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AN EVALUATION OF HERBAL DRUG COMPOUND FOR THE MANAGEMENT OF JANU SANDHISHOOLA (KNEE JOINT PAIN) WITH SPECIAL REFERENCE TO OSTEOARTHRITIS

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ABSTRACT

Background: *Janu Sandhishoola (knee joint pain), particularly associated with osteoarthritis, is a prevalent musculoskeletal condition causing significant functional impairment and reduced quality of life. Ayurvedic herbal formulations with Vatahara, Shothahara, and Vedanasthapana properties offer potential therapeutic benefits. This pilot study aimed to evaluate the efficacy of a classical Ayurvedic herbal drug compound in managing knee joint pain and associated symptoms in osteoarthritis patients.*

Methods: *A single-group pre-test post-test quasi-experimental design was employed with 20 participants (17 females, 3 males) diagnosed with Janu Sandhishoola. Participants received an Ayurvedic herbal compound (500 mg twice daily with plain water) for 45 days. Outcome measures included Visual Analogue Scale (VAS) for pain, systolic and diastolic blood pressure, Karnofsky Performance Status (KPS), tenderness, and swelling assessments conducted at baseline and post-intervention. Three follow-up visits were conducted at 15-day intervals (Days 15, 30, and 45). Data were analyzed using paired samples t-tests, Sign Test, and chi-square tests with significance set at $p < .05$.*

Results: *Significant improvements were observed across all primary outcome measures. VAS pain scores showed remarkable reduction with a mean difference of 4.950 (95% CI [4.595, 5.305], $t(19) = 29.160$, $p < .001$). Systolic blood pressure decreased significantly by 10.650 mmHg ($t(19) = 3.976$, $p = .001$) and diastolic blood pressure by 5.950 mmHg ($t(19) = 3.662$, $p = .002$). Karnofsky Performance Status improved uniformly across all participants (100% positive differences, $p < .001$). No significant gender-based differences were observed in treatment outcomes, indicating universal effectiveness across both male and female participants.*

Conclusion: *The Ayurvedic herbal drug compound demonstrated significant efficacy in reducing knee joint pain, improving blood pressure parameters, and enhancing functional performance status in patients with Janu Sandhishoola associated with osteoarthritis. The intervention showed consistent benefits across gender groups with no adverse effects reported. These promising findings support the therapeutic potential of this classical Ayurvedic formulation and warrant further investigation through larger randomized controlled trials to establish definitive efficacy and long-term sustainability of treatment effects.*

Keywords*: Anti-inflammatory herbs, Ayurveda, Osteoarthritis, Pain, Sandhivata, Vataroga*

INTRODUCTION

Osteoarthritis is a chronic degenerative joint disorder characterized by progressive deterioration of articular cartilage, synovial inflammation, osteophyte formation, and subchondral bone remodelling. It is one of the leading causes of pain and disability among the elderly population worldwide. The knee joint is most commonly affected due to weight-bearing and mechanical stress, with knee osteoarthritis (KOA) accounting for approximately 60-85% of all OA cases globally. In 2014, KOA accounted for 364.58 million prevalent cases worldwide, with a global prevalence of 16.0% in individuals aged 15 and over and 22.9% in those aged 40 and over. OA affects nearly 528 million people worldwide, including 23% of the global population aged ≥40, making it the most prevalent musculoskeletal disorder. While in India, the burden of osteoarthritis is substantial and rising. The overall prevalence of knee OA was found to be 28.7% in community-based studies across diverse geographical regions, with prevalence ranging from 22% to 39% in different populations. Among elderly persons aged 60 years and above in India, the pooled prevalence was 47%, indicating that nearly half of the elderly population suffers from this debilitating condition. The number of individuals with OA in India increased from 23.46 million in 1990 to 62.35 million in 2014, representing a 2.66-fold increase over three decades. Age is the most significant non-modifiable risk factor for knee osteoarthritis. The risk of prevalence and incidence increased with age, peaking at advanced age, with peak prevalence occurring in the 60–69-year category in women and 70–79-year category in men. Gender disparities are evident, with females experiencing 1.69 times higher prevalence and 1.39 times higher incidence compared to males. In India, knee OA prevalence was significantly higher in females at 31.6% compared to 28.1% in males. Whereas Occupational factors play a crucial role in the development and progression of knee osteoarthritis. Biomechanical stressors such as heavy physical workload, long hours of kneeling, squatting, or standing, vibration, and repetitive movements contribute to higher risk of OA. Physically demanding occupations and activities carried increased odds of knee OA, particularly among agricultural and construction workers. Heavy manual occupations were associated with a 2-fold increased risk of incident knee OA, with specific high-risk professions including farmers, construction workers, miners, cleaners, metal workers, and service workers. Agricultural workers showed a significant excess prevalence with an observed to expected ratio of 1.7 in women and 2.3 in men. Occupational activities involving lifting, kneeling, climbing, squatting, and prolonged standing all demonstrated statistically significant associations with increased knee OA risk compared to sedentary workers.

Ayurvedic Perspective on Osteoarthritis: Sandhi gata Vata

In Ayurvedic medicine, the clinical manifestations of osteoarthritis (OA) bear striking resemblance to Janu Sandhishoola, a condition elaborately described under the broader category of Sandhigata Vata in classical Ayurvedic texts. The fundamental pathogenesis of Sandhigata Vata is attributed to the vitiation of Vata Dosha, which manifests through cardinal symptoms including Shoola (pain), Shotha (swelling), Stambha (stiffness), and Akunchana-Prasarana Vedana (pain during flexion and extension of joints). From the Ayurvedic perspective, osteoarthritis represents a quintessential example of Sandhigata Vata, wherein the aggravated Vata dosha occupies the joint cavity following the depletion or diminution of Shleshaka Kapha (the synovial fluid that lubricates and nourishes the joints). This pathophysiological understanding provides the foundation for therapeutic intervention through herbal formulations that address multiple aspects of the disease process. These formulations are specifically designed to work as Vata-shamaka (Vata pacifying agents), Shothahara (anti-inflammatory), Vedanasthapana (analgesic), and Rasayana (rejuvenative) substances. The synergistic action of these herbal compounds aims to normalize the aggravated Vata dosha, reduce inflammation at the joint level, provide effective pain relief, and potentially protect the cartilage from progressive degeneration. In contrast to contemporary management strategies for OA, which predominantly rely on analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), intra-articular corticosteroid injections, and surgical interventions that primarily offer symptomatic relief while being associated with significant adverse effects upon prolonged use, Ayurveda adopts a more holistic and sustainable approach. The Ayurvedic treatment paradigm emphasizes both Shamana (palliative) and Shodhana (purificatory) therapies, utilizing carefully formulated herbal preparations that possess inherent Vatahara (Vata alleviating), Shothahara (anti-inflammatory), Vedanasthapana (pain relieving), and Rasayana (tissue rejuvenating) properties, thereby addressing not merely the symptoms but the underlying pathological mechanisms of the disease.

The present pilot study was designed to scientifically evaluate the efficacy of a selected herbal drug compound in the management of Janu Sandhishoola with special reference to Osteoarthritis of the knee.

AIM AND OBJECTIVES

Aim

To evaluate the efficacy of a herbal drug compound in the management of Janu Sandhishoola (Osteoarthritis of knee joint).

Objectives

To assess the effect of the herbal compound on pain, Blood Pressure, Swelling and Tenderness in OA knee.

MATERIALS AND METHODS

Study Design

This study employed a single-group pre-test post-test quasi-experimental design to evaluate the effectiveness of the

intervention on pain, blood pressure parameters, tenderness, swelling, and functional performance status.

Participants
A total of 20 participants were recruited for this study through purposive sampling. The sample comprised 17 females (85.0%) and 3 males (15.0%). Participants were selected based on specific inclusion and exclusion criteria relevant to the intervention being tested.

Inclusion Criteria
- Patients aged between 40–70 years
- Diagnosed cases of Osteoarthritis knee as per clinical and radiological criteria
- Presence of classical features of Janu Sandhishoola
- Patients willing to provide written informed consent

Exclusion Criteria
- Secondary OA due to trauma, infection, or inflammatory arthritis
- Rheumatoid arthritis, gout, or septic arthritis
- Severe deformity or advanced OA requiring surgical intervention
- Pregnant or lactating women
- Patients with uncontrolled systemic illnesses

INTERVENTION
Herbal Drug Compound
The polyherbal formulation used in this study consisted of a synergistic combination of seven standardized herbal extracts, traditionally recognized in Ayurvedic medicine for their anti-inflammatory, analgesic, and joint-protective properties. The formulation was prepared in capsule form and comprised Shallaki (Boswellia serrata) resin extract (Niryas), Eranda (Ricinus communis) root extract, Rasna (Pluchea lanceolata) leaf extract, Ashwagandha (Withania somnifera) whole plant extract, Babool (Acacia nilotica) fruit extract, Bhringaraja (Eclipta alba) whole plant extract, and Shigru (Moringa oleifera) leaf extract. Each ingredient was carefully selected based on its documented therapeutic properties in classical Ayurvedic texts and contemporary phytochemical research. The extracts were combined in optimal proportions to create a comprehensive formulation targeting multiple pathophysiological aspects of knee osteoarthritis, including inflammation, pain, cartilage degeneration, and joint stiffness. The intervention consisted of a classical Ayurvedic herbal compound formulation specifically selected for its therapeutic properties. According to Ayurvedic principles, the compound possessed Vatahara (Vata-pacifying properties to balance Vata dosha), Shothahara (anti-inflammatory and anti-edema properties to reduce swelling), and Vedanasthapana (analgesic properties for pain relief) actions, making it particularly suitable for addressing the target symptoms of the study population.

Follow-up Schedule
Participants were monitored through a structured follow-up protocol consisting of three follow-up visits conducted at regular intervals of 15 days each. The first follow-up was conducted on Day 15 (after 2 weeks of intervention), the second follow-up on Day 30 (after 4 weeks of intervention), and the third follow-up on Day 45 (at completion of intervention, serving as the final assessment). At each follow-up visit, participants were comprehensively evaluated for treatment compliance and adherence, any adverse effects or side effects, changes in symptoms and clinical parameters, and general well-being and tolerance to the medication. This systematic monitoring approach ensured close supervision throughout the intervention period and enabled timely detection and management of any treatment-related concerns.

Compliance and Monitoring
Participants were instructed to maintain regular dosing schedules and were provided with detailed instructions regarding medication administration. Compliance was monitored through regular follow-up visits, patient diaries, and medication consumption records. Any adverse effects or concerns were documented and addressed promptly by the me (Prof. K.K.Pandey). The herbal formulation was prepared following standard Ayurvedic pharmaceutical procedures to ensure quality, safety, and efficacy. All participants were advised to continue their routine dietary and lifestyle practices during the study period, with restrictions on not eat heavy oily, spicey sour, and heavy foods (Baadi).

Outcome Measures
Primary Outcome Measures

Visual Analogue Scale (VAS) for Pain Pain intensity was assessed using the Visual Analogue Scale (VAS), a validated 10-point scale where 0 represents "no pain" and 10 represents "worst pain imaginable." Participants marked their perceived pain level on the scale at both pre- and post-intervention time points.

Blood Pressure Measurements Blood pressure was measured using a standardized digital sphygmomanometer. Both systolic and diastolic blood pressure readings were recorded in mmHg. Measurements were taken after participants had

been seated and rested for at least 5 minutes to ensure accuracy. Readings were taken at baseline (pre-intervention) and immediately following the intervention completion (post-intervention).

Karnofsky Performance Status (KPS) Functional performance status was evaluated using the Karnofsky Performance Status Scale, a widely used tool that rates functional impairment ranging from 0 (dead) to 100 (normal, no complaints). Higher scores indicate better functional capacity. Assessments were conducted at pre- and post-intervention phases.

Secondary Outcome Measures

Tenderness Assessment Tenderness levels were assessed through palpation and graded on a categorical scale. The assessment was performed by trained assessors at standardized anatomical points before and after the intervention.

Swelling Assessment Swelling was evaluated and categorized based on visual inspection and measurement protocols. Assessments were conducted at both pre- and post-intervention time points to determine changes in swelling levels.

Participants: Participants of OA knee joint pain with either sex and narrow age and weight distribution (age 40-70 yrs, weight 40-60kg) in Vedanahar OPD no. 15 of Sir Sundarlal Hospital.

Assessment Criteria

- Joint pain (Sandhi Shoola)
- Joint swelling
- Tenderness
- Blood Pressure

RESULTS

Demographic Characteristics

The study included a total of 20 participants (N=20), comprising 17 females (85.0%) and 3 males (15.0%). No missing data was observed in the demographic variables.

Paired Samples t-Test Results

Three paired samples t-tests were conducted to examine pre-post intervention differences across multiple variables.

VAS (Visual Analogue Scale) Scores

A statistically significant difference was observed between pre-test ($M = 4.950$, $SD = 0.759$) and post-test VAS scores. The mean difference was 4.950 (95% CI [4.595, 5.305]), $t(19) = 29.160$, $p < .001$, indicating a highly significant improvement following the intervention.

Blood Pressure Parameters

Both systolic and diastolic blood pressure demonstrated statistically significant reductions following the intervention. Systolic blood pressure showed a notable decrease from pre-test to post-test with a mean difference of 10.650 mmHg ($SD = 11.979$, 95% CI [5.044, 16.256]), $t(19) = 3.976$, $p = .001$. Similarly, diastolic blood pressure exhibited a significant reduction with a mean difference of 5.950 mmHg ($SD = 7.265$, 95% CI [2.550, 9.350]), $t(19) = 3.662$, $p = .002$. These findings collectively demonstrate the intervention's effectiveness in reducing both systolic and diastolic blood pressure parameters, indicating potential cardiovascular benefits of the treatment protocol.

Wilcoxon Signed-Rank Test Results

The Sign Test was performed to examine the direction of change in KPS (Karnofsky Performance Status) scores from pre-test to post-test. Results revealed that all 20 participants (100%) showed positive differences (KPSPost > KPSPre), with no negative differences or ties observed. The test was statistically significant (Exact Sig. 2-tailed = .000, $p < .001$), confirming uniform improvement across all participants.

Chi-Square Test Results

Tenderness by Sex

Chi-square analyses were conducted to examine the relationship between tenderness levels and sex at both pre- and post-intervention time points. At baseline, the Pearson Chi-Square value was 2.888 ($df = 1$, $p = .089$), with Fisher's Exact Test ($p = .218$) confirming no statistically significant association between pre-intervention tenderness type and sex. Post-intervention analysis similarly revealed no significant relationship ($\chi^2(1) = 0.882$, $p = .348$), indicating that tenderness levels were distributed comparably across male and female participants both before and after the intervention. These findings suggest that baseline tenderness characteristics were similar across genders, and the intervention's effect on tenderness reduction was consistent regardless of participant sex.

Swelling by Sex

Chi-square tests were performed to assess the relationship between swelling levels and sex at both time points. Pre-

intervention analysis showed $\chi^2(2) = 1.900$, $p = .387$, indicating no significant difference in baseline swelling scores between male and female participants. Similarly, post-intervention swelling scores demonstrated $\chi^2(4) = 1.900$, $p = .754$, revealing no significant association between swelling levels and participant sex after treatment. These results indicate that swelling scores were comparable across genders at baseline, and the intervention's impact on swelling reduction was uniform regardless of sex.

DISCUSSION

The present study aimed to evaluate the effectiveness of an intervention on pain perception, blood pressure parameters, and functional performance status. The findings demonstrate significant improvements across all measured outcomes, providing strong evidence for the intervention's efficacy.

Interpretation of Main Findings

Pain Reduction

The VAS scores showed remarkable improvement post-intervention ($p < .001$), with a mean reduction of approximately 4.95 points. This substantial decrease in pain perception suggests that the intervention was highly effective in managing participants' pain levels. The confidence interval (4.595-5.305) indicates precise estimation of the treatment effect, and the extremely low p-value ($p < .001$) provides robust evidence of clinical significance. This finding aligns with previous research demonstrating that targeted interventions can produce meaningful reductions in subjective pain experiences.

Blood Pressure Management

Both systolic and diastolic blood pressure showed statistically significant reductions following the intervention. The mean decrease in systolic pressure (10.65 mmHg, $p = .001$) and diastolic pressure (5.95 mmHg, $p = .002$) suggests potential cardiovascular benefits of the intervention. These results are particularly noteworthy as they indicate that the intervention may have broader physiological effects beyond pain management. The blood pressure reductions observed are clinically meaningful and could contribute to reduced cardiovascular risk in participants.

Functional Performance Status

The Karnofsky Performance Status (KPS) scores universally improved across all participants, as evidenced by the Sign Test results ($p < .001$). The absence of any negative changes or ties indicates consistent positive outcomes, suggesting that the intervention enhanced participants' functional capacity and overall performance status. This uniform improvement is particularly significant as it demonstrates the intervention's reliability and effectiveness across the entire sample.

Gender Distribution and Non-significant Associations

The sample was predominantly female (85%), which may reflect the target population's characteristics or recruitment patterns. Importantly, chi-square analyses revealed no significant associations between sex and intervention outcomes (all $p > .05$). This finding suggests that the intervention's effectiveness was not moderated by participant sex, indicating potential applicability across gender groups. However, the small number of male participants (n=3) limits definitive conclusions about gender effects, and future research with more balanced samples would be valuable.

LIMITATIONS

Several limitations should be acknowledged. First, the small sample size (N=20) and unbalanced gender distribution may limit generalizability. The predominantly female sample restricts our ability to draw firm conclusions about intervention effects in males. Second, the study appears to lack a control group, which limits causal inferences about the intervention's specific effects versus natural time-related changes or placebo effects. Third, the absence of follow-up data prevents assessment of long-term intervention sustainability.

Clinical Implications

Despite these limitations, the findings have important clinical implications. The significant improvements in pain, blood pressure, and functional status suggest that this intervention could be integrated into clinical practice for managing these outcomes. Healthcare providers may consider this approach as a viable option for patients experiencing similar conditions. The consistent positive outcomes across all participants indicate good treatment reliability.

Future Directions

Future research should include larger, more diverse samples with balanced gender representation. Randomized controlled trials with appropriate control groups would strengthen causal claims. Long-term follow-up studies are needed to assess intervention durability. Additionally, investigating potential mediating mechanisms could enhance theoretical understanding and optimize intervention protocols.

CONCLUSION

This study provides compelling evidence for the effectiveness of the intervention in improving pain perception, blood pressure parameters, and functional performance status. All three paired t-tests demonstrated statistically significant pre-

post differences (all $p \leq .002$), with the pain reduction showing particularly strong effects ($p < .001$). The universal improvement in Karnofsky Performance Status scores across all participants further validates the intervention's positive impact.

The intervention's benefits appear consistent across participants regardless of sex, though the small sample size necessitates cautious interpretation. The concurrent improvements in subjective (pain, functional status) and objective (blood pressure) measures suggest multifaceted intervention benefits that extend beyond single-domain effects. While acknowledging limitations including small sample size and lack of control group, these findings support the intervention's potential clinical utility. The statistically significant and clinically meaningful improvements observed warrant further investigation through larger-scale randomized controlled trials. Such research would help establish the intervention's efficacy more definitively and explore its potential for broader clinical implementation. In summary, this pilot study demonstrates promising results that justify continued research and suggest potential value for clinical practice in managing pain, cardiovascular parameters, and functional performance.

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