IAMJ

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL

Research Article ISSN: 2320-5091 Impact Factor: 6.719

CLINICAL EVALUATION OF DHATAKYADI CHURNA IN BALATISARA (PROTOCOL STUDY)

Mansi Tewari[1], Keerti Verma[2], Reena Dixit[3]

1. M.D 2nd year scholar, P.G Department of Kaumarbhritya, Rishikul Campus Haridwar
2. H.O.D, P.G Department of Kaumarbhritya, Rishikul Campus Haridwar
3. Professor, P.G Department of Kaumarbhritya, Rishikul Campus Haridwar

Corresponding Author: mansitewari97@gmail.com

https://doi.org/10.46607/iamj0513032025

(Published Online: March 2025)

Open Access

Article Received: 06/02/2025 - **Peer Reviewed:** 27/02/2025 - **Accepted for Publication:** 08/03/2025.

Check for updates

ABSTRACT

Diarrhea is a leading cause of morbidity and mortality in paediatric practices. The global annual burden of diarrhoea is enormous, affecting 3-5 billion cases and causing approximately 2 million deaths a year. Diarrhea is described in *Ayurvedic* text as '*Atisara*'. The term *Atisara* is derived from '*Ati*' and '*Sara*' i.e. the excessive passage of liquid matter (*Sarana*) with *purishayukta apdhatu* through *adhomarga* (anus) is termed as *Atisara.* The most important factor in the pathogenesis of *Atisara* (diarrhea) is *Mandagni*.

Atisara is a major cause of morbidity and mortality in rural communities of socio-economically backward and developing countries. It is a common cause of fluid loss in children and can result in dehydration and electrolyte imbalance, which causes morbidity in childhood. The two most important consequences of *Atisara* in children are malnutrition and dehydration.

Thus, in the present study, *Balatisara* is taken as the subject of intervention with the drug '*Dhatakyadi Churna*' mentioned in *Bhavaprakasha* under *Balarogadhikara.*

MATERIALS AND METHODS: This prospective, open label randomized clinical trial will be conducted at Rishikul Campus, Haridwar, Uttarakhand Ayurved University. Forty children aged 5-16 years, irrespective of gender, with classical symptoms of *Balatisara,* will be enrolled in the study. The outcome will be assessed ac-

cording to the subjective and objective parameters established for the study on each visit. Safety will be assessed based on the incidence of adverse events.

DISCUSSION AND CONCLUSION: Diarrheal diseases rank among the top three causes of death in the paediatric population of the developing world. The most important factor in the pathogenesis of *Atisara* (diarrhea) is *Mandagni*. *Aharaja* (dietic) and *Viharaja* (behavioral) *Nidana* results in *Mandagni,* which is the root cause of *Amadosha* and is the crucial factor for the manifestation of *Atisara*. As its *Samprapti* involves *Agnimandya* and *mala dravata* and the *Ayurvedic* formulation chosen for this study, "*Dhatakyadi Churna*" usually has *deepened*, *pachana,* and *grahi* properties. So, it is expected that the outcomes of this trial will suggest probable therapeutic options for the effective management of *Balatisara* in children.

Keywords: *Atisara, Mandagni, Deepana, Pachana, Grahi, Aharaja, Viharaja, Agnimandya, Samprapti, Balarogadhikara.*

INTRODUCTION

Atisara is a disease of intestinal disturbances that involves water & electrolyte imbalances, malnutrition, and undernutrition. *Atisara* not only affects the health of children but is also considered responsible for infant mortality, especially in tropical and subtropical countries**.** In addition to the risk of mortality, diarrheal illness, especially episodes among young children that are recurrent, prolonged, or persistent, can be associated with malnutrition, stunting, micronutrient deficiencies, and significant deficits in psychomotor and cognitive development [1]. *Ayurvedic* texts described the management of *Balatisara* with medicines having qualities like *Madhura, Mridu, Laghu, Surabhi sampurna, Sheetala* & *Samshamaka*, along with the properties of Deepana and Pachana karma, which break the *Samprapti* of *Atisara.*

The WHO has constituted a diarrheal disease control program, which includes traditional medicinal practices and the evaluation of health education and prevention approaches [2]. The factors determining susceptibility to diarrhoea include poor sanitation and personal hygiene, the non-availability of safe drinking water, unsafe food preparation practices, and low rates of breastfeeding and immunisation [3]. Diarrhea is usually a symptom of an intestinal infection that various bacterial, viral, and parasitic organisms can cause.

According to WHO, "Diarrhea is defined as the passage of three or more loose or watery stools per 24 hours, resulting in excessive loss of fluid and electrolytes in stools" [4].

The term *Balatisara* is first found in ***Harita Samhita*** in the context of treatment. Balatisara means Atisara, which occurs in children but has not been mentioned as a separate entity in *Brihatrayi*. Though several scattered references to the term *Balatisara* are found in the context of the treatment of *Atisara* in children in *Laghutrayi*, *Atisara* (Diarrhea) has been dealt with in much detail in *Ayurvedic* literature, but not in terms of children especially. However, in *Kaumarbhritya,* certain specific disorders in which *Atisara* is a major symptom have been mentioned in *Ayurvedic* literature. *Atisara* is described as a symptom in many diseases like *Dantobhedajanyatisara*, *Ksheeralasaka, Vyadhiifaka, Revati, Putna, Balagraha,* etc. [5]

Acharya Kashyapa[6] has not separately described *Balatisara,* but he has mentioned *Poorvaroopa* of *Atisara* in *Vedana Adhyaya* of *Sutrasthana*. ***Acharya Sushruta***[7] and *Acharya Madhava* [8] have mentioned six types of *Atisara – Vataja, Pittaja, Kaphaja, Sannipataja, Aamaja* and *Shokaja*. ***Acharya Charaka*** [9] and ***Acharya Vagbhatta***[10] have mentioned six types of *Atisara*, where in five types same as ***Acharya Sushruta*** except *Bhayaja* replace with *Amaja Atisara*. ***Acharya Sharangadhara*** [11] mentions seven types of Atisara: Vataja, Pittaja, Kaphaja, Sannipataja, Bhayaja, Shokaja, *and Aamaja*.

SAMANYA NIDANA-

Table no.-1

Sr. No.	*Samanya Nidana*	*Acharya Sushruta*[12]	*Bhava prakasa*[13]	*Acharya Vagbhata*[14]	*Acharya Madhava*[15]
1.	*Atiguru Swabhava, Matra*	+	+	+	+
2.	*Ati snigdha Aahara*	+	+	-	+
3.	*Ati ruksha Aahara*	+	-	+	+
4.	*Ati ushna Aahara*	+	-	-	+
5.	*Ati drava Aahara*	+	-	-	+
6.	*Virudhasana*	+	-	-	+
7.	*Ajeerna*	+	-	+	+
8.	*Ati Ambu Paan*	+	-	+	+
9.	*Adharaniya Vega Dharana*	+	-	+	+
10.	*Ritu Viparita Aahara Vihara*	+	+	-	+
11.	*Bhaya and Shoka*	+	+	-	+

***SAMPRAPTI GHATAKA* –**

Table no. -2

Dosha	*Vatapradhan (Tridoshaja)*
Dushya	*Rasa jaleeya Dhatu*
Agni	*Mandagni*
Srotasa	*Purisha, Udaka and Annavaha srotas*
Adhishtana	*Pakvashaya*
Srotas dushti	*Atipravriti*
Rog marga	*Madhyama marga*

MATERIALS AND METHOD-

AIM OF THE STUDY –

- To conceptualise the etiopathogenesis of *Balatisara* by contemplating both Ayurveda and modern points of view.
- Evaluation of ***DHATAKYADI CHURNA*** in ***BALATISARA***.
- To provide a safe and cost-effective *Ayurvedic* formulation to manage ***BALATISARA***.

SELECTION OF PATIENTS—Patients will be selected based on their symptoms of Balatisara from the OPD, P.G. Department of *Kaumarbhritya*, Rishikul Campus, Haridwar.

a) **Inclusion criteria: Children between the ages of 5 and 16, irrespective of their gender, with** mild to moderate cases of *Balatisara.*

b) **Exclusion criteria**: Children below the age of 5 years and above 16 years, cases of severe diarrhea, persistent vomiting, severe dehydration, cases of worm infestation-induced diarrhea, and children with known cases of children having any long-term illness like TB, IBS, and other metabolic disorders.

c) **Withdrawal criteria**: Aggravation of symptoms, personal matters, and LAMA (leave against medical advice).

ASSESSMENT CRITERIA – Children will be assessed based on objective and subjective criteria.

- **Subjective criteria-**

Table no. - 3

Sr. No.	PARAMETERS	GRADE 0	GRADE 1	GRADE 2	GRADE 3
1.	**eqgqeqZgw ey ço`fr (Frequency of stool)**	1-3 loose stools per day	4-6 loose stools per day	7-9 loose stools per day	> 10 loose motions per day
2.	**vfræo ey ço`fr (Consistency)**	Well, formed!	Sometimes formed and sometimes loose stool.	Loose stool	Watery stool
3.	**nqxZfU/kr ey (Foul smell)**	Foul smell	Mild offensive	Moderate offensive	Highly offensive
4.	**mnj'kwy (Abdominal pain)**	No abdominal pain	Occasionally	Mild pain	Moderate pain
5.	**vfXueka| (Decreased Appetite)**	The child himself asks for food & takes adequately	The child himself asks for food but does not take it adequately	The child does not ask for food & takes considerably	The child does not ask & does not take, even by request

- **Objective criteria**: Routine and microscopic examination of stool (pus cells and RBC) and Hb%.

SAMPLE SIZE—Based on the sample size calculation, the sample size is estimated to be 226.8. However, due to the shorter duration of the study and financial limitations, we will limit our sample size to 40.

TYPE OF STUDY- Open-label single clinical trial

LEVEL OF STUDY: OPD level

DURATION OF STUDY: 18 months

ASSESSMENT AND FOLLOW-UP:

- ✓ With drug – 7 days (Daily)
- ✓ Without drug – 7 days
- ✓ The follow-up will be done after 7 days of cessation of medicine.

METHOD OF TREATMENT-

- ✓ Selected drug: ***Dhatakyadi Churna***
- ✓ Form of medicine: *Churna*(powder) formulation
- ✓ Composition of medicine: *Bilva, Dhataki, Sugandha Bala, Gajapippali, Lodhra*

REVIEW OF DRUG [16] –

fcYoa p iq"ikf.k p /kkrdhuka tya lyks/kz xtfiIiyha pA

DokFkkoysgkS e/kquk fofeJkS ckys"kq ;ksT;kofrlkfjrs"kqAA

¼Hkkå çå e/;e [k.M ‰ƒ /ƒ‡„½

Table no. – 4

Sr. No.	Drug Name	Proportion	Part Used
1.	*Apakva Bilva*	1 part	*Phala*
2.	*Dhataki*	1 part	*Pushpa*
3.	*Lodhra*	1 part	*Twak*
4.	*Gajapippali*	1 part	*Phala*
5.	*Sugandha Bala*	1 part	*Mool*

***Panchabhautika Guna* of the drugs-**

Bilva – *Aegle marmelos* due to *Laghu, Ruksha guna, Katu, Tikta, Kasaya rasa, Katu vipaka,* and *Ushna veerya* acts as *Vatakaphahara, Deepana, Pachana* and *Grahi.*

Dhataki **–** *Woodfordia fruticosa* due to *Laghu guna, Katu, Kashaya rasa, Katu Vipaka* and *Sheeta veerya* acts as *VataKaphahara, Grahi* and *Kriminuth*

Lodhra- *Symplocos racemosa* due to *Laghu guna, Kashaya rasa, Katu vipaka* and *Sheeta veerya* acts as *Kaphapittanut* and *Grahi*.

Gajapippali - *Scindapsus officinalis* due to *Ruksha guna, Katu rasa, Katu Vipaka, and Ushna veerya* acting as *Vatakaphahara* and *Malavishoshaka.*

Sugandha Bala - *Valeriana wallichii* due to *Laghu, Snigdha guna, Katu, Tikta, Kashaya Rasa, Katu vipaka,* and *ushna veerya* acts as *Tridoshahara*, *Deepana* and *Shoolaprashamana*

Drugs and their pharmacological actions-

Table no 5

S. No.	DRUG	PHARMACOLOGICAL ACTION
1.	*Bilva*	Anti-diarrheal, Anti-microbial, Anti-inflammatory.
2.	*Dhataki*	Anti-diarrheal, Anti-bacterial, Anti-inflammatory.
3.	*Sugandha bala*	Anti-spasmodic
4.	*Gajapippali*	Anti-diarrheal, Anti-microbial, Anti-inflammatory
5.	*Lodhra*	Digestive, Anti-microbial, Anthelminthic

ROUTE OF ADMINISTRATION: Oral, along with management of dehydration by using standard ORS preparation.

PREPARATION OF MEDICINE:

- The drugs will be identified in the Dravyaguna department, and preparation will be done in *Rasa Shastra Evam Bhaishajya Kalpana*.
- The drug will be prepared according to Churna's method of preparation.

STORAGE OF MEDICINE: The medicine will be stored in air-tight containers.

DRUG DOSE [17] **-**

Ekk'kSo`f/nLrnw/oZa L;k|koR'kksM"koRlj%A

("kk0 la0 iz0 [k.M 6/15)

For the present study, I have taken drug doses of *Dhatakyadi Churna* according to *Sharangadhara Samhita*. One *Masha* for one year child and this 1 *Masha* increases yearly, up to 16 years. Thus, for the age of 05 to 16 years, the doses will be 5 *Masha* to 16 *Masha* in divided doses. (1 *Masha* = 1gm)

SAFETY OUTCOMES—Safety will be assessed based on adverse events on each follow-up visit. Any adverse events, if any, will be recorded per Good Clinical Practice guidelines.

ETHICAL CONSIDERATIONS -The study is approved by the Institutional Ethics Committee of the Uttarakhand Ayurveda University, Rishikul Campus, Haridwar. Before enrolment, the investigator will obtain written informed consent from the parents of eligible children.

DISCUSSION & CONCLUSION

According to recent WHO reports, there are nearly 1.7 billion cases of childhood diarrhoeal disease globally every year. Each year, diarrhoea kills around 443,832 children under five and an additional 50,851 children aged 5 to 9 years [18]. So, there is a need for a reliable, safe, and cost-effective formulation for *Balatisara* in *Ayurveda*. Therefore, *Dhatakyadi Churna*, described by Acharya Bhavaprakasha for Balatisara, has been selected for the study. The formulation includes contents like *Bilva* (*Aegle marmelos), Dhataki (Woodfordia fruticosa), Sugandha bala (Valeriana wallichii), Gajapippali (Scindapsus officinalis) and Lodhra (Symplocos racemosa*) which have stomachic, antidiarrheal, carminative, anti-inflammatory, antimicrobial, gastro-protective activity, inhibition of gastric motility activity and antispasmodic properties respectively which will help in breaking the *Samprapti* of *Balatisara.*

Bilva has maximum antibacterial activity against *Bacillus subtilis*, followed by Staphylococcus aureus, E. coli, and Pseudomonas aeruginosa [19]. Dried flowers

of *Dhataki* have significant antibacterial activity against 14 human pathogens and are active against Pseudoalcaligens and gram-positive bacteria [20],[21],[22]. *Sugandha bala* shows effectiveness against S. aureus and P. aeruginosa[23]. *Bilva* and *Sugandha bala* have *Deepana* and *pachana* properties, which eliminate the root cause of *Balatisara,* i.e. *Mandagni*. All the drugs are *Katu, Tikta, Kashaya Rasa pradhana. Therefore,* they have *Grahi* or *malavishoshaka* action. *Lodhra,* by its *kashaya rasa* and *sheeta veerya*, has *Raktastambana* (styptic) and *Shonitasthapana* actions [24]. *Acharya Charaka* mentioned it in *Purisha sangrahaniya Mahakashaya*. Thus, it is helpful for *Atisara* (diarrhea) and *Pravahika* (dysentery) [25].

Thus, it is expected that Dhatakyadi Churna will show promising results in children with the manifestation of *Atisara*.

REFERENCES

1. Kliegman, St Geme, Blum, Shah, Tasker, Wilson; Nelson textbook of pediatrics, volume-2, Edition 2021, chp- 366 –Acute gastroenteritis in children.
2. Syder JD, Merson MH. The magnitude of the global problem to acute diarrhoeal disease: A review of active surveillance data, Bulletin of the World Health Organisation 1982; 60:605.
3. Vinod K Paul, A. 2019 Ghai Essential Paediatrics 9th edition. New Delhi: CBS Publishers, chapter 11.
4. https://www.who.int/news-room/fact-sheets/detail/diarrhoeal-disease
5. D. and Singh, D. (n.d.) A Critical Review on *Balatisara* (Childhood Diarrhoea): Disease or Symptom. International Journal of Research in Engineering and Sciences, 39.
6. *Vriddha Jivaka. Kasyapa Samhita* Revised by Vatsya Introduction by Nepal Rajguru Pandita Hemaraja Sharma with Vidyotini Hindi Commentary. Varanasi: Chaukhambha Sanskrit Sansthan. Sutrasthana chapter 25 Vednaadhyaya page-50.
7. Shastri, D. Sushruta Samhita. Varanasi: Chaukhambha Sanskrit Sansthan. *Uttaratantra* chapter 40/7 page-274.
8. Yadunandana Upadhyaya, P. 2004. *Madhavakara Madhava Nidana*. Varanasi: Chaukhambha Sanskrit Sansthan. *Poorvardha* chapter 3/4, page-161
9. Chaturvedi, D. *Charaka Samhita*. Varanasi: Chaukhambha Bharti Academy. *Sutrasthana* 19/3 page 386.
10. Tripathi, D. *Ashtanga Hridaya*. Delhi: Chaukhambha Sanskrit Pratishthan. *Nidana sthan* 8 page-483.
11. Shreevastev, D. *Sharangadhara Samhita Purvakhanda*. Varanasi: Chaukhambha Orientalia. Chapter 7 page-63.
12. Shastri, D. *Sushruta Samhita*. Varanasi: Chaukhambha Sanskrit Sansthan. *Uttaratantra* chapter 40/3-5, page-272.
13. Shrikantha, P. 2005. *Bhavaprakasha* of *Bhavamishra*, page-129.
14. Tripathi, D. *Ashtanga Hridaya*. Delhi: Chaukhambha Sanskrit Pratishthan. *Nidanasthana* 8/1-3, page no. 483.
15. Yadunandana Upadhyaya, P. 2004. *Madhavakara Madhava Nidana*. Varanasi: Chaukhambha Sanskrit Sansthan. *Poorvardha* chapter 3/1-3, page-156.
16. Pandit Sri Brahma Sankara Mishra Vidyotini Hindi Commentary on *Bhavaprakasa Uttarartha*, Part 2 of *Bhavamisra*. Varanasi: Chaukhambha Bharti Academy, *chikitsasthan Bhavaprakasha Madhya khanda* page no. 808, 71/ 152.
17. *Sharangadhara Samhita Prathama Khanda* 6/15.
18. Ravi Shankar, Singh SP, Tripathi CB. Persistent diarrhea: approaches for the management among under-five children. Indian J. Prev. Soc. Med, 2004; 35(3, 4): 112-120.
19. Kumari Anupama, Tiwari R.C, Sharma Ved Bhushan, Tiwari Shashikant; *Bilwa* (Aegle marmelos): A review article. International Ayurvedic Medical Journal, ISSN: 2320- 5091.
20. Kumaraswamy MV, Kavitha H, Satish S; Antibacterial Potential of Extracts of Woodfordia fruticosa Kurz on Human pathogens. Word Journal of Medical Sciences. 2008; 3(2): 93-96. 27.
21. Parekh J, Chanda S; In vitro Antibacterial activity of the crude methanol extract of Woodfordia fruticosa Flower. Brazilian Journal of Microbiology, 2007; 38:204-207.
22. Shah AS, Juvekar AR; In-vitro and in-vivo Immunostimulatory activity of Woodfordia fruticosa flowers on non-specific immunity. Pharma Biol, 2010;48(9): 1053-1058.
23. Sharma, P. *Dravyaguna Vigyan* Part-2. Varanasi: Chaukhambha Bharti Academy. (page no. 64).

24. Sharma Priya Vrat, Classical Uses of Medicinal Plants, First edition, Varanasi Chaukhambha Vishvabharati, 1996; 331. 17.

25. Vaidya Bapalal G, *Nighantu Adarsh*, *Poorvardha*, First edition, Varanasi, Chaukhambha Bharti academy, 1981; 821-826.

Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Mansi Tewari et al: Clinical evaluation of dhatakyadi churna in balatisara (protocol study). International Ayurvedic Medical Journal {online} 2025 {cited March 2025}