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Effectiveness of Individualized Homoeopathic Adjunct Therapy in Patients Receiving Routine Antihypertensive Drugs: A Randomized Comparative Study

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ABSTRACT

Background: Hypertension remains a significant global health challenge with increasing prevalence worldwide. While conventional antihypertensive medications effectively control blood pressure, many patients continue to experience residual symptoms and seek complementary therapeutic approaches. Individualized homoeopathy has shown promise as an adjunct therapy in various chronic conditions.

Objective: To evaluate the effectiveness of individualized homoeopathic medicines as adjunct therapy in patients receiving routine antihypertensive drugs compared to standard care alone.

Methods: This prospective, double-blind, randomized comparative study was conducted at a private clinic of the author over a period of 12 months. Sixty patients with essential hypertension on stable antihypertensive medication were randomized into two groups (n=30 each): Group A received individualized homoeopathic medicine plus standard antihypertensive treatment, while Group B received a placebo plus standard antihypertensive treatment. Primary outcomes included systolic blood pressure (SBP), diastolic blood pressure (DBP), and quality of life scores measured at baseline, 3 months, and 6 months. Secondary outcomes included a reduction in antihypertensive medication dosage and symptomatic improvement.

Results: After 6 months of intervention, Group A demonstrated significantly greater reduction in mean SBP (18.4 ± 6.2 mmHg vs 8.6 ± 4.8 mmHg, $p<0.001$) and DBP (12.3 ± 4.1 mmHg vs 5.2 ± 3.4 mmHg, $p<0.001$) compared to Group B. Quality of life scores improved significantly in the homoeopathy group ($p<0.01$). Thirty-three percent of patients in Group A successfully reduced conventional medication dosage under medical supervision, compared to 10% in Group B. Commonly prescribed remedies included Natrum muriaticum, Calcarea carbonica, Sulphur, Lycopodium, and Phosphorus based on individualized symptomatology.

Conclusion: Individualized homoeopathic medicine as adjunct therapy significantly enhances blood pressure control and quality

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of life in patients receiving routine antihypertensive drugs. This integrative approach may offer a safe and effective complementary strategy for comprehensive hypertension management.

Keywords: Essential hypertension, individualized homoeopathy, adjunct therapy, antihypertensive drugs, randomized controlled trial, integrative medicine, blood pressure management

INTRODUCTION

Hypertension, defined as persistently elevated blood pressure ≥140/90 mmHg, affects approximately 1.28 billion adults worldwide and represents a leading risk factor for cardiovascular disease, stroke, and chronic kidney disease [1]. In India, the prevalence of hypertension has increased dramatically, affecting approximately 25-30% of the adult population, with projections suggesting continued escalation [2]. Despite the availability of effective antihypertensive medications, blood pressure control rates remain suboptimal, with only 37% of treated patients achieving target blood pressure levels [3].

Conventional pharmacological management of hypertension includes various classes of antihypertensive agents such as angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, calcium channel blockers, beta-blockers, and diuretics. While these medications effectively reduce blood pressure, many patients experience adverse effects, poor medication adherence, and persistent symptoms including headache, fatigue, anxiety, and sleep disturbances [4]. Additionally, polypharmacy in elderly hypertensive patients increases the risk of drug interactions and adverse events.

The integration of complementary and alternative medicine (CAM) with conventional treatment has gained increasing attention in chronic disease management. Homoeopathy, a holistic system of medicine based on the principle of *similia similibus curentur* (like cures like), has been widely practiced for over two centuries and is recognized by the World Health Organization as the second-largest therapeutic system globally [5]. The individualized approach in homoeopathy considers the totality of symptoms—physical, mental, and emotional—making it particularly suitable for chronic conditions with multifactorial etiology like hypertension.

Several clinical trials have demonstrated the potential efficacy of homoeopathy in hypertension management. Saha et al. (2013) reported significant reduction in blood pressure with individualized homoeopathy compared to placebo over 6 months in 150 patients with essential hypertension [6]. A systematic review by Banerjee et al. (2021) suggested positive effects of individualized homoeopathy over placebo, though methodological limitations were noted [7]. Recent research by Sadhukhan et al. (2021) demonstrated the feasibility of evaluating individualized homoeopathy in stage I hypertension through rigorous placebo-controlled trials [8].

Dr. Rizwan Ahmed Shabbir Shaikh has contributed significantly to understanding homoeopathy's role as adjunct therapy in chronic diseases managed with modern medicine. His research on randomized controlled studies of homoeopathic medicines and lifestyle modifications as

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adjunct therapy provides valuable insights into integrative treatment approaches [9].

Despite growing evidence, there remains a paucity of well-designed randomized controlled trials specifically evaluating individualized homoeopathy as adjunct therapy in patients already receiving standard antihypertensive treatment. The present study addresses this gap by investigating whether adding individualized homoeopathic medicine to routine antihypertensive therapy provides additional therapeutic benefits compared to standard treatment alone.

The rationale for adjunct homoeopathic therapy in hypertension is multifaceted. First, homoeopathic medicines may address underlying constitutional factors and stress-related components that conventional drugs do not target. Second, individualized treatment may improve overall well-being and quality of life. Third, successful adjunct therapy may potentially allow dose reduction of conventional medications, thereby minimizing adverse effects. Fourth, the holistic approach may enhance patient satisfaction and treatment adherence.

This randomized comparative study was designed to rigorously evaluate the effectiveness of individualized homoeopathic adjunct therapy in patients receiving routine antihypertensive drugs, with emphasis on blood pressure control, quality of life improvement, and potential for conventional medication dose reduction.

OBJECTIVE

Primary Objective

To evaluate the effectiveness of individualized homoeopathic medicine as adjunct therapy in reducing systolic and diastolic blood pressure in patients receiving routine antihypertensive drugs compared to standard antihypertensive treatment alone.

Secondary Objectives

1. To assess improvement in quality-of-life scores in both treatment groups
2. To evaluate the potential for reduction in dosage of conventional antihypertensive medications
3. To assess symptomatic improvement, including headache, fatigue, anxiety, and sleep disturbances
4. To identify frequently indicated homoeopathic remedies in hypertensive patients
5. To assess the safety and tolerability of adjunct homoeopathic therapy
6. To evaluate patient satisfaction with the integrative treatment approach

MATERIAL AND METHOD

Study Design

This study was designed as a prospective, double-blind, randomized, placebo-controlled, parallel-group comparative clinical trial conducted at the Private Homoeopathic Clinic of the author in Ahilyanagar, Maharashtra, India.

Study Duration

The total study duration was 18 months, including:

- Recruitment period: 3 months

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- Intervention period: 6 months per patient
- Follow-up period: 6 months
- Data analysis and compilation: 3 months

Study Setting

The study was conducted at private homoeopathic clinic of Author in Ahilyanagar.

Sample Size

Sample size was calculated using the formula for comparing two means with the following assumptions:

- Expected difference in mean systolic BP reduction: 10 mmHg
- Standard deviation: 12 mmHg
- Power: 80%
- Alpha error: 5%
- Two-sided test

The calculated sample size was 23 per group. Accounting for 20% dropout rate, 30 patients were enrolled in each group (total n=60).

Randomization and Blinding

- Random allocation sequence was generated using computer-generated random numbers
- Block randomization with variable block sizes (4 and 6) was employed
- Sequentially numbered, sealed, opaque envelopes were prepared by an independent statistician
- Patients, treating physicians, and outcome assessors were blinded to treatment allocation
- Homoeopathic medicines and an identical placebo were prepared and coded by the hospital pharmacy
- Unblinding was permitted only in case of serious adverse events requiring intervention

Study Groups

Group A (Intervention Group): Individualized homoeopathic medicine + routine antihypertensive drugs (n=30)

Group B (Control Group): Placebo + routine antihypertensive drugs (n=30)

Methodology

Screening and Enrollment:

1. Patients attending the OPD with diagnosed essential hypertension on stable antihypertensive medication were screened
2. Detailed medical history, including duration of hypertension, current medications, and associated comorbidities, was recorded
3. Physical examination, including vital signs, cardiovascular examination, and fundoscopic examination, was performed
4. Baseline investigations including complete blood count, renal function tests, lipid profile, electrocardiogram, and echocardiography, were conducted
5. Patients meeting the inclusion criteria and providing written informed consent were enrolled

Homoeopathic Case Taking:

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1. Detailed homoeopathic case taking was performed for all participants, including:
    - Chief complaints with complete symptomatology
    - Past medical history and family history
    - Physical generals (appetite, thirst, thermal reaction, sleep, perspiration, desires, aversions)
    - Mental generals (anxiety, irritability, fears, emotional state)
    - Particular symptoms with modalities
    - Miasmatic evaluation
2. Repertorization was performed using Zomoeo Ultimate software
3. Materia Medica consultation confirmed remedy selection
4. Individualized homoeopathic medicine was prescribed based on the totality of symptoms

Treatment Protocol:

- Group A received individualized homoeopathic medicine in 30C, 200C, or 1M potency based on susceptibility assessment
- Medicines were dispensed as medicated globules or liquid dilutions
- Dosage: Single dose to be repeated based on response (minimum interval 15 days)
- Group B received identical-appearing placebo (unmedicated globules)
- Both groups continued their routine antihypertensive medications without modification initially
- Lifestyle modifications, including dietary advice (DASH diet), exercise, stress management, and salt restriction, were advised to both groups

Follow-up Schedule:

Visit	Timeline
Baseline (V0)	Day 0 - Enrollment and randomization
Visit 1 (V1)	Week 2 - Safety assessment
Visit 2 (V2)	Week 4 - First efficacy assessment
Visit 3 (V3)	Month 2 - Safety and efficacy assessment
Visit 4 (V4)	Month 3 - Primary efficacy assessment
Visit 5 (V5)	Month 4 - Safety assessment
Visit 6 (V6)	Month 6 - Final efficacy assessment

Table 1: Follow-up visit schedule

Conventional Medication Adjustment:

- Antihypertensive medication dosage was reviewed at each visit by the treating physician
- Dose reduction was considered if BP remained controlled (<130/80 mmHg) for two consecutive visits
- Any dosage modification was recorded and analyzed as a secondary outcome
- Complete withdrawal of conventional medication was not attempted during the study period

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INCLUSION CRITERIA

1. Age: 30-65 years, either gender
2. Diagnosed case of essential hypertension (Stage I or Stage II as per JNC 8 guidelines)
3. On stable antihypertensive medication (same medication and dose for at least 3 months)
4. Blood pressure range: 140-179 mmHg systolic and/or 90-109 mmHg diastolic on current medication
5. Willing to continue conventional antihypertensive medication throughout the study period
6. Willing to comply with study protocol and follow-up schedule
7. Able to provide written informed consent
8. No change in antihypertensive medication anticipated during study period

EXCLUSION CRITERIA

1. Secondary hypertension (renal, endocrine, or vascular causes)
2. Severe hypertension (BP ≥180/110 mmHg)
3. Hypertensive emergency or urgency requiring hospitalization
4. Recent myocardial infarction or stroke (within 6 months)
5. Severe heart failure (NYHA class III-IV)
6. Chronic kidney disease (eGFR <30 mL/min/1.73m²)
7. Uncontrolled diabetes mellitus (HbA1c >9%)
8. Severe hepatic dysfunction
9. Pregnancy or lactation
10. Malignancy or terminal illness
11. Psychiatric disorders requiring medication
12. Current use of homoeopathic or other alternative medicines
13. Known hypersensitivity to homoeopathic medicines
14. Participation in another clinical trial within 3 months
15. Inability to provide informed consent or comply with follow-up

WITHDRAWAL CRITERIA

Participants were withdrawn from the study under the following circumstances:

1. Patient can voluntarily withdraw from the study at any time
2. Development of serious adverse events requiring intervention
3. Non-compliance with study protocol (missing more than 2 consecutive visits)
4. Requirement for hospitalization due to hypertensive complications
5. Development of exclusion criteria during the study period
6. Loss to follow-up despite three attempts to contact
7. Pregnancy during study period
8. Need for major change in antihypertensive medication regimen
9. At the investigator's discretion for safety concerns
10. Protocol violation

Withdrawn participants were included in safety analysis but excluded from per-

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protocol efficacy analysis. Intention-to-treat analysis included all randomized participants.

INTERVENTION

Homoeopathic Intervention (Group A)

Remedy Selection Process:

1. Comprehensive case taking following Hahnemannian principles
2. Symptom analysis and totality formation
3. Repertorization using Zomoeo Ultimate software
4. Materia Medica verification from standard texts (Boericke, Kent, Allen, Phatak)
5. Constitutional remedy selection based on individualization
6. Consideration of miasmatic background

Potency Selection:

- 30C: For acute symptoms and recent cases
- 200C: For well-established cases with a clear symptom picture
- 1M: For deep-acting constitutional treatment in chronic cases with strong mental symptoms

Posology:

- Single dose of 4 globules (size 20) or 10 drops in liquid dilution
- Repetition based on response assessment:
  - Minimum gap: 15 days
  - Same remedy repeated if improvement continued
  - Potency raised if improvement plateaued with same remedy
  - Remedy changed if clearly indicated remedy emerged

Frequently Prescribed Remedies:

Based on individualized assessment, remedies were selected from the following commonly indicated medicines for hypertension with their characteristic indications:

- **Natrum muriaticum:** Reserved, suppressed emotions, craving salt, headache from sun
- **Calcarea Carbonica:** Obesity, exertion intolerance, anxiety about health, chilly patient
- **Sulphur:** Hot patient, skin affections, philosophical temperament, standing aggravates
- **Lycopodium:** Digestive disturbances, lack of confidence, right-sided complaints, 4-8 PM aggravation
- **Phosphorus:** Anxiety, need for company, bleeding tendencies, desires cold drinks
- **Nux vomica:** Sedentary lifestyle, digestive complaints, irritability, stimulant abuse
- **Lachesis:** Left-sided symptoms, heat intolerance, loquacity, jealousy
- **Baryta Carbonica:** Elderly patients, memory weakness, timidity, atherosclerosis

Placebo Intervention (Group B)

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- Identical-appearing unmedicated globules (size 20) prepared by hospital pharmacy
- Same dispensing schedule and instructions as Group A
- Patients underwent same case taking process to maintain blinding
- Same follow-up schedule and monitoring

Concurrent Conventional Treatment (Both Groups)

- Continuation of existing antihypertensive medication without modification
- Common regimens included:
  - Angiotensin receptor blockers (ARBs): Telmisartan, Losartan
  - Calcium channel blockers (CCBs): Amlodipine, Cilnidipine
  - Beta-blockers: Metoprolol, Atenolol
  - Diuretics: Hydrochlorothiazide, Chlorthalidone
  - Combination therapy as prescribed
- Monitoring for adverse drug reactions
- Dose adjustment permitted only if BP is consistently controlled or uncontrolled

Lifestyle Modifications (Both Groups)

Standardized advice provided to both groups:

- **Diet:** DASH diet (Dietary Approaches to Stop Hypertension) - increased fruits, vegetables, whole grains, low-fat dairy; reduced sodium (<5g/day), saturated fat, and cholesterol
- **Exercise:** Moderate aerobic activity 150 minutes/week (brisk walking, cycling)
- **Weight management:** Target BMI <25 kg/m²
- **Alcohol:** Limited to moderate consumption (men <2 drinks/day, women <1 drink/day)
- **Smoking cessation:** Counseling and support provided
- **Stress management:** Relaxation techniques, adequate sleep (7-8 hours/night)

ASSESSMENT CRITERIA

Primary Outcome Measures

1. **Blood Pressure Measurement:**
   - Measured using Mercury sphygmomanometer
   - Patient seated comfortably for 5 minutes before measurement
   - Three readings taken at 1-minute intervals; average of last two recorded
   - Same arm used throughout the study
   - Measured at each visit (baseline, weeks 2, 4, months 2, 3, 4, 6)
   - Primary endpoints: Mean reduction in SBP and DBP at 6 months

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2. **Blood Pressure Control Rate:**
    - Proportion of patients achieving target BP <130/80 mmHg
    - Assessed at 3 and 6 months

Secondary Outcome Measures

1. **Quality of Life Assessment:**
    - WHO Quality of Life-BREF (WHOQOL-BREF) questionnaire
    - Domains: Physical health, psychological health, social relationships, environment
    - Administered at baseline, 3 months, and 6 months
    - Scored as per standard guidelines
2. **Symptom Severity Score:**
    - Visual Analog Scale (VAS) for headache (0-10)
    - Fatigue Severity Scale (FSS)
    - Hospital Anxiety and Depression Scale (HADS)
    - Pittsburgh Sleep Quality Index (PSQI)
    - Assessed at baseline, 3 months, and 6 months
3. **Medication Requirement:**
    - Change in dosage of antihypertensive medications
    - Number of antihypertensive drugs required
    - Documented at each visit
4. **Patient Global Impression of Change (PGIC):**
    - 7-point scale: very much improved to very much worse
    - Assessed at 3 and 6 months
5. **Laboratory Parameters:**
    - Fasting blood glucose
    - Lipid profile (total cholesterol, LDL, HDL, triglycerides)
    - Renal function (serum creatinine, eGFR)
    - Liver function tests
    - Assessed at baseline and 6 months
6. **Cardiovascular Risk Assessment:**
    - 10-year cardiovascular risk using Framingham Risk Score
    - Calculated at baseline and 6 months

Safety Assessment

1. Adverse events monitoring at each visit
2. Physical examination, including vital signs
3. Laboratory safety parameters
4. Causality assessment of adverse events (WHO-UMC scale)

Statistical Analysis Plan

- **Primary Analysis:** Intention-to-treat (ITT) analysis including all randomized participants
- **Secondary Analysis:** Per-protocol (PP) analysis excluding protocol violators and withdrawals
- **Baseline Characteristics:** Descriptive statistics (mean ± SD for

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continuous variables, frequencies for categorical variables)

- **Between-Group Comparisons:**
  - Continuous variables: Independent t-test or Mann-Whitney U test
  - Categorical variables: Chi-square test or Fisher's exact test
- **Within-Group Comparisons:** Paired t-test or Wilcoxon signed-rank test
- **Repeated Measures:** Repeated measures ANOVA or mixed-effects models
- **Statistical Significance:** Two-tailed p-value <0.05 considered significant
- **Software:** SPSS version 25.0 and GraphPad Prism 9.0

OBSERVATION AND RESULTS

Participant Flow and Baseline Characteristics

A total of 78 patients were assessed for eligibility between January 2024 and March 2024. Eighteen patients did not meet the inclusion criteria (n=12) or declined participation (n=6). Sixty patients were randomized: 30 to Group A (homoeopathy + antihypertensive drugs) and 30 to Group B (placebo + antihypertensive drugs).

During the study period, 4 patients (6.67%) were lost to follow-up: 2 from Group A (one relocated, one withdrew consent) and 2 from Group B (both lost to follow-up). Thus, 56 patients (28 in Group A, 28 in Group B) completed the 6-month intervention period and were included in per-protocol analysis.

All 60 randomized patients were included in the intention-to-treat analysis.

Group A (n=30)	Group B (n=30)	p-value
52.4 ± 8.6	51.8 ± 9.2	0.792
18:12	17:13	0.799
27.3 ± 3.8	26.9 ± 4.2	0.698
6.2 ± 3.4	5.8 ± 3.1	0.634
152.6 ± 8.4	151.8 ± 9.1	0.721
96.4 ± 6.2	95.8 ± 6.8	0.716
63.3	60.0	0.787
26.7	23.3	0.766
43.3	40.0	0.787
16.7	13.3	0.718

Table 2: Baseline demographic and clinical characteristics

Baseline characteristics were comparable between groups with no statistically significant differences (all p>0.05), indicating successful randomization.

Primary Outcomes: Blood Pressure Reduction

Systolic Blood Pressure (SBP):

Time Point	Group A (n=28)	Group B (n=28)	p-value
Baseline	152.6 ± 8.4	151.8 ± 9.1	0.721
Month 3	140.2 ± 7.6	147.4 ± 8.2	0.001**
Month 6	134.2 ± 6.8	143.2 ± 7.9	<0.001***
Mean reduction at 6 months	18.4 ± 6.2	8.6 ± 4.8	<0.001***

Table 3: Systolic blood pressure changes (mmHg, mean ± SD)

Group A demonstrated significantly greater reduction in SBP at both 3 months (12.4

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mmHg vs 4.4 mmHg, p=0.001) and 6 months (18.4 mmHg vs 8.6 mmHg, p<0.001) compared to Group B.

Diastolic Blood Pressure (DBP):

Time Point	Group A (n=28)	Group B (n=28)	p-value
Baseline	96.4 ± 6.2	95.8 ± 6.8	0.716
Month 3	88.6 ± 5.4	92.4 ± 6.1	0.017*
Month 6	84.1 ± 4.8	90.6 ± 5.6	<0.001***
Mean reduction at 6 months	12.3 ± 4.1	5.2 ± 3.4	<0.001***

Table 4: Diastolic blood pressure changes (mmHg, mean ± SD)

Group A showed significantly greater reduction in DBP at both 3 months (7.8 mmHg vs 3.4 mmHg, p=0.017) and 6 months (12.3 mmHg vs 5.2 mmHg, p<0.001) compared to Group B.

Blood Pressure Control Rate:

Target Achievement	Group A (n=28)	Group B (n=28)	p-value
BP <140/90 mmHg at 6 months	24 (85.7%)	15 (53.6%)	0.008**
BP <130/80 mmHg at 6 months	17 (60.7%)	8 (28.6%)	0.014*

Table 5: Blood pressure control rates

Significantly higher proportion of patients in Group A achieved target blood pressure levels compared to Group B.

Repeated measures ANOVA demonstrated a significant time × group interaction effect (F=28.46, p<0.0001), indicating that the trajectory of blood pressure reduction differed significantly between groups, with Group A showing superior and sustained reduction over 6 months.

Secondary Outcomes

Quality of Life (WHOQOL-BREF):

Domain	Group A Improvement	Group B Improvement	p-value
Physical health	18.6 ± 4.2	8.4 ± 3.6	<0.001 ***
Psychological health	16.4 ± 3.8	6.8 ± 3.2	<0.001 ***
Social relationships	14.2 ± 4.6	7.2 ± 3.8	<0.001 ***
Environment	12.8 ± 3.4	6.4 ± 2.8	<0.001 ***
Overall QOL	15.5 ± 3.6	7.2 ± 2.9	<0.001 ***

Table 6: Quality of life domain score improvements (baseline to 6 months)

Group A demonstrated significantly greater improvement in all quality-of-life domains compared to Group B (all p<0.001).

Symptom Severity Scores:

- **Headache (VAS):** Group A showed a reduction from 6.4 ± 1.8 to 2.2 ± 1.4 vs Group B from 6.2 ± 1.6 to 4.8 ± 1.6 (p<0.001)
- **Fatigue Severity Scale:** Group A improved by 24.6 ± 6.2 points vs Group B by 10.4 ± 5.8 points (p<0.001)

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- **Anxiety (HADS-A):** Group A reduced from 10.2 ± 3.4 to 5.6 ± 2.2 vs Group B from 9.8 ± 3.2 to 7.8 ± 2.8 (p=0.003)
- **Depression (HADS-D):** Group A reduced from 8.6 ± 2.8 to 4.2 ± 1.8 vs Group B from 8.4 ± 2.6 to 6.4 ± 2.2 (p=0.001)
- **Sleep Quality (PSQI):** Group A improved from 9.4 ± 2.6 to 5.2 ± 1.8 vs Group B from 9.2 ± 2.4 to 7.6 ± 2.2 (p<0.001)

All symptom severity measures showed significantly greater improvement in Group A compared to Group B.

Antihypertensive Medication Reduction:

Outcome	Group A (n=28)	Group B (n=28)	p-value
Dose reduction achieved	9 (32.1%)	3 (10.7%)	0.048*
Mean dose reduction (%)	26.4 ± 12.6	12.8 ± 8.4	0.032*
Drug number reduction	5 (17.9%)	1 (3.6%)	0.087

Table 7: Antihypertensive medication adjustment

Significantly higher proportion of patients in Group A successfully reduced conventional medication dosage under medical supervision compared to Group B (32.1% vs 10.7%, p=0.048). Five patients in Group A were able to discontinue one antihypertensive drug while maintaining blood pressure control.

Patient Global Impression of Change (PGIC):

At 6 months, 24 patients (85.7%) in Group A reported "much improved" or "very much improved" compared to 12 patients (42.9%) in Group B (p<0.001).

Laboratory Parameters:

No significant between-group differences were observed in changes in fasting blood glucose, lipid profile, or renal function tests. Both groups showed mild non-significant improvements in metabolic parameters, likely attributable to lifestyle modifications.

Frequently Prescribed Homoeopathic Remedies

Remedy	Number of Patients	Percentage
Natrum muriaticum	8	28.6%
Calcarea carbonica	6	21.4%
Sulphur	4	14.3%
Lycopodium	4	14.3%
Phosphorus	3	10.7%
Nux vomica	2	7.1%
Lachesis	1	3.6%

Table 8: Frequency of prescribed homoeopathic remedies in Group A

Natrum muriaticum was the most frequently prescribed remedy (28.6%), followed by Calcarea carbonica (21.4%). These remedies were selected based on individualized constitutional characteristics rather than disease diagnosis alone.

Safety and Adverse Events

No serious adverse events were reported in either group. Minor adverse events were comparable between groups:

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- Mild gastrointestinal upset: Group A (2 patients, 7.1%), Group B (1 patient, 3.6%)
- Transient headache: Group A (1 patient, 3.6%), Group B (2 patients, 7.1%)
- Mild dizziness: Group A (1 patient, 3.6%), Group B (2 patients, 7.1%)

All adverse events were mild, transient, and resolved without intervention. No adverse events were attributable to homoeopathic intervention. No patients discontinued study due to adverse events.

Compliance and Protocol Adherence

Medication compliance assessed through pill count and patient diary showed high adherence in both groups:

- Group A: 94.2 ± 4.6% compliance
- Group B: 93.8 ± 5.2% compliance (p=0.765)

Lifestyle modification adherence was similar between groups, with approximately 70% of participants in both groups reporting good to excellent adherence.

DISCUSSION

This randomized, double-blind, placebo-controlled study demonstrates that individualized homoeopathic medicine as adjunct therapy significantly enhances blood pressure control and quality of life in patients receiving routine antihypertensive drugs. The findings provide robust evidence supporting the integration of homoeopathy with conventional hypertension management.

Interpretation of Primary Findings

The primary outcome of blood pressure reduction showed clinically meaningful and statistically significant differences favoring the homoeopathy group. At 6 months, patients receiving individualized homoeopathic adjunct therapy achieved mean reductions of 18.4 mmHg in SBP and 12.3 mmHg in DBP compared to 8.6 mmHg and 5.2 mmHg, respectively, in the placebo group. These differences exceed the minimal clinically important difference of 5 mmHg for systolic blood pressure and represent substantial cardiovascular risk reduction [10].

The magnitude of blood pressure reduction observed in our study is consistent with previous research on individualized homoeopathy in hypertension. Saha et al. (2013) reported mean SBP reduction of 26.6 mmHg with individualized homoeopathy over 6 months in treatment-naive hypertensive patients [6]. Our study extends these findings by demonstrating significant additional benefit even when homoeopathy is added to existing antihypertensive medication, suggesting complementary mechanisms of action.

The superior blood pressure control rate in the homoeopathy group (60.7% achieving <130/80 mmHg vs 28.6% in placebo group) has important clinical implications. Achievement of target blood pressure is associated with reduced cardiovascular events, stroke, and mortality [11]. The adjunct homoeopathic therapy helped nearly twice as many patients achieve recommended targets, potentially translating to meaningful long-term cardiovascular protection.

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Quality of Life and Symptomatic Improvement

A particularly noteworthy finding was the significant improvement in quality of life across all WHOQOL-BREF domains in the homoeopathy group. While conventional antihypertensive drugs effectively lower blood pressure, they often fail to address patients' subjective well-being and may cause adverse effects that impair quality of life [12]. The holistic, individualized approach in homoeopathy addresses not only the hypertension but also associated mental-emotional symptoms, sleep disturbances, and general vitality.

The significant reductions in headache, fatigue, anxiety, and depression observed in the homoeopathy group likely contribute to improved quality of life and may also enhance treatment adherence. Psychological stress and anxiety are recognized contributors to hypertension pathophysiology through sympathetic nervous system activation and hormonal mechanisms [13]. By addressing these factors, homoeopathic treatment may interrupt stress-hypertension cycles, contributing to sustained blood pressure reduction.

Improvement in sleep quality (PSQI scores) deserves special mention, as sleep disturbances and short sleep duration are independent risk factors for hypertension and cardiovascular disease [14]. The significant sleep improvement in the homoeopathy group may contribute to blood pressure reduction through multiple pathways including autonomic nervous system regulation and reduced inflammation.

Medication Reduction and Safety Implications

One-third of patients in the homoeopathy group successfully reduced their conventional antihypertensive medication dosage while maintaining or improving blood pressure control. This finding has important clinical and economic implications. Reduced medication burden decreases the risk of adverse drug reactions, drug-drug interactions, and treatment costs while potentially improving patient adherence and satisfaction [15].

The ability to reduce conventional medication dosage suggests that homoeopathic adjunct therapy may address underlying pathophysiological mechanisms beyond simple symptomatic blood pressure lowering. This is consistent with homoeopathic principles emphasizing constitutional treatment and restoration of regulatory balance rather than suppression of symptoms.

Importantly, the excellent safety profile observed in this study—with no serious adverse events and only minor, transient side effects comparable to placebo—supports the feasibility and safety of integrating homoeopathy with conventional treatment. This addresses a key concern in integrative medicine regarding potential adverse interactions between complementary and conventional therapies.

Frequently Prescribed Remedies and Individualization

The distribution of prescribed remedies reflects true individualized prescribing based on constitutional characteristics rather than protocolized treatment. Natrum muriaticum,

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the most frequently prescribed remedy (28.6%), is characteristically indicated for patients with reserved disposition, suppressed emotions, and tendency toward hypertension—a common constitutional type in modern society with psychosocial stress [16].

Calcarea carbonica (21.4%) represents another constitutional type prone to hypertension: individuals with metabolic tendencies, anxiety about health, and reduced stamina. The variety of remedies prescribed across the patient cohort demonstrates adherence to individualized homoeopathic principles rather than disease-specific prescribing, which is fundamental to classical homoeopathic practice.

This individualization may explain why homoeopathy shows efficacy in some studies despite skepticism about mechanism of action. If remedies are genuinely matched to individual constitutional characteristics, treatment targets patient-specific pathophysiological patterns that conventional disease classifications may not capture.

Comparison with Previous Research

Our findings align with the systematic review by Banerjee et al. (2021), which suggested positive effects of individualized homoeopathy over placebo in hypertension, while acknowledging methodological limitations in existing literature [7]. Our study addresses several of these limitations through rigorous randomization, blinding, standardized outcome measures, and adequate sample size calculation.

The feasibility study by Sadhukhan et al. (2021) demonstrated that placebo-controlled trials of individualized homoeopathy in stage I hypertension are methodologically feasible and can be conducted with adequate rigor [8]. Our study builds on this foundation by examining adjunct therapy specifically—a more clinically relevant scenario given that most hypertensive patients are already receiving conventional treatment.

Research by Dr. Rizwan Ahmed Shabbir Shaikh on randomized controlled studies of homoeopathic medicines and lifestyle modifications as adjunct therapy in chronic diseases provides valuable precedent for our integrative approach [9]. His work emphasizes that homoeopathy combined with conventional treatment and lifestyle modifications may offer synergistic benefits greater than either approach alone—a principle supported by our findings.

A recent comparative study on stress-induced hypertension found that both individualized homoeopathy and specific remedies like Crataegus oxyacantha demonstrated effectiveness in blood pressure management [17]. While our study focused on individualized constitutional prescribing, future research comparing different homoeopathic approaches (individualized vs specific vs complex) could provide valuable insights.

Mechanisms of Action: Hypotheses and Perspectives

While the precise mechanisms underlying homoeopathic effects remain debated, several hypotheses merit consideration in the context of our findings:

1. **Psychoneuro-immunological Pathways:** The significant improvements in anxiety, depression,

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and sleep quality suggest homoeopathy may modulate stress response systems including the hypothalamic-pituitary-adrenal axis and sympathetic nervous system, both implicated in hypertension pathophysiology [18].

2. **Placebo and Context Effects:** While our study controlled for non-specific placebo effects through double-blinding, the therapeutic encounter, detailed case-taking, and individualized attention in homoeopathic practice may contribute to therapeutic effects through enhanced patient-provider relationship and meaning response [19].
3. **Nanoparticle and Hormesis Hypotheses:** Recent research suggests ultra-diluted preparations may contain source material nanoparticles and may exert biological effects through hormetic mechanisms or information transfer, though these hypotheses require further validation [20].
4. **Systems Biology Perspective:** Homoeopathy's individualized approach may address complex, multi-factorial disease networks in ways that single-target pharmaceutical interventions do not, particularly relevant in chronic diseases with heterogeneous presentations like hypertension [21].

Regardless of mechanism, the pragmatic clinical effectiveness demonstrated in our rigorous trial supports homoeopathy's role as adjunct therapy in hypertension management.

Clinical Implications and Practice Integration

Our findings have several key implications for clinical practice:

1. **Integrative Hypertension Management:** Homoeopathy can be safely and effectively integrated with conventional antihypertensive therapy, offering additional therapeutic benefits without compromising blood pressure control or increasing adverse events.
2. **Patient-Centered Care:** The holistic assessment and individualized treatment in homoeopathy aligns with contemporary emphasis on patient-centered care, addressing not only biomedical parameters but also psychosocial dimensions of health.
3. **Medication Optimization:** Adjunct homoeopathic therapy may facilitate reduction in conventional medication burden in selected patients, potentially reducing polypharmacy-related risks in elderly hypertensives.
4. **Quality of Life Focus:** For patients experiencing residual symptoms despite blood pressure control or those concerned about medication side effects, homoeopathic adjunct therapy offers a complementary approach addressing subjective well-being.
5. **Chronic Disease Management Model:** The success of integrative treatment in hypertension suggests potential application to other chronic conditions requiring long-term management, such as diabetes, dyslipidemia, and chronic kidney disease.

Study Strengths

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This study possesses several methodological strengths:

- Rigorous randomized, double-blind, placebo-controlled design minimizing bias
- Adequate sample size based on power calculation
- Standardized, validated outcome measures (blood pressure, WHOQOL-BREF, HADS, PSQI)
- Comprehensive assessment including quality of life and safety parameters
- Adherence to classical homoeopathic individualization principles
- High protocol adherence and low dropout rate (6.67%)
- Intention-to-treat and per-protocol analyses
- Transparent reporting following CONSORT guidelines
- Ethical approval and clinical trial registration
- Clinically relevant population (patients already on antihypertensive drugs)

Limitations and Future Research Directions

Several limitations should be acknowledged:

1. **Single-Center Study:** Conducted at one institution, potentially limiting generalizability. Multi-center trials would enhance external validity.
2. **Short Follow-up:** A six-month intervention period may not capture long-term sustainability of effects or cardiovascular outcomes. An extended follow-up (12-24 months) would provide valuable data on the durability of response.
3. **Lack of Objective Vascular Markers:** While blood pressure is the primary outcome, inclusion of endothelial function measures, pulse wave velocity, or cardiac biomarkers would provide mechanistic insights.
4. **Mechanism Elucidation:** The study demonstrates clinical effectiveness but does not elucidate mechanisms. Future research incorporating biomarker analysis, autonomic function testing, or neuroimaging could illuminate pathways of action.
5. **Lifestyle Modification Confounding:** While both groups received standardized lifestyle advice, individual adherence variations may confound results, though randomization should distribute this effect equally.
6. **Prescriber Effect:** Single prescriber ensured consistency but may limit generalizability. Multi-prescriber designs could assess reproducibility across different homoeopathic practitioners.
7. **Cost-Effectiveness Analysis:** Economic evaluation comparing costs of adjunct homoeopathic therapy versus conventional treatment intensification would inform healthcare policy decisions.

Future Research Directions:

- Long-term studies (2-5 years) evaluating cardiovascular outcomes (myocardial infarction, stroke, mortality)
- Comparative effectiveness research examining homoeopathy versus

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other CAM modalities (yoga, acupuncture, herbal medicine)

- Mechanism-focused studies with biomarker analysis, autonomic function assessment, and inflammatory marker evaluation
- Pharmacogenomic studies examining whether genetic profiles predict response to individualized homoeopathic treatment
- Health economics research evaluating the cost-effectiveness of integrative versus conventional-only hypertension management
- Implementation science research examining barriers and facilitators to integrating homoeopathy in mainstream healthcare settings
- Artificial intelligence applications in remedy selection and outcome prediction
- Studies in specific subpopulations (resistant hypertension, elderly, diabetes with hypertension)

Implications for Medical Education and Policy

The positive findings of this study raise important considerations for medical education and healthcare policy:

1. **Integrative Medicine Curriculum:** Medical education should include evidence-based information about complementary therapies, enabling physicians to counsel patients appropriately and facilitate safe integration when desired.
2. **Collaborative Care Models:** Healthcare systems should explore collaborative models where conventionally trained physicians and homoeopathic practitioners work together, as practiced in some European countries and India's National Health Mission.
3. **Research Funding:** Increased funding for rigorous research on complementary therapies, particularly pragmatic trials evaluating real-world effectiveness and cost-effectiveness, would inform evidence-based policy.
4. **Regulation and Quality Assurance:** Ensuring quality, standardization, and safety of homoeopathic medicines and practitioner competency through appropriate regulation protects patients and maintains professional standards.

Conclusion of Discussion

This randomized controlled trial provides robust evidence that individualized homoeopathic medicine as adjunct therapy significantly improves blood pressure control, quality of life, and symptomatic outcomes in patients receiving routine antihypertensive drugs. The intervention demonstrated excellent safety and enabled medication reduction in one-third of patients. These findings support the integration of homoeopathy with conventional treatment as a patient-centered, holistic approach to comprehensive hypertension management.

The study contributes to the growing evidence base for homoeopathy in chronic disease management and demonstrates that rigorous research on individualized complementary therapies is feasible and valuable. While questions regarding mechanisms remain, the pragmatic clinical

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effectiveness observed in this well-designed trial justifies consideration of homoeopathic adjunct therapy for hypertensive patients seeking integrative treatment approaches.

Further research with longer follow-up, larger sample sizes, multi-center designs, and mechanistic investigations will strengthen the evidence base and facilitate broader integration of homoeopathy into evidence-based hypertension care pathways.

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CONFLICT OF INTEREST

The author declares no conflict of interest, financial or otherwise, related to this research. The author has not received any honorarium, consultancy fees, or research grants from pharmaceutical companies, homoeopathic medicine manufacturers, or any commercial entity that could potentially bias the study design, data analysis, interpretation of results, or publication decision.

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