# The Immediate Effect of Cold Spinal Sprayon Autonomic and Respiratory Variables in Healthy Volunteers

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## Abstract:

**Background & Objectives:** Cold Spinal Sprayis specially made equipment that directs multiple small but powerful streams of water to spinal portion on the patient. It is clinically used as a treatment modality in Naturopathy however its effects on Autonomic and Respiratory variables (ARV) has not been reported. The present study was aimed at evaluating the effect of Cold Spinal Sprayon ARV in healthy volunteers in causing sympathetic/parasympathetic activation immediately post treatment.

**Methods:** A Pre-post study was conducted consisting of 60 healthy students from the SDM College of Naturopathy and Yogic Sciences, Ujire. Group 1(n=30) were assessed for Heart Rate, Heart rate Variability, Pulse Plethysmography (PPG) and Respiration before and immediately after the intervention using the Polygraph [BIOPAC MP36]. Each subject underwent the Cold Spinal Sprayfor 10 minutes during the treatment. Group 2 (n=30) were assessed for the ARV in neutral position (NP) without intervention. Both the sessions of Cold Spinal Spray& NP were of 10 minutes duration conducted over a period of 12 days. Statistical analysis was performed by independent samples t-test and student's paired t-test using Microsoft Excel-version 14 (2011, USA.).

**Results:**No significant differences were seen between the sessions in heart rate (HR), pulse plethysmogram (PPG), respiratory rate (RR), R-R wave Interval (RRI), square root of mean of sum of the squares of differences between adjacent NN intervals (RMSSD), number of interval differences of successive NN intervals greater than 50-milliseconds (NN50), proportion of NN50 (pNN50), very low frequency (VLF), low frequency (LF), high frequency (HF), ratio of LF and HF (LF/HF). Within group analysis showed significant decrease in PPG, HR, LF/HF ratio and increase in pNN50. Insignificant increase in RR, RRI, RMSSD, NN50, HF and decrease in VLF, LF were observed in cold spinal spray. In the NP group, PPG, HR was seen to be insignificantly reduced, other variables being more or less unchanged.

Interpretation & Conclusion: Cold Spinal Spraydoes not significantly improve the ARV compared to NP however within group analysis shows significant reduction in PPG, HR and LF/HF ratio and increase in pNN50. This indicates parasympathetic activity predominance. Therefore, Cold Spinal Spraymay be considered as having some effects on ARV in healthy volunteers but requires further validation to prove its effects.

Date of Submission: 17-12-2019

Date of Acceptance: 31-12-2019

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#### I. Introduction

Naturopathy is a drugless system of medicine that uses a wide range of therapeutic modalities to treat the individual holistically. [1] It recognizes the existence of vital curative forces the lack of which leads to ill health. [2] It is a system of health care that incorporates hydrotherapy, clinical nutrition and dietetics, raw food and fruit diet, therapeutic fasting, physiotherapy, manipulation and massage, acupuncture, magneto-therapy, mud therapy, sun-bathing, chromo therapy and breathing exercises, psychological counseling to promote health, prevent, diagnose and treat disease. [1][3]

Hydrotherapy is the external or internal use of water in any of its forms (water, ice, steam) for health promotion or treatment of disease. [4] It includes the use of baths, packs, douches/ jets, compresses, enema as various treatment modalities [5] Cold Spinal Sprayis a specially made equipment that directs multiple small but powerful streams of water to spinal portion on the patient on the patient [6]. It is a hydrotherapeutic procedure, which circularly hits or percusses parts of the body, simultaneously, when the patient is lying over the spinal spray tub. Cold Spinal Sprayhas been found more effective in the management of various disorders based on clinical experience of several naturopathic physicians however its underlying mechanisms in relation to ANS is less understood.

Autonomic Nervous system is a part of the peripheral nervous system that controls visceral functions.

It has sympathetic and parasympathetic divisions. [7] The sympathetic system promotes a "<u>fight or flight</u>" response, corresponding with arousal and energy generation and inhibits digestion. [8] The parasympathetic division promotes a "rest and digest" response and corresponds with calming of the nerves to return to regular function, enhancing digestion.[9] Autonomic and Respiratory Variables such as heart rate, HRV, PPG, respiratory rate are significant indicators of autonomic function.[10] SNS activity corresponds to increased heart rate, respiratory rate, PPG and decreased HRV and PSNS activity shows the opposite effect.[11][12]

To the best of our knowledge there is no such study reported on the effect of Cold Spinal Sprayin relation to autonomic and respiratory variables in healthy/obese individuals. It is essential to understand the underlying physiological mechanisms before applying them as therapeutic agents in pathological conditions. Hence, this study was selected to evaluate the effects of Cold Spinal Sprayon autonomic and respiratory variables in healthy volunteers.

## **II. Material And Methods:**

A total of 60 healthy volunteers divided into the intervention group 1(n=30) and control group 2(n=30) were recruited from our residential SDM College of Naturopathy and Yogic Sciences. Each group consisted of 10 male and 20 female volunteers with age varied from 18 to 25 years and Body Mass Index (BMI) varied from 18-28 kg/m<sup>2</sup>. All the subjects were in the same campus with similar atmosphere and diet. The sample size was determined based on the number of subjects who volunteered to participate in the trial. Study subjects were included in the following inclusion and exclusion criteria.

## **INCLUSION CRITERIA:**

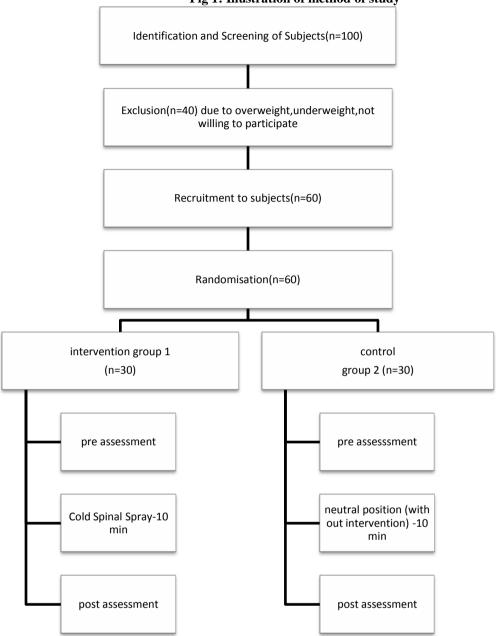
- Age: 18-25 years
- Gender: Male and Female
- BMI:  $<30 \text{ kg/m}^2$
- Subject with no known disease conditions or regular use of regular/relevant medications [43]

## **EXCLUSION CRITERIA:**

- Subjects with a history of mental illnesses
- Subjects with a history of alcohol/ substance abuse.
- Subjects undergoing menstruation/ pregnancy.
- Individuals with cold sensitivity
- Subjects who have undergone naturopathy treatments for the past two weeks
- Subjects unwilling to participate in the study.

## STUDY DESIGN:

• A Pre-post study design was used under which subjects were randomized from their respective classes. Group 1 (n=30) consisted of healthy students belonging to the 1<sup>st</sup> year of study and Group 2(n=30) consisted of students studying 2<sup>nd</sup> year of college. Each participant was assessed in a single session at the same time over a period of 12 days. Session for group 1 consisted of Cold Spinal Sprayand Group 2 was lying on spinal spray tub(Neutral Position) without intervention. Recordings of the ECG, PPG, and RS were made 5 minutes before and after each session. The duration of each session was 10 minutes. Figure-1 will show the illustration of method of study.



## Fig 1: Illustration of method of study

## **Procedure methodology**

Subjects from Intervention Group 1(n=30) received Cold Spinal Sprayand Control Group 2(n=30) lying on spinal spray tub while being assessed.

## Cold Spinal Spray:

Subjects were given Cold Spinal Sprayin the treatment section of the Naturopathy Hospital for a period of 10 minutes. Prior to the intervention, each subject was asked to lie on spinal spray tub in minimal clothing. During the intervention, the subject lying on spinal spray tubsequipment such that multiple small but powerful jet streams percussed simultaneously on the Spinal region of the body. After the intervention, the subject was dried with a towel and dressed before the post assessment.

## Neutral Position (NP):

The subjects were asked to lie on spinal spray tub for 10 minutes. Each subject was lying on spinal spray tub. Subjects were asked to keep their eyes closed and breathe normally. Control variables are essential in scientific research to indicate how a subject or system reacts under normal conditions (i.e., without intervention).

#### Statistical analysis

The statistical analysis of the data was done with the use of Microsoft Excel version 14 (2011, USA.). Mean and Standard Deviation [14] were used to summarize data of study participants of each group(n=30).Baseline and post intervention assessments were performed by student's independent samples-t-test to study the statistical significance of differences between the intervention and control groups i.e. Cold Spinal Sprayand NP .The students paired samples-t-test was used to compare the baseline and post intervention assessments of each group. P value < 0.05 was considered as significant. [14]

#### III. Result

There were no significant differences of the ARV between the Cold Spinal Spray session and lying on spinal spray tub without interventionat baseline assessment. (Table 1.)The result of the study showed that there is no statistically significant difference between the Cold Spinal Spray and NP of post intervention assessment (Independent sample-t-test) in the autonomic and respiratory variables such as HR, RR, RRI, Mean RR, SDNN, RMSSD, NN50, pNN50, VLF, LF/HF ratio. However PPG, LF showed a significant decrease (p<0.05) and HF significantly increased posttest (Table.2)

The result of within the group analysis done by using the paired samples-t-test showed the statistically significant reduction in PPG and HR both in Cold Spinal Spray and in NP. Though there were significant reductions in PPG and HR in both the sessions the reduction was highly significant in Cold Spinal Spray session (P<0.01) than NP. Further, Mean HR showed significant decrease in the NP session

There was a significant increase in pNN50 and a statistically significant decrease in LF/HF ratio in the Cold Spinal Spray session (p<0.01). There were no statistically significant differences observed either in the Cold Spinal Spray or NP sessions in variables such as RR, Mean RR, SDNN, Mean HR, RMSSD, VLF, LF, HF.

Though there are no significant changes in the above variables, within the group RR was increased in the Cold Spinal Spray session. RRI and Mean RR, SDNN was increased more in cold spinal spray session than in NP. RMSSD, NN50 were both found to increase only in the Cold Spinal Spray session. VLF, LF was reduced in Cold Spinal Spray and remained more or less same in NP session. HF was increased more in the cold Spinal Spray. LF/HF ratio was decreased more in Cold Spinal Spray than in NP sessions. (Table.3)

Variables	Sessions	Mean ± S.D	P value	
HR(b/m)	COLD SPINAL	92.19±16.63	0.230	
	SPRAY			
	NP	88.86±18.08		
PPG(b/m)	COLD SPINAL	88.56±21.18	0.169	
	SPRAY			
	NP	84.35±10.82		
RR(cycles/min)	COLD SPINAL	18.32±21.18	0.071	
	SPRAY			
	NP	19.75±10.82		
RRI(ms)	COLD SPINAL	0.70±0.11	0.192	
	SPRAY			
	NP	0.72±0.09		
Mean RR(ms)	COLD SPINAL	697.74±81.60	0.207	
	SPRAY			
	NP	717.71±104.96		
SDNN(ms)	COLD SPINAL	66.69±33.62	0.279	
	SPRAY			
	NP	62.27±23.79		
Mean HR(b/m)	COLD SPINAL	88.12±11.21	0.262	
	SPRAY			
	NP	86.10±13.11		
RMSSD(ms)	COLD SPINAL	59.80±51.25	0.438	
	SPRAY			
	NP	58.05±33.70		
NN50(count)	COLD SPINAL	83.40±63.84	0.063	
	SPRAY			
	NP	87.63±66.56		
pNN50(%)	COLD SPINAL	20.87±17.41	0.460	
	SPRAY	21.32±16.83		
	NP			
VLF(%)	COLD SPINAL	56.28±93.99	0.088	
	SPRAY			
	NP	32.04±18.61		
LF(n.u)	COLD SPINAL	58.88±19.71	0.098	

#### Table 1. Baseline Assessment of Cold Spinal Spray(n=30) and NP (n=30) Independent Sample t test

	SPRAY		
	NP	52.22±19.71	
HF(n.u)	COLD SPINAL	41.12±19.71	0.063
	SPRAY		
	NP	49.95±19.47	
LF/HF(ms <sup>2</sup> )	COLD SPINAL	2.60±3.30	0.077
	SPRAY		
	NP	1.63±1.55	
* P value < 0.05; ** P valu	e < 0.01.RRI= Intervals b	etween consecutive R-waves; PP	G= Pulse
plethysmogram; RR= Res	oiratory rate; HR= Heart	rate; SDNN= Standard Deviatio	n of NN Intervals
RMSSD= the square root of	of the mean of the sum of	the squares of differences betwee	en adjacent NN
intervals; NN50= the numl	per of interval differences	of successive NN intervals great	er than 50
		ng NN50 by the total number of l	
VLF= Very low frequency	band of the HRV; LF= L	ow frequency band of the HRV;	HF= High
frequency band of the HR	V; LF/HF ratio= Ratio of	low frequency to high frequency	; Cold Spinal
Spray; NP= Neutral Positi	0 <b>n.</b>		

Table 2: Post Test Assessment of Cold Spinal Spray (n=30) and NP (n=30) Independent Samples t test

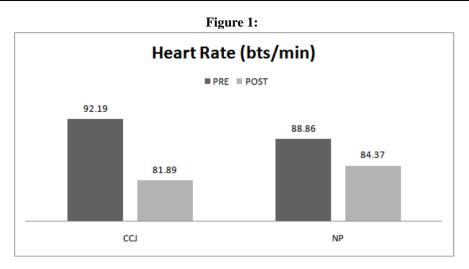
Variables	Sessions	Mean ± S.D	P value
HR(b/m)	COLD SPINAL SPRAY	81.89±20.05	0.300
	NP	84.37±16.28	
PPG(b/m)	COLD SPINAL SPRAY	74.99±9.86 0.025*	
	NP	79.87±9.00	
RR(cycles/min)	COLD SPINAL SPRAY		
	NP	19.67±3.31	
RRI(ms)	COLD SPINAL SPRAY	0.79±0.12	0.110
	NP	0.75±0.12	
Mean RR(ms)	COLD SPINAL SPRAY	789.46±116.32	0.102
	NP	752.176±107.93	
SDNN(ms)	COLD SPINAL SPRAY	70.43±45.20	0.236
	NP	63.64±23.92	
Mean HR(b/m)	COLD SPINAL SPRAY	78.35±12.26	0.082
	NP	82.77±12.00	
RMSSD(ms)	COLD SPINAL SPRAY	69.63±64.18	0.201
	NP	58.54±32.31	

NN50(count)	COLD SPINAL SPRAY	109.53±67.80	0.274	
	NP	99.20±64.29		
pNN50(%)	COLD SPINAL SPRAY NP	31.31±17.91 25.41±17.31	0.100	
VLF(%)	COLD SPINAL SPRAY	27.71±14.27	0.119	
	NP	31.93±12.58		
LF(n.u)	COLD SPINAL SPRAY	42.80±19.59	0.042*	
	NP	51.93±20.59		
HF(n.u)	COLD SPINAL SPRAY	57.2±19.59	0.042*	
	NP	48.07±20.56		
LF/HF(ms <sup>2</sup> )	COLD SPINAL SPRAY	1.10±1.39	0.068	
	NP	1.68±1.56		
* P value < 0.05; ** P	value < 0.01	•	•	

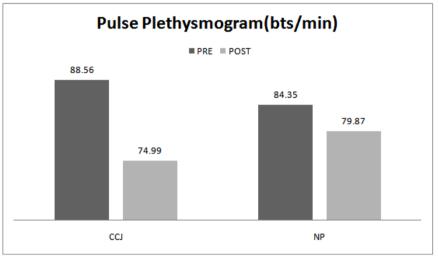
		test		
Variables	Sessions	Baseline Mean ± S.D	Post test Mean ± S.D	P value
HR(b/m)	COLD	92.19±16.63	81.89±20.05	0.0004**
	SPINAL			
	SPRAY			
	NP	88.86±18.08	84.37±16.28	0.0001**
PPG(b/m)	COLD	88.56±21.18	74.99±9.86	0.0002**
	SPINAL			
	SPRAY			
	NP	84.35±10.82	79.87±9.00	0.0138*
RR(cycles/min)	COLD	18.32±21.18	19.63±3.62	0.048
	SPINAL			
	SPRAY			
	NP	19.75±10.82	19.67±3.31	0.445
RRI(ms)	COLD	0.70±0.11	0.79±0.12	1.546
(IIIS)	SPINAL	0.70±0.11	0.77±0.12	1.5 10
	SPRAY			
	NP	0.72±0.09	0.75±0.12	1.080
Mean RR(ms)	COLD	697.74±81.60	789.46±116.32	5.165
mitan mitins)	SPINAL	071.17±01.00	707.40±110.52	5.105
	SPRAY			
	NP	717.71±104.96	752.176±107.93	1.156
		66.69±33.62	752.176±107.95	0.307
SDNN(ms)	COLD SPINAL	00.09±33.02	/0.43±43.20	0.507
	SPRAY	(2.07.02.70	(2.64.22.02	0.250
	NP	62.27±23.79	63.64±23.92	0.359
Mean HR(b/m)	COLD	88.12±11.21	78.35±12.26	1.098
	SPINAL			
	SPRAY			
	NP	86.10±13.11	82.77±12.00	0.002**
RMSSD(ms)	COLD	59.80±51.25	69.63±64.18	0.150
	SPINAL			
	SPRAY			
	NP	58.05±33.70	58.54±32.31	0.462
NN50(count)	COLD	83.40±63.84	$109.53 \pm 67.80$	0.008
	SPINAL			
	SPRAY			
	NP	87.63±66.56	99.20±64.29	0.0627
pNN50(%)	COLD	20.87±17.41	31.31±17.91	0.001*
	SPINAL			
	SPRAY			
	NP	21.32±16.83	25.41±17.31	0.0148
VLF(%)	COLD	56.28±93.99	27.71±14.27	0.058
	SPINAL			-
	SPRAY			
	NP	32.04±18.61	31.93±12.58	0.488
LF(n.u)	COLD	58.88±19.71	42.80±19.59	5.63E
LF(n.u)	SPINAL	00.00217.71	.2.00=17.07	0.001
	SPRAY			
	NP	52.22±19.71	51.93±20.59	0.457
HF(n.u)		41.12±19.71	57.2±19.59	5.63E
	COLD SPINAL	41.12±19./1	37.2±19.39	J.USE
	SPRAY	10.05 10.15	10.07.00.55	0.262
	NP	49.95±19.47	48.07±20.56	0.368
LF/HF (ms <sup>2</sup> )	COLD	$2.60 \pm 3.30$	1.10±1.39	0.002**
	SPINAL			
	SPRAY			
	NP	1.63±1.55	1.68±1.56	0.418
* P value < 0.05; ** P				

Table 3: Baseline and Posttest Assessment of Cold Spinal Spray(n=30) and NP (n=30). Students paired t
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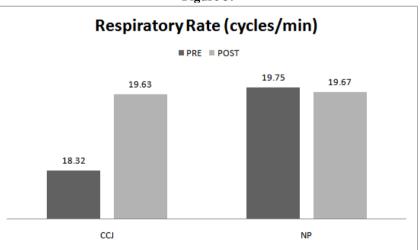
\* P value < 0.05; \*\* P value < 0.01.

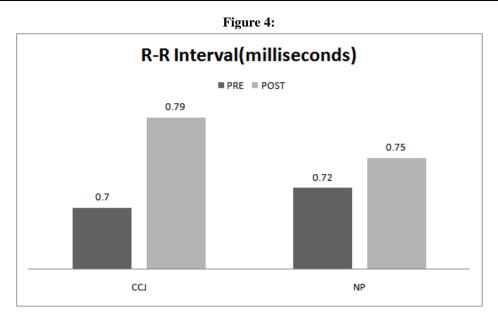




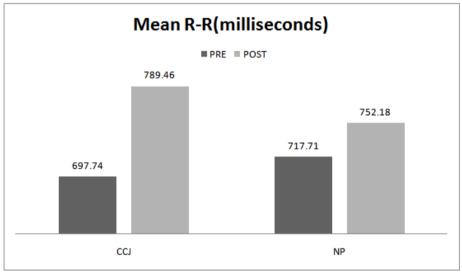




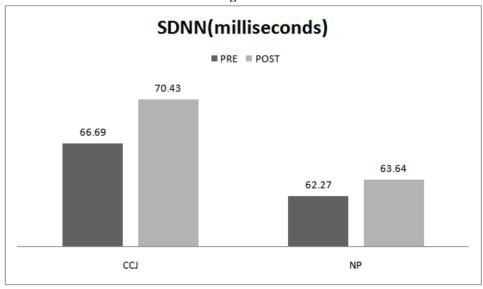


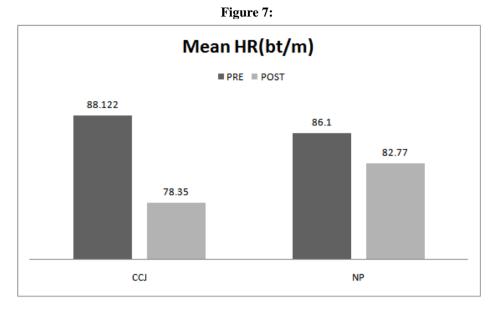




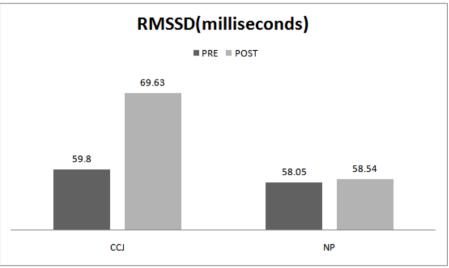




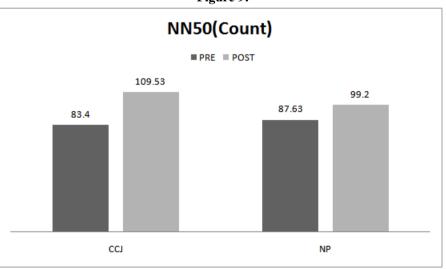


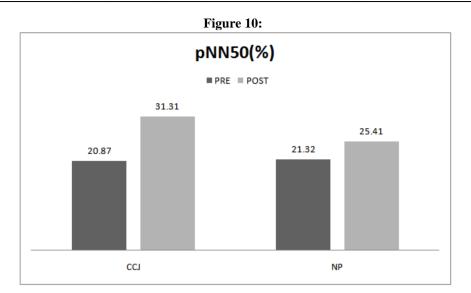




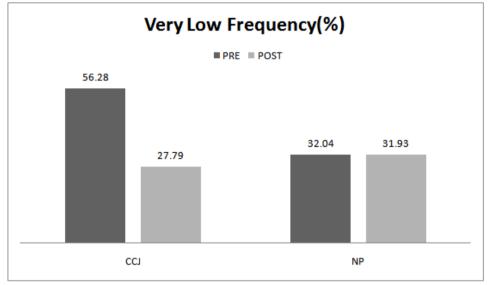




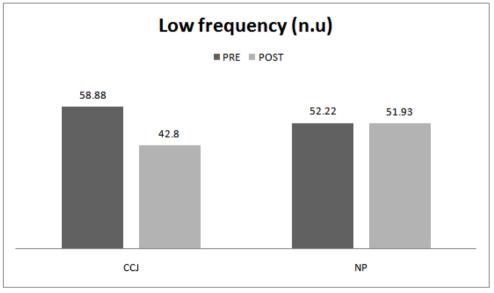


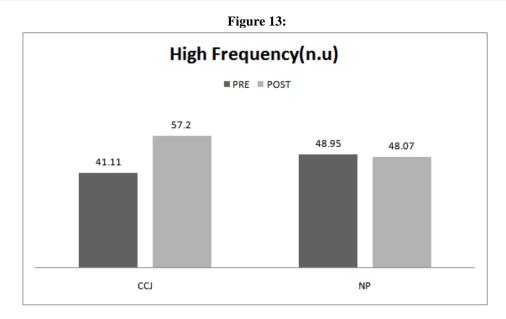




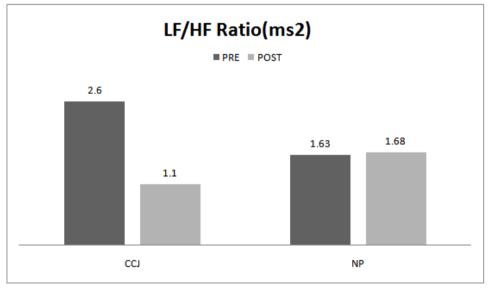












## **IV. Discussion**

The result of the study showed no significant difference between the Cold Spinal Spray and Neutral Position (NP) in all the autonomic and respiratory variables (ARV) such as HR PPG, RR, RRI, mean RRI, SDNN, RMSSD, NN50, pNN50, VLF, LF, HF, LF/HF ratio. It indicates that in influencing the ARV in healthy individuals, Cold Spinal Spray is not superior to Neutral Position.

In this study, within the group analysis of both Cold Spinal Spray and NP session showed significant reduction in PPG and HR. The reduction of PPG and HR indicates the physiological influence of the Cold Spinal Spray or in neutral position on the Medulla involved in the autonomic control of the heart sympathetic nerve activity. [15] The reduction maybe due to parasympathetic influence of vagus nerve on the heart mediated through Baroreceptors on NTS in response to the peripheral vasoconstriction that occurs as a result of cold stress. [16]

The increase in RR though not significant could be due to the sudden cold stress causing increased oxygen demand and gasping effect [5]. However this shows an increase in Sympathetic activity which is contradictory to the overall parasympathetic effect on the heart.

The increases in RRI, Mean RRI, RMSSD, NN50 and statistically significant increase in pNN50 more in the Cold Spinal Spray session indicate relaxative effect due to PSNS. The significant increase in time domain analysis of HRV such as RMSSD, NN50, and pNN50 are the indicative of vagal tone;[17] vagal modulation of cardiac function;[18] and strongly associated with cardiac vagal influence, and thus represents parasympathetic

activity.[19] It indicates that Cold Spinal Spravfor 10 minutes may have some effect on parasympathetic activity.

Insignificant decrease in LF and insignificant increase in HF after Cold Spinal Spray but statistically significant reduction in LF/HF ratio indicates it may have some effect on parasympathetic activity which supports the significant reduction in HR and PPG.

Hence, Cold Spinal Sprayreduces the HR, PPG and LF/HF ratio with improving parasympathetic activities as per the frequency domain results whereas neutral position standing reduces the HR and PPG without altering either sympathetic or parasympathetic activities. The difference in the results between time domain and frequency domain limits; significant increase in RR, limits understanding of its effects on autonomic variables and validity of its result.

#### LIMITATIONS

- Study was conducted among healthy individuals, which limits the scope of this study in its application to obese/hypertensive patients.
- The duration of the Cold Spinal Spraymight not be sufficient to produces the significant changes in time domain of the HRV variables.
- Furthermore, difference in temperature between the treatment room and research lab, influence of noise during treatment time as well as inability to use noise free data may have altered the results and caused bias.
- Short-term HRV limits the ability of measurement of time domain analysis accurately. Measurement of HRV through 24-hr monitoring would help to understand this better.
- Direct measurement of sympathetic activity like measurement of peripheral arterial resistance, Galvanic Skin Resistance, and optical sensors would have given better understanding of the state of the sympathetic nervous system.
- Further studies are required (Randomized control trials) in a large sample size with longer duration, adequate care and advanced techniques to evaluate its effect with underlying mechanism.

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Ashwin.V.P. "The Immediate Effect of Cold Spinal Sprayon Autonomic and Respiratory Variables in Healthy Volunteers". IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 12, 2019, pp 84-95.

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