Treatment of Hypertension with Alternative Therapies (THAT) Study: a randomized clinical trial

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Objectives **To examine the effect of spinal manipulation on blood pressure.**

Design **This randomized clinical trial compared the effects of chiropractic spinal manipulation and diet with diet alone for lowering blood pressure in participants with high-normal blood pressure or stage I hypertension. Blood pressure observers were blinded to treatment group.**

Setting **The study was conducted at the Berman Center for Clinical and Outcomes Research in Minnesota. Chiropractic treatments were administered by chiropractic physicians within private practice settings.**

Participants **One hundred and forty men and women, aged 25–60 years, with high-normal blood pressure or stage I hypertension, were enrolled. One hundred and twenty-eight participants completed the study.**

Interventions **(i) A dietary intervention program administered by a dietitian or (ii) a dietary intervention program administered by a doctor of chiropractic in conjunction with chiropractic spinal manipulation. The frequency of treatment for both groups was three times per week for 4 weeks, for a total of 12 visits.**

Main outcome measures **The primary outcomes for this study were change from baseline in diastolic and systolic blood pressure.**

Results **Study groups were comparable at baseline. Changes in potentially confounding covariates did not differ between groups. Average decreases in systolic/diastolic blood pressure were −4.9/5.6 mmHg for diet group and −3.5/4.0 mmHg for the chiropractic group. Between group changes were not statistically significant.**

Conclusions **For patients with high normal blood pressure or stage I hypertension, chiropractic spinal manipulation in conjunction with a dietary modification program offered no advantage in lowering either diastolic or systolic blood pressure compared to diet alone. *J Hypertens* 20:2063–2068 © 2002 Lippincott Williams & Wilkins.**

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Keywords: hypertension, chiropractic, diet, spinal manipulation, high blood pressure, randomized clinical trial

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Introduction

Although antihypertensive medications remain the treatment of choice for hypertension, approaches have changed considerably over the past few years. Options now incorporate lifestyle changes for prevention, early intervention and concomitant therapy. Recommended lifestyle changes are currently weight reduction, reduced dietary intake of sodium and fat, exercise and limited alcohol use [1]. The benefits of other alternative or complementary treatments, including relaxation therapy, acupuncture, and chiropractic spinal manipulation, are less clear.

The number of patients with hypertension who seek out alternative treatment is not known, but alternative medicine is popular among health care consumers [2,3]. Eisenberg *et al.* [3]. demonstrated a 47% increase in visits to alternative practitioners between 1990 and 1997, with 42.1% of adult respondents reporting use of alternative therapy in the past year. Given the cost of drug therapy for hypertension and the possibility of adverse effects from these drugs, alternative therapies proported to lower blood pressure are attractive to many patients with this condition. Such therapies need rigorous evaluation of their effectiveness in lowering blood pressure.

Some individuals within the chiropractic profession believe that spinal manipulation has a blood pressure-lowering effect [4,5]. Mechanisms that have been

proposed for how spinal manipulation might lower blood pressure include a reflex action on the autonomic nervous system, leading to either a decrease in peripheral resistance or a direct effect on aldosterone levels [6–9]. In a 1997 nationwide survey, doctors of chiropractic reported that they are treating 1% of their patients primarily for hypertension [10].

The primary aim of this study was to investigate the effect of spinal manipulation on blood pressure in individuals with high-normal blood pressure or stage I hypertension.

Methods

Participants

One hundred and forty participants enrolled in the study. All potential risks were described in detail verbally and on the consent form. The University of Minnesota Human Subjects Committee, as well as Allina Health System and Hennepin County Medical Center's Institutional Review Boards, approved the study. Participants attended three eligibility visits and provided their written informed consent prior to randomization.

Recruitment

Participants were recruited using newspaper and radio advertisements, as well as tear-off posters and brochures distributed in public places. One of the most successful recruitment efforts included postcard mailings sent to Twin City metro area residents who met the age criteria based on a mailing list obtained from the Minnesota Department of Transportation. In addition, brochures describing the study were mailed to University of Minnesota faculty and staff. All methods incorporated the same message and highlighted the alternative therapy aspect of the study.

Eligibility criteria

The study included men and women aged 25–60 years, with high-normal blood pressure or stage I hypertension diagnosed according to JNC-V guidelines [11]. Participants with diastolic pressures of 85–99 mmHg and systolic pressures below 160 mmHg were eligible for the study. Blood pressure eligibility was determined at two clinic visits with final eligibility based on the average of four blood pressure measurements taken at these visits.

Participants were excluded if they were taking more than one type of antihypertensive medication, or had a history of life-limiting health conditions or contraindications to chiropractic spinal manipulation. Exclusions also were made for individuals who reported any one of the following: a change in treatment for high blood pressure within the previous 3 months; receiving chiropractic spinal manipulation within the last 6 months; a history of severe mental illness; drinking more than an average of four alcoholic drinks per day; actively trying to lose weight, or not willing to fully participate in both treatment groups. Because spinal manipulation has been reported to lower pain levels for individuals with back pain [12], and there is a correlation between pain levels and blood pressure, participants reporting average pain levels of five or above on a 0–10 point visual analog type scale were also excluded.

Individuals who met all of the eligibility criteria and accepted the commitment involved were randomized into the study.

Randomization

Participants were randomized into one of two treatment groups: (i) dietary intervention program administered by an experienced registered dietitian (group 1) and (ii) dietary intervention program administered by a doctor of chiropractic in conjunction with chiropractic spinal manipulation (group 2). A set of sealed, numbered opaque envelopes that contained the treatment group assignments was prepared and placed in random order. When a patient was accepted into the study, the treatment group was determined by selecting the next envelope in sequence. Sixty-nine individuals were randomized into the diet alone group while 71 individuals were randomized into the chiropractic spinal manipulation/diet group.

Baseline visits and procedures

At the initial eligibility visit, participants completed a medical history and questionnaires regarding their dietary sodium intake, general health status (SF-36), and alcohol consumption. A total of 395 participants were seen at the initial eligibility visit. Participants who met the initial eligibility criteria were invited to the second eligibility visit; 150 of the 395 were excluded, most commonly due to ineligible blood pressure levels.

Blood pressure eligibility was verified on the second visit. Weight, height, blood pressure and physical activity levels were assessed. Of the 245 individuals who attended the second eligibility visit, 103 were excluded, primarily based on blood pressure readings below the designated ranges.

The third visit determined final eligibility. A complete history and physical examination were performed by a licensed chiropractor at the Berman Center for Outcomes and Clinical Research. The examination protocol followed that outlined by Haldeman *et al*. [13] for both the systems examination and the manual examination of the spine. The examination did not include X-rays or laboratory testing. Treating chiropractic physicians were given the option of ordering X-rays later if, in their opinion, they were indicated. Also at the third

visit, eligible participants were randomized, underwent an orientation to the diet program and received a schedule for future intervention visits.

Of the 142 individuals who attended the third eligibility visit, two were excluded based on examination findings indicating potential contraindications to spinal manipulation, leaving 140 individuals, all who agreed to participate and provided their written informed consent.

Treatments description

Dietary modification program

The Diet group subjects participated in 12 diet sessions, three per week for 4 weeks, given by an experienced registered dietitian at the Berman Center for Outcomes and Clinical Research. Participants were provided with written instructions on how to modify their current diet and were also given diet sheets, which included low-fat, low-salt recipes. The nutritionist explained the diet and covered a pre-set list of topics. The time spent (an average of 15–20 min) with the dietitian during each session was designed to be the same as the total time spent with the doctor of chiropractic for participants in the treatment group including both spinal manipulation and diet (DC/Diet).

Spinal manipulation and a dietary modification program

DC/Diet participants were allowed to select a chiropractic physician from a pool of seven who agreed to participate as clinicians in the study. Most provider selections were based on geographical proximity to the participant's home or work. DC/Diet patients received all of the written diet information received by the Diet group, but from the chiropractor. In addition, DC/Diet participants received chiropractic spinal manipulation. The frequency of treatment was three times per week for 4 weeks, for a total of 12 visits.

Individual treatments, including specific areas determined to require spinal manipulation, were at the discretion of the clinician. However, several measures were taken in order to achieve consistency in treatment techniques across clinicians. All seven chiropractors had at least 5 years of clinical experience and were chosen because they use diversified spinal adjustments (manipulation) as their primary treatment intervention within their general practice. Diversified manipulation was defined for the purposes of this study as a high velocity, short-lever impulse or force applied directly to a joint space in such a way as to momentarily move the joint beyond its passive range of motion. Therapy considered as preparatory to chiropractic spinal manipulation such as ultrasound, moist heat or soft-tissue massage was allowed. Use of physio-therapy modalities was included in the study protocol in an effort to replicate as closely as possible the way chiropractic providers normally treat patients. Prior to the initiation of participant recruitment, study manuals were prepared for each doctor of chiropractic and his or her staff. The manual outlined the purpose of the study, a general treatment protocol, specific diet intervention instructions and examples of data collection forms. This information was presented and explained in detail at a training session attended by the chiropractic physicians. Following this session, the study coordinator and the co-principal investigator visited each participating chiropractic clinic to provide any additional training necessary to the chiropractic physician and staff on coordination of information transfer, instructions on administering dietary advice and to ensure that treatment techniques were consistent with the protocol. Follow-up teleconferences and visits were conducted as needed. All treating clinicians agreed not to offer dietary advice other than that included in the standard diet instructions (e.g. supplements), aerobic exercise advice, acupuncture or activator treatment to participants.

Follow-up visits and procedures

Endpoint measures were carried out following treatment. Every attempt was made to schedule the first measurement visit approximately 24 h after the final treatment session. Procedures performed at this visit included weight and blood pressure. The second endpoint assessment was scheduled within 72 h following this visit and included blood pressure measurements and an exit interview.

Outcomes

The primary outcomes for this study were change from baseline in diastolic and systolic blood pressure. Prior to randomization, two blood pressure readings were recorded at each of three evaluation visits. The average of these six measurements was used to establish baseline blood pressure. Following the 4-week treatment period, two blood pressure readings were recorded at each of two endpoint assessment visits. The average of these four blood pressure readings determined the final endpoint measure.

All measures were performed with the random-zero sphygmomanometer; an instrument designed to minimize observer bias. Blood pressures were taken in the right arm with the patient seated in a temperature-controlled room (68–74°) following a 5-min rest. The average of two random-zero readings was recorded as the blood pressure for the visit. All blood pressure and other measurements were taken at the Berman Center by trained observers who were unaware of study group assignment.

Participant compliance with dietary advice was monitored using two parameters. The first was average change in weight and the second was the use of pre–

post questionnaires to determine change in alcohol consumption and use of salt at the table or while cooking. Weight was measured with shoes off on calibrated scales and rounded up to the nearest half pound. Questions regarding average alcohol and salt consumption were completed as part of the initial visit, with the same questions asked again at the first endpoint visit.

Participants also completed a series of questions regarding their level of physical activity prior to the study. They were asked to fill out a physical activity diary each week for the duration of the study. The activity diary is a two-page questionnaire that assigns points for every minute of aerobic physical activity. A total 4-week activity score was calculated for each participant.

Statistical analysis

Sample size was estimated based on a two-sample *t*-test (normal approximation) using the average change in diastolic blood pressure over 4 weeks of treatment as the primary endpoint. The following parameters were used: (i) alpha (type I error) = 0.05; (ii) power = 0.9; (iii) two-sided test of significance; (iv) SD 7 mmHg; and (v) an estimated treatment effect of 4 mmHg. The standard deviation was based on data from the Treatment of Mild Hypertension Study (TOMHS) and the Multiple Risk Factor Intervention Trial (MRFIT) hypertensives. Analysis was carried out by intention to treat; that is, all participants randomized were included in treatment comparisons and were counted in the treatment group to which they were randomly assigned, regardless of adherence. Follow-up measurements of blood pressure were available for 62 individuals from the Diet group and 66 individuals from the DC/Diet group.

Baseline factors potentially affecting blood pressure were compared between groups using *t*-test and chi-square tests. Variables included were blood pressure, weight, age, race, sodium intake, alcohol consumption, pain levels, general health status and blood pressure medication status. Analysis of variance (ANOVA) was used to compare pre–post-change in variables of interest, including weight, alcohol consumption and physical activity scores as well as changes in blood pressure between groups. A statistician at the Division of Biostatistics, University of Minnesota, conducted all analysis using SAS statistical software (SAS Institute Inc., Cary, North Carolina, USA).

Results

The overall non-completion rate for study subjects was approximately 9%, with five dropouts in the chiropractic/diet group and seven dropouts in the diet group. The reasons given for failure to complete the study include: not feeling comfortable with chiropractic treatment after it was initiated ($n = 4$), deciding against participating in diet group after randomization ($n = 4$), experiencing neck pain following chiropractic treatment ($n = 1$), unable to be contacted after one diet session ($n = 1$), becoming too ill to participate ($n = 1$); and being 'too busy' to complete the study ($n = 1$).

Baseline comparison by treatment

Baseline characteristics by group are provided in Table 1. There were no significant differences between the two groups at baseline. Overall, the average age of participants was 48 years, 44% were male and 8% were African-American. Average weight was 193 lbs, with an average body mass index of 30.5 kg/m^2. The diet group overall weighed more than the chiropractic group at 200 versus 187 lbs, and this difference was borderline significant ($P = 0.06$). Average baseline resting blood pressure was 136/89 mmHg. Approximately 40% of participants were taking blood pressure medication at entry. General health according to the SF-36 was 71. Twelve percent were smokers and the average alcohol consumption was just over three drinks per week.

Table 1 **Baseline characteristics**

Characteristics	Diet ($n = 69$)	DC/Diet ($n = 71$)	Between group *P*-values
Age (years)	47.6 ± 6.6	47.5 ± 7.2	0.95
Race (% black)	8.8	8.5	0.94
Weight (lbs)	200 ± 44	187 ± 36	0.06
Body mass index	31.3 ± 6.2	29.8 ± 5.6	0.14
Gender (% male)	46.4	42.3	0.62
Use salt when cooking (% yes)	88.4	85.7	0.64
Use salt at table (% yes)	71.0	67.6	0.66
Alcoholic drinks/week	3.1 ± 4.0	3.4 ± 4.8	0.75
Taking blood pressure medication (% yes)	40.6	33.8	0.41
Smoking cigarettes (% yes)	13.2	9.9	0.53
Baseline systolic blood pressure (mmHg)	136.5 ± 10.9	134.8 ± 9.4	0.32
Baseline diastolic blood pressure (mmHg)	88.8 ± 3.3	88.8 ± 3.7	0.95
Pain (SF-36)	81 ± 19	78 ± 20	0.31
General health (SF-36)	71 ± 17	71 ± 16	0.97

Over the course of the study, there was very little change in self-reported alcohol consumption for both groups (Table 2). At end of the study, both groups experienced essentially the same minimal average weight change (−0.8 lbs). These changes in potentially confounding covariates did not significantly differ between groups.

Changes from baseline in blood pressure by treatment group are shown in Table 3. Systolic and diastolic reductions in blood pressure were −4.9/5.6 mmHg for the diet group and −3.5/4.0 mmHg for the chiropractic group. Although between-group changes were not statistically significant ($P = 0.08$ diastolic and $P = 0.36$ systolic, respectively), a somewhat larger reduction was observed for participants in the diet group.

We were concerned about the possibility of temporal confounding because there was a difference between groups in the days between the final baseline visit and the final follow-up visit (41 versus 54 days, $P = 0.003$). To assess this possibility, covariate analysis (ANCOVA) was conducted to determine if length of time in the study influenced outcome. Models were constructed for both diastolic and systolic blood pressure, including group, sex, age, race, baseline pain levels, baseline general health status, cigarette smoking, blood pressure medication status, baseline blood pressure, length of time taken to complete the study and an interaction term for group and length of time in the study. Adjustment for these factors had little impact on the differences between study groups for change in blood pressure.

Discussion

In this study, we conclude that chiropractic spinal manipulation in conjunction with a dietary modification program offers no advantages in lowering either diastolic or systolic blood pressure compared to diet alone for individuals with high-normal blood pressure or stage I hypertension. In fact, the data suggests a slight advantage in the diet group for diastolic blood pressure.

Previous studies of the effect of spinal manipulation on blood pressure have suffered from methodological flaws, including small sample size [7,14–17], potential problems with generalizability [7,17,18] or were conducted on persons with lower or normal blood pressure at baseline [7,15,17,18]. More importantly, these studies investigated the transient effects of spinal manipulation on blood pressure immediately following treatment [7,14–17,19], which does not address the question of whether spinal manipulation might be a management tool in the treatment of essential hypertension. The present study is the first full-scale randomized clinical trial to attempt to determine if spinal manipulation might be useful treatment for high-normal or stage I hypertension.

Randomization was successful in achieving equality between groups on all important baseline variables. Although the diet group achieved somewhat greater decreases in blood pressure compared to the DC/diet group, these differences were not statistically significant ($P = 0.05$). There were virtually no differences between groups in pre–post-change scores for important variables known to affect blood pressure, such as alcohol consumption, weight loss and physical activity. There was also no indication of a time-dependent effect from spinal manipulation; chiropractic participants who completed the study within the shortest amount of time had no greater decreases in blood pressure than those who took longer. The drop in both systolic and diastolic

Table 2 **Pre/post treatment differences and follow-up variables**

Variable	Diet ($n = 62$)	DC/Diet ($n = 66$)	Pre–post difference between groups	*P*-value
Change in alcohol (beverages/week)	−0.1 ± 1.5	−0.1 ± 3.8	0	0.96
Change in weight (lbs)	−0.8 ± 4.5	−0.8 ± 3.9	0	0.95
Change in body mass index (kg/m^2)	−0.1 ± 0.7	−0.1 ± 0.6	0	0.93
Use salt when cooking (% yes)	90.3	83.1	7	0.23
Use salt at table (% yes)	59.7	64.6	4.9	0.57
Physical activity (average total points)	860	889	29	0.90

Table 3 **Blood pressure outcomes**

Variable	Group A (diet), $n = 62$, mean (95% confidence interval)	Group B (DC), $n = 66$, mean (95% confidence interval)	Pre–post difference between groups	*P*-value
Change in diastolic blood pressure (mmHg)	−5.6 (−6.8, −4.4)	−4.0 (−5.3, −2.7)	1.6	0.08
Change in systolic blood pressure (mmHg)	−4.9 (−6.7, −3.1)	−3.5 (−5.7, −1.3)	1.4	0.36

blood pressure found in both groups is most likely due to a small weight loss and regression to the mean.

The intervention was adequate in terms of the number of chiropractic sessions. Although little information exists about how many chiropractic adjustments might be optimal in the treatment of patients with high blood pressure, the number of treatments selected was based on the 1993 Minnesota BlueCross–BlueShield overall service average of 10.9 visits for chiropractic patients with all conditions. No evidence exists to indicate that hypertension requires more vigorous chiropractic therapy compared to that required for other conditions commonly treated by spinal adjustments. It is possible that more than 12 manipulations are needed to lower blood pressure, or that manipulations need to occur more frequently than three times per week for an effect to take place. However, the public health implication of treatment for a so-called 'silent' disease which places such high time demands on a patient is questionable.

One limitation of the study is the lack of a no-treatment control group. It was felt to be more important to control for attention received by the doctor of chiropractic. This study group was limited in age and blood pressure range. It is possible, although unlikely, that spinal manipulation would be effective in other groups. It is also possible that manipulative techniques other than diversified spinal manipulation would have a different effect. Again, for the purpose of generalizability, diversified spinal manipulation was chosen as, currently, it is the manipulative technique most frequently used by doctors of chiropractic.

We conclude that community-based chiropractic spinal manipulation itself does not appear to have a role in the management of high blood pressure.

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