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# Assessing the Therapeutic Effectiveness of Gnaphalium Polycephalum in Cases of Sciatica: A Single-Blind Randomised Placebo-Controlled Study

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**ABSTRACT :**

Background: Sciatica is characterised by pain radiating along the sciatic nerve and may be accompanied by numbness, paraesthesia, weakness and limitation of daily activities. Although conventional management can relieve symptoms, response varies and recurrence and treatment-related adverse effects remain concerns. In homoeopathic materia medica, Gnaphalium polycephalum is traditionally associated with sciatic neuralgia, especially when pain and numbness alternate. Objective: To evaluate the therapeutic effect of Gnaphalium polycephalum in patients with sciatica and to compare the response with placebo using the Visual Analogue Scale (VAS) and Sciatica Bothersome Index (SBI). Methods: A single-blind, randomised, placebo-controlled, two-arm interventional study was carried out at Swasthya Kalyan Hospital, Swasthya Kalyan Homoeopathic Medical College and Research Centre, Jaipur. Of 80 patients screened, 74 met the eligibility criteria and were allocated equally to Group A (Gnaphalium polycephalum 30C/200C) and Group B (identical placebo), with 37 participants in each arm. One participant from each group was lost to follow-up, leaving 72 participants for analysis (36 per group). VAS was the primary outcome and SBI the secondary outcome; both were assessed at baseline and after 12 weeks. Within-group changes were examined with the Wilcoxon signed-rank test, while between-group comparisons were made using the Mann-Whitney U test. Results: Group A showed a reduction in mean VAS from 5.00 +/- 1.49 to 2.58 +/- 0.81 and in mean SBI from 10.28 +/- 4.66 to 5.39 +/- 2.13 (both W+ = 666, $p < 0.001$). In Group B, mean VAS fell from 5.33 +/- 1.94 to 2.75 +/- 0.87 and mean SBI from 10.25 +/- 5.91 to 5.56 +/- 2.72 (both W+ = 666, $p < 0.001$). Between-group comparisons were not statistically significant for post-treatment VAS (U = 566, p = 0.322), post-treatment SBI (U = 632, p = 0.860), VAS change scores (U = 643.5, p = 0.962), or SBI change scores (U = 584.5, p = 0.471). Conclusion: Symptoms improved significantly within both groups during the 12-week study period, but Gnaphalium polycephalum was not statistically superior to placebo in this sample. Larger multicentric studies with improved allocation concealment, longer follow-up and objective diagnostic measures are warranted.

**Keywords:** Homoeopathy; Sciatica; Gnaphalium polycephalum; Visual Analogue Scale; Sciatica Bothersome Index; Randomised placebo-controlled trial

## 1. Introduction

Sciatica refers to pain that radiates from the lumbosacral region through the buttock and into the lower limb along the distribution of the sciatic nerve. Patients may also report paraesthesia, numbness, reduced sensation, motor weakness and difficulty with normal activities. In clinical practice the term is often used as a diagnosis, although it more accurately describes a group of symptoms caused by irritation or compression of the lumbosacral nerve roots or the sciatic nerve (Deyo & Mirza, 2016; Valat et al., 2010).

Sciatica can considerably affect mobility, sleep, work and everyday functioning, particularly because it is common among adults of working age. Reported epidemiological figures vary according to the diagnostic criteria used. Lifetime prevalence has been estimated at roughly 10%-40%, while annual incidence in adults is reported to be about 1%-5% (Konstantinou & Dunn, 2008).

Lumbar disc herniation, most often at the L4-L5 or L5-S1 level, is a frequent cause of sciatica and may lead to nerve-root compression, inflammation and abnormal neural discharge. Other recognised causes include degenerative lumbar spinal stenosis, spondylolisthesis, piriformis syndrome and extra-spinal pathology. Mechanical compression alone does not explain all symptoms; inflammatory mediators from herniated nucleus pulposus can sensitise the nerve roots and dorsal root ganglion, contributing to the burning, shooting or electric character of radicular pain (Brisby, 2006; Valat et al., 2010).

Management commonly involves analgesics, non-steroidal anti-inflammatory drugs, medicines for neuropathic pain, physiotherapy, epidural steroid injections and, in selected patients, surgery. Many patients improve with conservative treatment, but drug-related adverse effects and recurrent symptoms remain important limitations. Discectomy may provide earlier relief in appropriately selected cases, although long-term outcomes are not consistently better than those achieved with conservative management (Foster et al., 2018; Lurie et al., 2014). This has encouraged continued evaluation of complementary approaches that are safe, affordable and supported by appropriate clinical methods.

## 2. Study Need and Rationale

Homoeopathic materia medica describes Gnaphalium polycephalum as having a particular relationship with sciatic nerve pain. A characteristic indication is severe neuralgic pain alternating with numbness along the same distribution. Cramps of the calves and feet are also described, together with aggravation from lying down or walking and relief from flexing the thigh towards the abdomen (Allen, 2004; Boericke, 2007; Clarke, 2003).

Controlled clinical evidence specifically examining this medicine remains limited. Published homoeopathic studies of sciatica have largely used observational designs or individualised prescriptions, making it difficult to determine the effect of Gnaphalium polycephalum alone. Patel et al. (2021) observed improvement among patients receiving Gnaphalium, but the pre-post design could not distinguish a treatment effect from the natural course of the condition, regression to the mean or placebo response. Das et al. (2024) reported a double-blind placebo-controlled trial of individualised homoeopathic medicines for sciatica; however, Gnaphalium polycephalum was not studied as the sole intervention.

Against this background, the present dissertation-based study examined whether a pre-selected single medicine, Gnaphalium polycephalum, produced a measurable benefit in sciatica compared with a visually identical placebo. Pain intensity was assessed with the VAS, while the SBI was used to evaluate the degree to which sciatica-related symptoms troubled the participants.

## 3. Materials and Methods

### *3.1 Study design and setting*

The study used a single-blind, randomised, placebo-controlled, two-arm interventional design and was conducted at Swasthya Kalyan Hospital, a unit of Swasthya Kalyan Homoeopathic Medical College and Research Centre, Jaipur, Rajasthan. Participants were recruited through the Department of Materia Medica OPD. The overall study period was 12 months. Each participant was followed for 12 weeks, with scheduled assessments at 4, 8 and 12 weeks and additional visits when clinically required.

### *3.2 Participants and sample size*

Sample size was calculated for two independent parallel groups with a two-tailed alpha of 0.05 and 80% power. Using previous observational data and an assumed clinically meaningful difference between groups, the minimum requirement was estimated as 33 participants in each arm. Allowing approximately 10% for attrition, 74 participants were enrolled, with 37 assigned to each group.

Eighty patients presenting with clinical features suggestive of sciatica were screened. Six were not enrolled because they either failed to meet the eligibility criteria or declined consent. The remaining 74 participants were allocated equally between Group A and Group B. During follow-up, one participant from each arm dropped out. The final analysis therefore included 72 participants, 36 in each group.

### *3.3 Eligibility criteria*

Participants were eligible if they had clinical features consistent with sciatica (ICD-10: M54.3), unilateral or bilateral pain radiating from the lumbosacral region along the sciatic distribution, and a positive Straight Leg Raising test between 30 and 70 degrees that reproduced the characteristic radiating leg pain. They also had to provide written informed consent, agree to three months of follow-up and, where applicable, discontinue analgesic treatment after an appropriate washout period.

Patients were excluded when urgent surgical management was indicated or when major systemic illness could interfere with participation or assessment. Exclusion criteria included uncontrolled diabetes mellitus, active malignancy, severe hepatic or renal insufficiency, immunocompromised status, pregnancy or lactation, unwillingness to discontinue concurrent active treatment for sciatica, and inability or unwillingness to comply with follow-up.

### *3.4 Allocation, blinding and interventions*

Allocation was performed in a 1:1 ratio using odd and even OPD registration numbers, as specified in the study protocol. Participants in Group A received Gnaphalium polycephalum in 30C or 200C potency, selected according to clinical assessment and patient susceptibility, and dispensed on medicated globules. Group B received unmedicated lactose globules matched for appearance, colour, taste and labelling. Participants were unaware of their group assignment, and the research assistant recording outcome measures did not have access to allocation details. The treating physician remained aware of treatment allocation for clinical monitoring; accordingly, the trial was single-blind.

In Group A, repetition of the medicine was based on clinical response and Kentian principles. Doses were withheld while improvement continued, whereas repetition or a change in potency could be considered if improvement stopped or symptoms returned. The protocol did not permit a change to another homoeopathic medicine. If a different remedy became clinically necessary, the participant was to be withdrawn from the trial and managed separately. Both groups received general advice on posture, avoidance of heavy lifting and aggravating positions, hydration, balanced diet and smoking cessation where applicable.

### *3.5 Outcome measures*

Pain intensity measured with the Visual Analogue Scale (VAS) served as the primary outcome. The Sciatica Bothersome Index (SBI) was used as the secondary outcome to assess the burden of sciatica-related symptoms. The SBI includes leg pain, numbness or tingling, weakness of the leg or foot, and back or leg pain during activity. Each item is scored from 0 to 6, producing a total score of 0-24; higher scores represent greater symptom burden (Verma et al., 2019).

### *3.6 Statistical analysis*

Data distribution was examined with the Shapiro-Wilk test. As post-treatment outcomes did not satisfy normality assumptions and the scales were ordinal or quasi-ordinal, non-parametric tests were selected. Pre- and post-treatment scores within each group were compared using the Wilcoxon signed-rank test. Post-treatment values and change scores between groups were compared using the Mann-Whitney U test. All tests were two-tailed and statistical significance was set at 0.05. Mean +/- standard deviation is presented descriptively to show the magnitude of change.

**Table 1. Summary of study design and participant flow**

| Parameter | Description |
|---|---|
| Study design | Single-blind, randomised, placebo-controlled, double-arm interventional study |
| Setting | Swasthya Kalyan Hospital, Swasthya Kalyan Homoeopathic Medical College and Research Centre, Jaipur |
| Screened | 80 patients with clinical features of sciatica |
| Excluded before recruitment | 6 patients |
| Recruited and allocated | 74 participants: 37 in Group A and 37 in Group B |
| Dropouts | 2 participants: 1 from each group |
| Final analysis | 72 participants: Group A n = 36; Group B n = 36 |
| Group A | Gnaphalium polycephalum 30C/200C medicated globules |
| Group B | Identical placebo: unmedicated lactose globules |
| Primary outcome | Visual Analogue Scale (VAS) |
| Secondary outcome | Sciatica Bothersome Index (SBI) |
| Follow-up endpoint | 12 weeks |

## 4. Results

### *4.1 Participant profile*

Among the 80 patients screened, 74 entered the study and 72 completed the planned follow-up. Participants included both men and women, with many being married adults and belonging to lower socioeconomic groups. Right-sided sciatica was commonly recorded in both study arms. In the active-treatment group, 30C and 200C were the main potencies prescribed according to patient susceptibility.

### *4.2 Within-group outcomes*

VAS and SBI scores decreased significantly from baseline to 12 weeks in both groups. In Group A, mean VAS fell from 5.00 +/- 1.49 to 2.58 +/- 0.81, a reduction of 2.42 points (48.4%). Mean SBI decreased from 10.28 +/- 4.66 to 5.39 +/- 2.13, a reduction of 4.89 points (47.6%).

Group B showed a similar pattern. Mean VAS declined from 5.33 +/- 1.94 to 2.75 +/- 0.87, corresponding to a reduction of 2.58 points (48.4%). Mean SBI fell from 10.25 +/- 5.91 to 5.56 +/- 2.72, a reduction of 4.69 points (45.8%). All within-group comparisons were significant on the Wilcoxon signed-rank test ($W+ = 666$, $p < 0.001$). These results show improvement during follow-up in both arms; they do not, by themselves, demonstrate an advantage of the active treatment over placebo.

**Table 2. Within-group comparison of VAS and SBI scores**

| Group | Outcome | Baseline mean +/- SD | 12-week mean +/- SD | Mean change | % change | Wilcoxon W+ | p-value |
|---|---|---|---|---|---|---|---|
| Group A | VAS | 5.00 +/- 1.49 | 2.58 +/- 0.81 | -2.42 | -48.4% | 666 | <0.001 |
| Group A | SBI | 10.28 +/- 4.66 | 5.39 +/- 2.13 | -4.89 | -47.6% | 666 | <0.001 |
| Group B | VAS | 5.33 +/- 1.94 | 2.75 +/- 0.87 | -2.58 | -48.4% | 666 | <0.001 |
| Group B | SBI | 10.25 +/- 5.91 | 5.56 +/- 2.72 | -4.69 | -45.8% | 666 | <0.001 |

### *4.3 Between-group outcomes*

At 12 weeks, the mean VAS score was 2.58 +/- 0.806 in Group A and 2.75 +/- 0.874 in Group B. Although the value was slightly lower in Group A, the difference was not statistically significant ($U = 566$, $p = 0.322$). Mean SBI was 5.39 +/- 2.13 in Group A and 5.56 +/- 2.72 in Group B, again without a significant between-group difference ($U = 632$, $p = 0.860$). Comparison of change scores also showed no significant difference for VAS ($U = 643.5$, $p = 0.962$) or SBI ($U = 584.5$, $p = 0.471$).

Thus, participants in both arms experienced symptomatic improvement, but the analysis did not demonstrate that Gnaphalium polycephalum was superior to placebo in this sample.

**Table 3. Between-group comparison of post-treatment outcomes**

| Outcome | Group A mean +/- SD | Group B mean +/- SD | Between-group difference | Mann-Whitney U | p-value | Interpretation |
|---|---|---|---|---|---|---|
| VAS | 2.58 +/- 0.806 | 2.75 +/- 0.874 | -0.17 | 566 | 0.322 | Not significant |
| SBI | 5.39 +/- 2.13 | 5.56 +/- 2.72 | -0.17 | 632 | 0.860 | Not significant |
| VAS change score | Change favoured neither group | Change favoured neither group | - | 643.5 | 0.962 | Not significant |
| SBI change score | Change favoured neither group | Change favoured neither group | - | 584.5 | 0.471 | Not significant |

### *4.4 Degree of improvement*

Improvement was categorised according to percentage reduction in score: marked improvement was defined as a reduction of 75% or more, moderate improvement as 50% to less than 75%, mild improvement as 25% to less than 50%, status quo as 0% to less than 25%, and worsening as any increase in score. In Group A, VAS improvement was most often moderate, whereas SBI improvement was more commonly mild. In Group B, two participants achieved marked improvement on VAS; SBI improvement was generally mild or moderate, with no participant showing marked SBI improvement.

**Table 4. Degree of improvement by outcome measure**

| Group | Outcome | Marked n (%) | Moderate n (%) | Mild n (%) | Status quo/worse |
|---|---|---|---|---|---|
| Group A | VAS | 0 (0.00) | 21 (58.33) | 15 (41.67) | 0 |
| Group A | SBI | 0 (0.00) | 15 (41.67) | 21 (58.33) | 0 |
| Group B | VAS | 2 (5.56) | 16 (44.44) | 18 (50.00) | 0 |
| Group B | SBI | 0 (0.00) | 13 (36.11) | 23 (63.89) | 0 |

## 5. Discussion

This study examined Gnaphalium polycephalum in sciatica under placebo-controlled conditions, based on its traditional homoeopathic symptom picture. The medicine is particularly associated in materia medica with sciatic neuralgia in which pain alternates with numbness. Despite this long-standing clinical indication, controlled evidence evaluating Gnaphalium as a specific intervention remains limited.

Both groups improved between baseline and the 12-week assessment. The active-treatment group showed substantial reductions in VAS and SBI scores, but the placebo group improved to a comparable extent. Because the principal question in a placebo-controlled trial is whether outcomes differ between groups, the absence of significant between-group differences means that a specific treatment advantage for Gnaphalium polycephalum was not demonstrated for either pain intensity or symptom-related bother.

The within-group findings therefore need to be interpreted with care. A significant change over time indicates that participants improved during follow-up, but it cannot establish that the active medicine was responsible for more improvement than placebo. Sciatica has a variable natural course, and symptoms may lessen over several weeks with time, rest, advice, therapeutic contact, expectation or regression toward the mean. In this study, Gnaphalium polycephalum was associated with improvement over time, but its effect did not differ significantly from placebo.

The findings nevertheless add remedy-specific clinical data to a field in which such controlled evidence is scarce. The study also used patient-centred measures addressing both pain intensity and the burden of sciatica-related symptoms. Importantly, interpretation of the results should be based on the between-group comparison rather than on within-group significance alone.

Several methodological factors may have influenced the findings. The sample may not have been large enough to detect a small treatment effect. In addition, use of one fixed medicine rather than fully individualised prescribing may have reduced the likelihood that every participant received the closest indicated remedy. Allocation by odd and even registration numbers is more predictable than computer-generated randomisation with concealed allocation. The outcomes were based on patient-reported scales, and a 12-week follow-up may be insufficient to assess recurrence, persistence of benefit or delayed changes.

From a homoeopathic clinical perspective, Gnaphalium polycephalum may still be considered when its characteristic symptom pattern is present, including alternating sciatic pain and numbness, calf cramps, aggravation from lying or walking and relief from flexion. The present results, however, do not support a claim that the medicine is superior to placebo for an unselected population of patients with sciatica.

## 6. Strengths and Limitations

### *6.1 Strengths*

- Placebo-controlled two-arm design with pre-specified active and placebo groups.
- Use of clinically relevant outcome measures: VAS for pain and SBI for sciatica-specific symptom bother.
- Twelve-week follow-up allowing assessment beyond immediate symptomatic fluctuation.
- Use of non-parametric statistical methods using non-parametric tests appropriate for non-normal outcome distributions.
- No adverse events were recorded during the three-month treatment period.

### *6.2 Limitations*

- Sample size was modest, limiting power for subgroup analysis and smaller effect detection.
- Allocation by odd-even registration number is less rigorous than computer-generated randomisation with concealed allocation.
- The treating physician was not blinded, so the study was single-blind rather than double-blind.
- VAS and SBI are patient-reported outcomes and may be influenced by expectation, attention and reporting bias.
- Objective diagnostic and prognostic measures such as MRI grading and nerve conduction studies were not uniformly incorporated into the outcome analysis.
- Only one pre-specified medicine was studied; therefore, findings cannot be generalised to fully individualised homoeopathic management of sciatica.

## 7. Conclusion

After 12 weeks, statistically significant reductions in pain intensity and symptom-related bother were observed within both the Gnaphalium polycephalum and placebo groups. Between-group analysis, however, found no statistically significant advantage for the active treatment in post-treatment VAS, post-treatment SBI, or their change scores. On the basis of these data, Gnaphalium polycephalum was associated with symptomatic improvement during follow-up, but superiority over placebo was not demonstrated.

Further research should use larger multicentric samples, double blinding, computer-generated randomisation with concealed allocation, longer follow-up and objective diagnostic measures where feasible. It may also be useful to examine whether patients showing the characteristic Gnaphalium symptom pattern, particularly sciatic pain alternating with numbness, respond differently from a broader sciatica population.

## Ethical Considerations

The dissertation states that written informed consent was obtained from all participants and that approval was granted by the Institutional Review Committee of Swasthya Kalyan Homoeopathic Medical College and Research Centre, Jaipur. It also reports registration with the Clinical Trials Registry of India before enrolment. The IRC approval number and date, along with the CTRI registration number, should be added before final submission if available.

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The dissertation draft reports no external funding. This statement should be confirmed by the authors before submission.

## Conflict of Interest

A conflict-of-interest statement should be completed before submission. If there are no conflicts to declare, the authors may state that no conflict of interest exists.

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