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Original Article

Ayurveda Section

Intranasal *Vacha Taila Nasya* as Add-on Therapy for Postdural Puncture Headache: A Pilot Randomised Controlled Trial

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ABSTRACT

Introduction: Postdural Puncture Headache (PDPH) is a common complication of spinal anaesthesia, typically managed with conservative measures or invasive epidural blood patch. *Vacha (Acorus calamus) Taila Nasya*, described in Ayurveda for head disorders, offers potential as a safe, non invasive adjunct therapy.

Aim: To evaluate the efficacy and safety of *Vacha Taila Nasya* as an add-on therapy in routine postoperative care for PDPH.

Materials and Methods: This single-centre, pilot, randomised controlled trial was conducted at the Inpatient Departments of Shalyatantra and Stree Prasuti, Dr. D. Y. Patil College of Ayurved and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University), Pimpri, Pune, Maharashtra, India over a period of 1 year and 6 months. A total of 40 patients diagnosed with PDPH following spinal anaesthesia were enrolled. Participants were randomised into two groups: Group A (control: routine postoperative care including hydration, bed rest, analgesics, and caffeine as required) and Group B (intervention: routine postoperative care plus *Vacha Taila Nasya*, 2 drops per nostril, twice daily for 3 days). The study was conducted in an open-label design; however, outcome assessment was performed by a blinded investigator. The primary outcome was change in Visual Analogue Scale (VAS) pain score. Secondary outcomes included resolution of associated symptoms (neck stiffness, tinnitus, hypoacusis, photophobia, nausea) and incidence of adverse events. Data analysis was carried out using the Mann–Whitney U test with Statistical Package for the Social Sciences (SPSS) software, version 26.0 (IBM Corp., Armonk, NY, USA).

Results: Patients in the *Vacha Taila Nasya* group (Group B) demonstrated significantly greater pain reduction compared to the control group (mean VAS score reduction was 5.6±1.2 in Group B compared to 3.1±1.4 in Group A (p-value=0.004). Associated symptoms such as nausea, neck stiffness, and photophobia also improved significantly (p-value <0.05 for all). No major adverse events were observed; only 2 patients (10%) reported mild nasal irritation, which resolved spontaneously without intervention.

Conclusion: *Vacha Taila Nasya* was safe, feasible, and demonstrated promising efficacy as an adjunct therapy in the management of PDPH. As part of an integrative approach, it may reduce symptom burden, minimise reliance on conventional analgesics, and enhance patient comfort in the postoperative setting. Early adoption in selected cases could provide a simple, non invasive supportive therapy alongside routine care.

Keywords: Complementary therapy, Headache management, Integrative medicine, Nasya therapy, Spinal anaesthesia complication

INTRODUCTION

Spinal anaesthesia, also known as a spinal block or subarachnoid block, is a cornerstone of regional anaesthesia, particularly for procedures involving the lower abdomen, pelvis, and lower limbs. It is favoured for its rapid onset, profound sensory and motor block, and avoidance of risks associated with general anaesthesia. Since August Bier's landmark administration in 1898, spinal anaesthesia has become routine in perioperative care; however, it is not devoid of complications [1]. One of the most common adverse effects is PDPH, which occurs due to dural perforation during spinal anaesthesia and subsequent Cerebrospinal Fluid (CSF) leakage, resulting in intracranial hypotension [2]. PDPH typically manifests within 12–72 hours after dural puncture and is characterised by a postural headache—worsening in the upright position and relieved by lying supine—often accompanied by neck stiffness, nausea, photophobia, and occasionally cranial nerve involvement [3]. Though self-limiting in most cases, PDPH can delay recovery, prolong hospitalisation, and impair quality of life [4].

Conventional management strategies—including bed rest, hydration, caffeine, and simple analgesics—remain the mainstay; however, refractory cases pose therapeutic challenges. The epidural blood patch remains the gold standard for severe or persistent PDPH, but it is invasive, resource-intensive, and not without risk [5]. This underscores the need for safe, effective, and non invasive adjunct therapies to enhance patient recovery and reduce symptom burden.

Nasya therapy, described in classical Ayurvedic texts such as *Charaka Samhita* and *Ashtanga Hridaya*, involves intranasal instillation of medicated oils for disorders of the head (*Shira*) [6]. *Vacha (Acorus calamus)*, the principal herb in *Vacha Taila*, is documented to possess neuroprotective, analgesic, anti-inflammatory, and cerebrotonic properties [7]. Its pharmacological profile suggests potential benefit in modulating the neurovascular mechanisms involved in PDPH [8].

Rationale for Conducting a Pilot Randomised Controlled Trial

Before committing to a large-scale definitive trial, a pilot Randomised Controlled Trial (RCT) is essential to:

Assess feasibility:

- Evaluate recruitment capability and participant acceptability of *Vacha Taila Nasya* as an add-on to standard PDPH care.
- Determine adherence to the intervention and retention over the follow-up period.

Refine methodology:

- Optimise the intervention protocol (dose, frequency, timing relative to symptom onset).
- Validate outcome measures (pain severity, duration of headache, functional recovery) for a larger trial.

Estimate effect size and variability:

- Generate preliminary efficacy data to inform sample size calculation for a future definitive RCT.

Evaluate safety profile:

- Monitor adverse events related to *Vacha Taila Nasya* to establish a safety baseline.

Research question: Is *Vacha (Acorus calamus) Taila Nasya* effective as an add-on therapy in the management of PDPH?

Hypotheses

- **Null hypothesis (H_0):** *Vacha (Acorus calamus) Taila* Nasya is not effective as an add-on therapy in the management of PDPH.
- **Alternative hypothesis (H_1):** *Vacha Taila Nasya* is effective as an add-on therapy in the management of PDPH.

The aim of the study was to evaluate the efficacy and safety of *Vacha (Acorus calamus) Taila Nasya* as an add-on therapy in patients with PDPH.

Primary objective:

- To evaluate the efficacy of *Vacha Taila Nasya* in reducing pain intensity in PDPH using VAS.

Secondary objectives:

- To carry out a conceptual study on *Vacha (Acorus calamus) Taila*, including its pharmacological basis, formulation, and standardisation parameters.
- To assess the safety profile and document any adverse effects associated with *Vacha Taila Nasya*.
- To explore the feasibility and cost-effectiveness of *Vacha* (*Acorus calamus*) *Taila Nasya* as a supportive therapy to potentially reduce hospital stay duration and improve overall recovery outcomes.

MATERIALS AND METHODS

This was a single-centre, two-arm, parallel-group pilot randomised controlled trial with a 1:1 allocation ratio. The study was conducted in the Inpatient Departments (IPD) of Shalyatantra and Stree Prasuti at Dr. D. Y. Patil College of Ayurved and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University), Pimpri, Pune, Maharashtra, India over 18 months (January 2023 to June 2024). The trial protocol was reviewed and approved by the Institutional Ethics Committee of Dr. D. Y. Patil College of Ayurved and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University), Pimpri, Pune (IEC Approval Number: IEC/584/2022). Written informed consent was obtained from all participants prior to enrolment. The trial was prospectively registered with the Clinical Trials Registry-India (CTRI) under registration number CTRI/2023/01/049061.

Inclusion criteria:

- Patients aged 18-70 years of either gender.
- History of spinal anaesthesia followed by PDPH within 5 days of dural puncture.
- Presence of ≥3 clinical features of PDPH (frontal/occipital headache, neck pain without fever, dizziness, nausea).
- American Society of Anaesthesiologists (ASA) physical status I-II.
- Spinal puncture performed with a Quincke's 26G needle.

Exclusion criteria:

- Patient refusal.
- Known neurological disease, migraine, sinusitis, epilepsy, or history of head injury.
- Signs of meningitis (positive Kernig's or Brudzinski's sign).
- Spinal deformity or post-spinal meningitis.

Withdrawal criteria:

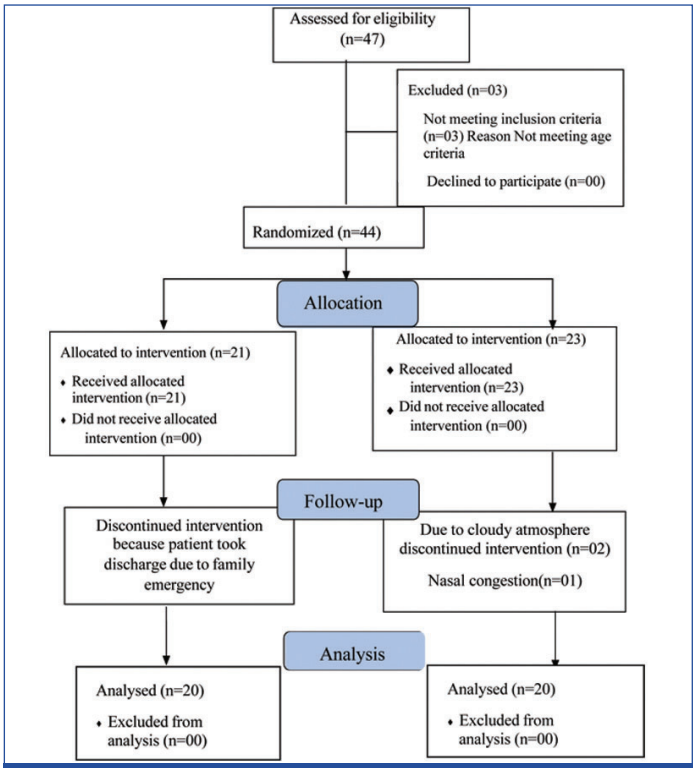
- Voluntary withdrawal of consent.
- Development of adverse events or other serious illness.

Participants were identified during postoperative monitoring. Eligible patients were approached by the study investigator, provided with verbal and written information about the trial, and enrolled after providing written informed consent.

Sample size calculation: For the pilot trial, the sample size was calculated using the formula: n=Z2PQL2 n=\frac{Z^2PQ} {L^2} n=L2Z2PQ Where P=0.05, Q=0.95, L=0.10, Z=1.96. This yielded n=19 per group, rounded to 20 patients per group for feasibility [9].

A total of 47 patients with suspected PDPH were assessed for eligibility between January 2023 and June 2024 at the Inpatient Departments of Shalyatantra and Stree Prasuti, Ayurved Hospital and Research Centre. Of these, seven patients were excluded: three did not meet the inclusion criteria, two declined consent, and two had contraindications due to pre-existing neurological conditions.

The remaining 40 patients were randomised in a 1:1 ratio to Group A (control, n=20), who received routine postoperative management, and Group B (intervention, n=20), who received routine postoperative management along with *Vacha (Acorus calamus) Taila Nasya*. All randomised participants received the allocated intervention, and there were no losses to follow-up or post-randomisation exclusions. Recruitment and follow-up were completed within the planned 18-month study duration, and the trial concluded as scheduled without premature termination [Table/Fig-1].



[Table/Fig-1]: CONSORT flowchart.

The authors acknowledge that the sample size calculation for this pilot study was based on a simplified proportion-based formula rather than a conventional power analysis. The primary intent was to assess feasibility and generate preliminary efficacy signals rather than provide definitive effect estimates. Hence, a minimum of 20 patients per group was considered adequate to identify trends, assess safety, and refine methodology.

Randomisation and Allocation

- **Sequence generation:** Random allocation was performed using the odd-even method based on patient registration numbers.
- **Allocation ratio:** 1:1 (Group A: Control, Group B: Intervention).
- **Concealment:** Sequential enrolment with allocation determined after eligibility confirmation.

- **Assignment:** The principal investigator enrolled and assigned participants to groups.

Interventions

Group A (Control):

- Standard postoperative management: Analgesics (Acetaminophen) and IV fluids for 3 days.

Group B (Intervention):

- Standard postoperative management (as above) plus *Vacha (Acorus calamus) Taila Nasya*:
  - **Dose:** 2 drops in each nostril, twice daily.
  - **Duration:** 3 days.
  - **Timing:** Morning and evening (*Nasya Kala*).

Nasya Procedure (with superscript citations from [10])

Performed as per *Charaka Samhita* guidelines [10]:

- **Purva karma:** *Abhyanga* (oil massage with *Tila Taila* to head/neck) and *Bashpa Swedana* [11].
- **Pradhana karma:** Patient placed in supine position with head extended 45°; 2 drops of *Vacha* (*Acorus calamus*) *Taila* instilled in each nostril [12].
- **Paschat karma:** Patient remained in position for ~100 seconds, secretions expelled, and gargling with warm water performed [13].

Outcome Measures

Primary outcome:

- Change in VAS pain score (0-10) for frontal-occipital headache from baseline to day 3.

Secondary outcomes:

- Resolution of associated PDPH symptoms (neck stiffness, tinnitus, hypoacusis, photophobia, nausea) graded per International Headache Society (IHS) guidelines [14].
- Adverse events related to *Vacha (Acorus calamus) Taila Nasya*, such as transient nasal irritation, mild burning sensation, sneezing, or nasal congestion, monitored and recorded throughout the study.
- Feasibility assessed across three domains:
- **Recruitment:** Proportion of eligible patients who consented out of those screened.
- **Adherence:** Extent of compliance with the prescribed regimen, confirmed through nursing logs and patient self-report.
- **Retention:** Proportion of enrolled participants completing the intervention and follow-up assessments without withdrawal.

Assessment Timeline:

- **Baseline:** Day 0 (prior to the first intervention).
- **Daily follow-up:** Day 1, Day 2, and interim assessment on Day 3 for ongoing progress and adverse events.
- **Final assessment:** End-of-treatment evaluation on Day 3, conducted after the last intervention, documenting final pain scores, resolution of symptoms, and overall safety.

Improvement grading [15]

- Major improvement: 75-100%
- Minor improvement: 50-74%
- Mild improvement: 25-49%
- No improvement: <25%

STATISTICAL ANALYSIS

Data were recorded in a standardised case record form. Data entry and analysis were performed using MS Excel and SPSS software, version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were used for feasibility outcomes. Preliminary between-group comparisons of VAS and symptom resolution were conducted to estimate effect size for a future definitive trial. The p-value <0.05 was considered to be statistically significant.

RESULTS

Baseline demographic and clinical characteristics were comparable between the two groups [Table/Fig-2]. The mean VAS score reduction was 5.6±1.2 in Group B as compared to 3.1±1.4 in Group A (p-value=0.004).

Variable	Group A (n=20)	Group B (n=20)
Age (years), mean±SD	38.4±8.6	39.1±9.2
Female, n (%)	12 (60%)	11 (55%)
Male, n (%)	8 (40%)	9 (45%)
ASA Class I, n (%)	13 (65%)	12 (60%)
ASA Class II, n (%)	7 (35%)	8 (40%)
Onset of PDPH (hours postanaesthesia), mean±SD	36±10	35±9
Baseline VAS score (0–10), mean±SD	8.4±0.9	8.5±0.8

[Table/Fig-2]: Baseline characteristics of participants.

Pain intensity decreased significantly in both groups over the three-day intervention period (Friedman test, p-value <0.05). However, the reduction was greater in the intervention group compared to the control group, with between-group analysis using the Mann-Whitney U test confirming significantly superior improvement in Group B (p=0.004; mean rank 25.63 vs. 15.38). This finding indicates that *Vacha Taila Nasya* provided additional pain relief beyond routine care.

Secondary outcomes also favoured the intervention group. Associated symptoms—including neck stiffness, tinnitus, hypoacusis, photophobia, and nausea—demonstrated significantly greater improvement in Group B compared to Group A, with all comparisons yielding p-values <0.001 [Table/Fig-3]. These results highlight a broader symptomatic benefit of the intervention in addition to pain reduction.

Symptom	Mean rank A	Mean rank B	p value
Frontal/occipital pain (VAS)	15.38	25.63	0.004
Neck stiffness	13.25	27.75	<0.001
Tinnitus	13.00	28.00	<0.001
Hypoacusis	11.50	29.50	<0.001
Photophobia	11.50	29.50	<0.001
Nausea	12.43	28.58	<0.001

[Table/Fig-3]: Between-group comparison of symptom improvement (Mann-Whitney U test).

With respect to safety, no major adverse events were reported in either group. Two participants in the intervention group experienced mild nasal irritation, which resolved spontaneously without discontinuation of therapy. No participants withdrew due to side-effects, suggesting that the intervention was well tolerated. Feasibility outcomes were also encouraging. Recruitment targets were met in full, with 40 participants enrolled within the planned timeframe. Retention was excellent, with 100% of participants completing follow-up. Adherence to the intervention protocol was complete, and all participants accepted the *Nasya* procedure once initiated, indicating high treatment acceptability.

Overall, this pilot trial met all feasibility benchmarks. The study demonstrated that recruitment and retention for a larger trial are achievable, no major safety concerns were identified, and preliminary estimates suggest clinically meaningful benefits in pain reduction and symptom resolution. These findings collectively support the feasibility and justification for progression to a larger, multicentre, definitive randomised controlled trial.

DISCUSSION

This pilot randomised controlled trial assessed the feasibility, safety, and preliminary efficacy of *Vacha (Acorus calamus) Taila Nasya* as an adjunct to routine postoperative management in PDPH. The results demonstrated a consistent and statistically significant improvement across both primary and secondary outcomes—most notably in frontal-occipital pain, neck stiffness, tinnitus, hypoacusis, photophobia, and nausea—in the intervention group compared to the control group which was similar as seen in study by Sharma V et al., [8].

The therapeutic effect of *Vacha Taila Nasya* may be attributed to its dual pharmacological and mechanistic actions. Classical Ayurvedic texts describe *Vacha* as possessing *Vedanasthapana* (analgesic) and *Shirovirechana* (head-clearing) properties, providing a traditional rationale for its use in disorders of the head [10]. Modern pharmacological studies further support its role, with β-asarone and other bioactive constituents exhibiting anti-inflammatory, vasoconstrictive, and neuromodulatory effects that align with the pathophysiology of PDPH [7]. The intranasal route, described in Ayurveda as a direct pathway to the head, is also consistent with contemporary evidence for olfactory and trigeminal transport enabling rapid central nervous system delivery [13,16].

When compared with previously published case reports, our findings show several points of convergence. Like earlier accounts, the present study confirms the rapid symptomatic relief of PDPH with *Nasya* therapy, with improvements in headache severity and associated symptoms manifesting within a few days [2]. Both this trial and case-based evidence reported excellent short-term safety, with only minor, self-limiting nasal irritation observed in a small number of patients [12].

However, there are also important distinctions. Most published cases have been single-patient narratives or small case series, offering descriptive observations without comparative data. In contrast, present study allowed for systematic allocation, blinded assessment, and formal statistical testing, thereby providing preliminary effect size estimates and feasibility outcomes that can guide a larger definitive trial. Furthermore, earlier case reports often involved a heterogeneous spectrum of headache disorders, whereas the present trial focused specifically on PDPH—a condition with distinct CSF and neurovascular mechanisms. The structured outcome measurement using validated scales (VAS and IHS-guided symptom grading) also contrasts with the subjective reporting often seen in prior literature.

Taken together, this comparison underscores both the continuity and advancement of evidence. While case reports have been invaluable in highlighting therapeutic potential and safety, present study provides the first controlled quantitative data supporting *Vacha Taila Nasya* as a feasible and effective adjunctive therapy for PDPH. These findings reinforce the need for a multicentric, adequately powered trial to validate and extend the preliminary efficacy signals demonstrated here.

Limitation(s)

The present study had certain limitations. It was conducted at a single centre, which restricts the generalisability of findings. The short follow-up period may have overlooked late adverse events or recurrence of symptoms. Additionally, the absence of blinding could have introduced performance and assessment bias.

CONCLUSION(S)

This pilot study provides preliminary evidence that *Vacha (Acorus calamus) Taila Nasya* is a safe, well-tolerated, and potentially effective adjunctive therapy for PDPH. The intervention demonstrates promise as a complementary approach to conventional postoperative care, enhancing symptom relief and patient comfort. While encouraging, these findings remain exploratory, highlighting the need for larger, rigorously designed, multicentre trials to confirm efficacy, clarify mechanisms, and assess broader applicability in diverse perioperative settings.

Other Information

Protocol availability: The full trial protocol is available upon reasonable request from the corresponding author and has been archived at the institutional research repository of Dr. D. Y. Patil College of Ayurved and Research Centre, Dr. D. Y. Patil Vidyapeeth (Deemed to be University), Pimpri, Pune, Maharashtra, India.

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