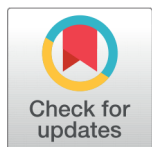


ORIGINAL ARTICLE



Cardiac Autonomic Effects of Ajwain (*Trachyspermum ammi*) in Hypertension: A Randomized Controlled Study

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Abstract

Background: Hypertension is linked with reduced heart rate variability (HRV). Ajwain (*Trachyspermum ammi*), a traditional medicinal herb, has reported autonomic benefits, but there is no study on HRV in hypertensive people. **Objective:** To evaluate the effect of Ajwain adjunct to routine antihypertension medicines on HRV in patients with stage 1 hypertension. **Method:** It was randomized control trial. Total 99 subjects with stage 1 hypertension were allocated to an intervention group (Ajwain 3 g twice daily along with routine antihypertensive medication, n=50) or a control group (routine antihypertensive medication, n=49). The intervention lasted 21 days. Primary outcomes were HRV indices [RMSSD, pRR50, LF, HF, LF/HF] along with systolic BP (SBP), diastolic BP (DBP). Data were analysed using SPSS v23 with significance at p<0.05. **Findings:** Within group analysis, both groups have shown significant improvement in HRV measures RMSSD and pRR50. HF power increased significantly in the Ajwain group (p=0.0158) but not in the control group. There was significant improvement in SBP, DBP, and pulse rate (p<0.0001). Between-group comparisons, no statistically significant differences in HRV and BP parameters after 21 days. However, the direction of change in HRV parameter was towards improving autonomic regulation with Ajwain along with routine antihypertensive medication group. **Novelty:** Ajwain supplementation for 21 days showed no added cardio-autonomic benefits beyond standard antihypertensive care, though this first-of-its-kind study offers important insights. Longer, standardized, and polyherbal-focused trials are needed to clarify Ajwain's cardio-autonomic effects in hypertension.

Keywords: Hypertension; Ajwain; Heart Rate Variability; Autonomic modulation; Randomized Controlled Trial; Ayurveda; Yoga & Naturopathy.

Trial registry no: - CTRI/2023/07/055294

1 Introduction

Hypertension (HTN) is a leading global health challenge causing cardiovascular mortality and morbidity. Globally, more than one billion adults were diagnosed with hypertension. Nearly one in three adults between ages 30 to 79 years have Hypertension⁽¹⁾. Heart rate variability (HRV) is one of the major assessments for predicting disease risk and assessing the efficacy of treatment in Hypertension⁽²⁾. The people having hypertension have low Heart rate variability (HRV) compared to healthy individuals and one of the major risk factors for hypertension⁽³⁾. The management of hypertension is addressed by various antihypertensive drugs. But outcomes from antihypertensive therapy are heterogeneous for HRV⁽⁴⁾. The drugs that lack strong autonomic modulation in HTN are not improving HRV. Hence improving lifestyle factors, holistic management become essential for good HRV in HTN.

Last few decades traditional and complementary medicine is widely used for treating various cardiovascular disorders⁽⁵⁾. In India, since ancient time to date, traditional herbal medicines from ayurveda and home remedies are used to treat various disorders effectively including neurophysiological and cardiovascular disorders⁽⁶⁾. In ayurveda's classical concept of cardiovascular and its autonomic balance maintained by all the three *doshas* *Vata*, *Pitta* and *Kapha* along with mind. The Pathogenesis (*Samprapti*) of cardio-autonomic diseases have the dominant role of *Vata dosha* along with the pathological contributions of *Kapha*, *Ama* and *Meda*. It is a *Vatapradhan*, *Tridoshaj* *Vyadhi* with *Rajas* and *Tamas dosha* of mind. Among various herbs Ajwain is one of the herbs which could fit to dissolve this pathology.

Interventions that restore autonomic balance by enhancing HRV might provide therapeutic benefits in hypertensive populations. Different researches have shown that various Ayurveda herbs including Ajwain are used in the management of HTN⁽⁷⁾. It is rich in bioactive compounds such as thymol, flavonoids, and essential oils with documented antihypertensive, antioxidant, anti-inflammatory, and cardioprotective properties⁽⁸⁾. Preclinical studies suggest Ajwain may exert vasodilatory effects, improve endothelial function, and modulate sympathetic activity⁽⁹⁾,⁽¹⁰⁾. However, its impact on cardiac autonomic modulation assessed via HRV has not been systematically evaluated in HTN patients. Hence considering its traditional use and preliminary studies outcomes this study was planned to see its impact on HRV among HTN subjects.

2 Methodology

This study was a prospective, Randomized Controlled Trial (RCT). Subjects were diagnosed for stage one hypertension, and history was taken to ensure they met the inclusion and exclusion criteria.

2.1 Eligibility criteria

Both genders, in the age group of 30–70 years, with stage one hypertension (140–159/90–99 mmHg) on prescribed antihypertensive medications and showed a willingness to participate in the study were included. Subjects with secondary or stage 2 hypertension onwards, having history of cardiovascular event or hospitalization due to angina were excluded. Participants having coronary heart disease, diabetes, neurological or, psychological illness was excluded from the study. Subjects having any addiction of smoking, alcohol or other substance use were excluded. If they were using complimentary herbal or home remedies were not included in the study.

The study subjects were randomly divided into intervention and control group (Figure 1).

Randomization was done by using random table generator. There were no similar studies done previously in this type of intervention hence we considered 100 sample size. By considering 15% total dropout rate total 116 subjects were recruited, 58 in each group. The recruitment started from December 2023 to May 2024 at The outpatient department of Subharti Yoga & Naturopathy Hospital and Chhatrapati Shivaji Subharti Hospital, Meerut, Uttar Pradesh, India.

Informed written consent was obtained from all the study participants at the time of recruitment in the study. The study protocol was approved by the Institutional ethical Committee (Ref No: - SMC/UECM/2023/583/282). The study was registered with the clinical trial registry of India (CTRI) with registration no: - CTRI/2023/07/055294.

Data Handling and Internal Control Measures

Data were gathered standardized case record forms. Baseline and post-intervention assessments were performed using same protocols. Data were anonymized by using codes for each subject. Data was extracted in excel sheet with double-entry verification. Adherence for treatment was monitored by using diaries and regular telephonic follow-ups. The subjects with complete baseline and follow-up data were included in the analysis.

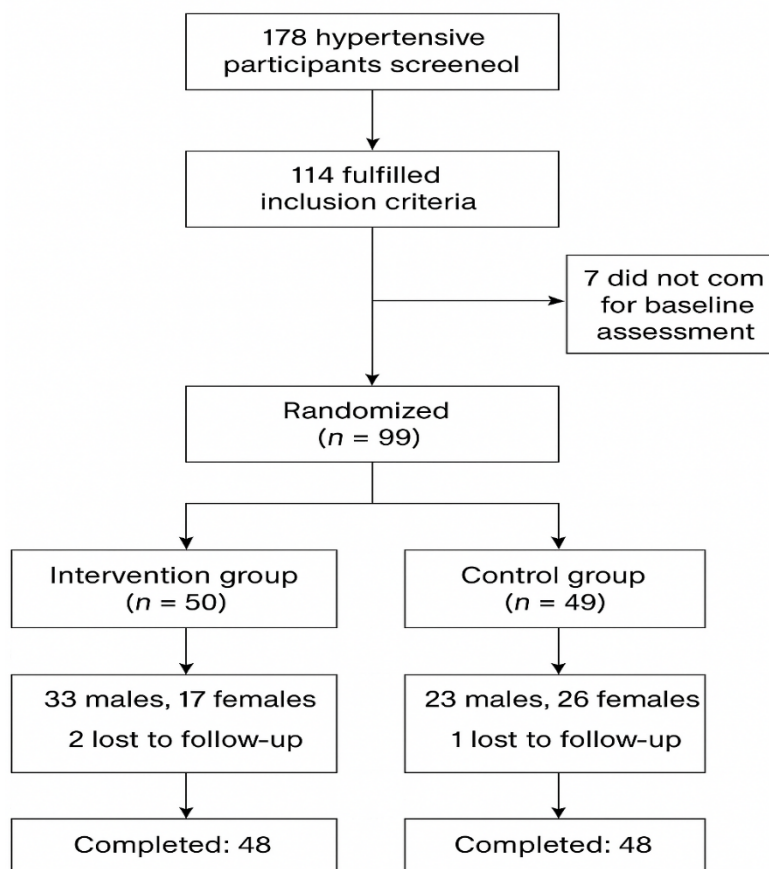


Fig 1. Consort flow diagram

2.2 Intervention

Ajwain (*Trachyspermum ammi*) seeds used in this study were purchased from a local market without additional processing or standardization of bioactive compounds. The seeds were used in their natural form, as commonly consumed in traditional medicine and dietary practices.

The intervention group was given 3-gram ajwain twice a day along with existing prescribed antihypertensive medicines. The participants were instructed to chew Ajwain and swallow with a glass of water daily for 21 days. Participants were instructed to maintain the intervention diary for 21 days. The medications used in this group were calcium channel blockers Amlodipine (5 mg or 10 mg daily), Beta-Blockers - Metoprolol (25 mg or 50 mg daily), Angiotensin-Converting Enzyme Inhibitors - Enalapril (5 mg or 10 mg daily), Angiotensin Receptor Blockers Telmisartan (40 mg or 80mg daily), Diuretics - Hydrochlorothiazide (12.5 mg or 25 mg daily).

The control group was instructed to continue with only their prescribed antihypertensive medicines. The same classes of antihypertensive drugs were taking both the groups ensuring uniformity in treatment, and the dosages were based on the participant's existing prescriptions. The participants were contacted on alternate days for 21 days via phone to reinforce adherence to ajwain seed and medications using intervention dairy and also to resolve any queries and to report the adverse effects. This design allowed us to evaluate the adjunctive effects of Ajwain on autonomic function and blood pressure regulation, without compromising the efficacy of standard hypertension treatment. The demographic details are given in Table 1.

Table 1. Demographic Details

Variables	Intervention group(n=50)	Cotrol group(n=49)	P-Value
Age	44.82 ± 9.3	44.22 ± 9.2	0.746
Gender			
Male	33 (66%)	23 (46%)	0.0440*
Female	17 (34%)	26 (54%)	
Height (in cm)	168.20±11.00	164.48±10.86	0.092
Weight (in kg)	64.90±7.57	62.42±6.02	0.0728
Body Mass Index (BMI) (in kg/m ²)	23.02±2.46	23.16±2.14	0.755

*P value <0.05 was considered statistically significant

2.3 Outcome Measures

2.3.1. Heart Rate Variability

To record HRV a PowerLab 17T device (AD Instruments Inc. Australia) with a Bipolar limb lead II configuration were used. Participants were instructed and prepared for assessment of HRV. Participants were instructed to avoid tea, coffee, nicotine, or heavy meals for at least 6 hours before the test to minimize autonomic fluctuations. participants were instructed to lie supine for 10 minutes before the recording to allow autonomic stabilization. Recording was conducted in a quiet room to reduce environmental stressors. were instructed to avoid talking, moving, or crossing their legs during the measurement. A 5- minute continuous HRV recording was performed to ensure reliable data collection^{(11), (12)}. The electrodes were placed in the same anatomical positions for all participants to reduce variability.

2.3.2. Blood pressure

Blood pressure and pulse rate were measured using a validated digital sphygmomanometer (Morepen BP15, India) to ensure accuracy. The cuff was tied snugly on the left hand. It was recorded twice and mean of the both readings were considered.

2.4 Statistical Analysis

Statistical analysis was conducted using IBM SPSS Statistics (version 23.0, IBM Corp., USA). The data was analyzed for normality using the Kolmogorov-Smirnov test. Normally distributed variables were analyzed using parametric tests, while non-normally distributed variables were analyzed using non-parametric tests. Most parameters followed a normal distribution except LF/HF (%), which showed a skewed distribution. Independent t-tests were used to compare normally distributed baseline data between the intervention and control groups. Mann-Whitney U tests were applied for skewed variables (e.g., LF/HF ratio). Within the group, a comparison was analyzed using paired t-tests for normally distributed data whereas, Wilcoxon matched pairs tests were used for non-normally distributed data. The effect size was calculated using Cohen's d formula. Analysis was performed by a researcher blinded to group allocation to prevent bias in interpretation.

3 Results and Discussion

Out of 178 hypertensive participants screened, 114 fulfilled the inclusion criteria and 106 showed willingness to participate in the study. 7 participants did not come to baseline assessment. Total 99 participants were randomly divided into two groups: Intervention group 50 and control group 49. The intervention group consisted of 33 males and 17 females, with a mean age and body mass index (BMI) was 44.82 ± 7.2 years and 23.02 ± 2.46 kg/m² respectively. The control group included 23 males and 26 females, with a mean age and BMI 44.22 ± 8.1 years 23.16 ± 2.14 kg/m², respectively. Two participants in intervention group and one in control group did not come to follow-up assessment. Hence 48 in intervention group and Control group completed study.

3.1 Within the group comparison

In the intervention group (Ajwain along with routine medicine) significant reductions were observed in SBP, DBP, and PR with $p < 0.0001$. Time-domain HRV parameters RMSSD ($p < 0.0036$) and pRR50 ($p < 0.0001$) showed notable increases. Among frequency-domain parameters, HF ($p < 0.0158$) increased significantly, while VLF, LF and LF/HF showed non-significant reductions. In the Control group, significant reductions were observed in SBP, DBP, and PR ($p < 0.0001$). Time-domain HRV

parameters also improved (RMSSD = 0.0165; pRR50 = 0.0001). However, frequency-domain parameters, HF, VLF, LF, LF/HF showed non-significant changes. Comparison of pre-test and post-test data in control and study groups is given in Table 2.

Table 2. Comparison of pre-test and post-test data in control and study groups.

S.No	Parameters	Intervention Group			Control Group		
		Pre-test Mean±SD	Post-test Mean±SD	P-Value	Pre-test Mean±SD	Post-test Mean±SD	P- Value
1	SBP	148.50±3.99	134.54±2.94	0.0001*	148.20±4.67	133.52±2.95	0.0001*
2	DBP	93.52±2.23	84.90±3.05	0.0001*	93.14±1.96	84.00±2.55	0.0001*
3	Pulse rate	93.14±3.89	83.10±5.51	0.0001*	90.68±4.28	81.42±4.82	0.0001*
4	RMSSD (ms)	33.18±27.36	49.78±35.99	0.0036*	43.16±38.28	64.40±55.29	0.0165*
5	pRR50 (%)	6.52±7.49	20.50±19.04	0.0001*	9.20±12.83	23.64±20.69	0.0001*
6	VLF (%)	34.84±16.33	32.14±17.52	0.315	35.05±20.30	32.73±22.03	0.5335
7	LF (n.u)	52.05±21.38	46.23±19.42	0.1127	43.65±23.12	39.66±21.46	0.3595
8	HF (n.u)	43.85±19.48	52.05±18.70	0.0158*	50.41±19.98	55.22±20.38	0.2361
9	LF/HF (%)	1.78±1.75	1.14±0.89	0.2078	1.31±1.45*	1.08±1.06	0.1358

SBP: Systolic Blood Pressure, **DBP:** Diastolic Blood Pressure, **RMSSD (ms):** Root Mean Square of Successive Differences, measured in milliseconds, **pRR50 (%)**: Percentage of successive RR intervals differing by more than 50 milliseconds, **VLF (%)**: Very-Low-Frequency, a component of heart rate variability, **LF (n.u.):** Low-Frequency (band of heart rate variability) in Normalized Units, **HF (n.u.):** High-Frequency (band of heart rate variability) in Normalized Units, **LF/HF (%)**: The ratio of Low-Frequency to High-Frequency power. *P value <0.05 was considered statistically significant.

3.2 Between the group comparison (Table 3)

After the 21-day intervention, there was no statistically significant difference between the intervention and control groups except pulse rate ($p < 0.0001$). Still, trends suggest that Ajwain with routine hypertensive medication group may enhance parasympathetic modulation (RMSSD, HF, pRR50), though the differences did not reach statistical significance.

This is the first study to evaluate the benefits of Ajwain on autonomic modulation on hypertensive subjects. HRV indices, particularly RMSSD and pRR50, improved significantly in both groups, reflecting enhanced vagal modulation. Similar benefits were observed in a trial of antihypertensive therapy. It indicates that blood pressure control contributes to HRV regulation⁽¹³⁾ However, the only HF power showed a significant rise in the Ajwain group, showing a possible parasympathetic enhancement benefit. There was significant change in pulse rate in between group indicating a potential autonomic influence of Ajwain. Earlier preclinical studies on demonstrated that Ajwain acts as antioxidant, anti-inflammatory, and have cardioprotective properties which may contribute to autonomic modulation^{(9), (14)}. Between groups comparison, there was no significant results this indicating that sympatho-vagal balance remained relatively stable. However, the direction of changes observed in the intervention group (increase in HF, reduction in LF and LF/HF ratio) indicates a trend towards improved autonomic regulation with Ajwain.

Within group analysis both the intervention and control groups demonstrated a significant reduction in systolic and diastolic blood pressure, as well as pulse rate, after 21 days of treatment. The blood pressure is not improved between-group, hence suggesting that additionally Ajwain is unable to reduce blood pressure along with anti-hypertensive medicines.

Ajwain supplementation may not independently enhance blood pressure reduction, but it may improve parasympathetic tone and autonomic regulation. This highlights its potential as an adjunctive therapy in the holistic management of hypertension. The heart revival study after giving a polyherbal formulation for 8 weeks improved sinus rhythm and ST-depression and Right bundle branch block on ECG in the study participants⁽¹⁵⁾. In our study we gave single herb for 3 weeks and assessed the HRV. This shows that the polyherbal formulations could be the better options than the single herb use with longer duration for the benefits of cardiac conduction and cardio-autonomic balance⁽¹⁶⁾.

3.3 Strength and limitations

This is the first study where we assessed Ajwain seeds impact on HRV among grade one hypertensive people. The study utilized standardized objective and validated assessment tools, ensuring accuracy and reliability in data collection. But the intervention period was shorter. The sample size was modest. There could be strong efficacy of hypertensive oral medications that could hide the subtle benefits of ajwain.

Table 3. Between Group Comparison

S. No.	Parameter	Time	Control Group Mean $\pm$ SD	Intervention Group Mean $\pm$ SD	p-Value	Mean Diff.	95% CI for mean Diff.	
							Lower	Upper
1	SBP	Pretest	148.20 $\pm$ 4.67	148.50 $\pm$ 3.99	0.73	-0.3	-2.02	1.42
		Post-test	133.52 $\pm$ 2.95	134.54 $\pm$ 2.94	0.086	-1.02	-2.19	0.15
		Difference	14.68 $\pm$ 3.49	13.96 $\pm$ 4.69	0.39	0.72	-0.92	2.36
2	DBP	Pretest	93.14 $\pm$ 1.96	93.52 $\pm$ 2.23	0.37	-0.38	-1.21	0.45
		Post-test	84.00 $\pm$ 2.55	84.90 $\pm$ 3.05	0.11	-0.9	-2.02	0.22
		Difference	9.14 $\pm$ 2.46	8.62 $\pm$ 3.23	0.37	0.52	-0.62	1.66
3	Pulse rate	Pretest	90.68 $\pm$ 4.28	93.14 $\pm$ 3.89	0.00*	-2.46	-4.08	-0.84
		Post-test	81.42 $\pm$ 4.82	83.10 $\pm$ 5.51	0.11	-1.68	-3.73	0.37
		Difference	9.26 $\pm$ 4.12	10.04 $\pm$ 4.31	0.36	-0.78	-2.45	0.89
4	RMSDD (ms)	Pretest	43.16 $\pm$ 38.28	33.18 $\pm$ 27.36	0.14	9.98	-3.23	23.18
		Post-test	64.40 $\pm$ 55.29	49.78 $\pm$ 35.99	0.12	14.62	-3.89	33.14
		Difference	21.24 $\pm$ 60.46	16.59 $\pm$ 38.37	0.65	4.65	-15.45	24.74
5	pRR50 (%)	Pretest	9.20 $\pm$ 12.83	6.52 $\pm$ 7.49	0.2	2.68	-1.48	6.85
		Post-test	23.64 $\pm$ 20.69	20.50 $\pm$ 19.04	0.43	3.14	-4.75	11.03
		Difference	14.44 $\pm$ 18.24	13.98 $\pm$ 17.64	0.9	0.46	-6.66	7.58
6	VLF (%)	Pretest	35.05 $\pm$ 20.30	34.84 $\pm$ 32.14	0.95	0.21	-7.1	7.52
		Post-test	32.73 $\pm$ 22.03	32.14 $\pm$ 17.52	0.88	0.6	-7.3	8.49
		Difference	-2.31 $\pm$ 26.10	-2.70 $\pm$ 18.78	0.93	0.38	-8.64	9.41
7	LF (n.u)	Pretest	43.65 $\pm$ 23.12	52.05 $\pm$ 21.38	0.06	-8.4	-17.24	0.44
		Post-test	39.66 $\pm$ 21.46	46.23 $\pm$ 19.42	0.11	-6.57	-14.69	1.56
		Difference	-3.99 $\pm$ 30.50	-5.82 $\pm$ 25.49	0.75	1.83	-9.32	12.99
8	HF (n.u)	Pretest	50.41 $\pm$ 19.98	43.85 $\pm$ 19.48	0.1	6.56	-1.27	14.39
		Post-test	55.22 $\pm$ 20.38	52.05 $\pm$ 18.70	0.42	3.17	-4.6	10.93
		Difference	4.81 $\pm$ 28.33	8.20 $\pm$ 23.19	0.51	-3.39	-13.67	6.88
9	LF/HF (%)	Pretest	1.31 $\pm$ 1.45	1.78 $\pm$ 1.75	0.07	-0.46	-1.1	0.18
		Post-test	1.08 $\pm$ 1.06	1.14 $\pm$ 0.89	0.22	-0.06	-0.45	0.33
		Difference	-0.24 $\pm$ 1.80	-0.64 $\pm$ 1.90	0.76	0.4	-0.33	1.13

SBP: Systolic Blood Pressure, **DBP:** Diastolic Blood Pressure, **RMSDD (ms):** Root Mean Square of Successive Differences, measured in milliseconds, **pRR50 (%)**: Percentage of successive RR intervals differing by more than 50 milliseconds, **VLF (%)**: Very-Low-Frequency, a component of heart rate variability, **LF (n.u.):** Low-Frequency (band of heart rate variability) in Normalized Units, **HF (n.u.):** High-Frequency (band of heart rate variability) in Normalized Units, **LF/HF (%)**: The ratio of Low-Frequency to High-Frequency power. *P value <0.05 was considered statistically significant

4 Conclusion

This study is first this kind to find the impact of Ajwain supplementation on cardio-autonomic modulation for hypertensive participants. The 21 days adjunct intervention of Ajwain (*Trachyspermum ammi*) did not show changes, statistically, in autonomic variables when compared to standard antihypertensive treatment. Further studies need to take long term intervention, consideration of polyherbal formulation with ajwain as major ingredient. The phytochemical extraction and standardization are essential to find the benefit of Ajwain for cardio-autonomic impact in HTN.

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During the preparation of this work, the authors used ChatGPT only to improve the readability and language of the manuscript. After using this tool/ service, the authors reviewed and edited the content as needed and take full responsibility for the content of the published article.

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