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Effect of a yoga and naturopathy-based lifestyle intervention with nine-month follow-up on heart rate variability in patients with hypertension: A randomized controlled trial

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ABSTRACT

Purpose: Hypertension is associated with autonomic nervous system (ANS) dysregulation. Heart rate variability (HRV) monitoring is frequently used as a gauge of the ANS balance. The aim of the present study was to assess the effects of yoga and naturopathy on the autonomic variables in patients with hypertension.
Methods: 262 hypertensive patients were randomly allocated to the study group (SG) or control group (CG) in a randomized controlled trial. For ten days, the SG (n = 131) group got received naturopathic treatments and yoga, whereas the CG (n = 131) group did not. HRV which was examined at the beginning and end of the 10-day intervention period and again after 9 months, served as the study's main endpoint.
Result: There was a significant change in the frequency domain of heart rate variability with a significant increase in High frequency (HF) and a significant decrease in low frequency (LF) and LF/HF (all $p < 0.05$) were observed after follow-up in both SG and CG, but the magnitude of change was more in SG with a significant difference in LF/HF between group.
Conclusion: Results of this study suggest that 10 days of integrated yoga and naturopathy intervention produces a shift of vagal activity towards parasympathetic activity.
Clinical trial registration number: CTRI/2019/01/016883.

1. Introduction

Hypertension, also known as high blood pressure (BP), is a prevalent ailment where systemic arterial BP is elevated (Kumar et al., 2017). Although a larger population of patients suffering from hypertension remain asymptomatic, some report headaches, lightheadedness, vertigo, altered vision, or fainting episodes (Kario et al., 2024). According to estimates from 2010, 28.5% (337–361 million) of adults worldwide had hypertension, compared to 31.5% (0.99–1.09 billion) of individuals in low- and middle-income countries (Mills et al., 2016). Due to its widespread prevalence across the world, hypertension is a major public health concern (Singh et al., 2017). It is the main contributor to cardiovascular disease risk and accounts for over 9.4 million annual fatalities worldwide (Vallianou et al., 2020). The main risk factors for hypertension in Indian patients are age, smoking and tobacco usage, obesity, eating fewer fruits and vegetables, eating too much salt and fat in their diets, and not exercising enough (Anchala et al., 2014).

Hypertension has long been linked to Autonomic Nervous System (ANS) Dysfunction (Valensi, 2021). The Heart rate variability (HRV) index, is a straightforward, non-invasive technique used to assess the cardiac autonomic functions (Siepmann et al., 2022). A healthy lifestyle, such as engaging in physical activity and implementing dietary changes have been shown to lower blood pressure (Williams et al., 2018). Naturopathic medicine is a type of primary health care that includes

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Manipulative therapy, Mud therapy, Magneto therapy, Acupuncture, Diet and Fasting therapy, Hydrotherapy, Physical therapy and Rehabilitation (Nair and Nanda, 2014). In general, the practice of yoga has been found to bring balance in the autonomic functions with a trend toward parasympathetic dominance (Peter et al., 2015). Various yoga breathing techniques are known to modify the cardiovascular functions (Srihari Sharma et al., 2019), baroreflex sensitivity (Mason et al., 2013) and autonomic responses (Akella et al., 2020).

Yoga and Naturopathy encourage people to change their lifestyle in order to live as near to nature as possible (Beer et al., 2001).Yoga and Naturopathy have also been found to positively influence cardiac autonomic modulation in both healthy and unhealthy populations (Tyagi and Cohen, 2016). Considering the importance of Yoga and Naturopathy in the traditional texts and the lack of scientific understanding of their effects over hypertension, the current study was undertaken to evaluate the effects of Yoga and Naturopathic intervention on autonomic functions in patients with hypertension.

2. Methods

2.1. Study design and setting

The current study was prospectively randomized and employed into parallel groups. Fig. 1 shows the trial flow that was conducted from February 2020 to March 2022 at the SDM College of Naturopathy and Yogic Sciences and its hospital in south India.

2.2. Participants

Upon completion of the eligibility screening process by a registered Naturopathy and Yoga Physician who is not part of the study, participants who satisfied the requirements were given an information sheet, detailing the aim and design of the research. Every participant indicated their willingness to participate in the study by signing an informed consent form.

2.3. Inclusion and exclusion criteria

A participant was eligible if they met the following inclusion requirements: Patients with hypertension, both male and female, aged 25 to 60, with a blood pressure reading of at least 130/90 mmHg or on antihypertensive medication. Patients with uncontrolled hypertension, those reporting secondary hypertension, and those with thyroid abnormalities or any documented acute illness were among the exclusion criteria.

2.4. Ethical consideration

The process was approved by the institutional review board of Yogic Sciences and SDM College of Naturopathy and Yogic Sciences in Ujire, India. Participants who fulfilled the eligibility conditions received a paper outlining the goal and intervention of the trial. The desire of each participant to engage in the study resulted in the acquisition of their signed informed permission to do so.

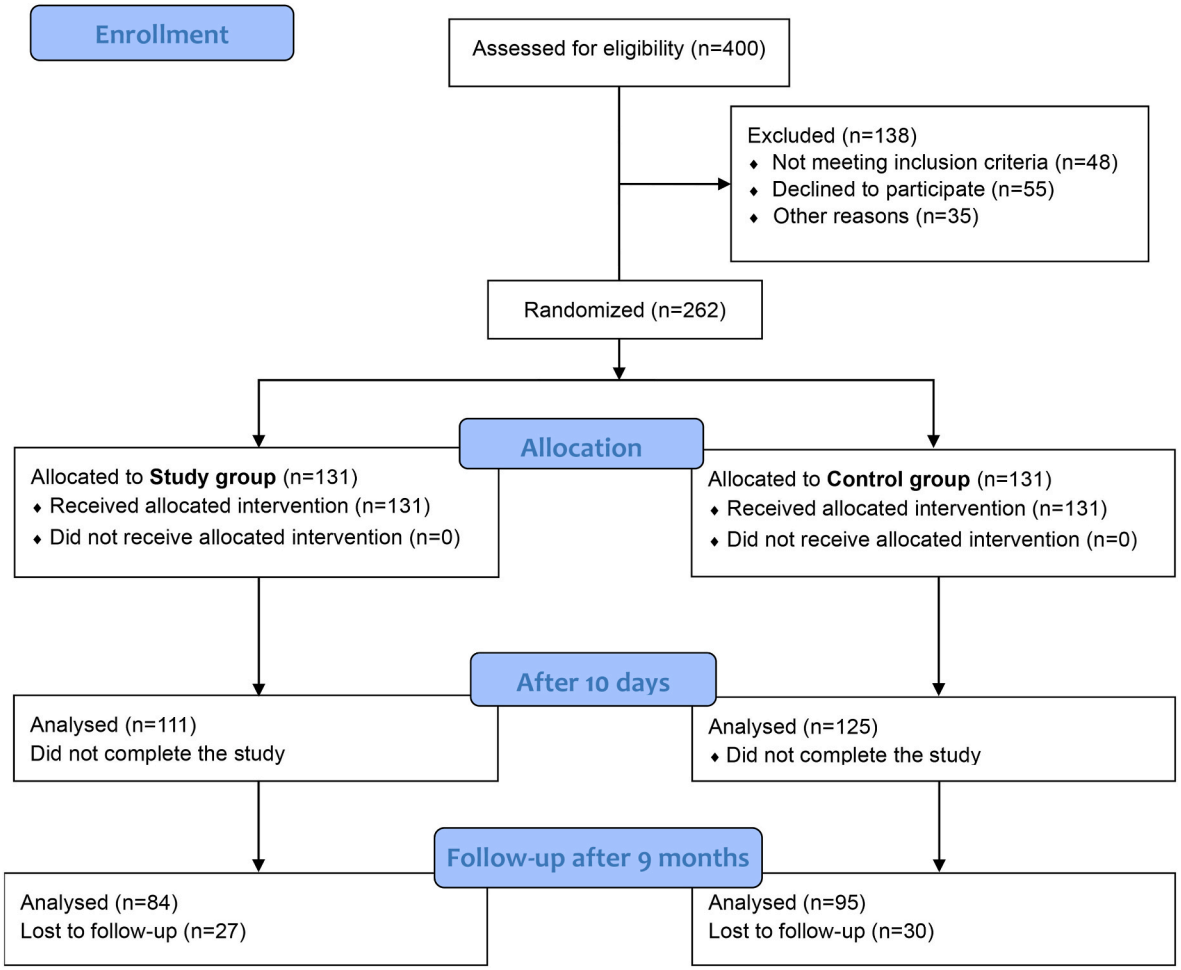

Fig. 1. CONSORT flow chart of the study.

2.5. Sample size

The sample size is calculated by using G*power 3.19 for assumption of repeated measures analysis of variance (RMANOVA) for within and between group interactions, considering a 1:1 allotment ratio for a parallel arm design at 80% power (1 – β), with 5% level of significance (α), and for expecting mild magnitude of change to effect size f(v) = 0.25 with 2 tailed hypothesis the total sample size was found to be 196. For a 25% anticipated attrition rate the total sample size was multiplied by a factor value of 1.33, the obtained number is 261 which is rounded to 262 (131 per group).

2.6. Randomization

To achieve randomization, a block randomization approach with various block lengths was employed. Utilizing computationally produced random numbers; randomization was carried out. Once every participant in a potential treatment group has completed the baseline assessment, the study coordinator will notify the study statistician to get the next group ready for randomization. The statistician will then notify the treatment coordinator about the group's randomization.

2.7. Blinding

An investigator who had done the assessments, all involved therapists and statisticians were blinded.

2.8. Interventions

Patients were assessed by a qualified physician upon admission and the details of their clinical case were noted on a treatment card. Due to the significant lifestyle changes anticipated, blood pressure (BP) was checked twice daily. The study was carried out over three years.

2.9. Study group (SG)

As indicated in Supplementary Table 1, all participants had received 10 days of integrated Yoga and Naturopathy treatments, during this period, the patients experienced different Yoga and Naturopathy procedures from 5:30 a.m. to 9:00 p.m. and the frequency of each treatment could be found delineated in the Supplementary Table 1. By considering the age difference, gentle Yoga protocols which will be comfortable for all the patients were designed. The 2000 calories of food were given by considering the recommendations of the DASH diet (Chiavaroli et al., 2019). The patients were told to include Naturopathy and Yoga into their everyday routines after the 10-day intervention. The directions for following up that were given at the time of discharge are presented in Supplementary Table 2.

2.10. Control group (CG)

For ten days, the individuals in CG received only their usual prescription medicine and neither Yoga nor Naturopathic therapies were given. Following recruitment, the patients from SG and CG were asked to return for follow-up visits after nine months.

2.11. Assessments

2.11.1. Heart rate variability

The Electro Cardiogram (ECG) was recorded using a conventional bipolar limb lead II arrangement by a 16-channel human physiology system (PowerLab 8/35, AD Instruments, Australia). In order to get the heart rate variability (HRV) spectrum, the ECG was digitally converted using a 16-bit analogue to digital converter at a sampling rate of 1 KHz. The Lab Chart 8 program (AD Instruments, Australia) was used to analyze the frequency domain and time domain of the HRV data.

2.11.2. Data extraction

The 16-channel polygraph yielded the following data. By counting the R waves of the QRS complex in the ECG, the heart rate was determined in beats per minute. The analysis of HRV data was done in both the frequency domain and the time domain. Low frequency (LF) band (0.04–0.15 Hz) and high frequency (HF) bands (0.15–0.5 Hz) were used to study the energy in the HRV series. LF and HF band values were expressed as normalized units in accordance with standards. Additionally, the LF/HF ratio was computed. The following time domain HRV components were examined: the square root of the mean of the sum of the squares of differences between adjacent NN intervals (RMSSD), the standard deviation of NN intervals (SDNN), and the proportion derived by dividing NN50 by the total number of NN intervals (pNN50)

2.12. Data analysis

All statistical analyses were performed using version 16 of the Statistical Package for the Social Sciences (SPSS). For every set of data that was given as mean standard deviation, the normality of the distribution was evaluated using the Shapiro-Wilk test. Non-parametric tests were employed since the data were not normally distributed. The baseline difference was analyzed using the ANCOVA model, and percentages and figures were presented to represent the descriptive features. The chi-square test was used to compare demographics, the Mann Whitney *U* test was used to compare data across groups, and the Wilcoxon signed ranked test was used to compare data within groups. A p-value of less than 0.05 was identified as statistically significant.

3. Results

This study aims to assess the impact of a combined strategy utilizing Yoga and Naturopathy on the HRV of hypertension patients. 400 of the 1500 patients who were screened and found to be eligible were chosen for the trial. Randomization was used to divide the 262 participants into two groups: the SG, which had 131 members, and the CG, which also had 131 members. However, since they did not comply with the therapy and follow-up, 20 people from the SG and 6 from the CG were eliminated from the final analysis. The study was carried out between February 2020 and February 2022.

In the study group, the mean age was 50.09 ± 8.57, while in the control group, it was 51.63 + 7.83 without any statistical difference between groups of $p = 0.63$. Additionally, 57.5% of subjects in the study group were male, and 42.4% were female, whereas in the control group, it was 58.8% male and 41.13% female, whereas the chi-square test shows that there was no statistical difference in gender differentiation between the groups with $p = 0.79$.

3.1. Heart rate variability

There was a significant increase in HF ($p < 0.001$) with a significant decrease in LF and LF/HF ($p < 0.05$) in SG after follow-up, which was not observed in CG (Table 1).

4. Discussion

Our study reports that integrated Yoga and Naturopathy therapy significantly improves HRV, which is a measure of cardiovascular health. According to the study's findings, there was an increase in HF with a decrease in LF and LF/HF. Additionally, a prior study on thermal therapy found that lowering blood was linked to lowered total peripheral resistance and improved peripheral circulation (Iiyama et al., 2008). The increase in HF could possibly be through parasympathetic activation. This indicates the role of yoga and naturopathy in altering or reducing sympathetic activity. Mooventhan et al. (Mooventhan and Nivethitha, 2016) showed that applying an ice bag to the head and spine helps reduce pulse rate and blood pressure. During head-out water

Table 1
Change in HRV before (baseline), after (post), and follow-up of yoga & naturopathy interventions with control and Study groups.

Variables	Study			Control			Between-group (post)		Between-group (Follow-up)	
	Baseline (n = 108)	Post (n = 108)	Follow-up (n = 73)	Baseline (n = 118)	Post (n = 118)	Follow-up (n = 90)	z	*P*-value	z or T	*p*-value
Average RR (s)	973.25 ± 750.53	906.17 ± 136.19	913.8 ± 125.18	918.59 ± 162.18	911.95 ± 140.12	935.33 ± 151.37	z = 0.11	0.9	0.71	0.59
Heart rate (bpm)	67.66 ± 9.82	67.13 ± 8.85	67.17 ± 9.14	67.87 ± 11.69	68.31 ± 11.78	66.79 ± 11.66	z = 0.36	0.71	T = 0.23	0.81
SDNN (ms)	37.61 ± 15.82	39.83 ± 18.17	43.69 ± 39.6	36.61 ± 18.93	53.58 ± 78.13	41.98 ± 25.88	z = 1.33	0.18	z = 0.81	0.41
RMSSD (ms)	33.79 ± 27.88	32.39 ± 23.62	41.89 ± 63.84	46.67 ± 76.47	62.62 ± 125.17	37.45 ± 37.59	z = 0.15	0.87	z = 1.07	0.28
pNN50 (%)	12.07 ± 16.47	10.47 ± 14.22	14.33 ± 17.62	13.25 ± 20.31	14.21 ± 22.12	12.26 ± 17.39	z = 0.26	0.79	z = 1.02	0.3
LF power (nu)	48.29 ± 19.35	51.55 ± 20.89	42.77 ± 21.44**	47.68 ± 22.03	47.29 ± 18.39	46.81 ± 21.36**	z = 1.47	0.14	z = 1.09	0.27
HF power (nu)	49.19 ± 18.14	46.79 ± 18.52	55.09 ± 19.05*	49.42 ± 19.65	50.25 ± 16.85	50.92 ± 20.44*	z = 1.39	0.16	z = 1.15	0.25
LF/HF	1.8 ± 3.48	2.34 ± 4.98	1.16 ± 1.25*	1.58 ± 2.01	1.32 ± 1.23	1.62 ± 2.78*	z = 1.79	0.07	z = 1.24	0.02
SD1	24.31 ± 20.32	23.81 ± 18.6	29.64 ± 45.23	33.13 ± 54.17	44.33 ± 88.64	28.09 ± 28.54	z = 0.05	0.95	z = 0.75	0.45
SD2	48.12 ± 18.83	49.81 ± 19.16	52.55 ± 35.63	61.2 ± 79.59	66.06 ± 78.3	50.44 ± 26.46	z = 1.03	0.3	z = 0.82	0.41

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, Average RR; Average time interval between normal-to-normal intervals, SDNN; Standard deviation of all normal-to-normal intervals. RMSSD; Root mean square of differences between adjacent normal-to-normal intervals, pNN50; percentage of the number of pairs of adjacent normal-to-normal interval difference by > 50ms, HF; High frequency, LF; Low frequency.

immersion, there is a shift of peripheral blood to the central area (thoracic vasculature) due to hydrostatic pressure. This causes an increase in central blood volume, stroke volume, cardiac output, and central venous pressure, which stimulates the arterial-venous pressure and decreases cardiopulmonary pressure, leading to bradycardia. This implies sympathetic withdrawal (Mourot et al., 2008). Sauna baths improve vascular endothelial function and affect the autonomic nervous system (warming up, cooling down, and relaxation). This changes the ANS, decreases blood pressure, increases vasodilation, and improves the function of vasculature (Zaccardi et al., 2017). A 20-min direct mud application to the spine has the ability to retain water for an extended period of time. Mud application reduces stress and blood pressure, heart rate, and respiration rate and promotes switching from sympathetic to parasympathetic activity (Valsakumar et al., 2021). A 1-h massage once a week for four weeks helps people relax, increasing parasympathetic activity and lowering blood pressure and heart rate. With no increase in cardiac output, mechanical pressure applied during the massage treatment induces vasodilation in the peripheral vasculature, thus lowering blood pressure. Histamine and Nitric oxide, two vasoactive chemicals, will be released during massage therapy. Histamine reduces sympathetic activity by stimulating touch sensation, and it also has a vasodilator effect through H1 and H2 receptors found in peripheral veins(Supa'at et al., 2013). Cardiovascular risk factors like SBP and DBP are decreased with the modified Dietary advice to stop hypertension (DASH) diet (Steinberg et al., 2017). Another study by Filippou et al. discovered that the DASH diet can lower blood pressure in both hypertensive and normotensive people. Another study examined the effects of a DASH diet high in antioxidant foods on inflammation and oxidative stress, as well as endothelial protection(Filippou et al., 2020). In a comparison between 12 weeks of Yoga and enhanced usual care, there was a drop in blood pressure (SBP and DBP), heart rate (HR), and blood pressure index (MAP) in patients with prehypertension to stage 1 hypertension (Cohen et al., 2011). The immediate effect of a neutral immersion bath with Epsom salt has been shown to shift to parasympathetic activity by improving RMSSD (Joicy et al., 2021). 25 min of alternate nostril breathing shifts parasympathetic activity by increasing RMSSD (Telles et al., 2014).

The autonomic nerve activity of participants in the Yoga and Naturopathy group was found to be raised by sympathetic withdrawal, as determined by objective HRV monitoring of sympathetic nerve function, parasympathetic nerve function, and autonomic nerve activity. Notably, there was a greater increase in autonomic nerve activity following the 10-day yoga and naturopathy therapies. These changes in the HRV suggest that the Yoga and naturopathy intervention for 10 days is more effective than the control group alone.

4.1. Limitation of the study

The study had a wide range of ages, gender differences were not considered, the intervention was provided for a short-term, and interventions including diet-pattern would not be easily replicated in different cultures and assessments such as autonomic function testing, continuous blood pressure monitoring, stress-related hormone assays, oxidative stress markers, and inflammatory markers would have been studied for the better understanding. The sample size was not calculated using any previous study. Hence, further long-term studies are recommended with the narrow age range and other objective measures to validate the results of our study and to find the underlying mechanisms.

5. Conclusion

The results of this study suggest that a 10-day integrated intervention of Naturopathy and Yoga helps to maintain sympathovagal balance by shifting towards the parasympathetic. However, further studies are needed to confirm these findings by considering the impact of age difference on the outcomes.

CRediT authorship contribution statement

Prashanth Shetty: Writing – review & editing, Resources, Methodology, Funding acquisition, Conceptualization. **K.J. Sujatha:** Writing – review & editing, Methodology, Data curation, Conceptualization. **A. Mooventhan:** Writing – original draft, Data curation. **H.C. Shashikiran:** Visualization, Supervision, Resources. **Durgarao Yalla:** Supervision, Project administration, Data curation. **Jyosna Thayill:** Software, Project administration. **P.G. Arun:** Visualization,

Investigation.

Author disclosure statement

No competing interests exist.

Data availability

On request, the corresponding author will provide the datasets used in this work.

Funding information

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dr. Prashanth Shetty reports financial support was provided by Government of India Ministry of Ayush. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbmt.2024.11.008.

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