

Research Article

Study of the efficacy of Blood pressure management program in patients with known history of Hypertension for Pune Region: A Retrospective Study

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ABSTRACT:

Context: Hypertension (HTN) has been gaining more importance, due rising apprehension of its causative function in cardiovascular complications like stroke, coronary artery disease. Blood Pressure Management Program (BPMP) is a combination of Panchakarma and allied therapies and herbal drug therapy.

Aims: This study was conducted to evaluate the effect of BPMP on systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), body mass index (BMI) and dependency on conventional therapy in HTN Patients.

Settings and Design: This retrospective study was conducted in July 2017, wherein the data of HTN patients who attended out-patient departments (OPDs) at *Madhavbaug* clinics in Pune, Maharashtra, India were identified.

Methods and Material: Data of patients who were administered BPMP (60-75 minutes) with minimum 6 sittings over 90 days (± 15 days) were considered. Variables were compared between day 1 and day 90 of BPMP.

Statistical analysis used: Data were pooled and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyse the data.

Results: Out of 30 enrolled patients, 28 were males while 2 females. BPMP showed significant improvement in SBP by 19.22% (from 144.73 ± 15.54 to 121.4 ± 14.34 ; $p < 0.001$), DBP by 14.34% (from 86.06 ± 9.94 to 75.26 ± 6.35 , $p < 0.001$), MAP by 17.31% (from 105.82 ± 11.20 to 90.20 ± 6.40 , $p < 0.001$). BMI (26.36 ± 3.38 kg/m² to 25.59 ± 3.07 kg/m²), also showed significant reduction. Dependency on concomitant medicines was reduced, with number of patients on no concomitant medicines increasing from 13% to 30%.

Conclusion: BPMP can be an effective option for management of HTN patients, along with conventional allopathic medications.

KEY WORDS: Blood pressure management program, BPMP, Panchakarma, Hypertension, Blood pressure, Systolic, Diastolic, Mean arterial pressure, Alternative medicine.

INTRODUCTION:

Currently, both developed and developing countries are facing the menace of non-communicable diseases (NCDs), which are rising to epidemic levels. Around 70% of all global deaths are contributed by NCDs, which comes out to nearly 40 million deaths. Cardiovascular diseases (CVDs), cancers, diabetes and chronic respiratory diseases mainly comprise these NCDs.^[1] Amongst these, CVDs in the form of stroke, hypertension (HTN) and coronary artery disease are the major culprit, accounting for 45% of NCDs, followed by chronic respiratory disorders in 22%, cancers in 12%, diabetes in 3% of the NCDs.^[2]

Recently, HTN has been gaining more importance, due rising apprehension of its causative function in cardiovascular complications like stroke, coronary artery disease. Being the most common CVD, it acts as major hurdle in optimal public healthcare, especially in developing countries.

HTN is estimated to be responsible for 20-50% of all the deaths due to CVD.^[3] This is corroborated by the fact that, it is one of the commonest culprit for development of CVD.^[2] Although there are multiple guidelines for treatment of HTN with plethora of

antihypertensive medications, the prevalence of HTN in urban and rural population in India has escalated from 2 to 25% and 2 to 15%, respectively.^[4] Directorate General of Health Sciences, government of India have estimated that this prevalence will rise to 159.46/1000 population in 2020.^[5] This scenario is further complicated by findings of one Indian study that patient adherence to antihypertensive medication was only 25-50%.^[6] This is reflected in poor blood pressure (BP) control and hence the anticipated rise in complications.

Due to role of multiple factors like age, numerous concomitant medications, comorbidities, age, mental depression associated with the diagnosis of disease; management of HTN has become complicated. Hence, it is need of the hour to search for newer therapeutic options which can diminish the fright and anxiety associated with disease and enhance quality of life.^[6] The therapeutic role of antihypertensive drugs is due to BP lowering activity.^[7] Similar action has been found in numerous herbal drugs, which serve as interesting potential targets for newer therapeutic options for treatment of HTN.^[8, 9, 10, 11, 12, 13, 14]

Ayurveda practice of Medicine suggests the use of traditional drugs in acute phase of disease, while adding "Panchakarma" therapy (internal body purification through multi-step process) in the chronic phase of disease. Blood Pressure Management Program (BPMP) is a combination of Panchakarma and allied therapies and herbal drug therapy. The techniques used in Panchakarma under this program are Swedana i.e. Passive heat therapy, Snehana i.e. Oleation and Shirodhara i.e. gentle pouring of liquids on forehead. These techniques are

widely recognised for their detoxification function.^[15, 16] It has been found in a study that HTN is associated with anxiety, depression, reduced feeling of personal strength, reduced quality of life, etc.^[17] Hence, we planned a retrospective study to investigate the efficacy of BPMP, as add-on therapy to standard antihypertensive therapy in patients of HTN. We evaluated the effect of BPMP on systolic BP (SBP), diastolic BP (DBP), mean arterial pressure (MAP), body mass index (BMI), and dependency of these hypertensive patients on standard conventional medications.

Subjects and Methods:

This was a retrospective study conducted between July 2017, wherein we identified the data of patients suffering from HTN (SBP 130-170 mm Hg, DBP 80-110 mm Hg) of either gender and any age, and who had attended the out-patient departments (OPDs) Madhavbaug clinics in Pune, Maharashtra, India. The data of patients who had been administered BPMP with minimum 6 sittings over a span of 90 days (\pm 15 days) were considered for the study. Cases were identified, and data was assessed from the records of Madhavbaug clinics in Maharashtra. The selection was based upon the availability of complete relevant baseline data (day 1 of BPMP) and final day data (day 90 of BPMP) of the patients. The information about prescribed concomitant medicines or comorbidities, if any, was also noted down.

The BPMP is a 3-step procedure which was performed on the patients of HTN after a light breakfast. One sitting of the procedure took 65-75 minutes, as described in table 1.^[16,18]

Table No. 1: Study Treatment: Blood pressure management program (HTN Kit)

Step of HFRT	Type of Therapy	Herbs used for therapy	Duration of Therapy
Snehana	Massage or external oleation (centripetal upper strokes directed towards heart)	100 ml Vatek oil <i>V. negundo</i> [100 ml extract processed in sesame oil]	30-35 minutes
Swedana	Passive heat therapy	<i>Dashmoola</i> (group of ten herbal roots) with steam at \leq 40 degrees Celsius)	10-15 minutes + 3-4 minutes of relaxation after procedure
Shirodhara	Decoction dripping therapy from a height of 7-8 cm	100 ml of Luke-warm <i>Jatamansi</i> decoction	30 minutes

On day 1 of BPMP, the patients had undergone BP measurement as per AHA 2017 guidelines.^[19] Three readings were taken few minutes apart and average of the 3 was considered for analysis (baseline reading). This process was repeated on day 90 of BPMP to calculate % change from baseline reading. The BMI for day 1 and day 90 of the patients was calculated by checking the weight and the height from the medical

data sheets of patients and using the formula: $weight \text{ in kilograms} / (height \text{ in meters})^2$. The dependency on standard medication was calculated both on day 1 and day 90 of BPMP as the percentage of patients out of the total enrolled ones who required a conventional allopathic therapeutic agent during the study period of 90 days.

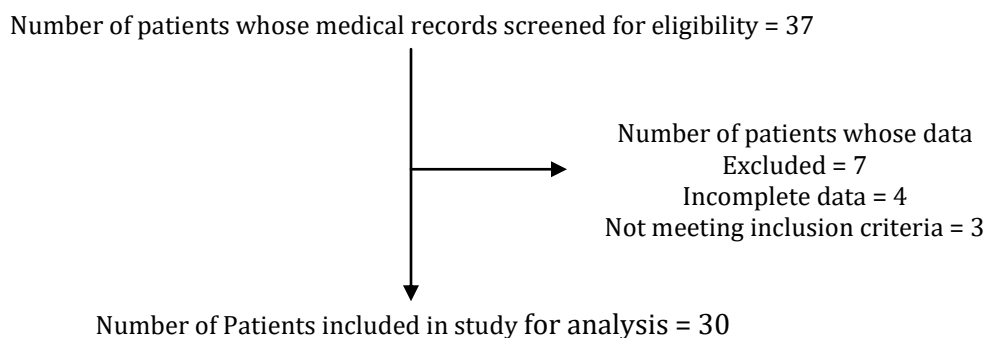
Statistical analysis:

Data were pooled and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyse the data. Categorical data were represented in the numeric form and continuous data were presented as the Mean \pm SD. Paired t-test was used to assess the difference between baseline values and 90th day after treatment. Histogram were used to represent graphs.

RESULTS:**Study population:**

A total of 37 patients' data was screened for inclusion in the study. However, based on the availability of data (Day 1 and Day 90) and the inclusion criteria, 30 patients were selected, and their data was considered for analysis (Figure 1). The baseline characteristics of these patients are shown in table 2.

Baseline characteristics of the study participants were as given in Table 2. The study comprised of 30 participants with striking male predominance (93.3 %). The mean age of the study participants was 49.27 \pm 15.03 years. Most of the patients with history of hypertension had Diabetes Mellitus (16.67%) and Obesity (10%).

Figure No. 1: Patient Enrolment Flow Chart**Table No. 2: Baseline characteristics of the study subjects (n= 30)**

Variable	N=30
Age	49.27 \pm 15.03
Gender	
Male	28 (93.3 %)
Female	2 (6.7 %)
Diagnosis History	
Obesity	3 (10 %)
DM	5 (16.67 %)
CVE	1 (3.33 %)
RHD	1 (3.33 %)
CHF	1 (3.33 %)

Abbr.: DM, Diabetes Mellitus; RHD, Rheumatic Heart Disease; CVE, cardiovascular event; CHF, Congestive Heart Failure.

Table No. 3: Effect of BPMP treatment on improvement of various body parameters in study patients

Patients	Variable	Baseline (Mean \pm SD)	After 90 days (Mean \pm SD)	Reduction value	% improvement	P-value
All (n=30)	SBP	144.73 \pm 15.54	121.4 \pm 14.34	23.33	19.22	< 0.001*
	DBP	86.06 \pm 9.94	75.26 \pm 6.35	10.8	14.34	< 0.001*
	MAP	105.82 \pm 11.20	90.20 \pm 6.40	15.61	17.31	< 0.001*
	BMI	26.36 \pm 3.38	25.59 \pm 3.07	0.76	2.97	< 0.001*

* indicates high statistically significant improvement

The comparison of clinical parameters between baseline values and after 90th day were as given in Table 3. The Body Mass Index was statistically highly significantly reduced ($P < 0.001$), systolic blood pressure ($P < 0.001$), diastolic blood pressure

($P < 0.001$) and mean arterial pressure ($P < 0.001$) were improved and significantly reduced to their normal range after 90 days of treatment. The graphical representation of the same is represented in Figure 2 and 3.

Figure No. 2: Comparison of Body Mass Index at the 1st day and after 90 days of the treatment

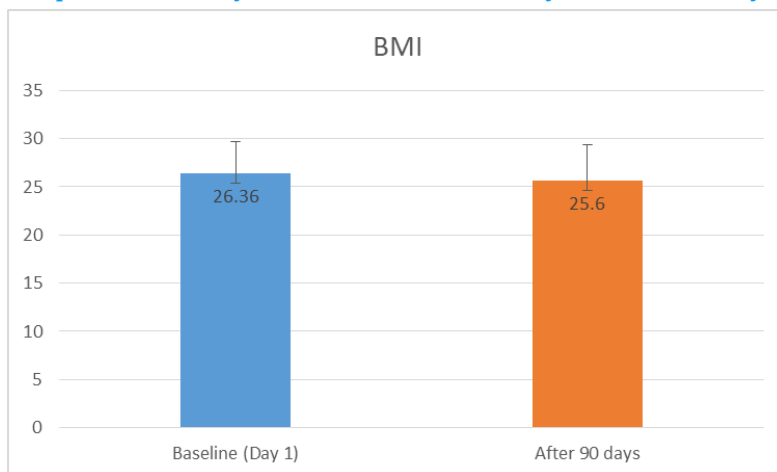
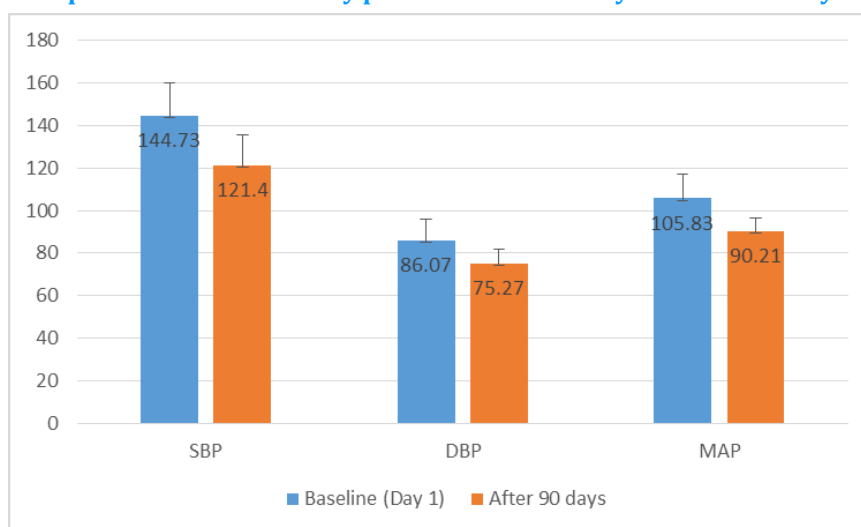


Figure No. 3: Comparison of various body parameters at 1st day and after 90 days of the treatment.



Consumption of allopathic medicines on days 1 and 90 were as shown in Table 4. Most of the congestive heart failure participants were treated with angiotensin II receptor blockers (50%), calcium channel blockers (36.67%), beta blockers (30%), nonsteroidal anti-inflammatory drugs and statin (20%) each. While, at the end of 90 days, the participants dependent on angiotensin II receptor blockers

(33.33%), calcium channel blockers (26.67%), beta blockers (23.33%), nonsteroidal anti-inflammatory drugs (6.63%) and statin (3.33%) were reduced. The participants with the absence of medication history (30%) were also improved after 90 days. The graphical representation of consumption of allopathic medicines on days 1 and 90 is depicted in Figure 4.

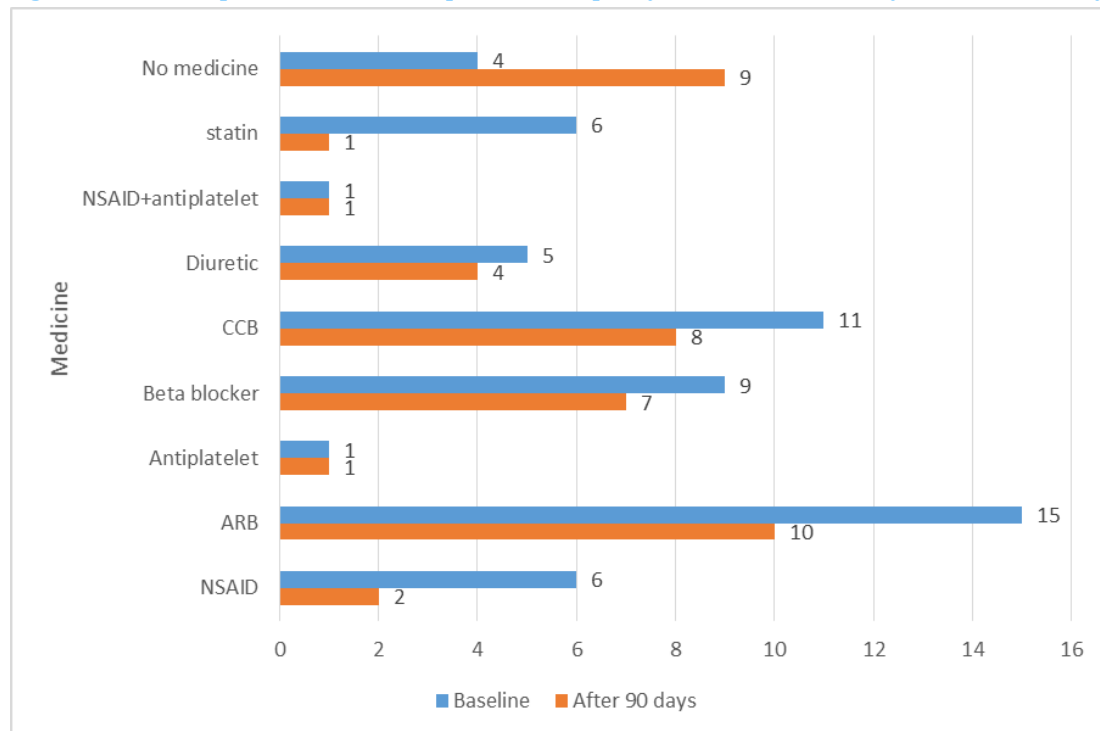
Table No. 4: Comparison of consumption of allopathy medicines at day 1 and after 90 days

Medicine	Baseline n(%)	After 90 days n(%)
No medicine	4 (13.33)	9 (30)
Statin	6 (20)	1 (3.33)
NSAID+ antiplatelet	1 (3.33)	1 (3.33)
Diuretic	5 (16.67)	4 (13.33)
CCB	11 (36.67)	8 (26.67)
Beta blocker	9 (30)	7 (23.33)
Antiplatelet	1 (3.33)	1 (3.33)
ARB	15 (50)	10 (33.33)
NSAID	6 (20)	2 (6.67)

Abbr.: CCB, Calcium channel blockers; ARB, Angiotensin II receptor blockers; NSAID, Nonsteroidal anti-inflammatory drugs

Dependency of medicines was reduced post treatment of 90 days in all medicines and highly reduced in ARB, Beta Blocker, CCB. No change was found in intake of NSAID + antiplatelet drugs.

Figure No. 4: Comparison of consumption of allopathy medicine at 1st day and after 90 days



DISCUSSION:

Although there are numerous treatment choices available for treatment of HTN management, it is still one of the commonest culprit of morbidity and mortality globally. Thus, it is the need of the hour to explore novel therapeutic alternatives for the management of HTN. Traditional class of antihypertensive drugs have therapeutic benefit in HTN by lowering BP. Similar property has been found in various herbal drugs, thus making Ayurveda a potent and viable alternative to standard therapy in the management of HTN. Panchkarma is administered as add on therapy for HTN management, by Ayurveda physicians.^[20] BPMP combines Panchakarma with allied therapies for the same. BPMP acts by increased release of serotonin and production of acetylcholine, which helps in reducing the BP, along with relaxation through supine position during the procedure.^[15] In pursuit of analysing the efficacy of BPMP in HTN, we found that it showed significant (very high statistical significance) improvement in SBP, DBP, MAP at 90th day of whole procedure. It also led to significant reduction in BMI at the end of procedure. Most importantly, we found that BPMP noticeably reduced patient's dependency on standard allopathic medication at the end of 90 days of therapy.

MAP is the static component of BP, which is function of heart rate, vascular resistance, ventricular contractility and elasticity of blood vessel over a period of time.^[21, 22] MAP was significantly reduced in

the present study, thus indicating optimal BP control. Importance of MAP lies in the fact that, it is independent predictor of mortality and morbidity due to CVD in patients with HTN. This has been corroborated in a prospective study done on hypertensive patients, that cardiovascular complications like stroke was significantly low in patients with optimal reduction in MAP.^[23] Hence, significant reduction in MAP after BPMP in our study indicates favourable prognosis in cardiovascular morbidity.

High BMI is considered to be one of the major risk factor for development of HTN in normal subjects. It signifies sedentary lifestyle and obesity.^[24] Also, it has been found that BMI is positively associated with increased SBP, DBP, morbidity and mortality in HTN, type II diabetes mellitus, CVD and other chronic diseases.^[25] Uncontrolled HTN frequently leads to development of congestive heart failure (CHF), hence various management plans across the globe have targeted sustained BP control in patients of HTN, to prevent the occurrence of CHF.^[26] In the present study, BPMP significantly reduced SBP, DBP, MAP, BMI. Thus BPMP can play significant role in preventing development of CHF in patients of HTN, thereby reducing morbidity and mortality.

In developing economy like India, the dependency of hypertensive patients on allopathic medicines

escalates the cost of healthcare to troublesome levels. Plethora of adverse effects of these drugs complicates the scenario, furthermore.^[27] Keeping this in mind, we analysed changes in patient's dependency on allopathic medication by BPMP. There was significant reduction in dependency on almost all the class of antihypertensive drugs, at the end of 90 days, with increase in number of patients who went off the allopathic drugs.

The findings of the present study can be generalised only after comparison with findings of other such studies with probably prospective design, larger sample size, and more follow up period. This will help in identifying long term outcomes of BPMP in the management of HTN.

CONCLUSION:

There was significant improvement in all parameters of blood pressure control, after BPMP. Also, there was substantive attenuation in patient's dependency on allopathic medications. Significant reduction in BMI, coupled with reduction in SBP, DBP, MAP after BPMP indicates better prognosis in patients with HTN. Hence, BPMP may serve as potent and viable alternative to standard allopathic treatment of HTN.

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