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# Homoeopathy in the treatment of migraine: A randomized placebo-controlled clinical trial

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**Abstract**
**Background:** Migraine is known to be a major cause of difficulty and disability affecting the daily work in approximately 15% of women and 6% of men among the population. It is usually an episodic headache associated with nausea, vomiting and other neurological symptoms.
**Aim:** This study aims to explore the efficacy of homoeopathic medicines in the treatment of migraine.
**Methodology:** Study design was a single-blind placebo-controlled randomized clinical trial. Total 60 patients were included in the study after screening and assigned to two groups i.e. test group (n=30) and control group (n=30). The test group received homoeopathic medicines and control group received identical placebo. For intensity assessment Headache Impact test (HIT 6) was used. HIT scores were recorded before and after treatment. The duration of the study was 6 months.
**Results:** Females were more commonly affected than males and the incidence was higher in the second and fourth decades of life and lower in elderly people. Paired t-test was applied to observe the difference in groups and found statistically significant ($p$<0.0001). The most frequent prescribed homoeopathic medicine was Natrum muriaticum. Onosmodium and Prunus spinosa were also frequently prescribed in acute conditions. Less indicated remedies were Lachesis, Sulphur, Silicea, Pulsatilla, Lycopodium, Spigelia and Sanguinaria.
**Conclusion:** Homoeopathic medicines found effective in the treatment of migraine in this study. more studies with larger sample size are suggested.

**Keywords:** Homeopathy, migraine, RCT, headache impact test

## 1. Introduction
Migraine is the second most common cause of headache affecting approximately 15% of women and 6% of men. 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. A useful description of migraine is a benign and recurring symptoms of headache associated with other symptoms of neurologic dysfunction in varying admixtures. Migraine can often be recognized by its activators, referred to as triggers [1].
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). It has been estimated that the lifetime prevalence of migraine is about 20% in females and 6% in males. Over 90% of migraine sufferers will have their first attack by the time they are 40 years old. 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 [2].
The aetiology 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. The relevance of the contraceptive pill in this context is difficult to establish but it does appear to exacerbate migraine in many patients and to increase the risk of stroke of the patient who suffers from migraine with aura. 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. The observations that migraine-like phenomena occur in rare genetic disorders associated with mutations in calcium channel

genes suggests the possibility that the aura may be due to paroxysmal changes in the function of neuronal ion channels. The headache is thought to be caused by vasodilatation of extracranial vessels and may, like the headache following an epileptic seizure, be a non-specific effect of the disturbances of neuronal function [2].

Treatment in a conventional mode of treatment consists of the medicines like aspirin or paracetamol, metoclopramide or 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 [2].

Though homeopathic literature suggests many medicines for the treatment of migraine, research evidence in this regard are very limited. A systematic review, which included four randomized, placebo-controlled trials provided mixed outcomes. One study suggested that homoeopathic remedies were effective. The others which were methodologically stronger trials did not support this notion. So it was concluded that the trial data available to date do not suggest that homoeopathy is effective in the prophylaxis of migraine or headache beyond a placebo effect [3]. In a separate randomized placebo-controlled, double-blind, parallel-group trial of individualized homoeopathic prophylaxis, sixty-three outpatients with migraine with or without aura were included. The outcome of the study could not recommend homoeopathy for migraine prophylaxis, but cannot conclude that it is without effect [4]. In another study, many treatments within complementary medicine have been shown to have some effect on both preventions of migraine and the acute attack. This paper presented an overview of the evidence available within homoeopathy, herbal medicine, dietary exclusion, acupuncture, and a variety of psychological techniques [5]. Homoeopathic remedies are also found to be successful in the treatment of migraine in some other studies [6].

There have been so many clinical trials carried out in homoeopathy on migraine. In a 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 (Walach 1997, Whitmarsh 1997). Another randomized controlled trial (n=73) on migraine showed a similar result as in the above study in all categories (Straumsheim, 1997). Brigo showed in a trail of 60 samples treated with single homoeopathic medicines the superiority of homoeopathic medicines than placebo (Brigo, 1991). In a prospective observational study on all types of headaches, there was an improvement in more than 60% of patients treated (n=53) with individualized homoeopathic prescription (Muscari Tomaioli 2001). In another prospective observational study, it was observed that there was > 30% improvement in the homoeopathic group within 12 wks of treatment (Walach, 2001) [7].

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.

## Methodology

A web-based literature searches and journal reviews were performed to identify all randomized, placebo-controlled double-blind clinical trials of homoeopathic treatments for migraine or headache. The disease profile was collected through different clinical book reviews and some relevant journals. Different Homoeopathic Materia Medica and therapeutic books were searched for their indications in the treatment of headache.

The objective of the study was to evaluate the efficacy of Homoeopathic medicines in the treatment of migraine. The study design was single-blind placebo-controlled randomized clinical trial. All the patients with headaches were screened for classical migraine. 60 samples were selected and randomly assigned to two groups of 30 each (Test group=30 and Control group=30). Selected homoeopathic medicines were given to the Test group and placebo was given to the control group.

### Inclusion criteria

Patient of both sexes of more than 18 years of age fulfilling the diagnostic criteria (signs and symptoms) of migraine were included in the study.

### Exclusion criteria

- Patients below the age of 18 years
- Patients with psychiatric comorbidities
- Pregnant women
- Lactating women
- Any pathological condition of the brain with headache

Detail data were collected using a proforma which included age, sex, type of migraine, presence or absence of family history, frequency of migraine, migraine severity and duration of migraine episodes and migraine triggers were documented. The severity of migraine and its effect on daily life was assessed using Headache impact test.[8] Patients were asked to maintain a headache diary and were followed up for six months.

## Results

Among the included patients 18 (30%) were male and 42 (70%) were female. The subjects were grouped into various categories of age and the majority of the patients in this study were in the age group between 18-29 years (23, 38.33%). About 12 (20%) and 16 (26.67%) patients were between the age group of 30-39 years and 40-49years respectively. 7 patients (11.67%) were between 50-59years. Migraine was least prevalent among age above 60 years accounting about 2 patients (3.33%). (Table -1)

**Table 1:** Age and sex distribution

| Age category (in Yrs.) | Male | Female | Total |
|---|---|---|---|
| 18-29 | 7 | 16 | 23 |
| 30-39 | 5 | 7 | 12 |
| 40-49 | 3 | 13 | 16 |
| 50-59 | 2 | 5 | 7 |
| < 60 | 1 | 1 | 2 |
| Total | 18 | 42 | 60 |

About 12 patients (20%) had a positive family history of migraine. In 32 patients (53.33%) there was no family history of migraine. But in 16 individuals (26.67%) the information regarding their family history of migraine was unknown. (Fig. 1)

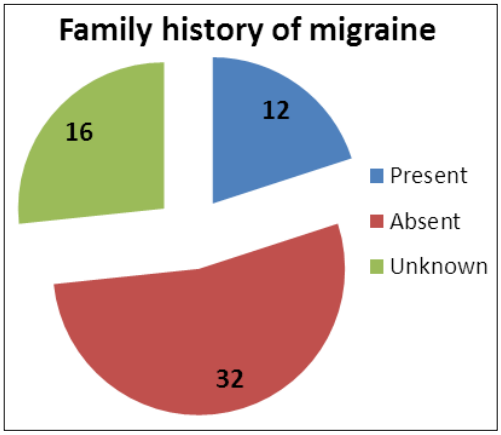


**Fig 1:** Family history of migraine

Regarding frequency of migraine episodes it had been observed that in 10 patients (16.67%) the episodes were daily, in 6 patients (10%) in alternate days, in 15 patients (25%) once in week, in 10 patients (16.67%) two times in a week, in 5 patients (8.33%) every 15 days and in least cases (4, 6.67%) there was episodes in monthly interval. But in 10 (16.17%) cases there were irregular episodes (not in a definite interval). (Fig.2)

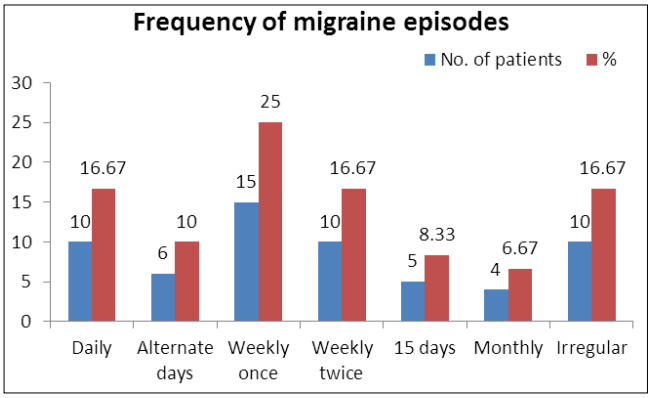


**Fig 2:** Frequency of migraine episodes

Majority of patients (49, 81.67%) in this study did not have any co-morbid conditions and only a few patients (11, 18.33%) had co-morbid conditions like hypertension and diabetes. The severity and its impact on daily life were assessed through the Headache Impact Test score (HIT-6). The no. of patients according to their severity of the headache and their impact on daily life is shown in the table – 2.

**Table 2:** Severity and impact of migraine

| Category of severity | Score of HIT-6 | No. of patients |
|---|---|---|
| Little to no impact | 36-49 | 17 (28.33%) |
| Some impact | 50-55 | 12 (20%) |
| Substantial impact | 56-59 | 8 (13.33%) |
| Severe impact | 60-78 | 23 (38.33%) |
| Total | | 60 |

In the majority of the patients (52, 86.67%) had no aura symptoms preceding headache. But few patients (8, 13.33%) had only visual aura before the headache starts. Among the associated symptoms majority had phonophobia (18, 30%) and photophobia (15, 25%). In other associated symptoms there were nausea in 12 (20%) patients, vomiting in 9 (15%) patients, blurring of vision in 2 (3.33%) patients, giddiness in 2 (3.33%) patients and pain in eyes in 2 (3.33%) patients. (Fig. 3)

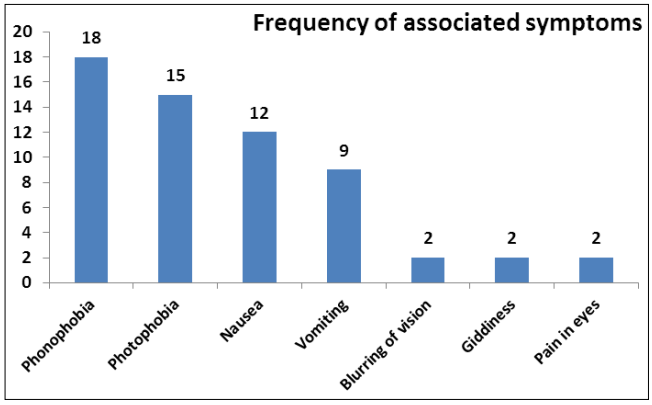


**Fig 3:** Frequency of associated symptoms

All the patients had more than one trigger (Fig. 4). Most common triggers among most of the patients were sun exposure (42, 70%), sleep deprivation (32, 53.33%) and stress (40, 66.67%). Triggers like travel, head bath, excessive sleep and hunger accounted in 26 (43.33%), 18 (30%), 12 (20%) and 10 (16.67%) patients respectively. Least observed triggers were alcohol (4, 6.67%), ice cream (4, 6.67%), menstruation (5, 8.33%) and stitching (2, 3.33%).

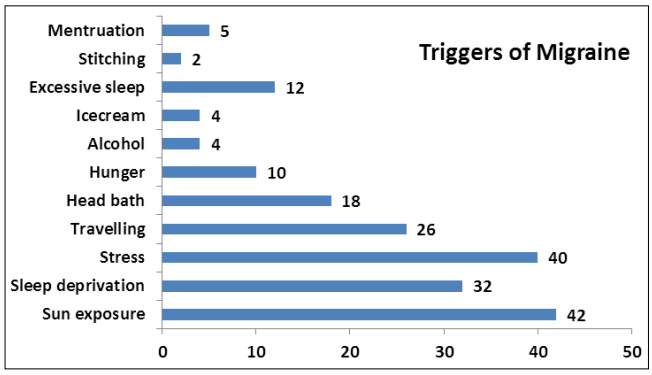


**Fig 4:** Triggers of Migraine

In the medicine group (n=30) the patients were prescribed according to their totality of symptoms. In the chronic group of medicines most frequently indicated medicine was Natrum mur. (14, 46.67%). Other chronic medicines were Silicea (n=3), Pulsatilla (n=2), Lachesis (n=2), Lycopodium (n=3) and Sulphur (n=3). In acute conditions, Onosmodium (n=10) and Prunus spinosa (n=10) were prescribed frequently. Other medicines like Iris vers. (n=3), Spigelia (n=3) and Sangunaria can. (n=2) were prescribed in acute conditions. (Table – 3)

**Table 3:** Frequency of indicated homoeopathic medicines

| Chronic group medicines | | Acute group medicines | |
|---|---|---|---|
| **Name of medicine** | **No. of patients prescribes** | **Name of medicine** | **No. of patients prescribes** |
| Natrum mur. | 14 | Onosmodium | 10 |
| Silicea | 3 | Prunus spinosa | 10 |
| Pulsatilla | 2 | Iris vers. | 3 |
| Lachesis | 2 | Spigelia | 3 |
| Lycopodium | 3 | Sangunaria can. | 2 |
| Sulphur | 3 | | |

The result of the treatment in both groups is given in table - 4. Before treatment in test group, there were 8 patients in HIT-6 scores of 36-49, 4 patients in HIT-6 scores of 50-55, 5 patients in HIT-6 scores of 56-59 and 13 patients in HIT-6 scores of 60-78 that means in 13 patients there was the severe impact of headache in their daily life. After treatment only in 2 patients, the severe impact was there. Most of the patients (n=27) came under little to no impact category. There was only 1 patient in some impact category and no patient in substantial impact category. Likewise, in the control group before treatment, there were 9 patients in HIT-6 scores of 36-49, 8 patients in HIT-6 scores of 50-55, 3 patients in HIT-6 scores of 56-59 and 10 patients in HIT-6 scores of 60-78. After treatment 11 patients had a severe impact. There were 2 patients in substantial impact category, 8 patients in some impact category and 9 patients in little or no impact category.

**Table 4:** Result of treatment in response to HIT-6 scores

| HIT-6 scores | Test group | | Control group | |
|---|---|---|---|---|
| | **Before treatment** | **After treatment** | **Before treatment** | **After treatment** |
| Little to no impact (36-49) | 8 | 27 | 9 | 9 |
| Some impact (50-55) | 4 | 1 | 8 | 8 |
| Substantial impact (56-59) | 5 | 0 | 3 | 2 |
| Severe impact (60-78) | 13 | 2 | 10 | 11 |
| **Total** | 30 | 30 | 30 | 30 |

**Statistical analysis**

Paired t-test was applied for statistical analysis of the data collected. The test was done taking the HIT-6 scores before and after treatment in both groups i.e. in test and control group. In the test group, the t value was 10.3686 which shows that the difference was extremely statistically significant (p = less than 0.0001). In the control group, the t value was 1.3340 and the difference was considered to be statistically insignificant (p=1.1926).

**Discussion**

The brain of the migraineur is especially sensitive to environmental and sensory stimuli; migraine- prone patients don't habituate easily to sensory stimuli. This sensitivity is amplified in females during the cycle. Headache is initiated or amplified by various triggers, including glare, bright lights sounds or other afferent stimulation; hunger; excess stress; physical exertion; stormy weather or air pressure changes; hormonal fluctuation; during menses; lack of or excess sleep; and alcohol or other chemical stimulation. Knowledge of patient susceptibility to specific triggers are often useful in management strategies involving lifestyle adjustments [1]. Migraine is the commonest variety of headache seen in younger age groups. It is a primary headache disorder affecting more commonly the feminine than in males. This finding of this study validates the results of some studies carried out in India [9]. Regarding the age category as observed during this study, it is higher within the second and fourth decades of life and lower in elderly people which can be in accordance with the previous studies done in other countries [10, 11]. This study showed that only a few patients presented the positive family history of migraine which can be suggestive of the study done by Balakrishnan R *et al*. [9] Regarding the frequency of migraine episodes it had been observed in the present study that there was less number of patients where the frequency is more than 10 times per month. In approximately 16% of patients, the frequency is more than 20 per month and in 6 % of patients, there is an attack in the monthly interval. These findings may not correlate with the results of the studies done by Bhatia *et al*. Co-morbid conditions are very less and only in cases it was observed. It may validate the previous studies [12, 13].

According to the Headache Impact Test, the score varies from 36 to 78. The score of 36-49 is considered as little or no impact on daily life, the score of 50-55 has some impact, a score of 56-59 has substantial impact and likewise, the score above 60 i.e., 60-78 is considered as severe impact. So in this study, most patients about 38.33% had a severe impact on their daily life and in less no. of patients had a substantial impact. This may be similar to the study by Kulkarni *et al*, which was a population-based study in which the pain intensity was severe in 40% of the population [14].

Most of the patients had migraine without aura and a few had the visual disturbances preceding headache. Among the associated symptoms most had phonophobia, photophobia and nausea. Less had vomiting, giddiness, blurring of vision and pain in eyes. All these findings may be similar to the outcomes of a study done by Bhatia MS *et al*. [12] In this study it was observed that almost all patients had more than one trigger. Most common triggers were sun exposure, sleep disturbances, stress, travel, hunger, etc. less common triggers were alcohol consumption, menstruation, ice cream intake and stitching. These findings are in some inconsistency with the results of the study by Yadav *et al*. [15].

In this study, all the patients were categorized into 2 groups one is test group and another is the control group. The patients of the test group were given by selected homoeopathic medicines according to their totality of

symptoms. The most frequent prescribed homoeopathic medicine was Natrum muriaticum. One of the studies indicated that Nat. mur. Was very effective in treating migraine [6]. Onosmodium and prunus spinosa were mostly prescribed in acute conditions. Less indicated remedies were Lachesis, Sulhur, Silicea, Pulsatilla, Lycopodium, spigelia and Sangunaria. The indications of these remedies in the treatment of migraine were verified from Homoeopathic Materia Medica [16].

Statistically, the study was significant at $p<0.0001$. After treatment, the no. of patients from severe, substantial and some impact categories were reduced and there became little or no impact in the test group. But in the control group, there was no change in the severities even after treatment.

## Conclusion

Migraine is the most common type of primary headache with a predominance of females, more frequent during the age of 20 to 40 yrs. with phonophobia, photophobia and nausea being the most common associated symptoms. Migraine is mostly without any aura. The results of this study are certainly encouraging but the limitation of this study is less sample size and. It is very less to explore so many well-proved polychrest homoeopathic medicines and some rare remedies which may be indicated in the treatment of migraine. And also there are so many aspects to explore in terms of homoeopathy which can only be established in a larger sample size.

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