

To Study Efficacy of Blood Pressure Management Program (BPMP) in Male Elderly Patients with Known Case of Hypertension: An Observational Study

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Abstract: Around 20% of the population are in prehypertension stage, and nearly 40% of the adult population from Hypertension (HTN). Blood Pressure Management Program (BPMP) is an Ayurvedic treatment strategy using *Panchakarma*. 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 elderly male patients of HTN. This observational study was conducted from January 2017 to February 2018, wherein the data of HTN patients who attended *Madhavbaug clinics in Maharashtra, India* were identified. 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. Out of 29 enrolled patients, 24 were finally selected for analysis. BPMP showed significant improvement in SBP by 24.66 (from 150.67 ± 12.97 to 126 ± 13.01 ; $p < 0.001$), DBP by 10.8 (from 87.7917 ± 7.72 to 76.917 ± 7.59 , $p < 0.001$), MAP by 15.4 (from 108.75 ± 7.14 to 93.25 ± 8.72 , $p < 0.001$). BMI (25.7275 ± 2.63 kg/m² to 24.91 ± 2.32 kg/m²), also showed significant reduction. Dependency on concomitant medicines was reduced, with the number of patients on no concomitant medicines increasing from 19% to 29%. BPMP can serve as an effective therapeutic regiment to combat HTN in elderly male patients.

Keywords: Blood Pressure Management Program, BPMP, Panchakarma, Hypertension, Systolic, Diastolic, Mean Arterial Pressure, Elderly Male

1. Introduction

Hypertension (HTN) has assumed epidemic level prevalence rates in past few decades. Around 20% of the population are in prehypertension stage, and nearly 40% of the adult population from HTN [1]. Same scenario is reflected in mortality rates due to HTN, which was estimated to 10 million deaths in 2010. It is estimated that HTN is the main culprit of stroke, heart failure and other heart diseases

in half of the patients [2]. Due to increased awareness in developed nations, prevalence of HTN has not increased in past few years, but it has shown consistent rise in developing countries like India [3]. Not only less accessible healthcare delivery system, but also less diagnosis rates also add to increased burden of the disease in developing countries. Uncontrolled/poorly controlled HTN frequently leads to fatal and nonfatal complications like haemorrhagic stroke, myocardial infarction, renal failure, etc [4]. Apart from these,

HTN contributes to a major chunk of financial burden of health expenses on a national scale, since it leads to loss of earnings, disability, premature mortality, etc [5].

Conventionally, HTN is diagnosed by systolic blood pressure >140mm Hg (SBP) and diastolic BP (DBP) > 100mm Hg [6]. Variety of drugs are available for treatment of HTN, which include beta blockers, angiotensin converting enzyme inhibitors (ACEIs), diuretics, calcium channel blockers, etc [7]. But these drugs frequently give rise to number of adverse effects like hypotension, worsening of asthma, heart block, dizziness, headache, hallucinations, etc [8]. Moreover, the management of HTN is complex due to vitality of consideration of numerous factors like comorbidities, age. Despite the availability of all the working guidelines for management of HTN and extensive lists of conventional medicines, HTN is continuously creating havoc. Therefore, we need some form of effective therapy which can ameliorate ill effects of HTN and also overcome shortcomings of conventional therapy, which can increase the quality of life in hypertensive patients [9].

Similar to the action of conventional medicines, many herbal drugs have been found to be effective in reducing BP in HTN [10, 11]. BP Management Program (BPMP) is an Ayurvedic antihypertensive management program which combines *Panchakarma* with Diet therapy in patients of HTN. Following detoxifying procedures are used in BPMP [12, 13]:

- I. *Snehana*/External Massage Therapy,
- II. *Swedana*/ Passive Heat Therapy,
- III. *Shirodhara*/Dripping Oil on Forehead.

Given the BP reducing action of herbal drugs and beneficial effects of *Panchakarma* in HTN, we planned this observational study to analyze the effect of BPMP on SBP, DBP, mean arterial pressure (MAP), body mass index (BMI), dependency of elderly male hypertensive patients on conventional antihypertensive medicines at the end of the study period.

2. Subjects and Methods

2.1. Study Design

Retrospective record based Observational study

2.2. Sample Size

Total Number of Subjects: 24

2.3. A Number of Screened Patients

Total 29 hypertensive elderly patients were enrolled in HTN program. Out of which we have observed the efficacy of BPMP in 24 patients' data which were elderly (age = ≥ 60 years) male patients.

2.4. Duration of Study

January 2017 to February 2018

2.5. Study Site

Madhavbaug Clinics from all over Maharashtra

2.6. Inclusion Criteria

We have observed the efficacy of HTN program in:

- i. Elderly male patients = Age ≥ 60 years
- ii. Patient with past history of HTN.

2.7. Methodology

Methodology adopted for the present study is depicted in figure 1.

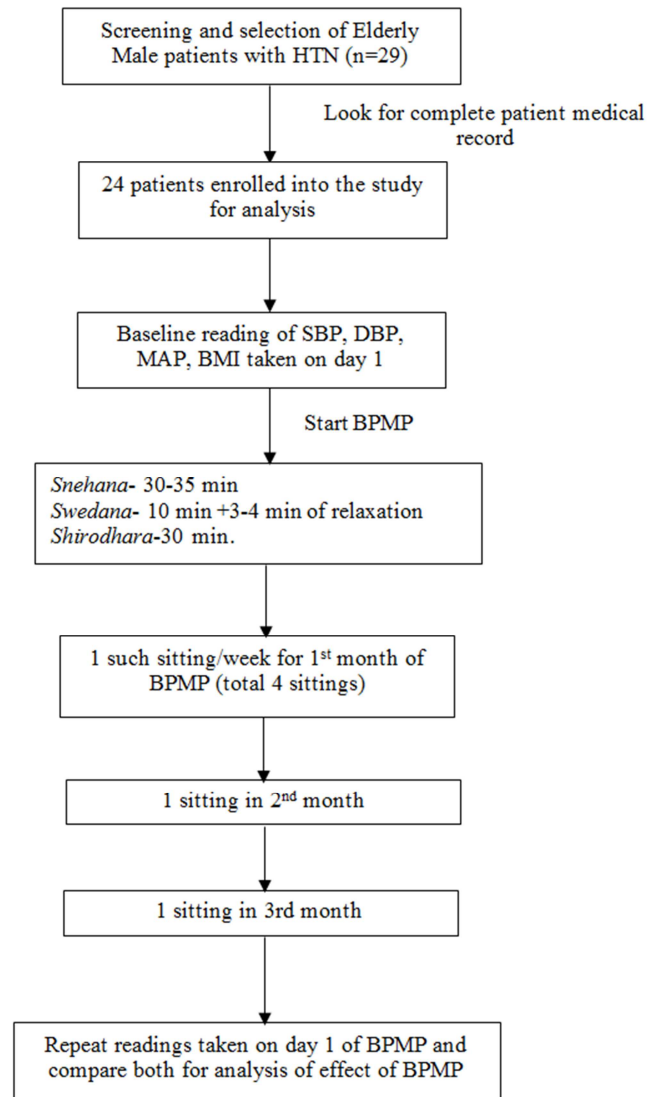


Figure 1. Methodology adopted for the present study.

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 [12, 13].

Table 1. Study Treatment: Blood pressure management program (HTN Kit).

Step of BPMP	Type of Therapy	Herbs used for therapy	Time Duration of Therapy
Snehana	Massage or external oleation (centripetal upper strokes directed towards heart)	It is 2% Rose flavoured Sesame oil.	30-35 minutes
Swedana	Passive heat therapy	Dashmoola (group of ten herbal roots) with steam at ≤ 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 Nardostachys jatamansi decoction	30 minutes

On day 1 of BPMP, the patients had undergone BP measurement as per JNC VIII guidelines [14]. 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 the 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.

2.8. Statistical Analysis

Data were pooled and coded in Microsoft Excel spreadsheet Paired T test were used to test statistical significance for Primary End Points - Reduction in Blood pressure (SBP and DBP) and Secondary End Point Reduction in BMI and MAP after 90-day follow-up as compared to day 1 (baseline). We used R (Version 3.5.0) software and excel to analyse the data.

3. Results

Study population:

A total of 29 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, 24 patients were

selected, and their data was considered for analysis. The baseline characteristics of these patients are shown in table 2.

Table 2. Baseline characteristics of the study subjects (n= 24).

Patients	24	
Age (Years)	66.5 \pm 7.86	
	Day 1	Day 90
SBP	150.67 \pm 12.97	126 \pm 13.01
DBP	87.7917 \pm 7.72	76.917 \pm 7.59
BMI	25.7275 \pm 2.63	24.91 \pm 2.32
MAP	108.75 \pm 7.14	93.25 \pm 8.72

SBP, Systolic blood pressure; DBP, Diastolic BP; BMI, Body Mass Index; MAP, Mean Arterial Pressure.

Note: Categorical data were expressed in terms of percentage and continuous data were expressed as Mean \pm SD

Consumption of allopathic medicines on days 1 and 90 were as shown in Table 3. The participants dependent on allopathic medicines were reduced after 90 days. The participants on medications such as angiotensin II receptor blockers (ARBs), beta-blockers, calcium channel blockers (CCBs) were notably condensed after 90 days. The graphical representation of consumption of allopathic medicines on days 1 and 90 is depicted in Figure 2.

Comparison of clinical parameters between baseline values and 90th day were shown in Table 4. Mean Arterial Pressure (MAP) ($P < 0.001$), Body Mass Index ($P < 0.001$), Systolic Blood Pressure (SBP) ($P < 0.001$), Diastolic Blood Pressure ($P < 0.001$) were reduced and significantly improved after the treatment, i.e., after 90 days. The graphical representation of the same is represented in Figure 3.

Table 3. Consumption of allopathic medicines on days 1 and 90.

	Baseline	Percentage	After 90 days	Percentage (%)
NSAID	2	9.52	1	4.76
ARB	11	52.38	7	33.33
Antiplatelet	1	4.76	0	0.00
Beta blocker	8	38.10	3	14.29
CCB	6	28.57	5	23.81
Statin	2	9.52	0	0.00
ACE	2	9.52	1	4.76
Thiazide Diuretic	6	28.57	4	19.05
Biguanide	3	14.29	3	14.29
Sulfonylurea	2	9.52	2	9.52
No Medicine	4	19.05	6	28.57
NSAID + antiplatelet	1	4.76	0	0.00

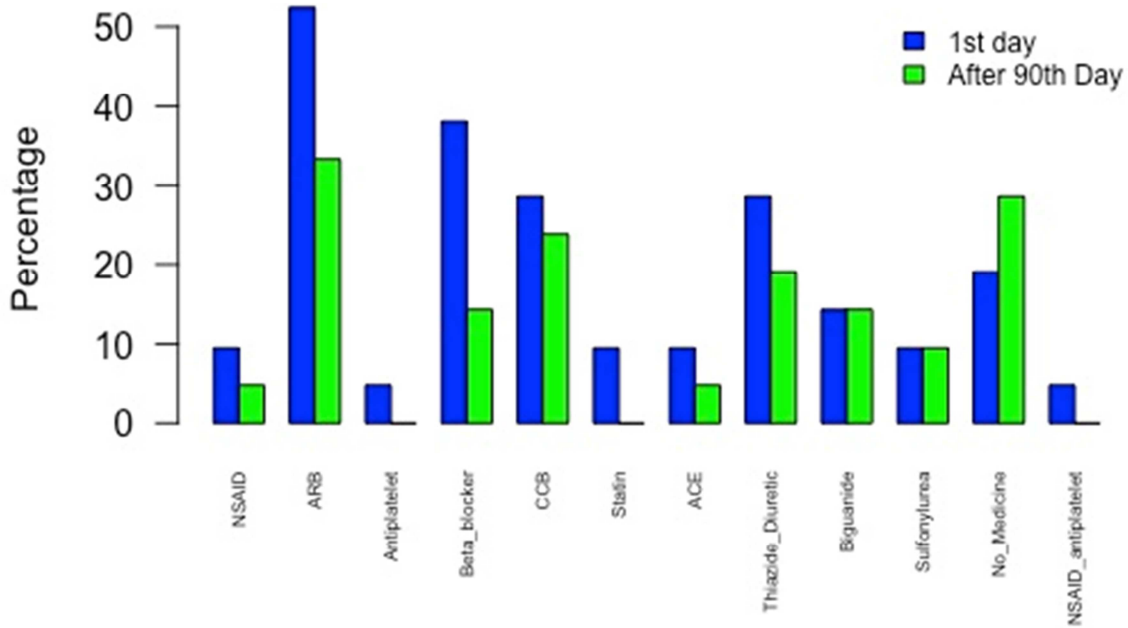


Figure 2. Consumption of allopathy medicines at days 1 and 90 days (n= 24).

Table 4. Comparison of clinical parameters between baseline values and 90th day.

Variable (n=24)	Baseline (day 1)	After 90 days	Difference	P-value
SBP	150.67 ±12.97	126 ± 13.01	24.66667	<0.001***
DBP	87.7917 ±7.72	76.917 ±7.59	10.875	<0.001***
BMI	25.7275 ±2.63	24.91 ±2.32	0.821667	<0.001***
MAP	108.75 ±7.14	93.25 ±8.72	15.49736	<0.001***

***Highly significant; MAP, Body Mass Index; SBP, DBP

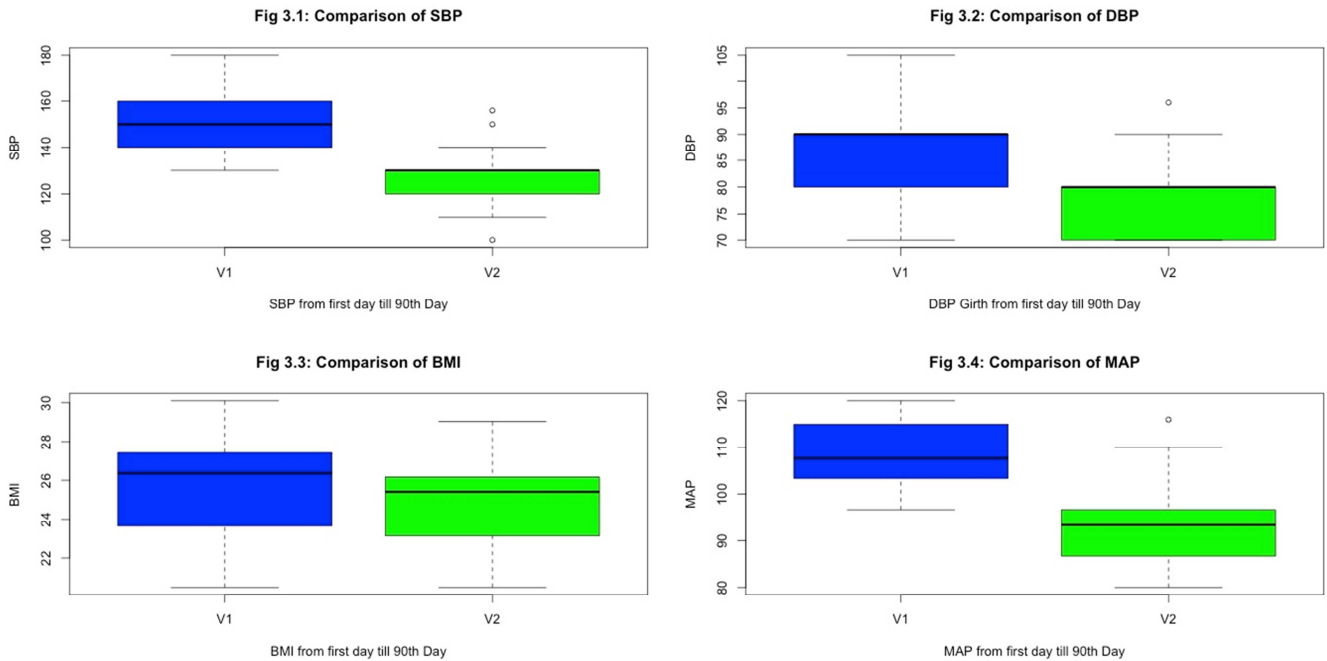


Figure 3. Comparison of clinical parameters between baseline values and 90th day.

4. Discussion

HTN is the leading cause of cardiovascular deaths all over

the world. Troublesome fact is that its prevalence is still increasing at alarming rates, especially in India. This is happening, despite the accessibility of numerous conventional drugs like beta blockers, diuretics, etc. and

guidelines for the treatment of HTN. Conventional medicines act like a double edged sword; their extensive adverse effect profile and increased cost of consumption adds tremendously to burden of disease in society. That is why we need such a therapy which can ameliorate all these drawbacks of conventional drugs and maintaining the same efficacy of conventional drugs.

Conventional antihypertensive drugs act in HTN by reducing BP via:

- i. Reduction in sympathetic tone,
- ii. Anti-inflammatory action,
- iii. Vasodilation,
- iv. Antioxidant,
- v. Reduction in sodium and water load [7].

Many herbal drugs act through above mechanism and also they have added advantage of less/ no adverse effects and less cost of therapy, as compared to conventional medications. Therefore, *Panchakarma* along with herbal drugs might serve as an effective alternate option for management of HTN. *Panchakarma* techniques used in BPMP itself have BP lowering effects by calming effect, thus reducing sympathetic overactivity, reduction in sodium and water load, etc [12, 13]. Also herbal drugs used in *Panchakarma* under BPMP have following beneficial effects in reducing BP by:

- i. Rose fragrance can decrease sympathetic activity. The probable mechanism responsible for this beneficial effect might be relaxation through inhalation of pleasant smell, and increased binding of essential oil component to GABA (Gamma-Aminobutyric acid) inhibitory receptors in brain, which reduce sympathetic stimulation [15].
- ii. *Nardostachys jatamasi*- Reduction of stress, antioxidant, cardio protective effects [16].

Also, it has been found that increased BMI is epidemiologically linked with increased occurrence of a variety of diseases like obesity, HTN, heart failure, atrial fibrillation, etc. BPMP resulted in significant reduction (high statistical significance) in BMI along with SBP, DBP, MAP. Thus, it combats all the parameters related to HTN.

Instead of an isolated measurement of SBP and DBP, some researchers favor the measurement of MAP for assessing the efficacy of antihypertensive drugs, since it takes into account both SBP as well as DBP. MAP act as better prognosticator in presence of multiple cardiovascular risk covariates [17]. In our study there was significant reduction in MAP, which suggest that BPMP might serve as an effective tool to combat HTN. Another advantage of BPMP, which we found in our study was that, it reduced dependency of patients on conventional medications. This is a more important finding for population like India, where adverse effects and increased cost of therapy greatly reduces compliance and adherence to therapy, thus increasing complications of HTN [9].

Despite all these significant positive findings of BPMP, we recommend similar studies with a larger number of study participants and increased duration of follow up, so that the findings of our study can be corroborated and forecasted to

larger populations.

5. Conclusion

Since HTN is multifactorial disease, it is important to combat the derangement in all the related parameters, namely SBP, DBP, MAP, BMI. In the light of effects of BPMP in our present study on these parameters, it is fair anticipation that BPMP will serve as an effective therapeutic option for treatment of HTN in elderly male patients.

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