ORIGINAL ARTICLE

Homoeopathic individualized LM-potencies versus Centesimal potencies for pain management of cervical spondylosis: A multicenter prospective randomized exploratory clinical study

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Objective: Primary objective was to assess the feasibility for a further definite study to compare the effectiveness of LM–vs-CM homoeopathic potencies in reducing pain due to cervical spondylosis.

Method: A multi center prospective randomized clinical pilot study was conducted by Central Council for Research in Homoeopathy at its three centers during June 2009 - June 2010. Out of 148 patients screened, 56 patients were enrolled and randomized as per the pre-set inclusion criteria. However 54 patients, LM group (n=28) and CM group (n=26) were analyzed. Pain was assessed using visual analog scale. The primary end point for pain from 1 to 60 days was calculated using Area under the curve method. Secondary outcome was to assess the quality of life using WHO QoL Bref questionnaire. Medicines were prescribed to the enrolled patients on the basis of their totality of symptoms and according to principles of homeopathy.

Results: AUC for pain was significantly less in the LM group [Median (IQR): 112 (86 to 299); p= 0.007] after the prescription of homeopathic medicines. Overall quality of life of the patients after homeopathic medication showed significant improvement in the WHO-BREF domains: Physical, psychological, and Environmental only.

Conclusion: Homeopathic medicines in LM potencies are better than CM potencies for pain management of cervical spondylosis. Further blinded RCT can be conducted for validation of the results.

Keywords: pain; cervical spondylosis; homeopathy; randomized clinical study.

INTRODUCTION

Cervical spondylosis (CS), a degenerative disease of cervical intervertibral disc and their associated intervertebral joints.[1] It is defined as "vertebral osteophytosis secondary to degenerative disc disease" due to the osteophytic formations that occur with progressive spinal segment degeneration.[2] Spondylosis is a natural process of aging; it is seen in 10% of individuals by age of 25 years and in 95% by the age of 65 years.[3] Though it is a natural consequence of a bipadel existence and is not a disease state. However, this degenerative process may cause symptoms in up to 10% to 15% of population and therefore is among the most common causes of patient visits to health care providers.[4] Neck pain is the second largest cause of time off work, after low back pain (LBP).[5,6] Some prognostic studies have suggested that chronic neck pain is related to repetitive working conditions.[7,8]

Neck pain experienced with CS is often accompanied by stiffness, with radiation into the shoulders or occiput that may be chronic or episodic with long periods of remission.[2] One third of patients with cervicalgia due to CS present with headache, and greater than two thirds present with unilateral or bilateral shoulder pain. A significant amount of these patients also present with arm, forearm, and/or hand pain. CS may cause

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one of three syndromes: radiculopathy, myelopathy or mechanical neck pain.[3] Cervicalgia, is the most common syndrome seen in clinical practice.[9]

Available non-operative managements for neck pain are analgesics, nonsteroidal anti-inflammatory agents, corticosteroids, muscle relaxants, and antidepressants. In a meta-analysis it has been found that physical modalities such as heat, cold, therapeutic ultrasound, massage, use of transcutaneous electrical nerve stimulator (TENS), and cervical traction were not found to have any reproducible benefit in the treatment of acute or chronic neck pain[10].

Homeopathic therapy has shown positive role in alleviating symptoms due to CS.[11] Another study using bowel nosode group of medicines and prescribed them on the basis of the corresponding micro-organism found in the stool culture also reflected its usefulness in relieving symptoms due to CS[12] but these studies had some methodological flaws. In the former study the authors used homeopathic medicines in centesimal potency while LM potencies were used in later study

Hahnemann in his 6th edition of Organon of Medicine[13] clearly mentioned the new method of preparation of medicines i.e. renewed dynamization or fifty millesimal (LM) potencies which caused less aggravation in comparison to centesimal (CM) potencies, where the patient had to wait as long as they were improving even in the slightest manner after single dose of medicine. Adler et al's[14] review of Hahnemann's Paris case records showed the superiority of the LM potencies in comparison with the CM potencies and it was based on a significant number of experiments with the two potencies.

The studies conducted by Mohan et al[11] and Nayak[12] also had different groups but these studies had methodological flaws viz. randomization, a different group size, which has been considered in this present study. There was many drop outs too. Taking the above findings into consideration a comparative study of individualized homeopathic medicines in LM vis-a-vis CM potencies was designed to explore its effectiveness in persons suffering from pain due to CS and to further assess the feasibility for a further definite study. The secondary objective of this study was to assess the changes in quality of life.

METHODS

Design

A multi center prospective randomized exploratory study was designed to compare the effectiveness of homoeopathic medicines in LM vis-a-vis CM potencies from June 2009-June 2010. The investigators were trained before the trial was carried out. The ethics committee of the Council approved the study protocol. Written informed consent of the study participants was obtained before enrolling them in the study and the study followed the declaration of Helsinki and Good Clinical Practices of India. This sample was assembled to be representative of the type of patients seen in general practice. Patients' case history was recorded in prescribed case recording format, devised by the Council.

Patient selection and Setting

Patients meeting all of the following criteria were enrolled for study participation: either sex, age group 30-60 years, at least[15] one symptom out of (i) cervical pain aggravated by movement or (ii) pain in occiput, between the shoulder blades, upper limbs; And with any one of the following symptoms: (i) retro-orbital or temporal pain, (ii) cervical stiffness—reversible or irreversible, (iii) numbness of upper limb, (iv) tingling, or weakness in upper limbs; (v) Dizziness or vertigo and any one signs of the following; (i) poorly localized tenderness in neck, (ii) limited range of movement in neck (forward flexion, backward extension, lateral flexion, and rotation to both sides).

Patients were excluded for any of the following conditions: evidence of a specific pathologic condition, such as malignancy, fracture, primary neurological disease or systemic rheumatic disease, previous surgery of the neck, neurological changes complicated by myelopathy or radiculopathy, Inflammatory disease(rheumatoid arthritis, ankylosing spondylitis, or polymyalgia rheumatic), other non-specific neck pain lesions (acute neck strain, postural neck ache, or whiplash), inability to comply with the study protocol (including psychiatric diseases), lactating mother and pregnant lady were excluded. Erythrocyte Sedimentation Rate(ESR), C-reactive protein(CRP) & RA factor, Magnetic Resonance imaging (MRI) was carried out to screen the eligibility of the patient.

Four investigators from three study centers: Central Research Institute(H), Noida (Uttar Pradesh), Regional Research Institute(H), Jaipur (Rajasthan), Princess Durru Shehvar General Hospital, Purani Haveli, Extension Centre of Drug Standardization Unit, Hyderabad (Andhra Pradesh) under Central Council for Research in Homoeopathy participated in the trial for collecting data.

Intervention

Homoeopathic medicines either in LM or CM potencies were given randomly as per the randomization chart. The selection of medicines was arrived at by repertorising

the symptoms of the disease and the patient as a whole. The repertorisation was done using the Complete Repertory in Hompath classic software[16]. But the final selection of the medicine was done in consultation with the Materia Medica. Homoeopathic treatment was given as per instructions given in Hahnemann's Organon of Medicine.[13] Its characteristics are: Selection of one drug at a time, using the 'Similia Principle' and the drug picture and disease picture should be as similar as possible. If the first prescription didn't work, Investigators were allowed to change the prescription after reviewing the case. All medicines were procured from GMP certified pharmaceutical companies approved by the Scientific Advisory Committee of the Council.

CM Potency

The indicated homoeopathic medicine in 30c potency was administered initially with frequent repetition (6 hourly, 4 hourly, 2 hourly) as per the intensity of pain. Each dose consisted of 4 pills, size no. 20. The medicine was stopped when improvement began. After a particular prescription, if the improvement remained stand still after repetition, a next higher potency 200c was given and later as per requirement. Placebo pills were given as soon as the improvement was observed.

LM Potency

The indicated homoeopathic medicine in 0/1 potency was administered initially with frequent repetition as per the intensity of the pain. One globule (poppy-seed size) of the medicine in the desired LM potency was dissolved in 120 ml of distilled water; containing 2.4 ml(2% v/v) of dispensing alcohol, premixed in it; followed by ten uniformly-forceful downward strokes given against the bottom of the phial. This solution was given to the respective patient with the instructions regarding the dosage as follows:

- Before each dose, ten uniformly-forceful downward strokes to be given to the bottle held in the hand, on a firm surface.
- To mix three tea-spoonfuls (15 ml) of this solution with eight tea-spoonfuls (40ml) of water in a separate clean glass and stir the solution well.
- One tea spoonful (5 ml) of this solution would constitute one dose and this is to be taken as advised by the investigator.
- The liquid remaining in the glass after taking this dose is to be discarded.

After a particular prescription, if the improvement commenced and the medicine was exhausted then the next higher potency was prescribed in serial order. If improvement was consistent then the same medicine was continued.

Sample size

As this was a exploratory study, to assess the feasibility, a small sample size of 60 (LM:CM: 30:30) was taken.

Randomization

A permuted block containing unique 20 sets of random numbers, two per set, numbers ranging from 1 to 2 was generated to ensure even treatment allocation, using www.randomizer.org. Only patients were blinded to study medication. Due to nature of therapy investigator was not blinded to treatment. The patient's enrolment numbers were used for the purpose of randomization.

Outcomes

The primary outcome was to compare the effectiveness of homoeopathic treatment (LM vis-à-vis CM potencies) in CS pain at the end of 60 days of treatment. The secondary outcome was to assess the quality of life of patients treated with homoeopathic medication using WHOQoL (Bref) health status questionnaires for quality of life.

The patients were assessed at 1st, 7th, 14th, 30th , 45th and 60th day for pain, tingling, stiffness, weakness and vertigo on a visual analogue scale (VAS) of 0 to 10 where '0' indicates no symptoms and '10' indicates worst possible symptoms. World Health Organization –quality of life–Bref (WHOQoL Bref) questionnaire has been designed to be applicable to people living in different conditions or cultures. This questionnaire has been validated in Indian population and was used to evaluate quality of life[17] of patients suffering from pain due to CS. It contains 26 items divided into four domains: physical, psychological, social relationships and environmental. Each item uses a 5-point response scale, with higher scores indicating a better QOL. All the patients were assessed for their quality of life at baseline and at study end.

Statistical analysis

Reporting adhered to the Consolidated Standards of Reporting Trials statement for reports of parallel-group randomized designs and RedHOT. The primary outcome measure was Area under the Curve(AUC) pain using the VAS corresponding to person's total pain at 6 time points (Day1, 7, 14, 28, 30, 45 and 60) in both the groups and was compared. Similarly other symptoms

like stiffness, tingling, numbness, weakness, vertigo were also analyzed for AUC.

SPSS ver.20, for Windows and Med Calc ver.12 for windows were used for all the data analysis. Minitab ver.16 for Windows was used for calculating confidence intervals of non-parametric inferences. Independent and paired t test were used for inferring WHOQoL Bref. The analysis was done as per the protocol. Percentage change was calculated for pain and total symptom score (TSS) using the formula = $\frac{Baseline\ score - Score\ at\ \ end}{Baseline\ score} x100$

A change of 75% and above improvement in TSS was considered as Clinical success and less than 75% was considered as clinically unsuccessful. P-value < 0.05 was considered as significant.

RESULTS

Enrolment took place from June 2009 to April 2010. Three centres actively screened the patients. Of the 148 patients, 54 patients (36%; 28 males; 26 females) were eligible for the study and were randomly assigned for treatment; the 94 ineligible patients were excluded as per the protocol, for the reasons of not meeting inclusion criteria or refusing to give consent (Figure1). The baseline demographics for the patients enrolled in the study are given in Table 1. There were no statistical differences between the two groups at baseline.

Table 1: Baseline characteristics of two potency arms

Characteristics	LM (n=28)	CM (n=26)	p-value
Age in years	45 (8.6)	44.8 (8.2)	0.90
Sex			
– Male	12 (43)	14 (53.8)	0.58
– Female	16 (57)	12 (46.2)	
Duration of disease (in yrs)	1.3(2.1)	2.3(3.2)	0.17
Occupation			
– Astrologer	0	2(7.7%)	
– Bank employee	2(7.1%)	2(7.7%)	
– Business	4(14.3%)	3(11.5%)	
– Cobbler	1(3.6%)	1(3.8%)	
– Computer professional	0	1(3.8%)	0.65
– Electrician	0	1(3.8%)	
– Housewife	12(42.9%)	9(34.6%)	
– Police	1(3.6%)	0	
– Physician	0	2(7.7%)	
– sales person	1(3.6%)	0	
– Tailor	4(14.3%)	2(7.7%)	
– Teacher	1(3.6%)	2(7.7%)	
– Others	2(7.2%)	1(3.8%)	
Symptoms			
– Pain VAS(0-10)	28(100%),7.8(2)	26(100%), 7.9(1.8)	0.85
– Stiffness VAS (0-10)	21(75%), 3.8(3)	18(69%), 4(3.2)	0.83
– Tingling VAS (0-10)	11(39%),1.7(2.4)	10(38.5%),1.6(2.3)	0.88
– Numbness VAS (0-10)	19(68%), 3.7(2.9)	20(77%), 4.2(2.8)	0.48
– Weakness VAS (0-10)	10(36%), 2(3)	11(42%), 2.4(3)	0.61
– Vertigo VAS (0-10)	19(68%),3.9 (3.5)	16(61%), 3.8 (3.5)	0.91
– Total Symptom Score (TSS)	28(100%), 23(10.5)	26(100%), 24.1(11.5)	0.71
WHO-Qol Bref			
– Physical health	12.5 (1.8)	12.5 (2.1)	0.99
– Psychological	11.8 (2.3)	12.5 (1.7)	0.24
– Social relationships	15.4(2.8)	15.04 (2.7)	0.67
– Environment	13.5(2.9)	13.8(2.4)	0.67

Data are presented in mean(sd), n(%); VAS: Visual Analog Scale; WHO-Qol Bref: World Health Organization quality of life brief questionnaire

Figure 1 : Flow of study patients

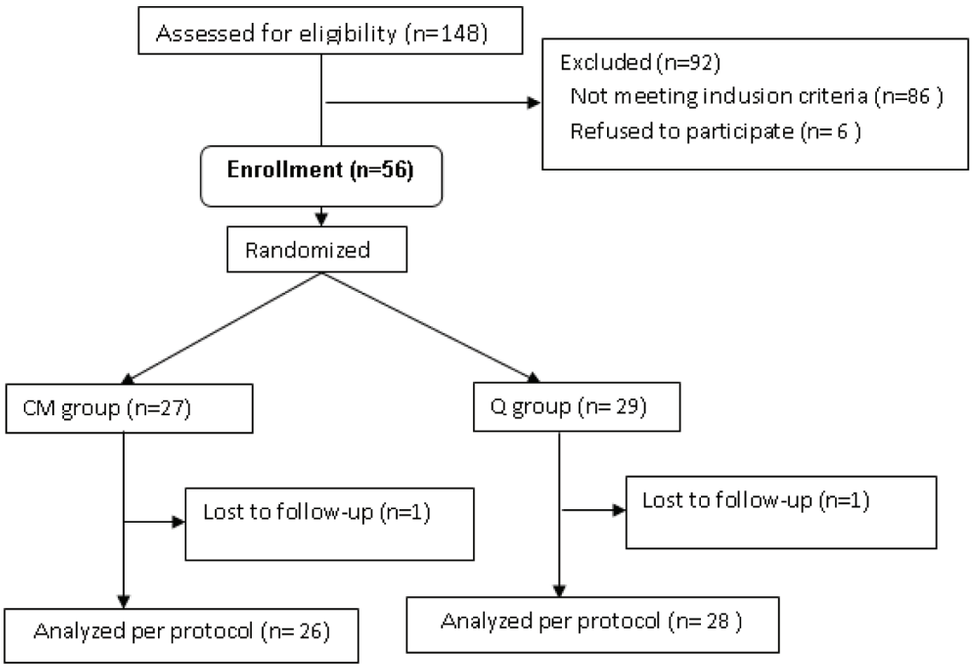


Table 2: Comparative variables between groups

Characteristic	LM (n=28)	CM (n=26)	Difference (95% CI)	p-value
Symptoms				
– AUC pain	112 (86 to 299)	225.5(135 to 378)	-80.8 (-150.5, -21)	**0.007**
– AUC stiffness	86 (0.9 to 168)	132 (0 to 236)	-36.5 (-112.5,10.5)	0.3
– AUC tingling	0	132.3	-102.5 (-139, 0)	**0.005**
– AUC numbness	76(0 to 173)	179(21 to 247)	-59 (-142.5, 0)	0.06
– AUC weakness	0(0 to 168)	0 (0 to 237)	0 (-10.5, 0)	0.54
– AUC vertigo	60(0 to 158)	75 (0 to 233)	0 (-90.5, 32)	0.66
AUC TSS	272.5(167 to 1159)	642(332 to 1455)	-270.7(-492.9,21.5)	0.08
WHO-Qol Bref				
– Physical health	13.5(2)	14(2.1)	-0.5(-0.6, 1.6)	0.41
– Psychological	12.9(1.6)	13.4(2.1)	-0.5(-0.5, 1.5)	0.31
– Social relationships	15.6(2.9)	14.8(2.9)	-0.8(-2.4, 0.8)	0.34
– Environment	13.7(2.8)	14(2.3)	-0.3(-1.1, 1.7)	0.68

Data are presented in Mean (SD), Median (Q1 to Q3). AUC scores were compared using Mann Whitney U test. *WHO-Qol Bref* domains were compared with paired t test.

The primary outcome measure for AUC pain (day 1–day 60) corresponding to person's total pain was compared. A significant difference in median pain AUC [Median difference, -80.8, 95%CI:-150.5 to -21, p=0.007) was found towards LM group [Median(IQR),112 (86 to 299)], in comparison to CM group [225.5(135 to 378)]. There was sharp reduction in pain as early as 7th day(1st follow up) which was maintained till the end in LM group in comparison to CM group as depicted in figure 2. Significant difference was also found in AUC tingling (p=0.005), whereas no difference (p >0.05) was found in AUC stiffness, AUC numbness, AUC vertigo and AUC weakness. There was no significant difference (p >0.05) observed in various domains of WHOQoL Bref between the groups (Table 2).

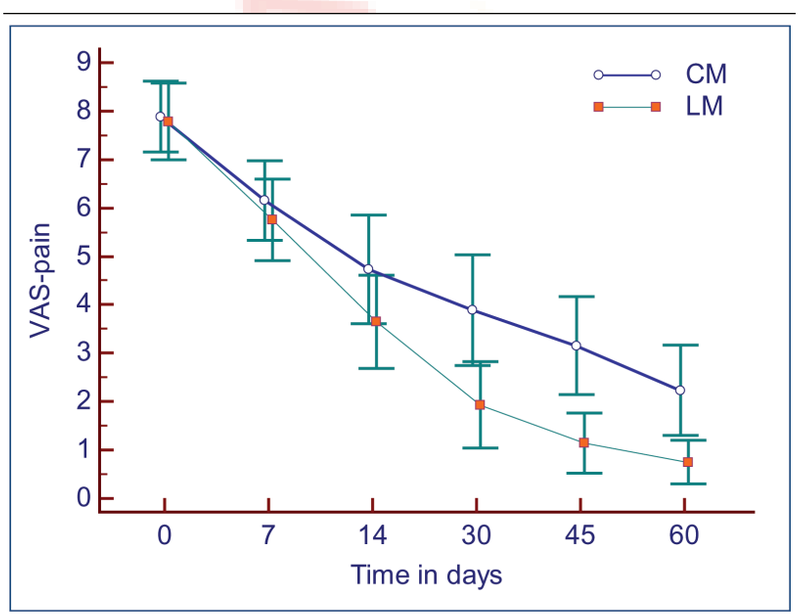
All the patients were given homoeopathic therapy either in LM or CM potencies. So an overall comparison

Table 3: Comparison of overall treatment

Characteristic	Mean(sd)		Diff.(95%CI)	p-value
	Day1 (n=54)	Day 60(n=54)		
Pain	7.8(1.9)	1.5(1.9)	6.4(5.8 to 6.9)	0.0001
Stiffness	4(3.2)	0.8(1.3)	3.1(2.3 to 3.9)	0.0001
Tingling	1.7(2.3)	0.4(0.8)	1.3(0.8 to 1.9)	0.0001
Numbness	3.3(2.5)	1.1(1.7)	2.4(2.1 to 3.6)	0.0001
Weakness	2.2(3)	0.7(1.3)	1.5(0.9 to 2.1)	0.0001
Vertigo	3.9 (3.5)	0.8(1.3)	3.6(2.7 to 4.5)	0.0001
WHO-QOL BREF				
Physical health	12.5	13.7	-1.3(-1.7 to -0.8)	0.0001
Psychological	12.1	13.1	-1.0(-1.5 to -0.6)	0.0001
Social relationships	15.2	15.2	0 (-0.4 to 0.4)	1
Environment	13.7	13.8	-0.1(-0.3 to 0)	0.05

Data are presented in mean(sd). Negative findings in WHOQol Bref domains indicate improvement.

Figure 2: Comparison of pain reduction in LM –vs-CM group at different time points



(pre-post) with mean scores was also carried out (Table 3). Paired t test showed significant difference (P = 0.0001) after homoeopathic therapy in both the primary and secondary outcome variables except for social relationship component of WHOQoL Bref (p=1).

Patients who had more than 75% improvement were considered as clinically successful. There was a statistically significant clinical success (χ=6.26,df=1, p= 0.01) in LM (82%, n=23) compared to CM group(50%, n=13) for pain. Similarly statistically significant clinical success (χ=7.65,df=1, p= 0.006) was found in LM (82%, n=23) compared to CM group (46%, n=12) in TSS.

Over the course of the trial most frequently used homeopathic medicines in both the groups are: *Lyc.* (n=11, 20%), *Sulp.* (n=8,15%), *Bry.* (n=7, 13%), *Phos.* (n=7, 13%), *Calc.* (n=5,9%), *Nux- v* (n=5, 9%), *Rhus- t* (n=4, 8%), *Nat-m* (n=2, 4%). The other less frequently used medicines in this trial are *Caust* (n=1), *Chel.* (n=1), *Con.* (n=1), *Sep.*(n=1) and *Sil.* (n=1).

DISCUSSION

Cervical region problems can have varying symptoms as they are caused by many different conditions such as excessive workload, postural disorders, psychological state, structural disorders, degenerative conditions, and trauma. In this study patient who received individualized homeopathic medicines in LM potencies had significantly less pain after 60 days of treatment than did patients who received individualized homeopathic medicines in CM potencies. The findings of this exploratory study with small sample size, supports Hahnemann's concept of renewed dynamization[13].

The majority of patients were found to be above 40 yrs of age. This observation was found to be similar to a previous study.[18] A contradiction to previous studies, the sex incidence was found to be insignificant with very slight increase in female.[19]

Individualized homeopathic medicines have better results in relieving neck pain in cervical spondylosis patients. This finding is supported by Mohan et al[11]. Even though the improvement commenced from 7th day onwards in both the groups but it was steeper in LM group. It shows that LM potency was capable of pain alleviation more rapidly than the CM potency. Clinical success in relieving pain for LM group was 82%.

All the patients irrespective to which group they were randomized improved in their physical health and psychological domains of WHO QoL Bref whereas in another study with surgical intervention for cervical spondylotic myelopathy, there was improvement in environment domain also.[18]

The strength of this study is that it represents a pragmatic setting of homeopathic practice reflecting the day-to-day clinical setting.

As the study did not have any control group and blinding, it can't conclude the efficacy of the homeopathic therapy in the pain management of patients with CS. To validate the rapid effect of homeopathic care in the pain management of CS further research effort may include blinding and inclusion of control group.

CONCLUSION

Homoeopathic intervention in LM potencies are better than CM potencies for pain management of CS. Further blinded RCT can be conducted for validation of the results.

CONFLICT OF INTEREST

We declare there is no conflict of interest.

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उद्देश्य : अध्ययन का प्रारंभिक उद्देश्य ग्रीवा कशेरूका संधि ग्रह में पीड़ा को कम करने में एल.एम.बनाम सी.एम. होम्योपैथी पोटेंसियों की प्रभावकारिता की तुलना हेतु एक अग्र सुनिश्चित अध्ययन की संभाव्यता का मूल्यांकन करना था।

पद्धति : केन्द्रीय होम्योपैथी अनुसंधान परिषद् द्वारा जून 2009–जून 2010 के दौरान इसके तीन केन्द्रों पर एक बहुकेंद्रिक अग्रदर्शी यादृच्छिक नैदानिक पायलट अध्ययन किया गया। अध्ययन में सम्मिलित करने के पूर्व निर्धारित मानदण्डों के आधार पर छांटे गये 148 मरीज़ों में से 56 मरीज़ों को यादृच्छिकता के आधार पर अध्ययन में नामांकित किया गया। 54 मरीज़ों एल.एम. समूह (स.=28) और सी.एम.समूह (स. =26) का विश्लेशण किया गया। पीड़ा का मूल्यांकन दृश्य एनालॉग स्केल का प्रयोग करते हुए किया गया। 1 से 60 दिनों के दर्द हेतु प्रारंभिक अंतिम बिन्दु की गणना एरिया अण्डर कर्व पद्धति का प्रयोग करते हुए की गई। द्वितीय परिणामों को विश्व स्वास्थ्य संगठन क्यू.ओ.एल. ब्रेफ प्रश्नावली का प्रयोग करते हुए जीवन गुणवत्ता का मूल्यांकन किया गया। अध्ययन में नामांकित मरीज़ों का उपचार लक्षणों की संपूर्णता और होम्यापैथी के सिद्धातों के आधार पर किया गया।

परिणाम : होम्योपैथी औशधियों के सेवन के उपरान्त एल.एम.समूह में (माण्धिका) (आई.क्यू.आर.):(86 से 299); पी.=0.007) दर्द की ए.यू.सी. में कमी पायी गई। होम्योपैथी चिकित्सा से उपचार के उपरांत मरीज़ों की समेकित जीवन गुणवत्ता में विश्व स्वास्थ्य संगठन–ब्रेफ मानकों : शारिरिक, मानसिक और पर्यावरणीय आधार पर सुधार आया।

निष्कर्ष : ग्रीवा कशेरूका संधिग्रह पीड़ा के उपचार में सी.एम.पोटेंसी की तुलना में एल.एम.पोटेंसी में होम्योपैथी औषधि प्रभावकारी होती है। परिणामों की वैधता हेतु ब्लाइंड यादृच्छिक नियंत्रित परीक्षण किया जा सकता है।

खोजशब्द : पीड़ी, ग्रीवा कशेरूका संधि ग्रह, होम्योपैथी, यादृच्छिक नैदानिक अध्ययन।