Effectiveness of Cold Spinal Spray on Blood Pressure and Heart Rate Variability in Patients with Hypertension—A Randomized Controlled Trial

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ABSTRACT

Background: The application of cold to the spine is documented as favourable for reducing blood pressure in patients with hypertension (HTN). However, hydriatic application in the form of a cold spinal spray (CSS) has not yet been explored.

Objective: To find the effectiveness of CSS on cardio autonomic variables among males with HTN.

Methods: One hundred male patients with HTN visiting the outpatient service were included in this randomized controlled trial. A single session of CSS (15°C–19°C) was given to 50 patients for a period of 20 minutes for the study group, and the control group was made to lie down on the spinal spray tub for 20 minutes without any intervention. Baseline blood pressure and short-term heart rate variability (HRV) measurements were obtained prior to the intervention, followed by a subsequent assessment after a 20-minute interval for both groups.

Results: Following 20 minutes of CSS a significant decrease was observed in systolic blood pressure (136.48±14.15 mmHg to 126.20±13.18 mmHg, $p<0.001$), diastolic blood pressure (87.96±6.77 mmHg to 84.06±6.84 mmHg, $p<0.006$), pulse pressure (48.44±11.99 mmHg to 42.08±10.88 mmHg, $p<0.007$), and mean arterial pressure (104.09±8.12 mmHg to 98.05±7.88 mmHg, $p<0.001$). No significant changes were noted in HRV variables in either of the two patient groups.

Conclusion: The current study findings suggest that a single session of CSS intervention could lower both systolic & diastolic blood pressure, pulse pressure and mean arterial pressure in male hypertensive patients. Further studies are needed to find the long-term effect of CSS among patients with HTN.

Key Words Autonomic functions, cardiovascular disorders, complementary and alternative medicine, hydrotherapy, naturopathy

INTRODUCTION

Hypertension (HTN) is a leading medical condition that is characterized by elevated systemic arterial blood pressure.[1] Worldwide, HTN is estimated to cause 7.5 million deaths per year, which is around 12.8 % of the total all-cause mortality. A report from multi-national representative samples showed that the occurrence of HTN was higher in males than in females.[2] In addition to being a primary contributor to chronic kidney failure, HTN also puts people at risk for heart failure, myocardial infarction, and stroke. In India, 300,000 of the 1.5 million annual fatalities caused by cardiovascular illnesses could be prevented with effective HTN control.[3] The World Health Organization supports the combination of non-pharmacological treatments and conventional antihypertensive medications in people with HTN to facilitate better management and lower mortality rate.[4] Massage, reflexology, mud therapy, hydrotherapy, acupuncture, and yoga are commonly used as non-pharmacological interventions to manage HTN.[5] Hydrotherapy is also known as pool therapy, aquatic therapy, and water therapy in the naturopathic medical system.[6] Hydrotherapy is used in various forms (water, ice, or steam) with the purpose of promoting health or treating a variety of disorders[7-10] at different temperatures, pressures, lengths of time, and sites, either internally or externally.[11] A localized, minimally pressurized (1 pound per square inch [PSI]) external hydrotherapy procedure called a spinal spray exposes the spinal region to water at a specified temperature for a predetermined amount of time in order to obtain the desired results.[12] A previous study reported sympathetic domination among healthy male volunteers immediately after cold spinal spray (CSS).[12] Another study showed that cold application in the form of a spinal bath with a duration of 20 minutes could reduce blood pressure in hypertensive patients.[13] Therefore, the response to cold exposure on healthy individuals and those with HTN appears to be contradictory. The objective of this trial is to investigate the immediate effect of CSS in male patients with HTN.

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MATERIALS AND METHODS

The current study includes 100 male patients aged 30–70 years old, diagnosed with HTN, recruited for the study after obtaining signed informed consent. Patients with spinal deformities, systolic blood pressure (SBP) above 160 mmHg, diastolic blood pressure (DBP) above 100 mmHg, and more than two groups of anti-HTN medicine were excluded. The study was approved by the institution's ethics committee.

Sample Size

Using G*power 3.1.9.4 software, the sample size was determined based on a recent study,[13] with effect size = 0.414, alpha value = 0.05, and power = 0.80.

Randomization

Through computerized randomization, patients were divided into two groups. To generate a sample size of 50 in each group, the simple randomization approach using a 1:1 ratio was applied to 100 patients. The sequentially numbered opaque and sealed envelope (SNOSE) approach was used for allocation concealment. An investigator who was not directly involved in the evaluation carried out the randomization. Patients in the control group (n=50) were made to lie down on the spinal spray tub without receiving the CSS, whereas the research group (n=50) received the CSS. Baseline and 20-minute post-intervention data were collected for all patients at the same time of day, between 9 am and 12 pm. Figure 1 consort chart represents the schematic design of the study.

Intervention

The CSS group was instructed to wear minimal clothing, exposing their entire back to the flowing stream of water while lying on the spinal spray tub. The spinal spray tub features a centrally positioned fiber-perforated tube, which is connected via a pipeline to a 0.5 HP (horsepower) motor located underneath the tub and connected to the water supply. The patient was positioned supine on the bathtub, and the instrument was activated with water at 15°C to 19°C. Over a duration of 20 minutes, a continuous stream of water was sprayed into the spinal area through the perforated tube. In contrast, patients in the control group were instructed to wear minimal clothing and spend 20 minutes lying on the spinal spray tub without receiving cold-water spraying.

Outcome Measurements

Blood Pressure

Using a non-invasive arm-type semiautomated electronic blood pressure monitor (Omron), blood pressure readings were recorded before and immediately after 20 minutes in both groups in a sitting position. A minimum of two measurements were made, with a rest period of 1 minute between the measurements, and the final outcome was calculated using the average of two readings. If the difference between the two measurements was > 10 mmHg, a third measurement was taken after a 1-minute rest period, and the average of the two measurements that did not differ by > 10 mmHg was used to get a final value.

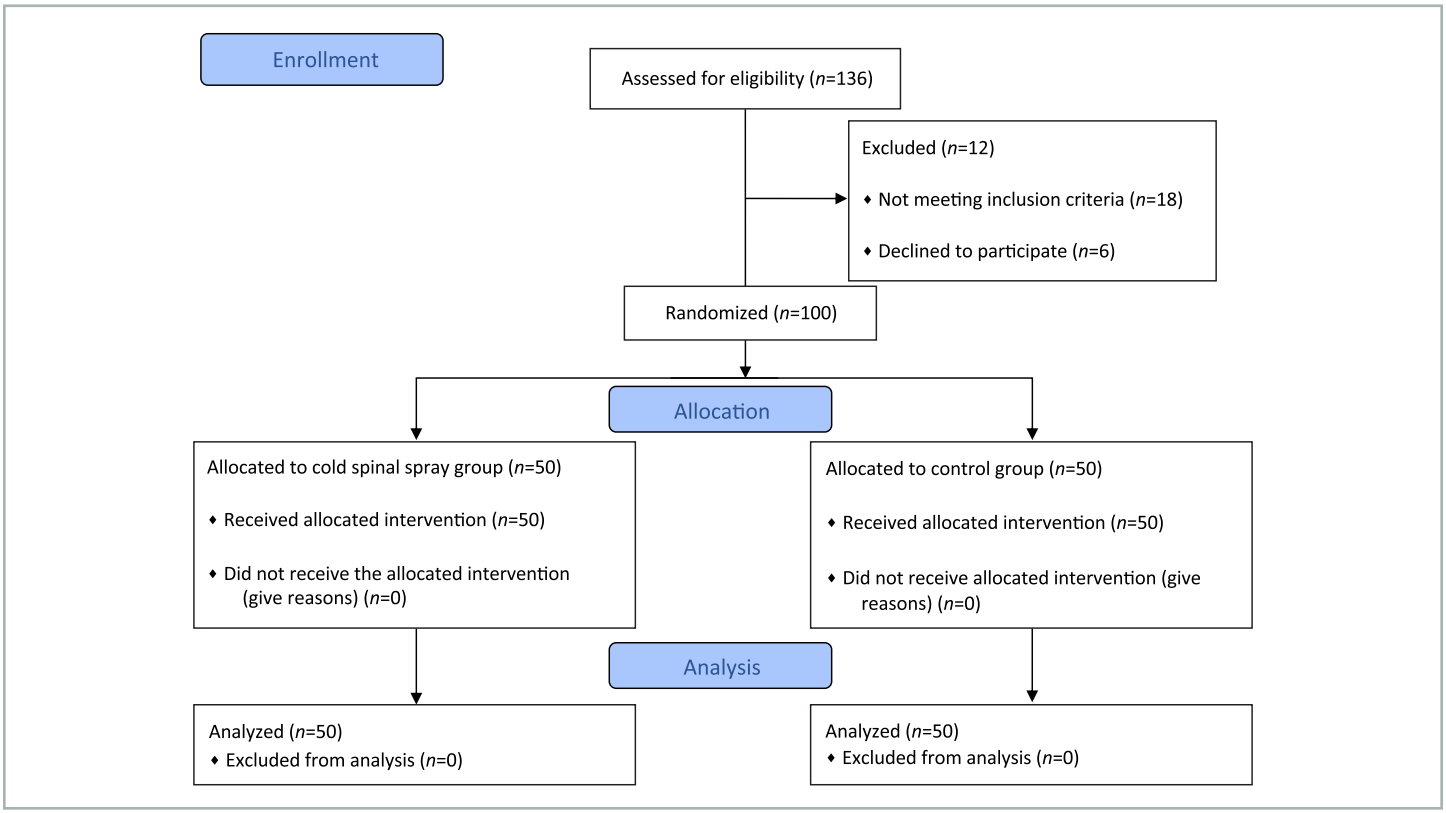

FIGURE 1 Consort Flow Diagram

Heart Rate Variability Spectrum

A 16-channel polygraph was used to measure the heart rate (HR) and short-term heart rate variability (HRV) before and after the intervention (BIOPAC MP160, 16-channel polygraph). For the purpose of recording the electrocardiogram, the Ag/AgCl pre-gelled electrodes were positioned using the limb lead II configuration. Data was collected using a 2000 Hz sampling rate. Using HRV analysis software (Kubios HRV version 2.0) created by the Biomedical Signal Analysis Group, baseline and post-intervention HRV data was collected and tabulated into time domain and frequency domain analysis (University of Kuopio, Finland). The time domain HRV variables include (1) the mean of the intervals between adjacent QRS complexes or the instantaneous heart rate (RRI), (2) the standard deviation of RR intervals (SDNN), (3) heart rate (HR), (4) Root mean square of successive RR interval differences (RMSSD), (5) the number of interval differences of subsequent NN intervals greater than 50 ms (NN50), and (6) percentage of successive RR intervals that differ by more than 50 ms (pNN50). Similar to this, the frequency domain of HRV is also examined, including the low-frequency (LF) band (0.04–0.15 Hz) and high-frequency (HF) band (0.15–0.4 Hz) in normalized units. The following formulas were used to calculate measurements such as mean arterial pressure (MAP) and pulse pressure (PP). SBP – DBP was used to calculate PP, and (DBP + 1/3*PP) was used to calculate MAP.[14]

Data Analysis

Means and standard deviations are used to express data (mean±SD). The Kolmogrov-Smirnov test was used to determine whether the data was normal. Indicating a normal Gaussian distribution was a p value of > 0.05. R statistical software version 4.2.0 was used to run the Wilcoxon signed rank test, Mann Whitney U test, and paired and unpaired t-test on the HRV data sets because they were not normally distributed.

RESULTS

In total, 136 patients were recruited for the trial, of whom 100 met the inclusion criteria (Figure 1). The CSS group consisted of 50 patients, with an average age of 54.02 ± 7.47 years and a BMI of 26.43 ± 3.24 kg/m^2. The control group also comprised 50 patients, with an average age of 54.48 ± 9.84 years and a BMI of 27.89 ± 5.21 kg/m^2. Among the patients in the CSS group, 32% were on diuretics, 36% were on ACE inhibitors, and 30% were on beta-blockers. In the control group, 26% were taking diuretics, 34% were on ACE inhibitors, and 32% were on beta-blockers.

Demographics of the patients who participated in the study are presented in Table 1. No significant differences were noted between the groups at baseline, and they were comparable. Immediately after CSS, a significant reduction in SBP (p<0.001), DBP (p<0.006), PP (p<0.007) and MAP (p<0.001) was noted in the CSS group. For the HRV, all variables (RRI, HR, SDNN, RMSSD, NN50, pNN50, LF, HF, LF/HF ratio) showed no significant changes in both CSS and control groups (Table 2).

TABLE 1 Demographic and anthropometry details of participants

	Cold spinal spray (n=50)	Control (n=50)
Age (years)	54.02±7.47	54.48±9.84
Height (meters)	1.65±0.07	1.62±0.07
Weight (kilograms)	70.92±10.24	72.93±13.09
Body mass index (kg/m²)	26.43±3.24	27.89±5.21
Diuretics	16 (32%)	13 (26%)
ACE inhibitors	18 (36%)	17 (34%)
Beta-blockers	15 (30%)	16 (32%)

TABLE 2 Changes in BP, and HRV parameters in included patients

	CSS (n=50) Mean±SD			Control (n=50) Mean±SD		
Parameters	**Before**	**After**	**p value**	**Before**	**After**	**p value**
SBP (mmHg)	136.48±14.15	126.20±13.18	<0.001	127.16±12.6	126.12±13.51	0.7
DBP (mmHg)	87.96±6.77	84.06±6.84	0.006	83.36±7.16	82.82±7.77	0.8
PP (mmHg)	48.44±11.99	42.08±10.88	0.007	43.90±9.62	42.90±10.47	0.4
MAP (mmHg)	104.09±8.12	98.05±7.88	<0.001	97.87±8.13	97.08±8.63	0.8
RRI (ms)	774.32±115.95	803.88±122.18	0.2	785.46±126.87	801.92±131.10	0.5
SDNN (ms)	61.89±46.97	46.63±35.33	0.2	39.84±31.78	40.29±29.59	0.5
HR (beats/min)	77.14±13.40	75.28±13.18	0.4	77.56±14.41	75.94±14.36	0.4
RMSSD (ms)	62.86±48.68	48.37±48.11	0.2	34.63±26.66	34.37±24.45	0.7
NN50 (count)	22.68±25.13	20.43±24.18	0.5	26.38±36.59	26.32±37.29	0.9
pNN50 %	7.74±6.99	5.86±6.91	0.089	9.43±12.55	9.03±12.36	0.8
LF (n.u)	50.91±17.38	52.78±19.00	0.6	52.03±18.62	56.32±20.36	0.2
HF (n.u)	48.27±17.17	50.35±17.11	0.7	47.69±18.39	43.51±20.73	0.2
LF/HF %	1.42±1.14	1.65±1.39	0.4	1.52±1.30	1.79±1.49	0.4

SD = standard deviation; BP = blood pressure; HRV = heart rate variability; SBP = systolic blood pressure; DBP = diastolic blood pressure; PP = pulse pressure; MAP = mean arterial pressure; RRI = instantaneous heart rate; SDNN = standard deviation of RR intervals; HR = heart rate; RMSSD = square root of the mean of the sum of the squares of differences; NN50 = the number of interval differences of subsequent NN intervals greater than 50 ms; pNN50 = percentage of successive RR intervals that differ by more than 50 ms; LF = low frequency; n.u. = normal units; HF = high frequency.

DISCUSSION

The current randomized controlled trial aimed to measure the effects of CSS on blood pressure and heart rate variability in male patients with HTN. This study found that a single session of CSS decreased SBP, DBP, PP and MAP in male patients with HTN. However, no changes in HRV parameters were observed in our study. In contrast, a previous study involving 60 patients with HTN reported significant reductions in LF, LF/HF ratio, and significant improvement in HF after 20 minutes of CSS by employing water temperatures between 18°C and 24°C.[15] The CSS possibly has an impact on all organs through nerves which are connected with the spine. Based on the temperature used in spinal spray, blood vessels may constrict or dilate.[12] Twenty minutes of cold application to the spine resulted in the activation of the parasympathetic system. It is widely documented that temperature affects blood pressure, which might be the cause for the decrease in SBP, DBP, PP and MAP in our study.[15]

In the current study, one of the following possible mechanisms might have led to the reduction in blood pressure. CSS may lead to immediate vasoconstriction which results in an increase of vascular pressure thereby activating the baroreceptors in the aorta and carotid sinus. This reduces sympathetic activity by stimulating the vagus nucleus and causing vasodilation and a drop in blood pressure.[16] CSS activates the transient receptor potential cation channel subfamily M (melastatin) member 8 (TRPM8) which is a thermally modifying sensory neuronal protein. TRPM8 reduces sympathetic activity and has a hypotensive effect.[17] Additionally, localized activation of TRPM8 by cold promotes the release of Ca2+ in the sarcoplasmic reticulum, which depletes stores of Ca2+ and inhibits vasoconstriction.[18] An increase in SBP of 10 mmHg will increase the risk of secondary cardiovascular disease (CVD) events by 15%. SBP is a more reliable indicator of cardiovascular diseases, particularly in persons under 50.[19] MAP, which is described as the average blood pressure during the cardiac cycle, is a vital element in the perfusion of significant organs. Even more than SBP and DBP, MAP has been proven to have clinical prognostic value in predicting the risk of CVDs, and it has also been shown to be a primary risk factor for predicting the risk of stroke.[20] Similarly, PP is the difference between SBP and DBP which predict adverse health outcomes in populations, and patients with cardiovascular or renal disease.[21]

No adverse effects were reported by the patients. This study had limitations in that it only assessed the immediate effects of CSS on blood pressure in male patients with HTN. Future research should aim to investigate the long-term effects of CSS on BP to provide further substantiation of our findings. Another potential limitation was the inclusion of only male patients, driven by the higher prevalence of HTN in males compared with females. However, this restriction limits the generalizability of our conclusions to a broader population. The absence of female participants hinders our ability to evaluate gender-specific effects, thereby reducing the applicability of our findings. To address this limitation, future studies should consider including both male and female participants to enable a comprehensive evaluation of gender differences and enhance the external validity of the results.

CONCLUSION

The study finding suggests that CSS could reduce blood pressure in male patients with HTN. Further randomized controlled trials are required to determine the long-term effects of CSS on HTN.

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CONFLICTS OF INTEREST DISCLOSURE

We have read and understood the *CANDJ*'s policy on conflicts of interest and declare that we have none.

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