

**“EFFECTIVENESS OF MENTAL SYMPTOMS AS AN ADJUNCTIVE
MANAGEMENT OF HYPERTENSION BY USING REPERTORY OF
THE HOMOEOPATHIC MATERIA MEDICA BY DR. J. T. KENT - A
RANDOMIZED CONTROLLED STUDY”**

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ABSTRACT

Background: In cardiovascular diseases, Hypertension is a major risk factor and its burden is increasing disproportionately in developing countries as they undergo demographic transition. The World Health Organization (WHO) ranks hypertension as one of the leading causes of premature death worldwide. It is directly responsible for 24% of all coronary heart disease deaths and 57% of all stroke deaths in India. Recent studies in India have shown that the prevalence of hypertension is 25% in urban areas and 10% in rural subjects in India. Systolic and diastolic blood pressures (BP) have a strong, continuous, graded, and

positive association with Cardiovascular diseases outcomes or life time risk of Cardiovascular diseases, with no indication of a critical value. The aim of this trial was to evaluate whether Homoeopathic medicines were prescribed on mental symptoms could improve the quality of life (QoL) with allopathic treatment. **Method:** A total 100 Cases of Hypertension were randomly allocated into two treatment groups, group A was treated with Homoeopathic medicines, prescribed on mental symptoms and group B was given Placebo with allopathic medicine. Data was analysed by using SPSS software and Excel. The statistical technique to be used was - 'Paired t-test' and 'Independent t-test'. **Results:** Treatment given to Both group A and group B were helpful in reducing the B.P. but there is no significant difference between the effect of homoeopathic medicine and placebo on reducing of B.P. WHOQOL-BREF as assessment tool in both groups. A few homoeopathic remedies were found useful during the study. **Conclusion :** Homoeopathic medicines selected on the basis of mental symptoms as

adjunctive treatment were found helpful in reducing the blood pressure and improving Quality of Life (WHOQOL-BREF) in cases of essential Hypertension. Homoeopathic medicines and placebo as adjunctive treatment are equally effective in lowering blood pressure. Repertory of the Homoeopathic Materia Medica by Dr. J. T. Kent was observed very useful in finding the similar rubrics and remedies.

KEYWORDS: Essential Hypertension, Homoeopathic medicine, Placebo, Randomized controlled trial, Systolic and diastolic blood pressure.

INTRODUCTION

Cardiovascular diseases (CVD) accounted for 1.5 million deaths^[1] (29% of the deaths)^[2] and 11% of all Disability Adjusted Life Years in India (all ages, 2005),^[3] and it is estimated that by 2020, Cardiovascular diseases will be the largest cause of mortality and morbidity in India.^[4] Hypertension is a major risk factor for Cardiovascular diseases and its burden is increasing disproportionately in developing countries as they undergo demographic transition.^[5-7] The World Health Organization (WHO) rates hypertension as one of the most important causes of premature death worldwide.^[8] It is directly responsible for 57% of all stroke deaths and 24% of all coronary heart disease deaths in India.^[9] Recent studies from India have shown the prevalence of hypertension to be 25% in urban and 10% in rural subjects in India.^[10] The prevalence rate of hypertension in urban India is 29- 45% in men and 25-38% in women,^[11-14] and these are projected to go up to 22.9 and 23.6% for Indian males and females, respectively, by 20 and 25.^[15] However, only about 25.6% of the treated patients had their blood pressure under control.^[16] Diastolic and systolic blood pressures (BP) have a continuous, strong, graded, and positive association with CVD outcomes or life-time risk of CVD, with no indication of a critical value.^[17] Homoeopathy is the second most useful health care system in the world, according to the statistics of the WHO.^[18] However, a meta-analysis in 2005 by Shang *et al.*,^[19] clinical effects of homoeopathy concluded that the homoeopathy is nothing a placebo effects; although a conflicting conclusion was arrived at earlier by another meta-analysis.^[20] In Homoeopathy, two double-blind, randomized controlled trials study on hypertension, could not generate statistically significant results. However, none of the trials tried individualized homoeopathy instead of the used 'specific remedy'.^[21,22] A few observational studies, although methodologically inadequate, revealed some efficacy of individualized homoeopathy in the management of essential hypertension and overall cardiovascular mortality.^[23-25]

The aim of this trial was to evaluate whether Homoeopathic medicines were prescribed on mental symptoms could improved the quality of life (QOL) with allopathic treatment. This was the randomized controlled trial conducted to compare Homoeopathic medicines were prescribed on mental symptoms and placebo along with allopathic treatment in essential hypertension.

CLINICAL FEATURES^[26]

Most people with Primary Hypertension don't have any obvious symptoms at all; also the possible symptoms of Hypertension vary quite a lot from person to person. It could be:

1. Chronic headaches
2. Dizziness or Vertigo
3. Blurred or double vision
4. Drowsiness
5. Nausea
6. Shortness of breath.
7. Palpitations
8. Fatigue-general tiredness
9. A flushed face
10. Nosebleeds
11. Tinnitus

MATERIALS AND METHODOLOGY

Study setting: The subject for this study was collected from OPD/IPD of Mangilal Nirban Homoeopathic Medical College and Research Institute, Bikaner, Rajasthan.

Study duration: The study was undertaken for a period of 12 months. The follow-up of the patient was done at an interval of 7-14 days, as per gravity of the case, for duration of 3 months or for at least 6 visits, included in the study.

Sampling method: Simple Random Sampling Method. Sample size: 100 cases of essential Hypertension were selected from college OPD / IPD on the basis of randomization.

A total 100 Cases of Hypertension were randomly allocated in to two treatment groups.

Group A.

- Homoeopathic medicines were prescribed on mental symptoms by Kentrepertory.

- 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 was obtained from a GMP certified company.
- Form - Globules No. 30.
- Route of administration – Oral.
- Dispensing - This was done by the college dispensary from a certified pharmacist.

Group B.

- Placebo
- Manufacturer - Medicine was obtained from a GMP certified company.
- Form - Globules No. 30.
- Repetition according to symptomatology.
- Route of administration - Oral.
- Dispensing - This was done by the college dispensary from a certified pharmacist.

Inclusion criteria

1. Subjects between the age of 20 - 60 years of both sexes and all ethnic groups.
2. Essential Hypertension is considered for the study.

JNC Classification - Normal: < 120 mm of Hg SBP and < 80 mm of Hg DBP
Elevated: 120-129 mm of Hg SBP and < 80 mm of Hg DBP

Stage 1 Hypertension: 130-139 mm of Hg SBP or 80-89 mm of Hg DBP
Stage 2 Hypertension: ≥ 140 mm of Hg SBP or ≥ 90 mm of Hg DBP

3. Diagnostic criteria are mainly on clinical parameter.

Exclusion criteria

1. Subjects with hypertension associated with any other chronic and systemic disease.
2. Cases of Pregnancy and lactating mothers excluded from this study.

Study Design: Prospective, Single blind, Randomised control trial.

Statistical technique and data analysis: Data was analysed using SPSS software and Excel. The statistical technique used was – 'Independent t-test' and 'Paired t-test'. Independent t-test will be used to compare two treatment groups and Paired t-test will be used to assess the before and after scores in each patient.

Out come assessment: The outcome measures were lowering of Hypertension and analysis was done by using WHOQOL-BREF scale before and after treatment.

Investigation

1. Blood Pressure: By the sphygmomanometer systolic >150mm of Hg and diastolic >90mm of Hg Arterial blood pressure is measured.
2. Chest radiography
3. ECG
4. Urine analysis
5. Urea and Electrolyte
6. Lipid profile

Statistical analysis of Pre and Post treatment changes in the “Systolic and Diastolic B.P. in Groups A and Group B”

Table No 1: Distribution of Paired before and after treatment of BP in group A for 50 cases,

Group A Paired BP	Before Treatment	After Treatment
Systolic	147.72	122
Diastolic	88.24	80.64

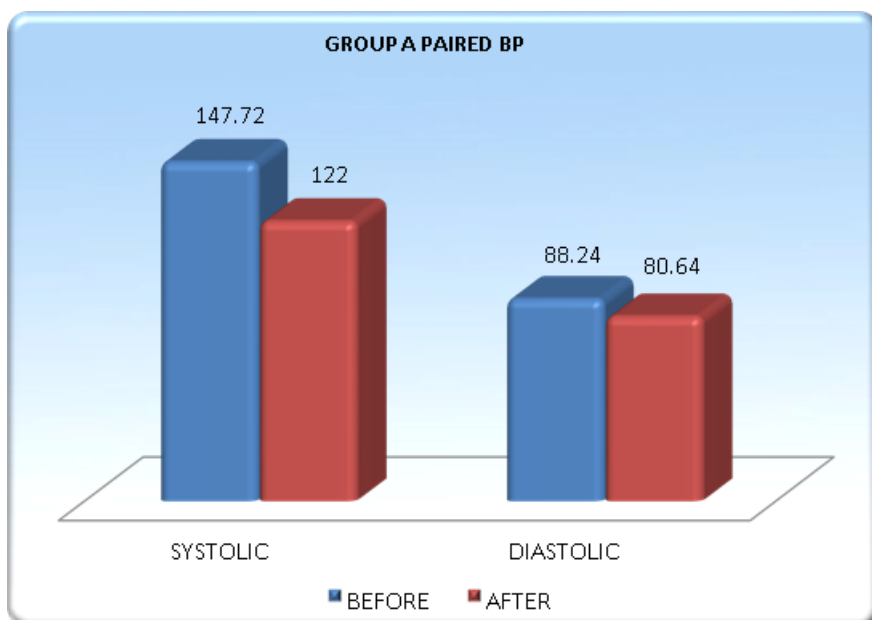


Fig 1: Graphical representation of Paired before and after score of BP in group A.

In the above fig-1, it was observed that there is significant improvement in both systolic and diastolic BP. (Before and After mean score in group A)

Table No 2: Distribution of Paired before and after treatment of BP in group B for 50 cases.

Group B Paired BP	Before Treatment	After Treatment
Systolic	147.08	124.24
Diastolic	87.84	81.4

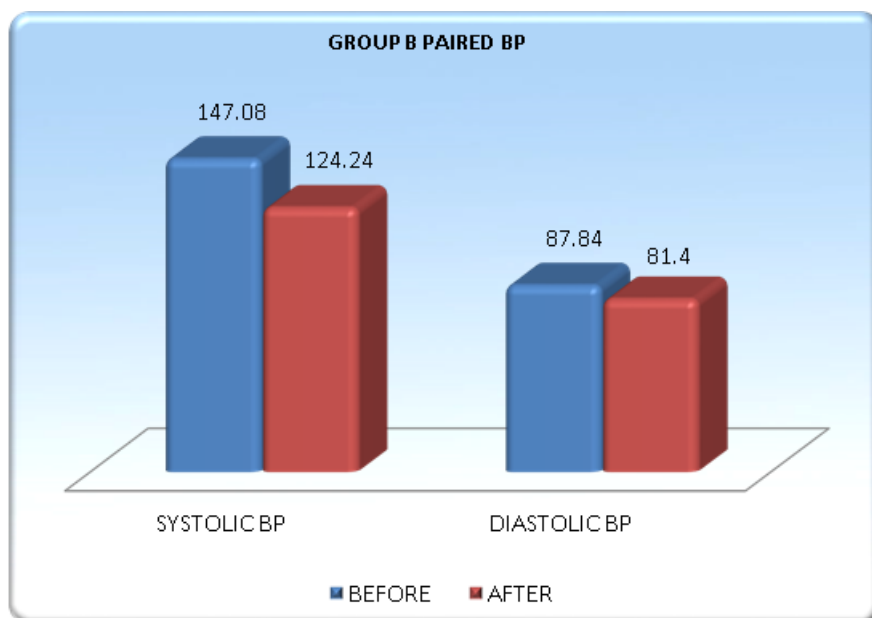


Fig 2: Graphical representation of Paired before and after score of BP in group B.

In the above fig-2, it was observed that there is significant improvement in both systolic and diastolic BP. (Before and After mean score in group B)

Table No 3: Distribution of Independent After BP score in both groups for 100 cases.

Independent BP	Group A	Group B
Systolic	122	124.24
Diastolic	80.64	81.4

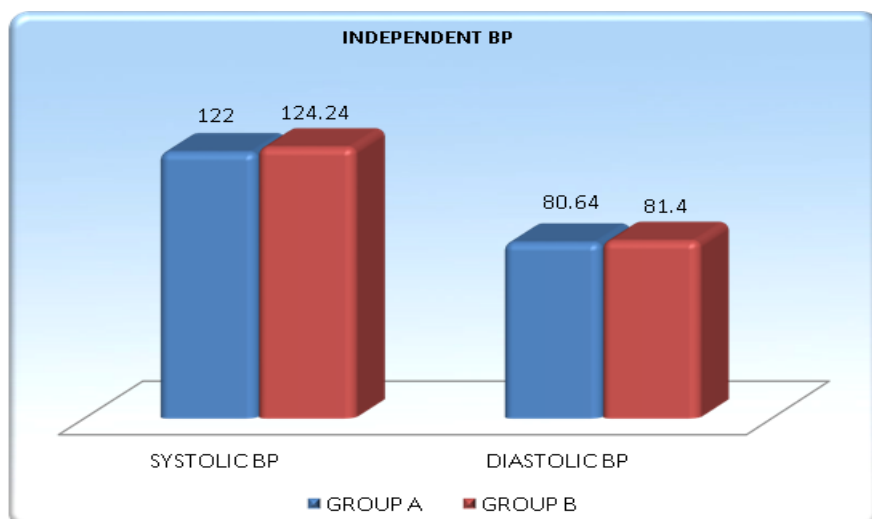


Fig3: Graphical representation of Independent After BP score in both groups.

In the above fig-3, it was observed that there are no significant difference in after score of BP in both groups.

Statistical analysis of Pre and Post treatment WHOQOL-BREF score in all domains of Groups A and Group B.

Table No 4: Distribution of Paired before and after score in all domains of Group A for 50 cases.

Group A Domain Paired	Before	After
Domain-1	40.36	57.74
Domain-2	26.34	56.28
Domain-3	52.36	58.9
Domain-4	55.68	56.2

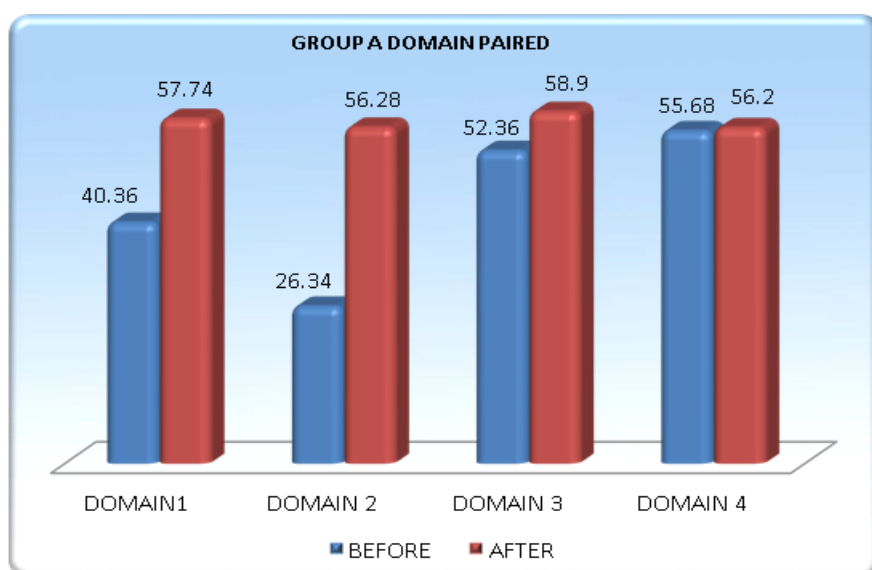


Fig 4: Graphical representation of Paired Before and after score of all domains in Group A.

In the above fig-4, it was observed that there are significant improvement in all 4 domains of group A, but more significant improvement seen in domain 2, and less significant in domain 4 of group A.

Table No 5: Distribution of Paired before and after score of all domains in Group B for 50 cases.

Group B Domain Paired	Before	After
Domain-1	45.44	51.2
Domain-2	40.32	46.5
Domain-3	51.04	52
Domain-4	53.22	53.48

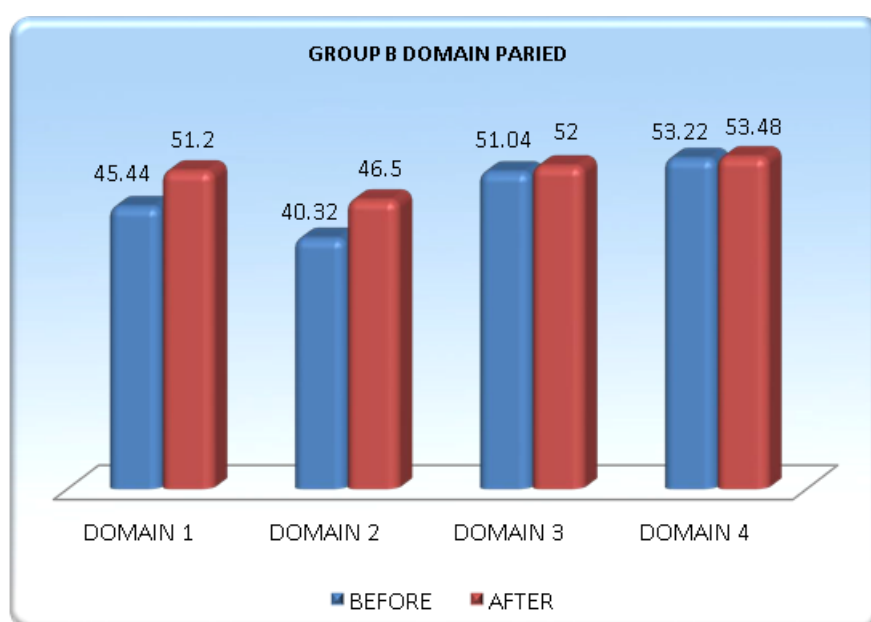


Fig 5: Graphical representation of Paired Before and after score of all domains in Group B.

In the above fig-5, it was observed that there are no significant improvement in all 4 domains of group B.

Table No 6: Distribution of Independent after score of all domains in both groups for 100 cases.

Independent Domain	Group A	Group B
Domain-1	57.74	51.2
Domain-2	56.28	46.5
Domain-3	58.9	52
Domain-4	56.2	53.48

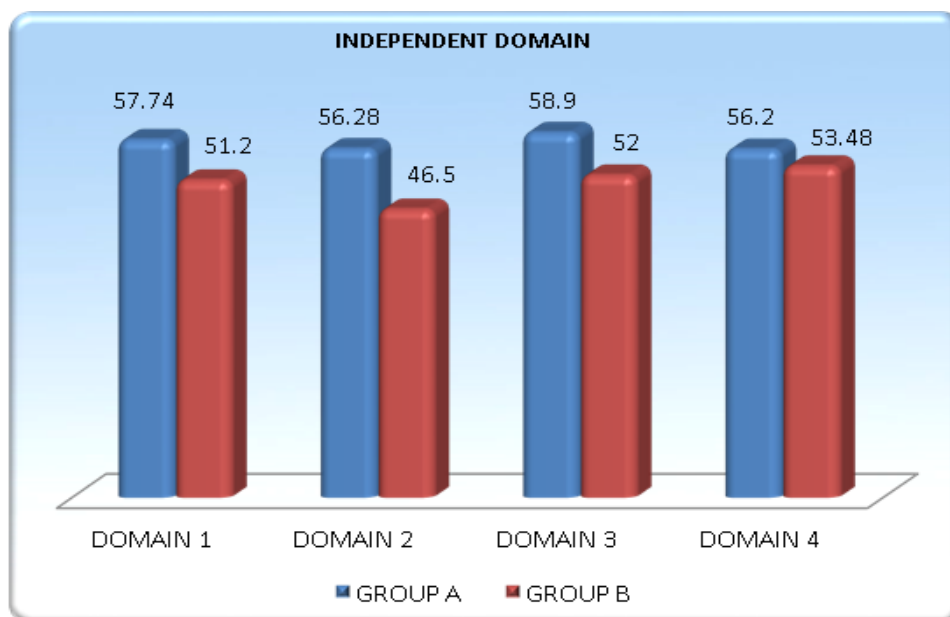


Fig 6: Graphical representation of Independent after score of all domains in both groups.

In the above fig-6, it was observed that there are significant difference in after score in all 4 domains in both groups.

Table No 7: Comparison with level of significance in different domains Of WHOQOL – BREF(Paired t-Test).

VARIABLES	95% CONFIDENCE INTERVAL		p – VALUE
	BEFORE	AFTER	
PHYSICAL HEALTH			
GROUP- A	19.508 to	15.251	0.032
GROUP- B	8.108 to	3.411	0.000
PSYCHOLOGICAL			
GROUP- A	32.710 to	27.169	0.001
GROUP- B	8.618 to	3.741	0.000
SOCIAL RELATIONSHIPS			
GROUP- A			
GROUP- B	8.807 to	4.272	0.000
	1.679 to	0.240	0.000
ENVIRONMENT			
GROUP- A	1.027 to	0.012	0.000
GROUP- B	0.626 to	0.106	0.000

DISCUSSION

1. The study showed maximum 14(28%) patients of essential Hypertension in age group 20-30 yrs, 31-40 yrs, 51-60 yrs and 8(16%) patients in age group 41-50 yrs in group A and maximum 18(36%) patients of essential Hypertension in age group 31- 40 yrs, 13(26%)

patients in age group 51-60 yrs, 11(22%) patients in age group 20-30 yrs, 8(16%) patients in age group 41-50 yrs in group B mention in his study. In this study both groups contained 32% patients of essential Hypertension in age group are 31-40 yrs. In previous study shows that the age group of 25-40 yrs were more affected.^[27]

2. Maximum 34 male patients and 16 female patients suffer from essential Hypertension in group A and maximum 35 male patients and 15 female patients suffer from essential Hypertension in group B. In this study both groups contained 69% male patients suffer from essential Hypertension. Singh M., Kotwal A. mention in his artical female patients were more affected.^[27]
3. In this study the incidence in urban areas was 33(66%) patients where as in rural was 17(34%) patients in group A and maximum 29(58%) patients in urban and 21(42%) patients in rural area in group B. In urban areas patients of stress and anxiety accelerate the cases of essential Hypertension. In this study both groups contained 62% patients in urban area found the essential Hypertension. In previous study also found that the essential Hypertension cases more found in Urban areas.^[28]
4. The study showed maximum 15(30%) patients of standing jobs, 11(22%) patients housewife, 8(16%) patients businessmen, 5(10%) patients student, 4(8%) patients labour job and unemployed ,3(6%) patients sitting job in essential Hypertension cases in group A. The maximum 12(24%) patients standing jobs, 11(22%) patients housewife, 8(16%) patients labour job, 7(14%) patient sitting job, 6(12%) patients students, 4(8%) patients and 2(4%) patients unemployed in essential Hypertension cases in group B. In this study both groups contained 27% patients are standing jobs which include Teacher, Lawyer, Policeman, MR, TTE suffer from essential Hypertension. Manimunda SP. et al mention in his artical that the sitting job like clerk, diver, shopkeeper, banker, chemist is more prevalence in hypertension.^[29]
5. In this study the maximum 38(76%) patients of middle class, 7(14%) patients of lower class and 5(10%) patients of high class in group A and 37(74%) patients of middle class, 12(24%) patients of lower class and 1(2%) patient of high class in group B suffer in essential hypertension in this study. Both groups contained 75% patients of middle class suffer in essential hypertension in this study. Gupta R. et. al. conclude in his artical that the middle class more affective in Hypertension.^[30]
6. In this study the maximum 10(20%) patients addiction smoking & tobacco, 5(10%) patients addiction alcohol, 2(4%) patient more consumed the salt and 1(2%) patients obesious in group A and 14(28%) patients addiction smoking & tobacco, 4(8%) patients

- addiction alcohol, 2(4%) patients obese and 1(2%) patient more consumed the salt in group B. Previous study also shows alcohol, smoking, chewing tobacco and obesity were significant risk factor for hypertension among Indian patient.^[31]
7. Family history of essential Hypertension 11(22%) patients in group A and 10(20%) patients in group B. Anchala R. et al mention in his article that family history of Hypertension and diabetes is present in hypertension cases.^[32]
 8. The study shows present complaints in cases of essential hypertension that 66% patients headache, 62% patients vertigo, 58% patients palpitation, 56% patients dizziness, 16% patients blurred vision, 16% patients difficulty of breathing in group A and 62% patients headache, 60% patients vertigo, 62% patients palpitation, 58% patients dizziness, 12% patients blurred vision, 16% patients difficulty of breathing in group B. Ali, Zareen et. al. mention in his article that headache and dysnea is present in hypertension cases.^[33]
 9. In this study out of 50 cases restlessness, anger, vivacious and quarrelsome rubrics is present in 18% patients, anxiety future about, haughty and consolation agg. rubrics is present in 16% patients, grief rubrics is present in 14% patients, anxiety health about, gesture makes, cowardice, impulsive rubrics is present in 12% patients, company desire for, envy rubrics is present in 10% patients and fear of death rubrics is present in 8% patients in group A.
 10. In this study medicine prescribed on bases of mental symptoms and sulphur gives to 4 patients, calc.carb., iod., ign., kali.carb., lach., lyco., nat.mur., phos., pulse., medicine gives to 3 patients, ars.alb., bell., nux.vom., aur.met., verat.alb., arg.nit., sil., cala.phos., kali.phos., medicine gives 2 patients and baryta carb. medicine gives to 1 patients.
 11. In this study out of 50 cases maximum 62% patients gives 200 potencies and 38% patients gives 1m potencies.
 12. In this study Paired t-test in group A shows a significant improvement in the mean value of before and after treatment systolic and diastolic B.P. respectively 147.72 and 88.24 to 122 and 80.64 and group B shows a significant improvement in the mean value of before and after treatment systolic and diastolic B.P. respectively 147.08 and 87.84 to 124.24 and 81.4. Both systolic and diastolic BP in both groups shows not more significant difference. In this study Independent t-test after score of B.P. in both group were no more significant difference.
 13. In this study used WHOQOL-BREF as assessment tool in both groups. In Paired t-test all four domains (Physical Health, Psychological, Social relationships, Environment) of group A shows a significant improvement and Psychological domain show more significant improvement seen in group A and all four domains (Physical Health,

Psychological, Social relationships, Environment) of group B show not more significant improvement seen. In this study Independent t-test after score of all domains in both groups were significant difference.

CONCLUSION

Homoeopathic medicines selection on the basis of mental symptoms as adjunctive treatment were reducing of blood pressure and effective in improving Quality of Life (WHOQOL-BREF) in cases of essential Hypertension as compared to placebo group. Repertory of the Homoeopathic Materia Medica by Dr. J. T. Kent is very useful in finding the similar rubrics and remedies. This was a prospective, single blind, randomized control trial study with positive results and these results need further validation by conducting clinical trials. This study proved the Homoeopathic medicines were prescribed on mental symptoms improved the quality of life in case of essential Hypertension. The study also proves that Homoeopathic medicines are not Placebo. It is evident that in cases of essential Hypertension when Homoeopathic medicines were prescribed on basis of mental symptoms as an adjunctive treatment and placebo shows significant improvement in both systolic and diastolic blood pressure (B.P.) but there was no significant difference found between two groups in blood pressure (B.P.). In cases of essential Hypertension when Homoeopathic medicines were prescribed on mental symptoms as an adjunctive treatment show significant improvement in Quality of life (QOL) as compare to placebo group. In this study, group A where prescription has done as an adjunctive treatment following polycrystalline medicines were prescribed: Sulphur, Calcarea Carbonica, Iodatum, Ignatia, Kalium Carbonicum, Lachesis, Lycopodium, Natrium Muriaticum, Phosphorus, Pulsatilla, Arsenicum Album, Belladonna, Nuxvomica., Aurum Metallicum., Veratrum Album, Argentum Nitricum, Silicea, Calcium Phosphoricum, Kalium Phosphoricum and Barium Carbonicum. These medicines were found effective and helpful in improving the QOL. Kent repertory had been proved very effective in finding the similar rubrics and similar remedies. The duration of this study was for one year only and a small sample size was taken, further research and studies of longer duration and large sample size are required to establish its efficacy for the result (quality of life) in cases of essential Hypertension.

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