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Original Research Article (Clinical)

Effect of Ayurveda intervention in the integrated management of essential hypertension- a retrospective observational study



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ABSTRACT

Background: A study titled 'Integration of AYUSH (Ayurveda) with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)' implemented in India in three districts of three states, namely Bhilwara (Rajasthan), Gaya (Bihar), and Surendranagar (Gujarat) since 2015 for the management of various non-communicable diseases (NCDs) through integrated approach.

Objective(s): To evaluate the effect of Ayurveda medication, lifestyle modification, and Yoga in integration with standard care for the management of essential hypertension.

Material and methods: A retrospective analysis of the demographic and clinical records available from NPCDCS-AYUSH Integration Project was done. The data of participants with Essential Hypertension (EHTN), aged between 30 and 60 years, who had completed six months integrated management as per the treatment protocol of the NPCDCS-AYUSH Integration project between July 2018 and March 2019 were taken and distributed in two groups based on their intervention. Those advised for lifestyle modification and Yoga in addition to standard care with any of the five medicines/combinations i.e. Amlodipine or Atenolol or Amlodipine + Atenolol or Losartan or Telmisartan were assigned Group I and those who were given Ayurveda medication, lifestyle modification and Yoga in addition to standard care were assigned to Group II. The change in blood pressure was analysed and dose reduction/discontinuation of conventional medications was also observed.

Results: Data of 1938 participants who had completed treatment under the NPCDCS program was analysed. At the 6th month, systolic and diastolic blood pressure was significantly reduced ($P < 0.01$) in all categories of Group I and Group II from baseline. Further, the dose of conventional medicine was reduced in 33.1% of participants of Group I and in 30.4% participants of Group II when compared to 0 day while conventional medicines were discontinued in 15.1% of Group I and 36.7% of Group II participants.

Conclusion: Ayurveda medication along with lifestyle management and Yoga effectively controls systolic and diastolic blood pressure and further helps in reducing/discontinuation of dose of conventional medicines in EHTN participants.

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1. Introduction

Essential Hypertension (EHTN) is one of the major public health problems among non-communicable diseases (NCDs) in

developing countries where rapid urbanization leads to disturbed lifestyle, reduced physical activity, tobacco, alcohol use, and stressful conditions. These factors contribute to development of EHTN. Around 1.13 billion individuals are affected by hypertension worldwide with two-third of it in low and middle income countries [1]. As per WHO, cardiovascular diseases account for around 29% of total deaths from NCDs in India [2]. EHTN contributes to most cases whereas secondary hypertension contributes to around 5–10% cases which may be due to various causes like coarctation of the

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aorta, chronic kidney disease, polycystic kidney disease, renal artery stenosis, fibromuscular dysplasia, primary aldosteronism, Cushing's syndrome/disease, hyperthyroidism, hypothyroidism, hyperparathyroidism, obstructive sleep apnea, pregnancy, scleroderma, drug-induced hypertension, etc. [3].

Knowledge of Ayurveda was documented after years of experience, observation, and empiricism that are passed over generations. The main objective of Ayurveda is to make the individual strong to deal with various physical and mental stresses. Ayurveda emphasises the role of diet and lifestyle along with drug intervention for prevention and management of lifestyle diseases such as hypertension, diabetes, insomnia, etc.

Keeping in view of strength of Ayurveda, Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH, Government of India in collaboration with Directorate General of Health Services, Ministry of Health and Family Welfare (MoHFW), Government of India, had conceived a public health project on pilot basis in the year 2015 named "Integration of Ayurveda with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)" in three districts of three states, namely Bhilwara (Rajasthan), Gaya (Bihar), and Surendranagar (Gujarat) for the management of NCDs through integrated approach. In this project, the enrolled participants were distributed in two cohorts: pre-disease group i.e. Cohort A and disease group i.e. Cohort B. Each cohort was further sub-divided into two groups, i.e. A1 and A2, and B1 and B2. Group A1 was advised for lifestyle modification and Yoga and Group A2 was given Ayurveda medication in addition to lifestyle modification and Yoga. Similarly, Group B1 was advised for lifestyle modification and Yoga along with conventional medication and Group B2 was given Ayurveda medication in addition to lifestyle modification and Yoga along with conventional medication. The present study focuses on the retrospective analysis of the diagnosed cases of EHTN participants (Cohort B) enrolled under this program from July 2018 to March 2019, who were already on the standard care with conventional medicine and further treated with the diet, lifestyle modification, Yoga and Ayurveda medication as per the study protocol. The primary objective of this study was to evaluate the effect of Ayurveda medication, lifestyle modification and Yoga in integration with standard care for the management of EHTN.

2. Material and Methods

2.1. Data source

The data of the demographical and clinical records including subjective and laboratory parameters available from NPCDCS–AYUSH Integration Project across three districts of three states viz. 17 Community Health Centre (CHCs) and 1 District Hospital (DH) at Gaya district of Bihar, 10 CHCs and 1DH at Surendranagar district of Gujarat, and 22 CHCs and 1DH at Bhilwara district of Rajasthan were taken for analysis.

2.2. Study population

The data of participants with EHTN, aged between 30 and 60 years, who had completed 6 months integrated management as per the treatment protocol of the NPCDCS–AYUSH Integration project during July 2018 to March 2019 were taken. EHTN was diagnosed as per Joint National Committee (JNC-7) (Individuals with systolic blood pressure above 140 mmHg and diastolic blood pressure above 90 mmHg) [4].

2.3. Study design

A retrospective observational study was planned. The study participants were distributed in two groups, viz., I and II, based on their intervention i.e., those who were advised for lifestyle modification and Yoga in addition to standard care were assigned Group I and those who were given Ayurveda medication (M-*Sarpagandha Mishran* and *Pravala Pishti*), lifestyle modification and Yoga in addition to standard care were assigned Group II. The change in blood pressure was analysed using t-test and dose reduction/discontinuation of conventional medications was also observed. Follow-up of cases was observed after 3rd and 6th month from baseline.

2.4. Inclusion criteria

Data of participants on standard care with any of the five medicines/combinations i.e. Amlodipine or Atenolol or Amlodipine + Atenolol or Losartan or Telmisartan; participants completed continuous 6 months of integrated management with proper documentation of clinical criteria and those who have given written informed consent were included in the study.

2.5. Exclusion criteria

Data of participants on other anti-hypertensive conventional medicines and co-morbid situations; improper documentation of clinical criteria were excluded.

2.6. Ethical clearance

The current study is based on retrospective analysis of the available data of an ongoing project and no personal information is revealed in the study. Thus, ethical clearance waiver was obtained from all the three implementing states viz. F. No. 17–1/NPCDCS/RARIID/Patna/20–21/956, 5/Lab/Prei-iron/Ethics/2007-08CRAI-JPR, 4-4/RARISD/Ahmedabad/Tech./2020–21/1129.

2.7. Interventions given under integrated management

2.7.1. Ayurveda medications (pharmacological)

The M-*Sarpagandha Mishran* [5] 250 mg and *Pravala Pishti* 250 mg twice a day after meal with lukewarm water were administered for the management of EHTN. The medicines were procured from Good Manufacturing Practices (GMP) certified Government Ayurvedic pharmaceutical company i.e., Indian Medicines Pharmaceutical Corporation Limited (IMPCL). The medicines were prescribed for 6 months. The ingredients of M-*Sarpagandha Mishran* include *Sarpagandha* (Root), *Jatamansi* (Rhizome), *Vacha* (Rhizome), *Punarnava* (Root), *Brahmi* (Plant), *Shankhpushpi* (Plant) and *Guduchi* (Stem) while *Pravala Pishti* includes *Shuddha Pravala* (Purified Coral) and *Gulab Arka* (Distilled Rose Water).

The details of diet and lifestyle modification and *Asana/Kriya/Pranayama* advocated are listed in [Table 1](#).

2.8. Assessment criteria

1. Blood pressure level: As per Joint National Committee (JNC-7), the systolic and diastolic blood pressure at baseline, 3rd and 6th month.
2. Subjective symptoms of EHTN i.e. headache, irritability, giddiness, sleeplessness, feeling of being uncomfortable, tremors of the individual participants through following scoring: Absent: 0 Mild: 1 Moderate: 2 Severe: 3 (Mild indicates symptoms while performing an activity but with no hindrance in the work, moderate indicates symptoms that

Table 1
Details of advocacy on diet and lifestyles and Asana/Kriya/Pranayama advocated for EHTN.

Diet and lifestyles				
Advised diet and lifestyle	Restricted diet and lifestyle			
<ul style="list-style-type: none"> Regular blood pressure check-up. Lifestyle modifications like timely intake of balanced diet, more use of fruits and green vegetables. Regular physical exercise. Daily brisk walking for half an hour Reduce intake of oily, salty, sour and spicy food items. Weight reduction. Barley (<i>Yava</i>), sorghum (Jowar), wheat, green gram (<i>Mudga/Moong dal</i>), horse gram (<i>Kulatha</i>), moringa (<i>Shigru</i>), Bitter gourd (<i>karela</i>), bottle gourd (<i>Ghia/Lauki</i>), turnip (<i>Shalgam</i>), carrot (<i>Gajar</i>), radish (<i>Muli</i>), Indian gooseberry (<i>Amla</i>), cucumber (<i>Kira</i>), black grapes (<i>Draksha</i>), pomegranate (<i>Anar</i>), apple, pineapple, cold milk etc. Timely sleeping and awakening. Regular practice of Yoga, meditation etc. under the supervision of Yoga expert 	<ul style="list-style-type: none"> Excessive intake of salt (sprinkling over salad, curd etc.) Excessive use of butter, ghee, chillies (red-green), pickles, Sesame Oil (<i>Til taila</i>), Bengal gram (<i>Chana Dal</i>), mustard oil (<i>Sarson ka Taila</i>), sour fruits, curd, tea, coffee etc. Intake of animal fat, processed/oily food items. Alcohol consumption and smoking. Practice of day sleeping and awakening at night 			
Details of Asana/Kriya/Pranayama advocated				
Yogasana	Pranayama	Kriya	Meditation	Contraindications
Tadasana, Katichakrasana, Konasana, Uttanapadasana, Pavanamuktasana, Vajrasana, Ushtrasana, Shashankasana, Bhujangasana, Gomukhasana, Makarasana, Vakrasana, Shavasana	Nadishodhana, Ujjayi, Shitali, Sitkari and Bhramar	Jalneti	Breath awareness	Head stand (<i>Shirshasana/Topsy-turvy</i>) postures and hyperventilation breathing practices.

create hindrance in the work, and severe indicates the inability to perform any work because of symptoms.)

3. Assessment of reduction/discontinuation of the dose of standard care:

2.8.1. In case of single conventional medicines (amlodipine/atenolol/losartan/telmisartan/amlodipine + atenolol)

- a) Reduced: Reduction in the dose/frequency of conventional medicine
- b) Discontinued: Conventional medicine stopped.
- c) Drug change: Conventional medication changed.
- d) No reduction: Dose/frequency of conventional medicine remain same.
- e) Medicine restarted: Conventional medicine restarted after discontinuation at 3rd month.

2.8.2. In case of combination of amlodipine with atenolol

- a) Reduced: Reduction in the dose/frequency of either single or both of conventional medicine or discontinuation of either of the conventional medicine.
- b) Discontinued: Both conventional medicines stopped.
- c) Drug change: Either one or both conventional medication changed.
- d) No reduction: Dose/frequency of conventional medicine remain same.
- e) Medicine restarted: Conventional medicine restarted after discontinuation at 3rd month.

4. Changes in subjective symptoms after treatment:

- a) Static: No change in subjective symptoms at the 3rd and 6th month from baseline
- b) Improved: Improvement in subjective symptoms at the 3rd and 6th month from baseline
- c) Worse: Increase in severity of subjective symptoms at the 3rd and 6th month from baseline.

2.9. Outcome

2.9.1. Primary outcome

To determine the effect of integrated management on systolic and diastolic blood pressure.

2.9.2. Secondary outcome

To determine the effect of Ayurveda medication, lifestyle modification and Yoga on standard care in the integrated management of EHTN based on the dose reduction/discontinuation of medications of standard care.

2.10. Statistical analysis

Statistical analysis was carried out using SPSS Version 15.0. The within group continuous data for blood pressure collected at two time points was compared using paired t-test. Between group comparison was done using independent sample t-test. The data collected in binary form related to effect of the integrated approach as assessed by reduction in dose/frequency of conventional medicine was compared using 2 sample proportion test. A p-value of <0.05 has been considered significant. The demographic variables and chief complaints have been presented in percentage of total participants analysed under the study.

3. Results

A total of 1938 hypertensive participants (511 in group I, 1427 in group II) had completed the integrated management of 6 months during 1st July 2018 to 31st March 2019 under five sub-category of medicine of standard care and were included in the analysis as in Fig. 1 and the baseline characteristics of study participants is shown at Table 2.

The mean age of participant of the study was slightly more in Group I [56.7 (12.32)] than Group II [54.7 (11.39) p-value = 0.600] with more number of females in both groups than males. Large amount of participants were illiterate [Group 1 (62.8%), Group II (46.9)]. Occupation-wise, around half of the participants were housewives [Group I (51.9), Group II (47.6), p-value = 0.502]. Effect of integrative management on chief complaints of EHTN is shown in Table 3.

Grading of the symptoms of EHTN i.e. headache, irritability (anger spurts), giddiness, sleeplessness, feeling of being uncomfortable, and tremors was done at baseline and follow-up and recorded in case record forms. There was significant improvement in all the symptoms in Group I and II at 3rd and 6th month when compared to baseline.

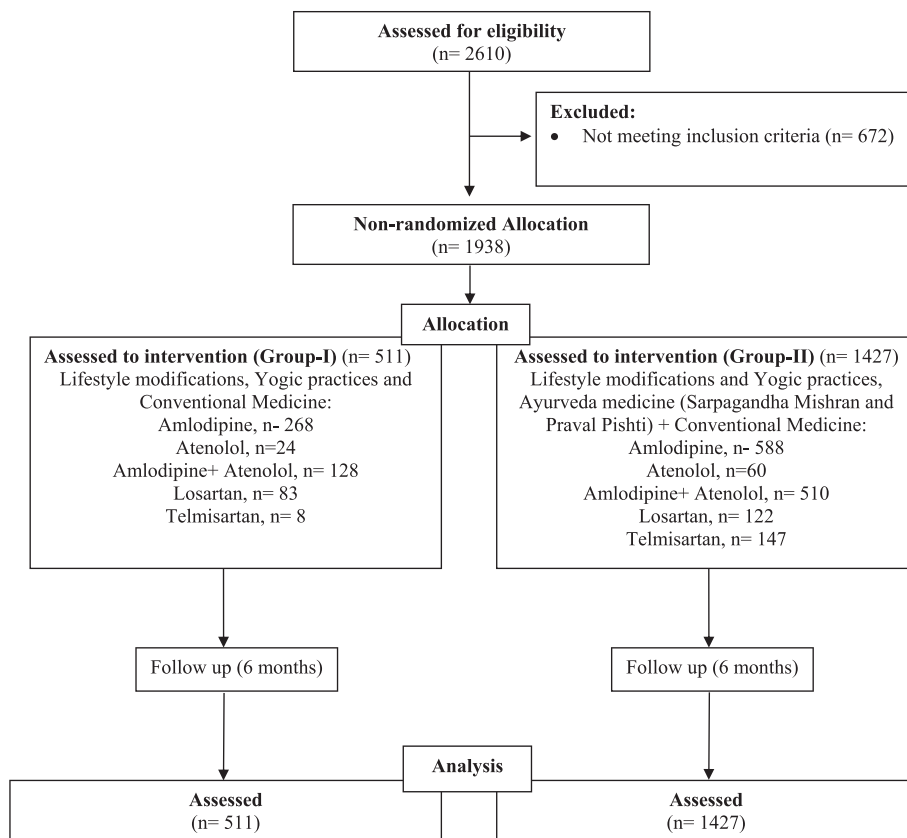


Fig. 1. Schematic diagram of the study design.

3.1. Effect of Integrative management on outcome

The effect of integrative management in blood pressure is shown on Table 4. Significant reduction in the systolic and diastolic blood pressure was observed from baseline to 3rd as well as 6th months after the integrative management in all drug categories. Further, the effect of integrated management on dose/frequency of conventional drug at 3rd and 6th month as compared to baseline is exhibited in Table 5 and Table 6 while the effect at 6th month in comparison to 3rd month is shown in Table 7:

In the above table, the dose/frequency of conventional medicine as well as drug stoppage shows significant results in Group II as compared to Group I at 3rd month. At 6 month, the reduction of

conventional medicines were found non-significant results on comparing the groups; however, significant results were observed in drug stoppage in Group II. This shows that conventional medicines have been discontinued at the 6th month in large number of participants due to further control of blood pressure through integrated management.

The Odds Ratio for dose reduction of conventional medicines between Group I and II at 3rd and 6th month from baseline is shown in Table 6. It was also observed that chances of dose reduction of conventional medicines are 1.88 times higher (95% CI 1.47 to 2.39) if Ayurvedic and conventional integrated regimen were followed for 3 months, while 0.88 (95% CI 0.71 to 1.09) times higher the integrated approach is followed for 6 months (Table 6). The effect of integrative management on standard care at 6th month in comparison to 3rd month is shown in Table 7.

Table 2
Baseline characteristics of study participants (n = 1938).

S. No.	Variables	Group I (n = 511)	Group II (n = 1427)	p-value
1.	Age (Yrs.): Mean (SD)	56.7 (12.32)	54.7 (11.39)	0.600
2.	Sex: %			0.029
	Male	212 (41.5)	672 (47.1)	
	Female	299 (58.5)	755 (52.9)	
3.	Education (%)			<0.001
	Illiterate	321 (62.8)	669 (46.9)	
	Up-to primary	66 (12.9)	268 (18.8)	
	Up-to middle	53 (10.4)	217 (15.2)	
	Up-to senior secondary	39 (7.6)	143 (10.0)	
	College and above	32 (6.3)	130 (9.1)	
4.	Occupation (%)			0.502
	Desk Work	59 (11.6)	149 (10.4)	
	Field work	129 (25.3)	455 (32.0)	
	House Wife	264 (51.9)	678 (47.6)	
	Others	57 (11.2)	142 (10.0)	

4. Discussion

Hypertension is attributed to multiple factors including stress, faulty dietary habits, and disturbed lifestyle. Management of these modifiable risk factors is necessary for optimal treatment outcome. Ayurveda provides a holistic approach towards disease management. It not only provides pharmacological treatment but also addresses psychological and behavioural aspect through Yoga, dietary corrections, and lifestyle management.

Current study explored the effect of integrated management on blood pressure and dose/frequency of conventional medicines of EHTN participants. During the retrospective analysis, it was observed that the participants on standard care have not reported any of the major chief complaints of EHTN like nasal bleeding, vision changes, etc. The possible reason might be that the

Table 3
Showing the effect of integrative management on chief complaints of EHTN.

Chief Complaints as compared to 0 day	Treatment Group = B1	Treatment Group = B2					
		Improved Static Worsened					
		Improved	Static	Worsened			
Headache	After 3 months	85.6	14.4	–	78.1	21.6	0.3
	After 6 months	90.0	9.8	0.2	86.9	12.5	0.5
Irritability (anger spurts)	After 3 months	77.0	23.0	–	80.4	19.5	0.1
	After 6 months	87.7	12.3	–	86.8	13.2	–
Giddiness	After 3 months	80.4	19.6	–	78.4	21.2	0.4
	After 6 months	89.1	10.6	0.3	90.3	9.7	–
Sleeplessness	After 3 months	82.6	17.4	–	77.5	21.9	0.5
	After 6 months	89.2	10.5	0.2	88.6	10.9	0.4
Restlessness	After 3 months	86.7	13.0	0.4	84.0	15.6	0.4
	After 6 months	95.6	4.4	–	89.1	10.7	0.2
Tremors	After 3 months	88.6	11.4	–	85.7	14.3	–
	After 6 months	99.0	1.0	–	93.2	6.8	–

Values have been reported as %; Treatment Group B1: Headache (n) = 480, Irritability (n) = 309, Giddiness (n) = 357, Sleeplessness (n) = 419, Feeling of being uncomfortable (n) = 270, Tremors (n) = 105; Treatment Group B2: Headache (n) = 1307, Irritability (n) = 928, Giddiness (n) = 1139, Sleeplessness (n) = 1130, Restlessness (n) = 1071, Tremors (n) = 176.

participants were already taking conventional medicines from certain period. There was considerable improvement in systolic and diastolic blood pressure in the hypertensive participants after introduction of lifestyle, diet modification and Yoga (Group I) by which about 27.78% participants benefitted either in the form of dose reduction or discontinuation of conventional medicine after three months of intervention which further improved after six months of interventions to 48.14% [Table 5]. The overall improvements were even more substantial with integrative approach through Ayurveda, lifestyle and diet modification, and Yoga (Group

II), in which about 44.92% participants benefitted either in the form of dose reduction or discontinuation of conventional medicine after three months of intervention which further improved after six months of interventions to 66.99% [Table 5]. The inter-group comparison is statistically significant in only Group II sub-group A while the results for lowering blood pressure were found significant clinically in all the groups. Further, the percentage for dose reduction and discontinuation were more in Group II as a whole than Group I at 3rd and 6th month as compared to baseline. This signifies the active role of Ayurveda intervention i.e. *Sarpagandha Mishran* and *Praval Pishti* in management of EHTN.

Both the groups, in all five drug categories, exhibit significant results in terms of blood pressure management. This may be due to lifestyle corrections including dietetics and Yoga practices which are important for removal of modifiable risk factors and for regulating physiology of the body. Dietary modification in the form of reduced intake of oily, salty, sour, and spicy food items, avoiding consumption of alcohol and tobacco helps in managing hypertension [6].

Further, administration of Ayurveda medication i.e. *M-Sarpagandha Mishran* and *Pravala Pishti* helps in managing the raised blood pressure and augment the effect of conventional medicines. According to physiological point of view, it can be well-understood that the need of medication in a disease condition arises when human body fails to recover itself or when the required duration for recovery is longer. In both situations, it is common expectation that the intake of medicine should not be lasting lifelong. In case of EHTN, it is clear that human physiological mechanism is able up to an extent; however, it cannot resolve cause of EHTN permanently. The conventional intervention is efficient enough to control the pathology but has limitations in establishing normal physiological mechanism and thereby provides a permanent cure. On the other hand, Ayurveda interventions along with Yoga are aimed to break the pathology as well as to boost the natural physiological mechanisms. It was one major reason behind need of dose reduction of conventional medicine. In other words, Ayurveda intervention, Yoga therapy along with individualised lifestyle management is a way for effective management of EHTN. *M-Sarpagandha Mishran* helps in controlling EHTN specifically by the anti-hypertensive action of reserpine [7]. Other ingredients of the formulation strengthen the effect of formulation through anti-hypertensive, cardioprotective, and anti-stress actions. Yoga and lifestyle

Table 4
Showing effect of integrated management on systolic and diastolic blood pressure.

Conventional medicine given	Treatment Group	Systolic (mmHg) [Mean (SD)]				Diastolic (mmHg) [Mean (SD)]			
		0 day	After 3 month	After 6 month	^a p-value	0 day	After 3 month	After 6 month	^a p-value
A	Group I (n = 268)	150.68 (15.03)	130.39 (10.19)	126.90 (9.83)	<0.001	91.32 (9.29)	82.53 (6.03)	80.04 (5.43)	<0.001
	Group II (n = 585)	152.36 (15.79)	127.52 (13.30)	123.59 (10.97)	<0.001	91.21 (8.85)	79.18 (7.96)	78.63 (6.62)	<0.001
	#p-value	0.113	<0.001(*)	<0.001(*)		0.050	<0.001(*)	<0.001(*)	
B	Group I (n = 24)	151.08 (13.37)	128.08 (9.60)	124.50 (11.17)	<0.001	92.75 (4.44)	81.58 (6.21)	79.25 (4.78)	<0.001
	Group II (n = 60)	147.52 (16.41)	128.64 (17.11)	127.25 (13.57)	<0.001	90.85 (14.93)	79.25 (7.65)	79.75 (6.46)	<0.001
	#p-value	0.414	0.019(*)	0.072		0.942	0.141	0.159	
C	Group I (n = 128)	154.48 (19.10)	134.13 (14.18)	129.88 (12.21)	<0.001	93.76 (11.53)	84.48 (6.49)	81.74 (6.30)	<0.001
	Group II (n = 510)	153.74 (19.28)	132.12 (15.52)	129.38 (14.24)	<0.001	91.12 (10.63)	81.46 (8.60)	80.18 (7.19)	<0.001
	#p-value	0.762	0.394	0.063		0.027	0.008(*)	0.487	
D	Group I (n=83)	155.95 (13.17)	128.58 (8.39)	125.66 (7.46)	<0.001	95.78 (9.31)	83.61 (6.21)	80.70 (5.73)	<0.001
	Group II (n=122)	153.33 (16.27)	130.86 (11.23)	126.54 (9.87)	<0.001	93.26 (8.81)	83.69 (5.95)	80.91 (6.21)	<0.001
	#p-value	0.135	0.113	0.106		0.669	0.528	0.526	
E	Group I (n = 8)	142.75 (16.66)	131.00 (16.63)	124.75 (12.09)	<0.001	92.00 (2.82)	82.00 (9.13)	77.50 (5.09)	<0.001
	Group II (n = 147)	148.50 (14.58)	122.82 (9.96)	119.99 (8.88)	<0.001	91.80 (8.41)	74.54 (5.84)	75.64 (5.11)	<0.001
	#p-value	0.991	0.507	0.113		0.625	0.222	0.036(*)	

*p-value of <0.05 has been considered as significant.
A = Amlodipine, B = Atenolol, C = Amlodipine + Atenolol, D = Losartan, E = Telmisartan.
#Compared between group using independent sample t-test.
^a Compared at 3 months and 6 months w.r.t 0 day using paired t-test.

Table 5
Showing the effect of management on dose/frequency of conventional drug at 3rd and 6th month as compared to 0 day.

	Conventional Medicine given at 0 day	Effect of the integrated approach					
		Dose/frequency reduction			Medicine stopped		
		Group I	Group II	^a p-value	Group I	Group II	^a p-value
After 3 months	A	27 (10.1)	188 (32.0)	<0.00001	29 (10.8)	77 (13.1)	0.347
	B	8 (33.3)	19 (31.7)	0.880	4 (16.7)	10 (16.7)	1.000
	C	43 (33.6)	168 (32.9)	0.888	4 (3.1)	84 (16.5)	0.0001
	D	24 (28.9)	21 (17.2)	0.046	2 (2.4)	2 (1.6)	0.696
	E	1 (12.5)	63 (42.9)	0.089	0 (0.0)	9 (6.1)	0.471
	Total	103/511 (20.1%)	459/1427 (32.2%)	<0.001	39/511 (7.6%)	182/1427 (12.7%)	0.001
After 6 months	A	64 (23.9)	170 (28.9)	0.126	46 (17.2)	225 (38.3)	<0.00001
	B	6 (25.0)	17 (28.3)	0.756	8 (33.3)	23 (38.3)	0.667
	C	65 (50.8)	190 (37.3)	0.005	12 (9.4)	169 (33.1)	<0.00001
	D	33 (39.8)	33 (27.0)	0.056	11 (13.3)	39 (32.0)	0.002
	E	1 (12.5)	23 (15.7)	0.810	0 (0.0)	67 (45.6)	0.011
	Total	169/511 (33.1%)	433/1427 (30.3%)	0.254	77/511 (15.1%)	523/1427 (36.6%)	<0.001
		Drug Change			No reduction		
		Group I	Group II	^a p-value	Group I	Group II	^a p-value
After 3 months	A	33 (12.3)	44 (7.5)	0.022	179 (66.8)	279 (47.4)	<0.00001
	B	4 (16.7)	8 (13.3)	0.696	8 (33.3)	23 (38.3)	0.667
	C	9 (7.0)	37 (7.3)	0.928	72 (56.3)	221 (43.3)	0.008
	D	7 (8.4)	18 (14.8)	0.173	50 (60.2)	81 (66.4)	0.368
	E	0 (0.0)	26 (17.7)	0.193	7 (87.5)	49 (33.3)	0.001
	Total	53/511 (10.4%)	133/1427 (9.3%)	0.490	316/511 (61.8%)	653/1427 (45.7%)	<0.001
After 6 months	A	35 (13.1)	44 (7.5)	0.009	123 (45.9)	149 (25.4)	<0.00001
	B	6 (25.0)	11 (18.3)	0.490	4 (16.7)	9 (15.0)	0.849
	C	15 (11.7)	21 (4.1)	0.0008	36 (28.1)	130 (25.5)	0.222
	D	9 (10.8)	18 (14.8)	0.417	30 (36.1)	32 (26.2)	0.128
	E	0 (0.0)	44 (29.9)	0.067	7 (87.5)	13 (8.8)	<0.00001
	Total	65/511 (12.7%)	138/1427 (9.6%)	0.053	200/511 (39.1%)	333/1427 (23.3%)	<0.001

Values have been expressed as n (%).

A = Amlodipine, B = Atenolol, C = Amlodipine + Atenolol, D = Losartan, E = Telmisartan.

n (Group I – Amlodipine) = 268, n (Group I – Atenolol) = 24, n (Group I – Amlodipine + Atenolol) = 128, n (Group I – Losartan) = 83, n (Group I – Telmisartan) = 8, n (Group II – Amlodipine) = 588, n (Group II – Atenolol) = 60, n (Group II – Amlodipine + Atenolol) = 510, n (Group II – Losartan) = 122, n (Group II – Telmisartan) = 147.

^a Compared using two sample proportion test.

modification help in reducing serum cholesterol level which is one of the key requirements to break pathology of EHTN [8]. This in turn helps managing the dose/frequency of conventional medicines during follow-up and maintenance of blood pressure within normal limits along with strengthening physiological mechanism and thereby avoiding drug dependence. Though conventional medicines have its own significance; however, the integrated management through Ayurveda intervention provides a holistic approach towards management of EHTN with least side-effects.

During the study, dose reduction or discontinuation of conventional medicine at 3rd month indicates positive effect of Ayurveda medication along with lifestyle management and Yoga which may be due to the effect of integrated management at both physiological and psychological level. Lifestyle modification in the form of following daily routine, seasonal routine, and dietary changes help in removal of causative factors and to break the disease cascade. Further, Yoga helps in reducing systolic and diastolic blood pressure [9,10]. This effect is mediated through various *Yogasana*, *Pranayam*, and meditation which reduce stress and anxiety and normalize the physiology of the body [11]. However, the percentage improved significantly at sixth month which signifies the role of Ayurveda medication in substantial reduction/discontinuation of

conventional medicines when taken for long duration. Further, no adverse drug reaction/adverse drug event was reported in the analysed data.

Tab M-*Sarpagandha Mishran* is an Ayurvedic compound herbal formulation that posses anti hypertensive properties [5]. The ingredients of the formulation exhibits multi-factorial action on the central nervous system as well as to lipid levels in the body. Perez et al. in their Cochrane database review reported the anti-hypertensive activity of reserpine which is major phyto-constituent of *Sarpagandha* [12]. Reserpine, a major alkaloid of *Sarpagandha*, acts through binding to protein receptors called vesicular monoamine transporters at presynaptic neurons and inhibits uptake of neurotransmitters like norepinephrine, dopamine serotonin into pre-synaptic storage vesicles [13,14]. This in turn causes reduction in levels of catecholamine and serotonin at nerve terminals and leads to decrease in heart rate and decreased arterial blood pressure [15].

Jatamansi is known to possess hypolipidemic, anti-depressant and cardio protective activity [16]. Naik et al reported significant reduction in systolic and diastolic blood pressure with *Jatamansi* powder in a study conducted on 20 hypertensive participants [17]. *Brahmi* exhibits anti-oxidant, anti-inflammatory, anti-depressant, anti-epileptic, and anti-hypertensive activities [18]. This anti-

Table 6
Showing the Odds Ratio for dose reduction of conventional medicines between Group I and II at 3rd and 6th month from baseline.

Reduction in dose of Conventional medicine		Group I	Group II	Crude Odds-ratio	95% CI	p-value
At 3rd month as compared to baseline	No	408 (79.9%)	968 (67.8%)	1.88	1.47 to 2.39	<0.001
	Yes	103 (20.1%)	459 (32.2%)			
At 6th month as compared to baseline	No	342 (66.9%)	994 (69.6%)	0.88	0.71 to 1.09	0.253
	Yes	169 (33.1%)	433 (30.4%)			

Table 7
Showing the effect of integrative management on standard care at 6th month in comparison to 3rd month.

Status of drug at 3rd month	Assessment of drug at 6th month as compared to 3rd month	Group I					Group II				
		A	B	C	D	E	A	B	C	D	E
Dose/frequency reduced	Dose/frequency further reduced	0 (0)	0 (0)	6 (14)	0 (0)	0 (0)	4 (2.1)	0 (0)	23 (13.7)	0 (0)	0 (0)
	Drug stopped	8 (29.6)	1 (12.5)	11 (25.6)	5 (20.8)	0 (0)	76 (40.4)	4 (21.1)	58 (34.5)	12 (57.1)	48 (76.2)
	Drug changed	4 (14.8)	6 (75)	19 (44.2)	18 (75)	1 (100)	50 (26.6)	13 (68.4)	58 (34.5)	7 (33.3)	14 (22.2)
	Same reduced dose/frequency was continued	15 (55.6)	1 (12.5)	7 (16.3)	1 (4.2)	0 (0)	58 (30.9)	2 (10.5)	29 (17.3)	2 (9.5)	1 (1.6)
	Total (n)	27	8	43	24	1	188	19	168	21	63
Drug stopped	Continued to be stopped	12 (41.4)	1 (25)	2 (50)	0 (0)	0 (0)	35 (45.5)	2 (20)	21 (25)	1 (50)	3 (33.3)
	Drug restarted	17 (58.6)	3 (75)	2 (50)	2 (100)	0 (0)	42 (54.5)	8 (80)	63 (75)	1 (50)	6 (66.7)
	Total (n)	29	4	4	2	0	77	10	84	2	9
Drug change	Dose/frequency reduced	1 (3)	0 (0)	2 (22.2)	1 (14.3)	0 (0)	1 (2.3)	0 (0)	4 (10.8)	2 (11.1)	11 (42.3)
	Drug stopped	8 (24.2)	2 (50)	0 (0)	4 (57.1)	0 (0)	5 (11.4)	0 (0)	14 (37.8)	10 (55.6)	9 (34.6)
	Drug change	7 (21.2)	2 (50)	6 (66.7)	0 (0)	0 (0)	9 (20.5)	7 (87.5)	18 (48.6)	3 (16.7)	3 (11.5)
	Same drug was continued	17 (51.5)	0 (0)	1 (11.1)	2 (28.6)	0 (0)	29 (65.9)	1 (12.5)	1 (2.7)	3 (16.7)	3 (11.5)
	Total (n)	33	4	9	7	0	44	8	37	18	26
No reduction in drug dose/frequency	Dose/frequency reduced	1 (0.6)	0 (0)	33 (45.8)	0 (0)	0 (0)	36 (12.9)	0 (0)	60 (27.1)	1 (1.2)	0 (0)
	Drug stopped	14 (7.8)	0 (0)	11 (15.3)	27 (54)	0 (0)	29 (10.4)	0 (0)	54 (24.4)	52 (64.2)	30 (61.2)
	Drug change	22 (12.3)	7 (87.5)	16 (22.2)	23 (46)	7 (100)	71 (25.4)	23 (100.0)	89 (40.3)	27 (33.3)	19 (38.8)
	Same dose/frequency was continued	142 (79.3)	1 (12.5)	12 (16.7)	0 (0)	0 (0)	143 (51.3)	0 (0)	18 (8.1)	1 (1.2)	0 (0)
	Total (n)	179	8	72	50	7	279	23	221	81	49

Sub Group A = Amlodipine, Sub group B = Atenolol, Subgroup C = Amlodipine + Atenolol, Sub group D = Losartan, subgroup E = Telmisartan. Values have been expressed as n (%).

The (n) values mentioned in Table 7 are of the patients who have reported reduction/drug stopped/drug changed/no reduction at 3rd month. The fate of the patients with said n value at 6th month has been compared with 3rd month. The percentage has been calculated vertically. [Eg.: on adding the n values of drug reduction/drug change/drug stoppage/no reduction of conventional medicine A i.e. Amlodipine in Group I, the total n value stands 268 (27 + 29+33 + 179)].

hypertensive activity is medicated through release of nitric oxide from the endothelium and its effect on vascular smooth muscle Ca²⁺ homeostasis [19].

Different studies have reported anti-depressant, anti-epileptic, anti-hypertensive, and antioxidant activities of *Vacha* (*Acorus calamus*) [20]. It possesses anti-hypertensive effect mediated through Ca²⁺ antagonism and NO pathways [21]. *Shakhpushpi* has been known as a important medicine for anxiety neurosis and hypertension [22]. It possesses neuroprotective, nootropic, and anxiolytic activity [23]. *Guduchi* (*Tinospora cordifolia*) exhibits adaptogenic effect, improves physical performance, and suppresses over-activation of the sympathetic nervous system thereby, causing reduction in mean systolic blood pressure and Heart Rate (HR) [24].

Punarnava is used as a potent medicine for renal disorders. It has hepatoprotective, antioxidant, and anti-diabetic activities [25]. Alcoholic extract of *Boerhavia diffusa* produces significant diuretic activity in male albino rats with k + excretion comparable to frusemide [26]. Root extract of *B. diffusa* reduces systolic and diastolic blood pressure in chronic renal failure in dogs [27]. *Pravala Pishti* (Coral compound) contains natural calcium which acts as rejuvenator and help in maintaining the elasticity of the blood vessels.

Medicines of some participants had been changed at 6th month which may be due to either decrease in blood pressure which can be maintained through less potent and mild conventional medications or the blood pressure might had raised which need change of medication. Medications of some participants have been restarted which were stopped at 3rd month. The possible cause may be the rise in blood pressure. The duration of Yoga performed by individual participants, the dietary differences in Indian population, difference in following advised dietary rules and Indian seasonal variations, can be considered as confounding variables in this study. However due to large sample size this might be minimised.

4.1. Limitation of the study

There was a large variation in duration of conventional medication taken by the participants before starting the integrated

management. Further, the data of control arm for the conventional medicine alone was not available for analysis as both the groups were having lifestyle and Yoga along with conventional medicines in the project. The sampling method adopted was convenient sampling and randomization of cases was not there. Hence, further work with randomized sampling may be required to validate results of present work. Furthermore, the treatment duration was 6 months as per the study protocol. Hence, follow-up of longer duration is necessary for assessment of beneficial effects of dose reduction/discontinuation of conventional medicines with integrated management.

4.2. Way forward

Future studies may be carried out with assessment of other parameters such as effect on quality of life of the participants. The future studies should include control group with conventional medicine alone for better comparison of results. In screening of hypertensive cases, obesity assessment may be included for analysis.

5. Conclusion

Ayurveda medication (*M-Sarpagandha Mishran* and *Praval Pishti*) along with lifestyle management and Yoga effectively controls systolic and diastolic blood pressure and further helps in reducing/discontinuation of dose of conventional medicines in EHTN participants.

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Conflict of interest

None.

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