CASE SERIES OF SYMPTOMATOLOGY COMPRESSION RATES OF CHIROPRACTIC PATIENTS WITH ACUTE LOW BACK PAIN AT 2-WEEKS AND 4-WEEKS

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ABSTRACT

Objective: The study purpose was to investigate symptom compression rates (the mean rate of improvement of patient outcomes) of chiropractic patients with acute low back pain over a 4-week period.
Methods: Thirty-six patients with acute low back pain received 4 weeks of chiropractic care. Survey data points were recorded at baseline, 2 weeks and 4 weeks later. Outcome instruments used were the Visual Analog Scale (VAS) pain score, Roland-Morris Low Back Pain and Disability Questionnaire (RDQ), and Short Form-36 (SF-36) General Health Survey. Additionally, the SF-36 was sub-analyzed by scales: physical functioning, role limitations due to physical health, energy/fatigue, and bodily pain. A repeated-measures analysis of variance (ANOVA) was used to analyze data over time.
Results: VAS score decreased by 37.5% ($p=0.00$) from baseline to 2-weeks post, and by 66.2% total ($p=0.00$, partial $\eta^2=0.557$) from baseline to 4-weeks post. RDQ score decreased by 32.9% ($p=0.002$) from baseline to 2-weeks post, and by 44.3% total ($p=0.000$, partial $\eta^2=0.260$) from baseline to 4-weeks post. SF-36 score increased by 17.0% ($p=0.000$) from baseline to 2-weeks post, and by 25.1% total ($p=0.000$, partial $\eta^2=0.534$) from baseline to 4-weeks post. The greatest attribute that decreased on the SF-36 sub-analysis was role limitations due to physical health which increased by 42.4% ($p=0.002$) from baseline to 2-weeks post, and 51.4% total ($p=0.000$, partial $\eta^2=0.496$) from baseline to 4-weeks post.
Conclusion: Proportionately, the most rapid improvements in VAS, RDQ, and SF-36 occurred during the first two weeks of care compared to the last 2 weeks of care.
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Trial Registration: University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR), trial number: UMIN 000016786 (Reg# R000019480) data: March 13, 2015.

Key Indexing Terms: Low Back Pain; Patient Outcome Assessment; Chiropractic; Spinal Manipulation

BACKGROUND

Low back pain (LBP) has been found to be the 5th most common reason for adults to visit their primary care provider in the US [1, 2], and is common internationally as well [3-6]. Additionally, LBP is the second leading cause of disability in persons under 45 years of age [7, 8]. It has been estimated to cost the United States 7-20 billion US dollars [9, 10] a year related to worker absenteeism (absent from work due to injury) and

presenteeism (at work, but with reduced performance due to injury). In addition to economic costs, LBP often results in reductions in health-related quality of life (HRQOL) [11]. Effective and cost-effective treatments are needed to provide care for this condition while minimally impacting the economy.

Chiropractic doctors are healthcare providers that treat LBP through spinal manipulative therapy (SMT) [12-16] as well as various forms of passive and active care in a cost-effective manner [17]. SMT is a form of care that has been shown to improve patient outcomes amongst individuals suffering from acute and chronic LBP [15,18-22]. Studies have demonstrated that SMT results in improvements in pain sensation [23, 24], range of motion due to spinal hypomobility [25- 28], and function [13].

More research is needed on how quickly and significantly chiropractic care can reduce acute LBP symptoms over the initial 4-weeks of care [29, 30, 31], due in part to varying studies with clinical practice guidelines (CPGs) that do not fully support SMT [32]. The rate of symptomatology improvements (the mean rate of improvement of patient outcomes) can have direct impacts on worker absenteeism [33- 37], presenteeism [10, 38,39], medical care costs [40,41], QOL [42- 44], and other relevant variables. If chiropractic care can result in faster improvements in patients with acute LBP than standard allopathic care that likely would have significant implications for worker presenteeism, QOL, and additional factors.

One method of tracking improvements for patients with LBP over time are surveys, a self-reported outcome measure. They are subjective in nature and represent the patient's viewpoint of their health. Common survey tools used to measure patient improvement rates amongst patients with LBP are the Visual Analog Scale (VAS) pain score [45], Roland-Morris Low Back Pain and Disability Questionnaire (RDQ) [46], and the Short Form-36 (SF-36) General Health Survey [29]. Through the utilization of survey data, researchers can determine the subjective patient-centered LBP rate of improvement in response to chiropractic care.

The specific objective of this study was to measure the symptomatology compression rate of patients receiving chiropractic care for acute LBP over a 4-week period.

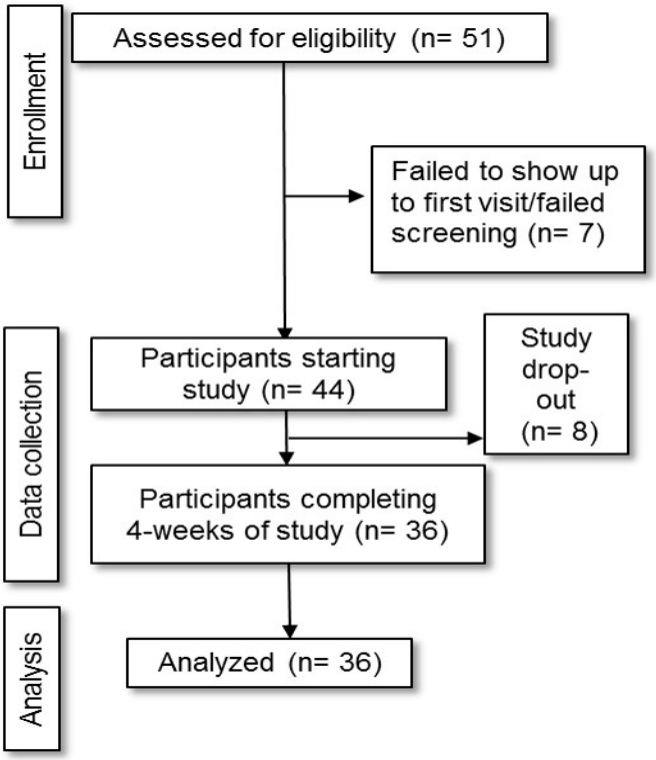
METHODS

This study was reviewed and approved by the Texas Chiropractic College Institutional Review Board for human subjects in accordance with the Declaration of Helsinki. All subjects were provided with a written and oral explanation of the study procedures prior to participation and signed a consent form. This case series was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR), trial number: UMIN 000016786 (Reg# R000019480).

Study Design, Rationale, and Setting

This was a case series of the impact of chiropractic care on LBP patient outcomes over a 4-week period (Fig. 1). Survey data points were recorded at baseline, 2 weeks and 4 weeks later. Survey dependent variables measured for LBP patients were: VAS pain score, RDQ score, and SF-36. The main outcome assessments were the VAS and RDQ. The secondary outcome assessment was the SF-36. The 2-week interval between survey assessments was chosen based on existing research [30, 31] and test-retest reliability studies of survey data using that time frame [47]. Study subjects received chiropractic care at the Moody Health Center of Texas Chiropractic College.

Figure 1. Experimental design.



Chiropractic Clinician

The state-licensed chiropractor providing care in this study had 28 years of clinician experience and 25 years of experience as a chiropractic college instructor. During that time, he primarily taught spinal manipulation courses. He has maintained an active chiropractic practice throughout his years as a chiropractic college instructor. A singular chiropractor was used in this study to keep the care provided as similar as possible between patients to reduce the possibility of having multiple treating chiropractors act as a covariate for data analyses.

Participant Recruitment and Randomization

Study enrollment took place from February 2013 to October 2014. Participants (Table 1) were recruited from the greater Houston area, an ethnically diverse region of America with over 2 million residents. According to the 2010 Census report, the racial make-up of the area was approximately 50.5% white, 23.7% black, 6.0% Asian, 0.7% American Indian and Alaska Native, 0.1% Pacific Islander, 19% mixed races, with 43.8% of the population classifying themselves as Latino [48]. Researchers utilized a media blast to recruit participants through online resources (Craigslist and Backpage), print resources (Greensheet, Natural Awakenings magazine, and the San Jacinto College newspaper), and via word-of-mouth. Study applicants contacted the primary investigator for screening and their contact information was provided to the treating chiropractic clinician if they met the inclusion and exclusion criteria (Fig. 2). This criteria was in part adapted from the exclusion criteria that the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) recommends as contraindications to spinal manipulation [13]. All study applicants provided an informed written consent on college-approved documents prior to receiving treatment from the chiropractic clinician.

Table 1. Participant demographics and anthropometric attributes.

	LBP
Sex (M/F)	16/20
Age (y)	47.8 ± 16.0
Mass (kg)	84.5 ± 18.8
Height (m)	1.68 ± 0.10
Body Mass Index (kg/m^2)	30.0 ± 6.2
Age range (yrs)	17-80

Most data listed as mean ± SD.

Fifty-one individuals applied for the study. Of these, 7 applicants failed to show up to their first visit and/or failed screening. Eight participants withdrew from the study after 1-2 visits. The most common reason cited for withdrawing was scheduling conflicts. Thirty-six participants completed the study. Only their data was analyzed. Researchers did not adhere to a power analysis and attempted to recruit as many LBP participants as possible for the study based on the available research budget.

Chiropractic Care Provided

During the initial screening exam, the chiropractic clinician determined whether the patient had acute non-specific LBP and the nature of the patient's chief complaint. Through his examination the doctor recorded a focused patient history, engaged in physical examination of the patient, ordered screening X-rays as needed, and assigned a diagnosis. The clinician tested patients' muscles on the 5/5 strength grading scale,

reflexes on the 5/5 Wexler scale, and utilized a hand-held goniometer to measure spinal range of motion at the lumbar spine.

Figure 2. Study inclusion and exclusion criteria.

Inclusion criteria were:
1) acute non-specific low back pain (less than 6 weeks)
2) between the ages of 18-80 years of age
3) they provided their informed written consent

Study participants with any of the following were excluded from the study:
1) unstable fractures
2) severe osteoporosis
3) multiple myeloma
4) osteomyelitis
5) primary bone tumor
6) Paget's disease
7) cauda equina
8) rheumatoid arthritis
9) ankylosing spondylitis
10) Reiter's syndrome
11) abdominal aortic aneurysm
12) spondylolisthesis

After the clinician diagnosed the patient he recorded baseline anthropometric and demographic data. Then he gave them a baseline survey packet. Three survey packets were generated for the study and they were: “baseline,” “2 weeks later,” and “4 weeks later.” On their cover sheet there was a blank for the study participant’s identification number. The packets measured VAS, RDQ, and SF-36 in that order. The VAS pain score was recorded on a line with 0 to 100 marked in 20 unit increments. At each increment mark a facial pain drawing was included. The drawing at the 100-mark (sad face) corresponded to extreme pain and the drawing at the 0-mark (happy face) corresponded to no pain. After study participants completed the survey, research assistants checked them and asked respondents to complete any unfinished questions. The clinician was blinded to the subjects’ survey responses.

Care provided by the treating doctor consisted of SMT, passive modalities, and active care rehabilitation. The chiropractic clinician used a diversified, high-velocity, low-amplitude technique for SMT [49]. Spinal manipulation was limited to the lumbar spine and no attempt to record an audible cavitation was performed. Passive modalities included ice packs, hot packs, ultrasound, interferential current, traction, stretching, flexion-distraction, advice on activities of daily living, and postural/ergonomic advice as deemed appropriate by the chiropractic clinician. Active care consisted of McKenzie

exercises for the patient to improve localized back strength, proprioception, and coordination. The study did not restrict access to standard medical care.

The clinician provided care over the course of a 4-week time period at 2 visits per week. Each visit typically lasted 20-30 minutes per participant. A 4-week care model was chosen based on treatment guidelines suggesting that most cases of LBP improve significantly within that time frame [50]. The first two weeks of care typically focused on passive care. The last 2 weeks primarily focused on active care. All care provided to participants was free. At the conclusion of the study, participants were provided with a gift card to cover transportation costs throughout the month.

Statistical Analysis

Data was initially placed into Excel (Microsoft Corporation, Redmond, WA, USA) and then later exported to SPSS version 20.0 (IBM, Armonk, NY, USA) for analysis. Results were reported as mean $\pm$ standard deviation (SD) unless otherwise specified.

Researchers used a repeated-measures analysis of variance (ANOVA) to analyze dependent variables over the 3 time points. Mauchly's test was used to check the sphericity assumption of all repeated-measures analyses and the Greenhouse-Geisser correction was utilized during instances of sphericity violation [51]. Pairwise comparisons were made between data time points (baseline to post 2-weeks, and baseline to post 4-weeks) to observe for significant interactions.

Additionally, the SF-36 was sub-analyzed by scales: physical functioning (averaging questions # 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12), role limitations due to physical health (averaging questions # 13, 14, 15, and 16), energy/fatigue (averaging questions # 23, 27, 29, and 31), and bodily pain (averaging questions # 21 and 22). The alpha level of $P \leq 0.05$ was considered statistically significant for all measured variables.

RESULTS

Tables 2-3 illustrate study results. Study drop-out rate was 18.2% (8 participants dropped out), which is similar to work by other researchers [52]. Participant dropout almost entirely occurred after the 1st or 2nd visit and was mostly reported by participants to be due to scheduling difficulties. The clinician was only available in the afternoons between 3-6 PM. Only participant data from individuals that completed the 2-week and 4-week assessments was included for analysis. Mauchly's test was significant for repeated-measures LBP VAS ($p=0.000$), and SF-36 ($p=0.002$). As a result, the Greenhouse-Geisser correction was used to determine a valid F ratio to reduce Type I error rate for those analyses. There was a significant main effect for VAS over the 4 weeks, $F(1.46, 70) = 44.05$, $p = 0.000$, partial $\eta^2 = 0.557$ (large effect size). There was a significant main effect for RDQ over the 4 weeks, $F(2, 70) = 12.29$, $p = 0.000$, partial $\eta^2 = 0.260$ (large effect size). Lastly, there was a significant main effect for SF-36 over the 4 weeks, $F(1.52, 70) = 40.07$, $p = 0.000$, partial $\eta^2 = 0.534$ (large effect size).

VAS score decreased by 37.5% (p=0.000) from baseline to 2-weeks post, and by 66.2% total (p=0.000) from baseline to 4-weeks post. RDQ score decreased by 32.9% (p=0.002) from baseline to 2-weeks post, and by 44.3% total (p=0.000) from baseline to 4-weeks post. SF-36 score increased by 17.0% (p=0.000) from baseline to 2-weeks post, and by 25.1% total (p=0.000) from baseline to 4-weeks post. The greatest attribute that increased on the SF-36 sub-analysis was role limitations due to physical health which increased by 42.4% (p=0.002) from baseline to 2-weeks post, and 51.4% total (p=0.000) from baseline to 4-weeks post.

There were no serious adverse events reported in the study. If patients had mild pain following spinal manipulation they were instructed to rest.

Table 2. Results of the 0-100 Visual Analog Scale (VAS) for pain, and Roland-Morris Low Back Pain and Disability Questionnaire (RDQ). The P-values are from pairwise comparisons: baseline to 2-weeks post, and baseline to 4-weeks post.

	Baseline value	2-week post value	P-value	% decrease base-post 2wks	4-week post value	P-value	% decrease base-post 4wks
LBP VAS	52.6 ± 19.7	32.9 ± 23.5	*0.000	37.5	17.8 ± 18.5	*0.000	66.2
LBP RDQ	7.0 ± 5.4	4.7 ± 4.8	*0.002	32.9	3.9 ± 5.2	*0.000	44.3

Most results listed as mean ± SD. * = statistically significant data.

DISCUSSION

The study results indicate most of the improvements in pain and function occurred during the first two weeks of care. Table 4 lists other researchers that have tracked similar variables (VAS/NRS, RDQ, SF-36) on the outcome of SMT for acute LBP since 2010 involving 30 or more participants [29, 30, 31, 52].

Only 2 peer research groups collected data 2 weeks after SMT began, Goertz et al and Walker et al. Goertz et al found pain decreased by 32.8% and RDQ decreased by 19.1%, while Walker et al found pain decreased by 25.5%. This study's findings were a reduction of pain by 37.5% and RDQ by 32.9% over the initial two weeks. These collective findings demonstrate a trend of 25.5-37.5% pain reduction and 19.1-32.6% reduction in RDQ during the initial 2 weeks of SMT. This is useful information, but it must be contextually compared to usual care and/or sham care. Goertz et al demonstrated that their usual medical care group actually increased their NRS score by 5.2% and RDQ score by 1.6% after two weeks. Interestingly, Walker et al used a sham

treatment and found that the NRS score decreased by 17.7% at 2-weeks. This emphasizes the point of including placebos as an extra study group.

Table 3. Short Form-36 (SF-36) and sub-analysis of SF-36 sections physical functioning, role limitations due to physical health, energy/fatigue, or bodily pain. The P-values are from pairwise comparisons: baseline to 2-weeks post, and baseline to 4-weeks post.

	Baseline value	2-week post value	P-value	% increase base-post 2wks	4-week post value	P-value	% increase base-post 4wks
SF-36 overall	55.1 ± 22.0	66.4 ± 22.3	*0.000	17.0	73.6 ± 17.4	*0.000	25.1
Physical functioning	56.5 ± 27.5	66.3 ± 26.9	*0.006	14.8	74.7 ± 23.5	*0.000	24.4
Role limitations	36.8 ± 42.5	63.9 ± 41.6	*0.002	42.4	75.7 ± 36.6	*0.000	51.4
Energy/fatigue	43.2 ± 23.5	55.3 ± 22.5	*0.001	21.9	64.5 ± 18.0	*0.000	33.0
Bodily pain	49.0 ± 18.5	64.6 ± 19.5	*0.000	24.2	71.5 ± 16.5	*0.000	31.5

Most results listed as mean ± SD. * = statistically significant data.

Regarding the 4-week time point, Cruser et al, and Goertz et al collected comparable data to this study. Cruser et al discovered that NRS scores decreased by 61.5% and RDQ decreased by 64.5%. Goertz et al found NRS to decrease by 32.8% and RDQ to decrease by 27.3%. This study's findings were a pain reduction of 66.2%, RDQ by 44.3%; while SF-36 increased 25.1%, and SF-36 PF increased 24.4%. Cruser et al and Goertz et al compared their SMT groups to usual care groups and they both demonstrated that SMT resulted in significantly greater reductions in NRS of 22.4-28.8% overall lower values at 4-weeks. Cruser et al and Goertz et al similarly demonstrated reductions of overall RDQ of 21.8%-22.9% when comparing their SMT group to their usual care group.

Table 4. Comparison of original research chiropractic outcome studies from 2010 to present that tracked VAS/NRS, RDQ, and SF-36 involving 30 or more participants per acute LBP study group. The values in columns 2-4 are listed in the order of the study group names in the initial column and separated by a comma. Time point improvements are listed for all measured time points under 8 weeks in duration. UC= usual care, SMT= standard medical treatment, CMT= chiropractic manipulative therapy, RDQ= Roland-Morris Low Back Pain Disability Questionnaire, SF= short form, VAS= visual analog scale, NRS= numeric rating scale, wks= weeks, BP= bodily pain subcomponent of SF-36, and PF= physical functioning subcomponent of SF-36.

Study and year, participants per group	Baseline time point	Time point improvement #1	Time point improvement #2
Bishop et al 2010 40 chiropractic + UC 39 UC	RDQ 12.2,13.1 SF36.0-P 38.0,38.8 SF36-PF 47.5,46.3	RDQ 8wks 10.7,13.0 SF36-P 8wks 45.8,46.6 SF36-PF 8wks 59.1,53.6	
Cruser et al 2012 30 chiropractic 30 UC	 NRS 5.2,5.5 RDQ 12.4,12.5 SF36 18.8,18.9 SF36-PF 22.2,20.4	NRS 4wks 2.0,3.7 RDQ 4wks 4.4,7.3 no post SF36 no post SF36	
Goertz et al 2013 45 CMT + SMT 46 SMT	 NRS 5.8,5.8 RDQ 11.0,12.7	NRS 2wks 3.9,6.1 RDQ 2wks 8.9,12.9	NRS 4wks 3.9,5.2 RDQ 4wks 8.0,12.0
Walker et al 2013 92 chiropractic 91 sham	 NRS 5.1,5.1	NRS 2wks 3.8,4.2	

Understanding the mean rate of improvement of patient outcomes (symptomatology compression) in response to chiropractic care is necessary to estimate the medical and societal savings of chiropractic care [53]. For example, if a typical acute LBP patient requires eight weeks to recover from LBP when seeking standard care (e.g., allopathic care and rest) then there likely will be 1)medical costs to the patient and their insurance plan, 2)some loss of work productivity due to absenteeism and/or presenteeism, and 3)negative impact on the individual's QOL transiently. Some of these costs would be altered if the patient also underwent chiropractic care. If chiropractic care can

significantly cause patient's acute LBP symptoms to be compressed faster (i.e. faster improvement rate week-by-week) then that may result in significant economic savings by decreasing losses in work-productivity due primarily to presenteeism and result in less tangible positive impacts on the patient's QOL. This point; however, has been challenged in research literature [53]. Some researchers suggest that the increased utilization of chiropractic care just offsets the more expensive forms of medical care [54]; however, this issue has not been corroborated by the bulk of research literature on the chiropractic healthcare cost's topic [55- 58].

This study could have been improved by tracking days of worker absenteeism and presenteeism throughout the study. Marker data like that could help validate the societal economic benefits of SMT for treating acute LBP.

Possible future directions of acute LBP chiropractic research that could stem from this study are: 1)tracking improvements on a week-by-week basis for 4-8 weeks using VAS, RDQ, SF-36, worker absenteeism log, and worker presenteeism log which are all subjective measures; 2)observing improvements on a week-by-week basis for 4-8 weeks using objective measures (computer gait analysis using GAITRite or VICON, sEMG back muscle recordings during functional tasks, muscle performance with Biodex, balance impact measured with the NeuroCom SMART Balance Master, virtual reality coordination physical task success as measured with Gesture Xtreme VR system, and other objective measures), 3) performing a similar study as this experiment but focusing on special populations to see if they react more to SMT (e.g., older chiropractic patients with joint restrictions, obese patients with known spinal hypomobility, etc.), and 4)measurement of the capabilities of reducing transference of acute LBP into chronic LBP [59] through chiropractic care. Proposed direction #2 is particularly important because larger patient outcome studies in chiropractic (with 30 or more participants per group) are primarily developing subjective (survey) data on patient improvements, and there is a lack of studies using objective measures tracking acute LBP outcomes with 30+ participants. To corroborate this fact, on May 8, 2015 the researchers of this publication searched PubMed-Central (PMC) using keywords "*chiropractic* AND '*low back pain*" with limits set to past 5 years. This yielded 869 total articles. Out of those articles only 19 were found that measured objective data in accordance with the following exclusion criteria: 1) review article, 2) case study or article involving less than 10 participants, 3) a proposed trial, and 4) research poster abstract. Thus, astoundingly only 2.2% (19/869) of lumbar spine manipulation chiropractic research studies published over this five-year window utilized objective measures. Almost half of those 19 studies were performed on cats thus emphasizing how little objective research is being performed on humans.

Limitations

This study did not have a placebo or control group. A placebo group would have helped differentiate any benefit to care that the patient may have thought would occur [60,61]. A control group (e.g., allopathic care only) would have provided valuable information on different modes of care for acute LBP [62-64]. These additional groups were not utilized

due to the limited funds to conduct this study and desire to focus on patient outcome changes over time.

The chiropractic clinician in this study has been a chiropractic college instructor for 25 years and a clinician for 28 years. It is plausible to suggest he may have provided more optimal care than the typical field chiropractor due to always having to keep up-to-date on treatment techniques. Perhaps utilizing multiple field chiropractors (e.g. 8) as Walker et al did could improve the external validity of this study's findings [31].

This study would have been strengthened if objective measurements (surface EMG, computerized range of motion sensors, etc.) had been utilized instead of strictly subjective survey data. Researchers originally explored the possibility of using objective measures, such as resting heart rate, systolic blood pressure, C-Reactive Protein (CRP), Erythrocyte Sedimentation Rate (ESR), Lactate Dehydrogenase (LDH) isoforms 2 and 5, and local skin lower back temperature. However, these were deemed to have specificity and sensitivity too low to track changes in LBP [65,66]. In addition, some of the equipment needed to capture these objective outcome measures were not available and the cost to acquire them exceeded the financial resources of the study.

CONCLUSION

Our preliminary findings suggest that proportionately the most rapid improvements in VAS, RDQ, and SF-36 occurred during the first two weeks of chiropractic care compared to the last two weeks of care in our case series. More data on control and placebo groups should be obtained to compare their rates of improvement to those found in this study to help quantify the impact of chiropractic care on symptomatology compression, particularly regarding its impact on worker presenteeism.

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