



## A NON-RANDOMISED SINGLE ARM PROSPECTIVE CLINICAL STUDY TO SEE THE EFFECT OF NATRIUM MURIATICUM 30C IN THE PATIENTS OF ESSENTIAL HYPERTENSION

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### ABSTRACT

**BACKGROUND-** Hypertension is the most common lifestyle disorder which have a worldwide prevalence. Essential hypertension has prevalence rate is 90-95% and secondary hypertension rate is 5%, it may lead to complication and increase mortality rate. (According to the World health organization), homoeopathy is the 2<sup>nd</sup> most useful and safe system in the world and has lot of potential to help reducing high blood pressure. This study aim was, to study the role of Natrium Muriaticum 30C in the patients of essential hypertension.

**METHOD -** It is Non randomized, single arm, prospective clinical interventional study at outpatient department of Bharati Vidyapeeth Deemed to be University Homoeopathic College & Research Centre, Katraj, and Pune. In this study total 35 patients (male and female) were enrolled. Out of which 5 patient while 30 patients completed the study at the age group of 18-50 years. Blood pressure was measured in sitting position by sphygmomanometer according to standard procedure.

**RESULT** –The final outcome was decrease in blood pressure after 10-12 weeks of outpatient care. Before and after treatment analysis was done by using Student paired “t” test. A significant reduction observed in blood pressure levels of hypertensive patients before and after treatment & patients symptomatically relieved as well. The mean and SD reduction in SBP was  $10.267 \pm 3.591$  mm Hg & DBP was  $10.733 \pm 4.856$ .

**CONCLUSION-** Homoeopathic medicine Natrium Muriaticum 30C produced significant effect in reduction of the blood pressure level on essential hypertensive patients.

**KEYWORDS :** Essential Hypertension, Natrium Muriaticum, Homoeopathy

### INTRODUCTION

Essential hypertension is defined as the term applied to 95% of hypertensive patients in which the elevated blood pressure has resulted from complex interaction between multiple genetic and environmental factors. Patient of arterial hypertension with no definable cause are said to have primary, essential, or idiopathic hypertension. Individuals of generalized or functional abnormalities may be affected with hypertension. Hypertension is the most common cause affecting one billion people worldwide, in which there is a readily identifiable, and reversible risk factor for myocardial infarction, stroke, heart failure, arterial fibrillation, aortic dissection and peripheral arterial diseases.<sup>[1]</sup>

According to Study by Global Burden of Hypertension in 2005 and then 2010, there is an alarming rise in the prevalence of hypertension. In the modern civilization, hypertension is the by-product of which has become a silent killer due to modern stressful lifestyle.<sup>[2]</sup>

Hypertension in adults aged 18years and older is defined as systolic BP of 140mmHg or more and /or diastolic BP of 90 mmHg or more or any level of BP in patient taking any hypertensive medication. Hypertension is generally based on average of two or more outpatient visits. A recent classification recommended for determining the blood pressure criteria was normal blood pressure, prehypertension, hypertension (stage 1 and stage 2).<sup>[3]</sup>

According to WHO, HTN is rated as one of the most important cause for immature deaths worldwide. Latest studies in India have shown that prevalence of HTN in 2013 was 29.8% in which rural 27.6% & urban 33.8% where only 25% rural & 38% of urban Indians are being treated for HTN. Whereas control of BP is only 10.7% in rural India & 20.2% in urban India. In Maharashtra, the overall prevalence of hypertension is 25% and a huge variation in the prevalence of hypertension is

found across the Districts like Dhule, Gadchiroli (with a low HDI rank), Mumbai and Satara (with high HDI rank) are the districts with the higher (above 30%) prevalence of high Blood pressure.

### AETIOPATHOLOGY:

Primary Essential Hypertension – The term Essential hypertension is applied for 95% of hypertensive patients as they have elevated blood pressure from complex interaction between multiple genetic and environmental factors. Exacerbating factors like Obesity, sleep apnoea, increased salt intake, excessive alcohol use, cigarette smoking, polycythemia, NSAID therapy and low potassium intake will define the proportion of the essential hypertension.<sup>[3]</sup>

### CLINICAL FEATURES:-

Uncomplicated hypertension is almost always asymptomatic but has many presentation like –

- Headache symptoms with dizziness,
- Vertigo and occipital headache.
- Hot flushing attacks and insomnia
- Fainting attack and fatigue.
- Mental irritability.
- Cardiac symptoms like palpitation, cardiac pain and dyspnoea on exertion.
- Various gastrointestinal symptoms may develop as nausea, vomiting, diarrhoea etc.

### CONVENTIONAL MODE OF TREATMENT-

- Diuretic like thiazides, high ceiling k+ sparing drug
- ACE inhibitors (captopril ramipril etc.)
- Angiotensin (AT receptors) blocker (losartan, telmisartan)
- Calcium channel blocker (verapamil, diltiazem, nifedipine)
- Central sympatholytic (clonidine, methyldopa)
- Vasodilators in Arteriolar (hydralazine) and Arteriolar + Venous (sodium nitroprusside)<sup>[8]</sup>

The conventional mode of treatment like various Anti-hypertensive drugs have been used for controlling high blood pressure with much adverse effect in the body like sedation, mental exertion, insomnia, dryness of mouth, nose and eyes, constipation, impotence, water and salt retention, bradycardia, postural hypertension and many more effects. Whereas the holistic approach of homoeopathy gives better result without any adverse effects. Homoeopathic management is helpful in such cases, as case taking is done in detail to find out the homoeopathic root cause of the disease on the basis of detail history is taken and then the correct similimum is considered. The acute episode of primary hypertension can be managed with the acute remedies prescribed on the basis of symptom similarity.

As per WHO statistics, homoeopathy is the 2nd most useful health care system in the world and it has lot of potential to help in reducing the high blood pressure in the community. With this fast going life it is very important to have some specific medicine which can be universally applied on specific conditions like other interventional medicines. Scientific validation of Natrium Muriaticum by clinical trial made this drug a choice of remedy for this study. In this study Natrium Muriaticum has been used in its 30 potency, which is prepared from common salt (sodium chloride). Natrium Muriaticum mostly affects the emotions, heart, kidney and spleen. Patient is thirsty, poorly nourished on account of digestive disturbance. In the modern life style, people are suffering from anxiety leading to a stressful life. Physical as well as mental exhaustion leading up to a cachectic state. In Natrium Muriaticum the patient suffers from depression. Irritability expresses itself in a special sensitivity towards external impression, noise, and light; to cigarette, smoke etc. Desire for salt and salty food is marked in Natrium Muriaticum. And excessive salt intake is also one of the main cause of essential hypertension.<sup>[9][10]</sup>

This study is non-randomized single arm, prospective clinical trial to observe whether Natrium Muriaticum 30c is effective in cases of primary HTN or not. Follow up of all patients was done regularly and treatment strategy follows medication and lifestyle adherence strategies where necessary.

#### ASSESSMENT CRITERIA FOR BLOOD PRESSURE MEASUREMENT:-

Marked Improvement- When the reduction of blood pressure level is more than 10-20 mmHg?

Moderate Improvement- When the patient blood pressure level reduction is more than 6-10 mmHg.

Mild Improvement- When the patient blood pressure level reduction is less than 4-6 mmHg.

No improvement- No change in blood pressure even after treatment for more than 1 year.

#### METHODOLOGY

**Theoretical study:** Theoretical study of this topic was done from various books, Homoeopathic Journals, Research Journals, Researches and authentic internet search through websites such as Google Scholar, Pubmed, etc.

**Clinical study:** This study was conducted at outpatient department of Bharati Vidyapeeth Deemed University Homoeopathic College & Research Centre, Karaj, and Pune. It is Non randomized, single arm, prospective clinical interventional study to see the effect of Natrium Muriaticum 30C in cases of primary hypertension in the age group of 18-50 years.

**Case definition:-** Cases presented with complaints of elevated

blood pressure level in resting systolic BP to 130mmHg or more & diastolic BP 90mmHg or more with no identifiable causes of both sexes involving age group from 18-50 years.

**Intervention:-** Medicine was administered to all patients in 30 size globule & in the dosage of 3 pills x BD half an hour before meal orally on tongue, no water intake for at least 15 – 20 min.. In cases where medicine was not necessary, only placebo was prescribed, in the form of sugar of milk globules.

**Sampling procedure and follow up:-** Patients were enrolled in this study from Bharati Vidyapeeth Medical Foundation Homoeopathic Hospital, peripheral OPD, Various rural & urban camp series, OPD and IPD from 2020-2021 (Approximately 52 weeks). Total 30 Cases (male & female) age groups of 18-50 yrs. were selected based on inclusion and exclusion criteria those who wanted to participate willingly in research. Participants were enrolled in the study only after signing the informed consent form. Each case was followed up for approx. 3 months.

- i. All the patients will be duly followed and details of the symptomatic, clinical, investigative changes were recorded and prognoses were studied.
- ii. Follow up were differ from patient to patient.
- iii. Usually first follow-up was on seventh day.
- iv. 2<sup>nd</sup> follow up and onward follow up were after 15days or earlier/later according to need of the patients.
- v. Standard Follow-up was prepared giving details.
- vi. It was based on Homoeopathic principles.

All participants were also asked to continue with their prescribed medication for duration of the study. Medical history, physical examination (including vital signs, systemic examination) was recorded on a case form. BP readings were taken on right arm with manual sphygmomanometer in sitting position according to standard operating procedures. Individual with any systemic illness, secondary organ damage from hypertension were excluded from the study. No study participants were included who are in a direct relationship with or dependent on, the sponsor or research team (students, employee of the institution, close relatives).

**Investigations:-** The Routine tests of patients include

1. Complete blood count,
2. Serum electrolytes.
3. Blood Sugar level (Random)./HBA1C
4. renal function test and
5. 12 lead ECG have been done before the enrolment in research study.
6. BP was measured by Sphygmomanometer and record was maintained.

**Parameter used:-** systolic blood pressure & diastolic blood pressure.

- Allocation: Single arm study.
- Intervention: Homoeopathic medicine Natrium Muriaticum 30C
- Mode of intervention : Orally

**Inclusion criteria:-**

- Patient of 18 to 50 years
- Both sex
- Patient from various socio-economic status
- patient having the symptom similarity with that Natrium Muriaticum 30 c will be included in the study
- blood pressure measurement having SBP 130-160mmhg and DBP 80-100mmhg
- Diagnosis of essential hypertension – history examination, and routine investigation shows no evidence of secondary causes.

**Exclusion criteria:-**

- All the cases of secondary hypertension

- Patient with severe complication hypertension
- Malignant hypertension
- potency 200C 1M, 10m Will be excluded
- having SBP more than 160 mmhg and less than 120 mmhg and DBP more than 100mmhg and less than 80
- Gravida or breast feeding women

**Outcome Measures:-**

The primary outcome measure is the systolic and diastolic blood pressure values after the period of the study. These were compared with the initial values, and the difference analyzed using statistical tests, to find the efficacy or otherwise of the treatment. The statistical analyses were conducted separately for systolic and diastolic blood pressure values by using the student paired "t" test. The test helps to establish whether the changes observed before and after treatment were significant or not.

**OBSERVATION AND RESULTS**

Total 30 patients (n- 30) were selected based on the age group of 18-50 years. Out of which 22 male (73.33%), 8 female (26.67%) according to Gender wise distribution. It depicts that 20% of the patients belongs to age class 20-30yrs, 36.67 % belongs to age class 30-40yrs and 43.33% belongs to age class 40-50yrs.

**Distribution of patients according to SBP of patients before and after treatment:-**

Category	Systolic Blood pressure mmhg	Before treatment		After treatment		Criteria
		F	%	f	%	
Normal	<120	0	0%	1	3.33 %	Control
Pre hypertension	120-139	8	26.67 %	27	90%	Moderately control
Hypertension	≥ 140	22	73.33 %	2	6.67 %	Not control

**Table 1: Distribution of patients according to SBP of patients before and after treatment**

Above table shows that before intervention most of the patients (73.33%) had hypertension, 26.67% had pre hypertension and none of them had normal SBP but after intervention only 6.67% of the patients had hypertension, most (90%) had pre hypertension and 3.33% were in normal range of SBP. So we can see improvement as the number of hypertension patients reduced after intervention

**Distribution of patients according to DBP of patients before and after treatment:-**

Category	Diastolic blood pressure mmHg	Before treatment		After treatment		Criteria
		f	%	F	%	
Normal	< 80	0	0%	4	13.33 %	Control
Pre hypertension	80-89	4	13.33 %	24	80%	moderately control
Hypertension	> 90	26	86.67 %	2	6.67 %	Not control

**Table 2: Distribution of patients according to DBP of patients before and after treatment:**

Above table shows that before intervention most of the patients 86.67 had hypertension, 13.33 had pre hypertension and none of them had normal DBP but after intervention only 6.67% of the patients had hypertension, most 80% had pre hypertension and 13.33% were in normal range of DBP. So we can see improvement as the number of hypertension patients reduced after intervention.

**Paired difference of systolic blood pressure before after treatment:**

Variable	Mean ± SD	T-value	p-value	Decision
SBP before treatment	139.80 ± 4.25	15.66	0.000	Reject H <sub>0</sub>
SBP after treatment	129.53 ± 6.07		**	
Reduction (difference)	10.267 ± 3.591	Difference is Highly Significant		

**Table 3 : Paired difference of systolic blood pressure before after treatment**

**Test used: Paired t-test, \*\*: Highly Significant Difference, T-value: Test Statistic value**

Above table shows that before treatment SBP mmhg was 139.80 ± 4.25, after treatment SBP mmhg score reduced to 129.53 ± 6.07. To check the effectiveness of treatment paired t-test was used. Test statistic value is 15.66 and p-value (0.000) is very small and difference is highly significant, it suggests that we reject H<sub>0</sub> and accept H<sub>1</sub> that is, Natrium Muriaticum 30C is effective in the management of Essential Hypertension.

**Descriptive statistics of DBP values before and after intervention:-**

Variable	Mean ± SD	T-value	p-value	Decision
DBP before treatment	91.800 ± 4.529	12.11	0.000	Reject H <sub>0</sub>
DBP after treatment	81.067 ± 2.959		**	
Reduction (difference)	10.733 ± 4.856	Difference is Highly Significant		

**Table 4: Descriptive statistics of DBP values before and after intervention**

Above table shows that before treatment DBP mmHg was 91.800 ± 4.529, after treatment DBP mmHg score reduced to 81.067 ± 2.959. To check the effectiveness of treatment paired t-test was used. Test statistic value is 12.11 and p-value (0.000) is very small, and highly significantly difference, it suggests that we reject H<sub>0</sub> and accept H<sub>1</sub> that is, Natrium Muriaticum 30C is effective in the management of Essential Hypertension.

**Statistical analysis:-**

- (A) P' Value of more than (>) 0.05 was considered non-significant.
- (B) P' value of less than (<) 0.05 was considered to be statistically significant.
- (C) P' value of less than (<) 0.001 was considered to be statistically highly significant

**Distribution of patients according to Reduction in SBP value after treatment according to outcome assessment:-**

Post treatment outcome	SBP mmhg	
	F	%
High Improvement	19	63.33%
Moderate Improvement	10	33.33%
Mild Improvement	1	3.33%
No Improvement	0	0%
Mean ± SD	10.267 ± 3.591	

**Table 5: Distribution of patients according to Reduction in SBP value after treatment**

**Distribution of patients according to Reduction in DBP value after treatment according to outcome assessment:-**

Post treatment outcome	DBP mmhg	
	F	%
High Improvement	20	66.67%
Moderate Improvement	9	30%
Mild Improvement	0	0%

No Improvement	1	3.33%
Mean $\pm$ SD	10.733 $\pm$ 4.856	

**Table 6: Distribution of patients according to Reduction in DBP value after treatment**

## DISCUSSION

Hypertension is the most common life disorder which have a worldwide prevalence. Essential hypertension has prevalence rate of 95% and if not treated on time it may lead to complication and increase the mortality rate. The primary aim of the present study was to observe the effect of Natrium Muriaticum 30 C to reduce the systolic and diastolic blood pressure in the patients of Essential hypertension, both male and female patient between the age group of 18 to 50 yrs. Since it was single arm study, only one group were included in this study without any control group. Many researches have been done in homoeopathic medicine on essential hypertension but very little work has been done on individual remedy. So in this study the single remedy Natrium Muriaticum 30C was selected. Natrium Muriaticum is prepared from common salt. And salt intake is one of the causes of hypertension. Natrium Muriaticum has got action on heart. In this study total 35 patients (male and female) were enrolled. Out of which, 5 patient dropped out after 1<sup>st</sup> or 2<sup>nd</sup> follow up while 30 patients completed the study. They were enrolled for 52 weeks of treatment. After the case taking, the patients were given Natrium Muriaticum 30C and 1<sup>st</sup> follow up was taken after 7 days and next follow up were as per the requirement of the patient. After 5 follow ups, evaluation of patient's blood pressure level before and after treatment was done. The result showed a positive effect on the hypertensive patients.

This effect was demonstrated by the result of statistical analysis (both systolic and diastolic blood pressure) using Student paired T test, which manifest hat before and after treatment. Level of blood pressure and that difference prove that, Natrium Muriaticum 30C has useful in the treatment of hypertension.

- 1) **Age wise distribution** – Age wise distribution was calculated in % where it was 20% patient from 20-30 years, 36.67% from 30-40 years and 43.33% from 40-50 years.
- 2) **Sex wise distribution** – sex wise distribution was calculated in %, it found out of 30 cases 73.33% male patient and 26.67% female patients.
- 3) **Comparison of severity in SBP & DBP According to self-assessment criteria-** high improvement 63.33% in reduction of SBP after treatment, high improvement around 66.67% in reduction of DBP after treatment. Moderate improvement around 30% in reduction of SBP after treatment, moderate improvement in 30% in reduction of DBP. Mild improvement around 3.33% in reduction of SBP after treatment, mild improvement around 0% in reduction of DBP. No improvement is around 0% in reduction of SBP, no improvement around 3.33% in reduction of DBP value after treatment.

Some limitations which require to be solved in further studies conducted in future:-

- One of the limitation is that there was exclusion of secondary and malignant hypertension, therefore it was difficult to answer the question whether Natrium Muriaticum 30C has same useful effect in treating the patients with complications or not.
- Sample size: Another limitation is related to small sample size. Due to this the question arises about the generalizability.
- Duration of study: Study duration also one of the limitation. As the study was of 2 and half months for each case therefore it doesn't reflect the efficacy of Natrium Muriaticum 30C in long term.

Finally this study data propose that homoeopathic medicine Natrium Muriaticum 30C has significantly favorable effect in patients suffering from essential hypertension.

## CONCLUSION

Hypertension is an important public health challenge because of its high prevalence and concomitant increase in risk of cardiovascular diseases. Essential hypertension is the term applied to the 95% of hypertensive patients in which elevated blood pressure result from complex interaction between multiple genetic and environmental factors. Hypertension continues to be the major risk factor for premature cardiovascular disease worldwide. While its incidence continues to grow largely as consequences of increased longevity where in turn, hypertension is overall the major contributor to the risk for cardiovascular diseases. In this study 30 patient both male and female completed this study. The result shows that, there was reduction of blood pressure in the cases of Essential Hypertension. Natrium Muriaticum 30C proves as a safe and effective in treatment of Essential hypertension. Natrium Muriaticum is a good choice of remedy for reducing the SBP & DBP in essential hypertension. This study is small research should be done in future considering large sample size and also extending the duration of study. In this study using student paired T test, which reject the null hypothesis that means accept the alternative hypothesis.  $\mu$  Value is 0.000 it means highly significant effect of Natrium Muriaticum 30C in the management of cases of Essential hypertension at the age group of 18-50 yrs. Homoeopathic medicine Natrium Muriaticum 30C produced significant effect in reduction of systolic and diastolic blood pressure on Essential hypertension.

## CONFLICT OF INTEREST

The authors have no conflict of interest among them regarding the research.

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