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INDIVIDUALIZED HOMOEOPATHIC TREATMENT WITH *RHUS TOXICODENDRON* IN SCIATICA: CHANGES IN PAIN AND DISABILITY IN A PROSPECTIVE SINGLE-ARM INTERVENTIONAL STUDY

***Aysha Bushra M[1], Suman Sankar A S[2], Richa S K[3], Surya Gayathri V[4]**

[1]Aysha Bushra M, PG Scholar, Department of Repertory, Sarada Krishna Homoeopathic Medical College, Kulasekharam, Kanyakumari, Tamil Nadu, India

[2]Suman Sankar A S, Professor, Department of Repertory, Sarada Krishna Homoeopathic Medical College, Kulasekharam, Kanyakumari, Tamil Nadu, IndSia

[3]Richa S K, PG Scholar, Department of Repertory, Sarada Krishna Homoeopathic Medical College, Kulasekharam, Kanyakumari, Tamil Nadu, India

[4]Surya Gayathri V, PG Scholar, Department of Repertory, Sarada Krishna Homoeopathic Medical College, Kulasekharam, Kanyakumari, Tamil Nadu, India

*Corresponding Author's Email ID: dr.ayshamohammed@gmail.com

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Abstract

Background: Sciatica is a common cause of pain and disability in adults, most often due to lumbar disc disease or degenerative spinal change. Conventional treatment with NSAIDs, analgesics, muscle relaxants, corticosteroids and surgery is limited by recurrence and adverse effects, and other approaches merit study. Rhus toxicodendron is one of the remedies most frequently prescribed for sciatica in homoeopathy, but prospective data on its outcomes, measured with validated pain and disability instruments, are limited.

Objective: To assess changes in pain and functional disability over three months in patients with sciatica treated with individualized Homoeopathic medicine Rhus toxicodendron, and to observe the clinical course.

Methods: In this prospective single-arm interventional study, 30 patients aged 30-75 years presenting with sciatica at the OPD, IPD and peripheral centres of Sarada Krishna Homoeopathic Medical College were studied. Detailed case taking was carried out using the standardized chronic case format. Diagnosis was based on symptom presentation, physical and clinical examination and a positive Straight Leg Raising test, with X-rays in all patients and MRI wherever needed. The symptoms were repertorised using Synthesis Repertory 9.1 in RADAR Opus, and only patients in whom Rhus toxicodendron was the indicated remedy after repertorisation were included. Rhus toxicodendron was started in 30C potency, and repetition and change of potency to 200C or 1M, followed the Organon of Medicine and according to the susceptibility of the patient. Follow-up was every 15 days for three months. Pain was assessed before and after treatment with the Short-Form McGill Pain Questionnaire (Pain Rating Index, Present Pain Intensity and Visual Analogue Scale) and disability with the Modified Oswestry Disability Index (ODI). Scores were compared using the Wilcoxon signed-rank test.

Results: Of the 30 cases studied, the majority belonged to the age group of 30-59 years (86.67%), and females constituted 70% of the study population. Scores were lower after treatment in every patient: the mean Pain Rating Index fell from 27.13 ± 4.16 to 12.83 ± 7.91, VAS from 74.33 ± 5.04 mm to 39.67 ± 17.12 mm and ODI from 57.10 ± 6.74 to 20.13 ± 18.22 ($p < 0.001$). Nineteen cases (63.33%) showed marked improvement, 2 (6.67%) moderate, 6 (20.00%) mild and 3 (10.00%) no significant improvement. Marked improvement occurred in 16 of 17 cases with symptoms for under 12 months, compared with 3 of 13 with longer duration. Homoeopathic aggravation occurred in 1 case (3.33%) and transient new symptoms in 5 cases (16.67%).

Conclusion: Improvement in pain and disability was observed over three months in patients with sciatica treated with individualized Rhus toxicodendron, most notably in those with shorter disease duration. Because there was no control group, effectiveness cannot be established, and randomized controlled trials are warranted.

Keywords: Homoeopathy; Sciatica; Rhus toxicodendron; Clinical outcomes; Oswestry Disability Index; McGill Pain Questionnaire; Pain management

Introduction

Sciatica is pain radiating along the distribution of the sciatic nerve, usually from the lower back to the buttock, thigh, leg and foot. It most often results from irritation or compression of the L4-S1 nerve roots, commonly due to lumbar disc herniation, spinal stenosis, spondylolisthesis or degenerative disc disease. [1,2] Reported prevalence varies widely with the diagnostic criteria used, from 1.2% to 43% in a review of epidemiological studies.[3] The annual incidence is estimated at 1-5%, and the condition is most common in adults aged 30-50 years [2]. Sciatica is a major cause of disability, reduced work productivity, restricted mobility and sleep disturbance, and is classified as M54.3 in ICD-10[4].

Conventional management includes NSAIDs, analgesics, muscle relaxants, corticosteroid injections, physiotherapy and, in selected cases, surgery. [1,5] Recurrence is frequent, and some patients continue to have pain and functional limitation or experience adverse effects from long-term drug use or invasive procedures. Sciatica is therefore a condition in which other treatment approaches merit careful study.

In homoeopathy, sciatica is managed by individualized prescribing based on the totality of symptoms. Rhus toxicodendron is among the remedies most frequently prescribed, classically for pain that is worse at rest, on beginning to move, and in cold, damp weather, and better with continued motion and warmth [6-8]. A randomized, double-blind, placebo-controlled trial reported better pain and functional outcomes with individualized homoeopathic treatment than with placebo,[9] and a pre-post study reported reduced pain and improved mobility, with Rhus toxicodendron among the commonly used remedies [10]. Other reports are small, uncontrolled or descriptive. [11-14] A pilot trial of Arnica and Rhus toxicodendron 30C in delayed-onset muscle soreness found no significant difference from placebo [15]. Prospective clinical data on outcomes of Rhus toxicodendron specifically in sciatica, measured with validated pain and disability instruments, are scarce.

It has since been proposed that homoeopathic research should give priority in conditions for which conventional medicines are inadequate, and that explanatory research should be restricted to patients whose symptoms match one pre-selected remedy in a narrowly defined condition [16]. Studies of a single remedy in one defined diagnosis have been reported, for example Rhus toxicodendron in fibrositis, where it was the remedy, most commonly indicated [17].

This prospective single-arm interventional study was therefore undertaken as a preliminary study in a defined condition, sciatica, in patients for whom Rhus toxicodendron was selected after repertorisation. It assessed changes in pain with Short-Form McGill Pain Questionnaire and functional disability Modified

Oswestry Disability Index over a period of three months, and describes the clinical course during treatment.

Materials and Methods

Study design and setting

This was a prospective, single-arm interventional study conducted at the OPD, IPD and peripheral centres of Sarada Krishna Homoeopathic Medical College, Tamil Nadu, India. The study period was two years. Written informed consent was obtained from all participants.

Participants Thirty patients were included by purposive sampling.

Inclusion criteria:

- Age 30-75 years, either sex
- Clinical diagnosis of sciatica with a positive Straight Leg Raising (SLR) test
- Intervertebral disc prolapses or protrusion, lumbar disc herniation or spondylolisthesis
- Rhus toxicodendron as the indicated remedy on repertorisation of the totality of symptoms

Exclusion criteria:

- Age below 30 or above 75 years
- Need for emergency medical treatment
- Severe systemic illness or surgical complications under treatment

Diagnosis and baseline assessment Patients presenting with sciatica at the OPD, IPD and peripheral centres of Sarada Krishna Homoeopathic Medical College were assessed. Detailed case taking was done and recorded in the college's standardized chronic case format, and the baseline symptoms of each patient were assessed. Sciatica was diagnosed from the symptom presentation, physical and clinical examination and a positive Straight Leg Raising (SLR) test. X-rays were taken in all patients to show bone abnormalities, spinal alignment, degenerative change, spondylolisthesis and other structural problems, and to rule out other possible causes of the low back pain linked to the sciatica. MRI was done where needed. Pain was assessed before and after treatment with the Short-Form McGill Pain Questionnaire (SF-MPQ), including the Pain Rating Index, Present Pain Intensity and Visual Analogue Scale, and the level of function (disability) in activities of daily living with the patient-completed Modified Oswestry Disability Index (ODI).

Remedy selection

Symptoms were analysed and repertorised using Synthesis Repertory version 9.1 in RADAR Opus software.[18] Patients were included when Rhus toxicodendron emerged as the indicated remedy by totality of symptoms.

Intervention

Rhus toxicodendron was started in 30C potency in all patients. Potency, dose and repetition were decided according to the susceptibility of each patient. Subsequent prescriptions were formulated based on clinical observations, following Hahnemann's instructions in the *Organon of Medicine* (Aphorisms 245–248, combined 5th and 6th editions) [19] and Kent's twelve observations on the action of remedies [20]. The remedy was not repeated while improvement continued. When improvement ceased or the action of the dose was exhausted, the remedy was repeated, and the potency was raised to 200C and then 1M as the case required. Follow-up was done every 15 days for 3 months.

Outcome measures

Assessments were done at baseline and at the end of 3 months.

- *Short-Form McGill Pain Questionnaire (SF-MPQ):*[21] 15 descriptors (11 sensory, 4 affective), each rated 0 (none), 1 (mild), 2 (moderate) or 3 (severe). The sum of the 15 scores gives the Pain Rating Index (PRI, range 0-45). The Present Pain Intensity (PPI) is a single rating of current pain: 0 (no pain), 1 (mild), 2 (discomforting), 3 (distressing), 4 (horrible) or 5 (excruciating).
- *Visual Analogue Scale (VAS):* a 100 mm line from 0 mm (no pain) to 100 mm (worst possible pain).
- *Modified Oswestry Disability Index (ODI):*[22] a patient-completed questionnaire on functional disability, expressed as a percentage (0-100%) and classified as minimal (0-20%), moderate (21-40%), severe (41-60%) or crippled (61-80%).

Overall improvement was graded as:

- **Marked:** ≥75%
- **Moderate:** 50-74%
- **Mild:** 25-49%
- **No significant improvement:** <25%

Clinical course (homoeopathic aggravation, new symptoms, acute intercurrent complaints and recurrence) was recorded at each follow-up.

Statistical analysis

Data were analysed and Descriptive statistics are given as mean ± SD, and as frequencies and percentages for categorical data. The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to check normality. Several post-treatment variables were not normally distributed, so pre- and post-treatment PRI, VAS, PPI and ODI scores were compared with the Wilcoxon signed-rank test. A p value below 0.05 was considered significant.

Results

Participant characteristics

Thirty patients were enrolled; the mean age was 48.67 ± 11.16 years (range 31-75). Most patients (26/30, 86.7%) were aged 30-59 years, and 21 (70%) were women. Housewives were the largest occupational group (14/30, 46.7%). Seven patients (23.3%) had diabetes mellitus alone and 2 (6.7%) had both diabetes and hypertension, while 15 (50%) had no significant co-morbidity. Left-sided sciatica was the most common presentation (13/30, 43.3%), followed by right-sided (9/30, 30.0%) and bilateral sciatica (8/30, 26.7%). Symptom duration was under 6 months in 11 patients, 6-12 months in 6, 1-3 years in 8 and 3-5 years in 5. Of the 8 patients with MRI, 7 (87.5%) had L4-L5 involvement and 3 each (37.5%) had L3-L4 & L5-S1 involvement.

Table 1. Baseline characteristics (n = 30)

Characteristic	Value
Age group	Number of Cases (%)
30-39	9 (30.0)
40-49	8 (26.7)
50-59	9 (30.0)
60-69	3 (10.0)
70-79	1 (3.3)
Sex, n (%)	Female 21 (70.0); Male 9 (30.0)

Characteristic	Value
Affected side, n (%)	Left 13 (43.3); Right 9 (30.0); Both 8 (26.7)
Duration of sciatica	Number of Cases (%)
< 6 months	11 (36.7)
6-12 months	6 (20.0)
1-3 years	8 (26.7)
3-5 years	5 (16.7)
Co-morbidity	Number of Cases (%)
Diabetes mellitus (with or without hypertension)	9 (30.0)
Hypertension (with or without diabetes)	4 (13.3)
Other (haemorrhoids, recurrent UTI, renal calculi, hypothyroidism; 1 each)	4 (13.3)
None significant	15 (50.0)
Baseline PRI, mean ± SD	27.13 ± 4.16
Baseline VAS, mm, mean ± SD	74.33 ± 5.04
Baseline ODI, %, mean ± SD	57.10 ± 6.74

Change in pain and disability

All three outcome measures improved significantly (Table 2). The mean PRI fell from 27.13 to 12.83 (a 53% reduction in the mean), the mean VAS from 74.33 to 39.67 mm (47%) and the mean ODI from 57.10% to 20.13% (65%). Every patient had lower scores after treatment on all three measures, giving 30 negative ranks and no ties on the Wilcoxon signed-rank test ($p < 0.001$ for each).

Table 2. Pain and disability scores before and after treatment (n = 30)

Measure	Before: mean ± SD	Before: median (IQR)	After: mean ± SD	After: median (IQR)	Z	p
PRI (0-45)	27.13 ± 4.16	26.0 (24.0-30.8)	12.83 ± 7.91	8.5 (7.0-18.8)	-4.787	< 0.001
VAS (0-100 mm)	74.33 ± 5.04	70.0 (70.0-80.0)	39.67 ± 17.12	30.0 (30.0-50.0)	-4.807	< 0.001
ODI (%)	57.10 ± 6.74	57.0 (52.0-60.0)	20.13 ± 18.22	12.0 (6.0-35.5)	-4.787	< 0.001

PRI, Pain Rating Index; VAS, Visual Analogue Scale; ODI, Oswestry Disability Index; IQR, interquartile range; Wilcoxon signed-rank test.

Present Pain Intensity. Before treatment, all patients rated their pain as distressing (16, 53.3%), horrible (12, 40.0%) or excruciating (2, 6.7%). After treatment, 7 (23.3%) reported no pain, 13 (43.3%) mild pain, 4 (13.3%) discomforting pain, 5 (16.7%) distressing pain and 1 (3.3%) horrible pain. No patient reported excruciating pain (Table 3).

Table 3. Present Pain Intensity before and after treatment, n (%)

PPI category	Before	After
No pain (0)	0	7 (23.3)
Mild (1)	0	13 (43.3)
Discomforting (2)	0	4 (13.3)
Distressing (3)	16 (53.3)	5 (16.7)
Horrible (4)	12 (40.0)	1 (3.3)
Excruciating (5)	2 (6.7)	0

Disability category. Before treatment, 23 patients (76.7%) had severe disability and 7 (23.3%) had crippling disability. After treatment, 19 (63.3%) were in the minimal category, 7 (23.3%) moderate, 3 (10.0%) severe and 1 (3.3%) crippled.

Table 4. Oswestry disability category before and after treatment, n (%)

Category (ODI %)	Before	After
Minimal (0-20)	0	19 (63.3)
Moderate (21-40)	0	7 (23.3)
Severe (41-60)	23 (76.7)	3 (10.0)
Crippled (61-80)	7 (23.3)	1 (3.3)

Overall response

Using the predefined grading, 19 patients (63.3%) showed marked improvement, 2 (6.7%) moderate, 6 (20.0%) mild and 3 (10.0%) no significant improvement. The median percentage improvement was 66.7% for PRI, 57.1% for VAS and 81.5% for ODI.

Table 5. Overall improvement grade (n = 30)

Grade	Number of Cases	%
Marked	19	63.3
Moderate	2	6.7
Mild	6	20.0
No significant improvement	3	10.0

Response by symptom duration and side

Response differed with symptom duration (Table 6). Marked improvement occurred in 16 of 17 patients (94.1%) with symptoms for under 12 months, compared with 3 of 13 (23.1%) with longer duration. No patient with a duration of 3-5 years had marked improvement, and 2 of 5 had no significant improvement. Marked improvement was seen in 7 of 13 patients (53.8%) with left-sided, 6 of 9 (66.7%) with right-sided and 6 of 8 (75.0%) with bilateral sciatica (Table 7). Of the patients with MRI, those with L3-L4 or L5-S1 involvement had marked or moderate improvement, while responses at L4-L5 ranged from marked to none. With only 8 MRI cases, no conclusion can be drawn.

Table 6. Improvement grade by duration of sciatica

Duration	n	Marked	Moderate	Mild	None
< 6 months	11	10	1	0	0
6-12 months	6	6	0	0	0
1-3 years	8	3	1	3	1
3-5 years	5	0	0	3	2

Table 7. Improvement grade by affected side

Side	n	Marked	Moderate	Mild	None
Left	13	7	1	4	1
Right	9	6	0	2	1
Both	8	6	1	0	1

Potency used

All patients started on 30C. The highest potency reached was 30C in 8 patients (26.7%), 200C in 19 (63.3%) and 1M in 3 (10.0%). Marked improvement occurred in 6 of 8, 12 of 19 and 1 of 3 patients respectively (Table 8). Because potency was raised according to response, these groups are not comparable and no inference about the relative efficacy of potencies can be drawn.

Table 8. Improvement grade by highest potency reached, n (%)

Highest potency	n	Marked	Moderate	Mild	None
30C	8	6 (75.0)	0	1 (12.5)	1 (12.5)
200C	19	12 (63.2)	1 (5.3)	4 (21.1)	2 (10.5)
1M	3	1 (33.3)	1 (33.3)	1 (33.3)	0

Clinical course and safety

Homoeopathic aggravation occurred in 1 patient (3.3%) and settled with further observation. New symptoms (vertigo in 4, scalp itching in 1) occurred in 5 patients (16.7%) and resolved. Acute intercurrent complaints (cough, ear affection, genital itching) occurred in 3 patients (10.0%) and were treated with the remedy indicated for the acute totality. Co-morbid symptom, vertigo observed in 2 patients (6.7%) improved after prescription based on the totality. Three patients (10.0%) had return of pain with minimal relief and no significant improvement. Among the 7 patients with sleep disturbance due to pain, sleep improved.

Discussion

The present prospective single-arm interventional study of the indicated Homoeopathic medicine Rhus toxicodendron in sciatica was conducted over two years at the OPD, IPD and peripheral centres of Sarada Krishna Homoeopathic Medical College, Tamil Nadu. Patients presenting with sciatica at these centres were assessed, and only patients diagnosed with sciatica in whom Rhus toxicodendron was the indicated remedy after repertorisation were studied. Thirty such patients aged 30-75 years, of either sex, were included after written informed consent. Detailed case taking was done and recorded in the college's standardized chronic case format, and the baseline symptoms of each patient were assessed. Sciatica was diagnosed from the symptom presentation, physical and clinical examination and a positive Straight Leg Raising (SLR) test. X-rays were taken in all patients to show bone abnormalities, spinal alignment, degenerative change, spondylolisthesis and other structural problems, and to rule out other possible causes of the low back pain linked to the sciatica. MRI was done where needed. Pain was assessed before and after treatment with the Short-Form McGill Pain Questionnaire (SF-MPQ), including the Pain Rating Index, Present Pain Intensity and Visual Analogue Scale, and the level of function (disability) in activities of daily living with the patient-completed Modified Oswestry Disability Index (ODI). Several post-treatment variables were not normally distributed, so the scores were compared with the Wilcoxon signed-rank test.

The totality of symptoms of each patient was framed and repertorised with Synthesis Repertory 9.1 in RADAR Opus, and Rhus toxicodendron was selected as the indicated remedy after repertorisation. It was started in 30C potency in all patients. Potency, dose and repetition were decided according to the susceptibility of each patient, following the Organon of Medicine (aphorisms 245-248) and Kent's observations on the action of remedies. [19,20] The remedy was not repeated while improvement continued. When improvement ceased or the action of the dose was exhausted, it was repeated, and the potency was raised to 200C and then 1M as the case required. Follow-up was every 15 days for three months.

The mean age of the patients was 48.67 ± 11.16 years, and 26 of 30 (86.7%) were aged 30-59 years. This agrees with sciatica being most common in middle-aged adults.[2] Women formed 70% of the sample (21 patients) and men 30% (9 patients). Housewives (46.7%) and coolie workers (13.3%) were the largest occupational groups, so repeated bending, lifting and prolonged standing were common among these patients. Half of the patients had no significant co-morbidity, and diabetes mellitus was present in 9 patients (30%). Left-sided sciatica was the commonest presentation (43.3%), followed by right-sided (30.0%) and bilateral (26.7%).

Response differed with the duration of symptoms. Marked improvement was seen in 16 of 17 patients (94.1%) with symptoms for under one year, but in only 3 of 13 (23.1%) with longer duration, and in none of the 5 patients with 3-5 years of symptoms. All three patients without significant improvement had symptoms for more than a year. Longer symptom duration has been reported to be associated with poorer outcomes [26]. Eight patients had MRI, and L4-L5 was the most commonly involved level (87.5%), followed by L3-L4 and L5-S1 (37.5% each). Imaging findings alone do not fully account for recovery in sciatica,[27] and eight scans are too few to relate imaging to response.

Pain and disability fell in every patient. The mean Pain Rating Index fell from 27.13 ± 4.16 to 12.83 ± 7.91, the mean VAS from 74.33 ± 5.04 mm to 39.67 ± 17.12 mm and the mean ODI from 57.10 ± 6.74 to 20.13 ± 18.22 ($p < 0.001$ for each). Before treatment, all patients reported distressing, horrible or excruciating pain on the PPI, and after treatment 7 (23.3%) reported no pain and 13 (43.3%) mild pain. All patients had severe (76.7%) or crippling (23.3%) disability on the ODI before treatment, and after treatment 19 (63.3%) were in the minimal category. A reduction of about 30% from baseline, or of 10 points on the ODI, has been proposed as the minimal important change in low back pain, [23,24] and the mean reductions here exceeded both. Overall, 19 patients (63.33%) showed marked improvement, 2 (6.67%) moderate, 6 (20.00%) mild and 3 (10.00%) no significant improvement.

Rhus toxicodendron was continued at 30C in 8 patients, and the potency was raised to 200C in 19 and to 1M in 3. Because potency was raised according to susceptibility and response, the groups are not comparable, and no conclusion about the best potency can be drawn from these numbers.

During follow-up, one patient (3.33%) had a homoeopathic aggravation, which settled with observation and without a change of remedy. Five patients (16.67%) had transient new symptoms (vertigo in four, scalp itching in one) that settled with placebo, and three (10.00%) had acute intercurrent complaints that were treated according to the acute totality. Aggravations and other reactions are recognised in homoeopathic practice,[28] but without a comparison group the cause of these events cannot be established.

In a randomized placebo-controlled trial of individualized homoeopathic medicines in sciatica, the primary outcomes did not differ significantly from placebo, although secondary measures, including the SF-MPQ, favoured treatment.[9] Interim data from a phase I pre-post study reported improvement in 64.5% of 34 participants at day 7,[10] a proportion close to the 63.3% with marked improvement here, although follow-up times and definitions of improvement differ. Controlled evidence for Rhus toxicodendron specifically in sciatica is lacking, and the present study provides preliminary data of the kind needed to plan such a trial. The strengths of this study are its prospective design, a diagnosis confirmed by a positive SLR test, the use of validated pain and disability instruments, a single remedy selected by repertorisation in one defined condition, and systematic recording of the clinical course at each follow-up. Testing one remedy in one condition follows proposals for developing homoeopathic clinical research, [16,17] and the study reports individual patient-level scores.

The study also has limitations. There was no control group, so natural recovery, regression to the mean and placebo effects could not be separated from any effect of the medicine. Assessment was not blinded, and the outcomes were patient-reported. Only patients in whom Rhus toxicodendron was the indicated

remedy were studied, so the results cannot be applied to all patients with sciatica. The sample was small and drawn from one institution, MRI was available in only 8 patients, follow-up lasted three months, potency was raised according to response, and the subgroup findings are descriptive. The results therefore show improvement in patients treated with Rhus toxicodendron. A larger, controlled, multi-centre trial with longer follow-up is needed.

Conclusion

In this prospective single-arm interventional study of 30 patients with sciatica in whom Rhus toxicodendron was the indicated remedy after repertorisation, pain and disability scores improved after three months in every patient. The mean Pain Rating Index fell from 27.13 to 12.83, the mean VAS from 74.33 to 39.67 mm and the mean ODI from 57.10 to 20.13 ($p < 0.001$ for each). Marked improvement occurred in 19 patients (63.3%), mainly those with symptoms for under a year. Improvement was observed, but because the study had no control group, the effectiveness of Rhus toxicodendron in sciatica cannot be established from these findings. A larger, randomized, placebo-controlled, multi-centre trial with longer follow-up, blinded outcome assessment and predefined rules for potency is needed.

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