A Somatovisceral Reflex of Lowered Blood Pressure and Pulse Rate After Spinal Manipulative Therapy in the Thoracic Region

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Abstract

OBJECTIVE: A randomized controlled trial (RCT) was designed to test effects of specific thoracic (T1 to T5) manipulations using an Activator instrument for changes in diastolic and systolic blood pressure, blood pressure classification, and pulse rates in 290 normotensive and hypertensive people in El Salvador.

METHODS: Informed consent was obtained from 290 subjects meeting the inclusion criteria. They were randomly assigned to one of three groups: Control (i.e., no treatment, N=95); Placebo treatment (N=96); or Active treatment (N=99). Subjects’ blood pressure and pulse rates were measured after relaxing for 15 minutes, then before intervention, and again just after treatment.

RESULTS: Systolic and diastolic BP, pulse rate, and BP classification decreased significantly only in the active treatment group. No significant changes occurred in the placebo treatment and control groups. Activator treatment’s effect size in changing hypertension classification as compared to no treatment was a medium $d = 0.37$, and $0.45$ when compared to placebo.

CONCLUSION: Specific thoracic spinal manipulations affected three measures: blood pressure, pulse rate, and changes in hypertension classification only in the active treatment group. Findings may represent in part a rebound effect from treatment anxiety, but this alone did not account for the observations. Activator instrument’s utility for sham settings was supported for future efficacy studies. The decrease was robust across several analyses, but the duration of the effect requires longer-term follow up.

Key words: Spinal manipulative therapy, Somatovisceral reflex, Activator instrument, Thoracic, Systolic blood pressure, Diastolic blood pressure, Pulse rate

Introduction

Hypertension is a well-documented worldwide health problem and is an important risk factor for cerebrovascular and ischemic heart diseases, which are among the leading causes of premature death among adults in most countries. Maintaining normal blood pressure can significantly reduce mortality from cardiovascular disease.

The World Health Organization (WHO), Pan American Health Organization (PAHO), and many other local multi-country officials have identified hypertension as a salient health concern in Central America, especially in El Salvador, where this randomized controlled trial (RCT) study was conducted. The study was carried out with approvals and endorsements from local El Salvador medical and health agencies and officials (PAHO).

Following on reports of the effects of spinal manipulation on blood pressure, previous studies have yielded equivocal results. Results have ranged from no effect to at least a transitory decrease in systolic and diastolic measurements and pulse rate. However, many of those studies had small sample sizes, differences in measurement, and did not assess meaningful changes in hypertension classes.

Objectives

This randomized controlled trial (RCT) was designed to explore the effects of upper thoracic (T1 to T5) spinal manipulation device on BP and PR changes in a random sample of patients with and without hypertension. The thoracic region includes innervation by the stellate ganglion that controls sympathetic innervation of the heart. In addition, the trapezius muscle is innervated by the...
spinal thoracic nerve – a cranial nerve that shares neural connections to body regulation systems. Touch or stimulation of this upper thoracic region may affect blood pressure for the reasons mentioned above, and any such contact may induce at least a temporary reduction of hypertension in response. This study was designed for the specific type of stimulation some chiropractors use for spinal manipulation. In this study, an Activator-type manipulation was performed by using an instrument can make several force settings from 0 (placebo) to 38 pounds. The current version of the Activator instrument offers five force settings ranging from 0 to 38 pounds delivered within 3 to 5 milliseconds. At the zero force setting the Activator makes an identical “click” sound as the full force setting, to facilitate naïve subject blinding.

Methods

Design

This is a randomized controlled trial superiority design to assess Activator diagnostic and treatment method in reducing hypertension. El Salvadorans with and without hypertension were recruited and randomly assigned to one of three treatment groups. Randomization to condition was performed by random draw from a set three numbers with replacement.

The RCT was approved by the Spinal Missions Institutional Review Board (IRB), and was accepted and registered by the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), and Federal-Wide Assurance (FWA) approval was obtained by HHS OHRP. This RCT was registered with the U.S. “ClinicalTrials.gov” and was assigned registration number NCT01591967. The study was self-funded by participants. Activator International donated two Activator instruments.

The inclusion criteria were:

* Male and female age 18 years and older.
* Subjects must not be pregnant.
* Subjects must not have any recent or current fractures of the arms or legs.
* Subjects must not have any visceral or abdominal condition such that being in the prone position would be detrimental to their health.
* Subjects must not have any known primary cancers of the spine or spinal column, nor any secondary metastatic process of the spine or spinal column.
* Subjects must not be under the influence of drugs or alcohol.
* Subjects must not have vertigo or any other imbalance condition.
* Subjects must not have any arm or leg prosthetic device.
* Subjects must be able to understand spoken and/or written Spanish and/or English.

The study was advertised by flyers and encouraged by word-of-mouth as open to the public. Samples of 90 per group were required in accord with 80% statistical power and 5% Type I error rate for 25% change in hypertension class. Of 293 patients reporting for the study, 290 met the inclusion criteria. The three exclusions were: a female three months pregnant, one intoxicated male, and one male with a leg prosthesis.

All patients were given informed consent in Spanish and English. According to randomization, 99 subjects went to the Activator treatment group, 96 to placebo/sham group, and 95 to the control (no treatment and no placebo) group. Subject descriptions for each group are in Table 1. Post hoc tests confirmed success of randomization with respect to equal distribution of hypertension classes, sex, and other characteristics.

### Table 1
Success of Randomization Procedure

<table>
<thead>
<tr>
<th>Condition</th>
<th>Activator</th>
<th>Placebo</th>
<th>No Treatment Control</th>
<th>Average % for Each Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>% with normal BP</td>
<td>28.8%</td>
<td>21.2%</td>
<td>32.9%</td>
<td>27.7%</td>
</tr>
<tr>
<td>% over 50 years old</td>
<td>56.0%</td>
<td>61.0%</td>
<td>66.0%</td>
<td>61.2%</td>
</tr>
<tr>
<td>% male</td>
<td>31.7%</td>
<td>34.7%</td>
<td>38.4%</td>
<td>34.9%</td>
</tr>
<tr>
<td>% blinded</td>
<td>38.5%</td>
<td>36.6%</td>
<td>34.0%</td>
<td>36.4%</td>
</tr>
</tbody>
</table>

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Procedure

All patients sat in a relaxing climate-controlled room for at least 15 minutes before taking a brief medical and health history by non-treating members of the research team. All 290 subjects had baseline blood pressures (BP, both systolic and diastolic) and pulse rate (PR) measurements recorded with a digital oscillometric sphygmomanometer. The digital oscillometric sphygmomanometer was used to minimize operator errors associated with cuffs, stethoscopes, and reading errors. Oscillometric sphygmomanometers have been shown to introduce bias by underestimating high BP by 2.28% and stage II high BP by 0.77%. Investigators believed the convenience and portability of the digital device outweighed its systematic error (bias) introduced by cuff-and-stethoscope instruments and was better suited for travel and use in uncertain environments. Underestimating biases were minor and would consistently produce at least “conservative” estimates at high BP classifications. Errors should be distributed equally across three randomly assigned treatment groups.

Patients and data recorders were blinded as to patient assignment. The blinding condition was tested post hoc for success. Measures were taken three times: after history taking and 15 minutes rest, just before sham or treatment or the equivalent amount of time for the control group, and immediately after treatment or the equivalent passage of time. Subjects in the placebo group were treated identically to those in the active treatment group, except that the Activator IV TM instrument was set to zero (0) for the adjusting device to deliver zero force. The instrument still made a “click” sound, but no force was actually delivered. The active treatment group received treatment with an Activator IV adjusting instrument on setting number two (2) according to Activator clinical protocol for thoracic segments T1 to T5.

Figure 1

The Activator instrument for fixated joint manipulation. a. The complete Activator instrument with force set to zero for the placebo/sham. b. Force setting to “2” or 18 pounds for thoracic manipulation.

Safety monitoring

All study staff were CPR certified and BLS (Basic Life Support) certified. Author DM served as the Medical Director for this study. All staff received a pre-study safety briefing by authors DM and SR. All Activator Methods safety guidelines were followed. All data were tracked and ensured by author SR. Data were kept in locked briefcases while the study was in active data collection mode. Upon return to our U.S. offices, data were kept in locked file cabinets in locked offices with only author SR having access to the key. Data were entered onto password-protected computers in locked offices.

Data and Analysis

Data were transferred from collection sheets of the three time assessments (Time 0, Time 1, and Time 2) for blood pressure and pulse rate and entered into Microsoft Excel by two research students using double-entry method. Two data entry files were compared using Excel’s file comparison function and data entry discrepancies were reconciled with the original data collection forms.

Class membership was more clinically meaningful than raw data changes. Large samples might easily show statistically significant changes without shifts in classification. This is the definition of a significant change lacking meaning. Classifications then served as dependent variables. General linear models and analyses of variance were used to show mean differences by assigned condition. Changes in BP classification included initial BP classifications as a covariate. All analyses were performed on R software packages and basic stats.
packages. The alpha level of 0.05 was used for significance testing and effect sizes are reported for interpretation of outcomes.

**Results**

Ages ranged from 18 to 100 years old, median age = 52, with 66% female. Successful randomization is confirmed in Table I. All variables known to have an impact on blood pressure were satisfactorily distributed across treatment groups, and sample sizes were close to being equivalent. Effectiveness of blinding analyzed by one-way analysis of variance showed that the blinding group did not differ in outcome from the unblinded group.

**Linear modeling**

The main effect as illustrated in Figure 2 was a decrease in systolic and diastolic BP and pulse rate by an average 7% in the Activator active treatment condition. This effect was not observed in the other two groups, and represents a mild effect size of 0.30 over the placebo group and 0.38 over the control group.

All normotensives experienced a slight rise in both systolic and diastolic blood pressure before treatment or placebo, representing the typical anxiety effect. Only the active (Activator) group’s normotensives experienced a large decrease in pulse rate after treatment. However, the pulse rate for normotensives was trending downward before treatment (See Figure 2).

**Figure 2**

A comparison of the average levels of diastolic and systolic blood pressure measurements for each group over the three time assessments: baseline, pretreatment of second measurement, and after treatment or end of study. Pulse rates for each time and treatment category are the bottom three blocks of the figure.

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**Effect sizes as changes in hypertension classification**

The primary outcome of interest was improvement in hypertension classification. Hypertension class changes by group are displayed in Figure 3. The four classifications at intake – normotensive, prehypertensive, Stage I and Stage II, are on the x-axes across three observation periods. Y-axes represent the shift in classification at each measurement. Rows are the experimental conditions: active treatment (Activator) group, placebo/sham group, and control (no treatment and no placebo) group, from top to bottom. The effect from Activator can be seen in the new reduced
classification in the dotted box in the top right Activator condition.

**Figure 3**

The four categories of original blood pressure classification are on the x-axis. They are, from 1 to 4, normotensive, prehypertensive, hypertensive stage I, and hypertensive stage II. The y-axis represents the blood pressure classification during the study and at the end. Each circle roughly represents the number of patients in each category. The arrow represents the state of no change. Circles below the line show improvement by changing into lower categories. Circles above the line show patients experiencing an increase in blood pressure class. Only the Activator manipulated group showed improvement for the three hypertensive classes above normal. The change to lower blood pressure classes can be seen in the upper right of the figure in the dotted box.

Table 2 summarizes the percent of changes within each initial classification by the end of the study. Fewer normotensives migrated into higher hypertension classifications in the Activator treatment group. The odds ratio (OR) showed a protective factor for normotensives of 0.31 for placebo and 0.37 for no treatment. By category, 46% of Activator treatment subjects improved in early hypertensive or prehypertensive classification – about 4 times more than placebo and 2.65 times better than the controls. Similarly, 51% of Stage I and 57% of Stage II hypertensive patients improved, also better than placebo and control subjects. Odds ratios favored Activator treatments by 1.80 to 2.68 odds ratios for reducing blood pressure classification. Effect size of classification changes for Activator were 0.37 over no treatment, and a medium Cohen’s d = 0.45 over placebo. Why the active treatment was more dissimilar than placebo is interesting, and may suggest pre-treatment anxiety upon seeing the Activator instrument. If so, there might be an even greater effect size for the treatment condition, if anxiety could be experimentally controlled.

<table>
<thead>
<tr>
<th>Hypertensive State at Beginning of Study</th>
<th>Activator</th>
<th>Placebo</th>
<th>No treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Normotensive</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>percent worse / same / improved by end of study</td>
<td>11% / 89% / NA</td>
<td>34% / 60% / NA</td>
<td>25% / 71% / NA</td>
</tr>
<tr>
<td><strong>Prehypertensive</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>percent worse / same / improved by end of study</td>
<td>11% / 43% / 46%</td>
<td>33% / 56% / 12%</td>
<td>20% / 50% / 15%</td>
</tr>
<tr>
<td><strong>Stage I Hypertension</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>percent worse / same / improved by end of study</td>
<td>8% / 41% / 51%</td>
<td>31% / 50% / 19%</td>
<td>10% / 60% / 24%</td>
</tr>
<tr>
<td><strong>Stage II Hypertension</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>percent worse / same / improved by end of study</td>
<td>NA / 44% / 56%</td>
<td>NA / 71% / 29%</td>
<td>NA / 77% / 23%</td>
</tr>
</tbody>
</table>
Discussion

Previous studies showed a potential for a somatovisceral response from thoracic musculoskeletal stimulation and changes in blood pressure and pulse above anxiety-related responses. Specific thoracic (T1 to T5) Activator manipulations appeared to decrease systolic and diastolic BP and pulse rate. A recent literature review also reported spinal manipulative therapy lowering hypertension raw measurement and classification, as did an earlier chiropractic study in 1988 by Yates et al. (4)

Common physiological mechanisms explain how somatic input at the thoracic region may reduce BP and PR. One mechanism is by sensing direct neural input via the pontomedullary reticular formation (PMRF) and contralateral intermediodiaphragmatic cell column (IML), which would relax vasculature. Another is that fast muscle stretch from manipulation might reset blood pressure by decreasing sympathetic tone and the relaxing peripheral arteries innervated by the upper thoracic spinal nerves.

This study supports the notion that a mechanical force to musculoskeletal system could influence BP via sympathetic tone, at least on a transient basis. Whether or not change in classification of these patients was lasting requires longer observation in hours, days, or weeks. We suspect that since no lasting structural change would have been accomplished with such a brief clinical encounter, that the drop in blood pressure would have been transient and only up to a few minutes. We propose to test this in future studies that would involve 24 hour blood pressure holter monitoring.

Limitations

This RCT did not collect hypertensive medication history and current usage. Most of the subjects were hypertensive to some degree, perhaps reflective of the known hypertension prevalence in Central and South America. A double-blind method was not feasible as addressed above, so bias is possible despite analyses to control for blinding.

Systolic measures were already dropping from intake to pre-treatment in the active group, and the post-treatment measure appeared to extend this trajectory. Diastolic measures increased between intake to pre-treatment and dropped further afterwards. In other words, pre-treatment anxiety might have inflated the effect on the raw systolic and diastolic scores. Pulse rates also jumped up just before treatment was administered.

Conclusion

This RCT demonstrated that specific thoracic segmental manipulation had at least a transient effect in decreasing blood pressure and pulse rate. BP measurements are notoriously unstable and shift over the course of the day and according to patient apprehension and discomfort. The observed treatment improvement in blood pressure and pulse rate represents a somatovisceral reflex worthy of further investigation. Rather than continue to assess whether adjustments alone can produce lasting clinical effects, it is prudent in future studies to observe the extent of reassurance, encouragement, and corporeal touch in rendering the same or similar outcomes.

References