

Clinical Evaluation of Badar Mool Churna with Madhu in Pediatric Atisara: A Pilot Study

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Abstract

Background: Atisara is the *Ayurvedic disease* entity corresponding clinically to diarrhoeal illness and is characterized by frequent passage of liquid stool, altered stool features, abdominal discomfort, fluid depletion and digestive impairment. The study identifies Mandagni and Ama as central elements in its Ayurvedic pathogenesis and notes a classical Sushruta indication for Badara Moola administered with Madhu in Atisara. (Sushruta, n.d.)

Aim: To study the efficacy of Badar Mool in Atisara among children aged 6 months to 3 years.

Objective: To evaluate the clinical efficacy of Badar Mool Churna administered with Madhu in children aged 6 months to 3 years with uncomplicated Doshaja Atisara, while also examining the conceptual correlation of Atisara with diarrhoea, the probable mode of action of Badar Mool and an age-appropriate pediatric dosing schedule.

Methods: The study was a single-arm, open-labelled interventional clinical trial conducted in the Department of Kaumarbhritya, Bharati Vidyapeeth (Deemed to be University), College of Ayurved and Hospital, Pune. 35 children were screened, out of 27 were enrolled and 22 completed the study. *Badar Mool Churna* was administered orally with Madhu As a Anupam 3 times daily for five days at half of the classical age-based dose. Assessments were performed at baseline Day 0 day 3 and Day 5. Ordinal clinical parameters were analysed with the Wilcoxon signed-rank test, while body weight and FLACC pain scores were analysed with the paired t-test.

Results: Atisara Vega decreased from a mean score of 1.23 at baseline to 0.36 on Day 5 (70.73% improvement; $p < 0.001$). Mala Swaroop improved by 75.00%, mala gandha by 100%, mala amavastha by 80.00%, mala varna by 82.86%, Mucus by 81.48%, Trushna by 56.16% and FLACC pain score by 83.09%. Appetite score increased from 4.00 to 5.05. Eight children (36.36%) achieved complete remission, 10 (45.45%) showed marked improvement and 4 (18.18%) showed moderate improvement. No adverse event or treatment-related complication was reported in the supplied study.

Conclusion: Within the limitations of a small, uncontrolled single-arm study, the observed five-day clinical response supports the traditional use of Badar Mool Churna with Madhu in uncomplicated pediatric Atisara and justifies larger comparative studies with longer follow-up.

Keywords: Atisara; Badar Mool; Ziziphus mauritiana; Balatisara; pediatric diarrhoea; Grahi; Madhu; Ayurveda; open-label clinical study.

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1. Introduction

Diarrhoeal illness remains an important pediatric problem because repeated loose stools can rapidly disturb hydration, electrolyte balance, nutritional intake and growth, particularly in younger children. It emphasizes the vulnerability of infants after 6 months of age, when complementary feeding increases exposure to contaminated food, water and environmental pathogens,

and it describes diarrhoea clinically by a recent increase in stool liquidity and frequency rather than by frequency alone. (WHO)

Ayurveda describes a closely corresponding clinical entity under the term Atisara. The word is derived from Ati, indicating excess, and Sara, indicating flow or movement; clinically it denotes excessive passage of

liquid fecal matter. Classical descriptions recognize changes in stool frequency and consistency together with abdominal symptoms, weakness and fluid depletion, thereby providing a framework that is clinically comparable to acute diarrhoeal syndromes. (Madhavakara)

The Ayurvedic explanation of Atisara places *Agni* at the centre of disease development. Improper dietary practices, incompatible foods and other causative factors like weekend digestive capacity, generate Ama and disturb Dosha, especially Vata. The resulting disturbance in the gastrointestinal tract increases Dravata of Purisha and produces frequent loose stools. This framework is clinically useful because it links the visible symptom of stool abnormality with a broader disturbance of digestion and fluid movement. (Charaka)

The general Samprapti described in the source proceeds from Hetu Sevana to Vata-pradhana Dosha vitiation, Agnimandya, abnormal movement of the fluid component toward the gastrointestinal tract and increased liquidity of fecal matter in Pakwashaya. This sequence explains why therapy is not directed solely toward arresting bowel movements, but also toward restoration of digestive function and appropriate handling of Ama. (Vagbhata)

Ayurvedic management therefore differentiates between Ama and Pakwa states. The notes that premature Stambhana is avoided in the Ama stage, while Langhana and Pachana principles are emphasized until digestion improves. In the Pakwa stage, Grahi, Deepana and Pachana measures are selected according to the predominant Dosha and clinical features. (Sushruta)

Several Ayurvedic interventions have been described for Atisara, including Shunthi Kalpa, Vachadi Yoga, Musta Kwatha, Samangadi Kwatha and Bilva-containing combinations. The study identifies prior pediatric work on Bilwa Amra Yog and other clinical studies, yet it highlights a specific evidence gap for Badara Moola in children, despite a direct classical indication for its use with Madhu. (Nair et al., 2020)

Badara Moola is the root of *Ziziphus mauritiana*, family Rhamnaceae. In the drug review presented in the study , the root is described as possessing Madhura and Kashaya Rasa, Guru and Snigdha Guna, Sheeta Virya and Madhura Vipaka, with Vata-Pitta Shamaka, Grahi, Brimhana and Balya actions. These attributes provide a traditional pharmacodynamic rationale for its use where excessive stool liquidity coexists with weakness and digestive disturbance. (Bhavamisra)

A Sushruta reference reproduced in the specifically recommends Badari Moola with Madhu for Atisara. This classical statement was selected as the therapeutic basis of the present clinical work. The accompanying Madhu served as Anupana/Prakshepa at administration and also facilitated pediatric dosing of the powdered root. (Sushruta)

The modern pharmacological interpretation included in the source links the potential antidiarrhoeal effect of Badar Mool to tannins, flavonoids, saponins, betulinic

acid, ceanothic acid and alkaloids. The proposed mechanisms include astringency, reduced intestinal secretion, anti-inflammatory and antioxidant activity, antimicrobial support and possible modulation of intestinal motility. These mechanisms were not independently tested in the clinical trial and are therefore interpreted only as a plausible explanatory framework. (Ayurvedic Pharmacopoeia of India)

The study was consequently designed to examine whether a short course of Badar Mool Churna with Madhu could improve stool frequency, stool characteristics, thirst, appetite, urine output, body weight and colicky pain in children with uncomplicated Doshaja Atisara. The selected age range of 6 months to 3 years reflects the period of high vulnerability described in the supplied dissertation and allows the intervention to be evaluated in a clinically relevant pediatric population.

2. Literature Review and Conceptual Framework

2.2A Type-wise clinical profile relevant to the study

The type-specific descriptions of the study were clinically relevant to recruitment because participants had to show a predominantly Doshaja pattern rather than mixed manifestations. The study inclusion criteria therefore translated classical Lakshana into observable and symptom features that could be recognized in young children. (Sushruta)

Table 1A. Type-wise features of Doshaja Atisara emphasized in the supplied dissertation

Type	Predominant etiological pattern	Stool features	Associated clinical features
Vataja	Dry/scanty intake, exertion, urge suppression, climatic exposure	Drava or small-quantity stools; mucus/slimy features; variable sound	Shoola, abdominal distension, altered flatus/urine
Pittaja	Hot, sharp, pungent, sour or salty intake; heat exposure	Foul-smelling stool; green/red/black colour; forceful expulsion	Thirst, burning, sweating, colicky pain
Kaphaja	Heavy, sweet, cold and oily food; daytime sleep; inactivity	White, slimy/fibrous stool; mucus; undigested particles	Heaviness, continuous colic, loss of appetite

Vataja presentations in the source include both Ama and Pakwa stages. Ama-dominant stool is described as sticky or frothy and may contain undigested material, while Pakwa-stage stool may be passed in small quantities with gripping pain and bowel sounds. These distinctions reinforce the study emphasis on judging digestive status rather than relying on stool frequency alone. (Charaka)

Pittaja descriptions emphasize abnormal colour, foul odour, thirst and heat-related symptoms, whereas Kaphaja descriptions emphasize mucus, heaviness, unctuous or whitish stool and appetite loss. The study's repeated measures of Varna, Gandha, Mucus, Trushna and appetite therefore reflect clinically meaningful features that connect the classical classification with measurable follow-up outcomes. (Charaka)

2.3 Classical management principles and rationale for Badar Mool

Badara Moola was selected because Sushruta specifically indicates the root with Madhu for Atisara. The study rationale considers its Grahi and Stambhana-related actions relevant to controlling excessive bowel movement, while its Balya and Brimhana qualities are relevant to the weakness and nutritional compromise that may accompany repeated loose stool. (Sushruta)

Bhavaprakasha describes Badara as Madhura, Sheeta, Guru and Snigdha, strength promoting and capable of alleviating Vata and Pitta while relieving thirst and burning. These properties correspond closely to several symptoms evaluated in the present study, including Trushna, abdominal discomfort and altered bowel function. (Bhavamisra)

The drug review further classifies the root as Grahi, Brimhana, Balya, Dahaprashamana, Trushnahara, Vrishya and Raktaprasadana. Because the trial used the root powder rather than an isolated extract, the clinical interpretation concerns the whole Ayurvedic drug as administered, not any single phytochemical constituent. (Ayurvedic Pharmacopoeia of India)

3. Aim, Objectives and Hypothesis

The primary aim was to study the efficacy of Badar Mool in Atisara among children aged 6 months to 3 years.

Objectives

- To study the concept behind each type of Atisara.
- To assess the probable mode of action of Badar Mool in pediatric Atisara.
- To standardize an age-appropriate dose of Badar Mool for the study population.

NULL Hypothesis - stated that Badar Mool is not effective in reducing Atisara in children, ALTERNATIVE Hypothesis- stated that Badar Mool is effective in reducing Atisara in children.

4. Materials and Methods

4.1 Study design, setting and participants

The investigation was conducted as a single-arm, open-labelled interventional clinical trial in the Department of Kaumarbhritya, Bharati Vidyapeeth (Deemed to be University), College of Ayurved and Hospital, Pune. Children presenting to the Kaumarbhritya-Balaroga outpatient department with symptoms of Atisara were screened against the prespecified eligibility criteria.

The source states that Institutional Ethics Committee approval was obtained and that CTRI registration was completed prospectively before enrolment. Written parental proxy consent was obtained for each child. Stool

examination was performed when required to exclude ova, cysts and helminthic infestation.

The planned sample size was based on the reported local prevalence of eligible Atisara cases attending the study outpatient department, estimated at approximately 1.3%. Using $Z = 1.96$, $P = 0.013$ and $d = 0.05$, the source calculated a sample size of approximately 20 and increased this to 22 to account for a 10% dropout allowance.

Thirty-five children were screened. Twenty-seven were enrolled, five subsequently dropped out because their parents were unwilling to continue the medicine, and 22 completed the treatment and assessment schedule. The efficacy analysis described in the is therefore based on the 22 completers.

4.2 Eligibility criteria

Table 2. Eligibility criteria used in the clinical study

Inclusion criteria	Exclusion criteria
Age 6 months to 3 years	Moderate to severe dehydration
Doshaja Atisara as described in Sushruta Samhita	Chronic diarrhoea
No dehydration or mild dehydration	Mixed features of Vataja, Pittaja and Kaphaja Atisara
Recent onset, less than 3 days	Current antimicrobial medication
At least 60% of the predefined features of Vataja, Pittaja or Kaphaja Atisara	-
Either sex	-

Table 4. Age-wise classical dose and half-dose schedule used for Badar Mool Churna

Age	Classical dose	Study dose/day	Dose given three times daily
6 months	720 mg	360 mg/day	120 mg/dose
7 months	840 mg	420 mg/day	140 mg/dose
8 months	960 mg	480 mg/day	160 mg/dose
9 months	1080 mg	540 mg/day	180 mg/dose
10 months	1200 mg	600 mg/day	200 mg/dose
11 months	1320 mg	660 mg/day	220 mg/dose
12 months (1 year)	1440 mg	720 mg/day	240 mg/dose
2 years	2160 mg	1080 mg/day	360 mg/dose
3 years	2880 mg	1440 mg/day	480 mg/dose

The study drug was administered for five days. Parents or guardians received pre-measured sachets, were instructed about the appropriate quantity of Madhu and were advised to administer all three prescribed doses each day. Follow-up assessments occurred on Day 0, Day 3 and Day 5.

4.5 Outcome measures and follow-up

Table 5. Clinical assessment domains used in the study

Outcome domain	Parameter	Type of data / assessment
Primary bowel symptom	Atisara Vega	Ordinal score; frequency of diarrhoea in 24 hours
Mala Parikshana	Swaroop	Ordinal stool-form/consistency score
Mala Parikshana	Gandha	Ordinal stool-odour score
Mala Parikshana	Amavastha	Ordinal score for features of Ama
Mala Parikshana	Varna	Ordinal stool-colour score
Mala Parikshana	Mucus	Ordinal mucus score
Digestive recovery	Appetite	Age-adapted appetite questionnaire score
Hydration-related	Trushna	Ordinal thirst score
Hydration-related	Mutra Pravrutti	Ordinal urine-output score
Objective	Body weight	Kilograms
Objective pain	FLACC	Numerical pain score

The study specified rescue management if a child's condition deteriorated or dehydration progressed. Management was to follow IAP and WHO guidance, with ORS and/or intravenous fluids used according to clinical indication. Failure to administer all three daily doses or progression toward severe dehydration constituted drop-out criteria.

4.6 Statistical analysis

Ordinal subjective measures were analysed with the Wilcoxon signed-rank test because the same participants were assessed repeatedly and the scores were qualitative/ordinal. The dissertation lists Atisara Vega, Swaroopa, Gandha, Amavastha, Varna, Mucus, appetite, Trushna and Mutra Pravrutti under this analysis. Body weight and FLACC scores were treated as numerical measures and analysed using the paired t-test.

The supplied analysis interprets $p > 0.05$ as not significant, $p < 0.05$ as significant, $p < 0.01$ as highly significant and $p < 0.001$ as very highly significant. The present article reports the exact p-values where they were provided and retains the source terminology for the study's statistical interpretation.

4.7 Grading framework for repeated clinical assessment

The same clinical variables were assessed at Day 0, Day 3 and Day 5. The dissertation used simple ordinal grading for stool form, Ama status, odour, colour, mucus, thirst and urine frequency, allowing within-subject change to be followed consistently during the five-day treatment period.

Appetite: Assessed using age-appropriate questionnaires based on complementary food quantity and frequency. The appetite score was considered an indicator of digestive recovery.

Colicky Pain: Assessed using the FLACC scale (Face, Legs, Activity, Cry, Consolability), with scores ranging from 0–10:

- 0 – No pain
- 1–2 – Mild
- 3–5 – Moderate
- 6–8 – Severe
- 9–10 – Worst possible pain

FLACC was suitable for infants and toddlers due to limited verbal pain reporting.

5. Result

5.1 Baseline Demographic and Ayurvedic Profile

Among 22 children, 15 (68.18%) were male and 7 (31.82%) female. Five (22.73%) were <1 year, 7 (31.82%) were 1–2 years, and 10 (45.45%) were 2–3 years old. Most (77.27%) belonged to the middle socioeconomic group. Mandagni was present in 77.27% and Vishamagni in 22.73% of children.

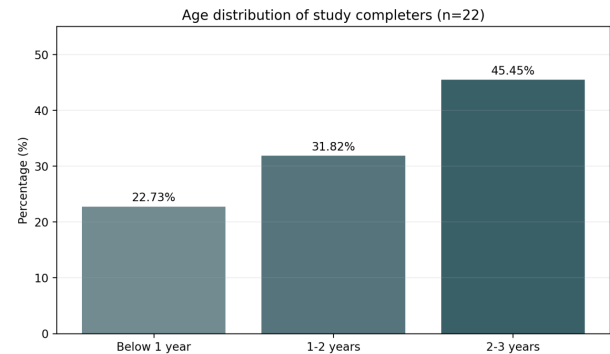


Figure 5. Age distribution of the study population using the tabulated values reported in the source.

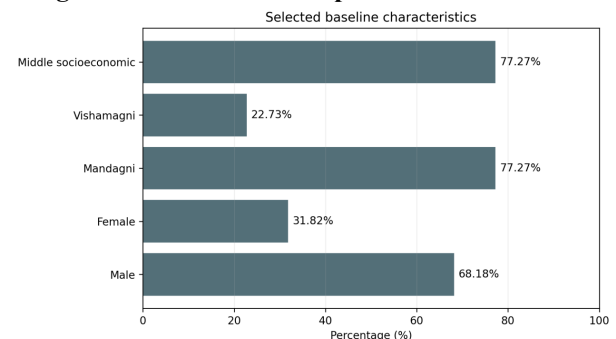


Figure 6. Selected baseline characteristics of the 22 children.

5.2 Effect on Atisara Vega and stool characteristics

A progressive improvement was observed over 5 days of treatment:

- Atisara Vega: 70.73% improvement
- Swaroopa: 75.00% improvement
- Gandha: 100% improvement
- Avastha: 80.00% improvement
- Varna: 82.86% improvement
- Mucus: 81.48% improvement

Most changes were statistically significant by Day 5, indicating overall improvement in stool frequency and characteristics.

5.3 Appetite, thirst, urine output, weight and colicky

Overall improvement was observed over 5 days:

- Appetite: 26.25% improvement.
- Thirst (Trushna): 56.16% improvement.
- Urine output (Mutra Pravrutti): Complete symptomatic resolution, but not statistically significant.
- Body weight: Remained relatively stable during treatment.
- Colicky pain (FLACC): 83.09% improvement, with statistically significant reduction.

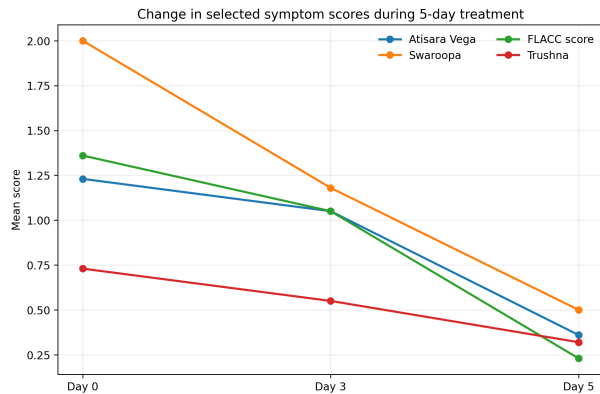


Figure 7. Mean scores for Atisara Vega, Swaroopa, FLACC pain and Trushna at Day 0, Day 3 and Day 5.

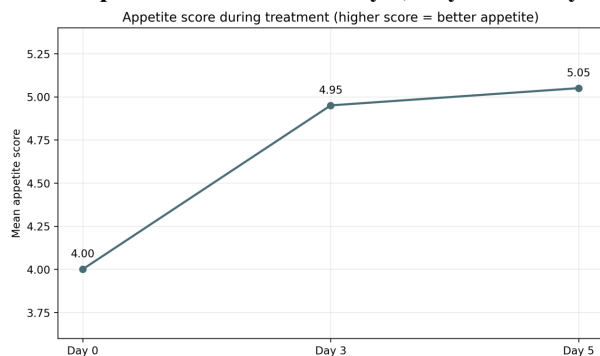


Figure 8. Change in mean appetite score during treatment; higher values indicate better appetite.

5.4 Overall statistical interpretation

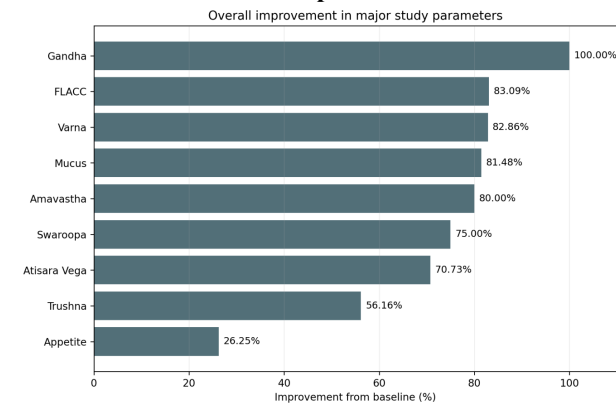


Figure 9. Percentage improvement in major symptoms from baseline to Day 5 as reported in the dissertation. Appetite is shown as percentage increase in its score.

5.5 Overall effect of therapy and safety

At the end of treatment, 8 of 22 children (36.36%) met the source criterion for complete remission, 10 (45.45%) showed marked improvement and 4 (18.18%) showed moderate improvement. No child was categorized as having only mild improvement or remaining unchanged. Thus, all 22 completers had at least moderate improvement according to the study's overall relief classification.

Table 8. Overall effect of therapy among the 22 study completers

Overall response	Criterion in source	n	%
Complete remission	100% relief	8	36.36
Marked improvement	76-99% relief	10	45.45
Moderate improvement	51-75% relief	4	18.18
Mild improvement	26-50% relief	0	0.00
Unchanged	<=25% relief	0	0.00

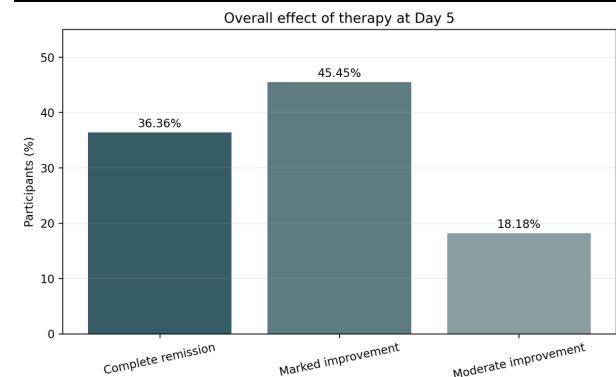


Figure 10. Distribution of overall therapeutic response at Day 5.

The conclusion section of the supplied dissertation states that no adverse events or treatment-related complications were observed during the study period. The age-appropriate dosing approach was described as practical, acceptable and well tolerated in the selected pediatric

population. Because the study was small and uncontrolled, this safety observation should be considered preliminary rather than definitive.

6. Discussion

6.1 Interpretation of the principal clinical response

The study showed progressive improvement in Atisara, with the greatest reduction in stool frequency and consistency by Day 5. Swaroopa, Gandha, Amavastha, Varna, and Mucus also improved, indicating better stool formation and digestive function.

The response was interpreted according to the Grahni and Stambhana properties of Badar Mool, which may help reduce excessive bowel movement and improve stool consistency. The possible effects of tannins and flavonoids may also contribute to reduced intestinal secretion and irritation, although these mechanisms were not directly tested.

6.2 Appetite, thirst and hydration-

Appetite improved mainly during the first 3 days, suggesting early improvement in Agnimandya and digestive function. Trushna (thirst) progressively decreased by Day 5, indicating improvement in diarrhoeal symptoms and fluid balance.

Mutra Pravritti reached zero by Day 5 but was not statistically significant, likely due to the low baseline occurrence of the symptom.

6.3 Body weight and pain

Body weight showed minimal change over the 5-day treatment period, decreasing from 11.15 kg to 11.01 kg. Despite statistical significance, the small absolute change indicates relative weight stability and no major acute weight loss among the study participants.

The FLACC pain score improved by 83.09%, indicating marked reduction in colicky abdominal pain. This improvement may be associated with reduced intestinal irritation and motility, along with improvement in stool frequency and consistency. As FLACC is an observational pain scale, it provides an objective assessment of pain in young children who cannot reliably report pain verbally.

6.4 Ayurvedic interpretation of the therapeutic response

According to the Ayurvedic interpretation, Badar Mool possesses Grahni, Balya and Vata-Pitta Shamaka properties. Kashaya Rasa helps reduce excessive fluidity and improve stool formation, while Madhura Rasa and Madhura Vipaka support nourishment and recovery from weakness.

Sheeta Virya may help reduce Pitta-related irritation, while Snigdha Guna provides a soothing effect on the gastrointestinal tract. These properties may explain the improvement in Trushna, stool characteristics and colicky pain.

The high prevalence of Mandagni (77.27%) supports the role of impaired digestion in the study population. Improvement in appetite and Amavastha suggests better digestive function.

Madhu was used as Anupana/Prakshepa with Badar Mool. Since no separate Badar Mool-only or Madhu-only

group was included, their individual contributions cannot be determined.

6.5 Modern pharmacological interpretation

According to the Ayurvedic interpretation, Badar Mool possesses Grahni, Balya and Vata-Pitta Shamaka properties. Kashaya Rasa helps reduce excessive fluidity and improve stool formation, while Madhura Rasa and Madhura Vipaka support nourishment and recovery from weakness.

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The high prevalence of Mandagni (77.27%) supports the role of impaired digestion in the study population. Improvement in appetite and Amavastha suggests better digestive function.

Madhu was used as Anupana/Prakshepa with Badar Mool. Since no separate Badar Mool-only or Madhu-only group was included, their individual contributions cannot be determined.

6.6 Overall Clinical Effect and Hypothesis

By Day 5, more than 80% of the participants showed complete remission or marked improvement, while the remaining participants showed moderate improvement. No participant showed mild improvement or no change.

The study findings support the alternative hypothesis and rejection of the null hypothesis within the before-after study design. However, the absence of a control group limits the ability to attribute the improvement solely to Badar Mool Churna with Madhu, as spontaneous recovery and supportive care may also have contributed. Overall, the treatment was associated with significant clinical improvement over five days. The short duration provided useful serial observations but could not assess long-term safety or recurrence. Therefore, the findings should be considered preliminary evidence requiring confirmation through larger controlled studies.

6.7 Relation to earlier Ayurvedic clinical work

This situates this study among earlier Ayurvedic investigations of Atisara, including pediatric work on Bilwa Amra Yog. The common theme across this body of work is an attempt to translate classical Grahni, Deepana and Pachana principles into measurable clinical outcomes such as stool frequency and consistency. The present trial differs by focusing specifically on Badara Moola and using a classical Madhu co-administration. (Nair et al., 2020)

Barkade's earlier work on Ayurvedic herbal compounds in Atisara and later journal-based clinical reports demonstrate continuing interest in evidence generation for Ayurvedic diarrhoeal management. The current study adds a distinct drug-specific dataset, but direct efficacy comparisons cannot be made because the supplied dissertation does not provide harmonized outcome definitions or head-to-head data across those studies. (Barkade, 1994)

The value of the present work therefore lies less in comparative superiority and more in preliminary clinical validation of a specific classical indication. Its standardized five-day administration, predefined age-based dosing and repeated outcome assessment provide a structured basis for future research on Badar Mool in pediatric Atisara. (Sharangadhara.)

7. Strengths, Limitations and Future Direction

Strengths: Classical rationale, authenticated drug, age-based dosing, defined criteria, serial assessments, and Ayurvedic + modern outcome measures.

Limitations: Small sample (22), single-arm open-label design, no control group, short 5-day follow-up, and limited generalizability.

Future: Larger randomized controlled studies with longer follow-up, standardized supportive care, safety assessment, and analysis according to Doshaja type are recommended.

8. Conclusion

Atisara Vega improved by 70.73%, Swaroopa by 75.00%, Gandha by 100%, Amavastha by 80.00%, Varna by 82.86%, Mucus by 81.48%, Trushna by 56.16% and FLACC pain by 83.09%. Eight children achieved complete remission, ten showed marked improvement and four showed moderate improvement. No adverse events or treatment-related complications were reported in the source.

The findings are consistent with the classical Grahī, Balya and Vata-Pitta Shamaka rationale for Badara Moola and with the astringent, anti-inflammatory, antioxidant and antimicrobial contributions of its phytoconstituents. These mechanisms remain inferential because the trial measured clinical outcomes rather than molecular endpoints. (Bhavamisra, n.d.)

Overall, the study provides preliminary clinical support for the classical use of Badar Mool Churna with Madhu in uncomplicated pediatric Atisara. Because the design was open-label and uncontrolled, confirmation in larger controlled studies with longer follow-up is necessary before drawing definitive comparative or causal conclusions.

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