Original Article

Effects of individualised homoeopathic intervention in Stage I essential hypertension: A single-blind, randomised, placebo-controlled trial

Roja Varanasi[1]*, Raju Kolli[2], Yogendra Rai[3], Dubashi Ramesh[4], R.G.R. Kiranmayee[4], G Ravi Chandra Reddy[5], H. Baig[4], Tejaswini Patole[6], Priyanka Srivastava[1], Rupali Bhalaerao[1], Anupriya Chaudhary[1], Arvind Kumar[1], V. Sarathy[2], G. R. Jayasri[2], Garima Sachdeva[3], Saurabh Kumar Jain[3], Neha Sharma[3], Sucharitha Amsole[4], Amita Oinam[6], Praveen Oberai[1], Raj K Manchanda[1]

[1]Central Council for Research in Homoeopathy, New Delhi, [2]Homoeopathic Research Institute for Disabilities, Chennai, Tamil Nadu, [3]Dr.D.P Rastogi Central Research Institute (H), Noida, Uttar Pradesh, [4]Drug Standardization Unit (Homoeopathy), Hyderabad, Telangana, [5]Clinic Research Unit (Homoeopathy), Tirupati, Andhra Pradesh, [6]Regional Research Institute (Homoeopathy), Imphal, Manipur, India

Abstract

Background: Hypertension (HTN) is a leading risk factor for death and disability and responsible for over 1.6 million deaths in India. Clinical case reports, observational studies and randomised controlled trials show the effects of homoeopathic medicine in HTN. **Objectives:** The results of this study will add to the evidence of effectiveness of individualised homoeopathic medicine in Stage I HTN. **Methods:** A single-blind, randomised, placebo-controlled trial was undertaken from October 2013 to March 2018. The primary outcome measure was to evaluate the change in systolic blood pressure (SBP) and diastolic blood pressure (DBP) every month for 3 months. Of 2127 patients screened, 217 patients who fitted the inclusion criteria were randomised to receive either homoeopathic Q potencies (or LM potencies) plus lifestyle modification (LSM) =116 or placebo + LSM = 101. LSM included physical activity and diet as part of the treatment regimen. Analysis was by intention to treat. **Results:** Repeated-measure ANOVA between the groups showed statistically significant difference (Wilk lambda 0.85, $F = 12.12$, df = 213, $P = 0.0001$), in both SBP and DBP favouring Individualised Homoeopathy (IH) along with LSM. *Post hoc* independent *t*-test showed a significant mean reduction in SBP (mean difference 7.12 mm Hg, 95% confidence interval [CI] 4.72–9.53, $P = 0.0001$) and DBP (mean difference 5.76 mm Hg, 95% CI: 4.18–7.23, $P = 0.0001$) favouring Homoeopathy plus LSM group. *Sulphur* ($n = 24$), *Natrum muriaticum* ($n = 21$), *Lycopodium* ($n = 16$), *Nux vomica* ($n = 12$) and *Phosphorus* ($n = 10$) were the most useful medicines. **Conclusion:** IH in LM potency along with LSM was found effective over placebo along with LSM in the patients suffering from Stage I HTN. Further trials in rigorous setting are warranted.

Keywords: Homoeopathy, lifestyle modification, Stage I hypertension

Introduction

Hypertension (HTN) is an important worldwide public health challenge because of its role in the causation of coronary heart disease (CHD), stroke and other vascular complications,[1,2] to a population undergoing socioeconomic evolution. It is directly responsible for 57% of all stroke deaths and 24% of all CHD deaths in India.[3]

According to the National Family Health Survey (NFHS) 4-National fact sheet, the prevalence of hypertension is more widespread in male (13.6 %) than female (8.8%) population and also it is higher in case of urban subjects than the rural counterparts. There is significant difference in HTN in rural and urban population. Anchala *et al*.,[4] in their study, determined that the overall prevalence of HTN in India is 29.8%, which is significantly different between rural (27.6%) and urban (33.8%) population. The increasing prevalence of HTN is attributed to population growth, ageing and behavioural

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***Address for correspondence:** Dr. Roja Varanasi, Central Council for Research in Homoeopathy, New Delhi, India. E-mail: varanasiroja@gmail.com

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risk factors such as unhealthy diet, harmful use of alcohol, lack of physical activity, excess weight and exposure to persistent stress.[5] Global urbanisation, sedentary lifestyle, stress at workplace, lack of physical activity and social support lead to increased anxiety and uncertainty and finally to chronic mental and emotional stress. Psychological stress is also proposed as a significant factor contributing to the development of HTN.[6]

The primary goal of therapy for HTN should be effective control of BP to prevent, reverse or delay the progression of complications and thus reduce the overall risk of an individual without adversely affecting the quality of life. Patients can be categorised into different risk groups based on their risk factors.[6] In low-risk patients, it is suggested to institute lifestyle modification (LSM) and observe BP for 2–3 months, before deciding whether to initiate drug therapy.[7] The treatment of HTN is multidisciplinary in nature and is based on drug and non-drug strategies, and the latter are managed and supported by LSMs. LSM in hypertensive patients shows 60% goal achievement in BP, and this modification seems to be important especially for the young, male and obese patients.[8,9]

Researchers are facing challenges in fundamental, clinical research in terms of fulfilment of the responsibility of treatment, cardiac failure, obesity, end-stage renal disease and atherosclerosis.[10] The anti-hypertensives prescribed to control the BP though useful for few days/months, long-term use is questionable due to its side effects. Joshi *et al*.[11] in their review paper have enlisted side effects of anti-hypertensive drugs, such as dizziness, ankle swelling, headache, fatigue, chest discomfort and cough. Olowofela and Isah[12] in their cross-sectional study listed 27 symptoms attributed to the use of anti-hypertensives. The most important symptoms being frequency of micturition, poor erection, headache, reduced sexual urge, insomnia, weakness, nightmares (bad dreams), coughing, fatigue/little initiative, swollen ankles/oedema, muscular cramp/myalgia, dizziness upon standing up, palpitation and warm feeling/flushes in the face.

According to the statistics by the WHO, Homoeopathy is the second most useful healthcare system in the world.[13] There are several medicines enlisted[14,15] in homoeopathic literature for managing elevated BP. In all the studies reported, LSM was an integral part of the management. Preclinical study[16] with homoeopathic medicine *Rauwolfia serpentina* (0c, 30c and 6c) indicated its efficacy to reduce systolic BP (SBP) in deoxycorticosterone acetate salt-induced hypertensive rat and also modulate serum clinical parameters and renal antioxidant defences. The case reports,[17] observational studies[18-21] and randomised controlled trial (RCT)[22] published using Homoeopathy in HTN have shown some positive effects in managing it. Baig *et al*.[20] showed significant reduction in both SBP and diastolic BP (DBP) and reduction in dosage of conventional medicine. Similar results were also found in a study in their by Lakhera *et al*.[21] Saha *et al*.[22] in their RCT included patients with all stages of HTN and used different potencies, mother tinctures with significant reduction in BP. The former study lacked scientific rigour, and in the latter study, population included all the stages of HTN with different types of homoeopathic drugs, such as potencies, mother tinctures. The analysis of sample with individual stage which was insufficient might have reduced power and distorted inference. A descriptive study by Patel,[23] exploring the effect of psychological conflicts on HTN and role of Homoeopathy, showed that intrapersonal conflicts, such as suppressed anger/hostile impulses or sudden outburst of anger towards persons/things and unacceptable dependency, were the few of HTN symptoms in most patients seeking homoeopathic treatment. *Natrum muriaticum, Lycopodium, Ferrum metalicum, Kali bichromicum, Silicea* and *Calcarea carbonica* were found effective in cases of essential HTN and resolving conflicts.

Hahnemann, the father of Homoeopathy, aimed at achieving 'a rapid, gentle and permanent restoration of the health', which seemed to him easier to achieve with his last dynamisation method, known as 50 millesimal, Quinquagintamillesimal (Q potencies) or LM potencies, in which the medicine is diluted ≈ 50,000 times at each step (potency) of the dynamising process.[24] These potencies can be repeated more often with ease and are thus suitable for chronic diseases. There are no trials which estimated the effects of homoeopathic Q potencies in Stage I HTN.

This single-blind, randomised, placebo-controlled trial was carried out on the population suffering from Stage I essential HTN as per the Joint National Committee criteria 7.[25] The aim of this trial was to determine whether individualised Homoeopathy (IH) along with LSM could produce any significant hypotensive effect different from placebo along with LSM in patients suffering from Stage I essential HTN. Single-blind design was adopted to prevent the subject bias towards the treatment arms. However, keeping in view the individualised nature of homoeopathic prescription, investigators were not blinded. We hypothesised that there might (alternative; H_a) or might not be (null; H_0) any significant difference between the groups receiving IH plus LSM and placebo plus LSM.

Methods

Trial design

This was a single-blind, randomised, placebo-controlled trial conducted at five centres: Dr D. P. Rastogi Central Research Institute (H), Noida; Drug Standardization Unit (H), Hyderabad; Regional Research Institute (H), Imphal; Homoeopathic Research Institute for Disabilities (earlier Clinical Research Unit (H)), Chennai and Clinical Research Unit (H), Tirupati, under Central Council for Research in Homoeopathy, from October 2013 to March 2018. The study protocol was approved by the 17th Meeting of Institutional Ethical Committee dated 14th August 2013 and was registered in the Clinical Trials Registry – India (CTRI/2018/08/015228 dated 07th August 2018 – retrospectively). It was conducted according to the standards of Good Clinical Practice of India,

and all procedures were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2013.[26] Five homoeopathic physicians with more than 20 years of homoeopathic practice, having a degree to practice Homoeopathy from a government-recognised institution, participated in the study as investigators and responsible for the prescription of homoeopathic medicines. Study staff such as senior research fellows who also had institutional qualification as per the regulations of the Government of India assisted the investigators in conduct of the study.

Participants

Patients aged between 30 and 60 years, both genders, suffering from Stage I essential HTN (SBP 140–159 mmHg; DBP 90–99 mmHg), who were not on any anti-hypertensive medicines and willing to participate in the study were included.

Patients who had established secondary HTN of known aetiology, such as renal disease, pheochromocytoma or Cushing's syndrome, known diabetics, history of myocardial infarction, severe coronary artery disease or clinically significant heart failure or valvular defect or known cases of cardiac diseases, any systemic illness (consumptive disease, autoimmune disease, cancer, hepatic disease, renal disease, hypothyroidism) or clinical features suggestive of systemic illness, i.e., liver function test, kidney function test above normal range, patients receiving any drugs known to affect BP or medical treatments that can influence the BP, having a history of alcohol or drug abuse, i.e., excessive alcohol intake, who are taking 60 mL in case of males and 30 mL in case of female each day for the last 1 year, women who are taking contraceptive pills, pregnancy and lactating mother, unable or unwilling to give informed consent were excluded.

Intervention

All the patients enrolled were subjected to detailed case-taking as per the homoeopathic principles to avoid bias in the treatment effects.

Homoeopathy

Patients were prescribed IH in 50 millesimal potency as per the homoeopathic principles for 90 days customised to each patient which started with 0/1 potency, followed by the next higher potency, serially, as per need of the case. Each dose was directed to be taken orally. The investigator or the pharmacist on instruction from the investigator dispensed the medicine/placebo as follows: one globule (poppy seed size) of the desired potency was dissolved in 120 mL of distilled water, containing 2.4 mL (2% v/v) of dispensing alcohol, premixed in it, followed by 10 uniformly forceful downward strokes given against the bottom of the phial. Each patient was advised to give 10 uniformly forceful downward strokes to the bottle with the hand on a hard surface and to take three tea spoonful (15 mL) of this solution and mix it in eight tea spoonful (40 mL) of water in a clean glass after stirring the solution for each dose of medicine taken. One teaspoonful (5 mL) of this solution constitutes one dose which was administered once daily. If any change was triggered after administration (improvement/deterioration), change of remedy followed homoeopathic principles.

Medicines were obtained from SBL Pvt. Ltd., a Good Manufacturing Practice-certified firm. Single individualised medicine was prescribed on each occasion taking into account presenting symptom totality, clinical history details, constitutional features, repertorisation as and when required and due consultation with Materia Medica. Dose was also individualised and was based on homoeopaths' judgment of susceptibility and treatment experience.

Placebo

Patients randomised to the control group received placebo for the duration of the study (90 days). It constituted un-medicated poppy-sized sugar globules impregnated with dispensing alcohol. Mode of dispensing of the placebo was similar to that of the medicine. Any change triggered after administration (improvement) was followed by placebo only.

Lifestyle modification

Patients of both the groups were advised for physical activity and dietary modification on daily basis from baseline till 3 months.

Physical activity

Patients who were involved in physical labour or who had to walk or cycle for >30 min/day or performed exercises regularly were asked to continue their routine activities. Patients engaged in sedentary or light physical activity, as assessed in the initial interview, were advised and regularly motivated to walk briskly for at least 30 min each day.

Diet modification

Diet modification for each participant included Dietary Approaches to Stop Hypertension (DASH) diet (reduction in total calories, refined carbohydrates and fats, not to exceed 20 g/day) and inclusion of fibre-rich foods (whole grains, legumes, vegetables and fruits) customised according to their region and culture.[8,27] All participants were strongly encouraged to avoid alcohol and to stop smoking if they did so.

Primary outcome

- To determine the mean change in SBP and DBP from baseline at every month for 3 months from baseline as per the routine method.

Secondary outcome

- Per cent of patients meeting the goal BP of SBP ≤135 mmHg and DBP ≤85 mmHg in patients of both the groups
- To assess adverse events if any in both the groups.

Evaluation of blood pressure, diet and physical activity

Measurement of blood pressure

Measurement of SBP and DBP at baseline and thereafter every month for 3 months was done using the routine method as described in Bates' Guide to Physical Examination and

History Taking.[28] BP was measured in sitting position by investigators/study staff. The patients were instructed to avoid smoking or drinking caffeinated beverages for 30 min before the BP is measured. Before taking the BP, the patient was asked to sit quietly for at least 5 min in a chair with feet on the floor, rather than on the examining table. Three readings from both the arms were taken at an interval of 5 min. Then, the average of the three readings was calculated. The value obtained was considered for the inclusion of the patient into the study. Symptoms related to BP including headache, dizziness, ringing/buzzing in ears, rapid heart rate, and chest tightness and other signs were recorded using a questionnaire.

Physical activity

Physical activity was assessed as per the Physical Activity Scoring System developed by Ramachandran *et al*.[29] The physical activity score was assessed every month for 3 months. The patient was adherent to or not adherent was assessed every 30 days for 90 days.

Diet

Diet was advised as per the region on a structured format, and adherence was assessed on diet adherence scale[4] every 30 days for 90 days.

Sample size

Based on previous study by Baig *et al*.,[20] and keeping the lowest margin, it was assumed that the reduction in the SBP from baseline to 3 months shall be 10 ± 5 mmHg (mean ± standard deviation) in PL + LSM group; and keeping an additional absolute reduction of 20% more due by adding of IH with 95% confidence level and 80% power, 120 evaluable patients in each group were required. Keeping the drop out of 20%, the total sample size was 294 patients.

Randomisation

All the patients included in the study were randomised to either IH + LSM or placebo + LSM. Participants are simple randomised in a 1:1 ratio. The investigator assigned the patient to one of the intervention groups using simple randomisation techniques, i.e., the patients with odd enrolment numbers were given IH + LSM and patients with even numbers were given PL + LSM. The assigned groups were maintained throughout the study.

Statistical methods

All the statistics was performed using IBM SPSS Statistics for Windows, version 20 (IBM Corp., Armonk, N.Y., USA). The principal analyses of primary and secondary outcomes employed the "intent-to-treat" approach. The overall significance level of the primary outcome was explorative. The last observations were carried forward to fill the missing values. Nature of data was assessed applying normality test at baseline. All the data were tested for normal distribution, i.e., Kolmogorov–Smirnov tests were used to analyse the normality of the data distribution. Thereafter, baseline characteristics were compared between the two treatment groups using parametric and non-parametric tests as per the nature of the variable. Standard errors for inferences with 95% confidence intervals (CIs) are presented. A repeated-measure ANOVA was used to show the repeated difference between the groups for 3 months. Resulting *P* values for treatment-group effects are considered explorative, and $P < 0.05$ was considered statistically significant.

Results

Of 2127 patients screened, 1910 patients were excluded and 217 were enrolled for the study (IH + LSM: 116; PL + LSM: 101) from October 2013 to December 2017. The reasons for

Table 1: Baseline characteristics of the study population

Variable	IH + LSM (*n*=116)	PL + LSM (*n*=101)	*P*
Age	46.05±8.6	45.7±8.3	0.81
Height (m)	1.8±0.3	1.7±0.4	0.01
Waist circumference (cm)	99.2±12.5	96.4±10.9	0.09
Hip circumference (cm)	101.1±7.5	99.9±7.2	0.22
Weight (kg)	73.0±14.5	69.9±13.3	0.10
Male	68 (54.0)	58 (46.0)	0.57
Female	44 (50)	44 (50)	
Occupation			
Sedentary	59 (50.9)	51 (50.5)	0.47
Moderate	48 (41.4)	46 (45.5)	
Heavy	9 (7.8)	4 (4.0)	
Type of occupation			
Mechanic	6 (5.2)	10 (10.4)	
Farmer	3 (2.6)	0 (0.0)	
Maid servant	7 (6.0)	1 (1.0)	
Field officer	1 (0.8)	4 (4.1)	
Driver	10 (8.6)	9 (9.3)	
Teacher	6 (5.2)	1 (1.0)	
Retired clerk	2 (1.7)	1 (1.0)	
Office work	19 (16.5)	17 (17.7)	
Business	28 (24.3)	17 (17.7)	
Homemaker	33 (28.4)	36 (37.5)	
Diet			
Vegetarian	19 (16.4)	21 (20.8)	0.40
Non-vegetarian	97 (83.6)	80 (79.2)	
Habit			
Smoking	12 (48.0)	13 (52.0)	0.64
Alcohol	31 (56.4)	24 (43.6)	0.49
Family history of HTN	69 (55.2)	56 (44.8)	0.32
BP			
SBP (mmHg)	145.74 (8.1)	146.86 (7.5)	0.29
DBP (mmHg)	93.79 (3.3)	93.52 (3.3)	0.55
Lipid profile			
LDL	112.99 (35.2)	115.96 (27.9)	0.49
HDL	46.60 (11.6)	47.02 (6.3)	0.74
VLDL	25.66 (9.0)	26.76 (8.9)	0.37
TGL	129.03 (45.3)	132.84 (44.4)	0.53
PAS	21.71 (11.6)	21.61 (11.1)	0.95

BP: Blood pressure; PAS: Physical activity score; IH: Individualised Homoeopathy; LSM: Lifestyle modification; HTN: Hypertension; SBP: Systolic BP; DBP: Diastolic BP; LDL: Low-density lipoprotein; VLDL: Very LDL; HDL: High-density lipoprotein; TGL: Trigylceride; PL: Placebo

exclusion were as follows: BP not in the inclusion range (56%); patients on anti-hypertensive medications (16%); patients' age does not meet the criteria (8%); patients not willing for the study (6%). 23 participants in each group dropped out. The flow of patients in the study is given in Figure 1. Baseline demographic characteristics, clinical indices and pathological–biochemical parameters were comparable between the groups [Table 1].

The percentage of participants who adhered to physical activity was IH + LSM: 81% and PL + LSM: 77.2%. Similarly, the percentage of participants who adhered to diet was IH + LSM: 83.6% and PL + LSM: 84.2%. Chi-square test for association showed no significant difference for both the parameters, i.e., physical activity ($\chi^2 = 0.47$, $P = 0.49$) and diet ($\chi^2 = 0.47$, $P = 0.49$).

Repeated-measure ANOVA between the groups showed statistically significant difference, in both SBP (Wilk lambda 0.85, $F = 12.12$, df = 213, $P = 0.0001$) and DBP (Wilk lambda 0.85, $F = 12.12$, df = 213, $P = 0.0001$) favouring IH + LSM. *Post hoc* independent *t*-test showed a significant mean reduction in SBP (mean difference 7.12, 95% CI 4.72–9.53, $P = 0.0001$) and DBP (mean difference 5.76, 95% CI: 4.18–7.23, $P = 0.0001$) favouring the IH + LSM group [Table 2]. Figure 2 shows the decreasing trend of SBP and DB*P* values at different time points with 95% error bars.

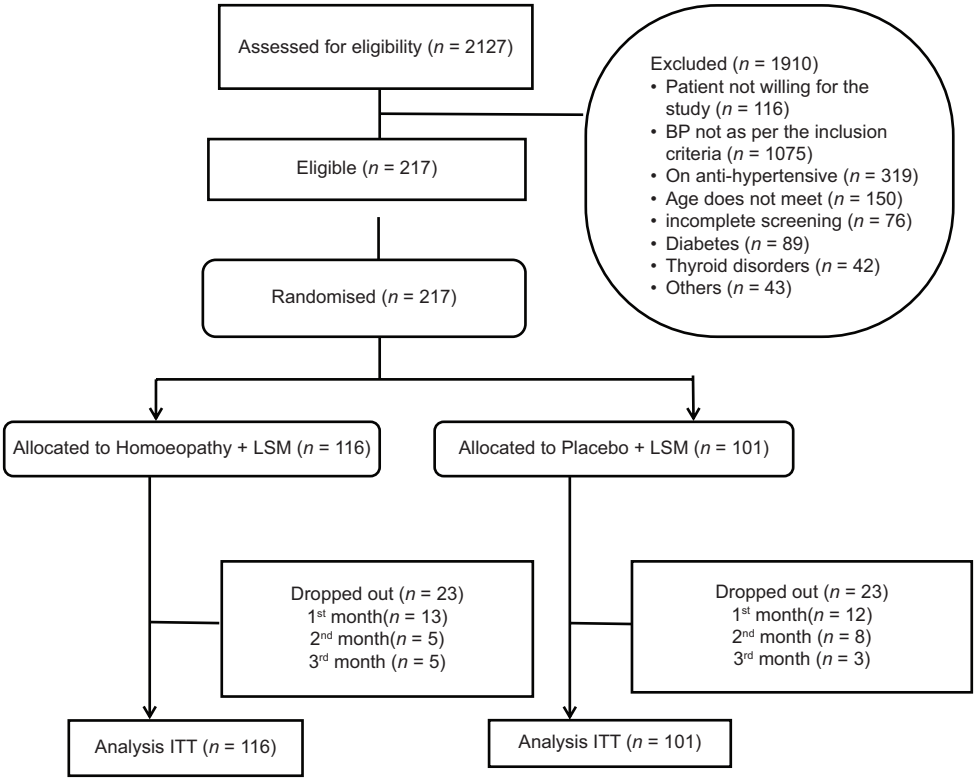

Figure 1: Flow of patients in the study

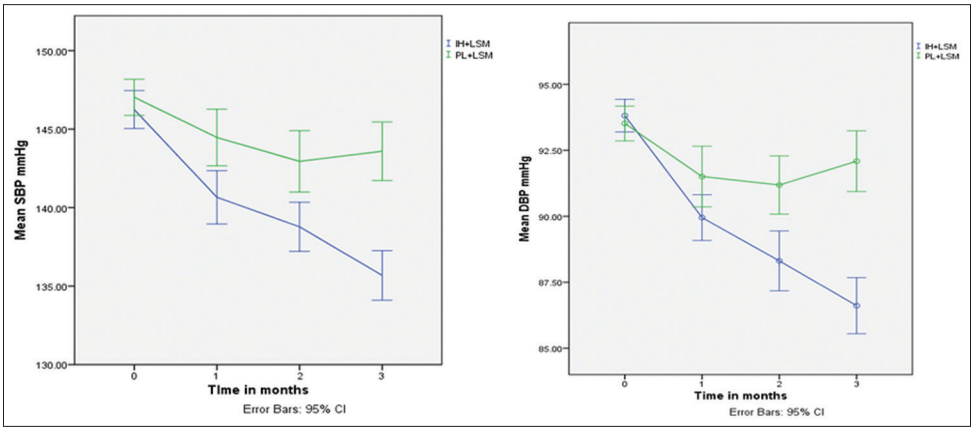

Figure 2: Systolic blood pressure and diastolic blood pressure at different months over 3 months

Table 2: Outcome at end of 3 months

Variable	IH + LSM group (n=116)	PL + LSM group (n=101)	Absolute mean difference/χ^2/relative risk	95% CI	P
	Mean difference±SE/n (%)				
Primary outcome					
SBP mmHg (change 0 to 3rd month)	10.5±0.8	3.4±0.9	7.12	4.7-9.5	0.0001
DBP mmHg (change 0 to 3rd month)	7.1±0.9	1.4±0.5	5.7	4.1-7.3	0.0001
Secondary outcome					
SBP ≤135 mmHg and DBP ≤85 mmHg	41 (35.3)	13 (12.8)	0.74	0.63-0.86	0.0001
SBP ≤135 mmHg	56 (48.2)	18 (17.8)	0.62	0.51-0.76	0.0001
DBP ≤85 mmHg	48 (41.3)	13 (11.2)	0.67	0.56-0.79	0.0001
Others					
LDL g/dL (change 0 to 3rd month)	−0.0±2.2	−1.7±1.8	1.7	−4.0-7.4	0.56
VLDL g/dL (change 0 to 3rd month)	−0.6±0.4	−0.1±0.5	-0.4	−1.8-0.8	0.48
HDL g/dL (change 0 to 3rd month)	0.5±0.7	−0.3±0.4	0.9	−0.9-2.7	0.32
TGL g/dL (change 0 to 3rd month)	−3.0±2.1	−2.2±2.7	-0.8	−7.6-5.9	0.80
PAS					
Adherent	94 (81)	78 (77.2)	0.47	-	0.49
Non-adherent	22 (19)	23 (22.8)			
Diet					
Adherent	97 (83.6)	85 (84.2)	0.47	-	0.49
Non-adherent	19 (16.4)	16 (15.8)			

PAS: Physical activity score; BP: Blood pressure; PAS: Physical activity score; IH: Individualised Homoeopathy; LSM: Lifestyle modification; HTN: Hypertension; SBP: Systolic BP; DBP: Diastolic BP; LDL: Low-density lipoprotein; VLDL: Very LDL; HDL: High-density lipoprotein; SE: Standard error; TGL: Triglyceride; PL: Placebo

The secondary outcome [Table 2] for achieving the goal by SBP ≤135 and DBP ≤85 was also determined. It was observed that 35.3% (n = 41) of patients achieved the goal in IH + LSM group and 12.8% (n = 13) in PL + LSM group. There was relative risk of 0.74 (95% CI 0.63–0.86; P = 0.001). Number needed to treat (benefit) was 4.45 (95% CI 2.9–8.8) to bring SBP/DBP less than 135/85 mm of Hg in one patient by IH + LSM.

Homoeopathic prescription follows holistic approach; the medicines prescribed for presenting complaints along with HTN were *Sulphur* (n = 24), *Natrum muriaticum* (n = 21), *Lycopodium* (n = 16), *Nux vomica* (n = 12), *Phosphorus* (n = 10), *Arsenicum album* (n = 8), and *Calcarea carbonica* (n = 7), *Pulsatilla* (n = 5), *Sepia* (n = 4), *Lachesis* (n = 2), *Argentum nitricum* (n = 2), *Aconite* (n = 2), *Silicea* (n = 1), *Belladonna* (n = 1) and *Rhus toxicodendron* (n = 1). No change of prescription was done during the 3 months of treatment. The most useful medicines which were prescribed in 10 or more patients are given in Table 3. There were no adverse events reported during the study period.

The clinical symptoms presented by the patients and sought treatment are given in Table 4. 68.8% of complaints were rheumatological (knees pain, back pain and neck stiffness), while 49.8% neurological/mental (burning of extremities, vertigo, headache, numbness, weak memory, irritability and anxiety). There was a strong association of homoeopathic medicines and improvement of clinical symptoms too. 68% of 73 patients reported improvement in their rheumatological complaints compared to only 34.3% of 70 patients in placebo group (χ^2 16.7; P = 0.0001). Similarly, 72.4% of patients with neurological complaints/mental complaints reported improvement in homoeopathic group compared to only 34% in placebo group (χ^2 = 15.98; P = 0.0001). Further sleepless also improved in 54.5% of 11 patients in homoeopathic group compared to 15.4% of 13 patients in placebo group (χ^2 = 4.11; P = 0.04). The association was insignificant in symptoms related to cardiac (palpitation), respiratory (breathing difficulties), gynaecological (irregular menses) and dermatological (pruritus).

Discussion

HTN is one of the major risk factors for cardiovascular event. This multicentric, single-blind, randomised, placebo-controlled trial conducted at five centres resulted in significant reduction in SBP and DBP with IH and LSM compared to placebo and LSM in patients suffering from Stage I HTN (absolute mean difference 7.12; 95% CI 4.7–9.5; P = 0.0001). 35% of patients in IH + LSM groups reached the goal of SBP/DBP ≤135/≤85 mmHg compared to 12.8% in PL + LSM group. Thus, there was 26% relative risk reduction in IH + LSM group. In this study, a strong association of improvement was also observed in Homoeopathy group compared to placebo group. The clinical symptoms related to rheumatological disorders, neurological/mental disorders and sleeplessness were prominent.

Baig *et al*.[20] study comprised of patients with all stages of HTN showed 14 mmHg reduction in SBP and 11 mmHg reduction in DBP with homoeopathy intervention as add on or stand alone. However, this study included the patients of Stage I HTN only with systematic motivation for LSM. Saha

Table 3: Indications of the most useful medicines

Name of the drug	Indications
Sulphur	Mental generals Extroverted, cheerful, religious, difficulty in concentration, absent minded, irritable, depressed subjects; lazy, aversion to work, weakness of memory, mental exhaustion, weary of life, forsaken feeling, anger, sadness, home sickness, desire for company, consolation ameliorates; anxiety about his children, about health, business Physical generals Desires for sweets; spices, butter milk, vegetable, meat, brandy, alcohol, coffee, warm drinks, salt; aversion: Sweet, warm food; thirst for large quantities of water; perspiration profuse worse after eating; stools: Irregular, sometimes hard, sometimes soft; sleeplessness; worse bathing; dreams of joyous; desire to be fanned; menses: Irregular, preceded by headache Characteristic particulars Pain in head, with heaviness and fullness of head, temples, occiput-pulsating pain; vertigo worse morning, and after stool; nose block with sneezing worse morning, pain in throat, dry cough worse night; palpitations; dyspepsia with sour eructation, nausea, pain in rectum, distension of abdomen, indigestion; stitching, shooting type of pain in cervical region; stitching pain in knee worse raising after, amelioration walking; drawing and tearing pains in lower limbs worse standing, walking, pain in back; burning micturition; eruptions of skin, succession of eruptions over legs, itching of skin worse night, warmth of bed, washing, scratching
Natrum muriaticum	Mental generals Irritability, angry at trifles, introverted, anticipatory anxiety, industrious, weeping tendency, awkwardness, worried about the complaints, weakness of memory, absent minded, anxiety, affectionate, aversion to company, consolation aggravates, ailments from grief Physical generals Aversion to milk, cold water; desires: Salt, tea, fruits, fish, sour foods; intolerance: Brinjal; profuse perspiration on scalp, forehead; constipation; thirst for large quantities; sleep full of dreams, unremembered; sleeplessness from thoughts Characteristic particulars Heaviness of head worse night, after eating, pulsating, throbbing, neuralgic pain in forehead, worse light, noise, seashore, sun exposure, talking loud, headache worse morning, rising from bed, amelioration: evening, vertigo on rising in the morning, worse raising the arms; palpitations; nausea in morning, daytime; pain knee joints worse night, prolonged standing; distension of abdomen; pain in back extending to shoulder, amelioration firm support; difficulty in breathing worse exertion; eruption in ankle
Lycopodium	Mental generals Anger on contradiction, indecisiveness, mildness, melancholy, fears to be alone, cannot withstand stress, little things annoy, anxious about health, forgetfulness, reproach others, poor concentration, introverted, grief, irritability, egoistic, aversion to company Physical generals Predominately hot patient, desires open air; desires warm food; sweets, olives, sour, spicy; perspiration from slightest exertion, which aggravates, perspiration during sleep, aggravation before menses; disturbed sleep; constipation, hard, difficult, unsatisfactory stools Characteristic particular Headache; throbbing, pressive, worse in the evening, heaviness of head, pain in occipital region; vertigo, worse moving the head, morning, evening; dim vision; Dryness of mouth worse night; flatulent dyspepsia with satiety not relieved by belching or by passing flatus; sour eructations worse evening, night, heartburn worse after eating; stiffness of joints; numbness of lower limbs with perspiration, burning in fingers; polyuria during night; sexual debility; pain in lower limbs, numbness; pain in knee, hip. Cramps in lower extremities; difficulty in breathing; palpitations; generally worse motion, amelioration continued motion
Nux vomica	Mental generals Aversion to company; cannot support injustice, restlessness; grief, brooding Physical generals Disturbed, sleep; constipation; thirstlessness; desire: spicy food Characteristic particulars Head pain, neuralgic worse day time; vertigo worse morning, physical exertion, amelioration lying; heaviness of head in the morning, evening; pain in both legs, worse constant motion; stiffness of back worse morning, during headache; breathing difficulty worse morning; gnawing pain in stomach amelioration eating; knee pain worse lying, motion, amelioration warmth
Phosphorus	Mental generals Weakness of memory, anxiety about his family, about health, affectionate, loathing, aversion to company, sadness, anxiety when alone, fearful, extrovert, grief, mildness Physical generals Disturbed sleep, constipation, thirst for large quantities, desire: Meat, fruit, fish, chicken, sweets, spicy, vegetable, aversion: Sweet, sweat: Scanty Characteristic particulars Vertigo worse while walking, morning, afternoon, pain in head, heaviness of head, dimness and pain of right eye, distension of abdomen, burning pain in abdomen worse after eating; palpitations, complaints generally worse after eating, amelioration sleep, difficulty in breathing worse after exertion; pain in lower extremities, worse exertion, amelioration rest, weakness, back pain, stiffness of back worse morning swelling in ankle, stiffness of back; pain in lower limbs worse motion; dry skin, blackish discolouration must scratch itching worse night

Table 4: Clinical symptoms reported by the patients

Complaints*	Total, *n* (%)	Homoeopathy + LSM, *n* (%)	Placebo + LSM, *n* (%)
Rheumatologic complaints	143 (68.8)	73 (67.0)	70 (70.7)
Improved	74 (51.7)	50 (68.5)	24 (34.3)
Not improved	69 (48.3)	23 (31.5)	46 (65.7)
χ^2, *P*		16.74, 0.0001	
Neurological/mental complaints	108 (49.8)	58 (50.0)	50 (49.5)
Improved	59 (54.6)	42 (72.4)	17 (34.0)
Not improved	49 (45.4)	16 (27.6)	33 (66.0)
χ^2, *P*		15.98, 0.0001	
Gastrointestinal complaints	90 (41.5)	50 (43.1)	40 (39.6)
Improved	46 (51.1)	34 (68.0)	12 (30.0)
Not improved	44 (48.9)	16 (32.0)	28 (70.0)
χ^2, *P*		12.84, 0.00001	
Respiratory complaints	40 (19.2)	21 (19.4)	19 (19.0)
Improved	20 (50.0)	12 (57.1)	8 (42.1)
Not improved	20 (50.0)	9 (42.9)	11 (57.9)
χ^2, *P*		0.90, 0.34	
Cardiac complaints	23 (10.6)	13 (11.2)	10 (9.9)
Improved	16 (69.6)	10 (76.9)	6 (60.0)
Not improved	7 (30.4)	3 (23.1)	4 (40.0)
χ^2, *P*		0.76, 0.38	
Sleeplessness	24 (11.5)	11 (10.0)	13 (13.1)
Improved	8 (33.3)	6 (54.5)	2 (15.4)
Not improved	16 (66.7)	5 (45.5)	11 (84.6)
χ^2, *P*		4.11, 0.04	
Dermatological complaints	17 (8.2)	11 (10.1)	6 (6.1)
Improved	8 (47.1)	7 (63.6)	1 (16.7)
Not improved	9 (52.9)	4 (36.4)	5 (83.3)
χ^2, *P*		3.43, 0.06	
Gynaecological complaints	6 (2.9)	4 (3.6)	2 (2.0)
Improved	1 (16.7)	1 (25.0)	0 (0.0)
Not improved	5 (83.3)	3 (75.0)	2 (100)
χ^2, *P*		0.60, 0.43	

LSM: Lifestyle modification

et al.,[22] in their study, inferred that the mean BP reduction was 26.6 mmHg. The authors included patients of all stages of HTN. In both the studies, medicines prescribed included mother tinctures, homoeopathic dilutions in Q potencies and centesimal potencies. However, the present study streamlined the medicines using Q potencies only. The greater advantage of Q potencies is that the medicines can be given serially and continuously and they are highly dynamic with power increasing succinctly with each serial dilution.

The various challenges faced by the investigators during the trial were large number of screening (n = 2127) to get cases of Stage I HTN as per the inclusion criteria. For each one case to be enrolled, 10 patients had to be screened. In one centre, of 746 cases screened, none of the cases was found fit for inclusion. Due to large number of screening and achieving the targeted sample (n = 294), duration of enrolment period was required to be extended for 3 years. For hands-on training and identifying the ground-level difficulties, the investigators were instructed for initiating the study as single-blind trial. After a meaningful enrolment, an interim analysis was conducted with significant results. Thereafter, the enrolment was stopped with sample achievement of 217 patients. Further, with a placebo arm due to ethical reasons and risk factors, follow-up period was restricted to 3 months only.

The study has limitations too. This study was conceptualised and planned for a double-blind, placebo-controlled trial with ambulatory BP measurement as one of the primary outcomes. However, single-blind trial could be conducted. Thus, blinding subjects to treatment group may protect against the expectation bias, thereby enhancing the internal validity of the findings, which provides benefit to the research. However, the experimenter bias cannot be ignored.[30] The ambulatory BP instrument requires hospital admission for monitoring of 24 h BP or the patient had to be given the instrument to be used at home. Both the methods were not feasible with the current study set-up. Therefore, this was not achieved in this study. Studies with pragmatic approach and double-blind design with infusion of real-time practice inclusive of all the stages of HTN can be the best option to reduce the long enrolment period with increase in long-time follow-up for better appraisal

of homoeopathic treatment. Further, the clinical symptoms were analysed as a dichotomous variable of improved and not improved. In future studies, patient reported outcome measures such as measure your outcome profile may also be incorporated to bring robustness to the study findings.[31]

Keeping in view nature of the disease, multiple risk factors and side effects of conventional drugs, the results of this study can be utilised in Stage I HTN so that the patients with low risk can be effectively managed with Homoeopathy along with LSM. As per the findings of Mahmoudian[17] and Patel,[23] future research designs with homoeopathic intervention may also document in-depth psychological perspective to establish connection of Homoeopathy with psychology in patients suffering from HTN along with standard outcome measures/ endpoints[32] for establishing causal relationship.

Conclusion

The study highlights the positive role of Homoeopathy in LM potency along with LSM for managing Stage I HTN. Along with reduction in BP, there was significant improvement in different symptoms. Further, pragmatic, double-blind studies in different settings and designs are required to substantiate the generated evidence.

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Conflicts of interest

None declared.

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आवश्यक उच्च रक्तचाप चरण I में व्यक्तिगत होम्योपैथिक हस्तक्षेप के प्रभाव : सिंगल – ब्लाइंड यादृच्छिक, प्लेसबो नियंत्रित परीक्षण

पृष्ठभूमि : उच्च रक्तचाप मृत्यु और विकलांगता के लिए चौथा प्रमुख जोखिम कारक है और भारत में 1.6 मिलियन से अधिक मौत के लिए जिम्मेदार है। नैदानिक विवरण, अवलोकन संबंधी अध्ययन और आरसीटी उच्च रक्तचाप में होम्योपैथिक दवा का प्रभाव दिखाते हैं। **उद्देश्य :** इस अध्ययन के परिणाम चरण I उच्च रक्तचाप में व्यक्तिगत होम्योपैथिक चिकित्सा की प्रभावशीलता के प्रमाण को जुटाएंगे। **सामग्री और विधियाँ:** अक्टूबर 2013 से मार्च 2018 तक सिंगल – ब्लाइंड यादृच्छिक प्लेसबो–नियंत्रित परीक्षण किया गया। प्राथमिक परिणाम तीन महीने तक हर महीने सिस्टोलिक रक्तचाप (एसबीपी) और डायस्टोलिक रक्तचाप (डीबीपी) में परिवर्तन का मूल्यांकन करना था। जाँच किए गए 2127 मरीजों में से, 217 मरीजों को शामिल करने के लिए निर्धारित मापदंड को होम्योपैथिक फ पोटैंसी और जीवन शैली संशोधन (एलएसएम) = 116 या प्लेसबो+एलएसएम = 101 प्राप्त करने के लिए यादृच्छिक किया गया। जीवन शैली संशोधन में उपचार गतिविधि के हिस्से के रूप में शारीरिक गतिविधि और आहार शामिल थे। उपचार करने के इरादे से विश्लेशण किया गया था। **परिणाम :** समूहों के बीच लगाए गए रिपीटिड मेजर एनोवा ने एसबीपी और डीबीपी दोनों में व्यक्तिगत होम्योपैथी का समर्थन करते हुए सांख्यिकीय रूप से महत्वपूर्ण अंतर दिखाया। (विल्क लैम्ब्डा 0.85, एफ = 12.12, डीएफ = 213, पी = 0.0001) । पोस्ट हॉक इंडिपेंडेंट टी टेस्ट में एसबीपी (औसत अंतर 7.12, 95: सीआइ 4.72 से 9.53, पी = 0.0001), व और डीबीपी में उल्लेखनीय कमी देखी गई (औसत अंतर 5.76, 95: सीआइ: 4.18 से 7.23, पी = 0.0001), जो कि होम्योपैथी और एलएसएम समूह के पक्ष में है। सल्फर (एन = 24), नेट्रम म्यूरिएटिकम (एन = 21), लाइकोपोडियम (एन = 16), नक्स वोमिका (एन = 12) और फास्फोरस (एन = 10) सबसे उपयोगी दवाएं थीं। **निष्कर्ष :** एलएसएम के साथ–साथ व्यक्तिगत होम्योपैथी को चरण ५ उच्च रक्तचाप से पीड़ित रोगियों में एलएसएम के साथ प्लेसबो पर प्रभावी पाया गया। कठोर परिस्थिति में आगे के परीक्षणों को अनुबद्ध करने की आवश्यकता है।

Effets d'une intervention homéopathique individualisée dans l'hypertension essentielle de stade I: un essai randomisé à seul insu, contrôlé par placebo

Contexte: L'hypertension est le quatrième facteur de risque de décès et d'invalidité et est responsable de plus de 1,6 million de décès en Inde. Les rapports de cas cliniques, les études observationnelles et les ECR montrent les effets du médicament homéopathique sur l'hypertension. **Objectifs:** Les résultats de cette étude viendront compléter les preuves de l'efficacité de la médecine homéopathique individualisée dans l'hypertension de stade I. **Matériel et méthodes:** Un essai randomisé à seul insu contrôlé contre placebo a été entrepris d'octobre 2013 à mars 2018. Le principal critère d'évaluation était d'évaluer la variation de la pression artérielle systolique (SBP) et de la pression artérielle diastolique (DBP) chaque mois pendant trois mois. Sur 2127 patients dépistés, 217 patients répondant aux critères d'inclusion ont été randomisés pour recevoir soit les puissances homéopathiques Q plus la modification du mode de vie (LSM) = 116 ou Placebo + LSM = 101. La modification du mode de vie incluait l'activité physique et l'alimentation dans le cadre du traitement. L'analyse a été faite dans le but de traiter. **Résultats:** La mesure répétée de l'ANOVA entre les groups, a montré une différence statistiquement significative (Wilk Lambda 0,85, F = 12,12, dF = 213, *P* = 0,0001), dans les deux SBP et DBP favorisant l'homéopathie individualisée. Le test t indépendant post hoc a montré une réduction moyenne significative de la SBP [diff. Moyenne. 7,12, IC 95% 4,72 à 9,53, *P* = 0,0001] et réduction moyenne du DBP [diff. Moyenne 5,76, IC 95%: 4,18 à 7,23, *P* = 0,0001] favorisant l'homéopathie plus le groupe LSM. *Le soufre* (*n* = 24), *Natrum muriaticum* (*n* = 21), *Lycopodium* (*n* = 16), *Nux vomica* (*n* = 12) et *le phosphore* (*n* = 10) étaient les médicaments les plus utiles. **Conclusion:** L'homéopathie individualisée associée au LSM s'est avérée efficace par rapport au placebo et au LSM chez les patients souffrant d'hypertension de stade I. D'autres essais dans des environnements rigoureux sont justifiés.

Efectos del tratamiento homeopático individualizado en la hipertensión esencial de estadio I: ensayo aleatorizado, simple ciego, controlado con placebo

Fundamentos: La hipertensión es el cuarto factor de riesgo principal de muerte e incapacidad, así como responsable de más de 1,6 millones de fallecimientos en la India. Los informes de casos clínicos, losestudios observacionales y los ECA evidencian los efectos de los medicamentos homeopáticos en la hipertensión.

Objetivos: Los resultados de este estudio se añaden a la evidencia de la eficacia de los medicamentos homeopáticos individualizados en la hipertensión de estadio I.

Materiales y métodos: Se ha realizado un ensayo aleatorizado, simple ciego y controlado por placebo entre octubre de 2013 y marzo de 2018. El parámetro primario fue evaluar los cambios en la presión sistólica (PS) y la presión diastólica (PD) mensualmente durante tres meses. 217 pacientes de los 2.127 pacientes examinados cumplían los criterios de selección y fueron aleatorizados para recibir un medicamento en potencia Q más indicaciones para la modificación del estilo de vida (MEV) (116) o bien placebo +MEV (101). La modificación del estilo de vida incluía actividad física y dieta como parte de la pauta terapéutica. El análisisfue de intención de tratamiento.

Resultados: Las mediciones ANOVA repetidas entre los gruposmostraron una diferencia estadística significativa (Lambda de Wilks0,85, F= 12,12, dF =213, *P* = 0,0001) tanto en la PS como en la PD a favor de la homeopatía individualizada. La prueba t independiente post hoc mostró una reducción media significativa de la PS [diferencia media 7,12, IC del 95% CI 4,72 a 9,53, *P* = 0,0001] y un descenso medio de la PD [diferencia media 5,76, IC del 95%: 4,18 a 7,23, *P* = 0,0001] a favor del grupo con homeopatía más MEV. Los medicamentos más utilizados fueron*Sulphur* (*n*=24), *Natriummuriaticum* (*n*=21), *Lycopodium* (*n*=16), *Nuxvomica* (*n*=12) y*Phosphorus* (*n*=10).

Conclusiones: Se ha constatado que la homeopatía individualizada junto con la MEV fue más eficaz que el placebo junto con la MEV en los pacientes que sufren hipertensión en estadio I. Se precisan más ensayos en un marco estricto.

Auswirkungeneinerindividualisiertenhomöopathischen Intervention beiessentiellerHypertonieim Stadium I: eineeinzigeblinde, randomisierte, plazebokontrollierteStudie

Hintergrund: Bluthochdruckist der viertgrößteRisikofaktorfürTod und Invalidität und fürüber 1,6 MillionenTodesfälle in Indienverantwortlich. KlinischeFallberichte, Beobachtungsstudien und RCTs zeigen die Auswirkungen der homöopathischenMedizinbeiBluthochdruck.

Ziele: Die Ergebnisse dieser Studiewird zum Nachweis der Wirksamkeit der individualisierten homöopathischen Medizin beitragen im Stadium I Bluthochdruck

Materialien und Methoden: Von Oktober 2013 bisMärz 2018 wurdeeineeinzigeblinde, randomisierte, plazebokontrollierteStudiedurchgeführt. Das primäre Ergebnismaß bestand darin, die Änderung des systolischen Blutdrucks (SBP) und des diastolischen Blutdrucks (DBP) drei Monate lang jeden Monat zu bewerten. Von 2127 untersuchtenPatientenwurden 217 Patienten, die dieEinschlusskriterienerfüllten, randomisiert, um entwederhomöopathische Q-Potenzen plus Lebensstilmodifikation (LSM) = 116 oder Placebo + LSM=101 zuerhalten. Die LebensstilmodifikationumfasstekörperlicheAktivität und ErnährungalsTeil des Behandlungsregimes. Die AnalyseerfolgtemitBehandlungsabsicht.

Ergebnisse: Die ANOVA mitwiederholterMessungzwischen den Gruppenzeigteeinenstatistischsignifikantenunterschied (Wilk Lambda 0,85, F= 12,12, dF =213, *P*= 0,0001), sowohlbei der SBP alsauchbei der DBP, die dieindividualisierteHomöopathiebegünstigte. Der unabhängige Post-Hoc-Test zeigteeinesignifikantemittlereReduktion der SBP [mittlereDifferenz 7,12, 95% CI 4,72 bis 9,53, *P*= 0,0001] und einemittlereReduktion der DBP [mittlereDifferenz 5,76, 95% CI: 4,18 bis 7,23, *P*=0,0001] zugunsten der Homöopathie plus LSM-Gruppe. Schwefel (*n*=24), *Natrummuriaticum* (*n*=21), *Lycopodium* (*n*=16), *Nux vomica* (*n*=12) und *Phosphor* (*n*=10) waren die nützlichstenMedikamente.

Schlussfolgerung: Die individualisierteHomöopathiezusammenmitdem LSM wurdebei den Patienten, die anBluthochdruckim Stadium I leiden, alswirksamgegenüber Placebo erwiesen. WeitereStudienunterstrengenBedingungensindgerechtfertigt.

個人化順勢療法干預對原發性高血壓 I 期的影響：單盲、隨機、安慰劑對照研究

背景：在印度，高血壓是死亡和殘疾的第四大風險因素，導致160多萬人死亡。臨床個案報告、觀察性研究和隨機對照測試顯示了順勢療法藥物對高血壓的效果。**目的：**本研究的結果將爲個人化順勢療法藥物治療高血壓的有效性提供證據。**材料與方法：**2013年10月至2018年3月進行單盲隨機安慰劑對照測試。主要結果指標爲3個月內每個月收縮壓（systolic blood pressure，SBP）和舒張壓（diastolic blood pressure，DBP）的變化。在篩選出的2127名患者中，217名符合納入準則的患者被隨機分配接受順勢療法Q層級療劑加生活方式改變（Lifestyle modification，LSM）=116或安慰劑+LSM=101。生活方式改變包括運動和飲食，這作爲治療方案的一部分。分析是按意向治療。**結果：**兩組之間重複測量方差分析（ANOVA）顯示，SBP和DBP均有利於個人化順勢療法，差異有統計學意義（Wilk-Lambda 0.85，F=12.12，dF=213，p=0.0001）。事後獨立比較t測試顯示SBP（平均差異7.12，95%信賴區間4.72-9.53，p=0.0001）和DBP（平均差異5.76，95%信賴區間4.18-7.23，p=0.0001）的平均數下降顯著，有利順勢療法加LSM組。硫磺（n=24）、氯化鈉（n=21）、石松（n=16）、馬錢子（n=12）和磷（n=10）是最有用的藥物。**結論：**在高血壓I期患者中，個人化順勢療法與LSM聯合應用比安慰劑與LSM聯合應用有效。有需要在嚴格環境下作進一步的測試。