

EFFICACY OF BIBHITAK (TERMINELIA BELLIRICA ROXB) PHALA MADHYA LEPA (FRUIT PULP APPLICATION) ON PAINFUL KNEE JOINT IN SANDHIGATAVATA - A PILOT STUDY

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ABSTRACT

Background: Sandhigata Vata is an age-associated disorder characterized predominantly by joint pain, swelling, painful flexion–extension, stiffness and crepitus, and it is commonly correlated with knee osteoarthritis. Conventional care may be inadequate or unsafe for some patients, creating a need for simple, affordable and non-invasive supportive interventions. Classical Ayurvedic texts describe Bibhitak phala madhya lepa, an external paste prepared from the fruit pulp of Terminalia bellirica, for pain, swelling and burning sensation. **Objective:** To evaluate the efficacy of Bibhitak phala madhya lepa in reducing knee-joint vedana (pain), shotha (swelling) and daha (burning sensation) in patients with Sandhigata Vata. **Methods:** This prospective, open-label, single-arm pilot clinical trial enrolled 10 pre-diagnosed patients aged 30–70 years from an institutional hospital. Eight participants had bilateral

involvement; therefore, 18 knees were treated and analyzed. Freshly prepared paste was applied once daily in the evening for at least one hour for seven days. Outcomes were assessed at baseline, day 7 and day 14. Pain was measured using a visual analogue scale, swelling by circumferential tape measurement, and burning sensation by a four-point ordinal scale. Paired t tests were reported for pain and swelling and a Wilcoxon signed-rank test for burning sensation. **Results:** Mean pain decreased from 8.33 to 6.39 ($t=5.07$; $p<0.05$), and

mean knee circumference decreased from 38.39 cm to 37.28 cm ($t=5.66$; $p<0.05$). Both changes were reported as statistically significant. Mean burning-sensation score decreased from 0.611 to 0.056, but the reported Wilcoxon result was statistically non-significant ($W=15$, $Z=-2.02$; $p>0.05$). No safety concern was described in the source report. The sample was predominantly female (80%), older (50% aged 61–70 years), rural (60%), and composed largely of homemakers (60%); 60% reported hard bowel habits. Conclusion: Bibhitak phala madhya lepa produced promising short-term reductions in pain and swelling, but evidence for burning sensation was inconclusive. Because the study was small, uncontrolled and based on knee-level analysis nested within participants, the findings should be considered hypothesis-generating and verified in a larger randomized controlled trial.

KEYWORDS: *Bibhitak; Terminalia bellirica; Sandhigata Vata; phala madhya lepa; knee joint; pain; swelling; pilot study.*

INTRODUCTION

Ayurveda aims to support a healthy and long life; disorders that limit mobility and independence obstruct that aim even when they are not immediately fatal. Osteoarthritis is a major example. In 2019, approximately 528 million people worldwide were living with osteoarthritis, representing a 113% increase since 1990. The condition affects the whole joint and surrounding tissues, causing pain, swelling and stiffness and restricting free movement; the knees, hips, spine and hands are most commonly affected.^[1]

Chronic joint pain can often be managed, but treatment remains inadequate for many people. Medicines may be unsuitable or unsafe in some contexts, while rehabilitation, exercise and physical therapy remain essential components of care.^[2]

In Ayurvedic nosology, Sandhigata Vata is a common Vatavyadhi in which aggravated Vata localizes in a joint. Its principal features include vedana during movement, shotha, akunchana–prasarana vedana (pain during flexion and extension), vata-purna-driti-sparsha (a crepitant or air-filled-bag-like sensation), and restriction of movement. These clinical features are commonly correlated with osteoarthritis of the knee. The condition is especially associated with vriddhavastha, when age-related dhatu-kshaya and bala-kshaya favor Vata aggravation. Everyday functions such as walking, bending, standing and household or field work may consequently become difficult.

The burden of advanced knee disease is also visible in surgical demand. The source report cites an estimate of approximately 200,000 knee arthroplasties in India in 2020, while emphasizing the value of conservative measures before invasive treatment becomes necessary.^[3]

Ayurvedic rationale and need for the study

Shamana chikitsa is preferred when a conservative, non-invasive approach is appropriate. Classical texts describe a paste of Bibhitak fruit pulp for local application over a painful, swollen or burning joint. Charaka describes Bibhitak phala madhya lepa in the context of shotha chikitsa, and Sharangadhara also records the use of Bibhitak fruit pulp paste for pain and burning sensation. These references motivated the re-evaluation of a simple classical formulation in a contemporary clinical setting.^[10,11]

Terminalia bellirica has been investigated for antioxidant, anti-inflammatory, immunomodulatory, antimicrobial, renoprotective, antidiabetic, antihyperlipidemic and anticancer activities. Its fruit contains tannins and other phytochemicals, including gallic acid, corilagin, ellagic acid, ethyl gallate, galloyl glucose, chebulagic acid and arjunolic acid.^[4]

The practical need was a low-cost, locally prepared and non-invasive option that might improve comfort and quality of life among older people with painful knees. The research question was: Is Bibhitak phala madhya lepa effective for management of knee-joint pain in patients with Sandhigata Vata? The null hypothesis stated that it is not effective; the alternate hypothesis stated that it is effective.

Definition of Sandhigata Vata

The report operationalized Sandhigata Vata as a condition in which vitiated Vayu becomes localized in the sandhi and produces shotha, pain during flexion and extension, and vata-purna-driti-sparsha. Sushruta adds diminution of joint movement (hanti sandhin), joint pain (sandhi shula) and swelling (sandhi shopha).^[5,6]

Definition and place of lepa therapy

Lepa kalpana is an external dosage form prepared by taking clean, freshly dried medicinal material, reducing it to a fine powder, filtering it, and triturating it with a required quantity of water or another specified liquid until a paste is formed. The preparation is intended for external application.^[7]

Lepa is classified under bahirparimarjana chikitsa, or external treatment. Sushruta describes lepa as an adya upakrama and gives it importance in wound-related measures; the report also notes the traditional description of lepa as relieving fatigue. Charaka describes multiple lepa formulations, and Vagbhata discusses lepa in Sutrasthana and classifies it according to therapeutic purpose. Sharangadhara records different lepa formulations for different diseases.^[12,13,14]

Types, thickness and seasonal context

The classical review in the source describes three principal types: (1) doshaghna lepa, intended to act locally on aggravated doshas; (2) vishaghna lepa, intended to neutralize local poisonous effects and described as more potent in that context; and (3) varnya lepa, intended to enhance skin color and complexion. Traditional thicknesses are described as one-quarter angula, one-third angula and one-half angula, depending on indication and textual interpretation.^[12,14]

The report further summarizes season-specific lepa combinations described by Vagbhata: kola majja, vrishanmoola, shabara and goura sarshapa in Hemanta; simhimoola, tila, krushna, darvi bark and dehusked yava in Shishira; darbha root, hima/ushira, shirisha, mishi and tandula in Vasanta; kumuda, utpala, kahlara, durva, madhuka and chandana in Grishma; kaleeyaka, tila, ushira, mamsi, tagara and padmaka in Varsha; and taleesa, gundra, pundra, yastika and agaru in Sharad. This broader review establishes lepa as a flexible external pharmaceutical form rather than a single fixed recipe.

Application principles

Traditional instructions recommend applying lepa against the direction of hair growth to facilitate contact with hair follicles and sweat channels; using it on the day of preparation; avoiding reuse the following day; not placing a fresh layer over the same area while the previous layer remains; and removing the paste after drying. The report notes that lepa should generally not be applied at night and that excessive talking, laughter, anger, grief, sweating, fire or sun exposure and daytime sleep should be avoided during application. Oil may be applied after removal. The present protocol adapted this tradition by administering the application in the evening under a defined study schedule.

Drug Review and Study Objective

Bibhitak (*Terminalia bellirica*).

Attribute	Description
Botanical identity	<i>Terminalia bellirica</i> (Gaertn.) Roxb.; the source title uses “ <i>Terminelia belliirica</i> Roxb”.
Family	Combretaceae; traditionally Hareetakee kula.
Rasa and vipaka	Kashaya rasa and madhura vipaka.
Virya and guna	Ushna virya; guru and ruksha guna.
Traditional karma	Chakshushya, keshya, kaphapittajit, bhedaka, kriminasana and kasahara.
Traditional uses	Chardi, kasa, krimiroga, vibandha, svarabheda and netraroga.
Reported constituents	Gallic acid, tannic acid, glycosides, tannins, corilagin, ellagic acid, ethyl gallate, galloyl glucose, chebulagic acid and arjunolic acid.

The Ayurvedic Pharmacopoeia of India and Bhavaprakasha Nighantu provide the traditional identity and properties of Bibhitak. Contemporary reviews connect the plant’s diverse biological activities with its polyphenolic and tannin-rich phytochemistry. Gallic acid, in particular, is widely discussed for anti-inflammatory and analgesic potential, although a topical clinical mechanism cannot be established from this pilot study alone.^[4,8,9]

Traditional benefits and precautions

The source review records traditional benefits of regular lepa application, including improvement of complexion and skin glow, reduction of excessive odor, sweating and pigmentation, and enhancement of well-being, strength and ojas. These claims belong to the classical literature and were not outcomes in the present trial. It also lists general contraindications for lepa in certain conditions—including atisara, jwara, karnashula, vatavyadhi, adhmaana and arochaka—again as a textual review rather than trial-specific exclusion criteria. Their inclusion underscores the importance of clinical judgment and supervision when translating classical procedures into research.

AIM AND OBJECTIVE

The aim was to evaluate the efficacy of Bibhitak phala madhya lepa in the management of knee-joint vedana, with special reference to Sandhigata Vata. The prespecified objective extended this assessment to three symptoms: vedana (pain), shotha (swelling) and daha (burning sensation). The project objective was considered achieved for pain and swelling but not for burning sensation.

Ethical and institutional context

The work was conducted as a SPARK 2023–2024 pilot project at an institutional Ayurvedic hospital. Institutional Ethics Committee approval was reported as having been obtained at synopsis submission. Written informed consent was obtained, participation was voluntary, withdrawal was permitted at any time without affecting treatment, and confidentiality was maintained in accordance with the stated policy for ethical conduct of research. A dedicated case-record form and follow-up proforma captured demographic information, personal history, clinical findings, treatment and serial outcome scores.

METHODS**Study design and duration**

This was described as a prospective, non-randomized, open-label, single-arm clinical trial with a total project duration of two months. The intervention itself was administered for seven days, with assessments at baseline, day 7 and follow-up on day 14. The report also uses the terms “randomly selected” and “simple random sampling” for recruitment. Because there was no allocation to multiple study arms, these statements are best understood as describing selection from the available clinical population rather than randomized treatment assignment.

Setting, population and sample

Ten pre-diagnosed patients with Sandhigata Vata were recruited from the outpatient and inpatient departments of the institute’s attached hospital, irrespective of sex, religion, socioeconomic status, education, occupation or habitat. The target age range was 30–70 years. Eight participants had bilateral knee involvement and two had unilateral involvement; therefore, the lepa was applied to 18 knees and the therapeutic statistics were calculated at the knee level.

The source reports that Cochran’s formula produced an estimated full sample of 60; ten percent would have yielded six participants, but the pilot sample was increased to 10 for statistical analysis. No underlying prevalence estimate, confidence level, precision or allowance for attrition was provided. Accordingly, the sample-size statement should be interpreted as a pragmatic pilot justification rather than a reproducible power calculation.

Eligibility criteria

Inclusion criteria	Exclusion criteria
Pre-diagnosed Sandhigata Vata with knee-joint pain.	Knee pain caused by fall, accident, fracture or other injury.
Age 30–70 years.	Haemarthrosis.
Either sex.	Refusal of consent or unwillingness to participate.

Drug procurement, authentication and standardization

Bibhitak fruits were purchased from a local market. Authentication was performed by the Rasashastra and Bhaishajya Kalpana department of the Ayurvedic medical college and by the botany department of a nearby college; certificates were included as Annexures 1 and 2 in the source report. Prepared fine powder of Bibhitak phala madhya was submitted to a nearby college chemistry department for standardization, with the certificate included as Annexure 3. The numerical analytical results of standardization were not reproduced in the report text and therefore cannot be evaluated in this article.

Preparation of the formulation

Shade-dried fruits were ground, the outer covering was removed, and the inner pulp (phala madhya) was separated together with the seed. The material was reduced to a fine powder. For each treatment, an adequate quantity of lukewarm water was added to prepare a fresh, spreadable paste.

Methods: Intervention, Outcomes and Analysis

Intervention protocol

Protocol element	Specification
Formulation	Fine powder of Bibhitak phala madhya mixed with adequate lukewarm water.
Route	Local external application over the affected knee joint.
Frequency	Once daily.
Timing	Evening.
Application period	At least 1 hour per session.
Treatment duration	7 consecutive days.
Dose	Quantity adjusted to the size of the knee joint.
Assessment schedule	Baseline/day 1, day 7 and follow-up on day 14.

Outcome measures

Vedana (pain) was assessed using a visual analogue scale (VAS). The case records show 0–10 values for each knee, with higher scores indicating greater pain. Shotha (swelling) was

measured circumferentially with a measuring tape. Individual records were entered in inches, while summary analysis was presented in centimeters; the reported aggregate values are consistent with approximate unit conversion. Daha (burning sensation) was graded on a four-point ordinal scale: 0=no burning; 1=burning only after exertion; 2=daily burning for some hours; and 3=continuous burning.

Burning grade	Operational description
0	No burning sensation
1	Burning sensation only after exertion
2	Daily burning sensation for some hours
3	Continuous burning sensation

RESULTS

Participant profile

Characteristic	Category distribution
Age	30–40: 1 (10%); 41–50: 1 (10%); 51–60: 3 (30%); 61–70: 5 (50%).
Sex	Female: 8 (80%); male: 2 (20%).
Socioeconomic status	High: 5 (50%); middle: 4 (40%); lower: 1 (10%), as stated in the observation section.
Occupation	Homemaker: 6 (60%); farming: 2 (20%); business: 1 (10%); employee: 1 (10%).
Habitat	Rural: 6 (60%); urban: 4 (40%).
Bowel habit	Hard: 6 (60%); soft: 4 (40%).
Diet	Mixed: 6 (60%); vegetarian: 4 (40%).
Marital status	Married: 10 (100%).
Addiction	No addiction: 9 (90%); tobacco: 1 (10%).
Exercise	Light: 5 (50%); moderate: 4 (40%); none: 1 (10%).

Appetite was recorded as good in five participants, disturbed in three and low in two. The participant-level records described pain duration from 7 months to 7 years and swelling duration from 6 months to 7 years. Burning sensation was absent in five participants and present in five, which sharply limited the effective sample for that symptom. Eight of the ten participants contributed two knees, producing 18 knee observations overall.

Internal reporting discrepancy

The observation section identifies high socioeconomic status as the largest group (50%), whereas the discussion later describes the medium class as the largest group (50%). The participant-level summary is not sufficiently clear to reconcile this contradiction. This article therefore retains the explicit observation-table distribution and flags the inconsistency rather than silently choosing one interpretation.

Baseline clinical pattern

Baseline knee pain was generally severe, ranging from 6 to 10 on affected knees in the participant-level table, apart from one left knee recorded as 0 despite bilateral measurements. Baseline swelling values ranged approximately from 12.9 to 16.7 inches in the case summaries. Five participants had non-zero burning grades. These data illustrate heterogeneity in symptom burden and reinforce that the summary analysis was performed at the knee level, while some variables—especially burning sensation—were entered at the participant level.

Results: Therapeutic Outcomes

Outcome	Before treatment	After treatment	Test statistic	Reported p value	Inference
Pain (VAS)	Mean 8.33	Mean 6.39	$t=5.07$	<0.05	Significant
Swelling (cm)	Mean 38.39	Mean 37.28	$t=5.66$	<0.05	Significant
Burning sensation	Mean 0.611	Mean 0.056	$W=15$; $Z=-2.02$	>0.05	Not significant

Pain

Mean VAS pain decreased by 1.94 points, from 8.33 before treatment to 6.39 after treatment. The reported standard deviation of the paired change was 1.625, standard error 0.383, t statistic 5.07 and $p<0.05$. The report therefore rejected the null hypothesis for pain and described the response as statistically significant. Participant-level day-7 values generally decreased or remained stable, though some knees showed little change, highlighting that the aggregate effect was not uniform.

Swelling

Mean knee circumference decreased by 1.11 cm, from 38.39 cm before treatment to 37.28 cm after treatment. The reported standard deviation of the change was 0.832, standard error 0.196, t statistic 5.66 and $p<0.05$. This was considered statistically significant. The source narrative rounds the values to 38.4 cm and 37.2 cm; the tabulated values above are retained as the more precise report.

Burning sensation

Mean burning-sensation grade decreased from 0.611 to 0.056. Baseline and after-treatment standard deviations were reported as 1.092 and 0.235, with standard errors of 0.257 and 0.055, respectively. The Wilcoxon signed-rank statistics were $W=15$ and $Z=-2.02$, with $p>0.05$; the report classified the result as statistically insignificant. Only five participants reported burning at baseline, so the study was under-informative for this symptom. The

numerical combination of $Z=-2.02$ and $p>0.05$ is unusual under a conventional two-sided normal approximation and should be checked against the original statistical output in future reporting; this article preserves the report's stated inference.

Follow-up pattern and safety reporting

Follow-up measurements on day 14 generally showed maintenance or further small reductions in circumference and burning grades. The report's intervention schedule identifies day 7 as the end of daily application and day 14 as follow-up, but the summary tables label the post-treatment value simply as "A.T." without clearly distinguishing which visit supplied the primary endpoint. No adverse event, skin reaction, withdrawal or protocol discontinuation was reported. Because the absence of a described event is not equivalent to prospective safety proof, future studies should use a defined adverse-event checklist and report adherence and tolerability explicitly.

DISCUSSION

Principal findings

This pilot study suggests that seven days of once-daily Bibhitak phala madhya lepa may reduce knee pain and measured swelling in Sandhigata Vata. The mean VAS change of 1.94 points and circumference change of 1.11 cm were statistically significant according to the reported paired tests. Burning sensation improved numerically but was not statistically significant, and only half the participants had that complaint at baseline. The findings therefore support a signal for pain and swelling while leaving the daha-shamana effect unresolved.

Interpretation through the Ayurvedic framework

The age distribution was consistent with the report's Ayurvedic rationale: half the sample was 61–70 years old, an age described as Vata-predominant and associated with progressive dhatu-kshaya. The female predominance was interpreted in relation to menopausal age and asthi-kshaya. The high proportion of homemakers was linked to the sex distribution and, in the source discussion, to possible nutritional neglect. Rural residence was interpreted as a marker of greater manual and field work, considered a Vata-provoking exposure. Hard bowel habit was viewed as krura koshta and an expression of increased ruksha guna of aggravated Vata. These are explanatory interpretations drawn from the report; the pilot design did not test causal relationships between these characteristics and treatment response.

Probable mode of action

Lepa is a bahirparimarjana intervention. The classical explanation is that a locally applied preparation interacts with tvacha and is assimilated through bhrājaka pitta, thereby pacifying aggravated doshas at the application site. Bibhitak phala majja is described as Vata–Kapha-hara, with kashaya rasa and ushna virya. The astringent quality is traditionally associated with binding, while the warming potency is considered Vata-pacifying; together these properties were proposed to explain benefit in pain and swelling.

A biomedical hypothesis is also plausible but remains unproven here. Terminalia bellirica fruit contains tannins and phenolic compounds such as gallic acid, ellagic acid and corilagin. Reviews report anti-inflammatory and antioxidant activity, and gallic acid has documented pharmacological actions that may be relevant to pain and inflammation.^[4,9]

However, the study did not measure transdermal absorption, tissue concentrations, inflammatory biomarkers, active-constituent content or formulation stability. It therefore cannot determine whether observed changes resulted from specific phytochemical action, warmth and hydration of the paste, local rest during one-hour application, expectancy effects, measurement variation or natural symptom fluctuation. The mechanism should be framed as a testable hypothesis, not a demonstrated pathway.

Clinical relevance

A simple topical intervention prepared from an inexpensive fruit could be useful if it offers reproducible relief without systemic medication exposure. The protocol is feasible in a resource-constrained setting: the raw material was locally procured, preparation required grinding and lukewarm water, dosing was adjusted to joint size, and treatment was delivered once daily. These features support further pragmatic evaluation, particularly among older adults seeking non-invasive supportive care. Nevertheless, statistical significance in a pilot study does not establish clinically important benefit, comparative effectiveness or long-term safety.

Strengths

- The study translated a clearly cited classical intervention into a prospective clinical protocol.
- Drug authentication and external standardization were undertaken, with certificates retained in the report annexures.

- Three symptom domains were assessed with serial observations through day 14.
- Participant-level records and summary test statistics were provided, allowing the main findings to be reconstructed.
- The intervention was inexpensive, non-invasive and operationally simple.

Limitations

- The sample comprised only 10 participants and 18 knees, with no untreated, placebo or active-control group.
- Open-label treatment without blinded outcome assessment permits expectancy, observer and regression-to-the-mean effects.
- Eight participants contributed both knees, but the analysis treated 18 knee observations without adjustment for within-person clustering.
- The report alternately describes the study as non-randomized and the sampling as random; the selection process and recruitment flow are not fully reproducible.
- The primary endpoint visit is ambiguous because day 7 and day 14 were both assessed, while the summary tables use only “after treatment.”
- Individual circumference values were recorded in inches, but aggregate analysis was presented in centimeters; measurement site, tape tension and assessor reliability were not standardized in the text.
- The VAS anchors and clinically important difference were not specified. Burning was sparse at baseline, limiting statistical information.
- There was no radiographic grading, diagnostic severity classification, analgesic-use record, adherence estimate or formal adverse-event summary.
- No confidence intervals or effect sizes were reported, and the stated Wilcoxon Z and p-direction should be verified.

Comparison with the study objective

The objective was achieved in the limited pilot sense: improvement was demonstrated for vedana and shotha using the source analysis, whereas evidence for daha was insufficient. The result is appropriately described as indicative rather than definitive. It supports progression to a carefully controlled study, not routine clinical adoption as a proven treatment.

CONCLUSION

In this prospective single-arm pilot, Bibhitak phala madhya lepa applied to 18 painful knees in 10 patients with Sandhigata Vata was associated with statistically significant reductions in pain and swelling. Mean pain decreased from 8.33 to 6.39, and mean knee circumference decreased from 38.39 cm to 37.28 cm. Burning sensation decreased numerically but was reported as statistically non-significant. The treatment was described as cost-effective and non-invasive, and no adverse event was documented.

The evidence remains preliminary. The very small sample, lack of a comparison group, open-label assessment, inconsistent reporting of randomization and endpoint timing, and knee-level analysis without clustering adjustment prevent causal or generalizable conclusions. The most defensible interpretation is that the intervention showed a promising feasibility and efficacy signal for vedana and shotha that merits confirmation.

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