

Homoeopathic therapy in cervical spondylosis pain management: A randomised, double-blind, placebo-controlled trial

Jaya Gupta^{1*}, Ramesh Bawaskar², Prakash Rao³, Ashish Shivadikar⁴, Paul Sumithran⁵, Ramendra Pal⁶, Shahid Ali⁷, Hima Bindu^{1,7}, M D Arya⁸, Chetna Deep Lamba¹, Arvind Kumar¹, Dimpi Kulshreshtha¹

¹Central Council for Research in Homoeopathy, New Delhi, ²Regional Research Institute for Homoeopathy, Mumbai, Maharashtra, ³Clinical Research Unit, Puducherry, ⁴Regional Research Institute for Homoeopathy, Gudivada, Andhra Pradesh, ⁵Central Research Institute for Homoeopathy, Kottayam, Kerala, ⁶Regional Research Institute for Homoeopathy, Jaipur, Rajasthan, ⁷Drug Standardisation Extension, Unit, Hyderabad, Telangana, ⁸Dr. D P Rastogi Central Research Institute for Homoeopathy, Noida, Uttar Pradesh, India

Abstract

Background: Homoeopathic medicines are known to be effective in alleviating pain and other troublesome symptoms of patients suffering from cervical spondylosis. **Objective:** The primary objective was to evaluate the effectiveness of predefined homoeopathic medicines in the pain management of cervical spondylosis using the Cervical Spondylosis Pain Management Scale (CSPMS). **Methods:** A prospective, double-blind randomised placebo-controlled multicentric clinical trial was conducted from April 2012 to May 2013. **Results:** Sixty-seven cases were enrolled in the Homoeopathy group and 69 in the placebo group. One hundred and thirty-four cases that completed the follow-ups were analysed. The improvement in pain was 56.18% in the Homoeopathy group and 46.45% in the placebo group, as per CSPMS. The mean improvement between the groups was not significant: 60.36% in the Homoeopathy group and 48.66% in the placebo group. The mean score of quality of life, assessed using the 'Patient's Global Impression of Change Scale,' was 2.29 ± 1.90 quality of life in the Homoeopathy group and 2.93 ± 2.28 in the placebo group. There was 27.95% more improvement in the Homoeopathy group, as compared to the placebo group. Among the most used medicines were *Rhus toxicodendron* ($n = 19$) 28.8%, *Calcarea carbonica* ($n = 7$) 10.6%, *Kalmia latifolia* ($n = 7$) 10.6% and *Paris quadrifolia* ($n = 8$) 12.1%. **Conclusion:** Homoeopathic medicines are effective in management of acute pain due to cervical spondylosis.

Keywords: Cervical spondylosis, Cervical Spondylosis Pain Management Scale, Homoeopathy, Pain, Patient's Global Impression of Change Scale, Randomised controlled trial

INTRODUCTION

Cervical spondylosis is a degenerative disorder of cervical spine, intervertebral discs, ligaments and cartilaginous material.^[1] The main aetiology of cervical spondylosis is age-related disc degeneration and sedentary occupation. However, there are few exceptions where spinal injuries to the discs can augment the degenerative process in younger patients.^[2] Cervical spondylosis can be classified into three clinical syndromes: Type I syndrome (cervical radiculopathy), Type II syndrome (cervical myelopathy) and Type III syndrome (axial joint pain). The first two reflect neurologic involvement, whereas the third represents painful joint dysfunction. There is often overlap between these

syndromes, which can coexist simultaneously.^[3] Cervical spondylosis can be mechanical and metabolic both.^[4] The most common symptoms of cervical spondylosis include intermittent, persistent neck and shoulder pain. The pain is quite often associated with stiffness and numbness and may radiate to the affected nerve root. Pain may also radiate

***Address for correspondence:** Dr. Jaya Gupta,
Central Council for Research in Homoeopathy, New Delhi, India.
E-mail: jgupta21@gmail.com

Received: 10.09.2019; **Accepted:** 28.10.2020; **Published:** 29.12.2020

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: WKHLRPMedknow_reprints@wolterskluwer.com

How to cite this article: Gupta J, Bawaskar R, Rao P, Shivadikar A, Sumithran P, Pal R, *et al.* Homoeopathic therapy in cervical spondylosis pain management: A randomised, double-blind, placebo-controlled trial. *Indian J Res Homoeopathy* 2020;14:242-50.

Access this article online

Quick Response Code:



Website:
www.ijrh.org

DOI:
10.4103/ijrh.ijrh_70_19

to the shoulders and occiput. Many patients present with interscapular pain, pain in the arm, forearm and/or hand. The significant radiological changes noted in cervical spondylosis are (a) narrowing of disc space, (b) presence of osteophytes arising from the disc margins and (c) osteoarthritic changes in the posterior zygapophyseal joints. Most people with spondylotic changes of the cervical spine on radiographic imaging remain asymptomatic, with 25% of individuals under the age of 40, 50% of individuals over the age of 40 and 85% of individuals over the age of 60 showing some evidence of degenerative changes. The most frequently affected levels are C6–C7, followed by C5–C6. Symptomatic cervical spondylosis most commonly presents as neck pain. In the general population, the point prevalence of neck pain ranges from 0.4% to 41.5%, the 1-year incidence ranges from 4.8% to 79.5% and lifetime prevalence may be as high as 86.8%.^[5,6]

Cervical spondylosis is usually diagnosed on clinical grounds alone. Neurological change should always be sought in the upper and lower limbs, but objective changes occur only when spondylosis is complicated by myelopathy or radiculopathy or when unrelated causes such as disc prolapse, thoracic outlet obstruction, brachial plexus disease, malignancy or primary neurological disease are present. The diagnosis of cervical spondylosis comprises physical examination: checking the range of motion and reflexes; imaging tests: neck X-ray, computed tomography scan, magnetic resonance imaging and myelography and nerve function tests: electromyography and nerve conduction study.^[7,8] Non-operative medical management which is available for cervical spondylosis includes non-steroidal anti-inflammatory drugs, muscle relaxants, analgesics, antidepressants and anticonvulsants. Physiotherapy procedures such as transcutaneous electrical nerve stimulator and cervical traction and physical application modalities such as heat and cold are common treatments for cervical spondylosis in the modern system of medicine.

Individualised homoeopathic medicines have better results in relieving neck pain in cervical spondylosis patients.^[9] Another study, using bowel nosode group of medicines on the basis of corresponding microorganism found in stool culture, also reflected its usefulness in relieving symptoms of cervical spondylosis,^[10] but these studies have methodological flaws such as randomisation and difference in group size.

In a previous study conducted by the Central Council for Research in Homoeopathy (CCRH) from June 2009 to June 2010,^[11] the effectiveness of homoeopathic fifty millisimal (LM)-versus-centesimal (CM) potencies in reducing pain due to cervical spondylosis was assessed. LM potencies were found better than CM potencies for pain management of cervical spondylosis.^[11] As no double-blind placebo-controlled trial was undertaken by the council so far, this study was undertaken with predefined Homoeopathic medicines in centesimal potencies as intervention.

METHODS

Study design

This was a multicentre, prospective, double-blind randomised placebo-controlled clinical trial. The investigators from seven study centres were given training before initiation of the study. The investigators were the regular research officers of the council. The approval of the study protocol was taken by the Ethical Committee of the council.

Ethical statement

All procedures were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration^[12] of 1975 and Good Clinical Practices India.^[13] The study was registered with CTRI: CTRI/2011/12/002270 (dated 22 December 2011). Written informed consent from the participants was obtained before enrolling them in the study.

Study setting

The study was conducted at seven centres under CCRH: Drug Standardisation Ext. Unit, Hyderabad; Regional Research Institute (H), Mumbai; Central Research Institute (H), Jaipur; National Homoeopathy Research Institute In Mental Health, Kottayam; Dr. D P Rastogi Central Research Institute (H), Noida; Regional Research Institute (H), Gudivada; and Clinical Research Unit (H), Puducherry.

Participants

Inclusion criteria for the patients were as follows:

Male and female patients between 30 and 60 years, with a chief complaint of neck pain including pain in the suboccipital and interscapular regions for the last 2 weeks, having one or more episodes of neck pain and neck stiffness attack per month on average for at least 3 months, with positive radiological findings for cervical spondylosis; pain intensity of minimum 4 as per Visual Analogue Scale (VAS). Patients not on anti-inflammatory or any other therapy in the past 1 week, which is known to affect the study outcome.

Patients were excluded for any of the following reason:

Cervical myelopathy or radiculopathy; patients with neck pain and normal X-ray findings, patients taking physiotherapy, those having neck trauma/fracture/history of surgery/congenital spinal abnormalities, any systemic disease of bones and joints, other non-specific lesions: acute neck strain, postural neck ache or whiplash injury, any systemic disease such as hypertension, diabetes mellitus, cardiovascular or cerebrovascular disease; inability to comply with the study protocol, alcoholics or drug users including psychiatric disease; pregnant and lactating women, patients deemed ineligible by an investigator and patients unwilling to sign the written informed consent form.

Sample size estimation

Assuming 50% (P1) improvement in the medicinal group and 25% (P2) improvement in the placebo group, the required sample size for this study was 116 (58/group) with $\alpha = 0.05$ and power 80%. Including dropout rate of 20%, the total sample size required was 140 (70/group). As this study was conducted

at 7 centres, 20 recruitments (10/group) were required to be done per centre.

Randomisation

Randomisation was done using a computer-based software www.randomizer.org. After the final selection of medicine, Group 1 was dispensed intervention from Series I and Group 2 from Series II. The groups formed were randomly assigned for either series based on the randomly generated codes made available from the above-mentioned software. The coding of Series I and Series II was done by the pharmacist at headquarters. Patient's enrolment number was used for the purpose of randomisation. The initial randomisation was maintained during all follow-up visits. Randomisation chart was available with the investigator and pharmacist. The placebo group and medicine group were coded as Series I and Series II, respectively, at four study centres, whereas at the other three study centres, the placebo group and verum group were coded as Series II and Series I, respectively.

Screening

Investigations carried out to screen the eligibility of the patients were as follows: erythrocyte sedimentation rate, C-reactive protein, rheumatoid factor, serum calcium, serum phosphate, serum alkaline phosphates and X-ray cervical spine up to C7.

Intervention

Two series of homoeopathic medicines were used which were procured from GMP-compliant licensed homoeopathic pharmaceutical company approved by the council. One comprised verum, i.e. homoeopathic medicines in 30c dilutions, and the other comprised identical matching placebo. Based on the outcome of the previous studies and taking into consideration the acute totality of pain of cervical spondylosis, the following remedies were shortlisted for the Homoeopathic arm in the study: (1) *Paris quadrifolia*, (2) *Calcarea carbonica*, (3) *Gelsemium sempervirens*, (4) *Cocculus indicus*, (5) *Cimicifuga racemosa*, (6) *Rhus toxicodendron*, (7) *Causticum*, (8) *Radium bromide*, (9) *Kalmia latifolia* and (10) *Lachnanthes tinctoria*. Selection of medicine was done after case taking based on acute totality, out of predefined medicines. The indicated medicine in 30c potency or identical matching placebo was given (4 pills of size no. 30). Three doses were given at 6 hours intervals daily, for 7 days.

Outcomes

The primary outcome of the study was to evaluate the effectiveness of predefined homoeopathic medicines in cervical spondylosis pain using the Cervical Spondylosis Pain Management Scale (CSPMS) on the eighth day of treatment. Assessment of pain and stiffness was done using a VAS, which is a patient-oriented scale. To avoid any outcome assessment bias, this scale was filled daily by the patients themselves for 8 days. This was a 10 point scale marked as 0–10 where '0' indicates 'no pain' and '10' indicates 'worst possible pain'. Similarly, for stiffness, '0' indicates 'no stiffness' and '10' indicates 'the worst possible stiffness'. For limitation of

movement and tenderness, CSPMS was used. For quality of life, the Patient's Global Impression of Change Scale was used.

Statistical analysis

Statistical analysis was done using statistical software of IBM SPSS 20.0 version IBM SPSS (statistical package for social sciences) statistics collaboration and deployment services, USA (www.ibm.com/products/SPSS-statistics). Data were expressed as number (%) and mean \pm standard deviation. Independent samples *t*-test and Chi-square test were used to compare the medicine and placebo groups at baseline. The Friedman test was used for group differences at the baseline, 3rd day and 8th day of follow-up (pre- and post-treatment data). As the data showed non-normal or skewed distribution, non-parametric test was used. Mann–Whitney test was used for analysing patient's global impression of change.

RESULTS

Out of 498 screened cases, 136 cases (36 males and 100 females) who fulfilled the inclusion criteria comprising the Homoeopathy ($n = 67$) and placebo ($n = 69$) groups were enrolled in the study. However, two cases dropped out, and 134 cases that completed the follow-ups were analysed for study [Figure 1]. The mean age for the Homoeopathy group was 45.7 ± 7.6 years and for the placebo group was 45.9 ± 8.9 years [Table 1]. The baseline characteristics for the patients enrolled in the study are given in Table 1.

Figures 2 and 3 depict the pain reduction on the VAS scale.

When percentage change from baseline to the eighth day for individuals was computed, marked improvement 53% was observed in the Homoeopathy group, and 47.1% in the placebo group. Although statistically significant difference could not be found between both the groups ($P = 0.283$), more patients were improved (markedly and moderately) in all aspects with Homoeopathy than with placebo [Table 2].

The mean improvement in the homoeopathy group was 60.36%, as compared to only 48.66% in the placebo group. However, statistically significant difference could not be found between both the groups ($P = 0.099$) [Table 3].

Using CSPMS, in the Homoeopathy group, there was 56.18% improvement in 'pain', while in the placebo group, there was 46.45% improvement. In 'stiffness', 55.70% cases were improved in the Homoeopathy group, while in the placebo group, 48.75% improvement was seen. "Limitation of movement" was relieved in 65.97% cases in the homoeopathy group, while up to 57.73% in the placebo. "Tenderness" too was improved in 68.67% cases in the treatment group, as opposed to 51.28% in the control group [Table 4].

Regarding quality of life of patients which was assessed using the 'Patient's Global Impression of Change Scale'

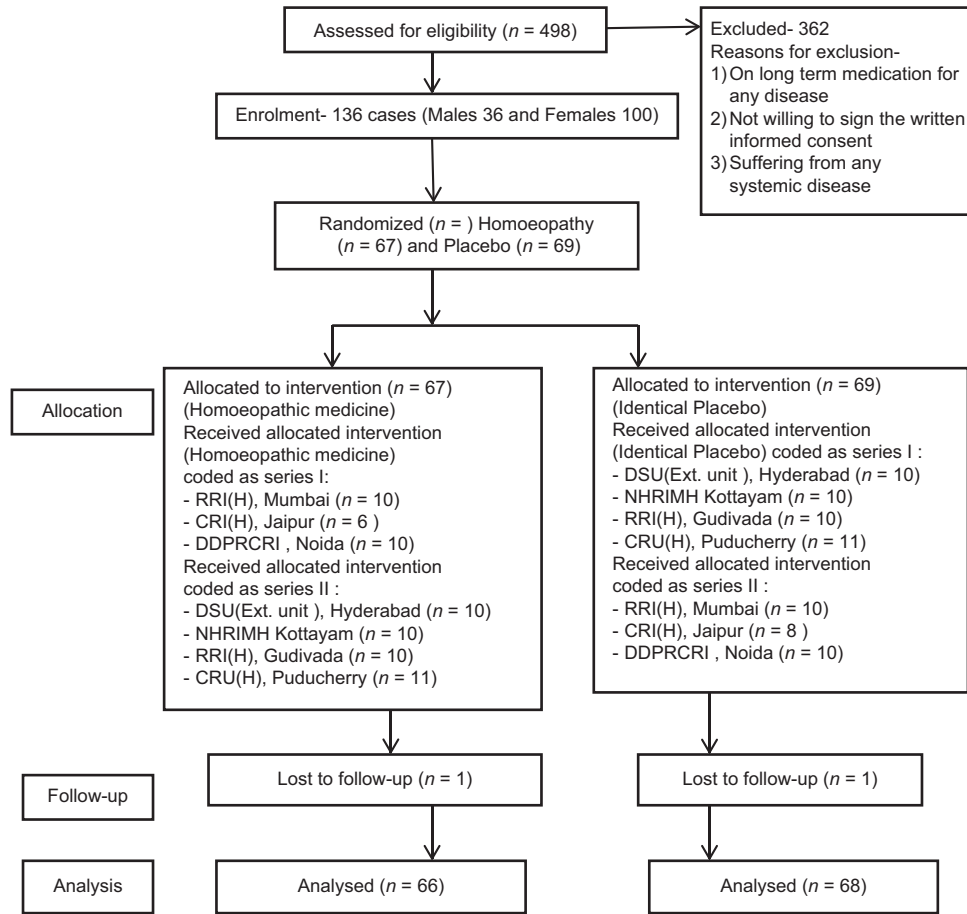


Figure 1: Study flowchart

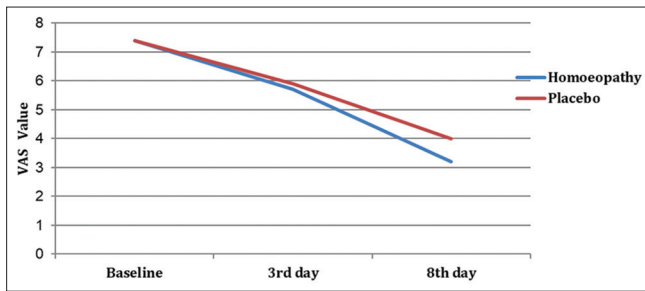


Figure 2: Reduction of pain on Visual Analogue Scale

(0–10 scale, where ‘0’ was ‘much better’ and ‘10’ was ‘much worse’ on scale), the mean score was 2.29 ± 1.90 in the Homoeopathy group, whereas in the placebo group, the mean score was 2.93 ± 2.28 . When improvement in both the groups was compared, there is 27.95% more improvement in the Homoeopathy group than the placebo group, although that was not statistically significant [Table 5].

The most commonly indicated medicines were *Rhus toxicodendron* (n = 19; 28.8%), *Calcarea carbonica* (n = 7; 10.6%), *Kalmia latifolia* (n = 7; 10.6%) and *Paris quadrifolia* (n = 8; 12.6%) [Table 6].

DISCUSSION

Over the years, many studies have shown the efficacy of homoeopathic medicines in cases of cervical spondylosis. The published literatures, including case reports and case studies in peer-reviewed journals indicate the efficacy of Homoeopathy in cervical spondylosis.^[9,14] The result of this study is in line with another study which demonstrated that with *Calcarea fluorica* (in various potencies) given to 154 patients on the basis of few pathological symptoms, clinical improvement was 60.38% as compared to 48% improvement on the basis of mental and physical generals and 12.8% improvement on the basis of totality of the symptoms.^[9]

On comparing the improvement percentage between both the groups, it has been observed that the percentage improvement was more in the homoeopathy group than in the placebo group.

The study has given a platform for future studies, but with longer follow-up period. The limitation of this study was that the follow-up period of 8 days only, which was too short to bring noticeable, significant changes in the patients. Follow-up period of 6 months would have been ideal and given scope for proper assessment of cases, thus leading to more discernible changes in the outcome. Another limitation was that, as per the protocol, the investigators

involved in the study were allowed to prescribe only predefined homoeopathic remedies in 30c potency, which contradicts the routine homoeopathic practice where there could be requirement of change of medicine and potency in prescription.

Further, after selecting a medicine for patients at baseline, the investigators were supposed to continue the same medicine during follow-up period, which contradicts the routine homoeopathic practice where there could be requirement of

change in prescription. It was observed in one of the reviews that, often, homoeopaths do not find the correct remedy at once and/or change the remedy as the clinical picture changes. In case of a double-blind trial, a homoeopathic practitioner often encounters the challenge due to any three possibilities, namely a failure to reach correct similimum, any symptom shift in totality of symptoms or patient being a participant of a placebo group.^[15]

It is also worth mentioning that since the patients in the placebo group also underwent the homoeopathic case recording procedure, which involved detailed consultation, the procedure might have contributed considerably to a possible treatment effect, thus decreasing the likelihood of identifying differences between the groups.^[16]

In the present study, double-blind, placebo-controlled methodology was adopted, which is the gold standard in conventional medicine for clinical trials using single-drug intervention. However, it seems that this methodology might be a constraint for achieving the sample size, as for finding patients requiring a particular remedy, a large number of patients need to be screened as also reflected in other homoeopathic studies.^[17] This could not be made possible in this study.

Based on this study, a future RCT study with flexibility to change the potency as per the requirement of the case when the pathological base prescription is to be given is advisable. Eight-day follow-up period being very less, it is suggested that a follow-up period of at least six months would lead to a better outcome.

Table 1: Baseline information

Variables	Homoeopathy group (n=67)	Placebo group (n=69)	P
Sex			
Male	17 (25.8)	19 (26.5)	0.925 [#]
Female	50 (74.2)	50 (73.5)	
Age	45.7±7.6	45.9±8.9	0.866 [*]
Symptoms present			
Pain	66 (100)	68 (100)	0.548 [#]
Stiffness	62 (93.9)	64 (94.1)	0.913 [#]
Limitation of movement			
Flexion			
Movement possible	20 (30.3)	18 (26.5)	0.763 [#]
Restricted movement	26 (39.4)	31 (45.6)	
Movement impossible	20 (30.3)	19 (27.9)	
Extension (side)			
Movement possible	23 (34.8)	23 (33.8)	0.972 [#]
Restricted movement	22 (33.3)	24 (35.3)	
Movement impossible	21 (31.8)	21 (30.9)	
Side bending			
Movement possible	19 (28.8)	18 (26.5)	0.765 [#]
Restricted movement	26 (39.4)	31 (45.6)	
Movement impossible	21 (31.8)	19 (27.9)	
Rotation			
Movement possible	9 (13.6)	14 (20.6)	0.564 [#]
Restricted movement	27 (40.9)	26 (38.2)	
Movement impossible	30 (45.5)	28 (41.2)	
Tenderness			
Vertebral			
Absent	11 (16.7)	15 (22.1)	0.430 [#]
Present	55 (83.3)	53 (77.9)	
Trapezius			
Absent	28 (42.4)	31 (45.6)	0.712 [#]
Present	38 (57.6)	37 (54.4)	

*Independent samples t-test applied, [#]Chi-square test applied

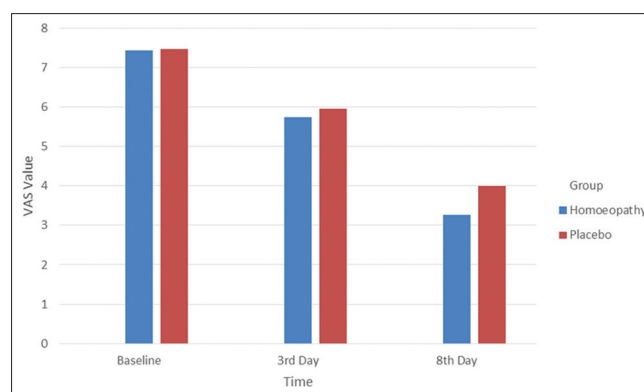


Figure 3: Bar graph showing reduction of pain in Visual Analogue Scale score

Table 2: Percentage (%) change from baseline to 8th day for individuals

Improvement status	Homoeopathy (%)	Placebo (%)	Total (%)	P
Marked improvement	35 (53.0)	32 (47.1)	67 (50.0)	0.283 [†]
Moderate improvement	7 (10.6)	2 (2.9)	9 (6.7)	
Mild improvement	9 (13.6)	9 (13.2)	18 (13.4)	
Not significant	7 (10.6)	12 (17.6)	19 (14.2)	
Status quo	7 (10.6)	9 (13.2)	16 (11.9)	
Worse	1 (1.5)	4 (5.4)	5 (3.7)	
Total	66 (100.0)	68 (100.0)	134 (100.0)	

[†]Chi-square test

Table 3: Comparison of the distribution of percentage (%) change between the two groups

Mean (%)±SD		Mean difference	95% CI of the difference	P
Homoeopathy (n=66)	Placebo (n=68)			
60.36±37.35	48.66±43.89	11.71	-2.24-25.65	0.099*

*Independent samples *t*-test

Table 4: Statistical analysis for comparison of pre-post data of both groups

Friedman test and change (%) from baseline to 8 th day							
Symptoms	Visit	Homoeopathy group (n=66)			Placebo group (n=68)		
		Mean±SD	Change percentage from baseline to 8 th day	P	Mean±SD	Change percentage from baseline to 8 th day	P
Symptoms							
Pain	Baseline	7.44±1.97	56.18*	0.0001	7.47±1.79	46.45	0.0001
	3 rd day	5.74±2.08			5.96±1.90		
	8 th day	3.26±3.29			4.00±3.42		
Stiffness	Baseline	6.59±2.86	55.70*	0.0001	6.40±2.70	48.75	0.0001
	3 rd day	5.11±2.67			5.10±2.37		
	8 th day	2.92±3.32			3.28±3.31		
Limitation of movement							
Flexion	Baseline	1.00±0.78	61.00*	0.0001	1.01±0.74	51.48	0.0001
	3 rd day	0.85±0.71			0.79±0.64		
	8 th day	0.39±0.63			0.49±0.70		
Extension	Baseline	0.97±0.82	65.97*	0.0001	0.97±0.81	57.73	0.0001
	3 rd day	0.70±0.68			0.75±0.63		
	8 th day	0.33±0.59			0.41±0.67		
Side bending	Baseline	1.03±0.78	63.11*	0.0001	1.01±0.74	50.49	0.0001
	3 rd day	0.77±0.63			0.81±0.63		
	8 th day	0.38±0.63			0.50±0.70		
Rotation	Baseline	1.32±0.71	53.79*	0.0001	1.21±0.76	47.93	0.0001
	3 rd day	1.26±1.50			0.96±0.61		
	8 th day	0.61±0.72			0.63±0.77		
Tenderness							
Vertebral	Baseline	0.83±0.38	68.67*	0.0001	0.78±0.42	51.28	0.0001
	3 rd day	0.71±0.46			0.71±0.49		
	8 th day	0.26±0.44			0.38±0.49		
Trapezius	Baseline	0.58±0.49	53.45*	0.0001	0.54±0.50	40.74	0.0001
	3 rd day	0.48±0.50			0.53±0.53		
	8 th day	0.27±0.45			0.32±0.47		

Friedman test was applied to assess the changes from baseline to 3rd-day and 8th-day follow-ups for CSPMS. Reason for applying nonparametric test: CSPMS data. CSPMS: Due to non-normal and ordinal data/Likert scale, SD: Standard deviation

Table 5: Patients' global impression of change on 8th day

Patients' global impression of change on 8 th day	Homoeopathy group (n=66)	Placebo group (n=68)	Percentage difference of improvement in both groups	P	Effect size (Cohen's d)
Mean±SD	2.29±1.90	2.93±2.28	27.95	0.123 ^s	0.304963

^sMann-Whitney test was applied. SD: Standard deviation

In spite of all the constraints of a double-blind RCT design, this study has shown a positive response of homoeopathic medicines in allaying the cervical spondylosis pain in comparison to placebo within the duration of one week, and opened the avenue for more work on this subject.

CONCLUSION

Homoeopathic intervention with predefined medicines is effective in managing acute pain due to cervical spondylosis. Further studies can be taken up with longer follow-ups, to show the efficacy of homoeopathic medicines in cervical spondylosis pain management.

Table 6: Most indicated medicines

Medicine	Homoeopathy group, n (%)	Placebo group, n (%)
<i>Calcarea carbonica</i>	7 (10.6)	7 (10.3)
<i>Causticum</i>	6 (9.1)	9 (13.2)
<i>Cimicifuga racemosa</i>	4 (6.1)	5 (7.4)
<i>Cocculus indicus</i>	6 (9.1)	5 (7.4)
<i>Gelsemium sempervirens</i>	5 (7.6)	6 (8.8)
<i>Kalmia latifolia</i>	7 (10.6)	3 (4.4)
<i>Lachnanthes tinctoria</i>	2 (3.0)	4 (5.9)
<i>Paris quadrifolia</i>	8 (12.1)	11 (16.2)
<i>Radium bromide</i>	3 (4.5)	6 (8.8)
<i>Rhus toxicodendron</i>	19 (28.8)	13 (19.1)

Acknowledgement

The authors sincerely acknowledge Dr. Anil Khurana, Director General, CCRH, for his guidance in revising the manuscript. We are thankful to all programme officers of the institutes and units, where project was carried out, for their administrative support. We are thankful to Mrs. Maya Padmanabhan, Statistical Assistant, CCRH, for her help in statistical analysis of the study. Last but not least, we are thankful to all the patients for their participation in the study.

Financial support and sponsorship

This study was financially supported by the Central Council for Research in Homoeopathy.

Conflicts of interest

None declared.

REFERENCES

1. Belachew DA, Schaller B, Guta G. Cervical spondylosis: A literature review with attention to the African population. *Arch Med Sci* 2007;4:316-21.
2. Lisha AF. The biomechanics of cervical spondylosis. *Adv Orthop* 2012;2012:1-6.
3. Voorhies RM. Cervical spondylosis: Recognition, differential diagnosis, and management. *Ochsner J* 2001;3:78-84.
4. Ramani PS. Text book of Cervical Spondylosis. New Delhi: Jaypee Brothers Publishers; 2004.
5. Hoy DG, Protani M, De R, Buchbinder R. The epidemiology of neck pain. *Best Pract Res Clin Rheumatol* 2010;24:783-92.
6. Kelly JC, Groarke PJ, Butler JS, Poynton AR, O'Byrne JM. The natural history and clinical syndromes of degenerative cervical spondylosis. *Adv Orthop* 2012;2012:1-5.
7. Binder AI. Cervical Pain Syndromes. In: Isenberg PA, Maddison PS, Woo P, Glass DN, Breedveld FC, editors *Oxford Textbook of Rheumatology*. 3rd ed. Oxford: Oxford Medical Publications; 2004. p. 1185-95.
8. Binder AI. Cervical spondylosis and neck pain. *BMJ* 2007;334:527-31.
9. Mohan GR, Jayalakshmi C, Meena Devi AL. Cervical Spondylosis, a clinical study *Br Homoeopath J* 1996;85:131-3.
10. Nayak C. Study on effectiveness of homoeopathic bowel nosodes in the treatment of cervical spondylosis based on stool culture report. *Indian J Res Homoeopathy* 2008;2:42-8.
11. Nayak C, Singh V, Gupta J. Homoeopathic individualized LM-potencies versus centesimal potencies for pain management of cervical spondylosis: A multicentre prospective randomized exploratory clinical study. *Indian J Res Homoeopathy* 2012;6:16-23.
12. WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects. Available from: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>. [Last accessed on 2020 May 26].
13. Good Clinical Practices for Clinical Research in India. New Delhi: CDSCO; 2001. Central Drugs Standard Control Organization, Directorate General of Health Services, India. Good Clinical Practices for Clinical Research in India. Available from: <http://www.sgpgi.ac.in/sop/GCP-%20Indian.pdf>. [Last accessed on 2019 Jul 04].
14. Tiwari NL. Spondylitis, dyspepsia & tension headache. *Natl J Homoeopathy* 2004;6:1. Available from: <https://www.njhonline.com/CaseStudyView.jsp?id=454>. [Last accessed on 2020 Nov 17].
15. Linde K, Scholz M, Ramirez G, Clausius N, Melchart D, Jonas WB. Impact of study quality on outcome in placebo-controlled trials of homeopathy. *J Clin Epidemiol* 1999;52:631-6.
16. Linde K, Melchart D. Randomized controlled trials of individualized homeopathy: A state-of-the-art review. *J Altern Complement Med* 1998;4:371-88.
17. Andrade DCDS, Carmona F, Angelucci MA, Martinez EZ, Pereira AMS. Efficacy of a Homeopathic medicine of *capsicum frutescens* L. (Solanaceae) in the treatment of hot flashes in menopausal women: A phase-2 randomized controlled trial. *Homeopathy* 2019;108:102-7.

सर्वाइकल स्पॉन्डिलोसिस के दर्द के प्रबंधन में होम्योपैथी उपचार की प्रभावशालिता: एक यादृच्छिक डबल-ब्लाइंड प्लासिबो नियंत्रित परीक्षण

पृष्ठभूमि: होम्योपैथिक औषधियाँ सर्वाइकल स्पॉन्डिलोसिस से पीड़ित रोगियों के दर्द को कम करने और अन्य कष्टप्रद लक्षणों में प्रभावशाली होने के लिए जाना जाता है। **उद्देश्य:** इसका प्राथमिक उद्देश्य सर्वाइकल स्पॉन्डिलोसिस पेन मैनेजमेंट स्केल (सीएसपीएमएस) का उपयोग करते हुए सर्वाइकल स्पॉन्डिलोसिस के दर्द प्रबंधन में पूर्व-परिभाषित होम्योपैथी की औषधियों की प्रभावशालिता का मूल्यांकन करना था। **पद्धति:** एक संभावित, डबल-ब्लाइंड यादृच्छिक प्लासिबो नियंत्रित बहु-केंद्रित नैदानिक परीक्षण का निष्पादन अप्रैल 2012 से मई 2013 तक किया गया। **परिणाम:** होम्योपैथिक समूह में 67 प्रकरणों और प्लासिबो समूह में 69 प्रकरणों का नामांकन किया गया। उन 134 प्रकरणों का विश्लेषण किया गया जिनकी जाँच पूरी हो गयी थी। सीएसपीएमएस के अनुसार, होम्योपैथी समूह में दर्द में सुधार 56.18 प्रतिशत और प्लासिबो समूह में 46.45 प्रतिशत था। समूहों के बीच औसत सुधार महत्वपूर्ण नहीं था: होम्योपैथी समूह में 60.36 प्रतिशत और प्लासिबो समूह में 48.66 प्रतिशत। जीवन की गुणवत्ता का औसत अंक जिसका आकलन 'रोगी के मापांक में परिवर्तन की वैश्विक अभिव्यक्ति' का प्रयोग करते हुए किया गया, औसत अंक होम्योपैथी समूह में 2.29 ± 1.90 और प्लासिबो समूह में 2.93 ± 2.28 था। होम्योपैथी समूह में जीवन की गुणवत्ता में सुधार प्लासिबो समूह की तुलना में 27.95 प्रतिशत अधिक था। सबसे अधिक उपयोग किए जाने वाले औषधियों में था; रस टॉक्सिकोडेंड्रॉन (एन = 19) 28.8 प्रतिशत, कैल्केरिया कार्बोनििका (एन = 7) 10.6 प्रतिशत, काल्मिया लाटिफोलिया (एन = 7) 10.6 प्रतिशत और पैरिस क्वाड्रिफोलिया (एन = 8) 12.1 प्रतिशत। **निष्कर्ष:** होम्योपैथी औषधियाँ सर्वाइकल स्पॉन्डिलोसिस के कारण होने वाले गंभीर दर्द के प्रबंधन में प्रभावशाली होती हैं।

Efficacité de la thérapie homéopathique dans la prise en charge de la douleur de la spondylose cervicale: Un essai placebo aléatoire contrôlé en double aveugle

Contexte: Les médicaments homéopathiques sont connus pour être efficaces pour soulager la douleur et d'autres symptômes gênants chez les patients souffrant de spondylose cervicale. **Objectif:** L'objectif principal était d'évaluer l'efficacité des médicaments homéopathiques prédéfinis dans la gestion de la douleur de la spondylose cervicale à l'aide de l'échelle de gestion de la douleur de la spondylose cervicale (CSPMS). **Méthodes:** Un essai clinique multicentrique prospectif, randomisé en double aveugle, contrôlé par placebo, a été mené d'avril 2012 à mai 2013. **Résultats:** 67 cas ont été recrutés dans le groupe Homéopathie et 69 dans le groupe placebo. 134 cas ayant complété le suivi ont été analysés. L'amélioration de la douleur était de 56,18% dans le groupe Homéopathie et de 46,45% dans le groupe placebo, selon le CSPMS. L'amélioration moyenne entre les groupes n'était pas significative: 60,36% dans le groupe Homéopathie et 48,66% dans le groupe placebo. Le score moyen de qualité de vie, évalué à l'aide de l'« échelle d'impression globale du changement du patient », était de $2,29 \pm 1,90$ dans le groupe Homéopathie et de $2,93 \pm 2,28$ dans le groupe placebo. Il y avait 27,95% d'amélioration de la qualité de vie dans le groupe Homéopathie, par rapport au groupe placebo. Parmi les médicaments les plus utilisés figuraient Rhus toxicodendron (n = 19) 28,8%, Calcarea carbonica (n = 7) 10,6%, Kalmia latifolia (n = 7) 10,6% et Paris quadrifolia (n = 8) 12,1%. **Conclusion:** Les médicaments homéopathiques sont efficaces dans la prise en charge de la douleur aiguë due à la spondylose cervicale.

Eficacia de la terapia homeopática en el manejo del dolor de la espondilosis cervical: Un ensayo controlado aleatorizado con placebo doble ciego

Antecedentes: Se sabe que los medicamentos homeopáticos son eficaces para aliviar el dolor y otros síntomas problemáticos de pacientes que sufren de espondilosis cervical. **Objetivo:** El objetivo principal era evaluar la eficacia de los medicamentos homeopáticos predefinidos en el manejo del dolor de la espondilosis cervical utilizando la Escala de Manejo del Dolor de Espondilosis Cervical (CSPMS). **Métodos:** De abril de 2012 a mayo de 2013 se llevó a cabo un ensayo clínico multicéntrico aleatorizado controlado con placebo, doble ciego y aleatorizado. **Resultados:** se inscribieron 67 casos en el grupo de Homeopatía y 69 en el grupo placebo. Se analizaron 134 casos que completaron el seguimiento. La mejoría del dolor fue del 56,18% en el grupo de homeopatía y del 46,45% en el grupo placebo, según el CSPMS. La mejoría media entre los grupos no fue significativa: 60.36% en el grupo de Homeopatía y 48.66% en el grupo de placebo. La puntuación media de calidad de vida, evaluada mediante la escala de la impresión global del cambio del paciente, fue de 2.29 ± 1.90 en el grupo de Homeopatía y de 2.93 ± 2.28 en el grupo de placebo. Hubo un 27.95% más de mejora en la calidad de vida en el grupo de Homeopatía, en comparación con el grupo de placebo. Entre los medicamentos más utilizados se encontraban Rhus toxicodendron (n = 19) 28.8%, Calcarea carbonica (n = 7) 10.6%, Kalmia latifolia (n = 7) 10.6% y Paris quadrifolia (n = 8) 12.1%. **Conclusión:** Los medicamentos homeopáticos son eficaces en el manejo del dolor agudo debido a la espondilosis cervical.

Wirksamkeit der Homöopathischen Therapie bei Zervikaler Spondylose Pain Management: A Randomized Double-Blind Placebo-Kontrollierte Studie

Hintergrund: die Homöopathischen Medikamente sind bekanntermaßen wirksam bei der Linderung von Schmerzen und andere unangenehme Symptome von Patienten mit zervikaler Spondylose. **Ziel:** Das primäre Ziel war die Bewertung der Wirksamkeit von vordefinierten Homöopathische Medikamente in der Schmerztherapie von zervikale Spondylose mit der Zervikale Spondylose Schmerz-Management-Skala (CSPMS). **Methoden:** Eine prospektive, Doppel-blind randomisierte placebo-kontrollierte multizentrische klinische Studie wurde durchgeführt, die von April 2012 bis Mai 2013. **Ergebnisse:** 67 Fälle wurden eingeschrieben in der Homöopathie-Gruppe und 69 in der placebo-Gruppe. 134 Fälle, die abgeschlossen, die follow-up analysiert. Die Verbesserung der Schmerzen war 56.18% in der Homöopathie-Gruppe und 46.45% in der placebo-Gruppe, wie pro CSPMS. Die mittlere Verbesserung zwischen den Gruppen war nicht signifikant: 60.36% in der Homöopathie-Gruppe, und 48.66% in der placebo-Gruppe. Der Durchschnittswert der Lebensqualität, die anhand des "Patient's Global Impression of Change Scale", war 2.29 ± 1.90 in der Homöopathie-Gruppe und 2.93 ± 2.28 in der placebo-Gruppe. Es war 27.95% mehr Verbesserung der Lebensqualität in der Homöopathie-Gruppe im Vergleich zur placebo-Gruppe. Zu den am meisten verwendeten Medikamenten Rhus toxicodendron (n = 19) mit 28,8%, Calcium carbonicum (n = 7) 10.6%, Kalmia latifolia (n = 7) 10,6% und Paris quadrifolia (n = 8) 12.1%. **Fazit:** Homöopathische Medikamente sind wirksam im management von akuten Schmerzen aufgrund von Gebärmutterhalskrebs Spondylose.

宫颈脊柱病疼痛管理中同源疗法的疗效：一个随机双盲安慰剂对照试验。

背景：众所周知，同源性药物对缓解颈椎病患者疼痛和其他麻烦症状是有效的。目标：主要目标是使用颈椎脊柱病疼痛管理量表（CSPMS）评估预定义同源药物在颈椎脊柱病疼痛管理中的有效性。方法：2012年4月至2013年5月进行了前瞻性双盲随机安慰剂对多中心临床试验。结果：顺势疗法组67例，安慰剂组69例。对134起完成后续行动的案件进行了分析。根据Cspms，顺势疗法组的疼痛改善为56.18%，安慰剂组为46.45%。各组之间的平均改善不显著：顺势疗法组为60.36%，安慰剂组为48.66%。使用"患者全球变化印象量表"评估的平均生活质量评分在顺势疗法组为 2.29 ± 1.90 ，在安慰剂组为 2.93 ± 2.28 。与安慰剂组相比，顺势疗法组的生活质量提高了27.95%。使用最多的药物包括Rhus毒二龙（n = 19）28.8%，卡尔卡雷卡碳（n = 7）10.6%，卡尔米亚拉蒂福利亚（n = 7）10.6%和巴黎四合院（n = 8）12.1%。结论：同源性药物对颈椎骨病急性疼痛的治疗有效。