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To Study Efficacy of Blood Pressure Management Program in Overweight to Obese Male Patients with Known History of Hypertension: A Retrospective Study

Rohit Sane¹, Nilesh Kulthe², Harsha Mahajan³, Harshada Mekhale⁴, Sarita Patil⁵, Kranti Shinde⁶, Rahul Mandole^{7*}

^{1,7}Department of Research and Development, Madhavbaug Cardiac Care Clinics and Hospitals. Mumbai, India

²Department of Medical Operations, Madhavbaug Cardiac Care Clinics and Hospitals. Mumbai, India

³Madhavbaug Cardiac Care Clinics. Mumbai, India

⁴Madhavbaug Cardiac Care Clinics. New Mumbai, India

⁵Madhavbaug Cardiac Care Clinics. Nashik, India

⁶Madhavbaug Cardiac Care Clinics. Solapur, India,

ABSTRACT

Background and Objective: Hypertension is the leading cause of global burden of cardiovascular disease. It is an epidemic that globally affects one billion people and a common cause of death. This retrospective study was conducted in April 2017 to evaluate the effect of the Blood Pressure (BP) Management Program in overweight to obese category male hypertensive patients.

Methods: Data of 28 patients were included who had received the scheduled 6 sitting of BP management kit in a span of 90 days. In this study, the variables [mean systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), Body Mass Index (BMI) and dependency of allopathic medicines] were assessed on day 1 to day 90 of the BP management program.

Results: The mean SBP was significantly lower on day 90 (153.5 ± 9.6 mm Hg to 127.80 ± 10.23 mm Hg, $p < 0.001$). The mean DBP reduced significantly from day 1 (91.60 ± 9.13 mm Hg to 78.64 ± 6.92 mm Hg). The mean value of MAP was much lower on day 90 (112.21 ± 7.35 mm Hg to 94.80 ± 7.44 mm Hg, $p < 0.01$). The BMI was much lower from day 1 (27.47 ± 2.49 to 26.45 ± 2.21 , $P < 0.001$). Patients dependent on allopathic medicines were lesser at 90 days.

Conclusions: The BP management program was efficacious in controlling hypertension in male patients that were overweight or obese.

KEYWORDS

Blood pressure management, Alternative medicine, Panchakarma, Ayurveda



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INTRODUCTION

According to guidelines published by the American Heart Association, the American College of Cardiology; hypertension is defined as systolic blood pressure (SBP) 130 mm Hg/diastolic blood pressure (DBP) 80 mm Hg¹, whereas according WHO it is defined as high or raised blood pressure (BP), a condition in which the blood vessels have persistently raised pressure². Categories of BP are given in detail in table 1¹.

Hypertension is the leading cause of the global burden of cardiovascular disease. It is an epidemic that globally affects one billion people and a common cause of death. World health statistics 2012 state that the prevalence of hypertension was 29.2% in males and 24.8% in females³. Across the world, hypertension is responsible for 51% of cerebrovascular disease and 45% of ischemic heart disease deaths³. Recent reports suggested that nearly 1 billion adults (more than a quarter of the world's population) had hypertension in 2000, and this number is predicted to increase to 1.56 billion by 2025⁴.

In Indian population, about 33% of urban and 25% of rural Indians are hypertensive. Of these, 25% rural and 42% urban Indians are aware of their hypertensive status.

Only 25% rural and 38% of the urban Indians are being treated for hypertension. One-tenth of rural and one-fifth of urban Indian hypertensive population have their BP under control⁵.

Table 1 Categories of BP in adults

BP Category	SBP		DBP
Normal	<120 mm Hg	and	<80 mm Hg
Elevated	120-129 mm Hg	and	< 80 mm Hg
Hypertension			
Stage I	130-139 mm Hg	or	80-89 mm Hg
Stage 2	≥140 mm Hg	or	≥90 mm Hg

Individuals with SBP and DBP in 2 categories should be designated to the higher BP category

Uncontrolled hypertension or resistant hypertension is defined as hypertension, which will remain resistant (140/90 mm Hg or higher) although an optimal two-drug regimen which has been given adequate time to work (at least one month since last drug or dosage adjustment). It occurs in a smaller number of patients with essential hypertension. Mainly, uncontrolled hypertension is caused by inadequate therapy, patient noncompliance and inappropriate therapy⁶.

Uncontrolled hypertension has become a major problem in India. High blood pressure (BP) is ranked as the third most important risk factor for attributable burden of disease in south Asia⁷. The World Health Organisation (WHO) Non-communicable disease profile for India (2014) shows that cardiovascular (CV)

disease accounts for 26% of all deaths in India. Estimates from the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India show that by the year 2020, 159.46/1000 Indians will be hypertensive⁸. In densely populated countries like India, there are several risk factors which contribute to the prevalence of hypertension. Increasing age, unhealthy diet (especially salt intake > 5grams/day doubles the risk of hypertension), obesity, alcohol and tobacco consumption, physical inactivity and urban residence are some of the key factors out of them⁸.

There are many complications which arise due to hypertension or high blood pressure, namely- Stroke, coronary heart disease, diabetes, atherosclerosis, kidney disease, eye disease, pre-eclampsia, erectile dysfunction, etc⁸. In such a difficult scenario; it is practical to focus on multiple risk factors while treating hypertension. Hence, monotherapy alone is not sufficient to treat hypertension. Many researchers are studying different Interventions along with combination therapy of multiple blood pressure lowering drugs. This is very important, and concerns should be identified while advising the appropriate dosage of combinations of anti-hypertensive therapy and adherence to the therapy. At present,

management of hypertension involves lifestyle modifications along with pharmacotherapy. The classes of pharmacological agents used for the treatment of hypertension include angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), calcium channel blockers (CCBs), diuretics, alpha blockers, beta blockers, aldosterone antagonists, renin inhibitors, vasodilators and central-acting agents. The preferred choices for mono, dual combination and triple combination of anti-hypertensive regimens are ARBs; ARB + CCB; ARB + CCB + Diuretics, respectively⁷. However, the use of anti-hypertensives are associated with a plethora of adverse reactions which are expected to result in nonadherence to therapy, increased morbidity and mortality as well as economic consequences. These have also led to the withdrawal of some of these medicines from use. Frequent micturition, dizziness, headache, dry cough, diarrhoea, abdominal pain, weakness, insomnia are some of the adverse drug reactions⁹.

Obesity is another important reason of uncontrolled hypertension or treatment-resistant or refractory hypertension¹⁰. If energy intake and expenditure are disproportionate, of the result is obesity. Obesity is defined as the

accumulation of $\geq 20\%$ of body fat over the person's ideal body weight¹¹. Worldwide, cardiovascular diseases are becoming the leading cause of mortality. Hypertension and diabetes are the chief conditions associated with obesity¹². There is growing evidence that excessive weight and central obesity are main causes of hypertension, which causes 65%-75% of the risk of essential hypertension¹³. Hence, it is important to treat obesity to achieve better control over hypertension¹³. We, at *Madhavbaug Clinic* planned a strategy to use medicinal plants to treat these co-morbidities.

In the current era of modernization and industrialization; stress has become a part of life leading to the many stress-oriented psychosomatic disorders, one of which is hypertension. In the view of these complications in the treatment of hypertension, there is a strong need for safe and cost-effective alternative methods to control hypertension. *Ayurveda* has the potential to treat stress and anxiety and promoting calm¹⁴. Using *Ayurvedic* medicines and interventions may give a strong alternate option to current allopathic medicines.

Ayurveda, the ancient Indian medical system showing presence since last 1000s of years has been used widely to treat numerous disorders. According to the

Ayurveda principle, the blood pressure is caused by an imbalance of *Vata* and *Pitta*; hence majority treatments aim to correct this imbalance; which is the root cause of disease. *Ayurveda* treatment mainly consists of the use of different natural herbs in the form of a capsule or tea or juice or *Kadha* or tablets. In the view of this present scenario, we developed a blood pressure management program which includes use of these ancient herbs; i.e., *Nirgundi Oil*, *Dashmool kadha*, and *Jatamanasi kadha*.

Vitex negundo commonly known as *Nirgundi* is a plant which shows many pharmacological activities. As mentioned in *Ayurveda*; whole percolate extract of *Nirgundi* was found to contain polyphenols such as flavonoids as major constituents. These phenolic constituents possess anti-hypertensive activity¹⁵. The literature shows use of *Dashmool* as an agent which is used to clear the imbalance of vitiated *Vata* and *Pitta* in the body. Hence it is used as anti-hypertensive in some *Ayurveda* formulations¹⁶. *Jatamansi* (*Nardostachys jatamansi*) shows hypotensive activity against adrenaline induced hypertension. *N. jatamansi* is used to protect cells and tissues through its antioxidative properties¹⁷.

Individually these herbs have shown promising results as anti-hypertensive

agents; hence in this study, their combination was used.

MATERIALS AND METHODS

From April 2017 to July 2017, 34 known hypertensive patients underwent the Blood Pressure Management program at *Madhavbaug* clinics. Out of them, 28 met inclusion criteria and were in obese to overweight category. All these patients received 6 BP management sittings over 90 days in the out-patient departments (OPDs) at *Madhavbaug* clinics.

The inclusion criteria were as follows:

- Systolic blood pressure between 140 to 170 mmHg and diastolic blood pressure between 80 to 110 mmHg.
- BMI range from Overweight to obese category (BMI 23 and Above) according Asian BMI chart.
- Only Male patient were considered for this study.

Patients were belonging to the age group of 38 years to 68 years and had pre-diagnosed uncontrolled hypertension with SBP between 140 to 170 mmHg and DBP between 80 to 110 mmHg. These patients attended the out-patient departments (OPDs) of different *Madhavbaug* Clinics located in various cities of *Maharashtra*, India. The subjects enrolled in the study

were willing to follow the protocol strictly over the thirteen weeks of the study period. This study was a prospective, thirteen-week, open label, single arm, multicentric, pilot proof-of-concept study conducted to evaluate the efficacy of blood pressure management program using herbal medications such as *Nirgundi oil*, *Dashmool Kadha* and *Jatamansi Kadha* in overweight or obese patients with known history of hypertension. This program consisted of a series of procedures such as *Shehana*, *Swedana*, *Shirodhara*. Patients followed Diet chart/Plan of 1200 calories strictly.

Blood Pressure Management Kit Program

Snehana is a process wherein the body is lubricated with the help of oil, hence *Snehana* is also called as Oleation therapy. *Snehana* is a mandatory procedure before *Panchakarma*. *Sneha* meaning oil and the process which uses oil is called as *Snehana*. It is a lubrication of human body either internally or externally. Our study used *Nirgundi oil* as the lubricating oil and the type of lubrication or oleation used was external oleation. This procedure employed a specific form of massage (*Abhyanga*). It is also called as oleation. The expert therapist applied herbal *Nirgundi (Vitex negundo)* oil to the skin before starting the massage. This process

also improves circulation and acts like anxiolytic¹⁸. This massage technique uses centripetal or upward strokes directed towards the heart. The duration of this procedure was 30-35 minutes. Other details of the method are given in Table 2. *Swedana* is a steam treatment employing thermal vasodilation explained in *Ayurveda* medical science. It is also called as passive heat therapy. *Sweda* word is derived from *Sanskrit* word *Swid*, meaning 'To sweat or to perspire'. Hence, *Swedana* is the process of producing sweat with the help of steam, which is generated from medicated herbal decoctions. Our procedure employed use of *Dashmool kadha* for *Swedana* process. To administer this therapy the patients were asked to lie in a supine position inside a sudation box and their head was positioned outside the box. *Dashmoola* (group of ten herbs) steam of temperature not more than 40°C

was then passed steadily for 10-15 minutes. After the treatment, patients were asked to relax for 3-4 minutes. The total duration of this procedure was 15-20 minutes. It is the process of fomentation wherein persons were advised to take a steam bath in order to produce sweating. Sweating also causes elimination of salt and water. *Ayurveda* fomentation is usually given after an oil massage. Details of the procedure are given in Table 2.

Shirodhara massage is a classic *Ayurveda* therapy, where warm herbal oil/decoction is poured on the forehead in a continuous stream. *Shirodhara* treatment is an external treatment present in *Ayurveda*. *Shirodhara* comes from two words "Shira" means head and "Dhara" means stream. It is one of the treatment used to treat stress. It also reduces the level of stress hormones such as adrenaline and noradrenaline and thus relaxes the mind¹⁹.

Table 2 Study methodology: Blood pressure management program (HTN Kit)

Step of Method	Type of Therapy	Herbs used for therapy	Duration of Therapy
<i>Snehana</i>	Massage or external oleation (centripetal upper strokes directed towards heart)	100 ml Vatax oil <i>V.negundo</i> [100 ml extract processed in sesame oil]	30-35 minutes
<i>Swedana</i>	Passive heat therapy	<i>Dashmoola</i> (group of ten herbal roots) with steam at ≤ 40 degrees Celsius)	10-15 minutes + 34 minutes of relaxation after procedure
<i>Shirodhara</i>	Decoction dripping therapy from a height of 7-8 cm	100 ml of Luke-warm <i>Jatamansi</i> decoction	30 minutes

Shirodhara may begin with *Ayurveda* body massage or *abhyanga* after a person lies down with his/her eyes closed.

In our study, the luke-warm *Jatamansi* decoction was allowed to drip at a constant speed from a fixed height on the medial of the forehead and eyebrows. The oil was

poured continuously as a stream and in an oscillating manner. Care was taken to ensure that the oil does not enter the eyes or ears. The entire procedure took 30 to 60 minutes, depending on the condition of the patient. A therapist also gave a light head massage to the patient before or during the procedure.

The BP management program is a combination of *Panchakarma* and allied therapies. BP management programs uses various decoctions and oils and constitutes of a 3-step procedure. This blood pressure management program involved total 6 sittings of *Snehana*, *Swedana* and *Shirodhara*. In the 1st month 4 sittings once a week was performed and thereafter one sitting each month in the 2nd and 3rd month was performed, along with the conventional treatment, if it was ongoing for the patient. Table 3 provides details step wise procedure in tabular format.

Table 3 Baseline characteristics of the study participants

Variable	N = 28
Age (Years)	58.91 ± 10.75

Results are expressed in mean ± SD and N(%)

Endpoints

Primary outcome measure was reduction in SBP and secondary outcome measures were reduction in DBP, reduction in mean arterial pressure (MAP), reduction in usage

of conventional medicines and reduction in BMI. SBP and DBP assessment were done with the help of a sphygmomanometer after enrolment in the study at baseline. The follow up reading of SBP and DBP was taken on day 7, day 14, day 21 and day 28, day 90. The weight, height, BMI and the concomitant medication data was noted down on day 1 and again on day 90. MAP was measured for all the patients on day 1 and day 90 using the formula: $2/3\text{rd DBP} + 1/3\text{rd SBP}$.

Statistical analysis

Data were pooled and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyze the data. Categorical data were represented in the numeric form and continuous data were presented as the Mean ± SD. Comparison of all the variables was done on day 1 and day 90 were using paired t test. P value of less than 0.05 was considered as a significant for all the variables.

The paired t-test was used to assess the difference between baseline values and 90th day after treatment. Box plot and histogram were used to represent graphs.

RESULTS

A total of 34 male hypertensive patients were screened for participation in the study. Out of these 34 patients, 28 were

included in the study based on the selection criteria. Enrolled patients (28) completed the study period and the data were collected from these patients.

Figure 1 represents the number of patients screened and finally enrolled in the study. Demographic details of the patients enrolled are given in Table 4. The efficacy

parameters were analyzed at baseline (day 1) and after the last day of the study (day 90). Table 5 provides detailed information on efficacy measures.

Table 4 Demographic details of patients enrolled

Variable	Value
Age (mean; SD) years	53.25 ± 15.02
Male (n)	28

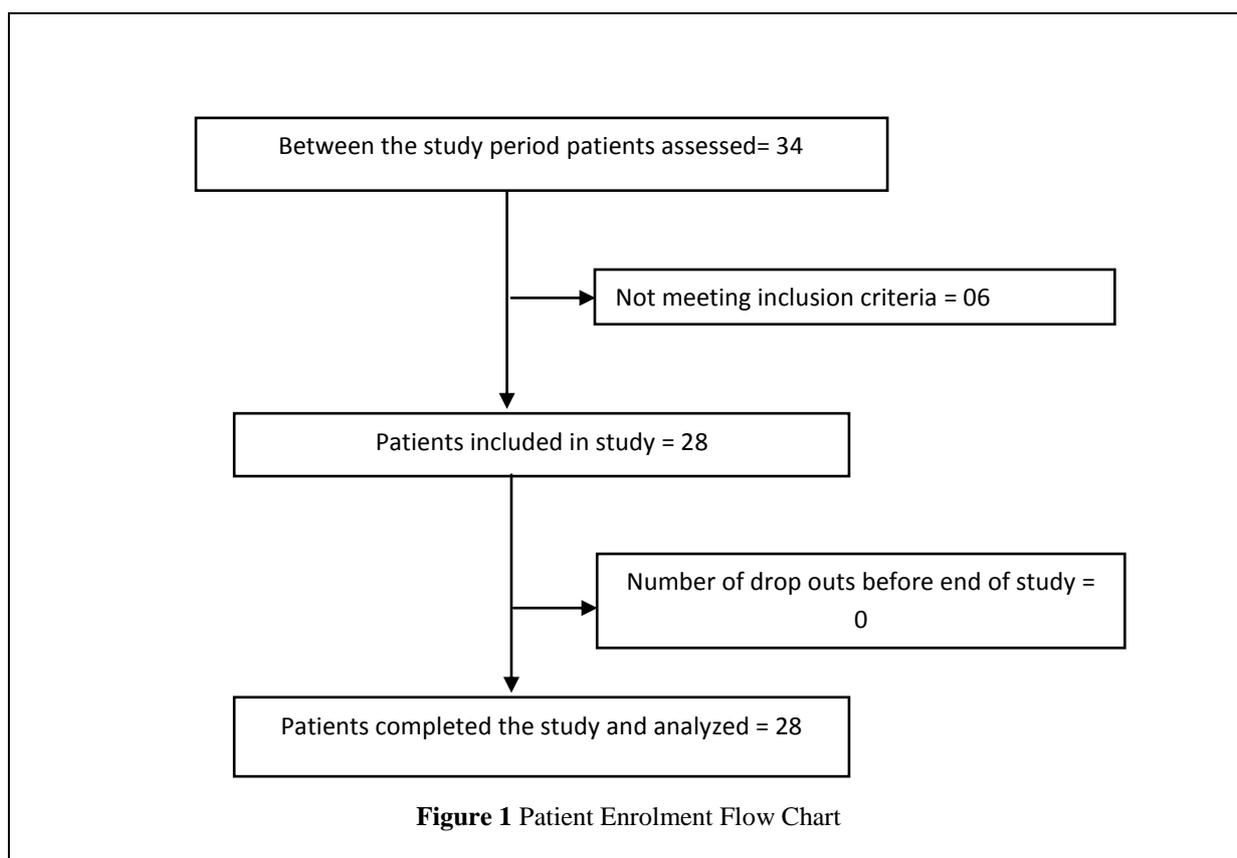


Table 5 Comparison of clinical parameters between baseline values and 90th day

Variable (n=28)	Baseline (day 1)	After 90 days	Difference	P-value
BMI	27.48 ± 2.50	26.45 ± 2.21	1.13	<0.001***
SBP	153.5 ± 9.62	127.93 ± 10.23	25.57	<0.001***
DBP	91.61 ± 9.13	78.64 ± 6.93	12.96	<0.001***
MAP	112.22 ± 7.35	94.81 ± 7.45	17.41	<0.001***

***Highly significant; BMI, Body Mass Index; SBP, Systolic blood pressure, DBP, Diastolic blood pressure; MAP, Mean arterial pressure

Comparison of clinical parameters between baseline values and 90th day are as shown in Table 5. The BMI (P < 0.001),

systolic blood pressure (P < 0.001), diastolic blood pressure (P < 0.001), mean arterial pressure (P < 0.001) were reduced

and significantly improved after the treatment, i.e., after 90 days. Comparison of the mean values done by paired t-test.

It was found that the mean SBP was significantly lower after day 90 (127.80 ± 10.23 mm Hg) as compared to the baseline value on day 1 (153.5 ± 9.6 mm Hg) ($p < 0.001$). The decrease in the mean SBP was shown reduction value as 25.50. This reduction shown improvement by a margin of 19.98% as given in table 5.

The mean DBP was reduced from baseline day 1 (91.60 ± 9.13 mm Hg) to the day 90 (78.64 ± 6.92 mm Hg) which shows reduction value 12.96 with % improvement 16.48 as shown in Table 5.

There was a significant decrease in the mean value of MAP on day 90 (94.80 ± 7.44 mm Hg) as compared to that on day 1 (112.21 ± 7.3 mm Hg) ($p < 0.01$). This shows reduction value as 17.41 with % improvement 18.36 as shown in Table 5.

There was a dramatic decrease in BMI as well from day 1 (27.47 ± 2.49) to day 90 (26.45 ± 2.21) $P < 0.001$; with reduction value 1.03 and percentage improvement 3.87. Details are given in Table 5.

Distribution of Allopathy medicine in 28 male patients for BP management program was seen in Table 6 below. The graphical representation of consumption of allopathic medicines on days 1 and 90 is depicted in Figure 1.

Table 6 Consumption of allopathic medicines on days 1 and 90

Medicine	Day 1	Day 90
NSAID	2 (7.14)	2 (7.14)
ARB	14 (50)	8 (28.57)
Antiplatelet	1 (3.57)	1 (3.57)
Beta blocker	10 (35.71)	5 (17.86)
CCB	9 (32.14)	4 (14.29)
Diuretic	5 (17.86)	2 (7.14)
Biguanide	0 (0)	0 (0)
Sulfonylurea	0 (0)	0 (0)
No medicine	4 (14.29)	7 (25)
NSAID + antiplatelet	1 (3.57)	1 (3.57)
Statin	2 (7.14)	1 (3.57)

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

There is a significant decrease in usage of conventional allopathic medicines from baseline to the day 90. There was maximum reduction in ARB usage (from

14 at baseline to 8 at day 90) following Beta blockers and CCB usage where usage was reduced from 10 to 5 and from 9 to 4 respectively. Number of subjects that

could stop allopathic medication increased substantially from baseline to 90 days, details are given in Table 5 and 6.

No adverse events were reported during study period.

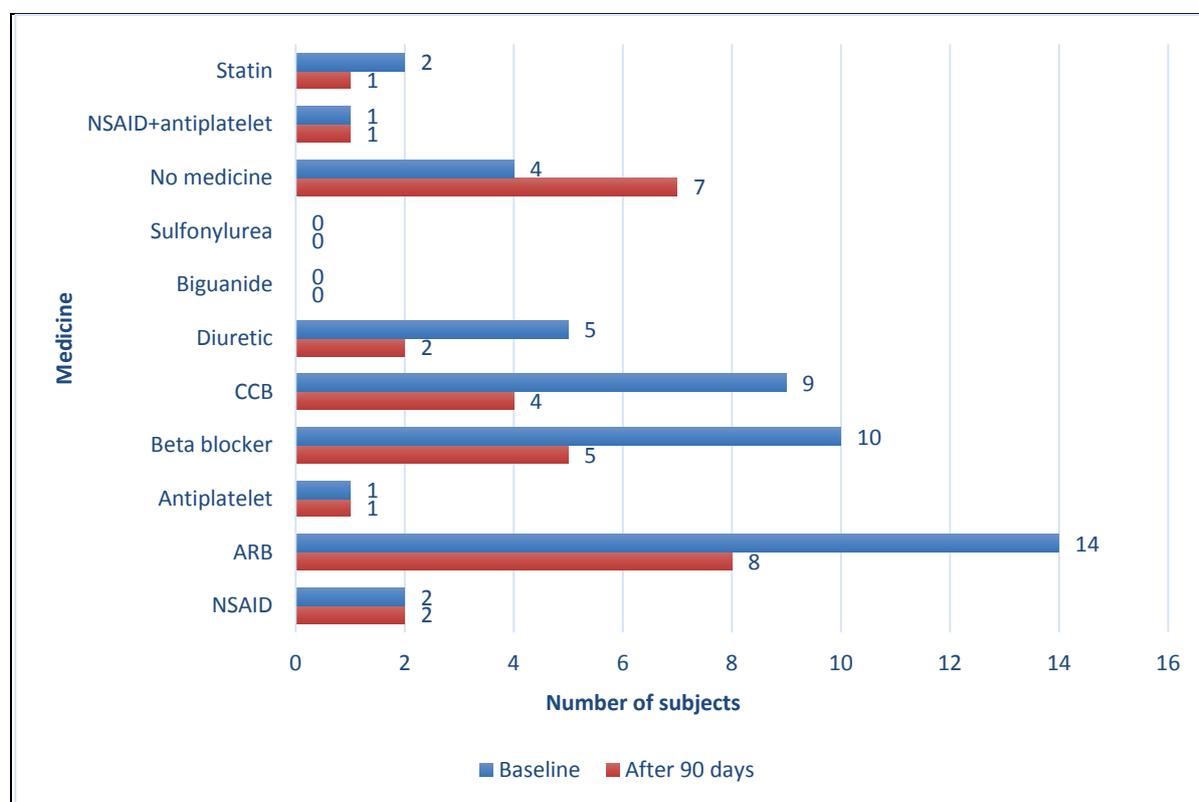


Figure 2 Consumption of allopathy medicines at days 1 and 90 days (N = 28)

DISCUSSION

Looking at global scenario; uncontrolled hypertension is major behavioral and physiological risk factor. 13% of global deaths are attributed to increased blood pressure. It is reported to be the fourth disease and cause of premature death in developed countries and the seventh in developing countries⁵ whereas while looking at a national scenario; the prevalence of hypertension ranges from 2-15% in urban India whereas 2-8% in rural India⁵. Monotherapy is not sufficient to

control blood pressure. Combination therapy has numerous side effects and is still unable to control high blood pressure, necessitating search of new interventions. These drawbacks of current pharmacotherapy took us to the ancient medical system of India, the *Ayurveda*.

After thorough research our team decided to use a dedicated blood pressure management program which uses herbal drugs which are without side effects and use a convenient methodology that increasing patient compliance. Our team

used *Nirgundi*, *Dashmoola* and *Jatamansi* as blood pressure lowering agents via the 3 step procedure of *Snehana*, *Swedana*, *Shirodhara*. These processes efficiently lowered blood pressure in the study population; which is confirmed in the results.

The literature has shown that these herbs *Nirgundi*, *Dashmoola* and *Jatamansi* possess anti-hypertensive activity. Whole percolate extract of *Nirgundi* (*Vitex Negundo*) contains polyphenols; this polyphenolic extract possesses excellent anti-hypertensive activity¹⁵. During our BP management program at *Madhavbaug* Clinic we used oil formulation of *Nirgundi* for external application in the process of *Snehana*. During this process of Massage; we used upward strokes towards Heart; which helps in improving circulation. A study conducted by Kshiteeja C *et al* demonstrates use of *Dashmool* roots as a remedy for hypertension¹⁶. In this study *Dashmool* was used to maintain equilibrium between *Vata* and *Pitta* *Dosha*. Decoction formulation was used in the study in a *Saman* process. We at *Madhavbaug* used *Dashmool Kadha*; a formulation to be taken internally; during the process of *swedana*. Another study conducted by Rajan M *et al* also reports use of *Dashmool* for the treatment of hypertension; where it was used during

shirodhara process²⁰. It was used as *Dugdha Dhara* for the said purpose. Yet in another study, *Nardostachys Jatamansi* was found to be effective and safe drug having potential of anti-hypertensive activity when given along with other drugs or along with lifestyle modification²¹. In this study, its extract significantly prevented alterations in lipid profile (Cholesterol, phospholipids, fatty acids & triglycerides). We, at *Madhavbaug*, used *Jatamansi Kadha* during *Shirodhara* process which enhances anti-hypertensive activity of *Jatamansi*.

In a study conducted by Anjali C and Prakash S, the use of *Rakadabashamak Vati* is reported where the roots of the *Jatamansi* were used²². Another study also reports the use of *Jatamansi* where they revealed its anti-hypertensive activity by acting on adrenaline induced blood pressure in dogs. This study uses root powder obtained in a pharmacognostic way¹⁷.

Our study showed maximum reduction in SBP as shown in Table 3 which was the primary outcome measure; following which reduction was seen in DBP and MAP. We also observed a decrease in BMI, which is one of the risk factors of hypertension. We also assessed consumption of allopathic medicines where we observed encouraging results. In

general, reduction was observed in the consumption of these medicines. Maximum reduction was seen in ARB, CCB, and ACE- inhibitor usage. The number of patients without allopathic medicine increased.

These findings from our study are encouraging yet this current study also possesses some limitations. There were only male patients enrolled as participants; hence efficacy studies in general population including female patients are recommended. Another limitation of the study was the use of only overweight or obese patients. The small study population was another limitation. Use of Sphygmomanometer is another limitation in the current era of ambulatory pressure monitoring. This was a one-arm, pilot study performed for proof of concept involving a short duration of 90 days. All these imitations create a need for larger studies with more number of patients to validate the findings from current study.

CONCLUSION

Treatment of the blood pressure management program was found to be safe; without any adverse effects, effective and cost-effective; using three herbal drugs, *Nirgundi oil*, *Dashmool kadha* and *Jatamanasi kadha*; in combination with

each other for the first time and employing a unique methodology of *Snehana*, *Swedana* and *Shirodhara*. This prospective pilot study showed that this method can be used as an effective blood pressure management program in patients of India.

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