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To Study the Efficacy of Belladonna, Sanguinaria Canadensis & Spigelia in Cases of Migraine



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ABSTRACT

Headache is a common pain and is not often an indication of anything serious. They can be a symptom of anxiety, stress, physical tension (especially in the back and shoulders), lack of sleep, over consumption of caffeine in tea or coffee or suddenly cutting down caffeine intake, food allergy, eyestrain, fever, hypoglycaemia (low blood sugar, especially if you have not eaten for some time), migraine, drug side effects (especially if you have started a new drug), sinusitis, cervical spondylosis (stiff neck, an ache which extends from spine to top of head, headache made worse by lifting, driving, or turning head slowly) and other spinal problems, premenstrual tension, post-herpetic neuralgia following shingles, malocclusion or sepsis after dental treatment (see your dentist), and high blood pressure. Migraine: Occasional severe headaches, usually confined to one side of the head, associated with nausea and vomiting, blurred vision, and other visual disturbances, intolerance to light and occasionally numbness and tingling in the arms. In a severe attack, the only thing to do is lie down in a darkened room until the symptoms wear off. Attacks are often heralded by abnormal tiredness, nausea, or flashing, shimmering or distortion of objects towards edge of visual field; once the headache comes on, these symptoms tend to disappear. The immediate cause of migraine headaches is constriction, then swelling of the arteries which supply the brain, but why the arteries suddenly behave in this way is not known. Stress, hypoglycemia, and certain foods are the most frequently cited "trigger factors" of this miserable complaint. Incidence and frequency of attacks tend to tail off in middle age, though they may worsen during the menopause in women. Homeopathic treatment of migraine is constitutional. The homeopathic treatment involves a peeling away of layers of illness, removing symptoms in the reverse order in which they appeared, each time reaching further back into the chain of cause and effect. Unlike many other modes of "health care" which swing into action once health has broken down, homeopathy is based upon helping the organism to resist breakdown.

INTRODUCTION

Migraine is a highly prevalent disorder characterized by attacks of moderate to severe throbbing headaches that are often unilateral in location, worsened by physical activity, and associated with nausea and/or vomiting, photophobia, and phonophobia.[1, 2] Migraine treatment can include preventive therapy aimed at reducing the frequency and severity of migraine attacks, as well as acute therapy used to abort a migraine attack. In association with the American Headache Society, the American Academy of Neurology (AAN) has recently published guidelines for preventive treatment.[3] The last AAN Guidelines for acute treatment were published in 2000.[4] Each one of us, at some time or the other, must have suffered from headache. Severe, disabling headache is reported to occur at least annually by 40% of individuals worldwide. Headache is usually a benign symptom, but occasionally it is the manifestation of a serious illness such as brain tumor, subarachnoid hemorrhage, meningitis, or giant cell arthritis. In emergency setting, approximately 5% of patients with headaches are found to have emergency serious illness underlying neurological disorder. Therefore, it is imperative that the serious causes of headache be diagnosed rapidly and accurately.

International society has classified 129 types of headaches out of which one is *MIGRAINE*. It is said that one person in ten has migraine headache.

Migraine-related disability includes both absenteeism from work and significant reductions in work productivity ("presenteeism"), as well as disruption of family relationships and ability to participate in social and leisure activities. The direct and indirect costs of migraine-related disability have been estimated to be as high as \$13 billion a year in the United States^[16] with the great majority of economic cost resulting from indirect sources such as work-related productivity loss. [5]

Even, many migraineurs live in fear knowing that an attack will disrupt their ability to work, to take care of their families or to meet social obligations. Thus there is some disability between attacks as well as during attack.

WORLD HEALTH ORGANIZATIONS VIEW ON MIGRAINE:

The World Health Organization's (WHO) Global Burden of Disease Study has identified migraine as one of the top 20 most disabling disorders among adults of all ages. The level of

functional impairment experienced by migraineurs has been found to be comparable to, or greater than, many chronic illnesses such as major depression, arthritis, diabetes, hypertension, back pain, and angina

The extent of the individual burden imposed by migraine can be estimated from epidemiological data. Approximately 18% of females and 6% of males aged 18 to 65 suffer from migraine in the United States, and approximately 25% of these patients experience 1 or more severe attacks per week, with a median duration of 24 hours.[6,7] Approximately 50% of migraineurs report severe impairment (bed rest is required) during their attacks. Notably, in addition to attack-related disability, migraineurs also experience inter episode impairment in functioning and quality of life. It is uncertain whether this impairment is due to prolonged post attack recovery, associated comorbidity, or the disruptive and demoralizing effect of having to live with the uncertainty of an acute episodic illness where attacks come swiftly and result in disability for 24 hours or longer. [6]

PATHOGENESIS BEHIND THE PAIN

The bones of the skull and tissues of the brain itself never hurt, because they lack pain-sensitive nerve fibers. Several areas of the head can hurt, including a network of nerves which extends over the scalp and certain nerves in the face, mouth, and throat. Also sensitive to pain, because they contain delicate nerve fibers, are the muscles of the head and blood vessels found along the surface and at the base of the brain.

The ends of these pain-sensitive nerves called nociceptors, can be stimulated by stress, muscular tension, dilated blood vessels, and other triggers of headache. Once stimulated, a nociceptor sends a message up the length of the nerve fiber to the nerve cells in the brain, signaling that a part of the body hurts. The message is determined by the location of the nociceptor. A person who suddenly realizes "My toe hurts," is responding to nociceptors in the foot that have been stimulated by the stubbing of a toe. [7]

A number of chemicals help transmit pain-related information to the brain. Some of these chemicals are natural painkilling proteins called endorphins, Greek for "the morphine within." One theory suggests that people who suffer from severe headache and other types of chronic pain have lower levels of endorphins than people who are generally pain-free.

CLINICAL FEATURES

Definition:

- A benign, episodic recurring syndrome of headache, nausea, vomiting, photophobia or phonophobia and/or other symptoms of neurological dysfunction in varying admixtures, there may or may not be an aura.
- Women: men (2to 3:1)
- Family history: more than 60% of cases.
- Approximately 80% of patients with migraine have migraine without aura
- 15 to 20% have migraine with aura.

Some patients may suffer both types of attacks at different times. The clinical presentation of migraine varies from patient to patient and even in the same patient from time to time. Migraine should always be thought of as a complex systemic disorder with headache being one of the most common presenting features. There may be other accompanying neurological, gastrointestinal or autonomic features. [8]

The typical attack of migraine consists of a sequence of events divided into four different phases; the Prodrome, the Aura, the Headache and the Postdrome. These phases blend imperceptibly with one another during the course of an attack.

PHASES OF MIGRAINE	PRODROME	AURA	HEADACHE	POSTDROME
DURATION	Usually preceded a headache by several hrs and days	20-25 min	4-72 hrs: Aura and headache phase can't differentiate so isolated duration is difficult to say	
SYMPTOMS	Systemic, mental or psychological preceded the aura	-Visual auras most common. -Aura can consist of neurological symptoms. -Scotomas and/ or hallucination	Headache- most consisting and debilitating. -Pain is not always <i>throbbing</i> in nature < movement > lying in dark room -Can affect any region of the head or face. -Pain may radiate to neck Headache accompanied by nausea, vomiting,(which characteristic gives relief) -Photophobia -Phonophobia -Osmophobia	Drained out, exhausted, depressed feeling Recognition of this phase helps to confirm diagnosis
COMMON/ UNCOMMON		Scotomas, hallucination in 1/3of case	-Unilateral only in 50-70%	

International headache society classified migraine as follows:

1. Migraine without aura (Common Migraine)
2. Migraine with aura (Classical Migraine)
3. Ophthalmoplegic migraine
4. Retinal migraine
5. Childhood periodic syndromes that may be precursors to or associated with migraine
6. Migrainous disorder not fulfilling above criteria.[9,10]

Severe headache attacks, regardless of cause, are more likely to be described as throbbing and associated with vomiting and scalp tenderness. Milder headaches tend to be nondescript – tight, band-like discomfort often involving the entire head – the profile of tension-type headache

TYPES OF MIGRAINE:

MIGRAINE WITHOUT AURA (COMMON MIGRAINE)

Migraine should always be thought of as a complex systemic disorder with headache being one of the most common presenting features. There may be other accompanying neurological, gastrointestinal or autonomic features.

In this syndrome, no focal neurologic disturbance precedes the recurrent headaches. Migraine without aura is by far the most frequent type of vascular headache. The International Headache Society criteria for migraine include moderate to severe head pain, pulsating quality, unilateral location, aggravation by walking stairs or similar routine activity, attendant nausea and/or vomiting, photophobia and phonophobia, and multiple attacks, each lasting 4 to 72 h.

MIGRAINE WITH AURA (CLASSIC MIGRAINE)

In this syndrome, headache is associated with characteristic premonitory sensory, motor, or visual symptoms. Focal neurologic disturbances are more common during headache attacks than as prodromal symptoms. Focal neurologic disturbances without headache or vomiting have come to be known as *migraine equivalents* or *migraine accompaniments* and appear to occur more commonly in patients between the ages of 40 and 70 years. The term *complicated*

migraine has generally been used to describe migraine with dramatic transient focal neurologic features or a migraine attack that leaves a persisting residual neurologic deficit.

The most common premonitory symptoms reported by migraineurs are visual, arising from dysfunction of occipital lobe neurons. Scotomas and/or hallucinations occur in about one-third of migraineurs and usually appear in the central portions of the visual fields. The entire process lasts 20 to 25 min. This phenomenon is pathognomonic for migraine and has never been described in association with a cerebral structural anomaly. It is commonly referred to as a *fortification spectrum*. [11, 12, 13]

AIMS AND OBJECTIVES

Aim: To Study the Efficacy of Homoeopathy in Cases of Migraine

Objectives:

1. To study in detail the efficacy of homeopathy in managing acute migraine
2. To cut short the total time duration required for complete eradication of the symptoms and achieving cure.
3. To prevent any acute complications with the help of homeopathic intervention.
4. To prevent recurrence of the acute attack with the help of homeopathic medicines.

Purpose of selection

The disease to which man is liable is rapid morbid processes of abnormally deranged vital force which have a tendency to finish their course more or less quickly but always in moderate time (aphorism 72, 6th edition organon of medicine). Acute diseases can be defined as the one which has sudden onset, short duration, and a short course of less than 10 days. In acute diseases, the symptoms take a quick evolutionary course and it is easy for the physician to ascertain the complete picture of the disease.

Managing acute migraine is a very challenging job. They have a sudden onset and short duration. There is no time to wait and watch. In acute cases, both the remedy and the potency have to hit the bull's eye. In case of chronic cases, he/she can buy some time in case the prescription does not hit right in the first go, it may be in terms of remedy as well as potency. But it is not the case in acute cases. Acute migraine is even more difficult to treat since there is added pressure to make the patient fine within a very short span of time. The patient is in

acute distress and wants instant relief of the symptoms. Acute migraine hampers all the day-to-day activities.

Also, the susceptibility is very much high in acute cases. Acute migraine if not treated on time have a rapid progress and may lead to acute complications. If not completely treated and cured, it may lead to recurrence, both of which we want to avoid.

MATERIALS AND METHODS

1. Type of study:

A. Source of data-From the OPD's of the authors.

B. Type of study- 30 cases will be studied over a period of 1 year. Being acute cases, follow-up may be within 24 hours to 7 days depending upon the pace of the disease.

a. Theoretical study- The subject will be studied through various books on Homoeopathic posology, selection of potency and high potencies, journals, that the subject is thoroughly known.

b. Clinical study- OPD patient's data will be collected. Each patient's data will be processed in standardized format with the following steps-

1. Data receiving: Each patient will be given adequate time and data will be elicited in a comprehensive manner as to elicit proper patient's picture in the disease.
2. Processing of the case will be done as per the principles and guidelines of homeopathy.
3. References from Homoeopathic Material Medica, Repertory, will be availed for selection of remedy. All cases will be followed up for sufficient period required as per the guidelines from Organon and Homoeopathic Philosophy.
4. References from Repertory and Materia medica will be availed for selection of single remedy out of the indicated group of remedies.

C. Case definition- All acute cases of migraine headache will be taken into consideration. Acute case can be defined as the one which has sudden onset, short duration and a short course of less than 10 days.

D. Study design- Pilot study: All acute cases which satisfy the case definition will be studied.

***CRITERIA FOR INCLUSION AND EXCLUSION**

INCLUSIVE CRITERIA

- Cases, which have been diagnosed as per guidelines laid down in standard books of clinical medicine.
- All types of migraine.
- All age groups.
- All the cases with proper, complete documentation in the SCR format, with follow-ups of at least 6 months.

EXCLUSION CRITERIAS

- Cases with presentation of Periodic Abdominal pains and Cyclic Vomiting (migraine variants), especially in pediatric age group; cases of complicated migraine.
- Migraine-like headaches i.e. a typical migraine associated with some structural pathology e.g. Arteriovenous malformations, slow growing tumors like gliomas, meningiomas etc.
- Pregnant women, women with peri-menopausal symptoms, women on hormonal preparations.

Criteria for assessment- Will be

- a. Complete disappearance of signs and symptoms.
- b. Patient in general.
- c. No new symptoms.

Cure-

- a. Complete disappearances of symptom-complex within 72hours .
- b. Complete disappearance of pathology if any.

Good Response-

- a. Improvement more than 70% of the symptom complex within 72 hours.
- b. Incomplete regression of the pathology, if any.

No Relief/Worse-

No improvement whatsoever within 2-3 days.

For ease of evaluation I have graded the follow up thus,

Grade I- Complete removal of symptoms and signs within definitive period of each case.

Grade II- Complete removal of symptoms but signs remain.

Grade III- Some symptoms and signs remain.

Grade IV- No relief, followed by natural recovery or progressive worsening of case.

I. Selection and administration of drugs-

Selection of remedy will be done after verification from standard textbooks of Material Medica. Dose and repetition will be based on principles of Homoeopathic posology. High potency will be selected. Route of administration will be oral. All cases will be given placebo once improvement is seen (aphorism 246).

Case recording- All the cases will be recorded as per the standard case performa as prescribed by the institute. Being acute cases, stress will be laid on onset, pace and characteristics that the patients show. Unnecessary details of irrelevant chronic phenomenon were not taken as per the guidelines are given in aphorism 92.

STATISTICAL ANALYSIS

Effectiveness of Homoeopathic medicines in migraine was assessed according to statistical principles on the basis of change in score taken before and after treatment with homeopathy. The data obtained from patients before introduction of variable has formed the control which was compared with outcome of the symptom complex through the objective assessment after homeopathic treatment in same patients. Since efficacy of Homoeopathic medicines on patients having definite group of signs and symptoms before administration of homoeopathic remedy were taken as control and compared with their symptomatology after administration

of similar remedy as response, no separate strategies of elimination of error or bias like use of controls, randomization, cross over design or placebo group and blinding techniques were used in this study.

The following marks were given to the clinical features of cases-

Table 1-Scores before treatment-

Sr.No.	Clinical Features	Score
1	Presence of sign	3
2	Presence of symptom	2
3	Presence of pathology	4

Table 2-Scores after treatment-

Sr. No.	Clinical Features	Score
1	Disappearance of sign	2
2	Amelioration of symptoms	1
3	Aggravation of symptoms	3
4	Disappearance of pathology	4

OBSERVATION AND RESULTS

1. Sex: After studying the 30 cases it was observed that prevalence of female was seen in the 25 cases and male in 5 cases.

Table 1:- Sex distribution

Sex	No. of Patient	Percentage
Male	5	16.67%
Female	25	83.33%

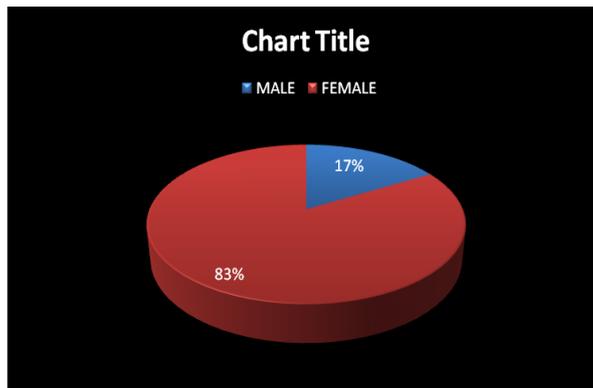


Figure 1:- Sex distribution

2. Age: the reported age group is also varied. The youngest patient is 13 years old and the oldest is 60 years old.

Table 2:- Age distribution

Age Group	No. of Patient	Percentage
0-10	0	0.00%
11-20	3	10.00%
21-30	8	26.67%
31-40	14	46.67%
41-50	3	10.00%
51-60	2	6.67%
	30	

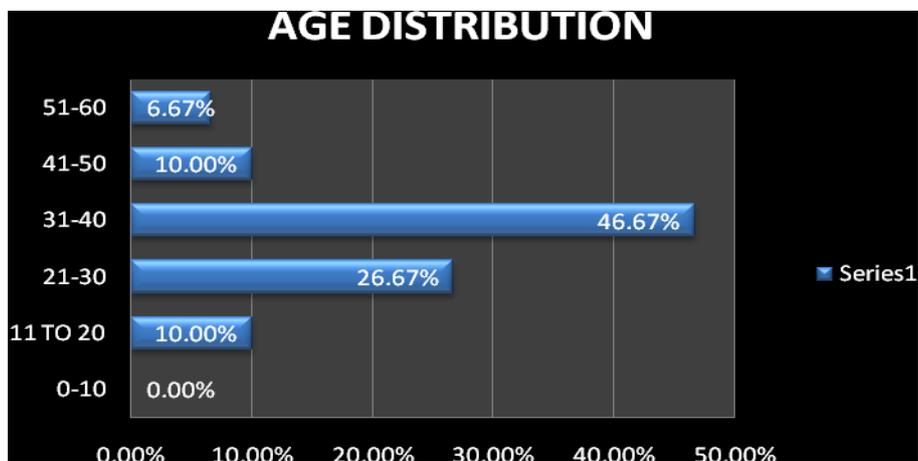


Figure 2:- Age distribution

3. Type of Migraine: Amongst the 30 cases 27 cases were migraine without aura (i.e. 90%). 3 cases were of migraine with aura (i.e. 10%).
4. Different locations presented in the cases: mainly some patients gave data of only unilateral or bilateral headache. Some experienced it in the whole head, while some patients narrated specific location and the direction of spread of the headache also.

Table 3:- site of pain

location	No of cases
Frontal area	10
Occiput	6
Parietal	1
Temporal	9
Vertex	4

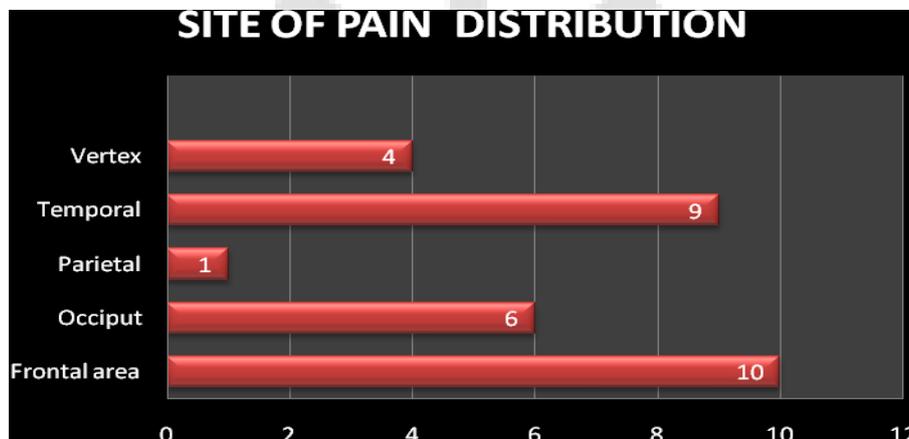


Figure 3:- Site of pain

The sidewise distribution of headaches was as follows:

Bilateral	15
Left side	4
Right side	6
Unilateral	2
Whole head	3

5. Acute Remedy used in migraine episodes:

Table 4:- Remedy Action Percentage

Acute	Improvement
Belladonna	90%
Sanguinaria Canadensis	84%
Spigelia	80%

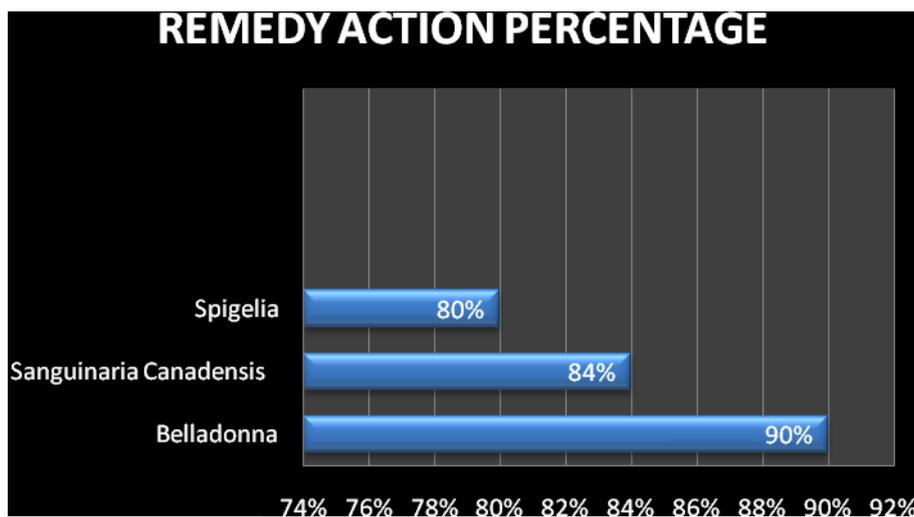


Figure 4:- Remedy Action Percentage

Statistics-

Distribution of scores before and after Homoeopathic treatment-

Case No.	X	Y	X-Y	A - \bar{A}	(A - \bar{A}) ²
1	19	11	8	2.34	5.47
2	6	3	3	-2.66	7.07
3	14	9	5	-0.66	0.43
4	9	7	2	-3.66	13.39
5	4	3	1	-4.66	21.71
6	10	2	8	2.34	5.47
7	17	8	9	3.34	11.15

8	8	6	2	-3.66	13.39
9	15	12	3	-2.66	7.07
10	12	5	7	1.34	1.79
11	15	6	9	3.34	11.15
12	23	12	11	5.34	28.51
13	12	5	7	1.34	1.79
14	13	10	3	-2.66	7.07
15	14	13	1	-4.66	21.71
16	10	9	1	-4.66	21.71
17	12	4	8	2.34	5.47
18	16	12	4	-1.66	2.75
19	15	9	6	0.34	0.11
20	18	10	8	2.34	5.47
21	12	8	4	-1.66	2.75
22	12	6	6	0.34	0.11
23	12	2	10	4.34	18.83
24	13	2	11	5.34	28.51
25	18	11	7	1.34	1.79
26	14	5	9	3.34	11.15
27	15	9	6	0.34	0.11
28	10	10	0	-5.66	32.03
29	13	13	0	-5.66	32.03
30	17	6	11	5.34	28.51

Statistical Working

X= score before treatment Y= score after treatment

A= difference between the scores.

\bar{A} =mean of the difference between the scores

S=S.D of Differences S E= Standard Error of Mean

Now we assume

H₀ – null hypothesis states that homeopathy is **not useful** in a migraine headache.

H₁ – alternate hypothesis states that homeopathy **is useful** in a migraine headache.

$$\bar{A} = \Sigma A / n = 5.66$$

$$S = \sqrt{\Sigma (A - \bar{A})^2 / n-1} = \sqrt{348.5/29} = 3.465$$

$$SE = S / \sqrt{n} = 3.465/5.47 = 0.6334$$

$$t = \bar{A} / SE = 5.66/0.6334 = 8.98$$

Thus t =8.98

At 5% level for 29 degrees of level of freedom the value of t = **2.05**

At 1% level for 29 degrees of level of freedom the value of t = **2.76**

Thus the value obtained is more than the above values so; we **reject the null hypothesis** and **accept the alternative hypothesis**. [11]

Therefore HOMOEOPATHY is useful in migraine headache.

DISCUSSION

1. Sex: The study carried out in the 30 cases migraine shows that Males represent 5 (16.67%) of the group and Female represent 25 (83.33%) of the group) which gives a ratio of 1: 5
2. Age: The patient came to us with migraine in which the youngest is 13 and oldest is 60. The highest age group of patient between 31 years to 40 i.e. 14 and other group age between 21 years to 30 i.e. 8. So its shows the prevalence of migraine in the middle age group is the highest, which corresponds to standard textbook.
3. There was no case from geriatric age group. This corresponds to the observations in the standard book that migraine episodes become less after 40 years.
4. Amongst the 30 cases, 27 cases were migraine without aura (i.e. 90%). 3cases were of migraine with aura (i.e. 10%). This corresponds to the reported incidence i.e. 80 to 85% of patients having migraine without aura and the rest 15 to 20 % of cases are of migraine with aura.
5. In this study, all the patients had come with Migraine as the chief complaint and also had a multitude of other clinical entities covering the sector of Mind, RS, CVS, MSS, GIT and having the pathogenesis of Neurosis/ Psychosis, Allergic, Degenerative and Chronic Inflammation were found to be associated with migraine.

6. The physical factor came highest in a causation and maintenance migraine so found out the relation in the genesis of a migraine.
7. Onset of Migraine or aggravation has direct relationship to sun heat, menses, in 9 cases in this study. The reason for this association and its relevance to a homoeopath, in terms of characteristic prescribing data has to be assessed and confirmed in further studies
8. The general Personality profiles and Dispositional features of Migraine needs to be studied along with the Mind and Head sector of the various remedies that come up to get more clarity and to find out the reason as to why a particular remedy group comes up prominently in Migraine case, if at all
9. One important observation is that 3 cases in this study had a direct relationship of menarche as the A/F for the onset of migraine. Whether this is attributable to hormonal changes or to the various stresses one would normally associate with that epoch of life is a matter of further in-depth study. In this study some important factors have come up that have played an important role in Evolution and Maintenance of migraine
10. It was observed that Belladonna was effective in cases where headache was in all parts of the head. Sanguinaria C was effective in right sided migraine whereas spigelia was effective in left-sided cases.

SUMMARY & CONCLUSION

Out of the 30 cases which were evaluated, 20 cases were cured within 72 hours while 10 cases showed good response (more than 70% improvement within 72 hours). In none of the 30 cases, was there any acute complication. Total time duration required for complete eradication of symptoms was also greatly reduced with the help of homeopathic medicines. Statistical analysis also shows that there is great difference in scores before treatment and after treatment.

Therefore, according to the 30 cases, I have studied; I can say that homeopathic medicines are very much useful in treatment of migraine. This inference is not only for statistical purpose but it gives us guidelines for prescribing in an acute migraine. This will then be a feather in cap for Homoeopathy. This will also make people get over the myth that

Homoeopathy takes very long to act and has little or no role in treating acute emergency like migraine.

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