

THE EFFECTIVENESS OF *PARIS QUADRIFOLIA* IN CASES OF CERVICAL SPONDYLITIS-A PROSPECTIVE SINGLE BLIND RANDOMIZED PLACEBO CONTROLLED TRIAL

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ABSTRACT

Background: The vast population is affected by Cervical Spondylitis in some form or the other, but due to fast, mechanical life, tension, lack of exercise and wrong posture in lying or sitting, continues working on computer, carrying axial loads (i.e. heavy school bags by children), use of cushy pillows and a soft bed, long driving, also contribute to it. It may also be due to mechanical injury. **Methods:** A randomized single blind controlled trial was conducted at Dr. Madan Pratap Khunteta Homoeopathic Medical College, Hospital and Research Centre, Jaipur. 70 diagnosed cases were enrolled in the study. Randomly selected 35 cases received *Paris quadrifolia* (Group-A) and 35 cases received

Placebo (Group-B). VAS (Visual Analogue Scale) was used to assess the improvement in the study. **Results:** Paired t- test shows that Group-A (*Paris quadrifolia* with physiotherapy) and Group-B (Placebo with physiotherapy) both, shown significant result in cases of cervical spondylitis. Comparison of both groups by independent t-test shows that both groups, Group-A (n=35) and Group-B (n=35) have significant difference in results. This study showed that there was improvement in cases of Cervical spondylitis from Group-A (*Paris quadrifolia* with physiotherapy) and Group-B (Placebo with physiotherapy) both, but the improvement in Group-A (*Paris quadrifolia* with physiotherapy) was far better than Group-B (Placebo with Physiotherapy).

KEYWORDS: Cervical spondylitis, *Paris quadrifolia*, randomized, VAS (Visual Analogue Scale).

INTRODUCTION

In the present era, majority of the persons have Cervical problems. In addition to age and possibly gender, Aetiological factors are poorly understood and are usually multifactorial, it is due to fast, mechanical life, anxiety, depression, lack of exercise and wrong posture in lying or sitting, continues working on computer, carrying axial loads (i.e. heavy school bags by children), use of cushy pillows and a soft bed, long driving, also contribute to it. It may also be due to mechanical injury.^[1]

Cervical Spondylitis is derived from Greek words Cervical (neck) and spondylo (spinal vertebra).^[2]

Cervical Spondylitis is an inflammation of soft tissues between the neck vertebrae or inflammation of the synovial joints of the Cervical bone.^[3] This may give pain in the neck, stiffness, shoulder and hands; with numbness and tingling, postural disturbance.^[4]

Pain and stiffness is common condition. Sometimes the pain in neck lasts for a few days and wears off on its own but when it persists for a long time, it presents greater problem.^[5]

The estimated 1 year incidence of neck pain from available studies ranges between 10.4% and 21.3% with a higher incidence noted in office and computer workers. While some studies report that between 33% and 65% of people have recovered from an episode of neck pain at 1 year, most cases run an episodic course over a person's lifetime and, thus, relapses are common. The overall prevalence of neck pain in the general population ranges between 0.4% and 86.8% (mean: 23.1%); point prevalence ranges from 0.4% to 41.5% (mean: 14.4%); and 1 year prevalence ranges from 4.8% to 79.5% (mean: 25.8%). Prevalence is generally higher in women,^[6,7] higher in high-income countries compared with low- and middle-income countries^[8] and higher in urban areas compared with rural areas.^[9]

Paris quadrifolia, commonly known as One-berry, True Love, Herb Paris, is a perennial herb with creeping, fleshy root stock. Herb distributed in North and central Europe, Siberia and Asia Whole plant is used for medicinal preparation. The medicine was introduced in Homoeopathy and proved by Staf, Allen & Hering.^[10]

Paris quadrifolia by Allen T.F., "*Encyclopedia of pure materia medica*"^[11]

- The head is heavy; the Cervical muscles will not hold it upright; it sinks forward, Pressure in the occiput.

- Intermitting drawing pain in the muscles of the right side of the occiput (after three hours), Sensation as if a great weight were lying upon the nape.
- Stitches through and through both sides of the back and nape of the neck.
- Stitches, extending into the back, while sitting.
- Long-continued stitches beneath the left scapula
- Tearing in the left shoulder.
- Stitches in the shoulders, as if in the bone.
- Tearing in the shoulders, extending into the fingers.
- A burning sensation in the left shoulder, as if in the bone.
- Drawing in the upper arm.
- Heaviness of the right arm.
- Sensation of heaviness in the arms, even during rest

MATERIALS AND METHODS

Study setting

The study was conducted at Dr. M.P.K. Homoeopathic Medical College Hospital and Research centre, Jaipur, Sindhi camp and saipura campus. The cases were selected from OPD/IPD for a period of 9 months and each case was followed up for atleast 6 follow-ups.

Sample size

70 cases were selected. 35 cases for each group by using simple random sampling method.

Group A -35 cases (*Paris quadrifolia* with Physiotherapy).

Group B -35 cases (Placebo with Physiotherapy).

Inclusion criteria

1. Diagnosed cases of Cervical Spondylitis has been included in the study irrespective of their sex, caste, religion & duration of illness.
2. All cases of any age group with the clinical features fitting to Cervical Spondylitis has been taken up for the study and the diagnosis has been made on exclusion criteria of X- ray findings visualized in AP and lateral view of X-ray Cervical spine for other than spondylitis pathologies.

Exclusion Criteria

1. X-Ray findings visualized in AP and lateral view of X-ray Cervical spine for other than spondylitis pathologies.

Data collection

- 1. Case taking proforma-** A special case taking proforma was designed for the study with the approval of guide.
- 2. Case taking -** Detailed case taking for every screened case after randomization was done on especially designed case taking proforma, based on homoeopathic principles.
- 3. Diagnostic criteria -** Clinical examination and relevant investigation were carried out to establish the diagnosis.
- 4. Follow-ups-** All the cases were reviewed at the interval of 7-15 days and data was recorded for minimum 6 follow-ups.
- 5. Record-** Centralized data was recorded in approved master chart in proper excel format.
- 6. Maintenance -** There are forms that are completed by for each subject Recruited, including two consent form for the patient's information & his/her written consent for the enrolment in the study.

Data analysis

The data were entered into MS Excel spreadsheet and analysis was done Statistical Package for Social Sciences (SPSS) version 16.0 software.

10. Statistical Analysis

The statistical technique which was applied is 'Paired t-test' and 'Independent t-test'.

'Paired t-test' was used to assess the before and after scores in pre & post inter group & 'Independent t-test' was used to compare between intra groups.

11. Outcome Assessment & Result

The percentage changes of symptoms score from baseline to end of treatment were calculated by using following formula:

$$\text{Percentage} = \frac{\text{Score at Baseline} - \text{Score at the end}}{\text{Score at Baseline}} \times 100$$

Outcome of the treatment was measured in gradation as

- Cure – 100% (Feeling of mental & physical well-being with relief in all signs & symptoms for which patient originally approached without any relapse for 6 months).
- Marked Improvement= 75%-99%
- Moderate Improvement= 40%-74%

- Mild Improvement= up to 40%
- Status quo= 0%
- Worse=increase in symptoms score

OBSERVATIONS AND RESULTS

A total of 70 patients were enrolled in the study, maximum incidence of Cervical spondylitis was observed in the age group 25–35 years i.e. 26 cases (37.14%) whereas minimum incidence was in the age group 55–65 years i.e. 3 cases (4.28%). Maximum incidence of Cervical spondylitis were observed in male patients i.e. 39 cases (56%) in comparison to female patients i.e. 31cases (44%). Maximum incidence of Cervical spondylitis were observed in middle class population i.e. 44 cases (62.85%) and minimum incidence of Cervical spondylitis were observed in lower class population i.e. 11 cases (15.71%). Maximum cases of Cervical spondylitis were observed in Urban patients i.e. 49 cases (70%) in comparison to Rural patients i.e. 21cases (30%). Maximum cases of Cervical spondylitis found to be more in students i.e. 18 cases (25.27%) and minimum incidence in labourer i.e. 7 cases (10%). While incidence of Cervical Spondylitis of 15 cases (21.42%) was found in Housewife, 16 cases (22.85%) employees and 14 cases (20%) in Business/Self-employed. Maximum cases of Cervical spondylitis with H/O over lifting 10 cases (14.28%), H/O wrong posture 20 cases (28.57%), H/O injury to neck 5 cases (7.14%) and no any H/O present illness in 35 cases (50%).

Table 1: Distribution of cases of Cervical spondylitis acc. to presenting complaints.

Symptoms	No. of Cases	Percentage %
Pain	70	100%
Stiffness	38	54.28%
Numbness	14	20%
Vertigo & vomiting	10	14.28%
Cracking on movement	6	8.57%
Radiate pain	32	45.71%
Occipital headache	30	42.85%
Heaviness in neck	21	30%

Table 2: Severity of pain in cases of Cervical spondylitis as per VAS (visual analogue scale) before treatment and after treatment.

No. of cases → VAS score ↓	Group A (<i>Paris quadrifolia</i> with physiotherapy)		Group B (Placebo with physiotherapy)	
	Before T/t (no. of cases)	After T/t (no. of cases)	Before T/t (no. of cases)	After T/t (no. of cases)
No pain (0)	0 (0%)	10 (28.57%)	0 (0%)	0 (0%)
Mild pain (1-3)	0 (0%)	24 (68.57%)	0 (0%)	23 (65.71%)
Moderate pain (4-6)	14 (40%)	01 (2.85%)	16 (45.71%)	12 (34.28%)
Severe pain (7-10)	21 (60%)	0 (0%)	19 (54.28%)	0 (0%)
Total (no. of cases)	35	35	35	35

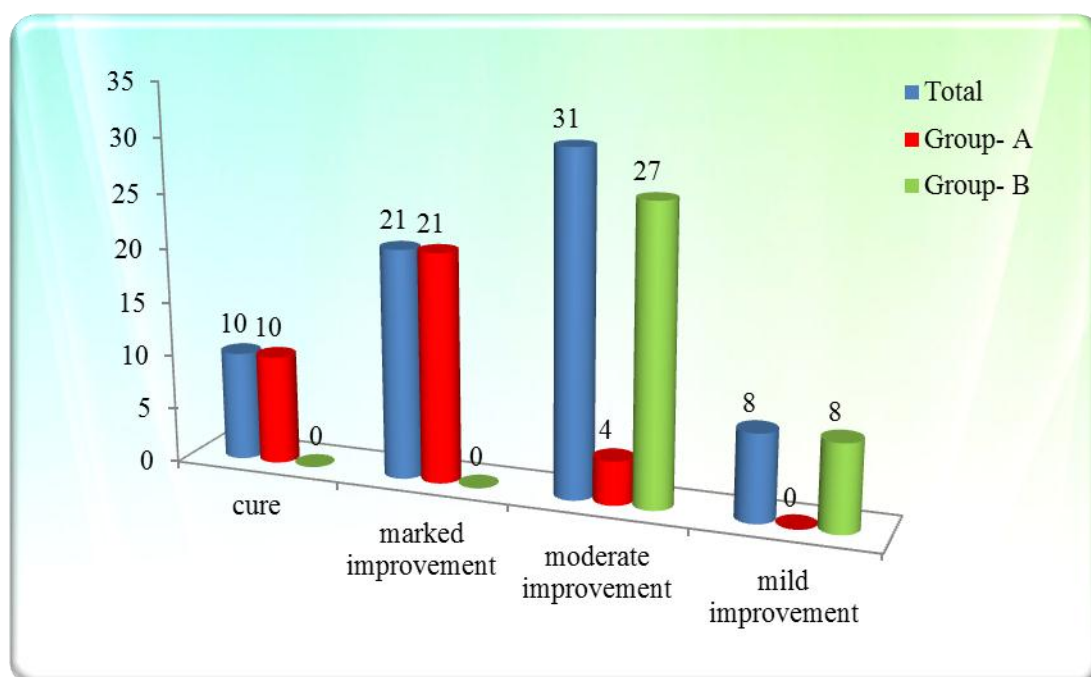


Fig. 1: Graphical distribution of 70 cases of Cervical spondylitis in different groups according to outcome assessment as per VAS (visual analogue scale).

As shown in above graph & table, 10 cases (14.28%) have shown cure in their symptoms, out of which maximum cases were from Group –A (*Paris quadrifolia* with physiotherapy) i.e. 10 cases, 21 cases (30%) showed marked improvement in their symptoms, out of which maximum cases were from Group- A (*Paris quadrifolia* with physiotherapy) i.e. 21 cases, 31 cases (44.28%) show moderate improvement in their symptoms, out of which maximum

cases were Group-B (Placebo with physiotherapy) i.e. 27 cases and 8 cases (11.42%) show mild improvement in their symptoms, out of which maximum cases were from Group-B (Placebo with physiotherapy) i.e. 8 cases.

STATISTICAL ANALYSIS & RESULTS

For assessing the improvement VAS (visual analogue scale) was used. Scores before treatment and after treatment were compared in both groups. The analysis was conducted through the software SPSS (ver.16) applying Paired t- test, and independent t-test.

In this study, 'Paired t-test' is applicable to pre & post inter group i.e. Group-A (*Paris quadrifolia* with physiotherapy) to Group-B (placebo with physiotherapy) in cases of Cervical spondylitis. There was a significant difference in the scores for *Paris quadrifolia* with physiotherapy (M=5.85, p = 0.000) and placebo with physiotherapy (M=3.42, p =0.00) i.e. (Group-A and Group-B). These results suggest that Group-A (*Paris quadrifolia* with physiotherapy) had shown significant result in cases of Cervical spondylitis. (Table 4, 6).

In this study, independent t-test is applicable to study the inter-group i.e. Group-A (*Paris quadrifolia* with physiotherapy) & Group-B (Placebo with physiotherapy). Levene's test indicated equal variance (F= 12.88, P=.001) so $df= 68$. There is significant (p < 0.005) improvement in Cervical spondylitis with Group-A (*Paris quadrifolia* with physiotherapy) (M=1.14, SD= 0.94) than Group-B (Placebo with physiotherapy) (M=3.31, SD= 1.40), $t(68)= 7.573$, P< 0.005. (Table 7, 8).

Therefore rejecting null hypothesis(H_0) and accepting alternating Hypothesis (H_1) that Group-A (*Paris quadrifolia* with physiotherapy) have a significant role in treating the cases of Cervical spondylitis as compared with Group-B (placebo with physiotherapy).

Table 3: Paired Samples Statistics Group-A.

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Group A_before	7.00	35	1.350	.228
	Group A_after	1.14	35	.944	.160

Table 4: Paired Samples Test Group-A.

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Group A_before	7.00	35	1.350	.228
	Group A_after	1.14	35	.944	.160

Table 5: Paired Samples Statistics Group-B.

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Group A_before	6.74	35	1.521	.257
	Group A_after	3.31	35	1.409	.238

Table 6: Paired Samples Test Group-B.

		Paired Differences					T	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Group B_before Group B_after	3.429	.778	.131	3.161	3.696	26.077	34	.000

Table 7: Group Statistics of After - After score of both groups.

	Group	N	Mean	Std. Deviation	Std. Error Mean
Score_after	A	35	1.14	.944	.160
	B	35	3.31	1.409	.238

Table 8: Independent Samples Test.

		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	T	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
Score_after	Equal variances assumed	12.884	.001	-7.573	68	.000	-2.171	.287	-2.744	-1.599
	Equal variances not assumed			-7.573	59.387	.000	-2.171	.287	-2.745	-1.598

CONCLUSION

This was a single blind randomized controlled trial with positive results. From this study, it has been observed that Group-A i.e. *Paris quadrifolia* with physiotherapy was more beneficial to the patients suffering from Cervical spondylitis, as compared to Group-B i.e. Placebo with physiotherapy.

In this study, Group-A (*Paris quadrifolia* with physiotherapy) showed improvement in patients suffering from neck pain. In this study, the Cervical spondylitis is likely to occur in the urban people, mostly cases observed in students & employee due to fast mechanical life,

lack of exercise and wrong posture in lying or sitting, keeping the neck constantly in one position while reading, writing & continue working on computer, use of cushy pillows and a soft bed & long driving.

This study showed that there was improvement in cases of Cervical spondylitis from Group-A (*Paris quadrifolia* with physiotherapy) and Group-B (Placebo with physiotherapy) both, but the improvement in Group-A (*Paris quadrifolia* with physiotherapy) was far better than Group-B (Placebo with Physiotherapy).

This study was conducted with small sample size. So, in future different population with large sample size is recommended for more reliable results. The study period was short. So, to confirm the conclusions long term studies are recommended.

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