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-thirds 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 coartation of the aorta, renal artery stenosis, and other causes.

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

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1. 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.

2. Objective(s)

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

3. 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 medicines was also observed.

4. 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.

5. 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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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 emphasizes 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 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/Prem-Iron/Ethics/2007-08/RARIID/JPR, 4-4/RARISD/Ahmedabad/Tech./2020–21/1129.

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 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 1 DH at Surendranagar district of Gujarat, and 22 CHCs and 1 DH at Bhilwara district of Rajasthan were taken for analysis.

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 Praval Pishiti), 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/Prem-Iron/Ethics/2007-08/RARIID/JPR, 4-4/RARISD/Ahmedabad/ScienceTech./2020–21/1129.

2.7. Interventions given under integrated management

2.7.1. Ayurveda medications (pharmacological)

The M–Sarpagandha Mishran [5] 250 mg and Praval Pishiti 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), Fatamansi (Rhizome), Vacha (Rhizome), Punarnava (Root), Brahmi (Plant), Shankhpushpi (Plant) and Guduchi (Stem) while Praval Pishiti includes Shuddha Praval (Puri 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
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/ateno/losartan/te'misartan/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 spurs), 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.
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: %             |                  |                     |         |
|        | Male               | 212 (41.5)       | 672 (47.1)          | 0.029   |
|        | 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       | 39 (7.6)         | 143 (10.0)          |         |
|        | secondary          |                  |                     |         |
|        | College and above  | 32 (6.3)         | 130 (9.1)           |         |
| 4.     | Occupation (%)     |                  |                     |         |
|        | Desk Work          | 59 (11.6)        | 149 (10.4)          | 0.502   |
|        | Field work         | 129 (25.3)       | 455 (32.0)          |         |
|        | House Wife         | 264 (51.9)       | 678 (47.6)          |         |
|        | Others             | 57 (11.2)        | 142 (10.0)          |         |
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 Pishiti 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 modifications 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 intervention i.e. M-Sarpagandha Mishran and Praval Pishiti 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 3

| 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 |
| Irritability (anger spurts) | After 6 months | 90.0 | 9.8 | 0.2 | 86.9 | 12.5 | 0.5 |
| Giddiness | After 3 months | 77.0 | 23.0 | – | 80.4 | 19.5 | 0.1 |
| | After 6 months | 87.7 | 12.3 | – | 86.8 | 13.2 | – |
| Sleeplessness | 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 | – |
| Restlessness | 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 |
| Tremors | 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 |

Values have been reported as %; Treatment Group B1: Headache (n= 480), Irritability (n= 399), 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).

### Table 4

| Conventional medicine given | Treatment Group | Systolic (mmHg) [Mean (SD)] | Diastolic (mmHg) [Mean (SD)] |
|----------------------------|-----------------|-----------------------------|-----------------------------|
|                            | 0 day | After 3 month | After 6 month | *p-value | 0 day | After 3 month | After 6 month | *p-value |
| A Group I (n = 268) | 150.68 (15.03) | 130.39 (10.19) | 126.90 (9.98) | <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 (7.05) | 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 | 0.513 | 0.016 | 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.

#p-value at 3 months and 6 months w.r.t 0 day using paired t-test.
Modification help in reducing serum cholesterol level which is one of the key requirements to break pathology of HbTN [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 HbTN 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.

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

| Drug Change | Conventional Medicine given at 0 day | Effect of the integrated approach | Medicine stopped |
|-------------|--------------------------------------|----------------------------------|-----------------|
| Group I     | Group II                             | p-value                          | Group I         | Group II |
| A           | B                                    | C                                | D               | E        |
| 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) 0.0008 |
|             | 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 |
| A           | B                                    | C                                | D               | E        |
| 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 (45.8) 0.011 |
| Total       | 169/511 (33.1%) 433/1427 (30.3%) 0.254 77/511 (15.1%) 523/1427 (36.6%) <0.001 |

Values have been expressed as n (%).

| Drug Change | Conventional Medicine given at 0 day | Effect of the integrated approach | Medicine stopped |
|-------------|--------------------------------------|----------------------------------|-----------------|
| Group I     | Group II                             | p-value                          | Group I         | Group II |
| A           | B                                    | C                                | D               | E        |
| 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 (6.7) 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 |
| A           | B                                    | C                                | D               | E        |
| 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 (6 (15.0) 21 (41) 0.0008 36 (28.1) 130 (25.5) 0.222 |
|             | D (9 (10.8) 18 (14.8) 0.417 30 (26.1) 32 (26.2) 0.128 |
|             | E (0 (0.0) 44 (29.9) 0.067 7 (8.5) 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 |

| Drug Change | Conventional Medicine given at 0 day | Effect of the integrated approach | Medicine stopped |
|-------------|--------------------------------------|----------------------------------|-----------------|
| Group I     | Group II                             | p-value                          | Group I         | Group II |
| A           | B                                    | C                                | D               | E        |
| After 3 months | A (103 (20.1%) 459 (32.2%) 0.001 103 (20.1%) 459 (32.2%) 0.001 |
|             | B (342 (66.0%) 994 (69.6%) 0.088 169 (33.1%) 433 (30.4%) 0.253 |

Values have been expressed as n (%).
A = Amlodipine, B = Atenolol, C = Losartan, D = Telmisartan.
E = Sarpagandha Mishran

No (Group I – Amlodipine) = 268, n (Group I – Atenolol = 24), n (Group I – Losartan) = 122, n (Group I – Telmisartan) = 8, n (Group II – Amlodipine) = 588, n (Group II – Atenolol = 60), n (Group II – Losartan) = 510, n (Group II – Telmisartan) = 147.

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%) 0.001 1.00 |
| At 6th month as compared to baseline    | No 342 (66.0%) 994 (69.6%) 0.088 0.71 to 1.09 0.253 |
|                                          | Yes 169 (33.1%) 433 (30.4%) |

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 monamine transporter at presynaptic neurons and inhibits uptake of neurotransmitters like norepinephrine, dopamine serotinin into presynaptic 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].
hypertensive activity is mediated 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]. Shakpushpi has been known as an 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 herbal disorder. 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 frusemid [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 have raised which need change of medication. Medications of some participants were 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 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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