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A PROSPECTIVE RANDOMIZED STUDY TO COMPARE THE EFFECT OF BACILLUS MORGAN (Bach) AND NATRUM MURIATICUM IN CASES OF MIGRAINE

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ABSTRACT

Background: Migraine is a benign and recurring syndrome of headache, nausea, vomiting and other symptoms of neurologic dysfunction in varying admixtures. It can often be recognized by its activators (red wine, menses, hunger, lack of sleep, glare, oestrogens, worry, perfumes, let down periods) and its deactivators Headache is frequently encountered neurological symptom characterized by a feeling of discomfort or pain in head. **Methods:** A prospective randomized comparative study was conducted at Dr. M. P. K Homoeopathic Medical College, Hospital and Research Centre, Jaipur. 70 cases were enrolled in the study. Randomly selected 35 cases received *Bacillus morgan (Bach)* & 35 cases received *Natrum muriaticum*. "VAS" scale was used to assess the improvement in the study. **Results:** After comparing pre and post treatment scores. A paired t-test was conducted to compare before and after score of *Bacillus morgan (Bach)* and *Natrum muriaticum* in cases of Migraine. There was a significant difference in the scores for *Bacillus morgan (Bach* before (M= 8.17, SD=1.014) and after score (M=3.43, S=1.57) conditions; t=19.4, p=0.000 and scores for *Natrum muriaticum* before (M=8.29, SD=1.100) and after score (M=1.2, SD=0.19) conditions; t=36.74, p=0.000. There is comparatively more improvement in Migraine with *Natrum muriaticum* (M=8.29, SD=1.100) than *Bacillus morgan (Bach*) (M=8.17 SD=1.014), t =.452, p<o.oo5, therefore rejecting null hypothesis and accepting alternating hypothesis that *Natrum muriaticum* is more significant than *Bacillus morgan (Bach)* in cases of Migraine.

KEYWORDS: Migraine, *Bacillus morgan (Bach), Natrum muriaticum,* Bowel nosodes.

INTRODUCTION

The word Migraine was derived from the Latin word "hemicrania" meaning "half" (hemi) "skull" (crania). This term was first used by Galen of Pergamon to describe the pain felt across one side of the head during a Migraine.[1]

Migraine is the most common cause of vascular headaches. A useful definition of Migraine is a benign and recurring syndrome of headache, nausea, vomiting and other symptoms of neurologic dysfunction in varying admixtures. It can often be recognized by its activators (red wine, menses, hunger, lack of sleep, glare, oestrogens, worry, perfumes, let down periods) and its deactivators (sleep, pregnancy, exhilaration, sumatriptan).[2]

The HIS criteria for Migraine include moderate to severe head pain, pulsating quality, unilateral location, aggravates by walking stairs or similar routine activities, attendant nausea, vomiting, photophobia and phonophobia and multiple attacks each lasting 4 to 7 hours. Migraine is among the most common patient complaints encountered in neurology practice.

It is the third most common disease in the world with estimated global prevalence of 14.7% (that is around 1 in 7 people). It is 7th most disabling disease among all diseases and the leading cause of disability among all neurological disorders.[3]

The prevalence of Migraine for women and men are 18% and 6% respectively according to 1989 American Migraine Study (AMS) cases of Migraine were higher among whites than blacks and among those of lower household income than upper income group.

Prevalence increased from age 12-40 years, declining thereafter. The incidence of Migraine peaks during adolescence.

One population-based studies conducted in US found that incidence of Migraine with aura peaked between 12 and 13 years of age and migraine without aura between 14 and 17 years of age. It is most common between the ages of 25 and 55. It is the 3rd most prevalent illness and 6th most disabling illness in the world.[4] It is more common in women than in men (2 to 3:1) and family history is present in more than 60% of cases.

Table 1: Triggering factors of Migraine.

Behavioural - Physiologic triggers	Too much or too little sleep Skipped meals Stress or post stress Menstruation Fatigue Physical activity Depression
Dietary triggers	Alcohol or caffeine Aspartame Chocolate Fasting or missing a meal Foods containing tyramine (smoked foods, meat, chicken, liver, red wine, cheese, figs and beans) Monosodium glutamate Nitrite laden meat (bacon, hot dog)
Environmental triggers	Loud noises Weather changes Perfumes or fumes High altitude Exposure to glare or flickering lights

Natrum muriaticum

The prolonged taking of excessive salt causes profound nutritive changes to take place in the system. ill effects of grief, fright, anger, etc. Depressed, particularly in chronic diseases. Consolation aggravates. Irritable; gets into a passion about trifles.

Throbbing, blinding headache. Aches as if a thousand little hammers were knocking on the brain, in the morning on awakening, after menstruation, from sunrise to sunset. Feels too large; cold. Chronic headache, semi-lateral, congestive, from sunrise to sunset, with pale face, nausea, vomiting; periodical; from eyestrain; menstrual. Before attack, numbness and tingling in lips, tongue and nose, relieved by sleep.

Modalities -Worse, noise, music, warm room, lying down about 10 am, at seashore, mental exertion, consolation, heat, talking.

Better, open air, cold bathing, going without regular meals, lying on right side; pressure against back, tight clothing.[5]

Bacillus morgan (Bach)

They have congestive headaches with flushed face < morning, hot weather, travelling, excitement, thundery weather. Weekly sick headache, migraine. Vertigo from hypertension,

headache associated with nausea. Migraine at the beginning of menses and due to hepatic complaints.[6]

Patient is anxious apprehensive avoids company and have a suicidal tendency.[5]

MATERIALS AND METHODS

Study setting: Study was conducted at

❖ Site 1-O.P.D/I.P.D of Dr M.P.K. homoeopathic medical college, hospital & research centre, Sindhi camp, Station road, Jaipur (Raj.)-302006.

❖ Site 2-O.P.D/I.P.D of Dr M.P.K. homoeopathic medical college, hospital & research centre, Homoeopathy University, Saipura, Sanganer, Jaipur (Raj.)-302029.

Study duration: The study duration was for 1 year, all cases were registered within 12 months of study with effect from July 2016 to June 2017, out of which cases were registered in first 9 months so that minimum 6 follow-ups could be obtained from the last case.

Sample size: Selection of cases will be done randomly from college O.P.D. /I.P.D. Sample size: 70 cases.

Bacillus Morgan (Bach)- 35 cases

Natrum muriaticum -35 cases

Selection criteria

Inclusion Criteria

1). Diagnosed cases of Migraine will be included in the study irrespective of their sex, age, caste, religion & duration of illness.

2). Patient agreeing to the information about study and signing the consent form.

Exclusion Criteria

1). Suspected secondary headache

2). Pregnant and lactating women.

3). Patients with any other systemic diseases.

Drop out criteria

1). Cases required emergency treatment during the study

2). Cases without proper follow ups

Study design

1. Allocation: patients fulfilling the eligibility criteria were enrolled and randomized systematically to receive either *Bacillus morgan (Bach)* and *Natrum muriaticum*.
2. Type of study: prospective, comparative, experimental, randomized controlled trial was done to compare the effects of *Bacillus morgan (Bach)* and *Natrum muriaticum* in cases of migraine.

Intervention

- *Bacillus Morgan (Bach)* and *Natrum muriaticum*
- Potency – According to patient's susceptibility

CO-Intervention

- Supportive dietary advice if required
- Avoidance of triggers

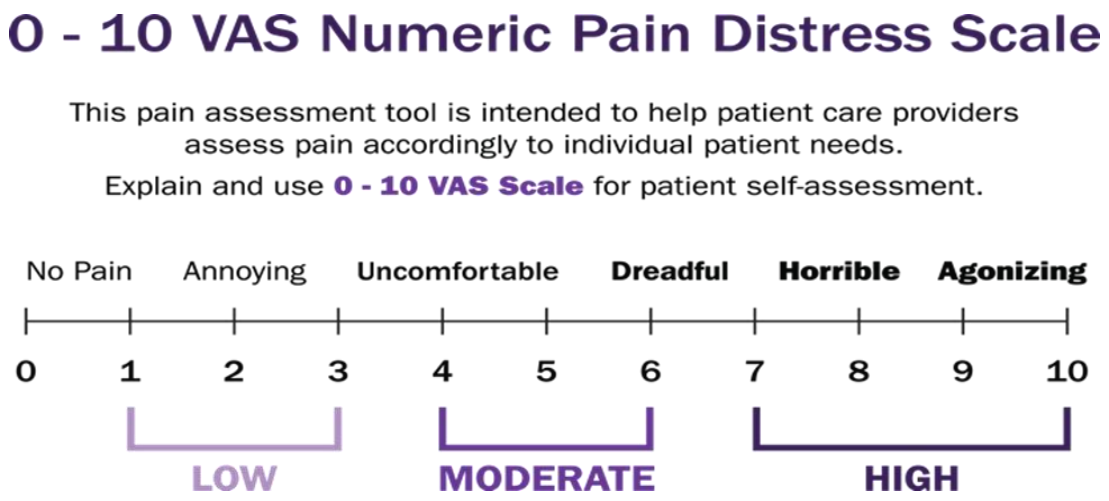
Selection of tools

1). A detailed case taking proforma was designed for the study

2). Patient information sheet

3). Patient consent form

4). Parameter scale - Visual Analogue Scale (VAS)



Data collection

- **Case taking proforma:** A special case taking proforma was designed for the study with the approval of guide.

- **Case taking:** Detailed case taking for every screened case after randomization was done by lottery method on especially designed case taking proforma, based on homoeopathic principles.
- **Record**: Data was recorded in approved master chart in proper excel format.
- **Maintenance:** There are forms that are completed by for each subject recruited, including two consent forms for the patient's information & his/her written consent for the enrolment in the study.

Data analysis

The data were entered into MS Excel spreadsheet and analysis was done by Statistical Package for Social Sciences (SPSS) version 16.0 software.

Statistical Analysis

The collected data will be analyzed by applying "PAIRED t- test" and "independent t-test". Paired t-test was used to assess the before and after scores in pre and post inter group and independent t- test was used to compare between inter groups.

Outcome Assessment: According to the scores obtained from VAS scoring method, following formula will be applied after calculating before and after scores.

$$\frac{\text{Baseline score} - \text{score at the end} \times 100}{\text{Baseline score}}$$

Following parameters would be fixed according to the type of response obtained after the treatment

- Cured- 100% (Feeling of mental and physical well-being with relief in all signs and symptoms for which patient originally approved without any relapse for 6 months).
- Marked improvement- 75% - 99%
- Moderate improvement-50%- 74%
- Mild improvement- 25%- 49%
- Status quo- 0%- 24%

OBSERVATION AND RESULTS

Maximum incidence of Migraine was observed in age group of 26-35 i.e., 31 cases & minimum incidences observed in age group of 56-65 i.e., 2 cases. Incidence of migraine is more among females i.e. 42 cases (60%) than males i.e. 28 cases (40%). Maximum incidence

of Migraine was observed in lower class group (57%), in middle class group (36%) and minimum among upper class group (7%). Maximum cases 56% (39 cases) seen in rural population and 44% (31 cases) in urban population. Family history present in 52% (39 cases) and absent in 48% (36 patients).

Table 2: Severity of pain in cases of Migraine as per VAS (Visual Analogue Scale) before treatment and after treatment.

No. of cases / VAS score	Bacillus morgan (Bach)		Natrum muriaticum	
	No. of patients (before treatment)	No. of patients (after treatment)	No. of patients (before treatment)	No. of patients (after treatment)
No pain (score-0)	0	1	0	9
Mild pain (1-3)	0	18	0	26
Moderate pain (4-6)	1	16	1	0
Severe pain (7-10)	34	0	34	0
Total no. of patients	**35**	**35**	**35**	**35**

As shown in the above table in maximum Bacillus morgan cases before treatment were with score (7-10) i.e., 34 cases (severe pain) and after treatment maximum cases were with score (1-3) i.e., 18 cases (mild pain) and 1 case with score 0 i.e., no pain. In Natrum muriaticum maximum cases before treatment were with score (7-10) i.e., 34 cases (severe pain) and after treatment maximum cases were with score (1-3) i.e., 26 cases (mild pain) and 9 cases with score 0 i.e., no pain.

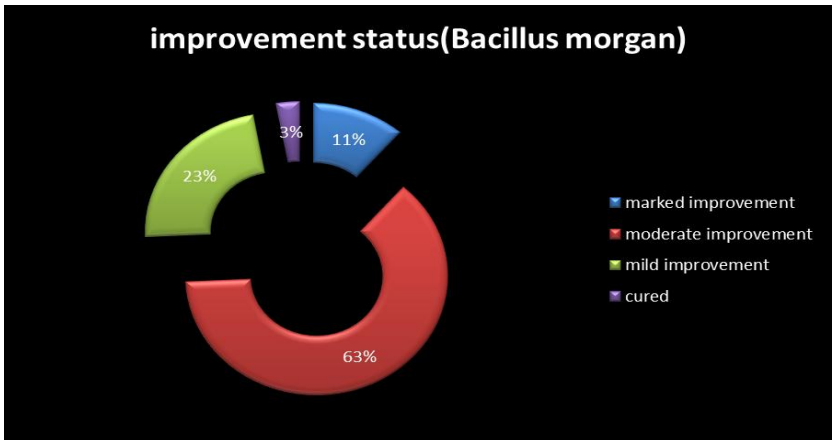


Figure-1: Improvement status of 35 patients in Bacillus morgan.

As shown in the figure marked improvement is seen in 11% (4 patients), moderate improvement in 63% (22 patients), mild in 23% (8 patients) and 3% (1 patient) cured.

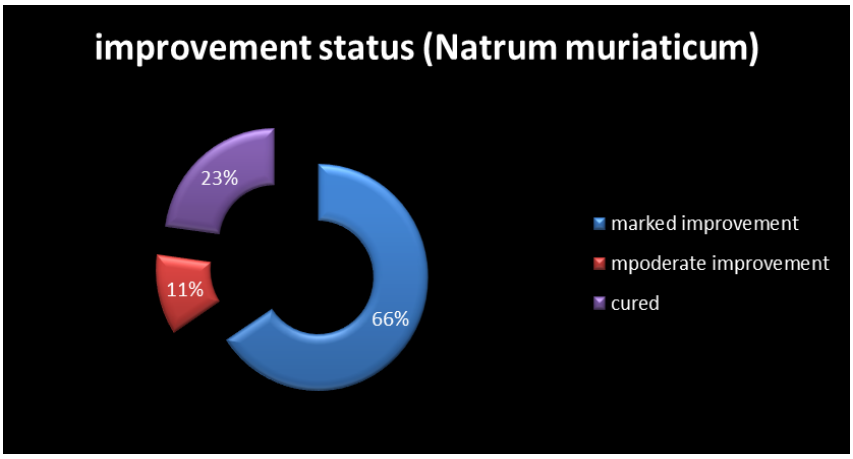


Figure-2: Improvement status of 35 patients in Natrum muriaticum.

As shown in the figure 66% (23 patients) show marked improvement, 11% (4 patients) show moderate improvement and 23% (8 patients) cured.

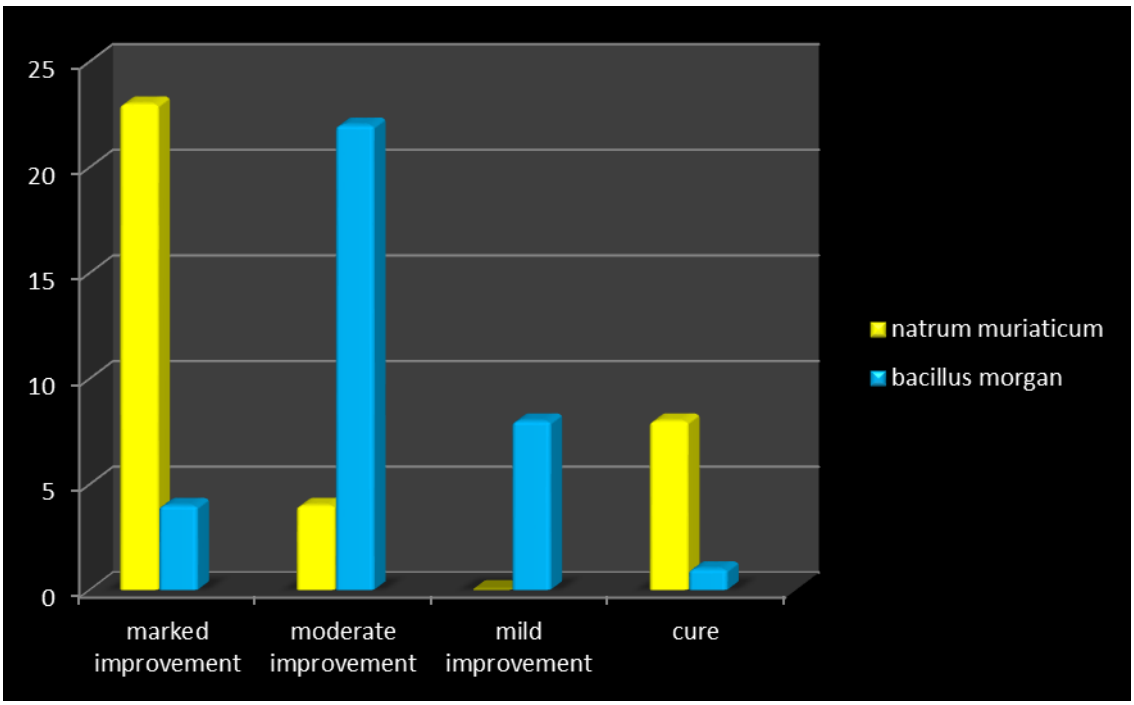


Figure-3: Overall improvement status.

As shown in the above graph, 9 cases (12.8%) have shown cure in their symptoms, out of which maximum cases were from *Natrum muriaticum*, 27 cases shown marked improvement out of which maximum cases were from *Natrum muriaticum* i.e., 23 cases (32.8%), 26 cases shown moderate improvement out of which maximum cases were from *Bacillus morgan*

(Bach) i.e., 22 cases (31.3%) and 8 cases shown mild improvement out of which maximum cases were from *Bacillus morgan* i.e., 8 cases (11.3%).

STATISTICAL ANALYSIS

For assessing the improvement VAS (visual analogue scale) was used. Scores before treatment were compared in both groups. The analysis was conducted through the software SPSS (ver. 16) applying paired t-test, and independent t-test.

Table 3: Paired Samples Statistics *Bacillus morgan.*

		Mean		Std. Deviation	Std. Error Mean
Pair 1	Before_Bacillus	8.17	35	1.014	.171
	After_Bacillus	3.43	35	1.577	.267

Table 4: Paired Samples Test.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Before_Bacillus After_Bacillus	4.743	1.442	.244	4.248	5.238	19.460	34	.000

There was a significant difference in the scores for *Bacillus morgan (Bach)* before (M=8.17, SD=1.014) & after score (M=3.43, SD=1.57) conditions; t=19.4, p=0.000.

These results suggest that *Bacillus morgan (Bach)* had shown significant result in cases of Migraine.

Table -5: Paired Samples Statistics *Natrum muriaticum.*

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	Before_Natrum	8.29	35	1.100	.186
	After_Natrum	1.23	35	.910	.154

Table 6: Paired Samples Test.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Before_Natrum - After_Natrum	7.057	1.136	.192	6.667	7.447	36.749	34	.000

There was a significant difference in the scores for *Natrum muriaticum* before (M=8.29, SD=1.100) & after score (M=1.23, SD=0.19) conditions; t=36.74, p=0.000.

These results suggest that *Natrum muriaticum* had shown significant result in cases of Migraine.

T –test for difference of two means for independent samples

This test is applicable to study the inter-group analysis. *Bacillus morgan* & *Natrum muriaticum* of difference of first and final score of VAS (Visual Analogue Scale).

Table – 7: Independent Samples Test.

		Levene's Test for Equality of Variances t-test for Equality of Means								
		F	**Sig.**	**t**	**Df**	**Sig. (2-tailed)**	**Mean Difference**	**Std. Error Difference**	**95% Confidence Interval of the Difference**	
									Lower	**Upper**
Before_ score	Equal variances assumed	.153	.697	-.452	68	.653	-.114	.253	-.619	.390
	Equal variances not assumed			-.452	67.556	.653	-.114	.253	-.619	.390

Levene's test indicated equal variance (F= 0.153, P= .697) so, df= 68. There is comparatively more improvement in Migraine with *Natrum muriaticum* (M= 8.29, SD= 1.100) than *Bacillus morgan (Bach)* (M= 8.17 SD= 1.014), t = .452, p<o.oo5, therefore rejecting null hypothesis and accepting alternating hypothesis (part 2) that *Natrum muriaticum* is more significant than *Bacillus morgan (Bach)* in cases of Migraine.

Taken together, these results suggest that though *Natrum muriaticum* is more significant in cases of Migraine in comparison to *Bacillus morgan (Bach)* but *Bacillus morgan (Bach)* also shown significant results.

CONCLUSION

Although it can be concluded from this study that *Natrum muriaticum* is more effective than *Bacillus morgan (Bach)* in managing the cases of Migraine. This study showed that Migraine is more commonly occur in females than males in middle age group and in low socioeconomic status, but further studies with bigger sample size & longer follow–up are necessary. So, that it can provide advantage into clinical practice.

REFERENCES

1. Migraine history. [last assessed on nov. 20]. https://www.news medical.net/health/Migraine-History.aspx.
2. Munjal YP, editor. API textbook of medicine.10th edition. New Delhi: Jaypee brothers medical publishers (P) Ltd, 2015.
3. Facts and figures. [last assessed on 22 oct.] https://www.migrainetrust.org/about-migraine/migraine-what-is-it/facts-figures/.
4. Braunwald Fauci Kasper Hauser Longo Jameson. Harrison's principles of internal medicine. 15th. US: Mc Grawhill, 2001.
5. Boericke William. Boericke's manual of homoeopathic materia medica with repertory. 3rd. Delhi: Bjain publishers (P) Ltd, 2007.
6. Nayak Chaturbhuja. An update on bowel nosodes with comparisons. 1st. Delhi: Bjain publishers (P) Ltd, 2015.