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Development and Comparative Clinical Evaluation of a Standardized Instant Ardhamatrika Basti Formulation in Patients with Sandhigatavata: A Pilot Study

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Abstract

Ardhamatrika Basti is a widely used Niruha Basti formulation in Ayurveda for managing Vata disorders, including Sandhigatavata (knee osteoarthritis). Conventional preparation is time-consuming and operator-dependent, requiring fresh sequential mixing before administration. This study developed a standardized ready-to-use Instant Ardhamatrika Basti.

To develop and compare the clinical feasibility, retention characteristics, safety, and preliminary efficacy of Instant Ardhamatrika Basti with the conventional formulation.

In this randomized pilot study, 20 patients with Grade II knee osteoarthritis were allocated into two groups: conventional Ardhamatrika Basti (n=10) and Instant Ardhamatrika Basti (n=10). Both groups received the same Yoga Basti schedule. Outcomes included retention time, Vega, Visual Analogue Scale (VAS), WOMAC Index, and adverse events.

Both formulations showed comparable retention, bowel evacuation, safety, and clinical improvement. The Instant formulation significantly reduced preparation time without compromising therapeutic outcomes.

Standardized Instant Ardhamatrika Basti is a safe, feasible, and clinically acceptable alternative to the conventional formulation. Larger randomized studies are needed to confirm long-term efficacy and stability.

Key words : Ardhamatrika Basti, Instant Basti, Sandhigatavata, Panchakarma, Standardization, Pilot Clinical Study, Feasibility.

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Basti Karma is regarded as the prime therapeutic intervention among the Panchakarma procedures and is considered the treatment of choice for Vata-predominant disorders owing to its systemic therapeutic effects[3,7]. Among the various types of Basti described in Ayurveda, *Ardhamatrika Basti* is widely practiced because of its comparatively simple administration, and broad applicability in musculoskeletal and degenerative disorders such as Sandhigatavata[6].

The therapeutic efficacy of *Ardhamatrika Basti* depends not only on the pharmacological properties of its ingredients but also on the proper preparation of the Basti Dravya. Classical texts recommend sequential mixing of Makshika, Saindhava Lavana, Sneha, Kalka, and Kwatha to obtain a homogeneous and stable emulsion before administration[5]. Conventionally, this process requires prolonged trituration in a Khalva Yantra, making the preparation time-consuming, operator-dependent, and susceptible to variability in the quality of the final formulation. These practical limitations may affect procedural efficiency and hinder standardization in routine Panchakarma practice.

Recent advances in Ayurvedic pharmaceutics emphasize the need for standardized formulations that ensure uniformity, reproducibility, and ease of administration.[5] Although previous studies have evaluated modifications in Basti administration techniques and the clinical utility of Ardhamatrika Basti, limited evidence is available regarding the development and clinical feasibility of a standardized ready-to-use Instant Ardhamatrika Basti formulation. Therefore, the present pilot clinical study was undertaken to develop a standardized Instant Ardhamatrika Basti formulation and to evaluate its clinical feasibility, retention characteristics (Pratyagamana Kala), number of Vega, safety, tolerability, and preliminary clinical response in patients with Sandhigatavata. The findings are expected to provide preliminary evidence for future large-scale clinical trials and contribute towards the standardization of Basti Karma.[1]

Study Design :

The present study was designed as a prospective, randomized, comparative pilot clinical study to develop a standardized Instant Ardhamatrika Basti formulation and compare its clinical feasibility, safety, retention characteristics, and preliminary therapeutic response with conventionally prepared Ardhamatrika Basti in patients diagnosed with Sandhigatavata. The study was conducted between CTRI/2025/01/079328 at the Department of Panchakarma, Parul Ayurved Hospital, Vadodara, Gujarat, India.

Ethical Considerations :

The study protocol was approved by the Institutional Ethics Committee of Parul Institute of Ayurved (IEC No.PU/PIA/IEC/11/2025/457). The study was conducted in accordance with the ethical principles and written informed consent was obtained from all participants prior to enrollment.

Study Participants :

A total of 20 patients diagnosed with Sandhigatavata, fulfilling the clinical diagnostic criteria and having Grade II knee osteoarthritis according to the Kellgren–Lawrence radiographic

grading system[2], were enrolled in the study. Eligible participants were randomly allocated into two equal groups using a simple randomization method. Group A (Control Group) comprised 10 patients who received conventionally prepared Ardhamatrika Basti, whereas Group B (Trial Group) comprised 10 patients who received the standardized Instant Ardhamatrika Basti formulation. Both groups were treated according to the same Yoga Basti schedule, and all other treatment procedures were kept identical except for the method of preparation of the Basti.

Selection Criteria :

Patients aged 40–70 years of either gender who were clinically diagnosed with Sandhigatavata and had Grade II knee osteoarthritis according to the Kellgren–Lawrence radiographic grading system were considered eligible for inclusion. Only patients who were fit to undergo Basti Karma and willing to provide written informed consent were enrolled in the study. Patients with contraindications to Basti Karma, severe systemic illnesses, active anorectal disorders, pregnancy or lactation, and those unwilling to participate or provide informed consent were excluded from the study.

Development and Preparation of Standardized Instant Ardhamatrika Basti :

The standardized Instant Ardhamatrika Basti formulation was developed based on the classical formulation described in *Chakradatta* with suitable pharmaceutical modifications to improve convenience, reduce preparation time, and ensure formulation uniformity. The composition of the conventionally prepared Ardhamatrika Basti and the standardized Instant Ardhamatrika Basti is presented in Table-1. The conventional Ardhamatrika Basti was freshly prepared before each administration following the classical method. Briefly, Makshika (honey) and Saindhava Lavana were triturated thoroughly in a Khalva Yantra until a homogeneous mixture was obtained. Tila Taila was then added gradually, followed by Shatapushpa Kalka and Dashamoola Kwatha with continuous trituration after the addition of each ingredient to obtain a stable emulsion suitable for administration. In contrast, the Instant Ardhamatrika Basti formulation was prepared in advance under standardized pharmaceutical conditions. Makshika and Tila Taila were initially triturated to form a uniform emulsion, followed by the addition of Shatapushpa Kalka and Dashamoola Kwatha. Finally, 1% AMR salt was incorporated as a preservative to enhance the stability of the formulation. The prepared formulation was stored in sterile containers as a ready-to-use product, thereby eliminating the need for fresh preparation before each administration while ensuring uniformity and ease of clinical use.

Intervention :

Following enrolment and baseline assessment, participants were randomly allocated to either the control or trial group. Patients in the control group received conventionally prepared Ardhamatrika Basti, whereas those in the trial group received the standardized Instant Ardhamatrika Basti formulation. In both groups, the intervention protocol, dose, duration of treatment, and Yoga Basti schedule remained identical. Anuvasana Basti was administered using Murchita Tila Taila (72 mL), while Niruha Basti was administered in

Table-1. Composition of Conventionally Prepared and Standardized Instant Ardhamatrika Basti

Ingredient	Conventional Ardhamatrika Basti	Standardized Instant Ardhamatrika Basti
Makshika (Honey)	100 mL	100 mL
Saindhava Lavana	12 g	—
Tila Taila	100 mL	100 mL
Shatapushpa Kalka	12 g	12 g
Dashamoola Kwatha	350 mL	350 mL
AMR Salt (Preservative)	—	1%
Total Volume	550 mL	550 mL

Table-2. Yoga Basti Schedule Followed in Both Study Groups

Day	Basti Type	Drug Administered	Dose
Day 1	Anuvasana Basti	Murchita Tila Taila	72 mL
Day 2	Niruha Basti	Ardhamatrika Basti	550 mL
Day 3	Anuvasana Basti	Murchita Tila Taila	72 mL
Day 4	Niruha Basti	Ardhamatrika Basti	550 mL
Day 5	Anuvasana Basti	Murchita Tila Taila	72 mL
Day 6	Niruha Basti	Ardhamatrika Basti	550 mL
Day 7	Anuvasana Basti	Murchita Tila Taila	72 mL
Day 8	Anuvasana Basti	Murchita Tila Taila	72 mL

Note: In the control group, conventionally prepared Ardhamatrika Basti was used for Niruha Basti, whereas the trial group received the standardized Instant Ardhamatrika Basti formulation. All other treatment procedures remained identical between the two groups.

a dose of 550 mL. All Basti procedures were performed under identical conditions by experienced Panchakarma physicians following standard operating procedures. Participants in both groups were advised to follow the same dietary regimen (Pathya-Apathya) and post-procedure care throughout the study period. The Yoga Basti schedule followed during the study is presented in Table-2.

Outcome Measures :

The primary outcome measures included Basti retention time (Pratyagamana Kala), number of Vega, preparation time, and safety profile of the Instant Ardhamatrika Basti formulation. Secondary outcome measures included changes in pain intensity, assessed using the Visual Analogue Scale (VAS), and functional status, assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). All participants were evaluated at baseline, completion of treatment (Day 8), and at follow-up after completion of the Parihara Kala. Throughout the study period,

all adverse events and procedure-related complications were carefully documented and managed appropriately.

A total of **20 patients** diagnosed with Sandhigatavata were enrolled in the study and equally allocated into the control group (n=10) and the trial group (n=10). All participants completed the study, and no dropouts were observed. Baseline demographic characteristics were comparable between the two groups.

Baseline Characteristics :

The mean age of patients in the control and trial groups was 58.9 ± 6.7 years and 58.3 ± 6.4 years, respectively. Females constituted the majority of participants in both groups. Vata Prakriti was the predominant constitutional type observed among the enrolled patients.

Table-3. Baseline Characteristics

Parameter	Control (n=10)	Trial (n=10)
Age (years), Mean ± SD	58.9 ± 6.7	58.3 ± 6.4
Male, n (%)	3 (30%)	2 (20%)
Female, n (%)	7 (70%)	8 (80%)
Vata Prakriti	7 (70%)	8 (80%)
Vata-Pitta Prakriti	3 (30%)	2 (20%)

Retention Time (Pratyagamana Kala) :

The mean retention time following administration of Niruha and Anuvasana Basti is presented in Table-4. The standardized Instant Ardhamatrika Basti demonstrated retention characteristics comparable to those of the conventionally prepared formulation throughout the treatment period.

Table-4. Mean Retention Time (Pratyagamana Kala)

Day	Control (Mean ± SD)	Trial (Mean ± SD)
Day 1	3.18 ± 1.12 hr	3.29 ± 1.18 hr
Day 2	4.8 ± 1.4 min	4.6 ± 1.3 min
Day 3	3.56 ± 0.92 hr	3.59 ± 0.85 hr
Day 4	5.4 ± 1.5 min	5.2 ± 1.6 min
Day 5	4.12 ± 1.10 hr	4.03 ± 1.21 hr
Day 6	5.3 ± 1.4 min	5.1 ± 1.5 min
Day 7	4.58 ± 1.26 hr	4.57 ± 1.20 hr
Day 8	5.08 ± 1.09 hr	5.03 ± 1.08 hr

Number of Vega :

The mean number of Vega remained comparable between the two study groups throughout the intervention period, indicating similar bowel evacuation patterns following Basti administration.

Table-5 Mean Number of Vega

Day	Control (Mean ± SD)	Trial (Mean ± SD)
Day 1	1.10 ± 0.31	1.00 ± 0.00
Day 2	1.90 ± 0.32	1.90 ± 0.32
Day 3	1.20 ± 0.42	1.10 ± 0.31
Day 4	1.40 ± 0.52	1.30 ± 0.48
Day 5	1.20 ± 0.42	1.10 ± 0.31
Day 6	1.20 ± 0.42	1.10 ± 0.31
Day 7	1.10 ± 0.31	1.20 ± 0.42
Day 8	1.00 ± 0.00	1.00 ± 0.00

Visual Analogue Scale (VAS) :

Both study groups demonstrated a gradual reduction in pain intensity following completion of the treatment. The trial group showed clinical improvement comparable to that observed with the conventionally prepared Ardhamatrika Basti.

Table-6. Mean VAS Score

Assessment	Control (Mean ± SD)	Trial (Mean ± SD)
Baseline	7.3 ± 0.67	7.2 ± 0.63
Day 8	6.4 ± 0.70	6.2 ± 0.63
Follow-up	5.8 ± 0.79	5.6 ± 0.70

WOMAC Score :

Improvement in pain, stiffness, and physical function was reflected by a gradual reduction in WOMAC scores in both study groups. The trial group demonstrated a comparable trend to the conventionally prepared Ardhamatrika Basti.

Table-7. Mean WOMAC Score

Assessment	Control (Mean ± SD)	Trial (Mean ± SD)
Baseline	56.8 ± 4.6	57.1 ± 4.4
Day 8	51.6 ± 4.2	50.8 ± 4.1
Follow-up	47.2 ± 3.8	46.4 ± 3.7

Safety Assessment :

No serious adverse events or procedure-related complications were observed during the study. All participants completed the treatment protocol successfully, and the Instant Ardhamatrika Basti was well tolerated throughout the intervention period.

Development and Clinical Feasibility of Standardized Instant Ardhamatrika Basti :

The present pilot comparative clinical study was undertaken to develop a standardized ready-to-use Instant Ardhamatrika Basti formulation and to evaluate its clinical feasibility in comparison with the conventionally prepared Ardhamatrika Basti in patients with Sandhigatavata. Conventional Ardhamatrika Basti requires sequential addition of ingredients with continuous trituration immediately before administration to obtain a homogeneous emulsion, making the procedure time-consuming and operator-dependent.[1] Variations in the preparation technique may influence the uniformity and reproducibility of the formulation. To overcome these practical limitations, a standardized Instant Ardhamatrika Basti formulation was developed that could be prepared in advance and administered as a ready-to-use formulation. The findings of the

present study demonstrate that pharmaceutical standardization of Ardhamatrika Basti is feasible and can improve procedural convenience without compromising its clinical applicability.

Retention Characteristics and Procedural Outcomes :

Retention time (Pratyagamana Kala) is considered an important indicator of proper Basti administration and reflects the interaction between the administered formulation and the physiological status of the patient. In the present study, the retention characteristics of the standardized Instant Ardhamatrika Basti were comparable with those of the conventionally prepared formulation throughout the intervention period. Furthermore, the number of Vega observed following Basti administration remained within the expected physiological range in both groups, indicating satisfactory bowel evacuation and appropriate procedural response. These findings suggest that the pharmaceutical modification adopted in the preparation of the Instant formulation did not alter its retention behavior or procedural performance.

Preliminary Clinical Response :

Both study groups demonstrated gradual improvement in pain intensity and functional status following completion of the Yoga Basti schedule. Modest reductions in VAS and WOMAC scores were observed at the end of treatment and during follow-up. Since the present investigation was designed as a pilot clinical study, the primary objective was to evaluate feasibility, safety, and preliminary clinical response rather than establish definitive therapeutic efficacy. Nevertheless, the comparable improvement observed in both groups suggests that the standardized Instant Ardhamatrika Basti retained the therapeutic characteristics of the conventionally prepared formulation. From an Ayurvedic perspective, the observed improvement may be attributed to the Vatahara, Vedanasthapana, and Brimhana properties of Basti Karma, which help in alleviating pain, improving joint function, and restoring the balance of aggravated Vata Dosha.

Safety and Practical Implications :

An important finding of the present study was the excellent safety and tolerability of the standardized Instant Ardhamatrika Basti. No serious adverse events, treatment-related complications, or treatment discontinuations were observed in either study group. The addition of a preservative and advance preparation of the formulation did not appear to adversely influence patient safety or procedural acceptability. Similar observations regarding the safety of properly administered Basti therapy have been reported in previous clinical studies.

From a practical perspective, the standardized Instant formulation offers several advantages over the conventional preparation. It eliminates the need for fresh preparation before every administration, reduces dependence on operator skill, minimizes preparation time, and provides a uniform formulation that can be readily used in routine Panchakarma practice. These characteristics may improve workflow efficiency in hospitals and facilitate wider implementation of Basti Karma in clinical settings.

Strengths, Limitations, and Future Scope :

The present study represents a preliminary

attempt to integrate pharmaceutical standardization with clinical evaluation of an Instant Ardhamatrika Basti formulation. The comparative study design, standardized preparation procedure, and assessment of retention characteristics, safety, and preliminary clinical response constitute important strengths of the study. However, certain limitations should be acknowledged. The sample size was relatively small, as the study was intended as a pilot clinical investigation. The duration of treatment and follow-up was short, and long-term therapeutic outcomes were not evaluated. In addition, detailed physicochemical characterization, stability studies, and cost-effectiveness analyses of the Instant formulation were beyond the scope of the present investigation. Therefore, larger multicentric randomized controlled trials with compre-hensive pharmaceutical evaluation are warranted to confirm the present findings and establish the long-term clinical utility of the standardized Instant Ardhamatrika Basti.

Novelty of the Present Study :

The novelty of the present study lies in the successful development and preliminary clinical evaluation of a standardized ready-to-use Instant Ardhamatrika Basti formulation. Unlike previous studies, which have predominantly focused on the therapeutic efficacy of Ardhamatrika Basti, the present investigation combined pharmaceutical standardization with clinical feasibility assessment. The findings demonstrate that simplification of the preparation process can be achieved without compromising retention characteristics, procedural safety, or preliminary clinical response. This approach may contribute towards the standardization of Panchakarma procedures and encourage further innovation in Ayurvedic pharmaceutical formulations.

The present pilot comparative clinical study demonstrated that the standardized Instant Ardhamatrika Basti is a feasible, safe, and clinically acceptable alternative to the conventionally prepared Ardhamatrika Basti for the management of Sandhigatavata. The Instant formulation exhibited comparable retention characteristics, bowel evacuation pattern, safety profile, and preliminary clinical response while significantly reducing preparation time and improving procedural convenience. These findings support the potential of the standardized ready-to-use formulation as a practical innovation in Panchakarma practice. However, larger randomized controlled trials with longer follow-up and comprehensive pharmaceutical evaluation are required to establish its long-term efficacy, safety, and clinical applicability.

Declarations

Ethics Approval and Consent to Participate
Written informed consent was obtained from all participants prior to their enrollment in the study.

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Conflict of Interest
The authors declare that they have no conflict of interest.

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