



## An observational study on efficacy of *Prunus Spinosa* 30 CH in treatment of Migraine in 20 - 50 years age group

Dr. Dheeraj Pandey<sup>1\*</sup>, Dr. Anil V Patil<sup>2</sup>

<sup>1\*</sup> Post Graduate Scholar, Department of Practice of Medicine, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College & Hospital, Katraj - Dhankawadi, Pune: 411043, India.

Email: [drdpbhms@gmail.com](mailto:drdpbhms@gmail.com)

<sup>2</sup> Former Associate Professor, Department of Practice of Medicine, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College & Hospital, Katraj- Dhankawadi, Pune, Maharashtra, India.

**Corresponding Author:** Dr. Dheeraj Pandey, Post Graduate Scholar, Department of Practice Of Medicine, Bharati Vidyapeeth (Deemed to be University) Homoeopathic Medical College & Hospital, Katraj-Dhankawadi, Pune: 411043, India. Email: [drdpbhms@gmail.com](mailto:drdpbhms@gmail.com)

### ABSTRACT

**BACKGROUND :** Migraine is one of the most frequent causes of severe, recurring headaches, and it affects more women than men approximately 15% of women and 6% of male among the population. It is usually an episodic headache associated with nausea, vomiting and other neurological symptoms. This research was conducted to assess the efficacy of homoeopathic medicine Prunus Spinosa 30 CH in migraine treatment.

**AIM :** This study aims to assess the efficacy of Homoeopathic medicine Prunus spinosa 30 CH in the treatment of Migraine.

**MATERIALS & METHOD:** Thirty cases of migraine diagnosed by IHS criteria (during the first visit) were selected as per inclusion criteria using purposive sampling technique. Prunus spinosa 30 CH was prescribed for these cases and followed for three months. Prunus spinosa 30 CH was repeated thrice for 2 weeks and placebos were administered in between. MIDAS score were checked before and after the administration of Prunus spinosa 30 CH. The data was statistically analysed by using mean, standard deviation and combined by using the student paired "t" test respectively. This tests helped to establish whether the changes observed before and after treatment were significant or not.

**RESULTS :** The final outcome was reduction in episodes, severity and symptomatic relief in migraine after 10-12 weeks of outpatient care. A significant reduction was observed in the Migraine Disability Assessment Scale score was  $20.67 \pm 7.62$ , after treatment this score reduced to  $8.07 \pm 3.49$  and no adverse effect were noted. After intervention most (66.67%) of the patients had marked improvement, 30% had moderate improvement and only 3.33% had mild



improvement. Test statistic value is 12.91 and p-value (0.000) is very small, it suggests that we reject H<sub>0</sub> and accept H<sub>1</sub> that is, Homoeopathic medicines Prunus spinosa 30 CH have an effect in the treatment of Migraine.

**CONCLUSION:** There is a reduction in migraine disability assessment scale score during and after homoeopathic treatment with prunus spinosa 30 CH.

**KEYWORDS:** Migraine, Prunus spinosa , MIDAS, Headache

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## INTRODUCTION :

Migraine is the second most common cause of headache affecting approximately 18% of women and 6% of men (one-year prevalence). Over 90% of migraine sufferers will have their first attack by the time they are 40 years old.

Migraine is derived from the Greek word hemikrania, which means "half of the skull." Migraine is also known as Hemicranias or Megrin.<sup>[1]</sup> Migraine is a primary episodic headache disorder characterized by various combinations of neurological, gastrointestinal and autonomic changes. It is a common disorder and is the major cause of absenteeism from work and avoidance of social and personal activities.<sup>[2]</sup> It is usually an episodic headache that is associated with certain features such as sensitivity to light, sound or movement; nausea and vomiting often accompany the headache. Migraine is the benign and recurrent headache associated with visual and gastrointestinal disturbance, neurological dysfunction in varying admixtures with varied in intensity, frequency and duration; commonly unilateral in onset. It is associated with conspicuous, sensory, motor and mood disturbances.<sup>[3]</sup> Migraine can often be

recognized by its activators, referred to as triggers.<sup>[1]</sup>

However, it is best to look upon migraine as a triad of paroxysmal headache, nausea or vomiting and an 'aura' of focal neurological events (usually visual). Patients with all three of these features are said to have migraine with aura ('classical migraine'). Those with paroxysmal headache (with or without vomiting) but no aura are said to have migraine without aura (common migraine).

A classical migraine attack begins with a non-specific malaise and irritability which may be followed by an aura of a focal neurological event, and then a severe throbbing hemicranial headache with photophobia and vomiting. During the headache phase patients refers to be in a quiet, darkened room and to sleep. The headache may persist for several days<sup>[3]</sup>. The etiology of migraine is largely unknown. There is often a family history of migraine, suggesting a genetic predisposition. The great female preponderance and the tendency of some women to have migraine attack at certain points in their menstrual cycle hint at hormonal influence. When psychological stress is involved, the migraine



attack often occurs after the period of strain so that some patients tend to have attacks at weekends or at the beginning of a holiday.<sup>[4]</sup>

Treatment in a conventional mode of treatment consists of the medicines like aspirin or paracetamol, domperidone, coden containing analgesic precipitations, 5-HT agonists, etc. Long-term use of coden containing analgesic precipitations should be avoided. There is a risk of ischaemic stroke in women attributable to taking oral contraception is increased if they have a migraine, especially if they smoke.<sup>[2]</sup>

Walach et al.<sup>[5]</sup> 1997 conducted randomized controlled trial of chronic headache (n=98) with an individualized homoeopathic prescription, it showed a reduction in all categories of both placebo and homoeopathic group. Another randomized controlled trial (n=73) on migraine showed a similar result as in the above study in all categories (Straumsheim, 1997)<sup>[6]</sup>. Brigo showed in a trail of 60 samples treated with single homoeopathic medicines the superiority of homoeopathic medicines than placebo (Brigo, 1991).<sup>[7]</sup>

Saha Subhranil, et.al. 2013, conducted a systemic review on the treatment of individualised homoeopathy for headaches and migraines. The study was included four randomised placebo-controlled trials with a total of 390 patients. The trials' methodological quality varied. The combined risk ratio for the four studies included in the meta-analysis was 1.58 (95% CI 0.8 to 3.1) [when corrected for publication bias, it becomes 0.98 (0.5, 1.9),

indicating a positive trend but no statistically significant difference in favour of homoeopathy]. The findings of the meta-analysis did not support the notion that homoeopathy has a significant effect.<sup>[8]</sup>

K Danno, et. al., 2013, the objective of study was to evaluate the effectiveness of homeopathic medicines for the prevention and treatment of migraine in children. This was an observational, prospective, open, nonrandomized, non-comparative, multicentre study. It was conducted in 12 countries worldwide. Fifty-nine (59) physicians trained in the prescription of homeopathic medicines and 168 children, aged 5–15 years, with definite or probable migraine diagnosed using International Headache Society 2004 criteria were the subjects in this study. A significant decrease in the frequency, severity, and duration of migraine attacks was observed and, consequently, reduced absenteeism from school.<sup>[9]</sup>

The present study was undertaken to explore the efficacy of the homoeopathic medicines in the treatment of migraine keeping in view of the above risks of taking conventional medicines and the outcome of the previously undertaken studies.

Homoeopathic remedy Prunus spinosa is clinically verified medicine and has marked effect in treatment of migraine.<sup>[10]</sup> Many of the migraine symptoms of Prunus Spinosa bear a close resemblance to migraine symptomatology. This study tries to integrate the knowledge of disease (Migraine complaints), Knowledge of



medicine (Prunus spinosa) and application of this knowledge to confirm whether there role for the remedy Prunus Spinosa 30 CH.

### Objective

To assess the efficacy of homoeopathic medicine Prunus Spinosa 30 CH in cases of migraine.

## MATERIALS AND METHODS

### Period of study

The study was conducted on the cases available from September 2021 to March 2022

### Sample size

The sample consisted of thirty cases of migraine complaints visiting the OPD, IPD and Peripheral Centres of Bharati Vidyapeeth (Deemed To Be University), Homoeopathic Medical College, Pune during the specified period.

### Type of study

This was a single-arm, quasi-experimental, interventional, prospective, before, during and after treatment comparison pilot study without control.

### Inclusion criteria

- Those cases fulfilling the International Headache Society, diagnostic criteria for Migraine. <sup>[11]</sup>
- Patients of both sexes will be included in the study.
- Patients of 20-50 years of age groups of various
- Socioeconomic groups will be included.

- Patient without any other systemic diseases.

### Exclusion criteria

- Cases that doesn't fulfil the International Headache Society, diagnostic criteria for Migraine. <sup>[11]</sup>
- Patients who were on homoeopathic medicines other than Prunus Spinosa 30CH
- Taking medicines from other systems for any other complaint.
- Cases with a serious complication of MIGRAINE.
- Patients with Psychiatric diagnosis.
- Pregnant and lactating women.
- Malignancy cases.
- Recent major surgery.
- Immunocompromised cases.
- Patients requiring emergency medical care.
- Patients who have participated in any other Research study in the last 6 months.

### Materials

*Standardised case record*

### Method

Thirty cases of migraine complaints were selected as per the inclusion criteria using purposive sampling technique. Diagnoses of the cases were made based on relevant clinical history, according to International Headache Society, diagnostic criteria for Migraine. <sup>[12]</sup> The 30 potency of *Prunus Spinosa CH* was prescribed for the above



cases and was followed for a period of 3 months.<sup>[10]</sup> The data were presented in standardised case record (SCR).

### Remedy used

The 30 potency of homoeopathic medicine *Prunus Spinosa*, manufactured by **Sharada Boiron Laboratories (SBL)** Division (which prepares the drug according to Homoeopathic Pharmacopoeia of India), was used in the study. Three globules of *Prunus Spinosa* 30CH (number 40 size) were given twice daily for a period of 2 weeks and placebos were administered in between if needed. Follow-ups were watched and analysed as per criteria set up in each case according to standard guidelines of Homoeopathy using the symptomatology of the patient as mentioned below.

### Follow up and Symptomatic assessment

Each case was followed up for approx. 3 months in cases Migraine;

- i. All the patients will be duly followed and details of the symptomatic, clinical, investigative changes were recorded and prognoses were studied.
- ii. Follow up were differ from patient to patient.
- iii. Usually first follow-up was on seventh day.
- iv. 2<sup>nd</sup> follow up and onward follow up were after 15days or earlier/later according to need of the patients.
- v. Standard Follow-up was prepared giving details.

Each follow up was assessed according to the guidelines given in standardised case record follow-up sheet where each symptom of the patient pertaining to migraine complaint was graded according to the MIDAS score.<sup>[13]</sup>

This provided an idea for comparing reduction of attack frequency, severity, and duration; migraine complaints before, during and after treatment, after prescribing *Prunus Spinosa* 30CH. The flow chart of study given as Figure 1.

### Statistical analysis

The collected data were analysed by mean, standard deviation and analysis of variants (ANOVA).

### Research hypothesis

Homoeopathic medicines *Prunus spinosa* 30<sup>th</sup> potency is effective in the treatment of Migraine.

### Null hypothesis

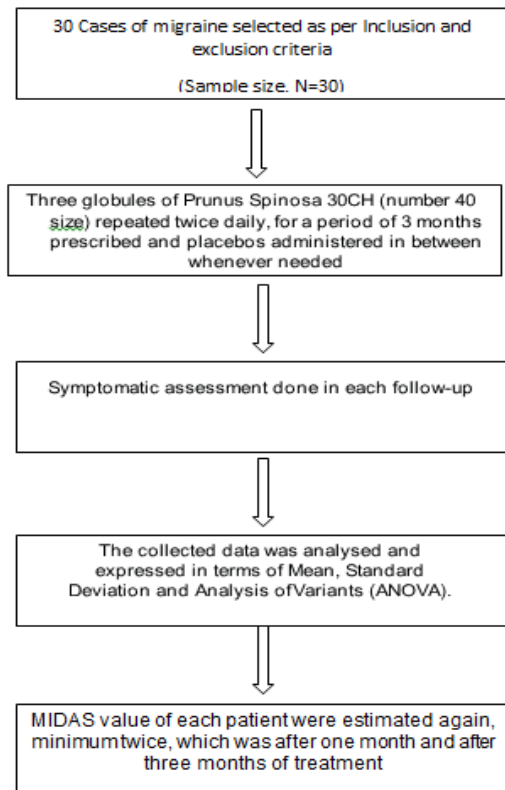
Homoeopathic medicines *Prunus spinosa* 30<sup>th</sup> potency is not effective in the treatment of Migraine.

### Ethical statements

The Institutional Ethics Committee of Bharati Vidyapeeth Deemed to Be University Homoeopathic Medical College & Hospital, Pune had approved the study through the letter dated 30 June 2020. Each patient was informed of the ethical issues related to the study through the informed consent form and was duly documented. The study was



performed following the protocol laid down in the 1964 Declaration of Helsinki.



**Fig.1. Flow Chart of Study**

Total 30 patients (n=30) were selected from the age group of 20-50 years. The highest percentage of patients belonged to the age group of 20-30 years (60 %) and the lowest from the age group of 40-50 years (16.67%) indicating that patients between the age of 20-30 years might be affected the most. 12 participants were male (40%) & 18 were female (60%). Mean reduction in intensity of symptoms in migraine was  $12.6 \pm 5.35$ . P value was 0.000, which is very small.

## RESULTS

This study of thirty patients showed a higher female prevalence (60%) with the 20-30

years' age group being the most affected (60%) by migraine complaints. [Table 1].

[Table 2] shows the distribution of patient according to the side of pain. It depicts 53.33% patients had right sided pain whereas 30.00% patient had left sided pain and 16.67% had pain of alternating side.

The distribution of patients according to the family history. It depicts the patients had family history of diabetes mellitus 13.33%, hypertension 10.00%, joints pain 13.33%, migraine 53.33% whereas no illness

was 16.67%. It shows that those who have migraine family history were more affected.

The distributions of patients according to aetiology, it depicts 20.00% had episodes of migraine before menstruation, 50.00% had due to noise. 20.00% had due to mental exertion, 26.67% had due to overexertion, 33.33% had due to sun exposure. Thirty diagnosed cases of migraine complaints were studied for a period of minimum 3 months. MIDAS score values were checked twice, (before, and after the treatment).

The final outcome was reduction in episodes, severity and symptomatic relief in migraine after 10-12 weeks of outpatient care. Pre-test and post-test analysis was done by using Student paired "t" test. Analysis was done using Student paired "t" test due to small sample size. A significant reduction was observed in the Migraine Disability Assessment Scale score was  $20.67 \pm 7.62$ , after treatment this score reduced to  $8.07 \pm 3.49$  and no adverse effect were noted. After intervention most (66.67%) of the patients had marked improvement, 30% had moderate

improvement and only 3.33% had mild improvement. Test statistic value is 12.91 and p-value (0.000) is very small, it suggests that we reject H0 and accept H1 that is,

Homoeopathic medicines Prunus spinosa 30 CH have an effect in the treatment of Migraine. [Table 3].

**Table 1.: Distribution of the patients according to demographic variables, n = 30**

Demographic variables		<i>f</i>	%
Age	20 - 30 years	18	60.00%
	30 - 40 years	7	23.33%
	40 - 50 years	5	16.67%
Gender	Male	12	40.00%
	Female	18	60.00%
Occupation	Business	4	13.33%
	Student	11	36.67%
	Home maker	6	20.00%
	Job	9	30.00%



<b>A. : Distribution of patients according to side of pain</b>		
Side of pain	<i>f</i>	%
Right Sided	16	53.33%
Left Sided	9	30.00%
Alternating Side	5	16.67%
<b>B. : Distribution of patients according to family history</b>		
Family History	<i>f</i>	%
Diabetes Melitus	4	13.33%
Hypertension	3	10.00%
Joints Pain	4	13.33%
Migraine	16	53.33%
No Illness	5	16.67%
<b>C. : Distribution of patients according to Etiology</b>		
Etiology	<i>f</i>	%
Before Menses	6	20.00%
Noise	15	50.00%
Mental Exertion	6	20.00%
Over Exertion	8	26.67%
Sun Exposure	10	33.33%

**Table 2: Distribution of Patients**

**Table 3 : Descriptive statistics of Migraine Disability Assessment Scale score before and after intervention**

<b>Table 8. : Descriptive statistics of Migraine Disability Assessment Scale score before and after intervention</b>				
MIDAS Score	Mean ± SD	T-value	p-value	Decision
Before treatment	20.67 ± 7.62	12.91	0.000**	Reject H <sub>0</sub>
After treatment	8.07 ± 3.49			
Difference	12.6 ± 5.35	Difference is Highly Significant		

**Table 7. : Distribution of patients according to MIDAS grades before and after treatment**

Grades	Before treatment		After treatment	
	<i>f</i>	%	<i>f</i>	%
Little or No Disability	0	0.00%	9	30.00%
Mild Disability	1	3.33%	15	50.00%
Moderate Disability	16	53.33%	6	20.00%
Severe Disability	13	43.33%	0	0.00%





## DISCUSSION

Migraine is the world's third most common ailment. Migraine is the world's sixth most disabling sickness. Migraine is a condition that runs in families. Around 90% of migraine sufferers have a family history of the condition. The majority of victims have attacks once or twice a month; around 4 million people suffer from chronic daily migraine, having at least 15 migraine attack days per month. Over 4 million persons suffer from persistent daily migraines on at least 15 days each month. The most prevalent cause of episodic migraine becoming chronic is medication usage. Chronic migraine sufferers frequently experience depression, anxiety, and sleep difficulties. The present study was primarily aimed to investigate the effectiveness of the homoeopathic medicine Prunus Spinosa 30CH in the cases of migraine between the age group 20-50 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 in homeopathic system on migraine but very little work has been done on individual homoeopathic medicine Prunus Spinosa. Therefore, single remedy Prunus Spinosa 30CH was selected for this study. In these study 34 cases (male & female) of migraine patients with age group 20-50 years were selected. Four patients dropped out from this study after 1or 2 follow up while rest 30 patients completed the study. They were subjected for 10-12 weeks of treatment with homoeopathic medicine Prunus Spinosa 30CH after proper case taking. It was observed that there was a highly significant

reduction in MIDAS score values in before and after, and before and during treatment groups. The strengths of this study are utilising the specific effect of Homoeopathy in migraine using *Prunus Spinosa* 30CH as the medicine. The weaknesses are small sample size ( $n=30$ ), no control group selected to compare the results and no randomisation done. Prunus Spinosa 30CH were administered and the change in intensity, severity, frequency of episodes of migraine blood before and after the treatment were evaluated, which showed a positive effect on the migraine status of the patients in the study sample.

During the study period, none of the patients was referred for serious conditions and no adverse effects were noted.

**Some limitations, which require to be solved in further studies, conducted in future :-**

Number of samples used in this study is very small. Therefore, generalization of the result and inference of the study need to be done cautiously.

Duration of study: Study duration also one of the limitation. As the study was of 2 and half months for each case therefore it doesn't reflect the efficacy of Prunus Spinosa 30CH in long term.

Lack of control group: The study becomes more reliable when we do randomized study with control group, but in present study, there was absence of control group.

Some good cases couldn't be considered in this study because of discontinued treatment in between the study period.



In some cases, necessary information was lacking and the study was based on the available data.

There were no standard studies to compare or take guidance from a study of this nature in homoeopathy. Therefore, some human errors are expected.

### RECOMMENDATIONS

1. Bigger sample size with extended time of research would provide better results.
2. It will be always scientific if control (placebo) group would have been kept simultaneously to verify the effectiveness of treatment.

Finally, this study data propose that homoeopathic medicine Prunus Spinosa 30CH has significantly favourable effect in patients suffering from migraine. It can be adopted as an alternative public health approach in restraining the high prevalence of migraine worldwide.

### CONCLUSION

From the above observations, it can be concluded that homeopathic medicines Prunus Spinosa 30 CH have effect in the treatment of migraine.

Prunus Spinosa can be used to treat migraine and it helps to reduce the intensity and frequency of number of episodes in cases of migraine. The results have showed that the before & after score of MIDAS scale were significantly reduced and differ.

Therefore, Prunus Spinosa is a good choice as a specific remedy for migraine patients. Since it is a small sample study, research should be done in future considering large sample & extending the duration of the study. Further studies with randomized

placebo control group can provide a greater resource for proving that Prunus Spinosa 30CH is effective in treatment of migraine.

This study showed marked improvement like reduction in intensity, frequency and recurrence of attacks of migraine.

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Nil.

### Conflicts of interest

Author declares no conflict of interest.

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