A comparative clinical study to evaluate the efficacy of mashabaladi kwath ghanavati with kubja prasarani tail in the management of greeva sandhigata vata with reference to cervical spondylosis.

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Abstract

INTRODUCTION: Ayurveda is a holistic science of life that maintains physical, mental, social, and spiritual well-being through Dosha balance. Disease arises when this balance is disturbed. Degenerative disorders are considered *Vata Vyadhi*, including *Sandhi Gata Vata* affecting joints. *Greeva Sandhi Gata Vata* involves the cervical region, causing pain, swelling, stiffness, and restricted movement. Cervical spondylosis is a degenerative spine disorder 40 with disc degeneration and osteophyte formation, leading to pain, stiffness, disability.

NEED OF STUDY: Cervical spondylosis is a common degenerative cervical spine disorder in India (13.76–28.6%), affecting productive years with pain, stiffness, restricted movement, and impaired limb function. Modern treatment offers mainly symptomatic relief with long-term or costly care. It correlates with *Greeva Sandhi*

Gata Vata in Ayurveda, where therapies, along with diet, lifestyle, and yoga, help manage contributing factors.

AIM: To Compare the efficacy of Mashabaladi kwath Ghanavati with *Greeva Basti* of kubja prasarani tail in management Greeva sandhi gata vata disease (cervical spondylosis).

Materials and methods: A prospective, interventional, open label, double arm, randomized and comparative clinical study conducted from 2026 to 2027 at Shri Narayan Prasad Awasthi Government Ayurved College and Hospital, Raipur. The subjects will be divided into two groups: One group 20 patients will be taken orally Mashabaladi kwatha Ghanavati with dose of 500 mg BD and Another group of 20 patients will be taken orally Mashabaladi kwatha Ghanavati with dose of 500 mg BD and Kubja prasarani Tail for local application as form Greeva basti. The patients assessed sandhi shool (pain & tenderness in intervertebral joints), *Sandhi Shotha*(inflammation with degenerative changes/swelling),*Stambha*(neck stiffness), *Spandan*(tingling sensation),*Akunjanprasaran Janya Vedana* (restricted neck movement),*Suptata* (numbness/loss of sensation in arms), *Shira shool* (headache) & *Bhrama* (vertigo) as subjective criteria and X-ray (Digital) Cervical spine – anterior posterior and lateral view and ESR as objective criteria. Statistical Analysis will be conducted using Paired T test, Wilcoxon signed rank test, Mann Whitney U test, Chi square test and independent sample T test with statistical significance set at p value <_ 0.05.

Key words: *Greeva sandhi gata vata*, cervical spondylosis, Mashabaladi kwath Ghanavati, Kubja prasarani tail, *Greeva basti*

Introduction:

Ayurveda is a holistic science of life aimed at promoting optimal physical, mental, social and spiritual well-being. Health is defined not merely as the absence of disease but as a balanced state of body and mind. Disease (Roga) arises when the *Doshas* become imbalanced. Degenerative disorders are broadly classified under *Vata Vyadhi*, among which *Sandhi gata Vata* affects the joints. *Greeva Sandhi gata Vata*, involving the cervical region, occurs when aggravated *Vata Dosha* localizes in the cervical joints. Classical texts describe symptoms such as *Shoola* (pain), *Shotha* (swelling), painful flexion and extension, heaviness, and impaired joint movement

indicating degenerative cervical joint pathology. In modern Cervical spondylosis is a common degenerative disorder of the cervical spine, mainly affecting individuals over 40 years. It involves progressive intervertebral disc degeneration, facet and uncovertebral joint changes and osteophyte formation. Clinically, it presents with neck pain, stiffness, and restricted neck movement, significantly affecting daily activities and quality of life, thereby creating a considerable healthcare and socioeconomic burden.

Need of study:

Cervical spondylosis is a common degenerative disorder of the cervical spine with a reported prevalence in India ranging from 13.76% to 28.6%, with around 13.76% commonly observed, and variations seen among urban, suburban, and rural populations. It frequently occurs during the most productive years of life and significantly affects neck mobility and upper limb function. Despite advances in contemporary medicine, available treatments for degenerative joint disorders mainly provide symptomatic relief and often involve long-term medication or costly interventions, with limited satisfactory outcomes. In Ayurveda, this condition can be correlated with *Greeva Sandhi gata Vata*, a *Vata*-dominant disorder affecting the cervical joints. Although several Ayurvedic formulations have shown statistically significant improvement in some clinical parameters, their effectiveness in relieving key symptoms such as neck pain, neck stiffness, restricted neck movements, numbness and headache remains limited. Considering the high prevalence, functional disability, and economic burden associated with cervical spondylosis, there is a need to explore more effective and affordable Ayurvedic management strategies for *Greeva Sandhi gata Vata* to improve patient outcomes and quality of life.

AIM:

To Compare the efficacy of Mashabaladi kwath Ghanavati with *Greeva Basti* of kubja prasarani tail in management *Greeva sandhi gata vata* disease (cervical spondylosis).

Objective: -

- Observing causes found in present time.
- To confirmatory Qualitative phytochemical & physiochemical screening of Mashabaladi kwath Ghanavati and Kubja prasarani Tail.

- Evaluating the Efficacy and studying the therapeutic effect of Masha Baladi kwath Ghanavati & Kubja prasarani tail in *Greeva Sandhi gata vata*.
- Evaluating the Efficacy and studying the therapeutic effect of Masha Baladi kwath Ghanavati and *Greeva Basti* Kubja prasarani tail in *Greeva Sandhi gata vata.*
- To study the any adverse effect of Masha Baladi kwath Ghanavati and Kubja prasarani Tail.
- To compare the efficacy of Ayurvedic Treatment protocol with conventional first line management of *Greevasandhi gata vata* (Cervical Spondylosis).

To obtain conclusions by analysing the results through statistical data

Hypothesis:

Null Hypothesis: -

(H0): - It is presumed that Mashabaladi kwatha Ghanavati may not be more effective than *Greeva Basti* of kubja prasarani taila individually to decreases the conditions associated with *Greeva sandhi gata vata* with reference to cervical spondylosis

Alternative Hypothesis: - (H_1)

(H_1): - It is presumed that Mashabaladi kwatha Ghanavati may be more effective than *Greeva Basti* of kubja prasarani taila individually to decreases conditions associated with *Greeva sandhi gata vata* with reference to cervical spondylosis.

Material and methods: - materials: Erandamoola,Pipplimoola,bala,Masha,Chitraka,,Devadaru,kapikkachu,saindhavala vana,Bhustrian,rasna,ashwaganda,hingu,shatapuspa,Bhallataka,gajapippli,Jatamans i,yastimadhu,vacha, prasarani will be authenticated in CCRAS Jhansi/CCRAS,CARI Bengaluru.

Methods:

The present study will be carried out in following phases

1. **Review of Literature: -**The review will be collected from various text books of ayurveda, modern medical science & research texts related to Greeva sandhi gata vata found in various famous ayurvedic college of India, certified article published in generals found in google scholar, PubMed etc will be compiled.

2. **Clinical study-** For started clinical study approved ctri as CTRI/2025/11/096993 (Registered on 06/11/2025)

Eligibility criteria:

Inclusion-criteria:

Patients between 30–60 years of age presenting with clinical features of Greeva Sandhi gata Vata (cervical spondylosis) such as neck pain, neck stiffness, neck swelling, restricted neck movements, numbness, and tingling sensation radiating to the arms, with or without radiological changes, including cases associated with cervical spinal stenosis, will be included in the study.

Exclusion-Criteria:

Patients below 30 years or above 60 years of age, with a history of neck trauma or fracture, or those who have undergone recent cervical, spinal, or shoulder surgery, implanted instrumentation, or surgery for cervical spondylotic myelopathy will be excluded. Patients diagnosed with intervertebral disc prolapse, inflammatory arthritic disorders such as rheumatoid arthritis and ankylosing spondylitis, as well as malignancy, tuberculosis, or HIV infection, will not be included. Additionally, pregnant and lactating women, patients with uncontrolled hypertension or diabetes mellitus, and those receiving steroid or cytotoxic therapy will also be excluded from the study.

Sample size determination:

This study is based on a prospective, interventional, open-label, double-arm, randomized, comparative clinical trial to evaluate the efficacy of Mashabaladi Kwatha Ghanavati and Kubja Prasarani Taila in the management of Greeva Sandhi gata Vata with reference to Cervical Spondylosis. In this study, 40 patients fulfilling the inclusion criteria will be registered and randomized in a 1:1 allocation ratio.

- Group A-Mashabaladi Kwatha Ghanavati
- Group B-Mashabaladi Kwatha Ghanavati and Greeva basti of Kubja Prasarani Tail Each group will consist of 20 patients. Simple randomization will be followed, which will be based on computer-generated random numbers to ensure unbiased allocation of participants.

Sample Size Formula and Estimation Bias

$n=Z2\times p(1-p)/e^2$

Where:

- Confidence level(Z) =1.96(95%)

- Margin of error (e) = 10%
- Estimated population proportion (p) = 13.7% (0.137)
- Population size = 360

Using the above formula, the calculated sample size becomes 40, i.e., 20 patients in each group.

Intervention:

The experimental groups will undergo an intervention involving Mashabaladi Kwatha Ghanavati in the dose of 500 mg. The prescribed dose will be one tablet twice daily orally after meals with normal water for 60 days& second one is Mashabaladi Kwatha Ghanavati (500 mg, 1 tablet twice daily after meals with normal water for 60 days) along with Greeva Basti using Kubja Prasarani Taila over the cervical region as per classical procedure for the prescribed duration.

Before starting the trial, Kostha Shuddhi will be carried out for 7 days using Harityakadi Churna to improve digestion, regulate bowel movement, and enhance Agni and drug absorption. Participants will be advised to follow Pathya–Apathya and appropriate Vihara throughout the study period.

Follow-up assessments will be conducted every 7 days for up to 2 months, and a post-trial follow-up of 1 month will be done to evaluate the sustainability of the therapeutic effects.

Pharmaceuticals standardization and preparation of trial drugs:

The raw materials of Mashabaladi kwatha Ghanavati is erandamoola,Bala,Masha,Kapikacchu,Bhustrian,Rasna,Ashwagandha,Hingu,Saind hava lavana and raw materials of kubja prasarani tail as Pippali moola,Shatapuspa,Chitraka,Bhallataka,Devadaru,Rasna,Gajapippli,Jatamansi,Yasti madhu,Vacha,Prasarani,Saindhva lavana. These drugs will be authenticated at CCRAS, Bengaluru.

Drug identification and authentication:

The drugs of Mashabaladi kwatha Ghanavati and kubja prasarani tail were Collected some raw drugs from locality and some raw materials purchased from local market and authenticated by the Department of Dravya Guna, Government Ayurved College, Raipur, Chhattisgarh and CCRAS Bengaluru to ensure correct botanical identity and quality.

Preparation of formulations

Preparation of Masha Baladi kwatha Ghanavati and Kubja prasarani Tail will be carried out under the guidance of faculty from the department of Kayachikitsa and Rasa shastra and Bhaishajya Kalpana of the government Ayurved College. The formulations were prepared in Government Ayurvedic Pharmacy Raipur, Chhattisgarh, following standard ayurvedic pharmaceutical procedures.

Quality testing and standardization

The ingredients and prepared formulations will undergo physiochemical analysis at the Government Authorized State Drug Testing Laboratory evum Anusandhan Kendra (DTL), Raipur, Chhattisgarh, which is an NABL-accredited laboratory.

This ensured compliance with standard quality parameter.

Anticipated outcome: -

1. Changes in Neck Disability Index score from pre-intervention baseline value at the end of 15 days.
2. Changes in Universal Goniometer readings from pre-intervention baseline value at the end of 15 days.
3. Mashabaladi kwath Ghanavati & kubja prasarani tail will prevent the recurrence of *Greeva sandhi gata vata.*

Statistical analysis:

"A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF MASHABALADI KWATH GHANAVATI WITH KUBJA PRASARANI TAILA IN THE MANAGEMENT OF GREEVA SANDHIGATA VATA WITH REFERENCE TO CERVICAL SPONDYLOSIS'' In this context, after studying the data obtained in the analysis, "Wilcoxon Sign Rank Test and paired t-test" were used for analysis and after doing comparative study, "Mann Whitney U test and Independent Sample T test. A confidence interval of 95% will be established and p- value of _< 0.05 will be considered as statistically significant.

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