Effect of Spinal Manipulation of Upper Cervical Vertebrae on Blood Pressure: Results of a Pilot Sham-Controlled Trial

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Abstract

Objective: The purpose of this pilot sham-controlled clinical trial was to estimate the treatment effect and safety of toggle recoil spinal manipulation for blood pressure management.

Methods: Fifty-one participants with prehypertension or stage 1 hypertension (systolic blood pressure ranging from 135 to 159 mm Hg or diastolic blood pressure ranging from 85 to 99 mm Hg) were allocated by an adaptive design to 2 treatments: toggle recoil spinal manipulation or a sham procedure. Participants were seen by a doctor of chiropractic twice weekly for 6 weeks and remained on their antihypertensive medications, as prescribed, throughout the trial. Blood pressure was assessed at baseline and after study visits 1, 6 (week 3), and 12 (week 6), with the primary end point at week 6. Analysis of covariance was used to compare mean blood pressure changes from baseline between groups at each end point, controlling for sex, age, body mass index, and baseline blood pressure.

Results: Adjusted mean change from baseline to week 6 was greater in the sham group (systolic, −4.2 mm Hg; diastolic, −1.6 mm Hg) than in the spinal manipulation group (systolic, 0.6 mm Hg; diastolic, 0.7 mm Hg), but the difference was not statistically significant. No serious and few adverse events were noted.

Conclusions: Six weeks of toggle recoil spinal manipulation did not lower systolic or diastolic blood pressure when compared with a sham procedure. No serious adverse events from either treatment were reported. Our results do not support a larger clinical trial. Further research to understand the potential mechanisms of action involving upper cervical manipulation on blood pressure is warranted before additional clinical investigations are conducted. (J Manipulative Physiol Ther 2016;39:369-380)

Key Indexing Terms: *Hypertension; Spinal Manipulation; Complementary Therapies; Chiropractic; Cervical Spine; Controlled Clinical Trial*

Hypertension, or high blood pressure (BP), affects nearly 30% of US adults, with only 35% of those individuals meeting their treatment goals.[1] Spinal manipulative therapy (SMT) is a manual therapy used by some doctors of chiropractic (DCs) for the treatment of hypertension.[2–7] Small clinical trials and observational studies of SMT have reported a BP-lowering effect for select patients.[8–13] However, many studies of SMT for BP management demonstrate a high bias risk under systematic review, whereas trials with a lower risk of

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bias have shown null or inconclusive results.[3,11,12] In the largest clinical trial conducted to date on the efficacy of SMT for BP control, Goertz et al[12] studied 140 patients with high normal BP or stage 1 hypertension and concluded that full-spine SMT delivered with the diversified technique, in conjunction with dietary modification, offered no advantage in lowering systolic (SBP) or diastolic (DBP) blood pressure compared with diet modification alone.

Since then, a pilot study by Bakris and colleagues[13] of a rarely used form of SMT that targets the C1 (atlas) vertebra demonstrated a substantial decrease in SBP and DBP compared with a sham in 50 unmedicated patients with stage 1 hypertension. The SMT participants sustained a mean drop of 17 mm Hg in SBP and 10 mm Hg in DBP over sham participants. Not surprisingly given these results, the study received national media attention with the implication being that chiropractic SMT may be a viable treatment alternative for persons with hypertension.[14] However, several methodological issues with the study potentially impact its generalizability to chiropractic practice. These issues include unclear allocation and blinding procedures[3]; the use of an uncommon chiropractic technique not widely available to patients (ie, practiced by less than 50 practitioners worldwide who have the advanced certification level of the trial provider); and the reliance upon a sole DC for many critical aspects of the trial, including development of the sham, identification of cervical spine misalignments, delivery of the SMT and sham, and evaluation of clinical outcomes.[13] Furthermore, participants were recruited from one medical practice, and the publication offered an incomplete description of the BP assessment procedures used to determine eligibility and outcomes,[13] leading a systematic review to rank the trial as having an unclear bias risk.[3]

However, the striking BP-lowering effects of this previous study[13] called for a well-designed clinical trial to evaluate further the efficacy and safety of cervical SMT for BP management.[15,16] Thus, our team conducted a pilot study with a more commonly used form of SMT that also targets the C1/C2 vertebrae, using research methodologies that were more rigorous and generalizable. Toggle recoil SMT involves a nonrotary, high-velocity thrust to the C1/C2 vertebrae.[17] Although the thrust of toggle recoil SMT differs from the gradual, prolonged force application used in the aforementioned trial,[13] both techniques embrace the same therapeutic paradigm, that is, the alignment of upper cervical vertebrae with a carefully controlled manual force that may influence BP via relaxation of upper cervical spinal muscles and by affecting autonomic control mechanisms located in the medulla oblongata and cervicocranial region.[18,19]

The purpose of this pilot sham-controlled clinical trial was to estimate the treatment effect and its variance, as well as the safety of upper cervical spinal manipulation for BP management.[20] Thus, our primary aim was to evaluate the BP-lowering effects of toggle recoil SMT on SBP and DBP against a control group that received a sham manipulation to the neck in individuals with prehypertension or stage 1 hypertension. Our secondary aim was to evaluate the safety of toggle recoil and the sham manipulation by categorizing adverse events (AEs) reported by study participants.

Methods

Study Overview

The Chiropractic for Hypertension in Patients (CHiP) study was a prospective, 2-arm parallel group, sham-controlled pilot trial with adaptive allocation.[21] The study setting was the research clinic of the Palmer Center for Chiropractic Research, Davenport, IA. Participants who were diagnosed with prehypertension or stage 1 hypertension completed 6 weeks of twice-weekly study visits, with outcomes measured after visits 1, 6, and 12. The comparison groups were toggle recoil SMT delivered to the upper cervical vertebrae or a sham manipulation.

All work was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. The study protocol was approved by the collegiate institutional review board (Palmer College of Chiropractic IRB# 2010G135-09/15/2010) and monitored by an independent data and safety monitoring committee. All participants completed an informed consent document indicating their understanding of the study protocol and consent to participate in the clinical trial. The trial was registered on ClinicalTrials.gov (NCT01020435).

Participants

Participants were recruited from the community through targeted direct mailers, American Heart Association events, and press releases using previously successful recruitment methods we have described elsewhere.[22]

Inclusion criteria were as follows: (1) SBP ranging from 135 to 159 mm Hg or DBP ranging from 85 to 99 mm Hg over 3 qualifying BP screening visits, (2) misalignment of either or both of the first 2 cervical spinal segments (C1/C2) as measured with the use of standardized radiography, and (3) age 21 to 75 years.

Exclusion criteria were as follows: (1) cardiovascular diseases or surgery, including second- or third-degree heart block, angina pectoris, defibrillator, valvular disease, recent myocardial infarction, cardiac surgery in the past 12 months, percutaneous angioplasty with or without stents in the past 2 months, vascular claudication, aortic coarctation, renal artery stenosis, or other cause of secondary hypertension; (2) history of stroke; (3) body mass index (BMI) greater than 39 mg/m^2; (4) pregnancy; (5) unwillingness to forego other forms of manual therapy during the study; (6) current use of specific medications (anticoagulants; anabolic steroids, glucocorticoids, corticosteroids; bromocriptine; cyclosporine or tacrolimus; erythropoietin; or MAO (monamine oxidase) inhibitors); (7)