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Research Article

A SHORT-TERM PILOT STUDY INVESTIGATING THE EFFICACY OF DASH DIET IN REDUCING SYSTOLIC AND/OR DIASTOLIC BLOOD PRESSURE IN PATIENTS WITH ESSENTIAL HYPERTENSION

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ABSTRACT

Background: Hypertension, being the commonest cardiovascular disorder, poses major health challenge to the population by causing coronary artery disease, stroke, left ventricular failure etc. Despite development of several therapeutic strategies, it results in millions of death every year. The aim of this study is to investigate the role of dietary intervention in treatment of essential hypertension. *Objective:* To assess the role of DASH (Dietary Approach to Stop Hypertension) diet on elevated blood pressure in patients with essential hypertension. *Methods:* A short-term, single arm, open-label, experimental, prospective, interventional, non-randomized, non-controlled, before and after comparison pilot study was conducted over 30 participants. Out of 64 hypertensive patients assessed, 19 were excluded and 43 eligible patients were allocated to DASH diet that included restriction of sodium and fat intake, consumption of vegetables and fruits in increased amount, inclusion of fish and low fat milk in the diet. Among 43, a total of 13 were dropouts. After dietary intervention of 2 months, all the data was collected on pre-specified outcome parameters. *Results:* Analysis of data after 2 months shows statistically significant fall in systolic blood pressure (151.9±12.3 *vs.* 147.8±14.3; *P*=0.0000), pulse pressure (58.3±7.5 *vs.* 55.1±9.3; *P*=0.0004), and mean pressure (113.0±8.1 *vs.* 111.0±9.2; *P*=0.0002). However, no significant change was detected in diastolic blood pressure (i.e. 93.6±6.3 *vs.* 92.6±7.3; *P*=0.1204). *Conclusion:* DASH diet may have beneficial effects in patients of essential hypertension. But it should be confirmed only after a multi-centric randomized controlled trial involving large sample size.

Keywords: Essential hypertension, DASH diet

INTRODUCTION

Hypertension is a chronic cardiac medical condition in which the systemic arterial blood pressure is elevated and sustained to 140 over 90 or higher, measured in mm of mercury, which is likely to induce cardiovascular damage or other adverse consequences [1-3]. The diagnosis of hypertension is made when the average of two or more diastolic blood pressure (DBP) measurements on at least two subsequent visits is ≥90 mm Hg or when the average of multiple systolic blood pressure (SBP) readings on two or more subsequent visits is consistently ≥140 mm Hg and DBP <90 mm Hg [4] . It is the commonest cardiovascular disorder posing major public health challenge to the population by causing coronary artery disease (24% deaths), stroke (57% deaths), left ventricular failure etc. [5] Despite development of several therapeutic strategies, it resulted in 2.3 million deaths in 1990 and expected to be doubled by 2020 [6] . Hypertension is present in 25% (34 million) urban and 10% (31.5 million) rural subjects and a total 70% of these would be stage I hypertension [6] . Mostly 90 – 95% cases are suffering from essential hypertension.

Essential, primary or idiopathic hypertension is defined as high BP, in which secondary causes such as renovascular disease, renal failure, pheochromocytoma, aldosteronism or other causes of secondary hypertension or mendelian forms (monogenic) are not present. Essential hypertension accounts for 95% of all cases of hypertension. It is a heterogenous disorder with different patient having different causal factors that lead to high BP, such as obesity, insulin resistance, high alcohol and salt intake, aging, sedentary life style stress, low potassium and calcium intake [5, 7, 8] . Essential hypertension remains a major modifaiable risk factor for cardio-vascular diseases (CVDs) despite important advances in understanding its pathophysiology and the availability of effective treatment strategies. High BP increases the risk of CVD worldwide, and there is evidence that the problem is only getting worse.

There are more than 350,000 male hypertensive patients in India accounting for about 6% deaths annually [6] . In India, studies show increase in prevalence from 5% in 1960s to 12–15% in 1990s [6] . Prevalence of hypertension is increasing rapidly (more than 2/5th) among urban population. Prevalence in rural areas is less, about 19.04%, but increasing steadily [9] . Thus there is an urgent need to develop population-based cost-effective hypertension control strategies [6].

A study with 298 older adult patients was conducted for 12 months to evaluate the efficacy of DASH diet where 50% patients received 7 therapeutic meals/week [10]. Another clinical trial was undertaken with 459 patients for 8 wks, which shows marked decrease of BP [11]. A multicentre, randomized control trial with 412 patients was done in the US for 30 days, where sodium intake was restricted (<100mmol/day) [12] . Another clinical trial with 375 participants for 3 consecutive 30 days was done where DASH diet was advised and the outcome parameters were mean arterial pressure and urinary sodium excretion rate [13] . All the studies showed lowering of systolic and/or diastolic BP. A double-blind, randomized, cross-over study with 55 patients for 8 weeks was conducted where 24 hrs ambulatory blood pressures (ABP) was measured. DASH diet was used along with Losartan (50 mg) in African-American participants to see whether diet enhances the BP response to Losartan in hypertensive patients [14] .

OBJECTIVES

The objective of this pilot study was to assess the efficacy of DASH diet in bringing changes in elevated blood pressure of hypertensive patients.

MATERIALS & METHODS

A single arm, experimental, interventional, prospective, non-randomized, non-controlled, short-term, before and after comparison pilot study was carried out on 30 patients suffering from essential hypertension at Mahesh Bhattacharyya Homeopathic Medical College & Hospital, Government of West Bengal; Drainage Canal Road, Doomurjala, Howrah – 711104, West Bengal, India from April, 2012 to June 2012. The study protocol was completely in accordance with the Helsinki declaration on human experimentation [15] and Good Clinical Practice (GCP) [16] . Clearance was obtained from the ethical committee of the institution. Consequently, before recruitment, each participant was explained verbally about the study with the help of Patient Information Sheet and thereafter a written consent was obtained from them. However, they were free to withdraw from the study at any point of time. A structured, specially

designed case record sheet and observational checklist for each patient was used to collect and keep record of the data. Data was extracted from the reports directly and independently in the end and were subjected to statistical analysis. Hypertensive status of the study population was initially confirmed after measuring the blood pressure twice on two separate occasions in two contra-lateral arms in supine position during rest. The blood pressures were measured using a mercury sphygmomanometer of standard cuff size all throughout the study.

Study inclusion criteria consisted of patients (1) suffering from essential hypertension (pre-hypertensives: SBP 120-139 mm Hg, DBP 80-89 mm Hg; stage I hypertensives: SBP 140-159 mm Hg, DBP 90-99 mm Hg; and stage II hypertensives: SBP ≥160 mm Hg, DBP ≥100 mm Hg) [17] ; (2) aged 18-65 years; (3) of both sexes; (4) with at least 6 months history of suffering; (5) history, examination and routine investigations revealed no evidence of obvious secondary causes; and (6) giving written informed consent.

Cases were considered excluded where (1) diagnosis was uncertain or findings from the history; (2) physical examination or routine investigations arouse suspicion of a secondary cause for hypertension; (3) diagnosed (provisional/confirmatory) cases of secondary hypertension; (4) any kind of continued anti-hypertensive therapy for at least 6 months; (5) cases of malignant hypertension (SBP>200 mm Hg and DBP>140 mm Hg) [17] with clinical features of hypertensive encephalopathy (severe headache, vomiting, visual disturbances, transient paralyses, convulsion, stupor and coma), cardiac decompensation (heart failure) and rapidly declining renal function (oliguria) [17] ; (6) patients suffering from isolated systolic hypertension (SBP≥140 and/or DBP<90 mm of Hg) as mostly found in elderly patients [17] ; (7) patients with labile (sometimes, but not always, arterial pressure in the hypertensive range, i.e. not sustained) hypertension [17] ; (8) patients not strictly conforming to the criteria given by Joint National Committee-7 [17] (although variation of ±10 mm Hg in SBP and/or DBP was considered); (9) presence of severe concomitant disease(s); (10) failure of vital organs/systems, e.g. heart, lungs, liver, kidney etc. as detected clinically; (11) presence of any systemic (endocrinal / cardiovascular / locomotor / neurological / hematological etc.) or infectious disease(s) already diagnosed or detected clinically or by routine laboratory investigations; (12) immune-compromised patients; (13) diagnosed cases of developmental defects or congenital abnormalities; (14) patients with pregnancy, breast feeding and likelihood of pregnancy; (15) history of drug or alcohol abuse; (16) inability to comply with the study protocol, including psychiatric diseases, and (17) if any exclusion criteria develop during the trial.

The DASH diet plan adopted was an overall dietary pattern including variety of food components – increased amount of fruits, vegetables and whole grains, low fat dairy products, less amount of saturated fat, refined carbohydrates and sodium, and avoidance of tobacco and alcohol. The patients were advised to undertake regular physical activities. Diet was planned keeping in mind the socio-economic status and level of education of the patients. Before appearance of the concept of DASH diet, the only non-drug options for managing hypertension were salt restriction, weight control and moderation in alcohol, but had much limitation [10] . The details of DASH diet plan is given below. [18, 19] (Table 1)

Table 1: Dash Diet Plan

Type Of Food	No. Of servings for 1600 - 3100 kcal diet	Servings on a 2000 kcal diet
Grains and grain products (include at least 3 whole grain foods each day)	6 – 12	7 - 8
Fruits	4 – 6	4 - 5
Vegetables	4 – 6	4 - 5
Low fat or non fat dairy foods	2 – 4	2 - 3
Lean meats, fish, poultry	1.5 - 2.5	2 or less
Nuts, seeds, and legumes	3 - 6 per week	4 - 5 per week
Fats and sweets	2 – 4	limited

Outcome measures were changes in blood pressure at timeline of 2 months. 'Lowering' was defined as fall of BP by at least 10 mm Hg. Study end-point was lowering of BP following intervention. Primary safety end-point was any adverse event during study in any of the groups. The stopping guidelines were marked deterioration in either group of health condition and/or constant increase in BP among subjects, constant progress of disease with appearance of complications, and adverse events (if any).

Consequent study variable was clinical improvement in signs and symptoms of hypertension. Independent variables were age, gender, occupation, height, weight, body mass index, waist-hip ratio, family history, risk factors (including stress, sedentary habit, rich food, smoking, alcoholism), life-style modifications, e.g. regular exercises etc.

RESULTS

Out of 64 hypertensive patients assessed by specified outcome parameters, 19 were excluded after screening by specified eligibility criteria, and 43 patients were found eligible to be enrolled in the trial. All of them were allocated to DASH diet. After 2 months of dietary intervention, 13 were drop-outs, and 30 patients were regular. Outcome measures were reassessed and analyzed after timeline of 2 months.

Baseline demographic findings were as follows: Hypertension was mostly prevalent in the age group of 36-55 years (n=16, 53.3%). Among the participants, few had family history of hypertension (n=9, 30%). Most of the patients were urban (n=24, 80%). Stress was present in 18 (60%) and rich food habit in 20 (66.6%) participants. High salt intake habit, smoking habit and alcoholism were present in 14 (46.6%), 10 (33.3%), and 8 (26.6%) participants respectively. (Table 2)

Table 2: Baseline Demographic Characteristics

Age	
18 – 35 yrs	4 (13.3%)
36 – 55 yrs	16 (53.3%)
56 – 75 yrs	10 (33.3%)
M : F	14 : 16
Weight (kg)	59.13 ± 4.84
Height (cm)	165.29 ± 8.13
BMI	21.71 ± 2.09
F/ H of Hypertension	9 (30%)
Marital Status	
Married	22 (73.3%)
Unmarried	8 (26.6%)
Habitat	
Urban	24 (80%)
Rural	6 (20%)
Risk factors:	
Stress	18 (60%)
Rich Food	20 (66.6%)
High salt intake	14 (46.6%)
Smoking	10 (33.3%)
Alcohol	8 (26.6%)

Table 3: Baseline Clinical Indices

Respiratory Rate	19.9 ± 1.47
Heart Rate	76.8 ± 4.72
Hypertension Stages :	
Pre-hypertension	6(20%)
Stage I	16 (53.3%)
Stage II	8(26.6%)
Co- morbid Conditions	

Hyperlipidemia	5 (16.6%)
Hyperglycemia	8 (26.6%)
ECG: Ischemic Heart Disease	3 (10%)

Table 4: Baseline Pathological & Biochemical Indices

Hemoglobin %	13.13 ± 1.45
Total WBC count	8708 ± 1347.41
ESR	44.73 ± 11.17
Fasting sugar	108.36 ± 26.24
PP Sugar	144.46 ± 24.47
Blood urea	26.16 ± 6.73
Serum Creatinine	0.96 ± 0.15
Total Cholesterol	214.9 ± 28.9
HDL	58.4 ± 8.8
LDL	127.3 ± 22.1
VLDL	29.2 ± 11.1
Triglyceride	184.5 ± 70.1

Baseline clinical indices were as follows: 16 (53.3%) participants were in stage I, 8 (26.6%) in stage II and 6 (20%) were in pre-hypertensive stage. (Table 3)

Baseline pathological and biochemical data showed that hyperlipidemia was present in 5 (16.6%) and hyperglycemia in 8 (26.6%) subjects. (Table 4)

ECG showed ischemic heart disease in 3 (10%) cases.

After dietary intervention of 2 months, systolic BP (SBP) was lowered in 23 (76.6%) participants, diastolic BP (DBP) in 20 (66.6%) participants, pulse pressure (PP) in 23 (76.6%) participants, and mean blood pressure (MBP) in 21 (70%) participants. (Table 5, Chart 1)

Table 5: Changes in Bp after 2 Months

Serial no.	Outcome Parameters	Lowered; N (%)	Not lowered; N (%)
1	SBP	23 (76.6%)	7 (23.3%)
2	DBP	20 (66.6%)	10 (33.3%)
3	PP	23 (76.6%)	7 (23.3%)
4	MBP	21 (70%)	9 (30%)

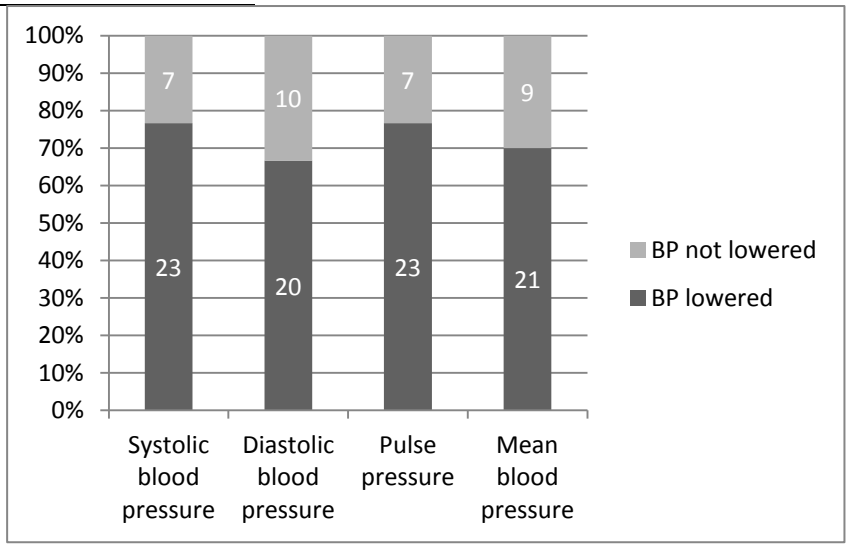

Chart 1: Bar Diagram Showing Changes in Bp after 2 Months

Individual changes in each outcome parameter were as follows: paired *t*-test comparing before and after measurement of SBP (159.9±12.3 *vs.* 147.8±14.3; t_{29}=6.31; *P*=0.00000068), PP (58.3±7.5 *vs.* 55.1±9.3; t_{29}=3.96; *P*=0.00044592), and MBP (113.0±8.1 *vs.* 111.0±9.2; t_{29}=4.23; *P*=0.00021355) showed statistically highly significant result; however, changes in DBP (93.6±6.3 *vs.* 92.6±7.3; t_{29} =1.60; *P*=0.12043793) was statistically non-significant. (Table 6)

Table 6: Before & After Comparison of BP

Outcome parameters	Before (m±sd)	After (m±sd)	Paired *t* test: t_{29}	*P* value; Significance*
SBP	151.9 ± 12.3	147.8 ± 14.3	6.31	0.00000068; hs
DBP	93.6 ± 6.3	92.6 ± 7.3	1.60	0.12043793; ns
PP	58.3 ± 7.5	55.1 ± 9.3	3.96	0.00044592; hs
MBP	113.0 ± 8.1	111.0 ± 9.2	4.23	0.00021355; hs

*** P<0.05 considered as statistically significant; ns = not significant; hs = highly significant**

DISCUSSION & CONCLUSION

This study was implemented on both sexes, on a wide range of age group with varied symptom picture. The result showed a specified range of improvement in BP. Therefore, it can be concluded that dietary modification might have a significant role in controlling hypertension and DASH diet could be implemented in treatment of hypertension. Though this short-term pilot study showed statistically significant lowering in SBP, PP, and MBP, lowering of DBP was non-significant. But to reach a definite conclusion, randomized controlled trials (RCTs) on a larger sample size and longer duration in multicentre fashion should be replicated. Funding for the trial was done by Mahesh Bhattacharyya Homeopathic Medical College & Hospital, Government of West Bengal, Howrah, West Bengal, India. The funder had no role to play in determining the study design, data collection and analysis, decision to publish, or preparation of manuscript.

TRIAL IDENTIFIERS

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2. Universal Trial Number: U1111-1130-9341
3. Protocol Identification Number: 256/1/MBHMCH/CH/ADM /11/12

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