

Original Research Paper

Homeopathic

ROLE OF GNAPHALIUM POLYCEPHALUM IN PAIN MANAGEMENT OF SCIATICA IN PATIENTS OF BOTH SEXES, OF AGE GROUP OF 30-65 YEARS

Dr. Aanchal Garg	Post Graduate Scholar, Department of Homoeopathic Materia Medica, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune, Maharashtra.
Dr. Vaishali. V. Dolas*	PG Guide, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune, Maharashtra. *Corresponding Author
Dr. Arun.b. Jadhav	Head of Institute, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College, Pune, Maharashtra.

ABSTRACT

 $\textbf{BACKGROUND:} Good\ posture, efficient\ breathing\ and\ pain\ free\ life\ is\ the\ key\ to\ healthy\ life.$

A poor posture does not only affect the back but eventually leads to poor quality of life.

Since the increase in desk work, less manual labour and more sedentary lifestyle backache and sciatica which is also known as lumbar radiculopathy has become the most common ailment in today's era.

Sciatica in itself is not a disease and can be dealt with conservative treatment, ergonomic correction and physiotherapy way before surgery is an option.

Homoeopathy has miraculous results in treatment of sciatica because it has a large scale of medicines. It not only offers relief from pain but is also able to identify the problem in the sciatic nerve.

METHOD: It is a prospective, single arm, single arm, non-randomised clinical trial study, conducted at the OPD at BVDUHMC and Research Centre, Katraj-Pune and rural OPD at Pirangut.

Total 32 patients, male and female, aged 30-65 years, were enrolled in the study out of which 2 patients dropped out and 30 patients completed the follow-ups. General and local examination with Sciatica Bothersome Index(SBI), Maine Seattle Back Questionnaire(MSBQ) and Visual Analogue Scale(VAS) for pain were conducted at every follow-up.

RESULT: The final outcome was reduction in pain intensity and improvement in quality of life after 6-8 weeks of OPD, pretest and post test analysis was done using, students paired 't' test.

Significant reduction observed in scoring values of pain and quality of life in sciatica patients before and after treatment.

The mean reduction in VAS was 7.33(95% CI,0.88, 1.53), Maine Seattle Back Questionnaire was 6.4(95% CI, 1.37, 1.77), and Sciatica Bothersome Index was 10.6(95% CI, 1.80, 2.03).

CONCLUSION:Homoeopathic medicine Gnaphalium Polycephalum produced a significant effect in reduction of pain intensity of sciatica and also in improving the quality of life. Further studies with control groups can provide more validation and authenticity in proving Gnaphalium effective in alleviating the pain of sciatica.

KEYWORDS: Sciatica, lumbar radiculopathy, neuralgia, Gnaphalium polycephalum

INTRODUCTION

A poor posture will not only affect the back but will eventually lead to headaches, neck pain, back pain, fatigue and affect the quality of life. $^{\scriptscriptstyle (1)}$

Since the increase of desk work, less manual labour and more of sedentary lifestyle backache has become the most common ailments in today's life. It is something that everyone has gone through once in their lifetime.

The back is a unique structure and genetic make up, traumas, footwear, quality of mattresses, lifestyle, job, weight, diet, etc play a very major role. Sciatica is generally used to describe pain that radiates along the course of the nerve from back to buttock and the leg. (2) The discomfort can be minimal or disabling, accompanied by numbness, muscle weakness, or tingling.

Sciatica is not a disease but a symptom of the pain in the sciatic nerve. $^{(9)}$ Sciatica is the result of a sedentary lifestyle. Sciatica is not just pain in the leg, but in reality is a neurologic type of a pain radiating down the leg with or without backache. It is caused due to irritation, inflammation or compression of the sciatic nerve anywhere along its course. $^{(4)}$ It can be acute, recurrent or chronic, where acute pain can be lightning type and frightening.

Sciatica does not only cause pain but makes life miserable as it may cause terrible pain on standing, walking, bending, sneezing or coughing, etc. (5) It can hamper the quality of life of the affected individuals. It is observed that sciatic pain

improves within 4 to 6 weeks, all though the other symptoms like numbness and weakness might take time to resolve.

The discomfort caused by sciatica can be dealt with conservative treatment, physiotherapy and some auxiliaries. Ergonomic correction may also play an important role in recovery of the patient or prevention of recurrent episodes of pain. (6)

Modern medicine without a doubt can relieve the pain instantly or within a short time but does not really cure it. On the other hand homeopathy considers the patient as a whole and not just the fact that organ. With its holistic approach homeopathy aims at working on physical current constitution, mental state, emotional state, social life, his reaction to a particular stimuli, the disease, and also considers the recent alterations in that patient's life.

Prevalence of sciatica.

Sciatica being a common condition has a lifetime incidence ranging from 13% to 40% and an annual incidence of an episode of sciatica varying from 1% to 5%. Homeopathy does not solely relieve pain but also improves the quality of life.

ETIOLOGY

Sciatica can be caused by several different lumbar spine (low back) disorders. Sciatica is often described as a pain which can go from mild to intense in the left or right leg. Sciatica is the result of compression of one or more of the five sets of nerve roots in the lower back. $^{(7)}$

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Sciatica may be the result of something as simple as poor posture, straining of muscles or spasm, pregnancy, being overweight, wearing high heels, or sleeping on a too-soft mattress. Although in some cases, sciatica can be due to inflammation of the nerve caused by a form of arthritis $^{(8)}$, or caused by the pinching of the sciatic nerve by a tumor around the spinal cord in the lower back.

Common Sciatica Causes: (9)

- 1: Lumbar Bulging or Herniated Disc
- 2: Lumbar Spinal Stenosis
- 3: Spondylolisthesis
- 4: Trauma
- 5: Piriformis Syndrome
- 6: Spinal Tumors

Homoeopathy for Sciatica:

Homoeopathy is miraculous in treating pains of any kind and anywhere in the body but can be achieved only through thorough clinical examination, assessment of patient, proper case history, sound knowledge of remedies and correct prescription.

Gnaphalium polycephalum is one of our great remedies in the treatment of lumbago and sciatica.

Gnaphalium Polycephalum is a remedy of unquestioned benefit in sciatica, when pain is associated with numbness of the part affected. Intense pain along the sciatic nerve; numbness alternates with pain. $^{(10)}$

MATERIALS AND METHODS

Theoretical study:

The study of this topic was done from various books, high quality preview homoeopathic journals, researches and authentic internet search, through websites, Google scholar, PubMed etc.

Case definition:

-Patients with neuralgic pain radiating down the back to the buttock, thigh, calf and foot with or without numbness and weakness of the lower limb since 3 months or less were taken for the study.

- Minimum 30 patients, with informed consent of the patient were taken for the study.
- Patients of both sexes, age group of 30-65 years were studied.

The case taking was done by standard case taking proforma as per homoeopathic principle.

Study setting:

Bharati Vidyapeeth Homoeopathic Medical College, Pune and various peripheral OPD's.

Sample selection: Opportunity sampling, patients fulfilling the inclusion criteria below and available during the duration of study were taken as study subjects.

Sampling Technique: Simple non-randomised technique.

Inclusion criteria:

- All the patients fulfilling the case definition were included in the study.
- Patients of age group 30-65 years.
- Patients of both the sexes.
- Patient having hip pain radiating down the calf and foot with or without back pain since 3 months or less.
- Low back strains
- Spondylosis and Spondylolisthesis

Exclusion criteria:

• The patients not fulfilling the case definition.

- Patients not taking medicine as per direction or not cooperating for follow up.
- · Spinal and Intraspinal tumors
- · Metabolic diabetes
- · Pregnant females
- · Traumatic conditions

Study design:

Prospective, single arm, single blind, non-randomised clinical trial study was carried out in Bharati Vidyapeeth Homoeopathic Hospital.

The patients were informed and enrolment with the consent were done and all the 30 patients with 5 follow ups were in the respective OPD of BVDUHMC and peripheral OPD as well. The cases were selected according to inclusion and exclusion criterias.

Intervention:

-Selection of remedy: The remedy Gnaphalium was selected on basis of: its symptom similarity and its action upon the sciatic nerve. It acts upon the sciatic nerve reducing the neuralgic pain.

-Selection of the potency and Repetition:

In the study centesimal scale was used. The potency selection was based upon the guidelines given by Dr. CFS Hahnemann in his Organon of Medicine.

Repetition will be done as per the need of the case.

Preparation and Administration of Drug:- Homeopathic Medicines manufactured by standard Homoeopathic pharmacy, which are GMP certified, as per norms of Homoeopathic pharmacopoeia of India(HPI), were used in required potencies. Drug was administered orally only.

Drug Dispensing:-Will be done in globule (no 30.) or sugar of milk (powder) form. (Ref. Aph. No. 272).

Storage:- Drugs were stored as per rules of Homoeopathic Pharmacopoeia. Medicines were stored in Bharati Vidyapeeth Homoeopathic Pharmacy, Katraj, Pune-411043. Liquid were stored in amber colored glass bottles kept in a dark place, away from sunlight. Freshly prepared powder or globules dose were used for dispensing purposes. Log no. and Batch no. were maintained.

Declaration:-It is declared that the drugs used in the cases were not harmful to human beings as they have been well proved, having no side effects.

Diagnosis- Diagnosis was done and if needed guidance of senior homoeopaths, researchers and other physicians from allied sciences were taken.

Clinical tests: These tests are based on the stretching of sciatic nerve over the prolapsed disc:

Straight leg raising test (SLRT): Patient is in supine position, the examiner raises the leg straight one after the other. Upto 30° nerve is not put under stretch. Between 30-70° nerves come into contact with the prolapsed disc and the patient complains of pain.

Beyond 70° if a patient complains of pain it is usually not due to disc prolapse but could be due to sacroiliac joint involvement.

Lasegue test: Here the hip is flexed, knee is flexed and the leg is slowly straightened. The patient is supine. Flex the patient's hip and knee to 90° . The nerve roots are not under tension and no pain is elicited. Not extend the knee. If the patient

complains of pain, the test is positive and it indicates nerve root compression or inflammation.

Investigation-X-rays of the lumbosacral spine will be done at standard laboratories.MRI if needed will be done.

Follow up- All patients will be duly followed and details of the symptomatic, clinical changes will be recorded. First follow up will be taken within 15 days to monitor the patient and then depending on the case assessment the follow ups will be taken either weekly, fortnightly or monthly.

Selection of tools:

- -Case pro forma (refer the appendix)
- Scales
- -Sciatica Bothersome Index
- -Maine Seattle Back Questionnaire.
- VAS pain

Sampling procedure:

Patient with neuralgic pain radiating down the back to the buttock, thigh, calf and foot with or without numbness and weakness of the lower limb since 3 months or less were taken for the study and fulfilling all the inclusions criteria were enrolled in the study from the general OPD and Peripheral OPD of Bharati Vidyapeeth Homoeopathic Foundation Hospital, Pune. Out of this all 30 patients with 5 follow ups.

Outcome assessment:

i) Sciatica bothersome index(By British Spine Registry)

(0= none to 6= extremely) is used to establish values for paraesthesia, weakness and leg pain.

This index was used to assess patients only during case taking and during the 5^{th} followup.

ii) The Maine-Seattle Back Questionnaire (MSBQ) was the main outcome measure [27]. The MSBQ is a shortened version of the Roland-Morris Disability Questionnaire that was modified for patients with sciatica and spinal stenosis [28]. The scale is composed of 12 items, each with the answer yes (1) or no (0), achieving a score range of 0–12. The MSBQ assesses disability and functional limits due to sciatic and back pain, and higher scores indicate worse limitations on activity. This questionnaire was used to assess patients only during case taking and during the 5th follow up.

MSBQ is the best measure for distinguishing between success and unsuccess in sciatica.

iii) Visual Analogue Scale (VAS) for Pain:

The pain VAS is a continuous scale consisting of a horizontal (HVAS) or vertical (VVAS) line, usually 10 centimeters (100 mm) in length. A higher score indicates greater pain intensity. Based on the distribution of pain, the following cut points on the pain VAS have been recommended: no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75– 100 mm). During every follow-up the difference between the scores of the scale was evaluated.

Statistical techniques and data analysis: Data is presented in the form of bar diagrams, tables and charts.

Data collection:

- Case was taken in complete form
- · General and systemic examination.
- Investigations of the case.
- Data was maintained on case papers of Bharati Vidyapeeth's Medical Foundation Homoeopathic Hospital.

There is a significant difference between the mean before & after treatment, therefore the null hypothesis stated earlier is rejected & the alternate hypothesis is accepted which says, the homoeopathic remedy Gnaphalium polycephalum has a significant effect in reducing the pain of sciatica.

Table-1. Gender Wise Distribution Of The Study Participants

GENDER WISE DISTRIBUTION OF PATIENTS N = 30								
GENDER NO. OF PTS (PERCENTAGE)9								
MALE	14	46.67%						
FEMALE	16	53.33%						

Table-2. Age Wise Distribution Of The Study Participants

	-90			7				
AGE	NO. OF	PERCENTAGE	MEAN					
GROUP	PATIENTS							
30-39	13	43.3%	Males	Females	Mean			
40-49	5	16.7%	Mean	Mean	age=			
50-59	7	23.3%	age=	age=	43.5			
			40.1	45.6	years			
60-69	5	16.7%	years	years				

Table-3. Occupation Wise Distribution Of The Study Participants

OCCUPATION WISE DISTRIBUTION OF PATIENTS N = 30										
OCCUPATION NO.OF PTS (PERCENTAGE)%										
Working	18	60%								
Housewife	6	20%								
Retired	6	20%								

Table 4. Descriptive Statistics Of The Sbi Score At Baseline And Last Follow-up

SBI Score	N	Minimum	Maximum	Mean	Std. Deviation
Baseline (Pre)	30	8.00	15.00	12.00	1.80
FU 5	30	.00	7.00	1.83	2.03

Table 5. Descriptive Statistics Of The Msbq Score At Baseline And Last Follow-up

I	MSBQ Score	N	Minimum	Maximum	Mean	Std.
						Deviation
	Baseline (Pre)	30	5.00	11.00	7.96	1.37
	FU 5	30	.00	7.00	1.56	1.77

Table 6. Descriptive Statistics Of The Vas Score At Different Follow-ups

	N	Minimum	Maximum	Mean	Std.
OBSERVATION					Deviation
VAS score at Baseline (Pre)	30	7.00	10.00	8.66	0.88
VAS score at First follow up	30	2.00	9.00	7.40	1.45
VAS score at Second follow up	30	.00	9.00	5.76	2.22
VAS score at Third follow up	30	.00	8.00	4.53	1.73
VAS score at Fourth follow up	30	.00	7.00	2.63	1.77
VAS score at Fifth follow up	30	.00	6.00	1.33	1.53

Table-7- Paired Differences Of Sbi Score Between Baseline And Last Follow-up

95% CI OF Difference											
SBI SCORE	N	MEAN	SD	SEM	MIN	MAX	LOW ER	UPP E R	Т	DF	P Value
BASELINE (PRE)	30	12.0	1.80	0.32	8.0	15.0	9.16	11. 17	20. 68	29	.000*
FOLLOW- UP	30	1.83	2.03	0.37	.00	7.00					

OBSERVATION & RESULT:

MEAN OF	10.16
DIFFEREN	
CE	

^{*}p value < 0.001 statistically highly significant

SBI scores at baseline (pre) and follow-up were compared using Student Paired t-test. This comparison showed statistically highly significant differences (p value <0.001) between baseline and follow-up. This suggests that there was a significant decrease in the mean SBI score value from baseline to follow-up.

Table-8- Paired Differences Of Msbq Score At Baseline And Last Follow-up

		95% CI OF Difference									
MSBQ SCORE	N	MEAN	SD	SEM	MIN	MAX	LOW ER	UPP E R	Т	DF	P Value
BASELIN E (PRE)	30	7.96	1. 37	0.25	5.0	11.0	5.80	6. 99	22. 06	29	.000
FOLLOW -UP	30	1.56	1.7 7	0.32	.00	7.00					
MEAN OF DIFFERE NCE						6.4					

^{*}p value < 0.001 statistically highly significant

MSBQ scores at baseline (pre) and follow-up were compared using Student Paired t-test. This comparison showed statistically highly significant differences (p value <0.001) between baseline and follow-up. This suggests that there was a significant decrease in the mean MSBQ score value from baseline to follow-up.

Table-9- Paired Differences Of Vas Score Between Baseline And Last Follow-up

							95%	CI			
		OF									
							Differ	ence			
VAS	N	MEA	SD	SE	MI	ΜA	LOW	UPP	Т	DF	P
SCORE		N		M	N	X	ER	ΕR			Value
BASELIN	30	8.66	0.8	.01	8.6	0.8	6.75	7.91	25.	29	.000*
E (PRE)			8	6	6	8			73		
LAST	30	1.33	1.5	0.2	1.3	1.5					
FOLLOW			3	8	3	3					
-UP											
MEAN						7	7.33				
OF											
DIFFERE											
NCE											

^{*}p value < 0.001 statistically highly significant

N = Total no. of patients.

DF=Degree of freedom

SEM = Standard error of mean

SD= Standard deviation.

VAS scores at baseline (pre) and last follow-up were compared using Student Paired t-test. This comparison showed statistically highly significant differences (p value <0.001) between baseline and last follow-up. This suggests that there was a significant decrease in the mean VAS score value from baseline to last follow-up.

Table 10 - Intergroup Comparison Of Vas Scores Between Different Follow-up Visits

VAS Scores	Sum of	df	Mean	F	P value
	Squares		Square		

Between	1171.111	5	234.222	85.920	.010*
different					
follow-ups					

^{*}p value < 0.001 statistically highly significant

Intergroup comparison was done to assess significant differences between the different follow-ups using One-way Analysis of Variance (ANOVA). This comparison showed statistically significant differences (p value <0.05) between different follow-ups. This suggests that there were significant differences in the mean values of VAS scores at each follow-up.

Table 11 - Pairwise Intergroup Comparison Of Vas Scores Between Different Follow-up Visits

(I)	(J)	MEAN	P		5%
		DIFFEREN	VALUE		
UPS	UPS	CE (I-J)		INTERVAL	
				LOWER	UPPER
				BOUND	BOUND
Baseline (Pre)	FU 1	1.26667 [*]	.039*	.0382	2.4952
	FU 2	2.90000 [*]	.000**	1.6715	4.1285
	FU 3	4.13333 [*]	.000**	2.9048	5.3618
	FU 4	6.03333 [*]	.000**	4.8048	7.2618
	FU 5	7.33333 [*]	.000**	6.1048	8.5618

^{*}p value <0.05 statistically significant, **<0.001 statistically highly significant

Pairwise Intergroup comparison was done between the different follow-ups using Post hoc Tukey's test. This comparison showed statistically significant differences (p value <0.05) between baseline and all the follow-up visits.

This suggests that after the treatment, the VAS scores of the patients have gradually decreased significantly with the subsequent follow-up visits.

Statistical analysis:

- (A) P Value of more than (>) 0.05 was considered nonsignificant.
- (B) P value of less than (<) 0.05 was considered to be statistically significant.
- (C) P value of less than(<) 0.001 was considered to be statistically highly significant

DISCUSSION

Sciatica is one of the most common lifestyle diseases which have a worldwide prevalence. Among this, sciatica has a prevalence rate of 95% and if not treated on time it may lead to complications and poor quality of life.

The present study was primarily aimed to investigate the effectiveness of the homoeopathic medicine Gnaphalium polycephalum in the management of cases of sciatica between the age group 30-65 years. Since it was a single arm study, only one group was involved in this study without any control group. Many researches have been done on sciatica but very little work has been done on individual homoeopathic medicine Gnaphalium Polycephalum. Therefore single remedy Gnaphalium Polycephalum was selected for this study. It has got action on the sciatic nerve producing neuralgic pain along the sciatic nerve with numbness and helps in reduction of pain. In this study 32 cases (male & female) of sciatica patients with age group 30-65 years were selected. Two patients dropped out from this study after 1 or 2

follow up while the rest 30 patients completed the study. They were subjected for 6-8 weeks of treatment with homoeopathic medicine Gnaphalium Polycephalum after proper case taking. They were administered Gnaphalium Polycephalum and the change in pain intensity and quality of life before and after the treatment were evaluated, which showed a positive effect on the pain of patients in the study. This effect was demonstrated by the results of the statistical analysis using a student paired "t" test⁽¹¹⁾, which manifests that the pretreatment and post treatment scores of pain and quality of life are indeed different.

It proves that Gnaphalium Polycephalum has scope in treatment of sciatica.

Age wise distribution—Age wise distribution was calculated by taking out the mean. The mean age is calculated as 43.5 years. Mean age of male patients is 40.1 years and the mean of female patients is 45.6 years. Most of the patients (43.3%) were found in the age group of 30-39 years. This suggests that young age has more risk of developing sciatica.

Sex wise distribution—Sex wise distribution was also calculated in percentage, where it was found that Out of 30 cases, 14 were male (46.67%) & 16 were female (53.33%) which indicates that prevalence of sciatica is more common in females as compared to males. Some limitations which require to be solved in further studies conducted in future:-

- One of the limitations is that only patients with acute sciatica were included in the study therefore it was difficult to answer the question whether Gnaphalium Polycephalum has the same useful effect in treating the patients with chronic sciatica.
- Sample size: Another limitation is related to small sample size. Due to this the question arises about the generalizability.
- Duration of study: Study duration was also one of the limitations. As the study was of 1 and half months for each case therefore it doesn t reflect the efficacy of Gnaphalium Polycephalum in the long term.
- Lack of control group: The study becomes more reliable when we do randomized study with the control group, but in the present study there was absence of control group.
- Age distribution: Although the age group selected for the study had a wide range i.e. from 30-65 years of age, most of the cases are falling in the range of 30-39 years age group. This factor may possibly confound the results obtained.

Finally this study data propose that homoeopathic medicine Gnaphalium Polycephalum has a significantly favorable effect in patients suffering from sciatica.

It can be adopted as an alternative conservative approach in treating acute sciatica worldwide.

As per the synopsis concern we mentioned certain scale for measurement of the improvement of the patient (reduction of pain intensity), that is:-

Assessment criteria for:-

Post treatment	Criteria	
outcome		
Improvement		
Marked	When the VAS score is 0-2	
Moderate	When the VAS score is 3-5	
Mild	When the VAS score is 6-8	
No improvement	No change in pain even after treatment	
	VAS score is more than 8	
Worse	When the condition of the patient deteriorated	
	in all aspects even after treatment.	

Dropped out	When the patient did not report back for any
Diopped out	when the patient aid not report back for any
	follow up & does not fulfill the requirements of
	lonow up & does not fulfill the requirements of
	the project, does not want to keep the patient
	the project, does not want to keep the patient
	under study for valid reasons.
	under study for valid reasons.

CONCLUSION

Backache and sciatica are amongst the most common ailments prevailing in the world. Persistent backache and sciatica may have an impact on the quality of life. Sciatica and backache is a lifestyle based ailment which affects the young and the old. In this, 30 patients completed the study.

The result indicates that there was reduction in pain intensity and improvement in quality of life of patients with sciatica. Treatment with Gnaphalium has produced an early, sustained and significant improvement in pain and is also proven as safe and effective in treatment of sciatica.

Therefore gnaphalium is a good choice as a specific remedy for pain and numbness of sciatica. Since it's a sample study, further studies on huge mass and large sample size with randomised placebo control groups can provide a greater resource for that Gnaphalium is effective in treatment of sciatica.

CONFLICT OF INTEREST

The authors have no conflict of interest among them regarding the research.

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