Original Article

Immediate Effect of Cephalic Compress on Heart Rate Variability in Hypertensive Individuals: A Randomized Controlled Trial

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ABSTRACT

Background and Objectives: The World Health Organization (WHO) estimates that at least 9 million people around the world die from excessive blood pressure each year, either directly or indirectly. In a study conducted in India, anti-hypertensive drugs were discovered to be the medications most commonly linked to adverse drug reactions (ADRs). This research was conducted to evaluate the immediate impact of cephalic compress on heart rate variability (HRV) in hypertensive people and thus to authenticate the clinical understanding of its effect. **Methods:** 100 participants were randomly kept into two groups: group-1 (n=50) and group-2 (n=50). Group 1 underwent cephalic compress for 15 minutes and Group 2 was asked for general relaxation for 15 minutes. Before and soon after the intervention, the subjects' blood pressure and HRV were measured. This randomized controlled trial was registered in the Clinical Trials Registry-India (CTRI/2021/12/038539) on 9/12/2021. **Results:** The data analysis showed significant decrease in SBP($p<0.01$), DBP($p<0.01$), LF ($p<0.01$), LF/HF ($p<0.01$) and a significant increase in Average RR($p<0.005$), NN50($p<0.01$), RMSSD($p<0.01$), HF($p<0.01$) in HRV assessment after giving cephalic compress. **Interpretation & Conclusion:** This study shows that cephalic compress enhances parasympathetic activity and improves sympathovagal balance in hypertensive individuals. Thus, the application of cephalic compress is the adjuvant management of essential hypertension.

Key words: Cephalic compress; Cold application; essential Hypertension; Heart rate variability; hydrotherapy.

Hypertension is one of the most common chronic non-communicable diseases worldwide, which is an influential cardiovascular disease risk factor. According to the World Health Organization (WHO), high blood pressure kills at least 9 million people annually in either direct or indirect ways all around the world[1]. After diabetes, hypertension continues to be the second most typical reason for end-stage renal disease (ESRD)[2]. From 31% of all DALYs (disability-adjusted life years in 1990 to 55% in 2016, it is anticipated that the percentage of DALYs related to non-communicable diseases (NCDs) in India has increased. In India, both men and women now have a higher incidence of hypertension, rising from 3.7% to 9.1% in men and from 24.5% to 26.6% in women, respectively[3]. Structure-related alterations in the heart and blood arteries are linked to hypertension and may raise the probability of cardiovascular mortality and morbidity[4].

Risks that cannot be controlled (major) such as age, gender, ethnicity, and inheritance are only a few of the many variables that impact the onset of hypertension. Other risk indicators that can be controlled (minor) include obesity, inactivity, smoking, caffeine use, salt sensitivity, low potassium levels, alcoholism, stress at work, in school, with food, cholesterol levels, diabetes, and structural damage[5,6]. Systemic hypertension, which contributes to over 45% of the world's cardiovascular disease mortality and morbidity, is a major risk factor for cardiovascular and cerebrovascular disorders[7]. Blood pressure is defined as the force exerted by the blood against any unit area of the vessel wall[8]. Systolic blood pressure (SBP) of ≥140 and/or diastolic blood pressure (DBP) of ≥90 mmHg is the conventional diagnostic threshold as it is presently recognized for hypertension worldwide, even though the 2017 American College of Cardiology/American Heart Association (ACC/AHA) hypertension recommendations suggested a lower threshold of between ≥ 130 and/or ≥ 80 mmHg[9]. Firstly, there is no known reason for hypertension in 85% to 90% of cases.

These people are categorized as having essential (primary) hypertension[10]. The term "essential hypertension" describes a persistent rise in blood pressure with a variety of genetic and environmental reasons[11]. Up to 65-75% of the possibility of primary hypertension may be attributed to overweight and obesity. Many people who are diagnosed with primary hypertension are also thought to be affected by additional

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factors, including sedentary behavior, excessive alcohol or sodium chloride consumption, and insufficient potassium intake[12]. The precise pathophysiology of primary hypertension is cell membrane abnormalities, renin production, salt sensitivity, and other vascular and hormonal variables, which seem to contribute to its onset[13]. The genesis, course, progression, and consequences of hypertension have all been linked to the autonomic nervous system (ANS), with increased sympathetic nervous system (SNS) activity and reduced parasympathetic nervous system (PNS) activity[14].

Thiazide-type diuretics or calcium-channel blockers will often have the greatest effect on decreasing blood pressure in older people or those of black ethnicity at any age. Blood pressure can be efficiently controlled in young people, who often have more renin-angiotensin system activity than elderly people, by using inhibitors of the renin-angiotensin system, such as angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers[6]. In a 2021 pharmacovigilance study conducted in India, anti-hypertensive drugs were discovered to be the medications most commonly linked to adverse drug reactions (ADRs)[15].

As there is a relatively high prevalence of adverse reactions while receiving antihypertensive therapy, it leads to a high rate of discontinuations. Prominent adverse effects observed by the patients include dry cough to angiotensin-converting enzyme inhibitors (ACEI), excessive urination to diuretics, and frequent urination in patients taking calcium channel blockers (CCB)[16]. Non-pharmacological therapy is beneficial, particularly in the prevention and management of hypertension. So, to successfully combat this, non-pharmacological approaches like complementary and alternative medicine (CAM) might be utilized[15].

CAM treatments for hypertension include naturopathy, yoga, herbal medicine, homeopathy, progressive relaxation, guided imagery, diet-based therapy, chiropractic, and osteopathy[17]. In conventional and alternative medicine, hydrotherapy is regarded as having an excellent therapeutic impact[18]. Cephalic compress is a type of hydrotherapy treatment, which gives a sedative effect when given for a long time and helps in delirium of infectious fever, congestive headache, rheumatic pains, and regulating blood pressure[19].

Despite the widespread use of cephalic compression in the treatment of several disorders, its specific effect on hypertension is not yet studied. It was thought that a cephalic compress would lower blood pressure in hypertensive people. Determining the immediate impact of the cephalic compress on heart rate variability in hypertensive people is the purpose of the current investigation.

MATERIALS AND METHODS

Trial design

This research is a parallel-arm randomized control trial. The patients were randomly assigned to Groups 1 and 2, with a 1:1 allocation rate.

Participants

The pre-diagnosed hypertensive subjects, who are admitted to the inpatient department of Sri Dharmasthala Manjunatheshwara (SDM) Yoga and Nature Cure Hospital, Shanthivana, Dharmasthala, Karnataka are recruited in the study. Out of 142 subjects, 100 subjects were recruited for the study based on the inclusion and exclusion criteria. Computer-generated randomization was used to divide the chosen participants who met the inclusion requirements into two groups.

Inclusion criteria:

- Age: 35-55 years
- Subjects with Systolic blood pressure (SBP) ≥140 mmHg and/or diastolic blood pressure (DBP) ≥90 mmHg; with or without antihypertensive drugs[21] or patients satisfying JNC 8[20].

Exclusion criteria:

- Fever, Hypersensitivity
- Secondary hypertension
- Subjects diagnosed with valvular heart disease, evidence of heart failure with ejection fraction 35%, acute coronary syndrome, previous Coronary artery bypass grafting, history of stroke, current abnormal thyroid function; chronic renal failure, pregnancy[21].
- Diabetic associated with hypertension.
- Females during menstruation[22,23].

Ethical Considerations & trial registration

Before the study, approval was obtained from the Institutional Ethical Committee. The study was registered under CTRI registration number CTRI/2021/12/038539. The subjects were given an oral and written explanation of the study's objectives, methods, intervention, and all of their rights in their preferred language and a signed informed consent was taken.

Intervention: The participants selected for the study were randomly assigned to Groups 1 and 2.

Group 1-case(cephalic) compress: The person who is taking the treatment had been with minimum dressing. Application of cloth dipped in cold water temperature of 18 to 24ºC for 15 mins. The cloth was folded into 4 folds and applied at either the top or back of the head i.e. the upper part of the neck and made him lie in the prone position on the massage table for 20 minutes. Before application, it had been wrung well and applied on the concert part of the body[19].

Group 2-Supine Rest: The subjects were said to rest in supine position for 15 minutes**.**

Assessments

Arterial Blood Pressure: Using a mercury sphygmomanometer, the blood pressure was measured. The first audible tapping sound (Korotkoff noises) was noted at the systolic pressure, and the diastolic pressure was noted as the measurement at which the Korotkoff noises were observed muted. Blood pressure samples weren't regularly monitored[24].

Heart rate variability (HRV): With the individuals comfortably supine on beds, the baseline electrocardiogram (ECG) was collected for 5 minutes using the bipolar limb lead II setup. Using AD Instruments Inc Power Lab 15T or Power Lab 8/35 equipment, signals were digitally converted and recorded. The beat-to-beat heart rate series was estimated from the point event series of sequential R-R intervals that were obtained after the R waves were recognized[25].

Data Extraction

Arterial Blood Pressure: Using a mercury sphygmomanometer, the blood pressure was measured.

Heart rate variability (HRV): 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) of the HRV series were each specifically examined for energy. Normalized units were used to express the low-frequency and high-frequency values. Normalized units are used to express the low-frequency and high-frequency values. Values in the time domain and frequency domain have been analyzed. Using the Lab chart program, the RMSSD, pRR50, and the VLF, LF, HF, and LF/HF values in the frequency domain have been extracted[26].

Data analysis: The data were statistically analyzed using SPSS 21.0 (SPSS Inc., Chicago, IL, USA). The Shapiro-Wilk test was used to assess the data distribution. Analyzed using the Mann-Whitney U test and the Wilcoxon rank sum test. As a marker of significance, a P value less than 0.05 with a 95% confidence interval (CI) was accepted.

RESULTS

The data obtained was analyzed for normality by the Shapiro-Wilk test. The pre-post data of each group has been analyzed separately using by Wilcoxon signed rank test and Dependent t-test. Comparative analysis between the groups was done by using the Mann-Whitney U test and independent t-test. In group 1cephalic compress group there were 42% male and 58% female with a mean age of 37.82 years, and in group 2 control group there were 59% male and 41% female with a mean age of 37.94 years.

CONTROL GROUP

In the control group, there is a significant decrease in mean values of SBP ($p<0.001$) and DBP ($p=<0.001$). In time domain of heart rate variability, a significant decrease is seen in heart rate(bpm) ($p<0.001$) and no significant change is seen in Mean RR ($p= 0.819$), RMSSD ($p= 0.889$), pRR50% ($p=0.342$). In the frequency domain of HRV, a significant increase is seen in LF ($p=0.005$) and a significant decrease in HF ($p=0.009$), and no significant change was seen in LF/HF Ratio ($p=0.003$). The control group's Mean ± SD scores are mentioned in Table 1.

CASE GROUP

In the case (the cephalic) group there is a significant decrease in SBP ($p<0.001$), and DBP ($p<0.001$). In the time domain of heart rate variability, a significant increase is seen in Average RR ($p<0.001$), RMSSD ($p<0.001$), pRR50% ($p<0.001$), and no significant change was seen in mean heart rate(bpm) ($p<0.870$). In the frequency domain of HRV, a significant decrease is seen in LF ($p<0.001$), LF/HF Ratio ($p<0.001$), and significant increase in HF ($p<0.001$). The cephalic group Mean ± SD scores are mentioned in Table 1.

BETWEEN-GROUP ANALYSIS

ANCOVA indicate variables with baseline difference between the groups. ANCOCA test was done for variables like HF, LF/HF RATIO, and Mean heart rate (bpm).

Significant changes are seen in SBP ($p<0.001$). No significant change was seen in DBP ($p= 0.088$) when compared between the groups with an effect size of -0.08.

In time domain of heart rate variability, significant change is seen in Mean RR ($P<0.007$) with an effect size of 0.55, RMSSD ($p<0.007$) with an effect size of 0.70 when compared between the groups. A significant change is seen in mean heart rate (bpm) ($p<0.001$) with effect size of 0.62) when compared between the groups. A non-significant change is seen in pRR50% ($p<0.060$) with a mean with effect size of 0.44 when compared between the groups.

In frequency domain of HRV, significant change is seen in LF ($p<0.001$) with an effect size of -0.80 when compared between the groups. A significant change is seen in HF ($p<0.001$) with an effect size of 0.63. A significant change is seen in LF/HF Ratio ($p<0.010$) with an effect size of 0.07 when compared between the groups.

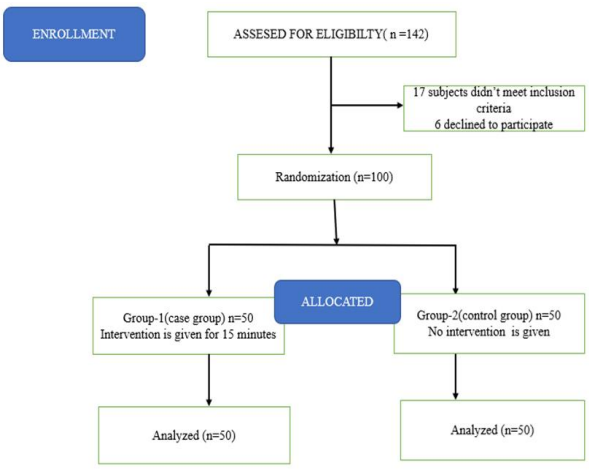

Figure 1: Illustration of trial profile

TABLE 1: COMPARISON OF PRE AND POSYT VALUES OF CEPHALIUC COMPRESS GROUP AND CONTROL GROUP

VARIABLES	CEPHALIC COMPRESS GROUP		CONTROL GROUP	
	Mean ± SD Pre	Mean ± SD Post	Mean ± SD Pre	Mean ± SD Post
AverageRR (ms)	797.60±94.49	840.82±91.60	781.26±117.45	783.20±116.31
Mean Heart Rate (bpm)	76.41 ±10.02	76.23±8.94	82.36±11.98	78.76±12.82
RMSSD (ms)	22.47± 15.72	33.65 ±22.33	22.23±10.33	21.41±10.47
pRR50% (%)	5.32± 10.26	9.22±13.77	3.13±3.99	4.4 ±6.79
LF (nU)	54.84 ±25.17	46.09±24.96	57.49±17.92	63.69±18.44
HF (nU)	29.05 ±17.46	36.40±19.05	43.33 ±17.70	37.40±18.32
LF/HF Ratio	3.00 ±2.49	1.84±1.70	1.94±1.64	3.33±5.41
SBP (mmHg)	146± 5.50	136.40 ±5.73	145.80±5.59	142.61±5.65
DBP (mmHg)	87.44 ±6.21	82.76 ±5.88	87.47±6.45	83.51±12.53

SBP=Systolic blood pressure, DBP=Diastolic blood pressure, RR=interval between successive R waves, RMSSD=The square root of the mean squared difference between adjacent N-N intervals, pRR50=The fraction of consecutive RR intervals that differ by more than 50 ms, VLF=Very low-frequency power, LF=Low frequency Power, HF=High frequency power, LF/HF=Low frequency/High-frequency ratio

DISCUSSION

The objective of the present investigation was to evaluate the immediate impact of cephalic compress on hypertension. Following the application of cephalic compress there was a significant reduction found in SBP, DBP from baseline. In the time domain of HRV, there was a statistically significant increase seen in mean values of Average RR, pRR50, RMSSD than baseline. In the frequency domain, a significant increase was seen in HF values, whereas significant reduction was found in the mean score of LF and LF/HF ratio values.

Regulation and maintenance of cardiovascular functions like SBP and DBP are modulated by the autonomic nervous system. SBP and DBP significantly decreased in the current investigation after receiving the application of a cephalic compress. Reduced blood pressure is linked to a change in the autonomic balance toward parasympathetic dominance[27,28] since we observed a decrease in blood pressure in the current investigation.

Heart rate variability (HRV) time-domain metrics such as the mean R-R intervals are more accurate markers of vagal modulation than frequency-domain measures[29]. The current study also justified, as the post values of AverageRR, pRR50%, and RMSSD increased significantly. The relationship between sympathetic activity and the LF band has been challenged because it has been shown that LF band power is a well-known indicator of the heart's sympathetic activity and is partially under parasympathetic control. The majority of HF band power is managed by the parasympathetic nervous system[29,30] and therefore the LF/HF ratio has been proven to be a reliable indicator of the balance of cardiac sympathovagal activity[31] which suggests that reduction in LF/HF ratio indicates parasympathetic dominance. The current study's frequency domain results demonstrate a significant rise in HF mean values but a significant decrease in LF and the LF/HF ratio. According to a study by Makinen T et al., a short period of cold acclimation can increase parasympathetic activity. This finding was supported by significant increases in the HF and RMSSD components of HRV, while a slight reduction in HR suggested that sinus node-level sympathetic activity had been blunted[32]. In healthy individuals, ice massage to the head and spine (IMHS) has been demonstrated to result in a considerable decrease in SBP, DBP, and (HR), and heart rate variability (HRV) also significantly improved toward vagal dominance[33,34]. Based on above information it is clear that the result of present study shows parasympathetic dominance.

The possible mechanisms have been discussed below. A study where ice massage is given to the head and spine found that β-adrenoceptor blockage brought on by denervation resulted in a reduction in LF power after selective cardiac Para sympathectomy, although it did not completely vanish[34]. In any type of cold application, after 10 mins vasodilation is observed which may be due to mechanisms such as axon reflex, diminished release of norepinephrine from adrenergic nerve endings, release of vasodilators like nitric oxide (NO) from endothelial cells as a result blood flow is increased which leads to reduce blood pressure[35].

It is said that temperature-sensitive ion channels transient receptor potential cation channel subfamily M member 8 (TRPM8) are the basis for thermoreception, play a role in blood pressure as there is low level of TRPM8 is twofold less compared to normotensive individuals when compared with hypertensive individuals When a cold application is given in hypertensive individuals an increase of TRPM8 is seen[36] as TRPM8 is a calcium-dependent ion channel when activated by slow cooling increases the intracellular Ca2+ concentration in endothelial cells, which activates endothelial nitric oxide

synthase (eNOS) and cytosolic phospholipase A2 (which activates cyclooxygenase) to produce nitric oxide (NO), a potent vasodilator that lowers blood pressure in hypertensive people[37].

The physiological modifications brought on by exposure to cold for the skin thoroughly explain the underlying mechanisms. Initially, adrenaline and noradrenaline rise, but the catecholamine response and resting levels of catecholamines both decline as soon as the cold trigger is withdrawn[38] which might be a factor in the blood pressure decrease observed in the current research right after receiving a cephalic compress.

Cephalic compression provides a calming and cardioprotective impact by raising parasympathetic activity while concurrently decreasing sympathetic activity as an additional effect. We suggest including this easy-to-use method in the routine management of hypertension and using it whenever an immediate decrease in blood pressure is necessary, whether in routine conditions or the course of a therapeutic procedure.

CONCLUSION

The current study findings demonstrated a substantial variance between the cephalic compress group and the control group in blood pressure, LF, LF/HF ratio, average RR, RMSSD, PRR50, and HF. It demonstrated how parasympathetic activation and sympathetic withdrawal shifted the sympathovagal balance toward parasympathetic dominance. Hence, its application can be expanded in management of hypertension and prevention of cardiovascular risk.

Limitations and Further Considerations

Further studies can be carried out with larger sample sizes and longer study periods with advanced assessment techniques like continuous blood pressure monitoring and baroreceptor sensitivity would have given a better understanding of the molecular mechanism of activation of the autonomic nervous system, as the small sample size of this study is a limitation and to fully comprehend the mechanics of cephalic compress in hypertension.

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