RESEARCH PAPER

Evidence-Based Clinical Study On Pain Management Of Sciatica With Organ-Specific Homoeopathic Medicines- An Original Article

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ABSTRACT: Background- Radiating leg pain, a common variety of low-back pain has an increasing lifetime prevalence up to 1.6 to 43% leading to severe pain and disability in patient's life. Rapid visits in out-patients department for its pain management with analgesics, NSAIDS, corticosteroids, muscle relaxants, and other biological agents neither support their efficacy nor tolerability of these therapeutics. Surgical approach to sciatica were rather controversial for its cost-effectiveness as well was its effectivity which doesn't last for two year or less. Homeopathic clinical trials has mostly emphasize on low-back pain and lumbar spondylosis, with limited studies specifically on sciatica. With very few evidence-based clinical trials exploring the innovative non-conventional approaches for sciatica. This clinical study targets to evaluate the effectiveness of organ-specific homeopathic remedies in managing sciatica pain.

Aims and Objectives- To assess the effectiveness of organopathic homoeopathic medicines in managing pain of sciatica.

METHODS: This is a non-randomized single-arm interventional study of one and half year carried out in Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Research centre, Pune. A positive SLR examination and radiological diagnosed patient of sciatica were included for this trial. A total of 35 patients received organ-specific homeopathic drugs. Of them, 32 finished their follow-ups and 03 patients were drop-out.

At each visits, Wong-Baker's Faces Pain Rating Scale for their pain intensity were noted as well as the associated debilitating symptoms. The organopathic drugs received by the subjects include hypericum, gaultheria, colocynth, gnaphalium and Rhus tox.

RESULT: A total of 32 patients were studied for this study. After analysis, the average score(mean) of WBFPS on the first day of treatment was 6.69±1.58 i.e. before treatment and after score of the last day of follow-up showed pain reduction with 2.44±2.48 . The test statistic in this case is statistically highly significant (Z=-4.682) with a p-value <0.05. The results suggest significant decrease in the average WBFPS of patients in the treatment of sciatica with organ-specific homoeopathic medicine.

CONCLUSION: In this study, organ-specific homoeopathic medicines showed sustained improvement in sciatica pain in a period of three-month duration. However, there is recurrence in few subjects. Additionally, there was reduction in tingling and numbness and other disability of sciatica. These results support the use of complementary organ-specific homoeopathic medicines in routine clinical practice in treating sciatica. A longer duration study with various study designs will increase strength of the study and yield more effective result.

KEYWORD: Sciatica, discogenic and non-discogenic sciatica, lumbar spondylosis, sciatica clinical trials, systemic review, homoeopathy, gnaphalium, hypericum, gaultheria, rhus tox, colocynthis.

How to cite this article: Yumnam M, Nerlekar MA. Evidence-based clinical study on pain management of sciatica with organ-specific homoeopathic medicines- an original article. Int J Drug Deliv Technol. 2026;16(11s): 795-802. DOI: 10.25258/ijddt.16.11s.81

INTRODUCTION:

Sciatica refers to the pain caused by irritation, compression or injury to sciatic nerve, typically characterized by unilateral radiating pain in a dermatomal pattern. Usually associated with sensory symptoms such as tingling/numbness and other functional limitations. It comes under ICD 11- ME 84.3. Sciatica or back-related leg pain is a common variation of Low-Back Pain with life-time incidence of 1.6% up to 43%.[8]

Also termed as lumbosacral radiculopathy/nerve root entrapment or irritation, a clinical pathognomonic entity typically presenting with radiating pain in sciatic nerve dermatomal pattern with shooting, burning or shock like pain which may be continuous or brought on by spinal movements or straining along with presentation of minimum or least accompanying signs of approximately around 12% with neurological findings such as myotomal weakness, hyporeflexia with negative Babinski sign and other sensory disturbances, both negative(numbness) as well as positive(tingling, burning, electric shock-like) sensory symptoms.[1]

A proper clinical history which distinguish from non-specific low back pain with its pathognomonic dermatomal features and examinations such as positive straight leg raising test (SLR test) and imaging studies suggesting of nerve-root compression can help in determining diagnosis and the causes of sciatica, but testing is not necessary in a typical case until intervention is required.[2]

Clinical protocol recommended stepwise approach for sciatica initiating with conservative or nonoperative treatment such as muscle-strengthening exercises, including spinal manipulative therapy (SMT) followed by pharmacological and interventional approaches including oral and epidural steroid injection, along with self-care education. Patient refractory to treatment with positive radiological findings consistent with their symptom, surgery can be considered with any approach either discectomy, percutaneous disc decompression or chemonucleolysis.[2,7]

Uses of standard typical treatment which focuses on reduction of pain either by employment of NSAIDs, analgesics, biological agents targeting neurotrophic factors, or by using epidural steroid injection does not show clinically diminished pain intensity for upto 3 months,or either low-evidence to support their efficacy and tolerability in primary care. Several studies reported surgical approaches such as discectomy effective in fast reduction of pain intensity and disability, but last approximate only till 12 months.[7,5,3]

Homoeopathic research mainly focuses primarily on low-back pain and lumbar spondylosis, but not typically sciatica. And until now, there is less studies on evidence-based clinical trials based on innovative non-conventional approach for sciatica. This clinical study aimed at evaluating the efficacy of homoeopathic medicines, particularly organ-specific homoeopathic remedy which target in the conservative management of sciatica pain.[4]

HOMOEOPATHIC APPROACHES USING ORGAN-SPECIFIC HOMOEOPATHIC REMEDIES FOR SCIATICA:

Organ-specific homeopathic remedies are certain remedies which have a specific affinity for certain organs. It is a way of using a localized, targeted and specific symptom-similarity using the specific/pathological totality of the all the symptoms of the affected organ, tissue or its function along with its modalities to choose a remedy. It is a form of treatment where the locality of the symptoms and its relation to the affected organ choose the remedy. It is simply homoeopathy specificity of drug action.[39]

HYPERICUM- Indicated in Sciatica with radiating shooting pain up spine down the limbs. Left-sided neuritis with tingling, burning pain and numbness. Aching along sciatica nerve with prolonged sitting.[34]

Several studies have shown that HP provided neuroprotective, anti-inflammatory and anti-nociceptive and analgesic effects in experimental mice with sciatic nerve injury model.[17]

COLOCYNTHIS- Sciatic pain, left-side, drawing and tearing; better by pressure and heat. Intense neuralgic pain, so severe that the patient is unable to keep still. Long-lasting action on large nerves, especially sciatic and spinal nerves.[34,35]

Extracts of Citrullus colocynth exhibit both analgesic as well as anti-inflammatory properties at different quantities/doses without inducing any acute toxicity.[26,27,17]

GNAPHALIUM- A remedy for unquestionable benefit for sciatica pain which is associated by numbness of affected part. Sciatica and lumbago with numbness alternating with pain. Intense pain along sciatic nerve. Sharp. shooting pain or electric like sensation down the back of the legs.[34,35,36]

Biological studies have demonstrated anti-oxidants, anti-inflammatory and other activities of the extracts and chemical constituents of Gnaphalium.[19,25]

GAULTHERIA-Sciatica and other neuralgia come within the sphere of this remedy with intense sharp, shooting pain. Violent neuralgic pain; pain extends from hip down through spine with persistent pain.

Gaultheria's oil contains methyl salicylate which has anti-rheumatic mechanism and remarkable analgesic. Methy salicylate has anti-inflammatory rheumatic mechanism as well as its lignane showing marked anti-inflammatory properties.[35,22]

RHUS TOX- Sciatica, worse cold, damp weather, at night. Backache, as if back will break, compelling him to move constantly in bed. During advance course of affection; stinging, burning, tearing pain, formication

and paralytic stiffness of limb, increases during rest, relieved only for short time by motion.

Studies shows neuroprotective effect of Rhus Tox suggests involvement of anti-oxidative and anti-inflammatory mechanism[34,35,24]

MATERIALS AND METHODS:

DESIGN: Non-randomized single-arm interventional study. A Prospective interventional study was carried out in the outpatient of medicine department of Bharati Vidyapeeth Homoeopathic Hospital and research centre, Pune, India.

STUDY REGISTRATION: Trial registered prospectively on 20/03/2024 in The Clinical Trial Registry-India (CTRI) for the protocol -trial registration number- CTRI/2024/03/064476.

ETHICS APPROVAL: The institutional ethics committee (IEC) gave its approval letter to the study protocol with ref: Protocol No.BVDUHMC/2023/02. The protocol obeyed with Good Clinical Practice. Before enrollment, all the patients received an informed consent form in English as well as the regional vernacular, Marathi and gave their consent signature.

ELIGIBILITY CRITERIA

INCLUSION CRITERIA:

- Patient with diagnosed case of sciatica.
- Patient of both sexes of the age group 25-65 yrs.
- Patient who are willing to give consent.

EXCLUSION CRITERIA:

- Patient below 25 years and above 65 years are excluded.
- Excluding patient presenting with RED FLAGS (such as cauda equina compression cancer, spinal fracture, infections).
- Peripheral neuropathy cases will be excluded.
- Pregnant women will be excluded in this study.
- Patient presenting with complications of sciatica will be excluded.

Study duration and timeline - For one and half year. Every case was monitored with regular five follow-ups for roughly three months. Wong-Baker's Faces Pain Rating Scale were used to assess their before and after treatment pain intensity

Withdrawal Criteria: Followed treatment algorithm for radiculopathy, patients with red flags in the 4th and 6th week were exempted from study and referred for imaging modalities and surgeons if needed.

STUDY MEDICATIONS Organ-specific homoeopathic medicines; **Gnaphalium, colocynthis, Hypericum, Gaultheria and Rhus tox.**

After proper case taking and evaluation, organ-specific homoeopathic medicines on the basis of symptom similarity were administered in different potencies.

OUTCOME MEASURES:

PARAMETERS USED: The Wong-Baker's Faces Pain Rating scale is a self-assessment tool that can help people communicate about their physical pain. It uses a combination of faces, numbers, and words, providing multiple ways for a person to express their pain level

The scale contains a series of six faces ranging from a happy face at 0 to indicate "no hurt" to a crying face at 10 to indicate "hurts worst" with the numbers increasing in intervals of 2. Each number relates to both a face and a small descriptive phrase. It is flexible because if someone uses the numbers, they may not need the faces or the wording.

Study flowchart:

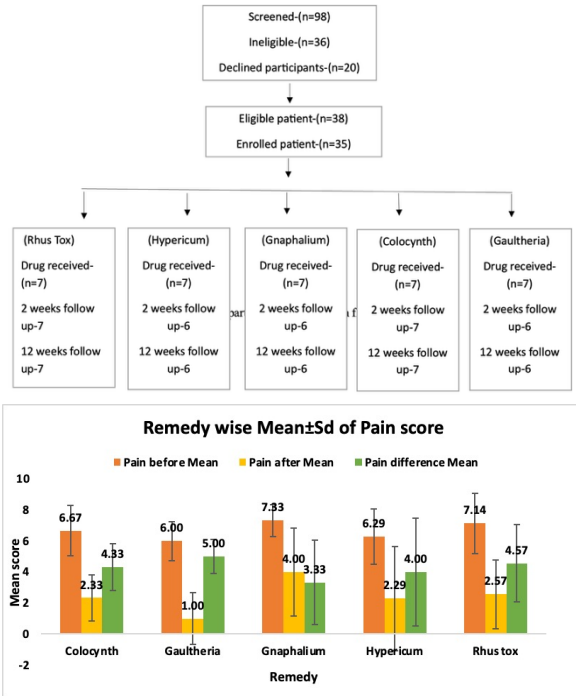

Fig. Patient participation and attrition flowchart

RESULTS AND OBSERVATIONS:

STATISCAL METHODS

For the Wilcoxon signed rank test, the Pain score difference was calculated using the difference for initial allotment score and final score after treating the patient. Ranking is applied to the absolute differences.

Negative ranks were calculated for the Pain score after treatment < Pain score before treatment. Positive ranks were calculated for the Pain score after treatment > Pain score before treatment. The tie was calculated for the pain score after last follow-up = Pain score before prescription/treatment.28 pairs of observations have negative ranks, and 4 pairs of observations have ties in the observations.

Here, the test statistic, Z=-4.682, with a p-value <0.05, is statistically highly significant.

There is significant difference between the pain Score before and after treatment.

Before the treatment, the median (IQR) pain was scored as 6(2). After final study, the median (IQR) pain score significantly reduced to 2(4).

The mean±sd of pain score (WBPFS) was 6.69±1.58 before treatment, reduced to 2.44±2.48 after treatment.

Table 1: Remedy-wise Pain score of patients.

REMEDY	N	Pain before Mean ±Sd	Pain after Mean ±Sd	Pain difference Mean ±Sd
Colocynth	6	6.67±1.63	2.33±1.51	4.33±1.51
Gaultheria	6	6.00±1.27	1.00±1.67	5.00±1.10
Gnaphalium	6	7.33±1.03	4.00±2.83	3.33±2.73
Hypericum	7	6.29±1.80	2.29±3.35	4.00±3.46
Rhus tox	7	7.14±1.95	2.57±2.23	4.57±2.51

Comparing the effectiveness of five organ-specific homeopathic remedies by evaluating changes in reported pain levels before and after treatment. Each remedy was prescribed on either 6 or 7 patients, with provided mean values and standard deviations. Each Organ-specific remedy affecting sciatica demonstrated a measurable decrease in mean pain levels. Gaultheria and Rhus tox showed the highest mean pain reduction; Gaultheria (5.00 ± 1.10) and Rhus tox (4.57 ± 2.51) and followed by Colocynth (4.33 ± 1.51). Remedies like Hypericum showed favourable outcomes with mean reduction (4.00+/-2.29). And with Gnaphalium exhibiting higher standard deviations.

Table 2: Frequency distribution of Causative factor

Causative factor	sub category	Number of patients	Percentage	Cummulative Percentage
PIVD-related	PIVD L4-L5, PIVD L4-S1 with root compression, facetal-arthropathy, annular tear	16	45.70%	45.70%
Degeneration /Spondylosis	Lumbar-spondylosis,L4-L5, L3-L5 degeneration	6	17.10%	62.80%
Disc space narrowing	Reduced disc space L3-L5, L4-L5 .	3	8.60%	71.40%
Spinal canal stenosis	Lumbar canal stenosis, focal canal stenosis, moderate stenosis	3	8.60%	80.00%
Anterolisthesis /sacralization	Grade 1 anterolisthesis L4-L5, sacralization L5	3	8.60%	88.60%
Nonspecific /unclear	"unspecific" "non-discogenic"	2	5.70%	94.30%
Other combinations	Disc bulge with sacralization, bilateral spondylosis	2	5.70%	100.00%

Table 2 shows the Frequency distribution of the Causative factors of sciatica pain among 35 patients, and Figure 2 represents the Pareto chart of the Causative factors of sciatica pain.

PIVD-related with L4-L5,L4-S1 with root compression, facetal arthropathy, annular tear diagnosed in 16 out of 35 patients (45.70%), followed by disc-related degeneration and lumbar degeneration patterns (17.10%). Together, they contribute to almost 63% of causes of Sciatica pain, followed equally by Disc space narrowing (8.60%), spinal canal stenosis(8.60%) and anterolisthesis/sacralization (8.60%). Other causes, like disc bulge with sacralization, bilateral spondylosis, were observed in 2 patients (5.70%); the remaining 5.70% of patients had nonspecific(non-discogenic) causes for sciatica pain.

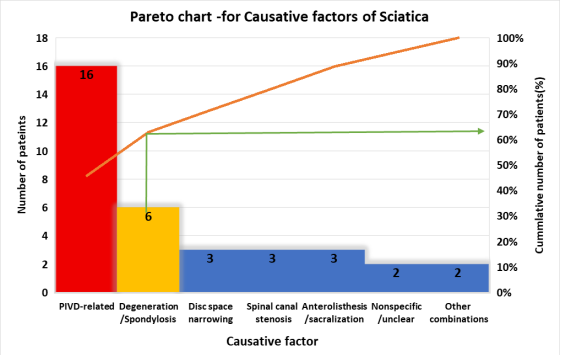

Figure 2: Pareto chart of the Causative factor

Demographic characteristics of patients

Table 3: Distribution of patients according to age

Age Group	No of patients	Percentage
25-34	6	17.14%
35-44	7	20.00%
45-54	12	34.29%
55-65	10	28.57%

- The age-wise distribution of patients among the participants,17.14% were aged 25–34 years, and 20.00% belonged to the 35–44 years category. The largest proportion,

34.29%, fell within the 45–54 years age group, followed by 28.57% in the 55–65 years bracket.

Table 4: Laterality Analysis in Sciatica Patients

LATERALITY	Number of patients	Percentage
Bilateral	1	2.86%
Left-sided sciatica	18	51.43%
Right-sided sciatica	16	45.71%

The analysis of laterality among patients presenting with sciatica symptoms. Left-sided sciatica was the most prevalent, affecting 51.43% of the patients. Right-sided sciatica followed closely, occurring in 45.71% of patients. Bilateral involvement was rare, seen in only 2.86% of patients.

Table 5: Distribution of Associated Complaints

Associate complaint	Number of patients	Percentage
Cramp lower limb	1	2.86%
Difficulty in movement	5	14.29 %
Difficulty walking	2	5.71%
Heaviness of thigh	4	11.43 %
No complaints	9	25.71 %
Tingling and numbness	10	28.57 %
Tingling and numbness +difficulty walking	1	2.86%
Tingling +difficulty lying down	1	2.86%
Tingling +difficulty walking	1	2.86%
weakness left foot	1	2.86%

Distribution of associated complaints among the participants; almost 26% of patients (9) had no associated complaints. Paresthesia were observed in majority of patients (28.57%) under observation, then by difficulty in movement (14.29%). 20% of patients in all both sensory and motor weakness including weakness of foot or cramp lower limb, tingling and numbness with difficulty walking and lying down.

Table 6: Summary of improvement in disability

Improvement in disability	Number of patients	Percentage
No	2	8.00%
No (recurrence)	3	12.00%
Slight improvement	2	8.00%
yes	18	72.00%

72.00% of the patients had improvement in the disability with associated complaints. Slight improvement was observed in 2 patients (8.00%). No improvement was observed in 8.00% of patients, whereas the remaining 12.00% of patients had improvement, and then there is recurrence of complaint.

Table 7: Distribution of analgesic usage

Use of analgesic	Number of patients	Percentage
No	29	90.63%
Yes	3	9.38%

The distribution of analgesic usage among 32 patients. Out of 35 patients, 3 patients dropped out during the study. Most patients (90.63%) did not use analgesics. Only 9.38% of the patients reported using analgesics.

Table 8: Distribution of adverse events

Adverse events	Number of patients	Percentage
Constipation	1	3.13%
NO	31	96.88%

The distribution of adverse events among 32 patients. Most patients (96.88%) had no adverse effects, whereas only 1 patient (3.13%) had a constipation problem during the treatment.

Discussion:

This research was carried out with patients who visited the outpatient medicine department of Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College and Hospital, Pune.

This clinical study consisted of 35 total patients, out of these 3 cases were drop-outs. Organ-specific homoeopathic medicine were prescribed to each participant. Regular five follow-up were conducted within 7-15 days according to the severity of pain and improvement.

The absolute difference between the Pain Score before and after treatment was executed and ranked using the Wilcoxon signed rank test**.** Prior to treatment, the mean±sd of pain score (WBPFS) was 6.69±1.58; following treatment, it was 2.44±2.48. The

test statistic in this case is statistically highly significant (Z=-4.682) with a p-value <0.05.

Remedy-wise Pain score of patients: The efficacy of five homeopathic organopathic treatments showed favourable improvement across the treatment. Gaultheria and Rhustox showed the highest mean pain reduction; Gaultheria (5.00 ± 1.10), and Rhus-tox (4.57 ± 2.51) and followed by Colocynth (4.33± 1.51). Among the associated complaints, majority of the patient had paraesthesia, followed by motor weakness with hyporeflexia, with 72% improvement in disability after treatment.

While many patients experience recurrence of symptoms. Certain lifestyle and postural factors, possible metabolic influence along with presence of multiple PIVD compressive radiculopathy aids to rapid recurrence of sciatica.

After thorough examinations of etiological factors of sciatica,63% have discogenic causes of sciatica, major being PIVD related causative factors, followed by

degenerative changes of lumbar spine, with disc space reduction with no compression of exiting nerve roots, spondylolisthesis with few cases of lumbar canal narrowing without red flag signs. Only 5.70% demonstrate non-discogenic causes of sciatica.

Age-wise demographic prevalence shows highest among the age group 45-55 years.17.4% falls under young adults with 25-35 years mostly with acute PIVD compressive radiculopathy.

The estimated gender-wise distribution in this study is 40% male and 60% female. Doesn't significantly support the higher prevalence of a single gender.

Among the patients, left-sided sciatica were most common among the patients, involving 51.43%. Right-sided sciatica being found not less common affecting 45.71% of patients. Only 2.86 percent of patients had bilateral involvement, which is usually a rare presentation, involves with lumbar canal stenosis affecting exiting roots on both sides. Despite the study's goal of reducing sciatica pain, few patients took analgesics. However, majority of patients did not take analgesics supporting its improvement with homoeopathic medicine. This study also confirms the tolerability of the medicines with no major adverse-events. Only one patient complained of a minor issue following the prescribed treatment. Constipation, a mild issue, which resolved on its own with dietary changes.

Hence, in this study for a duration of 3 month follow-up of 32 patients, we find supportive evidence that homoeopathic organopathic approaches for conservative management of sciatica showing positive results.

CONCLUSION:

This study demonstrated significant decrease in the average pain score WBFPS of patients in the treatment of sciatica with homoeopathic organ-specific remedies. Each remedy established a measurable decrease in mean pain levels, indicating a potential therapeutic effect across treatment validating organopathic approaches. In view of all this, effectiveness of homoeopathic organopathic drugs and its routine clinical use for conservative management of sciatica is supported

While further analysis demonstrated recurrence of symptoms in the last few follow-ups. Future clinical trials with longer duration opting multidisciplinary approach may yield more effective results specially in cases of sciatica with multiple nerve root (PIVD)radiculopathy.

LIMITATION: The limitation of our study is the minimum duration of study followed three months with only 5 follow-ups. There is unfulfilled assessment due to shorter study durations with rapid recurrence of complaints. Certain factors and conservative approach such as muscle strengthening exercises were exempted in this study. Study sample size is rather considered small.

ACKNOWLEDGEMENT:

Prof. Dr. Mrs Mrinal A Nerlekar, Professor, Practice of Medicine for her guidance and immense support enabling this trial to genuinely conduct successfully. Dr. Hrishikesh Badve, Orthopaedic surgeon for his expertise in disease diagnosis, clinical evaluation and analysis. The head of the institute and hospital are thanked by the authors for providing necessary facilities to conduct this study.

Funding: No external fundings were received

Disclosure statement: The authors have declared no conflict of interest.

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