

## Original Research

### Efficacy of homoeopathic medicines in cases of migraine - An open label study

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#### ABSTRACT:

Migraine is a common neurological disorder clinically presenting as recurrent attacks of headache with a range of accompanying symptoms is a highly disabling primary headache disorder. This study explored the utility of homoeopathic medicines in migraine patients over a 6 month follow up. **Aim:** To study the efficacy of homoeopathic medicines in cases of migraine. **Objectives:**

- To assess the efficacy of homoeopathic medicines in cases of migraine (pre and post treatment) using the "Migraine Disability Assessment Test" (MIDAS).
- To identify the medicines which are more effective in cases of migraine.

**Study Design:** Open label single arm study. **Method:** 100 cases of migraine were treated and each case followed up for 6 months. Patients were enrolled as per predefined inclusion and exclusion criteria. Enrolled cases were treated as per homoeopathic principles and treatment response was assessed using MIDAS questionnaire. **Result:** Overall Mean score of MIDAS at Baseline was  $82.57 \pm 17.50$  which reduced to  $43.08 \pm 8.66$  at three months and  $15.22 \pm 6.01$  at six months. The most frequently prescribed homoeopathic medicine in cases of Migraine was *Silicea* and *Nat mur.* were prescribed in 8 cases each; *Ignatia*, *Glonoina* and *Spelia* prescribed in 7 cases each; *Belladonna*, *Nux Vomica* and *Lycopodium* in 6 cases each; *Kali Bi*, *Lachesis*, *Dulcamara*, *Gels*, *Bryonia* and *Coffea cruda* in 5 cases each; *Thuja* and *Arsenic* 4 cases each and *Sanguinaria* and *Spigelia* 2 cases each. **Conclusion:** Homoeopathic medicines are effective in providing relief to the patients and significantly reduce the MIDAS scores in all cases. Significant relief can be found within 3 to 6 months of treatment.

**Keywords:** Homoeopathy, Migraine, MIDAS, Headache.

Received: 23 December, 2022

Accepted: 29 January, 2023

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**This article may be cited as:** Trigotra D. Efficacy of homoeopathic medicines in cases of migraine - An open label study. J Adv Med Dent Scie Res 2023;11(2):93-97.

#### INTRODUCTION

Migraine: [through O. Fr. fr. G. hemikrania, pain on one side of the head, fr. hemi-, half, + kranion, skull]. Sick, bilious, blind, or vascular headache; hemicranias; megrim; a symptom complex occurring periodically and characterized by pain in the head (usually unilateral), vertigo, nausea and vomiting, photophobia, and scintillating appearances of light. Classified as classic m., common m., cluster headache, hemiplegic m., ophthalmoplegic m., and ophthalmic m.<sup>1</sup>

The term migraine is derived from the Greek word hemikrania. This term was corrupted into low Latin as hemigranea, the French translation of which was migraine.<sup>2</sup>

Migraine is comprised of constellation of symptoms which includes mainly headache (varying intensity)

that occurs due to neurological conditions and may be accompanied with any of the symptoms like nausea, vomiting, sensitivity to light, sensitivity to sound, sensitivity to smell and other associated symptoms.<sup>3</sup>

Head pain is usually one sided; remain for long hours to days; type of pain can be dull, throbbing, pulsating, bursting, or any other; usually aggravated by movements, light, sound, conversations.<sup>3</sup> Migraine attacks incapacitate and disable the patients of doing their daily routine household and professional jobs.

**Migraine attacks may include all or any of the four stages:** Prodrome; Aura; Headache (with or without accompanying symptoms); and Postdrome.<sup>3</sup>

**At higher risk of developing migraines are:** Sex - women likely to develop three times more than men; Hereditary presence; Age - may begin at any age,

often occurring in adolescence, getting at peak in 30s and then declining by the following decades.<sup>4</sup>

**Causes of migraine are:** Changes in serotonin levels; Genetic factors; Environmental factors; Hormonal changes; Lifestyle changes, etc.

**Triggers of migraine include:** Drinks - alcohol, too much caffeine (coffee); Sensory stimuli - bright lights, loud sounds, passive smoke, strong odours (paint thinners, perfumes); Sleep changes - disturbed or less sleep; Weather changes; Medications - vasodilators, oral contraceptives; Foods - lack of meals, food additives, processed foods, dehydration; Mental factors - emotionally disturbed, stress; Physical factors - intense exertion or exercise, debauchery; Hormonal changes in women - changes in levels of oestrogen.<sup>4</sup>

**Classification of migraines:** Classic; Common; Hemiplegic; Retinal migraines.<sup>1</sup>

**Symptoms include:** Headache - unilateral or bilateral; Nausea; Vomiting; Photophobia; Phonophobia; Osmophobia; Ophthalmalgia; Blurred vision; Blind spots; Tiredness; Neck stiffness and tenderness; Mood swings; Depression; Hyperhidrosis; Polydipsia; Difficulty in speaking; Polyuria; Yawning; Food cravings; Pricking sensations; Tenderness of scalp; Weakness; Numbness, etc.<sup>3-4</sup>

**Diagnosis is based on:** history; type of headache; side of the head affected; effect on daily activities.

**Management:** Lifestyle modification and elimination of triggers<sup>5</sup>; Yoga or behavioural interventions; Homoeopathic Management:<sup>6</sup> following can one be the medicines in cases of migraine:

**Arsenicum:** Throbbing stupefying headache OVER LEFT EYE of such severity as to render him angry and irritable, temporarily > BY COLD WATER ON HEAD, < from wrapping up head warm; intermitting, tearing, boring, burning pain in right supraorbital region, extending over eye and into upper teeth, > by walking about.

**Belladonna:** VIOLENT HYPERÆMIA, with throbbing carotids, red face, intolerance of least jar, noise or light; hemiopia, retinal blindness, slight paralysis of tongue, even transitory hemiplegia. Attacks more afternoon or evening; before or during menses, with dysmenorrhoea, globus hystericus, titillating cough; all > in bed in a dark room, far removed from light and noise.

**Gelsemium:** Hemicrania with DIM SIGHT OR DOUBLE VISION, or preceded by great sensitiveness to notice, coming on suddenly with vertigo and great heaviness of head, semi-stupor; settled dull, heavy pain in occiput, mastoid process and upper cervical region down to shoulders, > when sitting, by reclining head high on pillow, < by exertion or study; paroxysm ends with profuse urination (Sang, Sil., Veratr. alb.).

**Glonoinum:** Hemicrania from excessive use of wine; nausea, is obliged to sit down, dimness before eyes, like a cloud, followed by most violent headache, > by vomiting. Sun headaches; increases and decreases with the sun. Head ache in place of menses. Effects of

sunstroke. Head heavy, but cannot lay it on pillow. Cannot bear any heat about head. Better by uncovering head. Throbbing head ache.

**Natrum mur.:** Attack begins in the MORNING IN BED, DIMINISHES AFTER RISING and moderate exercise, but becomes worse from rapid motion, accompanied by nausea and vomiting of transparent phlegm or water; dull, heavy headache with profusion of tears and drowsiness, sleep not refreshing; headache before, during and after menses; PAIN AS IF HEAD WOULD BURST, < COUGHING; loss of consciousness; twitching of limbs.

**Nux vomica:** Cannot bear noises, odors, light, etc. Does not want to be touched. Time passes too slowly. Headache in occiput or over eyes, with vertigo. Frontal head ache, with desire to press the head against something. Head ache in the sunshine. Bruised sensation of brain, generally one-sided (rt) better by lying on pain less side. Attack sets in the morning when awaking, getting worse during the day, nausea and vomiting during attack; becoming often most severe in occiput; drawing, aching feeling as of a NAIL DRIVEN INTO THE HEAD, or as if the brain were dashed to pieces.

**Pulsatilla:** General chilliness; scanty menses; bursting, throbbing or boring, stitching pains on one side of head, obscuration of sight, white tongue, nausea and vomiting; thickly furred tongue with clammy mouth and relief from cold air; shifting pains < evenings.

**Silicea:** Rush of blood to head, GREAT SENSITIVENESS OF HAIR falling out of hair, perspiration on head, pains running from neck up into head, paroxysms end with profuse urination; headache every seventh day; VIOLENT PERIODIC HEMICRANIA, vertex, occiput or forehead, often with nausea to fainting and obscuration of sight; < from mental exertion, motion, even jarring of room by footstep, stooping, talking, light, cold air, touch; > heat, lying down in dark.

**Theridion:** Flickering before eyes; nausea < by closing eyes and by noise; EXTREME HYPERÆSTHESIA OF ACOUSTIC NERVE; throbbing over left eye and across forehead, sick stomach, < on rising from lying; desire for stimulants.

## MATERIALS & METHODOLOGY

1. **Study Setting:** The present study will be undertaken at OPD of Trigotra Homoeopathic Medical Centre, Chandigarh
2. **Study Duration:** This study will be undertaken for a period of 12 months, out of which in first 3 months pre-trial and selection of cases will be done, after that next 6 months for follow up. Each follow up will be at 7 days of interval. In last 3-months analysis of the result.
3. **Sample Size & Sampling Technique:** 100 patients were required as per synopsis. Keeping probable drop out in consideration 106 cases were enrolled.

**4. Inclusion / Exclusion Criteria:**

- **Inclusion Criteria:**

- ✓ Cases of Migraine irrespective of gender, religion, caste and socio-economic status, of age group 10 to 45 years will be included in the study.
- ✓ Patient willing to give voluntary informed consent for the study.
- ✓ With or without aura, chronic migraine (according to ICHD).

- **Exclusion Criteria:**

- ✓ Co-morbidities other than migraine.
- ✓ Pregnant and lactating women.
- ✓ Patients suffering from autoimmune diseases, HIV, etc.
- ✓ Patient pursuing other treatment and are not willing to leave it.
- ✓ Complications of migraine (according to ICHD).

5. **Dropout:** Cases that have less than 8 follow-ups will be dropped out from the study.

6. **Withdrawal Criteria:** If any emergency or medicinal aggravation.

7. **Study Design:** An Open label study.

8. **Intervention:** Homoeopathic Medicines based upon individuality and totality of symptoms:

- Potency: Selection of potencies was done according to patient's susceptibility and homoeopathic principles.
- Doses and Repetition: According to patient's susceptibility and homoeopathic Principles.
- Manufacturer: Medicine will be obtained from a GMP certified company.
- Form: Globules No. 40.
- Route of Administration: Oral.

9. **Follow-up Criteria:** Patients enrolled in the study were required to pay visit every 7<sup>th</sup> day or earlier, if needed. If there was no sign of improvement till first month, then the patient was referred to medicine OPD.

10. **Investigations:** Nil.

11. **Selection of Tools:**

- MIDAS Scale.
- Repertorisation through RADAROPUS software with synthesis repertory.
- SPSS Software version (21.0)

12. **Data Collection:**

- **Recording of data:**

- ✓ Data has been recorded in approved Case Report Format.
- ✓ Centralized data was collected in approved master chart in proper excel format.

- **Confidentiality:**

- ✓ All the evaluation forms, reports and other records will be kept in locked file cabinet. Any information about the patient will not be leaked out until required.

- **Maintenance:**

- ✓ There are forms that are completed by for each subject recruited, including two consent form for

the patient's information and his/her written consent/assent for the enrolment in the study. These were updated from time to time.

13. **Outcome Assessment:** To assess any significant difference in symptoms of Migraine with help of Pre and Post treatment MIDAS Scale.

- 100% to 75% marked improvement
- 74%- 50% moderate improvement
- 49%- 25% mild improvement
- < 25% not significant
- 0% status quo
- Aggravation -worse

14. **Data Analysis & Statistical Technique:** The data was summarized in the form of master chart in MS Excel. The appropriate statistical tests were used for the analysis of data using statistical software.

15. **Ethical Clearance:** Ethical clearance was obtained from Institutional Ethical Committee.

16. **Expected Outcome:** Homoeopathic medicines came out useful in cases of migraine.

## RESULTS

The most frequently prescribed homeopathic medicine in cases of Migraine was Silicea and Nat mur., followed by Ignatia amara, Glonoine and Sepia and Belladonna, Nux vomica and Lycopodium. Among the 100 cases of Migraine 79 cases showed marked improvement while 29 cases showed Moderate improvement. Mean score of MIDAS at Baseline was  $82.57 \pm 17.50$  which reduced to  $43.08 \pm 8.66$  at three months and  $15.22 \pm 6.01$  at six months which was statistically significant at all levels as  $p < 0.05$ . Mean score of MIDAS at Baseline was  $8.40 \pm .99$  which reduced to  $5.10 \pm 1.344$  at third month and  $.900 \pm .703$  at six months which was statistically significant at all levels as  $p < 0.05$ .

## DISCUSSION

In this study 106 cases of migraine were taken. At the end of study 100 treated cases were analysed. In this study 64% patients were females and 36% were male. Similar prevalence trend has been reported by other studies.<sup>7-12</sup> However in childhood migraine is more reported in boys as compared to girls.<sup>[13]</sup> The study sample was taken from age group of 10-45 years of age. Since only 3 cases in this study were from age group of 10-20 years the data was insufficient to find any difference in gender predilection in this age group. Migraine prevalence is known to increase with age in childhood peaking at around 12 years in children. Its highest in young adults and later it decreases with age.<sup>7-12</sup> Among the studied cases maximum i.e. 40 cases (40%) are between 21-30 age group and 31% were from age group 31-40 only 26% were from 41-45 age group. Among the 100 cases of migraine studied in this group 42% were from urban area 58% of cases were belongs to rural area. In terms of occupation 18 % were in teaching profession (5% and 13% teacher); 27 cases (27%) were Housewives;

14 (14%) were student; 10 (10%) were labour; 3 cases (3%) were carpenter; 13 (13%) were having sitting job. No specific trend was reported. Family history is a known risk factor for migraine<sup>14-17</sup> in this study 57% cases reported having family history of migraine while 43% did not. However, some forms of migraine may be underdiagnosed or underreported due to a lack of knowledge or available resources. Many a times patients are either unaware or haven't learned about family history of migraine. Among the 100 cases of Migraine treated with homeopathy for 6 months, 79 cases showed marked improvement (>75% improvement) while 21 cases showed Moderate improvement (>50% improvement) from baseline. Homeopathic treatment is known to provide beneficial effect in cases of migraine.<sup>18-22</sup>

The most frequently prescribed homeopathic medicine in cases of Migraine was *Silicea* and *Nat mur.* were prescribed in 8 cases each; *Ignatia*, *Glonoina* and *Sepia* prescribed in 7 cases each; *Belladonna*, *Nux Vomica* and *Lycopodium* in 6 cases each; *Kali Bi*, *Lachesis*, *Dulcamara*, *Gels*, *Bryonia* and *Coffea cruda* in 5 cases each; *Thuja* and *Arsenic* 4 cases each and *Sanguinaria* and *Spigelia* 2 cases each. Homeopathic literature, materia medica and repertories contains many medicines indicated for migraine.<sup>23-28</sup> Medicine selection is based on symptoms similarity and RADAR OPUS software was used for finding the similar remedy in this study.

The objective of this study was to find evidence based support of effectiveness of homeopathic treatment. To fulfil this objective, the patients were assessed using MIDAS before during and after treatment.

The MIDAS Questionnaire<sup>29-31</sup> was developed to assess headache-related disability with the aim of improving migraine care. In this patients answer five questions, scoring the number of days, in the past 3 months, of activity limitations due to migraine. Assessing migraine severity helps identify treatment response, refractory cases and patients with differential treatment needs. However, due to episodic occurrence of attacks, difference in lifestyles and variation in intensity of attacks themselves in terms of pain, duration, associated symptoms and disability, this assessment becomes challenging.

**Overall significant reduction of mean score was found in all domains of MIDAS as well as overall scores:**

- mean score at baseline of Q1 was  $6.090 \pm 4.53$  which reduced to  $2.59 \pm 2.14$  at three months and  $1.040 \pm 1.19$  at six months.
- mean score at baseline of Q2 was  $19.11 \pm 5.96$  which reduced to  $10.93 \pm 3.89$  at three months and  $4.230 \pm 2.13$  at six months.
- Mean score at baseline of Q3 was  $12.23 \pm 4.62$  which reduced to  $7.24 \pm 2.88$  at three months and  $2.700 \pm 1.67$  at six months.
- Mean score at baseline of Q4 was  $19.83 \pm 5.53$  which reduced to  $9.85 \pm 2.91$  at three months and  $3.31 \pm 2.15$  at six months.
- Mean score at baseline of Q5 was  $25.32 \pm 5.62$  which reduced to  $12.47 \pm 2.89$  at three months and  $3.94 \pm 2.39$  at six months.
- Overall Mean score of MIDAS at Baseline was  $82.57 \pm 17.50$  which reduced to  $43.08 \pm 8.66$  at three months and  $15.22 \pm 6.01$  at six months.
- At baseline all the patients were suffering from severe disability due to migraine but at 6 months after treatment only 15 patients were having severe disability; 61 patients were having moderate disability; 19 patients were having mild disability and 5 patients were having little or no disability.

Statistical analysis provides conclusive evidence for effectiveness of homeopathic medicines in cases of migraine.

## CONCLUSION

Homeopathic medicines are effective in providing relief to the patients and significantly reduce the MIDAS scores in all cases. Significant relief can be found within 3 to 6 months of treatment.

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