

Immediate Effect of Cold Spinal Spray on Autonomic Variables in Hypertensive Individuals - A Randomised Control Trial

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Abstract: ***Background:** Hypertension (HTN) has become an important public health issue. From the past few decades, different classes of antihypertensive drugs are used in treating HTN and non-pharmacological complementary therapies like naturopathy are efficiently employed. Clinically naturopathic physicians were using the cold spinal spray as one of the therapy in managing hypertension. It is important to understand the immediate efficacy and underlying mechanism of cold spinal spray in, patients with primary hypertension. **Methods:** Pre diagnosed primary hypertensive subjects are screened as per the criteria of diagnosis and 60 subjects were selected after considering the inclusion and exclusion criteria. Subjects were randomly assigned and group one underwent 20 min of cold spinal spray (CSS) whereas group two was made to lay down in the same tub for 20 min. Baseline assessments were done followed by 20 min of intervention and finally, immediate post-assessments were done. Data were assessed and analysed. **Results:** Group one with CSS intervention showed a significant decrease in low frequency (LF), low frequency/high frequency (LF/HF) ratio and an increase in high frequency (HF) after the intervention ($p < 0.01$). Group two without intervention showed decreased LF/HF ratio, increased LF and HF but LF increased after the intervention but was not significant ($p > 0.01$). Comparing the groups showed a significant difference in all components of HRV ($p < 0.05$) and group one have more significant results than group two. **Conclusion:** Comparing both the groups, results suggested a significant decrease in sympathetic activity and a shift of sympathovagal balance towards vagal dominance immediately after the intervention of cold spinal spray is observed. Therefore CSS can be helpful in the immediate reduction of blood pressure in primary HTN patients.*

Keywords: Cold spinal spray, Hypertension, Randomised control trial, Autonomic variables, Spinal spray

1. Introduction

HTN or high blood pressure (BP) is a chronic medical condition in which the systemic arterial blood pressure is elevated [1]. It is a multifactorial disease with a persistent elevation of systolic blood pressure (SBP) ≥ 140 mmHg and diastolic blood pressure (DBP) ≥ 90 millimetres of mercury (mmHg) [2]. Primary hypertension is observed in 90-95 % of cases and secondary can be seen in 5 – 10 % of cases [3], [4]. According to a survey study, HTN is one of the most prevalent diseases worldwide and around 6% of total deaths are caused because of hypertension thus world health organization (WHO) rates this disease as a cause of early death worldwide. Globally HTN is estimated to cause 13.5% of the total hypertensive individuals are above 45 years [5],[6]. Studies say that in 2025 around 1.5 billion people will be affected by hypertension [7]. High blood pressure is a major risk factor for stroke, myocardial infarction (MI), heart failure and arterial aneurysms and is a leading cause of chronic kidney failure (CKD). [8] HTN is directly responsible for about 57% of stroke death and 24% of coronary heart disease death in India. The prevalence of

HTN in Indian urban adults is 25% and 10-15% in rural adults [9]. The south Indian population 22.1% of people are suffering from this serious condition [10], [11]. It is necessary to prevent and treat this disease in the initial stage itself to reduce the risk of cardiovascular diseases like coronary artery disease, stroke, heart failure, and renal diseases [12]. Blood pressure reduction is crucial in reducing adverse cardiovascular outcome a small reduction in it can reduce the risk of heart failure and stroke remarkably [13]. Lifestyle modifications along with lipid-lowering therapy and anti-hypertensive therapies cause a 75% reduction in the risk factors of cardiovascular disorders in hypertensive individuals. Various factors like consequences of urbanization such as lifestyle, diet, stress, increased population, and shrinking employment are contributed to this rising trend of HTN [14]. Primary hypertension comes around 95% of all cases of hypertension. Rising blood pressure with age is a necessary prerequisite to primary hypertension and differentiates it from secondary hypertension. [15].

Anti-hypertensive drugs (AHD) are used and the studies show that these medications also help in lowering the progression of renal disease and all-cause of deaths [16], [17]. The long term use of these medications may cause adverse effects also. This also causes the resistance of the body to treatment and reduces the therapeutic efficiency [18]. Due to the high cost and unavailability of medications large hypertensive population goes untreated [19]. Less than 40% of treated hypertensive patients have their blood pressure controlled by using antihypertensive. 10-20% of subjects experience no expected results at all [20].

The first line of treatment for hypertension is preventive lifestyle changes such as dietary changes, physical exercise, and weight loss which have all been shown to a significant reduction in blood pressure in hypertensive people [21]. Prevention and self-care are two important things as per the Joint National Commission-7 (JNC7) [22]. There is a growing body of research on non-pharmacological treatment modalities such as complementary and alternative medicine (CAM) for reducing blood pressure [23]. CAM is a form of self-care preventive modality widely used in developed and developing countries. 14% of the worldwide population uses CAM for the management of hypertension [24].

Naturopathy is one of the CAM which is a way of life and a concept of healing that uses various natural means of treating human infirmities and disease [25]. Naturopathy focuses on non-invasive treatments to help your body to do its healing. A naturopathic physician employs an array of healing practices including diet and clinical nutrition etc. [26]. In naturopathy, the use of water in any form for therapeutic purposes is known as hydrotherapy [27]. The pouring of the water to the body is applicable in various diseases conditions and it gives both physiological and internal beneficial effects [29]. The physiological effects of water produce a relaxation response in the neuroendocrine system by regulating the metabolism, breathing pattern, stabilizing blood pressure, reducing the muscle tension, lowering the heart rate, and slow brain wave pattern [30]. The warmth and buoyancy influence the spinal segmental mechanisms. The cold applications are mainly used to explain vasoconstriction, pain reduction effects, and the effects in the nervous system activity [31]. The cold spinal spray is the one that uses both mechanical and thermal effects of water. Spinal bathtub which is developed by a renowned Naturopath from South India named Acharya Lakshman Sharma [28]. The altered form of spinal bathtub is spinal spray equipment in which water will be applied just to the spinal column from the nape of the neck till the lower part of the spine with a sufficient amount of pressure. This spinal spray treatment with water of cold temperature is extensively indicated in every naturopathy set up to reduce the systolic and diastolic blood pressure for hypertensive patients [32], this is because according to Dr. J H Kellogg, prolonged application of cold causes reduction in blood flow and heart rate, in the reaction period of the cold application there will be dilation of the superficial blood vessels, reduction in the rate of respiration with increasing in the depth of respiration. All these factors may influence the reduction of blood pressure [27]. There is no scientific evidence recorded regarding the use of CSS as a therapeutic modality for reducing blood pressure. So this

study aims at providing scientific evidence for the use of cold spinal spray as an immediate measure to reduce the increased blood pressure in hypertensive individuals.

2. Literature Review

An A study on heart rate variability which says there is an increased sympathetic activity and a decreased vagal tone associated with hypertension [33]. A study which was done on, immediate effect of cold spinal bath on autonomic and respiratory variables in hypertensive, say that there is an increased parasympathetic dominance during the cold application in hypertensive patients [35]. A review paper concluded that the cold and hot therapies effects the sympathetic and parasympathetic system and is a good treatment for stress full condition for longer duration [34]. One more study which used the application of ice bag to the spinal region also suggested the parasympathetic dominance [36]. One study indicates that using CAM is helpful in common cardiovascular risk factors including obesity, hypertension, and other co-morbidities that are major public health issues [37]. By application of the water with different temperatures, one can increase or decrease the rate of blood flow through an organ or area of the body and can either increase or decrease the total volume of blood in an organ or area of the body based on the five physiological principles revulsive effect, derivative effect, spinal cord reflex, collateral circulation, and arterial trunk reflex [25]. In another study, they found that short-term exposure to cold water immersion restores the impaired vagal modulation. Water immersion increases the vagal-related HRV indices. It may be due to the stimulation of pressure-dependent baroreceptors, and also due to the co-activation of cold receptors with the cold water immersion [40]. The heart rate and HRV measures after water immersion give the idea of improving the parasympathetic activity to get good cardiac effects [38]. A study by Hani Al Haddad and his friends explained that the hydrostatic pressure created by the head-out water immersion condition shifts peripheral blood into the thoracic vasculature, thereby increases central blood volume, stroke volume, cardiac output, and central venous pressure. This helps in the improvement of parasympathetic activity and inhibits sympathetic activity [39].

3. Problem Definition

Clinically cold applications are used to treat hypertension but it is necessary to prove it scientifically. However, in literature, there were no scientific papers published on the use of cold spinal spray-on autonomic functions in patients with hypertension and there is no scientific evidence whether it is significant for hypertensive patients without any complications. It is important to understand the underlying mechanisms of CSS to find out its physiological effects. Hence the present study is objecting for assessing the effect of cold spinal spray-on sympathetic and parasympathetic changes in hypertensive patients by assessing HRV.

4. Materials and Methods

60 primary hypertensive healthy individuals with the mean age of 50 ± 12.5 were recruited from SDM naturopathy

hospital. Randomization was done by computer-generated randomization for the allocation of the subjects into either of the groups. The inclusion criteria include Pre diagnosed primary hypertensive patients who are under medication, both male and female subjects willing to participate in the study by signing the consent form. Exclusion criteria was like subject with open wounds, subject with habits of regular smoking and alcohol consumption, females under menstruation, Subjects with history or complaints of mental illness, cardiac diseases, and renal disease, weak and debilitating subjects and the subjects who are not willing to participate in the study. Study protocol was approved by the Institutional Ethics Committee and a written informed consent was obtained from each subjects.

A spinal spray tub made up of fiber, which is raised a little in the back region to give proper support to the back, will be used. A perforated fiber pipe is attached to the centre of the tub which is connected to 0.5 horsepower motor which will supply water for the treatment purpose. Group one underwent the cold spinal spray of temperature 18- 24 degree Celsius treatment and group two lying in the spinal spray bath tub in the same position respectively for 20 minutes. The temperature of the water of cold spinal spray will be measured by a digital thermometer and is maintained between 18°C to 24°C for group one. Assessment will be done 5 minutes before and immediately after intervention and subjects were seated on a chair and ECG leads were connected to the four-channel polygraph equipment (BIOPAC, Montana, USA; model No: BSL 4.0 MP 36) and monitored on a closed-circuit TV. Instructions were given to the subjects to remain relatively undisturbed during the session of taking readings.

The raw data obtained from each subject in each recording session were tabulated separately. The group median, mean, standard deviation, and p values were calculated for all the variables to see the distribution and normality assumption. Appropriate statistical tests were used for the analysis & interpretation of the results. Statistical analysis will be done using software and related packages (IBM SPSS statistics version 25). The data was checked for the Normality of difference/change scores from pre-test to post-test of various parameters in the same group by Wilcoxon signed-rank test and between groups by Mann Whitney U test and $p < 0.05$ considered as significant.

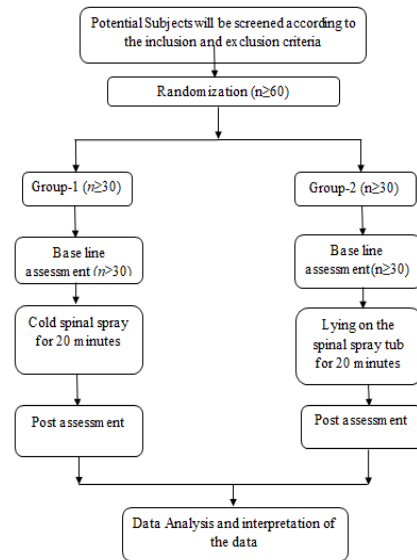


Figure 1: Illustration of the study plan

5. Result/ Discussion

The baseline demographic variables were the same for both groups. There is a decrease in the SBP, DBP, pulse, respiration, LF, HF/LF ratio in both groups. In the group 2 the median SBP, pulse, mean HR, NN50, pNN50, LF/HF of subjects decrease after the therapy whereas the median LF increase after therapy. The medians of all autonomic variables change after the therapy with cold spinal spray in the group 2 except for VLF. The median SBP, DBP, pulse, respiratory rate, mean HR, LF, and LF/HF decrease after therapy whereas its opposite in case of variables means RR, RMSSD, NN50m pNN50, HF. The LF after the treatment in the group 2 is high when compared to LF after treatment in the group 1. These same results were observed for the HF/LF ratio. The HF value for the group 2 is lower than that of the group1. Significant decrees in the pre and post value of median respiration were found in both the groups.

When comparing both groups there are more statically significant results is observed for the group1 which shows the arousal sympathetic activity by giving the cold spinal spray for hypertensive. Comparing both the groups there is a reduction in a mean difference of the post-assessment value of cold spinal spray compared to another group without the cold spinal spray.

Table I: HRV parameters before and after treatment (n=30 in each group)

Variable	Group 1		Group 2		P value (t test in mean RR and LF, all others Mann Whitney U test)	
	PRE	POST	PRE	POST	One tailed	Two tailed
	Mean ±SD	Mean ±SD	Mean ±SD	Mean ±SD		
SBP	148.06±10.35	143.53±11.50	147.86±5.22	147.06±5.55	0.2565	-
DBP	93.46±7.68	85.66±6.56	97.53±6.38	96.8±5.57	0.0000	0.000 Alt :greater
Pulse	81.73±8.61	75.66±6.92	84.86±5.34	84.2±5.78	0.0000	0.000 Alt :greater
Respiration	15.89±1.77	15.06±1.45	15.61±1.50	15.47±1.19	0.3136	
mean RR	771.63±127.25	810.4±156.5	789.66±125.02	792.73±129.73	0.6359	
mean HR	80.6±12.25	71.36±12.06	82.2±12.81	79.83±13.69	0.01161	0.005805 Alt :greater
RMSSD	33.51±23.44	39.95±22.67	31.59±21.80	28.1±17.41	0.05011	0.02506 Alt :less
NN50	24.66±26.36	34.7±22.33	26.93±24.68	22.7±21.33	0.01559	0.007796 Alt :less
pNN50	5.98±7.23	11.75±6.99	9.35±8.21	8.53±7.51	0.04757	0.02378 Alt :less
VLF	59.93±37.54	70.06±80.72	43.56±61.48	48.43±65.64	0.08229	-
LF	72.67±15.11	52.27±18.25	51.61±18.41	55.62±22.98	0.5819	-

HF	25.49±10.45	47.21±18.29	46.44±19.01	50.52±21.37	0.4598	-
LF/HF	3.57±±2.77	1.79±1.59	2.28±1.20	1.70±1.32	0.9176	-
-level of significance : 0.05						
-SD: Standard deviation, HRV: Heart rate variability, SDNN: SD of NN interval, RMSSD: Root mean square of the successive differences,						
TF: Total frequency, LF: Low frequency, HF: High frequency						
-Alternative Hypothesis for Wilcoxon Signed Rank test						
<ul style="list-style-type: none"> • Alt : less-The median of autonomic variable before therapy is less than that after therapy in group 1& 2. • Alt : greater- The median of autonomic variable before therapy is greater than that after therapy in group1& 2. 						
-Alternative Hypothesis for Mann Whitney U test						
<ul style="list-style-type: none"> • Alt : less-The median of autonomic variable after therapy in group 2 less than in group 1. • Alt : greater- The median of autonomic variable after therapy in group 2 is greater than in group 1. 						
-Alternative Hypothesis for t test						
<ul style="list-style-type: none"> • Alt: less- The mean of the autonomic variable after therapy in groups 2 less than in the group 1. • Alt: greater- The mean of the autonomic variable after therapy in group 2 greater than in the group1. 						

The present study aims to evaluate the immediate effect of cold spinal spray on primary hypertensive individuals. The results of the study show a significant difference between the cold spinal spray group and the neutral group without cold spinal spray in autonomic and respiratory variables. When comparing both groups more significant results are observed for the study group by giving a cold spinal spray which shows the arousal of sympathetic activity in primary hypertensive. The reduced LF, LF/HF ratio, and the increased HF value clearly show a shift in sympathovagal balance towards parasympathetic dominance. The other components of HRV give the same idea of parasympathetic dominance after the intervention. The observed in the present study can be compared to the findings observed after cold immersion bath. A study shows that following a water immersion bath, there is an increase in parasympathetic activity associated with lowering the sympathetic tone observed in HRV measures. There is a shift towards parasympathetic activity and inhibits sympathetic activity resulting in bradycardia and also an increase in vagal related HRV measures [41]. Tiina and her associates showed one of the exemplifying relationships between HRV and thermoregulation in receptor to the cold says that an increase in the high-frequency power domain is an indicator of the increase in the cardiac parasympathetic activity. The significant increase in the time demines variables of HRV indicates the vagal tone and vagal modulations of cardiac functions which represent the parasympathetic activity [42]. This mechanism of thermoregulation may be due to arterial vasoconstrictions which induce a further reduction in core temperature. When a cold application is given it stimulates the pressure depended on the baroreceptor and co-activation of the cold receptor and thereby increasing parasympathetic activity-related variables [43]. When the skin is exposed to cold vasoconstriction takes place initially followed by a dilatation of peripheral blood vessels. This mechanism supports the present study.

The other possible mechanism behind the hypotensive effect of cold spinal spray may be the activation of the transient receptor potential action channel subfamily M member 8 (TRPM8). The TRPM8 is a thermally regulated protein expressed in sensory neuron which is activated by the cold temperature or reduced body temperature. They respond to

the stimulus from temperature and pressure in the peripheral nervous system and cause the entry of Na⁺ and Ca²⁺ ions to the cell leads to a depolarization which inhibits the vasoconstriction activity and a reduction in sympathetic nerve mediated contraction [44], [45]. TRPM8 channels are activated in sensory axon collateral nerves on the local application of cold water which releases the vasodilator substance, remote from the site of application. That is the contractile action of sympathetic neurotransmitters can be antagonized by TRPM8 activation or the vasoconstrictor inhibition by the TRPM8 agonist. The concurrent blockage of the sympathetic vasoconstriction tone may be due to its effect on intracellular calcium stores. This shows that the TRPM8 activation by cold stimulus moderately lowers the SBP, DBP and maintains flow mediated dilatation in pre and primary hypertensive patients [46], [47]. The blood pressure reduction immediately after the intervention may due to a decreased resting catecholamine level and attenuated catecholamine response [49]. In the present study within both groups, there is a significant reduction in blood pressure and pulse rate after the intervention. This may be due to the short term resting postural regulatory mechanism by vestibulosympathetic reflex [47]. It has been proved that the body position significantly influence the cardiac autonomic activity. The relevant dominance of vagal activity is observed in a supine or semi supine position used in a spinal spray tub. There for a reduced blood pressure is measured in the supine position at rest in present study. This can be considered as a reason for the variation of the parameters in the control group [48]. Comparing both the group results and findings suggests that the cold spinal spray can be effectively useful as a naturopathic technique for treating the primary hypertensive patients.

6. Conclusion

The results of the study showed that the cold spinal spray enhances parasympathetic activity in patients with primary hypertension. As there were significant changes in the variables representing the ANS functioning, it can be concluded that cold spinal spray has a potential role in maintaining cardiac tone and reduction of blood pressure of the hypertensive individuals through the vagal dominance produced by the influence of ANS. Hence the cold spinal

spray may be used as a simple, relaxing, non-invasive, and effective means of treatment for the hypertensive.

7. Future Scope

This was the first study conducted based on the effect of cold spinal spray for hypertensive. More variables can be included in the assessments. A similar study can be carried out with a longer duration of intervention. The limitation of the study can be considered as the no control over the atmospheric changes might have influenced the results and the Control group does not have any satisfactory treatment modality during the study. Long term effects are not studied here.

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