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Immediate Effect of *Ice Massage to Head and Spine* vs *Cooling Pranayamas* on Heart Rate Variability in Hypertensives

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aims: To compare the immediate effect of Ice Massage (IM) to head and spine with cooling pranayama (sheetali and sheetkari pranayama) in hypertensive individuals on Blood Pressure and Heart Rate Variability.

Study design: An open-label, randomized, clinical trial.

Methodology: 100 hypertensive subjects were selected and randomly allocated into Group 1(n=50) (cooling pranayama) and Group 2 (n=50) (ice massage to head and spine). Group 1 practiced each pranayama for 10 mins and Group 2 was administered ice massage for 20 minutes. Subjects were assessed for Blood pressure and HRV at baseline and after treatment.

Result: There was a significant decrease in the blood pressure, heart rate, and LF/HF ratio and an increase in the HF power, NN50, and pNN50 values in both the groups after ice massage and

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cooling pranayama. But there was a larger significance found in group 2 (ice massage to head and spine) blood pressure variables ($P \le 0.001^{***}$), VLF ($P = 0.002^{**}$), LF ($P = 0.003^{**}$).

Conclusion: The study showed that both ice massage to the head, spine and sheetali, sheetkari pranayama appeared to be effective means in the reduction of blood pressure. The immediate effect of ice massage on the head and spine is more effective in comparison to cooling pranayamas in the reduction of blood pressure in hypertensives.

Keywords: Hydrotherapy; massage therapy; Cooling pranayama; hypertension; heart rate variability.

ABBREVIATIONS

Hypertension (HTN), Heart rate variability (HRV), Massage (IM), Complementary Alternative Medicine (CAM), RR interval (RRI), SD=Standard deviation. SBP=Systolic blood pressure. pressure. DBP=Diastolic blood HR=Heart rate, Mean RR= Mean of R-R interval, RMSSD=The square root of the mean squared difference between adjacent N-N intervals, NN50=Consecutive normal sinus (NN) intervals exceed 50 ms, pNN50=The fraction consecutive NN intervals that differ by more than 50 ms, VLF=Very low-frequency power, LF=Low frequency Power, HF=High frequency power and LF/HF=Low frequency/High-frequency ratio.

1. INTRODUCTION

"Hypertension (HTN) is defined as having a systolic blood pressure (SBP) of 130mmHg or higher and/or a diastolic blood pressure (DBP) of greater than 80mmHg. The most prevalent chronic medical illness is characterized by a persistent increase in arterial pressure" [1]. "Every 20/10 mmHg increase in systolic (SBP)/diastolic (DBP) blood pressure above the normal blood pressure cut-offs, regardless of age or gender, increases the risk of a fatal cardiovascular event" [2]. "Hypertension is the leading single contributor to all-cause death and disability worldwide and is the most common preventable risk factor for cardiovascular disease (CVD; including coronary heart disease, heart failure, stroke, myocardial infarction, atrial fibrillation, and peripheral artery disease), chronic kidney disease (CKD), and cognitive impairment" [3]. The autonomic nervous system is thought to be the most important element in the development of Essential Hyper Tension (EHT), with the sympathetic nervous system (SNS) playing a key role. Activation can occur spontaneously, as a result of direct autonomic nervous system (ANS) dysfunction, or it can be triggered by hypertension inducing variables such as obesity, insulin resistance, excessive

alcohol consumption, over intake of salt, stress, and dyslipidemia [4].

Despite its greater prevalence, hypertension is one of the commonest diseases that can be prevented. Different lifestyle modifications to treat or prevent hypertension have been established in various studies. Maintaining healthy body weight, regular physical activity, reduced salt or sodium intake, potassium supplementation, and avoiding harmful alcohol consumption are all recommended approaches for controlling hypertension [5]. The blood pressure of only half of medically treated hypertensive patients is under control despite using anti-hypertensive medications, as shown by a study report [6]. Hence to overcome this, non-pharmacological interventions such Complementary and Alternative Medicine (CAM) can be efficiently employed [7]. "The American Cardiology/American College of Association (ACC/AHA) issued guidelines in 2017 that emphasized the importance of lifestyle therapies such as regular exercise and yoga as an alternative method to medication for managing HTN" [8].

Yoga and Naturopathy are two popular CAM therapies that are used all over the world. Yoga is a way of life that includes Yama and Niyama which are moral and self-discipline codes, as well as other mind-body practices including asana, meditation. pranayama, and Many communicable psychosomatic diseases have been reported to improve with yoga [9]. Pranayama a component of yoga, is the deliberate alteration of one's breathing process. diaphragmatic such rapid breathing. slow/deep breathing, alternating nostril breathing, and breath-holding/retention, which is normally performed in a seated position [10]. Breath control is a key component of Yoga, and it involves slowing or pacing one's breathing, manipulating one's nostrils, and holding one's breath, all of which generate a variety of physiological responses in healthy individuals

[11]. Slow breathing enhances oxygen saturation, decreases blood pressure, and lowers anxiety via increasing cardiac-vagal baroreflex sensitivity (BRS) [12]. Pranayama improves the vagal tone and decreases sympathetic activity [13]. Sheetali and sheetkari pranayama are other forms of pranayama that involve inhalation through the mouth. These are commonly referred to as cooling pranayama [14]. Studies conducted show that the practice of sheetali and sheetkari pranayama showed a significant reduction in blood pressure and improvement in Heart Rate Variability (HRV) [15,16].

Hydrotherapy, one major treatment modality of naturopathy uses the application of water externally or internally in any of its forms (ice. water, steam) with various temperatures. duration, and the pressure applied to various sites for the treatment of several diseases, or health promotion [17]. Previous studies have shown the reduction of blood pressure and improvement in HRV through Vagal dominance [18,19]. IM and cooling pranayama both have been proven to reduce blood pressure and cause HRV changes. The immediate reduction of blood pressure is very important and but the limited evidence in non-pharmacological treatment makes it necessary to study the immediate effect on the same topic also no study compares the effectiveness of IM to head and spine and sheetali and sheetkari pranayama in hypertensives. Hence, this study aims at comparing the immediate effect of IM and cooling pranayamas in reducing blood pressure and identifying the HRV changes.

2. MATERIALS AND METHODS

2.1 Study Design

In the present open-label, randomized, clinical trial, the effects of ice massage on to head and spine and sheetali and sheetkari pranayamas on blood pressure and heart rate variability in hypertensives are compared. The patient recruitment was started on 20th December 2019 and completed on 11th January 2021. The study has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The study protocol was approved by the institutional ethical committee. The committee did not raise any objection to the study protocol and methodology. Ice massage to the head and spine and Sheetali and sheetkari

pranayama were considered uniformly safe as no adverse events have been reported by any previous studies on this exercise. Written consent was obtained from all the participants. This study was registered in the Clinical Trial Registry of India.

2.2 Patient Population

Both male and female hypertensive patients were eligible for enrolment in the study aged between 30-and 70 years, having SBP between 140-180 mmHg, DBP between 90-110 mmHg, and not taking more than two anti-hypertensive medications. The other eligibility criteria were willingness to participate in the trial and provision of written informed consent. Exclusion criteria were Patients refusing to take part in the study, diagnosed with secondary HTN, Diabetes Mellitus, valvular heart disease, pericarditis or myocarditis, previous coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA), a recent history of stroke, abnormal thyroid function, chronic renal failure. hemochromatosis, alcohol abuse. hepatitis B, C or HIV, pregnancy [20], Hypertension is associated with other metabolic disorders.

2.3 Patient Recruitment and Randomization

350 Patients with essential HTN who were admitted to Yoga and Nature Cure hospital, Karnataka were screened for the inclusion and exclusion criteria. 100 Patients satisfying eligibility criteria were enrolled in the study after taking informed consent. All the participants were randomized in a 1:1 ratio into group 1(cooling pranayamas) and group 2 (ice massage to head and spine) by a computer-generated table of random numbers.

2.4 Intervention

A detailed demographic and clinical assessment were done for all patients at the beginning of the trial by a yoga physician (such as age, duration of the disease, history, presence of any other disease). Subjects of group 1 were asked to sit in a comfortable posture with the spine erect closed eyes. Placing hands on the knees in chin or jnana mudra throughout the practice. Sheetali pranayama involves Protruding the tongue, rolling its sides to form a tube, allowing the breath to flow in through the tube, and exhaling

through the nose with the mouth closed. The practice was continued for 10 minutes. Followed by sheetkari pranayama which involves pressing the lower teeth and upper teeth together and separating the lips comfortably allowing the air to pass through the gaps in between the teeth and exhaling through the nose with the mouth closed. Practice will be continued for 10 minutes [21].

Subjects of group 2 were asked to lie prone on the massage table. Then IM was given to the head and spine by continuous longitudinal displacements [22] by the means of a rubber bag filled with ice [23] (1-2°C) for 20 minutes [24]. The use of ice bags is to avoid overuse injuries among the patients.

2.5 Assessments

The subjects were assessed for blood pressure and Heart Rate Variability. The assessment was carried out in a supine position and the recording leads were connected to the four-channel polygraph equipment (BIOPAC, Montana, USA; model No: BSL 4.1 MP 36). The electrocardiogram [ECG] was recorded using a standard bipolar limb lead II configuration. The ECG was digitized using a 12-bit analog-to-digital converter (ADC). The R waves were detected to

obtain a point event series of successive R-R intervals, from which the beat-to-beat heart rate series was computed. The data recorded was visually inspected off-line and only noise-free data were included for analysis. The HRV power spectrum was obtained using fast Fourier transform analysis (FFT). The energy in the HRV series of the following specific bands was studied, viz., the very low-frequency component (0.0-0.05 Hz), low-frequency component (0.05-0.15 Hz), and high-frequency component (0.15-0.50 Hz). The low frequency (LF) and highfrequency (HF) values were expressed as normalized units. The low frequency and highfrequency values are expressed as normalized units. Both time domain and frequency domain values were analyzed. In time-domain mean RR. mean HR, the square root of the mean of the sum of the squares of differences between adiacent normal-to-normal (NN) (RMSSD), Consecutive normal sinus (NN) intervals exceed 50 ms (NN50), the proportion derived by dividing NN50 by the total number of NN intervals (pNN50), and frequency-domain very low frequency (VLF), LF, HF, Low frequency/High-frequency ratio (LF/HF) values were extracted from FFT Analysis using the software Kubios 3.2.0 version [25].

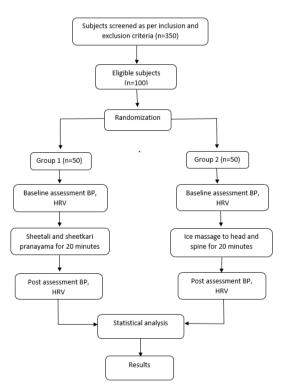


Fig. 1. Illustration of the trial profile

Blood pressure is measured in the supine position, in a quiet and calm environment using a digital sphygmomanometer (OMRON HEM – 7113) operating on the oscillometric principle [26] by a trained professional. Subjects were asked to relax and to remain relatively undisturbed during the session.

2.6 Statistical Analysis

Statistical analysis was done using Statistical Product and Service Solutions (SPSS) (Version 23.0) IBM. Data were checked for normal distribution using the Kolmogorov Smirnov test. Non-parametric test, Mann Whitney u test was used to find significant results between groups, whereas Wilcoxon signed-rank test was applied

for comparison of pre and post-test between groups. p-value less than 0.05 was accepted as an indicator of significance.

3. RESULTS

The demographic data is depicted in the table. In Group 1 there were 56 % of males and 44 % of females with a mean age of 51.42 years and in Group 2 there were 56% of males and 44% of females with a mean age of 53.02 years.

The results of the pre-post comparisons for both the groups are detailed below (Table 1: Comparison of pre and post-test values within the groups).

Table 1. Comparison of pre and post-test values within the groups

	GROUP 1		GROUP 2			
VARIABLES	MEAN PRE ±	MEAN POST	P VALUE	MEAN PRE ±	MEAN	P VALUE
	SD	± SD		SD	$POST \pm SD$	
SBP	151.3±7.74	118.8±11.9	<.001***	153.1±7.86	106.8±8.31	<0.001***
DBP	102.2±8.01	87.84±8.32	<.001***	102.7±7.17	72.60±8.42	<0.001***
MEAN RR	1497.05±161.1	1521.49±173.0	.04*	1561.5±133.9	1633.5±154.	≤0.001***
					76	
MEAN HR	41.88±5.79	38.73±5.51	<.001***	39.4±3.65	38.64±3.60	<.001***
RMSSD	197.1±156.5	259.7±192.0	.008**	218.5±162.2	361.4±192.9	≤.001***
NN50	119.6±36.9	127.02±37	<.001***	120.2±33.9	140.98±28.9	<.001***
pNN50	59.98±18.11	61.6±18.5	.16	60.44±17.52	70.4±13.1	<.001***
VLF	32.9±23.3	30.53±18.4	.28	28.33±17.37	19.86±11.32	<.001***
LF	55.85±18.81	51.28±17.97	.002**	53.1±15.12	41.04±12.39	<.001***
HF	48.54±17.84	54.5±17.11	.008**	50.32±17.09	58.3±16.5	<.001***
LF/HF ratio	1.59±1.76	1.39±1.98	<.001***	1.34±0.96	.80±.426	<.001***

^{*} P<0.05 Statistically significant. ** P<0.01 and ** P<0.001 Highly statistical significance.

SD=Standard deviation, SBP=Systolic blood pressure, DBP=Diastolic blood pressure, HR=Heart rate, Mean RR=
Mean of R-R interval, RMSSD=The square root of the mean squared difference between adjacent N-N intervals,
NN50=Consecutive normal sinus (NN) intervals exceed 50 ms, pNN50=The fraction of consecutive NN intervals
that differ by more than 50 ms, VLF=Very low-frequency power, LF=Low frequency Power, HF=High frequency
power and LF/HF=Low frequency/High-frequency ratio

Table 2. Comparison of post-test values between the groups

VARIABLES	Group 1	Group 2	P value
	MEAN POST ± SD	MEAN POST ± SD	
SBP	118.8±11.9	106.8±8.31	<.001***
DBP	87.84±8.32	72.60±8.42	<u><.001***</u>
MEAN RR	1521.49±173.0	1633.5±154.76	.002**
MEAN HR	38.73±5.51	38.64±3.60	.61
RMSSD	259.7±192.0	361.4±192.9	.006
NN50	127.02±37.0	140.98±28.9	.04*
pNN50	61.6±18.5	70.4±13.1	.04*
VLF	30.53±18.4	19.86±11.32	.002**
LF	51.28±17.97	41.04±12.39	.003**
HF	54.5±17.11	58.3±16.5	.4
LF/HF ratio	1.39±1.98	.80±.426	.02*

* P<0.05 Statistically significant. ** P<0.01 and ** P<0.001 Highly statistically significant.

SD=Standard deviation, SBP=Systolic blood pressure, DBP=Diastolic blood pressure, HR=Heart rate, Mean RR= Mean of R-R interval, RMSSD= Square root of the mean squared difference between adjacent N-N intervals, NN50=Consecutive normal sinus (NN) intervals exceed 50 ms, pNN50=The fraction of consecutive NN intervals that differ by more than 50 ms, VLF=Very low-frequency power, LF=Low frequency Power, HF=High frequency power and LF/HF=Low frequency/High-frequency rate

Group 1: There was a significant decrease in SBP and DBP (P < 0.001). Time-domain of HRV showed an increase in mean RMSSD (P = 0.008), NN50 (P < 0.001), an increase in RR (P = 0.04), and PNN50 (P = 0.160), and a significant decrease in HR (P < 0.001) after the intervention compared to their pre values. The frequency domain of HRV shows a decrease in VLF (P = 0.282), a significant increase in HF (P = 0.008), and a significant decrease in LF (P = 0.002), LF/HF ratio (P < 0.001) after intervention as compared to the pre values.

Group 2: There was a significant decrease in SBP and DBP (P < 0.001). Time-domain of HRV showed a significant increase in mean RR ($P \le 0.001$), RMSSD ($P \le 0.001$), NN50 (P < 0.001), and PNN50 ($P \le 0.001$) and a significant decrease in HR ($P \le 0.001$) after the intervention compared to their pre values. The frequency domain of HRV shows, a significant increase in HF (P < 0.001), and a significant decrease in VLF

(P<0.001), LF (P<0.001), and LF/HF ratio (P<0.001) after intervention as compared to the pre values.

Between the group (Table 2: Comparison of post-test values between the groups): There was a significant reduction in the SBP and DBP in group 2 when compared to group 1 (P < 0.001). Time-domain analysis of HRV showed increase in mean RR (P < 0.002), NN50 (P = 0.039), pNN50 (P = 0.042) and RMSSD (P = 0.006) and decrease in HR (P = 0.617) in group 2 when compared to group 1. In the frequency domain of HRV, there was a significant decrease in VLF (P = 0.002), LF (P = 0.003), and LF/HF ratio (P = 0.026) while, not so significant increase in HF (P = 0.404) in group 2 when compared to group 1.

Both IM to the head, spine and sheetali, sheetkari pranayama showed a reduction in blood pressure and a significant increase in RMSSD, NN50, and HF, and a significant

decrease in VLF, LF. Ice massage to the head and spine showed a significant decrease in blood pressure and a significant increase in NN50 (P=0.039*), pNN50 (P=0.042*), and a reduction in VLF (P=0.002**) and LF(P=0.003**) when compared to sheetali and sheetkari pranayama. This shows that there is parasympathetic dominance in both groups after the intervention. But ice massage group shows increased parasympathetic activity when compared to the pranayama group.

4. DISCUSSION

The present study compared the immediate effects of IM on head, spine and sheetali, sheetkari pranavama on HRV in hypertensives. The results of the current study are similar to results of previous studies using a variety of cold applications [18,19,27,28]. HRV time-domain measurements, such as mean RRI, RMSSD, and NN50, are better predictors of vagal modulation than frequency domain measures [29]. In the present study, Time-domain showed a significant increase in the RRI, NN50, pNN50, and RMSSD which indicate vagal dominance. A significant reduction in HR shows that 20 mins of ice massage to the head and spine for 20 mins parasympathetic improved **HRV** towards dominance or sympathetic withdrawal, which is in accordance with a previous study [19]. In a study, it was shown that application of ice on forehead and face reduces HR, and immersion of hand/foot has opposite effect [30]. "Another study done on ice bag application to head and spine showed a significant reduction in pulse rate and blood pressure, which supports the results of our study" [18].

The role of transient receptor potential cation channel subfamily M member 8 (TRPM8), transient receptor potential family. Cold-induced activation of TRPM8 in the sarcoplasmic reticulum membrane may promote Ca2+ release from the sarcoplasmic reticulum, resulting in Ca2+ store depletion and possibly inhibiting vasoconstrictor operation [31]. The physiological changes that occur after the skin are exposed to cold describe the underlying mechanisms in detail. Adrenaline and nor-adrenaline increase at first, but once the cold trigger is removed, the catecholamine response and resting catecholamine levels also decrease [32].

The results of our current study are consistent with those of a few previous studies on a variety of other pranayamas in normotensive and

hypertensive patients [33–36] In a previous study, it was proven that the practice of sheetali and sheetkari pranayama showed a significant reduction in blood pressure and indicate that the changes are mediated by a change in sympathovagal nervous system tone [15]. "Another study shows similar results in which the practice of sheetali pranayama significantly reduces blood pressure in patients with HTN and improves heart rate variability" [16].

Ancient yoga texts (such as Hatha Yoga Pradipika) define a broad range of pranayamas with various benefits, including increased concentration, relaxation, breathing capability, and blood pressure reduction [21]. "As a result of the action of slowly adapting receptors and hyperpolarizing currents, pranayama stretches the lung tissue, producing inhibitory signals via activation of slowly adapting stretch receptors and fibroblast-mediated hyperpolarization. These inhibitory signals from the cardiorespiratory region including vagus are thought to coordinate neuronal components in the brain, resulting in alterations in the autonomic nervous system and a condition marked by decreased metabolism and parasympathetic dominance. Pranayama affects numerous inflating and deflating lung responses, as well as the central nervous system, to restore physiological balance" [37]. "The baroreflex mechanism is thought to be a controller short-term blood pressure parasympathetic activation and sympathetic inhibition. This pranayama practice would induce a chill in the throat and likely stimulate the vagal nerve, resulting in a temporary increase in cardiac parasympathetic activity and thus blood pressure control (via baroreceptor reflex) [38]. The autonomic nervous system and hypertension have been well illustrated in previous studies on arterial baroreflex [39], and the current study's findings may be due to the above-mentioned mechanism of baroreflex modulation".

Overall, the study suggests that ice massage to the head, spine and sheetali, sheetkari pranayamas are effective in increasing the parasympathetic nervous system activity and inducing a relaxed and calm state of mind. Both the treatments can be used in the treatment of hypertension effectively. Whereas, ice massage to the head and spine can be used in the immediate reduction of blood pressure in hypertension. To the best of our knowledge, no study compares the effects of sheetali and sheetkari pranayama with ice massage to the head and spine which is another potent

treatment in the reduction of blood pressure. We recommend that this simple and cost-effective technique be added to the regular management protocol of Hypertension and utilized when immediate reduction of BP is required in day-to-day as well as clinical situations.

One limitation of our study is that the duration of intervention was short. Additionally, we did not follow up to know the duration of effects obtained. More research is needed to gain a better understanding of the mechanisms involved and to see how long such a BP-lowering impact lasts.

5. CONCLUSION

This is the first study, comparing the effects of ice massage on the head and spine with sheetali and sheetkari pranavama on blood pressure and autonomic variables in hypertensives. The study showed that both ice massage to the head, spine and sheetali, sheetkari pranayama appeared to be effective means in the reduction of blood pressure. However, the one-time practice of sheetali and sheetkari pranayama did not show much significance when compared to ice massage to the head and spine. Thus, these non-pharmacological treatment modalities can be prescribed individuals safely in with hypertension.

CONSENT

As per international standards or university standards, Participants' written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

This research was reviewed and approved by the Institutional Ethical Committee, SDM College of Naturopathy and Yogic Sciences (Registration number: EC-233).

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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