Original Research Paper

Homopaethic

NON - RANDOMIZED SINGLE BLIND STUDY TO OBSERVE THE ROLE OF ANTI MIASMATIC MEDICINE IN PATIENTS WITH MIGRAINE

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ABSTRACT
Background: Migraine is fairly common condition affecting about 15% of the population globally and In GBD 2015, it absolutely was ranked as third highest reason for disability worldwide in both males and females under the age of fifty years. Thus it is absolutely necessary and interesting to study the effectiveness of homoeopathic anti miasmatic remedies in patients with migraine.
Methods: 30 cases of migraine were included in this non randomized clinical study out of 40 registered cases and the data collected during the study was analyzed with paired t test. The study was conducted for period of 18 months.
Result: The study showed that the prevalence of migraine was more amongst females (83.33%) compared to male (16.66%). Moreover the age group 15-20 year age group (23.33%) followed by 25-30 years and 40-45 years (20%). During the study it was found that Natrum Muriaticum was indicated in moat of the cases (13.33%), followed by pulsetilla (10%) followed by lachesis, silicea and belladonna (6.66% each). The most common miasm was found to be sycotic miasm (53.33%) followed by psora miasm (30%) and syphilitic miasm (13.33%).
Conclusion: After the study of 30 patients it was found that administration of anti miasmatic medicines in the patients with migraine showed changes in the frequency of episode of headache (Mean difference -2.167, SD of difference 0.7915, p value <0.001), intensity of pain (Mean difference -1.700, SD of difference 1.179, p value <0.001) and changes in quality of life score, MIDAS scores (Mean difference -2.167, SD of difference 0.7915, p value <0.001) which were statistically significant.

INTRODUCTION

HEADCAHE: Headache which can be described as pain in the region of head, neck, head and neck, face is amongst the most common symptoms experienced by several individual during lifetime. About half of adults have a headache in a given year. Headache is among the most common reasons patients seek medical attention. Diagnosis and management is based on a careful clinical approach augmented by an understanding of the anatomy, physiology, and pharmacology of the nervous system pathways that mediate the various headache syndromes. Headaches occur due to many reasons and there are number of classifications for types of headache.

HISTORY: The first classification system was published by ARETAEUS OF CAPPADOCIA, a medical scholar of Greco-roman antiquity, where 3 different types[1]:
a) cephalalgia (by which he described a short lasting, mild kind of headache)
b) cephalea (the chronic type of headache)
c) heterocrania (a paroxysmal headache- which occurs on one side of head) were described.

Another type of classification having resemblance with modern types of classification was published by THOMAS WILLIS, in 1672, in De Cephalalgia. Further, CHRISTIAN BAUR, in 1787 gave a classification and divided headaches into: idiopathic (primary) and symptomatic (secondary) and defined 84 categories. The most well accepted and well recognized classification of headache is given by International Headache Society (IHS). It is considered as official classification of headache by WHO. The international classification of headaches disorders, 3rd edition (2018) This classification broadly divides headache into 3 type:

A) THE PRIMARY HEADACHES: (Migraine, tension type headache, trigeminal autonomic cephalalgias , other primary headache disorders)

B) THE SECONDARY HEADACHES:(attributed to trauma/ injury to head and/or neck, cranial and/ or cervical vascular disorder, non vascular intra cranial disorder, substance or its withdrawal, infection,disorder of homoeostasis, facial pain attributed to disorder of cranium, neck, eye, ear, nose, sinuses, teeth , mouth or other facial or cervical structures, psychical disorder)

C) PAINFUL CRANIAL NEUROPATHIES, FACIAL PAINS AND HEADACHE: (painful lesion of the cranial nerves and other facial pains, other headache disorder)

MIGRAINE: Migraine is one of the most frequent and common disabling neurological conditions which impacts the quality of life of the patient. There is no complete explanation of patho- physiology of the condition. It is a condition commonly seen in females than in male, the ratio being (2 to 3:1). It is commonly begins in late childhood, adolescence and early twenties. A positive family history is present in more than 60% cases.

It is a medical condition involving episodic recurrent headaches, most often unilateral and sometimes might be associated with nausea, vomiting, photophobia and phonophobia. The aura may or may not be present. Migraine must be considered as complex systemic disorder where headache is the most common clinical feature. Other neurological and gastro intestinal features can also be present. The typical migraine attack consists of sequence of events which is divided into 4 phases: 1)The prodrome 2) The aura 3) The headache 4)The postdrome.

Homoeopathic mode of treatment is based on administration of law of similar and thus it cures the patient and not the

disease condition. The selection of the medicine is based on the basis of totality of symptoms. The selection of dose of the similar medicine further depends on the stage of the disease, susceptibility of the person, age, sex and other various factors. Thus it is a wholistic complete system of treatment which not only helps treating patient of his present complains but by correcting his immunity and susceptibility improves his health and reduces chances of health derangements too. Moreover the concept of miasms and treatment of chronic disease which is unique to homoeopathy is seen effective to treat familial tendencies in a person. Hahnemann suggested that inherited influences which are remnants of infectious diseases of an "unknown primitive malady" function as obstacles to cure. He further explains in his literature- organon of medicine, in aphorism 78, the concept of chronic miasm from which chronic diseases arise[2]. Hahnemann's conditions for understanding the miasms can be enlisted as follows:

1. Miasms are spiteful invisible forces, each of which produces a range of suffering (disease) of a typical kind.

2. Miasms are negative influences that need to be eradicated in order to being about cure.

3. These miasms are transmitted through inheritance, sexual contact or (for Psora) merely by closeness or touch.

4. The innate self-curing capacity of the living organism is unable to overcome on its own the morbific influence (negative) of the miasms.

5. Anti-miasmatic homeopathic treatment is required in order to remove miasm-induced disease.

Hahnemann has described three main miasms:
1. Psora – "the mother of chronic diseases" that occurred as the result of the suppression of leprosy .
2. Sycosis – resulting from suppressed gonorrhea.
3. Syphilis – resulting from suppressed syphilis.

Hahnemann concluded that all chronic diseases originate from any of these 3 miasms (mainly Psora) or a combination of two or three of them. After Hahnemann described these miasms in detail many stalwards studied and worked on it and one such stalward, Dr. Kent clearly identified the remedies and related them to miasms. Thus in chronic conditions like migraine where the familial tendency is found in around 60% of cases administration of homoeopathic anti miasmatic medicine would enable physician to clear up the suppressions, correct the susceptibility of the parson and thus strengthen the constitution which can be evident in the form of improved immune response.

MATERIAL AND METHODS
Study Design: It was a non randomized single blind clinical study to observe the effects of homoeopathic anti miasmatic medicines in cases with migraine. The theoretical study of this topic was done from different books, previous research works, journals, authentic websites related to the topic. Clinical study related to cases of migraine of both sexes, of age group 18-45 and role of anti miasmatic treatment in those cases was studied. Case taking was done according to the standard case taking Performa as per homoeopathic principles.

Inclusion/ Exclusion Criteria:
Inclusion criteria: 1) Patients of both sexes were included. 2) Patients of 18- 45 age group of various socio economic groups were included. 3) Only diagnosed cases of migraine were included. 4) Patients not receiving any other mode of treatment since last 3 months of commencement of the study were included.

Exclusion criteria: 1) Cases which are chronic in nature associated with other gross pathology were excluded. 2) Cases under immune suppressive therapy will be excluded.

Selection of sample, site and duration of study:
- Site of study: the study was conducted at Bharati Vidyapeeth Homoeopathic hospital OPD, IPD and various rural and urban camps organized by the hospital.
- Duration of study: study was conducted for 18 months .
- Selection of sample: cases as per the definition were selected by the guide of department of organon of medicine and homoeopathic philosophy.

Data Collection: 30 cases (satisfying the inclusion criteria) of migraine were studied at Bharati Vidyapeeth homoeopathic hospital OPD, IPD and various rural, urban camps organized by the college.

Brief of procedures: it was a non randomized, single blind study. After the selection of the sample a detailed case taking was conducted as per the standard Performa. The theoretical data was collected as mentioned above from 30 cases (included in the study that satisfied the inclusion criteria). The remedy was selected on the basis of homoeopathic principles especially following the guidelines for treatment of chronic diseases mentioned in homoeopathic literature, repertorization, and reference of various materia medica under the guidance of the Post Graduate Guide. Literature of books of medicine was referred whenever required.

Allocation: Non randomized

Masking: single blind

Mode of intervention: oral route

Dose And Potency: drug was administered in various potencies (30CH,200CH,1M) on the basis of law of homoeopathic philosophy.

Outcome Assessment:
Follow up criteria- the cases of all the patients were studied thoroughly and the details of symptomatic, clinical changes were accessed. Duration of follow up will differ from case to case as per the requirement.

Statistical Techniques & Data Analysis:
relevant charts, tables, sheets or software were used to statistically assess the results of the study. Paired t test was applied to the before and after treatment data collected from the study.

RESULT AND DISCUSSION
RESULTS:
Thirty five patients fulfilling the inclusion criteria were included in the study. Out of these 35 patients, 30 patients were enrolled for the study while 5 patients could not complete the treatment. After taking the detailed case taking, analyzing and evaluating the case, considering the miasmatic background of each case the most similar anti miasmatic medicine was administered in indicated potency and was repeated when required. The frequency of attack of headache in last 6 months, the pain intensity scores and MIDAS scores of each patient before the onset of treatment and after the treatment were recorded and analyzed statistically using paired t-test. The results of the study of 30 patients with migraine are explained with the help of charts/ tables, diagrams and graphs. Also the age wise distribution of patients, sex wise distribution of patients, most indicated medicines, most indicated potencies, the most common miasmatic background all cases are all described in the form of tables and charts.

AGE DISTRIBUTION:
Table 1: Distribution Of Patients According To Age Group

AGE GROUP	NUMBER OF PATIENTS	TOTAL	PERCENTAGE
1) 15-20 YEARS	7	30	23.33%
2) 20-25 YEARS	5	30	16.66%
3) 25-30 YEARS	6	30	20%
4) 30-35 YEARS	4	30	13.33%
5) 35-40 YEARS	2	30	6.66%
6) 40-45 YEARS	6	30	20%

Distribution According To Sex:
Table 2: Distribution According To Sex In Sample

Sex	Number Of Patient	Total Number Of Patient	Percentage
MALE	5	30	16.66%
FEMALE	25	30	83.33%

Percentage Distribution According To Medicine:
Table 3: Distribution Of Remedy

MEDICINES	NUMBER OF CASES	NO. OF CASES
1) LACHESIS	2	6.66%
2) SILICEA	2	6.66%
3) GELSEMIUM	1	3.33%
4) NATRUM MURIATICUM	4	13.33%
5) ACTEA RACEMOSA	1	3.33%
6) SEPIA OFFICINALIS	1	3.33%
7) BRYONIA ALBA	1	3.33%
8) SANGUINERIA	2	6.66%
9) PULSETILLA	3	10%
10) BELLADONNA	2	6.66%
11) CALCEREA CARBONICA	1	3.33%
12) NUX VOMICA	1	3.33%
13) PHOSPHOROUS	1	3.33%
14) STANNUM METALLICUM	1	3.33%
15) COFFEA CRUDA	1	3.33%
16) SPIGELLIA	1	3.33%
17) SARSAPARILLA	1	3.33%
18) ARGENTUM NITRICUM	1	3.33%
19) DROSERA	1	3.33%
20) IGNATIA	1	3.33%

MIASMATIC ANALYSIS:
Table 4: Distribution According To Miasmatic Background

MIASM	NUMBER OF PATIENT	PERCENTAGE
1) PSORA	9/30	30%
2) SYCOTIS	16/30	53.33%
3) SYPHILITIC	4/30	13.33%

FREQUENCY OF EPISODE OF HEADACHE
Table:5 Before And After Score Of Frequency Of Headache

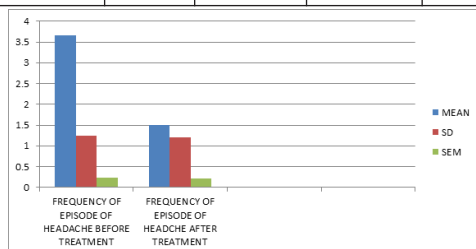|	MEAN	N	SD	SEM
FREQUENCY BEFORE TREATMENT	3.66	30	1.2410	0.2265
FREQUENCY AFTER TREATMENT	1.5	30	1.1962	0.2184

Figure 1: Mean, SD, SEM of frequency of headache before and after treatment

Frequency Of Episode Of Headache: Results Of Paired T Test:
Table 6: Result Of Paired T Test Of Before And After Frequency Scores

MEAN OF DIFFERENCE	SD OF DIFFERENCE	SEM OF DIFFERENCE	95% CONFIDENCE INTERVAL	CORRELATION COEFFICIENT	P VALUE	t VALUE	df	DECISION
-2.167	0.7915	0.1445	-2.462 to -1.871	0.7897	<0.001	14.99	29	H$_O$ REJECTED

PAIN SCORE:
Table 7: MEAN, SD, SEM Before And After Pain Scores

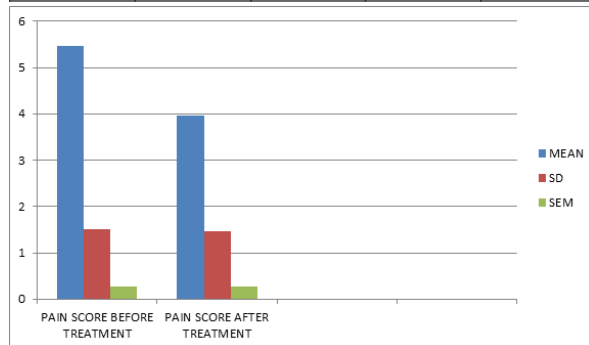|	MEAN	N	SD	SEM
Pain Score Before Treatment	5.467	30	1.502	0.2743
Pain Score After Treatment	3.967	30	1.474	0.2690

Figure: 2: Bar Graph Of Mean, SD, SEM Of Before And After Pain Scores

PAIN SCORES: RESULTS OF PAIRED t TEST:
Table 8: Result Of Paired T Test Of Before And After Pain Scores

MEAN OF DIFFERENCE	SD OF DIFFERENCE	SEM OD DIFFERENCE	95% CONFIDENCE INTERVAL	CORRELATION COEFFICIENT	P VALUE	t VALUE	df	DECISION
-1.700	1.179	0.2152	-2.140 to -1.260	0.6827	<0.001	7.899	29	H$_O$ REJECTED

MIDAS SCORES:
Table 9: MEAN, SD AND SEM Of Before And After Treatment Midas Scores

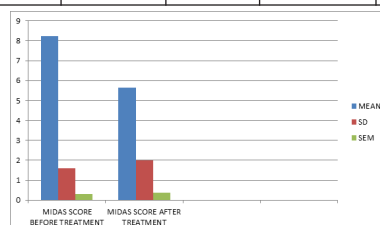|	MEAN	N	SD	SEM
Score Before Treatment	8.233	30	1.612	0.2943
Score After Treatment	5.633	30	1.991	0.3635

Figure3: Mean, SD, SEM Of Before And After MIDAS Scores

MIDAS SCORES: RESULTS OF PAIRED t TEST:
Table 10: t test Of Before And After MIDAS Scores

MEAN OF DIFFE RENC E	SD OF DIFF ERE NCE	SEM OF DIFFE RENC E	95% CONFI DENCE INTERV AL	CORR ELATI ON COEF FICIE NT	P VALUE	t VAL UE	Df	DECI SION
-2.600	1.248	0.2279	-3.066 TO -2.134	0.7796	<0.001	11.41	29	H$_0$ REJEC TED

DISCUSSION:

The study of the topic " non randomized single blind study to observe the effects of anti miasmatic medicines in cases with migraine" is based on clinical experiences of various stalwarts since Dr. Hahnemann till date as observed and studied by me in homoeopathic practice as P.G. scholar. Migraine is fairly common condition affecting about 15% of the population globally and In GBD 2015, it absolutely was ranked as third highest reason for disability worldwide in both males and females under the age of fifty years. Thus it is absolutely necessary and interesting to study the effectiveness of homoeopathic anti miasmatic remedies in patients with migraine.

As the condition migraine involves various sign and symptoms affecting an individual in lesser or greater extent it is necessary to access the changes in different parameters during the treatment in order to access its effectiveness. Thus, the results of the study were accessed by the frequency scores, pain scores and MIDAS scores (for assessment of changes in quality of life of a person) and changes in these parameters were evaluated statistically. All 30 patients were asked to mention the frequency score, pain score and fill the MIDAS questioner and these scores were recorded. Similarly they were asked to score the same at the end of treatment and the scores before treatment and after treatment were analyzed through paired t test using GraphpadPrisma software 9.0. other than these the miasmatic tendency of all these patients were also studied and was co related with the concept of chronic disease given by Hahnemann in literature of organon of medicine.

The study showed that the prevalence of migraine was more amongst females compared to male and then study group showed 83.33% patients were female whereas 16.66% of them were male. Moreover the age group 15-20 year age group (23.33%) followed by 25-30 years and 40-45 years (20%). During the study it was found that Natrum Muriaticum was indicated in moat of the cases (13.33%), followed by pulsetilla (10%) followed by lachesis, silicea and belladonna (6.66% each). The most common miasm was found to be sycotic miasm (53.33%) followed by psora miasm (30%) and syphilitic miasm (13.33%). After the study of 30 patients it was found that administration of anti miasmatic medicines in the patients with migraine showed changes in the frequency of episode of headache (Mean difference -2.167, SD of difference 0.7915, p value <0.001), intensity of pain (Mean difference -1.700, SD of difference 1.179, p value <0.001) and changes in quality of life score, MIDAS scores (Mean difference -2.167, SD of difference 0.7915, p value <0.001) which were statistically significant. Thus the H$_0$: there is no effect of anti miasmatic treatment in cases with migraine was rejected and the H$_1$: there is effect of anti miasmatic treatment in cases with migraine was accepted.

CONCLUSION

The main aim of the study entitled " non randomized, single blind study to observe the effects of anti miasmatic remedies in cases with migraine" was to find out the effectiveness of anti miasmatic remedies in migraine, effectiveness in reducing the frequency and/or intensity of pain and its effectiveness in improving the quality of life of the patients with migraine. The aim was also to get a better approach towards cases with migraine and improve the clinical orientation in such conditions. The study demonstrated that:

- The most commonly affected age group with migraine was 15-20 years, followed by the age groups of 25-30 years.

- Females were more commonly affected than males.

- After a detailed study of cases with migraine and their treatment through anti miasmatic medicines, it was found that the results were satisfactory and patients showed improvement in frequency of headache and/or severity of pain, quality of life.

- Furthermore a detailed and more extensive study on the subject would be more reliable. Increasing the sample size can be considered in further studies for making the study more reliable and statistically significant.

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