and volume) & *saranam* (flow); condition where watery stools pass in excess with increased frequency. Diarrhea is a rising problem especially in developing countries. It affects millions of children worldwide. *Aama* and *Vata* are the major pathological factors of diarrhea. As per *Ayurveda*, *Nidana Sevana* leads to production of *Ama*, *Vata* gets vitiated due to the malfunctioning of *Saman- Apana vata* which results in *Jathragni Mandhya* which increases *Dravata* of stool in *Pakvashaya* & causes *Atisara*. *Atisara* involve vitiation of *Strotasa* such as; *Annavaha*, *Udakvaha* and *Malavaha*. For the management of *balatisara* a number of compositions are found in various text books among which “*Lavanga Chatusam Churna*” an herbal compound has described by *Bhaishaya Ratnavali Balarogadhikara* is said to be an effective one. Ingredients of drug-*Jatiphala*, *Lavanga*, *Sweta Jeeraka* and *Shudha Tankana* which have *Deepana-Pachana*, *Tridosha Shamaka*, *Grahi*, *Stambhaka*, *Shoolaghna*, *Jwaraghna* properties. So, *Lavanga Chatusam Churna* has been chosen for the present study.

Key points- *Atisara*, *Agnimadhya*, *Lavanga Chatusam Churna*

INTRODUCTION:

The term *Balatisara* is found at first in *Harit Samhita* in context of treatment. The detailed description of *Atisara* in children is not explained in *Ayurveda*. However, in *Kaumarabhritya* certain specific disorder in which diarrhoea is major symptom have been mentioned in *Ayurvedic* literature. *Atisara* is described as a symptom in many diseases like *Dantoddhvejanyatisara*, *Ksheeralasaka*, *Vyadhijfakka*, *Revati*, *Putna*, *Balaagraha* etc. Even though separate description of *Balatisara* as a disease is not found in scriptures, but specific treatment remedies are available there specially for *Balatisara*¹.

Acharya Charaka, *Vagbhatta* and *Sushruta* mentioned 6 types of *Atisara* (diarrhea) (*Vataja*, *Pittaja*, *Kaphaja*, *Sannipataja*, *Bhayaja*, *Shokaja*) but *Acharya Sushruta* has mentioned *Amaja* type of *Atisara* (diarrhea) instead of *Bhayaja* variety. Involvement of *Vatapradhanatridosha dusti* can be figured out in *Samanya Samprapti* of *Atisara* (diarrhea) leading to *Agnimandya* then *Amaotpatti* and *Apa Dhatus* (body fluids) are enhanced in

excess and further brings diminution of strength of *Agni*, gets mixed with stool, causes downward movement in *Purishavaha srotas* by *Apana Vāta* leading to development of excess watery stool is known as *Atisāra*².

According to modern, it is one of the commonest & serious disease in children. These liquid stools are usually passed more than three times a day. However, diarrhoea is the recent change in consistency and character of stool is most important rather than number of stools passed³.

Diarrhea (*Atisara*) has long been recognized as an important health problem in all age groups and is a major cause of morbidity and mortality in rural communities of socio-economically backward and developing countries. Globally, diarrhea accounts for more than 5-8 million deaths annually, majority of them are infants and children below 5 years old^{4,5}. 88% of diarrhea-related deaths are caused by inadequate sanitation along with poor hygiene and clinically due to dehydration, which results from the loss of electrolytes in diarrheal stools⁶.

PREVELANCE:⁷

Diarrhea is a common disorder among children especially below 12 years of age. Diarrheal disease is the second leading cause of death in children under the age of 5 years, and is responsible for killing around 5,25,000 children every year (WHO May 2017).

WHO and UNICEF estimated that approximately 8 per cent of all deaths among children under age 5 worldwide in 2017. This translates to over 1,300 young children dying each day, or about 480,000 children a year, despite the availability of simple effective treatment (unicef data: Diarrhea in 2019).

Further, children aged < 11 years (14.01%) tends to suffer from diarrhea more compared to other age groups of children.

AIMS & OBJECTIVES

- Evaluation of **LAVANGA CHATUSAM CHURNA** in **BALATISARA**.
- To study the etiopathogenesis of **BALATISARA** in children and its modern correlation.
- To provide an economic, safe & cost effective *Ayurvedic* formulation in the management of **BALATISARA**.
- To study the adverse effects of drug if any during the treatment.

2. MATERIAL AND METHOD

1) Selection of patients-

Group	Registered Patients	Complete Treatment	Module	Duration
Single	60	51	<i>Lavanga Chatusam Churna</i>	According to age 5-12 years for 22 days

Out of 60 patients, only 51 patients could complete their treatment. 09 patients had left against their medical advice. Hence, the final assessment of the result was done only in 51 patients.

INCLUSION CRITERIA

- ✓ Age between 5 years to 12 years.
- ✓ Both male and female children.
- ✓ Case of diarrhea (mild to moderate).
- ✓ Diarrhea with no dehydration / mild dehydration.
- ✓ Associated with or without foul smell.
- ✓ With mild pain in abdomen or without pain

EXCLUSION CRITERIA

- ✓ Children age below 5 years and above 12 years.
- ✓ Not accepting orally.
- ✓ Persistent vomiting.
- ✓ Severe dehydration.
- ✓ Severe diarrhea.
- ✓ Worm infestation induced diarrhea.
- ✓ Known case of children having illness like T.B., Juvenile diabetes & HIV.

Drug:

For the present study *Lavanga Chatusam Churna* was used for the management of *Atisara*. The details of the formulation and method of preparation are as follows.

PREPARATION OF CHURNA:

- All the below mentioned herbal drugs were cleaned of mud and other impurities.
- All the ingredients were taken in equal proportions and grind to get coarse powder.
- Then fine powder sieved with sieve size 85.
- The *Churna* made was packed in air-tight containers and stored in dry place

Name of drugs	Proportion	Part use
<i>Jatiphala</i>	1 Part	Seeds
<i>Lavanga</i>	1 Part	Flower bud
<i>Sweta Jeeraka</i>	1 Part	Seeds
<i>Shudha Tankana</i>	1 Part	-

➤ TYPE OF STUDY:

- Open label single clinical trial.
- Period of study- 22 days
 - With Drug –15 days
 - Without Drug – 7days
- **Follow up:** There are 3 follow up.
 - 1st follow up 3 days, 2nd follow up is 5 days, 3rd follow up 7 days and last follow up is 7 days without medicine.

Dose of medicine

Age (in years)	Dose (Two divided doses)
5 years	300 mg
6 years	333 mg
7 years	368 mg
8 years	400 mg
9 years	430 mg
10 years	455 mg
11 years	480 mg
12 years	500 mg

Administration of Drug –

Route: Orally

Dose: According to age twice in day for a period of 15 days.

*Anupan: Madhu and Sita.***ASSESSMENT CRITERIA: On the basis of Subjective parameters**

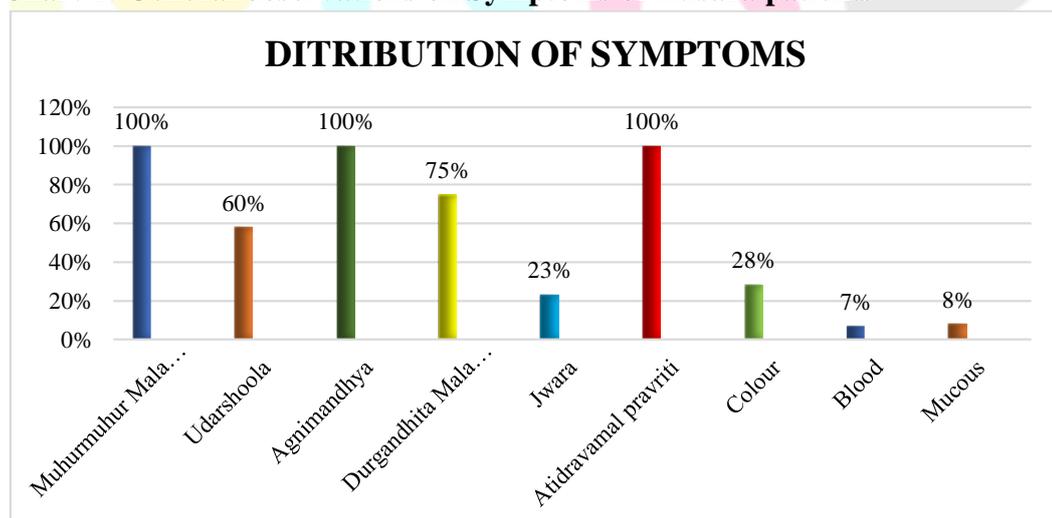
Parameters	Grade 0	Grade 1	Grade 2	Grade3
<i>Muhurmuhur Mala Pravriti</i>	Normal defecation	1-3 motions per day	4-5 motions per day	>5 motions per day
<i>Udarshoola</i>	No abdominal pain	Occasionally	Mild pain	Moderate pain
<i>Agnimandhya</i>	Normal hunger	Hunger sensation after 4-6 hours intake of food	Hunger sensation after 7-10 hours intake of food	No hunger sensation after >10 hours intake of food
<i>Durgandhita Mala Pravriti</i>	Normal Smell	Occasionally offensive	Offensive	Extremely offensive
<i>Jwara</i>	Normal body temperature	99.8°F body temperature	100-102°F body temperature	>102°F body temperature

ASSESSMENT CRITERIA: On the basis of Objective parameters

Parameters	Grade 0	Grade 1	Grade 2	Grade3
Consistency	Normal	Sometime soft & some time watery	Semi loose	Watery
Color	Normal	Other than normal	-	-
Blood	Absent	Present	-	-
Mucous	Absent	Present	-	-
Pus cells	Absent (0-5)	Present (>5)	-	-

OBSERVATIONS AND RESULT:

- ✓ In present study 60 patients were registered, 51 patients completed their treatment. The prevalence of the disease is more in 5-7 years of age group 45%, followed by 8-10 years 35% and minimum patients in 11-12 years of age group 20%. In this series the maximum i.e. 52% patients were male while rest of the patients i.e. 48% were female. Prevalence in Urban area 80% followed by Rural area 20%. Maximum 55% of patients were found which consumed junk/packet food while 7% of patients were found addiction of pica and 38% of patients were found not any addiction. Maximum 67% children had sudden onset of symptoms, where as 33% had gradual onset of the symptoms.
- ✓ In the present study, *Muhurmuhur Mala Pravriti*, *Agnimandhya*, *Atidrava Mala Pravriti* were found as chief complaint in 100% patients. *Durgandhita Mala Pravriti* in 75%, *Udarshoola* was found in 60% patients, colour was found 28% patients, *Jwara* in 23.3% of patients, Mucous was found in 8% and Blood was found in 7% of patients.

Chart 1: General observations on Symptoms of Atisara patients

✓ Highly significant improvement was observed in *Muhurmuhur Mala Pravriti* ($P < 0.001$). The relief percentage was 60%. *Udarshoola* ($P < 0.001$) with the percentage of relief was 52%. highly significant effect ($P < 0.001$) was found with 64% relief in *Agnimandhya*, *Durgandhita Mala Pravriti* ($P < 0.001$) with the percentage of relief was found 54%. *Jwara* ($P < 0.001$) with the percentage of relief was found 62.5%. *Atidrava Mala Pravriti* ($P < 0.001$) with 72.2%, colour of stool ($P < 0.001$) with percentage of relief 81.2%. Significant improvement was observed in blood in stool ($P < 0.029$) with 100% relief in complaint of patients. Mucous in stool show significant result ($P < 0.032$) with 75% relief. Pus cells in stool show significant result ($P < 0.032$) with 85.7% relief in complaint of patients.

TOTAL EFFECT OF TREATMENT MODULE IN THIS STUDY:

TABLE- Showing Improvement in Subjective Criteria:

Parameters	Mean		D	% of relief	SD	SE	W	P	Significance
	BT	AT							
<i>Muhurmuhur Mala Pravriti</i>	2.45	0.98	1.47	60	0.57	0.08	-4326.0	<0.001	HS
<i>Udarshoola</i>	1.97	0.94	1.02	52	0.50	0.08	-528.0	<0.001	HS
<i>Agnimandhya</i>	1.86	0.7	1.19	64	0.52	0.07	-1326.0	<0.001	HS
<i>Durgandhita Mala Pravriti</i>	2	0.91	1.08	54	0.60	0.10	-1326	<0.001	HS
<i>Jwara</i>	1.71	0.64	1.07	62.5	0.45	0.11	-666.0	<0.001	HS

Chart 2 : Showing the improvement in subjective parameters of patients of Atisara

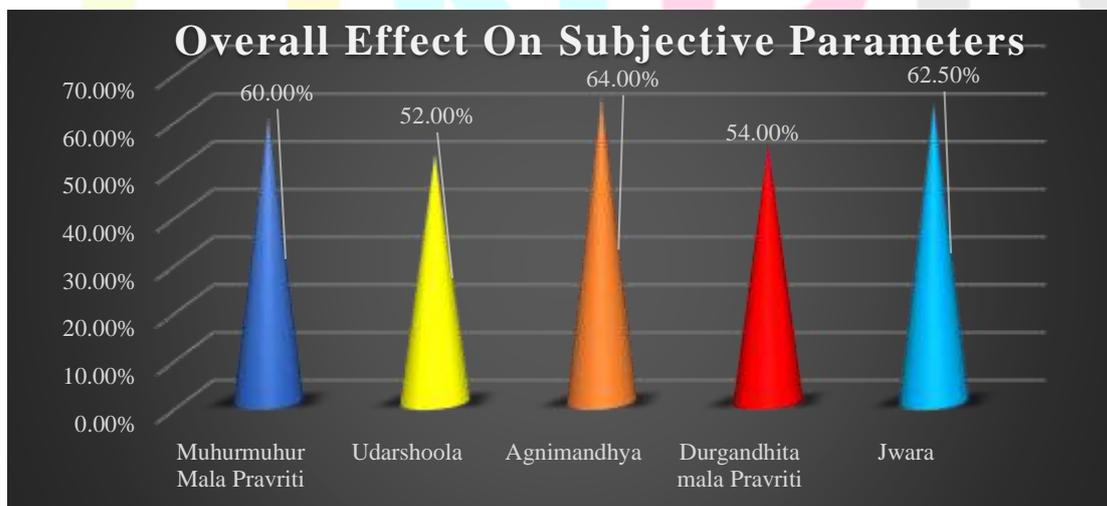
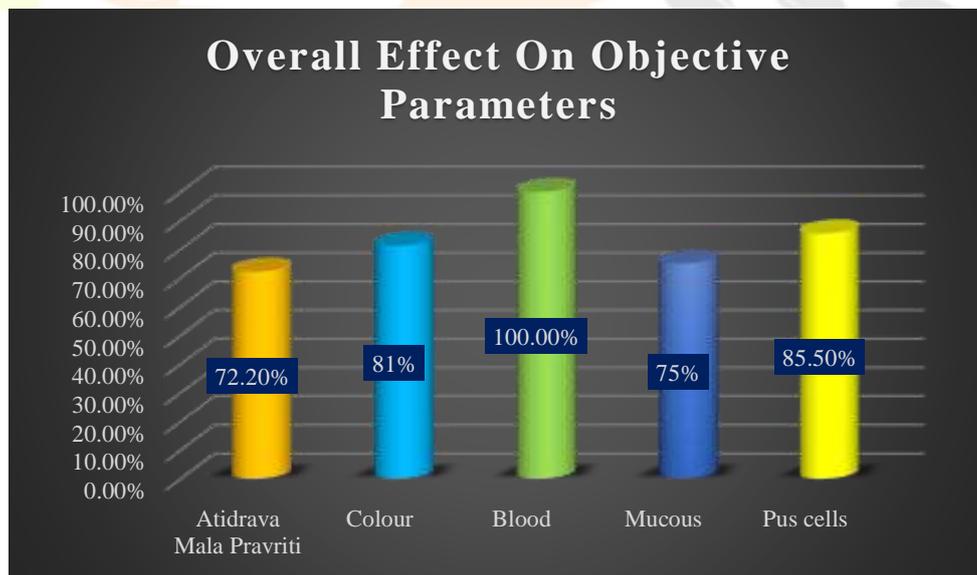
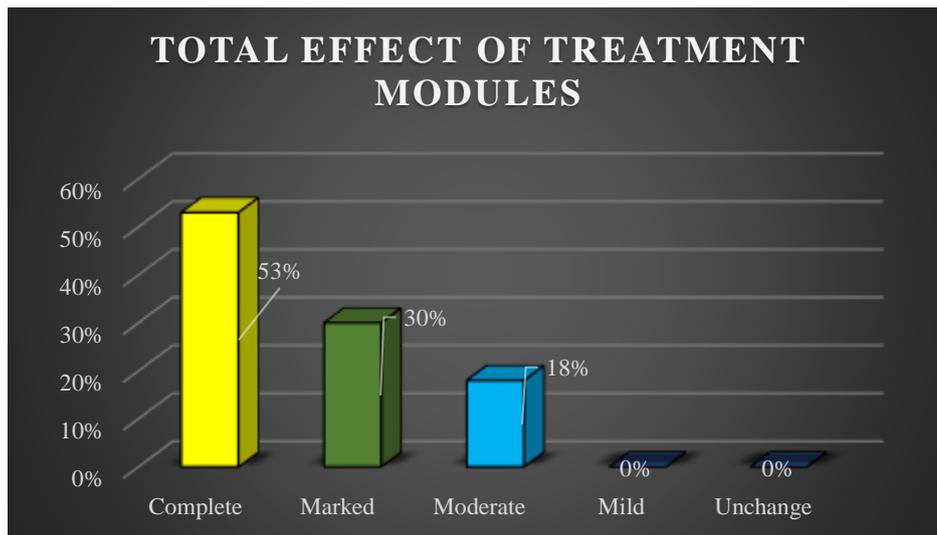


TABLE- Showing Improvement in Objective Criteria:

Parameters	Mean		D	% of relief	SD	SE	T	P	Significance
	BT	AT							
<i>Atidrava Mala Pravriti</i>	2.5	0.70	1.82	72.2	0.54	0.07	3843.0	<0.001	HS
Colour	1	0.18	0.81	81.2	0	0.1	408.0	<0.001	HS
Blood	1	0	1	100	0	0	26.00	<0.029	S
Mucous	1	0.25	0.75	75	0.44	0.2	37.50	<0.032	S
Pus cells	1	0.14	0.85	85.7	0.42	0.13	145.0	<0.003	S

Chart 3: Showing the improvement in objective parameters of patients of Atisara**TOTAL EFFECT OF TREATMENT MODULES:**

RESULT	NO. OF PATIENTS	PERCENTAGE
COMPLETE IMPROVEMENT	31	61%
MARKED IMPROVEMENT	15	29%
MODERATE IMPROVEMENT	05	10%
MILD IMPROVEMENT	00	0%
NO IMPROVEMENT	00	0%

Chart 4: Showing the improvement in patients of Atisara**DISCUSSION:**

The age group 5-12 years includes the school going children which are very much fond of eating the outside food, which may be the probable reason to cause *Atisara* in them. Most of the Indian housewives have the faulty life style like *Adhyashana*, *Vishamashana*, and eating stale food etc. which affects the *Agni* leading to *Ama* formation and diseases like *Atisara*. Urban slum area is the chief social cause for the formation of the diseases like diarrhea. Unhygienic water, food, cloths etc is the main source of infection in such people. In urban area the people of now days are consuming the fast food very frequently which may be the cause of *Ama* formation leading to *Atisara*. Most of the patients were suffering from *Mandagni* previously, which clearly indicates that *Agnimandya* is the prior stage of almost all the diseases. Here in case of *Atisara* also *Mandagni* leads to *Ama* formation which further leads to *Atisara*. In the present study the number of patients taking vegetarian food were more, may be because there are some vegetables which increases the bowel movement causing diarrhea.

Probable mode of action:**1. *Jatiphala*-**

- It is having *Deepana-Pachana* properties. Basically, it is *Vaat-kaphshamaka* because of its *Ushna Virya* but it is also having *Pittashamaka* properties due to *Tikta-Kasaya Rasa*.
- It having *Jwaraghna*, *Shoolaghna*, *Durgandhanashaka* & *Stambhaka* properties due to *Ushna Virya* and *Tikta Kashaya Rasa*. Hence, its efficacy on *Aamatisara*, *Pakkwatisara* and all type of *Doshajatisara*.
- We can be understood by above description. Apart from these pharmacological studies of *Jatiphala* has shown its Anti-diarrheal, Anti-inflammatory, carminative, Anti-spasmodic.

2. *Lavanga*-

- It is having *Deepana-Pachana* and *Jwaraghna* properties due to its *Tikta Katu Rasa* and *Sheeta Virya*.
- It is *Kapha-Pittahara* in nature by *Katu*, *Tikta Rasa*, and *Katu vipaka*.
- By *Snigtha Guna* of *Lavanga* is *Udar Shoolaghna* properties. Therefore, *Lavanga* therapeutically useful in *Atisara*. Its Anti-inflammatory, Analgesic properties.

3. *Sweta Jeeraka-*

- It is having *Deepana-Pachana* and *Grahi* properties due to its *Ushna Virya* and *Laghu Ruksha Guna*.
- It is *Kapha-Vata Shamaka* due to its *Ushna Virya* property.
- By *Laghu-Ruksha Guna*, *Ushna Virya* and *Katu Vipaka*, *Sweta Jeeraka* is *Jwaraghana*. Its *Shoolaghna* in nature due to *Ushna Virya*.
- Along with above properties therapeutic evaluation of its Antiseptic, Analgesic, Anti-inflammatory, and Sedative.

4. *Shudha Tankana-*

- Due to *Ushna-Ruksha Guna* and *Katu Vipaka*, it is *Kapha Shamaka*. It is having *Stambhaka*, *Grahi* and *Deepana-Pachana* properties due to its *Ushna-Tikta Guna*, *Ushna Virya* & *Katu Vipaka*.
- Pharmacological studies on *Tankana* suggests that it is potent Anti-diarrheal, anti-viral, antibacterial, anti-inflammatory, carminative and analgesic in action.

CONCLUSION:

The trial drug "*Lavanga Chatusam Churna*" is commonly available and is a cost-effective drug. It can be afforded by the poorest people of the society. From the present clinical study, it showed that efficacy of drug is very high; hence it can be used effectively to control *balatisara*. The trial drug has no adverse effect. Further study can be carried out in large sample in future.

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Research Through Innovation

Chart 4: Showing the improvement in patients of Atisara

