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Dose-response for chiropractic care of chronic low back pain

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Abstract

BACKGROUND CONTEXT: There have been no trials of optimal chiropractic care in terms of number of office visits for spinal manipulation and other therapeutic modalities.

PURPOSE: To conduct a pilot study to make preliminary identification of the effects of number of chiropractic treatment visits for manipulation with and without physical modalities (PM) on chronic low back pain and disability.

STUDY DESIGN/SETTING: Randomized controlled trial with a balanced 4×2 factorial design. Conducted in the faculty practice of a chiropractic college outpatient clinic.

PATIENT SAMPLE: Seventy-two patients with chronic, nonspecific low back pain of mechanical origin.

MAIN OUTCOME MEASURES: Von Korff pain and disability (100-point) scales.

METHODS: Patients were randomly allocated to visits (1, 2, 3 or 4 visits/week for 3 weeks) and to treatment regimen (spinal manipulation only or spinal manipulation with PM). All patients received high-velocity low-amplitude spinal manipulation. Half received one or two of the following PM at each visit: soft tissue therapy, hot packs, electrotherapy or ultrasound.

RESULTS: Pain intensity: At 4 weeks, there was a substantial linear effect of visits favoring a larger number of visits: 5.7 points per 3 visits (SE=2.3, p=.014). There was no effect of treatment regimen. At 12 weeks, the data suggested the potential for a similar effect of visits on patients receiving both manipulation and PM. Functional disability: At 4 weeks, a visits effect was noted (p=.018); the slope for group means was approximately 5 points per 3 visits. There were no group differences at 12 weeks.

CONCLUSIONS: There was a positive, clinically important effect of the number of chiropractic treatments for chronic low back pain on pain intensity and disability at 4 weeks. Relief was substantial for patients receiving care 3 to 4 times per week for 3 weeks.

Keywords: Low back pain; Spinal manipulation; Chiropractic; Dose-response; Randomized trial

Introduction

Mechanical low back pain (LBP) of musculoskeletal origin is both a prevalent and costly health problem. Studies indicate that 65% to 80% of adults will experience at least one episode during their lifetime, and the 1-year period prevalence ranges from 15% to 45% [1]. Annually, LBP accounts for up to 40% of all lost workdays and has been estimated to cost $49 billion within the industrial sector [2,3]. LBP accounts for a significant number of physician visits each year, second only to upper respiratory ailments [4].

Recently, several large studies have been conducted that call into question the characterization of back pain as a self-limiting condition. Many studies used "return-to-work" or "discontinued care seeking" as an index of recovery. However, a different picture of back pain emerged when pain and functional disability were the primary outcomes assessed. One population-based study showed that only 21% of patients were pain free at 3 months and 25% were pain

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free 12 months after the index visit [5]. The majority of patients reported significant pain and disability at 12 months. In fact, a practice-based observational study found that both acute and chronic LBP cohorts were still experiencing substantial pain and disability 3 and 4 years after presentation [6]. Other studies have corroborated these findings and have led to the more accurate characterization of low back pain as a chronic condition [7,8]. The essential distinction between acute and chronic pain has been described by Waddell [9] as "not necessarily the duration of pain, but the persistence of chronic pain beyond expected recovery times and the intractable nature of chronic pain."

According to a national health-care-usage survey, chronic LBP was one of the most frequent reasons people sought alternative therapy [10]. This reflects an increasing demand for complementary and alternative medicine (CAM) in general and an increasing belief that CAM therapy is more helpful than conventional medicine for treatment of back pain [11,12]. Of the estimated 42% of the US population who used CAM therapies in 1997, almost one-third sought chiropractic treatment [13]. Up to 40% of patients with LBP chose chiropractic care to address their back problems [14].

Manual therapy of the spine is practiced by a variety of health-care providers: chiropractors, osteopaths and physical therapists. The primary objective of spinal manipulation in the treatment of back pain is the alleviation of pain, muscle spasm and functional impairment [15]. The therapeutic manipulation consists of controlled directional, high-velocity, low-amplitude thrust [16].

The efficacy of spinal manipulation for treatment of LBP has been assessed in eight systematic reviews of randomized trials published before 1997 [17–24]. Of these, four found inconclusive evidence for the efficacy of manipulation for chronic LBP, although none found evidence of inefficacy or an advantage for standard medical care [17,18,20,21]. Later reviews within this group found moderate to strong evidence that manipulation was better than placebo, general medical practice, massage, bed rest and analgesics for chronic LBP [22–24]. A more recent trial showed a short-term advantage of osteopathic manipulation over chemonucleolysis for disc herniation [25]. Other recent trials did not exclusively investigate chronic LBP [26–31].

What is evident from the randomized trials on spinal manipulation is that the number of treatments and duration of care is diverse and not evidence based. Currently, treatment protocols are arbitrarily selected based on opinion or clinical experience for randomized trials and clinical practice [32]. The appropriate dosage of treatment as well as the duration needed to achieve optimal pain relief for different subgroups of low back pain has not been investigated. Our study was therefore designed to make a preliminary assessment of the dose-response relationship between the number of chiropractic visits for treatment with spinal manipulation and the pain relief in patients with chronic LBP.

Methods

Design

This study was a prospective, randomized controlled trial using a 4×2 balanced factorial design. The objectives were to identify 1) the effect of the number of visits to a chiropractor and 2) the effect of adding physical modalities (PM) to a regimen of spinal manipulation on chronic low back pain and disability. The study was conducted between February and October 2002 at the Western States Chiropractic College (WSCC) Outpatient Clinic, faculty practice. Neither participants nor providers were blinded. Before randomization, allocation was concealed from study personnel and participants in opaque, sealed envelopes in the possession of a project manager. The study analyst randomized the 72 participants using a computer-generated, equal allocation algorithm to one of four dosage groups and to one of two levels of treatment intensity (spinal manipulation only or combination of manipulation and PM). This permitted estimation of visit trends with 18 participants per group and the estimation of the effect of including PM in a regimen of manipulation with 36 participants per treatment level. Each participant was treated for 3 weeks. Visit Group 1 received a total of 3 office visits (1/week); Group 2, 6 visits (2/week); Group 3, 9 visits (3/week) and Group IV, 12 visits (4/week). All patients received spinal manipulation at each visit. Half of the patients within each visit group received one or two PM per visit, while the other half received none. The primary outcome was self-reported pain. The principal independent variable of interest was the frequency of visits to a chiropractor. Follow-up time points were 4 and 12 weeks after randomization. Study guarantees of participant rights and safety were approved by the Western States Chiropractic Institutional Review Board (FWA 851). Data were secured at the WSCC Center for Outcome Studies [33].

Study protocol

Participants were recruited through advertisements in local newspapers. Project managers conducted an initial eligibility screening by telephone. At the first baseline visit, all participants provided informed consent. They completed the first baseline questionnaire and received the screening physical examination. Eligible persons were invited to the second baseline visit. Participants completed a second baseline questionnaire, were randomized and received their first treatment from the therapist. Follow-up at 4 and 12 weeks after randomization was by mailed questionnaire. For ethical reasons, participants were permitted to seek care for LBP outside the study protocol. Study chiropractors were not permitted to recommend additional care upon completion of study treatment.

Participants

Potential participants were eligible if they had a current episode of chronic LBP. Low back was defined as the area

below the twelfth rib and above the gluteal fold [34]. Chronic was defined as an episode of pain of at least 3 months' duration [20,35]. Additional inclusion criteria were age 18 years and older and English literacy.

People were excluded if they had received chiropractic care in the 3 months before their baseline visit. They were also ineligible if they had contraindications to spinal manipulation [36] or complicating conditions that could be related to clinical outcomes. These included malignancy or history of cancer, spinal infection, vertebral tumors or fracture, lumbar instability, radiculopathy, cauda equina syndrome, blood dyscrasia, pregnancy, severe trauma within the last 3 months, low back surgery within the previous 12 months, referred LBP of organic origin or required referral for advanced imaging (eg, magnetic resonance imaging and computed tomography). Additional exclusion criteria were involvement in litigation for a health problem, or suspicion of noncompliance, indicated by a failure to attend a baseline visit before randomization.

Assessment and intervention

Four chiropractors with 2 to 22 years of practice experience served as the study therapists. They conducted a screening physical examination, including history, palpation, orthopedic/neurological examination and X-ray (if indicated) [36].

All participants received the principal therapy: high-velocity, low-amplitude spinal manipulation, as described by Bergmann et al. [37]. For the participants randomized to receive a combination of manipulation and PM, the treating chiropractor also administered one or two PM at each visit from among heat/ice, ultrasound, electrotherapy and manual soft tissue therapy (massage [38] and/or trigger point therapy [39]). These modalities are commonly used by chiropractors [40]. Specific manipulation and PM were determined at each visit by the therapist through ongoing evaluation of the participants [36]. The study therapists did not include any further intervention, such as exercise regimens and lifestyle advice [37].

Study outcomes and baseline variables

Low back pain and functional disability were evaluated using the Modified Von Korff (MVK) Scales of Underwood et al. [41]. This instrument consists of six 11-point numerical rating scales (NRS). The MVK Pain Scale, the primary outcome, is the average of three NRS assessing back pain today, worst back pain in last 4 weeks and average back pain in the last 4 weeks. We modified the instrument to evaluate LBP over the previous week, rather than 4 weeks. The MVK Disability Scale, a secondary outcome, is the average score of three NRS measuring interference with 1) daily activities, 2) social and recreational activities and 3) the ability to work outside or around the house. The two MVK scales are scored from 0 to 100 with a lower score more favorable. The MVK scales have been shown to be reliable, valid and responsive instruments for measuring pain and disability [41]. We assumed without further validation that the shorter recall period used in our study would not compromise instrument accuracy. For the purpose of interpreting the data, a 10-point difference between groups, 20% to 25% of the baseline score, was designated a priori as clinically important. This magnitude was used in an earlier study [42]. Additional therapy sought outside the study protocol from chiropractors, medical doctors, physical therapists, acupuncturists and massage therapists was also recorded.

Baseline variables included sociodemographics, general health status and the baseline scores of study outcomes. The general health status measures were the energy/fatigue, emotional well-being, self-rated health and depression screen indexes of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) [43]. The SF-36 has demonstrated content validity, construct validity, reliability, generalizability, acceptability and practicality [43–45].

Statistical analysis

All participants with follow-up data were included in the analysis in their assigned treatment group regardless of adherence to treatment schedule or of care received outside the study protocol (intention-to-treat analysis). Separate, preplanned analyses were conducted for the 4- and 12-week follow-up data. For pain and disability, linear least-squares regression models were fit to the data. Independent variables included visits, visits squared and visits cubed (for assessing dose-response trends); treatment regimen (for assessing the inclusion of PM); second baseline value of the dependent variable and all two-way and three-way interactions among visits, treatment regimen and baseline. Variable selection methods were applied to determine parsimonious models. Square-root transformations were applied to normalize the disability data, which were skewed to the right but did not fit a log-normal distribution. Models were identified using maximum R-squared variable selection and backward elimination of variables not meeting a 5% statistical significance criterion. Hierarchical models were fit. That is, if an interaction of two terms was statistically significant, then the two terms were also included in the model even if these terms were not individually significant. Adjusted least-square mean outcomes were estimated as the predicted mean using the final regression models with baseline set to the grand mean baseline value for the data.

We set the sample size a priori based on available resources. Post hoc power calculations were performed on 4-week pain and disability outcomes. Power analyses were based on partial correlations of the dependent variable with visits after adjusting for the baseline of the variable using a multiple linear regression model. Power for the observed partial correlations was 72% for pain and 91% for disability.

Significance of statistical tests were set a priori at the .025 level to adjust for two primary outcomes (pain at 4 and

12 weeks). All analysis was performed on SAS Version 8 [46]. Post hoc power calculations were performed using PASS 2000 [47].

Results

The staff conducted 201 phone screens (Fig. 1). Of these, 110 were ineligible or not interested. The study chiropractors conducted 91 screening physical examinations; 10 persons did not meet the study eligibility criteria. Of the 81 eligible persons, 72 agreed to enrollment in the study and were randomized. Only one participant was not compliant with treatment, stopping after 5 of 9 visits because of time and distance to the study site (moved). Three additional patients missed one or two visits in the groups assigned 9 or 12 visits. The response rate to mailed questionnaires was excellent: 96% at 4 weeks and 93% at 12 weeks. Those not responding were well distributed across visit groups. Of a possible 144 questionnaires, 136 were returned by the participants. No adverse events were reported.

Spinal manipulation was performed at almost every visit for all patients. Of the participants assigned PM, 75% received soft tissue therapy (massage/trigger point), 92% hot/cold, 44% electrotherapy and 22% ultrasound at least once. The mean number of PM (one or two PM required at each visit) ranged from 1.6 in Group 3 to 1.9 in Group 1. Visual inspection of the data revealed no pattern of use across the four visit groups.

Baseline characteristics are presented in Table 1. The mean age was 48 years (SD=14). Approximately half of the participants were women and 84% white non-Hispanic. The general health status indexes revealed that participants were in good health but showed signs of fatigue and 43% indicated the possibility of depression. Overall pain and disability were moderate: mean pain index of 49.3 (SD=22.5, 95% confidence interval [CI]=44.0 to 54.5) and mean disability index of 38.9 (SD=26.1, 95% CI=32.8 to 45.1). There was some disparity in pain and disability across groups.

Observed mean outcomes and SDs are shown in Table 2. The four regression models for pain and disability outcomes are found in Table 3, and group means and 95% confidence intervals, adjusted for baseline differences between groups, are presented in Table 4. Adjusted group means are also charted in Figs. 2 and 3 for clarity.

Pain

At the 4-week follow-up, there was a substantial linear effect of patient visits favoring a larger number of treatments with spinal manipulation (B=−5.7, SE=2.3, p=.014; Table 3). That is, there was a mean of 5.7 points of improvement per additional 3 treatments (one visit per week). Compared with the group receiving 3 treatments, participants assigned 9 treatments had an 11.4-point advantage and those assigned 12 treatments showed a 17.1-point advantage in mean pain score improvement (Fig. 2, Table 4). There was no statistically significant or clinically important effect of including/excluding PM at each visit in the regimen (p>.5).

At the 12-week follow-up, the best model selected by the maximum R^2 criterion included baseline pain (B=0.4, CI=0.2 to 0.6, p=.0008) and visits×PM interaction (B=−5.4, CI=−8.7 to −2.1, p=.003). Thus, the hierarchical model that included baseline pain, linear term in visits, treatment regimen and visits×treatment regimen interaction was fit. The regression coefficients and p values are summarized in Table 3, and adjusted means are summarized in

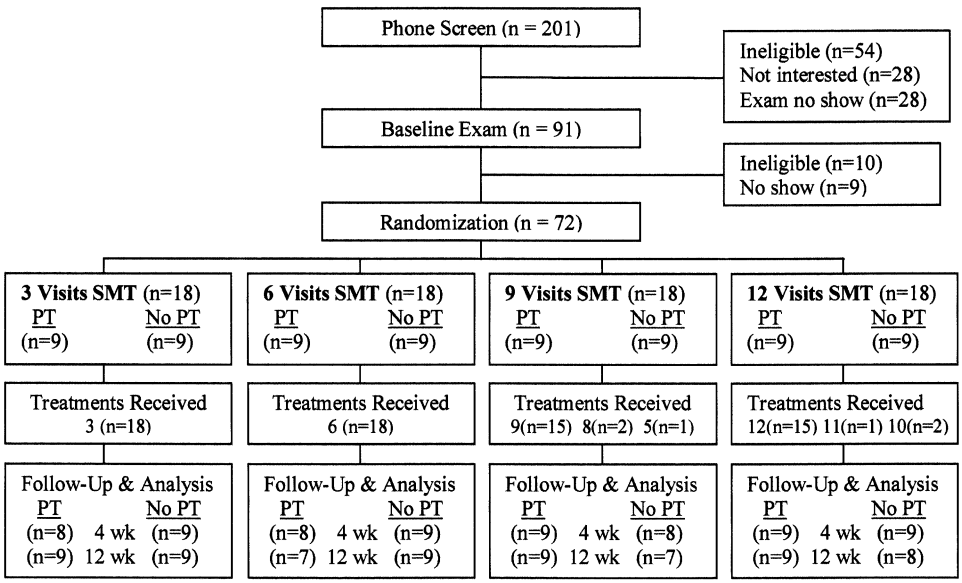

Fig. 1. Study flow diagram. PT=physical therapy; SMT=spinal manipulative therapy.

Table 1
Baseline characteristics: mean (SD) or percentage for the four dose groups

	1 Visit/week (n=18)	2 Visit/week (n=18)	3 Visit/week (n=18)	4 Visit/week (n=18)	All (n=72)
Age	54 (13)	46 (12)	44 (17)	47 (12)	48 (14)
Sex: female	44%	50%	67%	56%	54%
Race: white non-Hispanic	78%	89%	78%	89%	84%
Marital status: married	44%	33%	33%	39%	37%
Education: college degree	39%	56%	44%	56%	48%
Income: <$24,000/year	17%	28%	44%	33%	31%
Depression (yes)	39%	39%	50%	44%	43%
SF-36 general health	71 (20)	72 (17)	69 (15)	68 (16)	70 (17)
SF-36 energy-fatigue	49 (16)	44 (21)	43 (22)	50 (22)	47 (20)
SF-36 well-being	75 (16)	67 (20)	71 (16)	74 (14)	72 (17)
MVK pain intensity	53 (23)	51 (21)	45 (26)	48 (21)	49 (22)
MVK functional disability	44 (30)	40 (25)	38 (26)	33 (25)	39 (26)

MVK=Modified Von Korff scales (lower score is favorable); SF-36=Medical Outcomes Study 36-Item Short-Form Health Survey (higher score is favorable).

Table 4. Although the individual regression coefficients for visits, treatment regimen and the interaction of these two were not individually statistically significant (p>.15), the overall test that all three of these regression coefficients equal zero approached significance (p=.029). There was a linear visits effect in those patients who received PM and manipulation: 6.1 points of improvement in pain per additional visit per week. In those who did not receive PM (manipulation only), pain actually increased by a trivial 0.5 points per additional visit per week. However, Table 2 shows that those receiving 3 visits per week (manipulation only) had the smallest observed mean, whereas those receiving 4 per week had the largest observed means. This variation was not consistent with a linear term in dose.

Functional disability

At 4 weeks, we found a visit effect (p=.018) and no effect of treatment regimen (p>.50; Table 3). The regression coefficients for disability in Table 3 are for root-transformed data. Fig. 3 shows the linear effect of visits for the group means. The mean group differences were similar in magnitude to those found for pain at 4 weeks (Fig. 2, Table 4).

At 12 weeks, there was no effect of number of visits or treatment regimen (p>.50). Hence, the adjusted mean disability score for all groups was 19.9 (95% CI=14.4 to 26.3; Table 4). A comparison to baseline (mean=38.9, 95% CI=32.8 to 45.1) showed a substantial and statistically significant improvement (p<.0001) in functional disability for all study groups at this time point (Fig. 3, Table 4).

Table 2
Observed mean (SD) pain intensity and functional disability scores at baseline and follow-up (0 to 100–point scales)

Outcome	Time	Treatment	1 Visit/week	2 Visits/week	3 Visits/week	4 Visits/week
Pain	Baseline	SM & PM	53 (23)	55 (16)	45 (26)	49 (23)
	Baseline	SM	52 (24)	47 (24)	46 (28)	46 (20)
	Baseline	All subjects	53 (23)	51 (20)	45 (26)	48 (21)
	4 weeks	SM & PM	40 (31)	37 (22)	25 (22)	19 (16)
	4 weeks	SM	37 (29)	31 (21)	21 (12)	22 (24)
	4 weeks	All subjects	38 (29)	34 (21)	23 (17)	21 (20)
	12 weeks	SM & PM	38 (23)	37 (20)	29 (18)	19 (14)
	12 weeks	SM	46 (27)	46 (26)	18 (20)	50 (25)
	12 weeks	All subjects	42 (25)	42 (23)	25 (19)	33 (25)
Disability	Baseline	SM & PM	45 (32)	39 (29)	43 (25)	39 (29)
	Baseline	SM	44 (29)	41 (22)	33 (26)	27 (21)
	Baseline	All subjects	44 (30)	40 (25)	38 (26)	33 (25)
	4 weeks	SM & PM	31 (32)	21 (20)	21 (22)	10 (11)
	4 weeks	SM	27 (29)	25 (21)	13 (11)	10 (14)
	4 weeks	All subjects	29 (30)	23 (20)	17 (17)	10 (13)
	12 weeks	SM & PM	26 (21)	22 (24)	21 (14)	13 (14)
	12 weeks	SM	30 (21)	37 (31)	8 (17)	39 (30)
	12 weeks	All subjects	28 (21)	31 (29)	16 (16)	25 (26)

PM=physical modalities; SM=spinal manipulation; Time=follow-up time point; Visit/week=visit dose group.

Table 3
Regression models for pain and disability intensity

	4-Week pain			12-Week pain			4-Week disability			12-Week disability		
Parameter	B	CI	P	B	CI	P	B	CI	P	B	CI	P
Intercept	28.8	11.6–46.0	.002	20.4	−2.0–42.8	.074	3.8	1.8–5.7	.000	2.0	0.4–3.6	.014
Baseline	0.3	0.1–0.5	.012	0.4	0.2–0.7	.001	0.2	0.03–0.5	.025	0.4	0.2–0.6	.003
Visits/week	−5.7	−10.2–−1.2	.014	0.5	−6.3–7.2	.893	−0.6	−1.1–−0.1	.018	—	—	—
Treatment	—	—	—	4.0	−21.9–29.8	.761	—	—	—	—	—	—
Visits/week×treatment	—	—	—	−6.6	−16.0–2.7	.163	—	—	—	—	—	—

B=regression coefficient; CI=95% confidence interval; treatment=0 for manipulation only and 1 for a combination of manipulation and physical modalities; visits/week=1, 2, 3 or 4.

Confounding

A secondary analysis was conducted to identify potential confounding of results resulting from baseline differences among the groups with respect to age, gender and income. When potential confounding variables that contribute to the overall R^2 of the model were included in regression models for the various outcomes, these variables did not substantially change the associations described above (results not shown).

Outside care

Fifteen of 72 participants sought health care outside the study regimen for LBP by the 4-week follow-up and a total of 30 sought outside care by the 12-week follow-up (Fig. 4). Most outside care was sought by a few individuals: 5 persons had 15 of 32 outside visits made by 4 weeks and 6 persons had 60 of the total 117 outside visits made by 12 weeks. Exclusion of these 6 individuals from the analysis would increase unadjusted group means less than 0.3 points.

The 32 outside visits by 4 weeks included 6 to chiropractors and 5 to medical doctors. The remaining visits were to physical therapists (12) and massage therapists (9). The majority (19 of 32), including all of the chiropractic care, was sought by participants in the lowest visit group (Group I). Of the 117 total visits by 12 weeks, 26 were to chiropractors, 27 to medical doctors, 23 to physical therapists, 32 to massage therapists and 8 to acupuncturists. Much of the care was sought by members of Group I (48 of 117). Groups I and II made 25 of 26 outside visits to chiropractors. Patients allocated to receive study PM had 69 of 117 visits and those without PM had 48 of 117 visits.

Discussion

This was the first randomized trial to study the dose-response relationship between number of visits to a chiropractor and clinical outcomes. The principal finding was a relationship between pain outcomes and visits to a chiropractor for chronic LBP at 4 weeks (1 week after completion of treatment). Relief was substantial and the 23 of 100 to 28 of 100 points of pain relief achieved for participants receiving 9 and 12 treatments is clinically important to the patient, even by conservative interpretation of numeric rating scales for pain [48]. The inclusion/exclusion of physical modalities at each visit had no meaningful effect on pain improvement at this time point.

Pain results at 12 weeks must be interpreted with caution. The nonhierarchical analysis suggests a potential dose-response for patients receiving both manipulation and PM at each visit, and no such trend in patients receiving manipulation only (Fig. 2). This would mean that either PM or a combination of manipulation and PM produces a sustainable dose-response not found in patients receiving manipulation alone. However, the statistical significance of the variables depends on the model used. Also, inspection of the data in Table 2 for patients without PM suggests that groups receiving either three visits per week or four visits per week could represent random outliers. Findings may have been statistical artifacts of small group analysis and the results spurious. In particular, the magnitude of the difference between PM and no PM groups for four visits per week is difficult to explain. The effects of PM, of dose in those not receiving PM and nonlinear effects involving dose need further study because this pilot study was not adequately statistically powered to address all these questions.

Table 4
Adjusted means (95% confidence interval) for pain intensity and functional disability outcomes

Outcome	Time (weeks)	Treatment	1 Visit/week	2 Visits/week	3 Visits/week	4 Visits/week
Pain	4	All subjects	38 (29–46)	32 (26–38)	26 (21–32)	20 (12–29)
	12	SM & PM	40 (27–52)	34 (25–42)	27 (19–35)	21 (9–33)
	12	SM	42 (30–55)	43 (35–51)	43 (35–52)	44 (31–57)
Disability	4	All subjects	23 (15–32)	17 (13–23)	13 (9–18)	09 (4–15)
	12	All subjects	20 (14–26)	20 (14–26)	20 (14–26)	20 (14–26)

Time=follow-up time point; SM=spinal manipulation; PM=physical modalities; Visit/week=visit dose group.

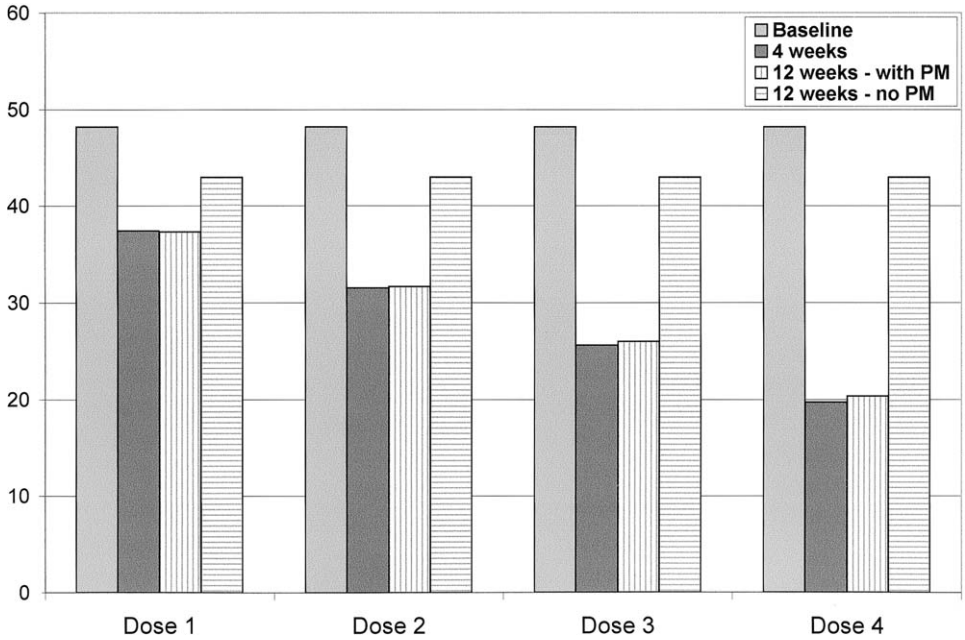

Fig. 2. Adjusted means for the 4-week and 12-week pain intensity models in Tables 3 and 4 are plotted by number of visits per week (dose). Adjusted least-square mean outcomes were estimated as the predicted mean using the final regression models with baseline set to the grand baseline mean. The means are different for patients with and without physical modalities (PM) at 12 weeks.

An effect of the inclusion of PM in the treatment regimen on LBP intensity would be unexpected in light of two recently published trials. Hurwitz et al. [28] demonstrated in a large trial that the inclusion of passive PM (hot/cold, ultrasound and electrotherapy) with manipulation was no more effective than manipulation alone for a mix of acute and chronic LBP. Hsieh et al. [29] obtained similar results for active soft tissue therapy in subacute patients. Our findings may have differed from those of the previous trials because active modalities were included in the treatment of chronic patients. Also, the number of treatments in the chronic pain study of Hurwitz et al. may have been insufficient to reveal an important effect of PM (mean=three to four visits), similar to the case of our three-visit group in Fig. 2. Our pilot raises the possibility that it may be premature to dismiss the inclusion of PM in a regimen of spinal manipulation for chronic LBP.

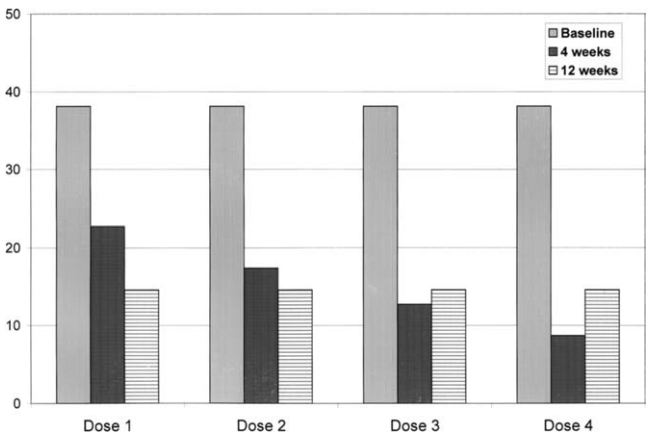

Fig. 3. Adjusted means for the 4-week and 12-week disability models in Tables 3 and 4 are plotted by number of visits per week (dose). Adjusted least-square mean outcomes were estimated as the predicted mean using the final regression models with baseline set to the grand baseline mean.

The dose-response for pain intensity in Fig. 2 suggests that more chiropractic treatments may be required to reach the optimal benefit that would have been indicated by a saturation of the dose-response curve. Recommendations on duration and frequency of manipulation/chiropractic care for chronic LBP vary widely and are based on clinical experience and opinion [32]. A multidisciplinary RAND panel found that evidence-based consensus was not possible but on average expected the typical patient to show improvement in 4 to 6 weeks with three visits per week [35]. In contrast, an all-chiropractic expert panel recommended 30 visits for the average chronic patient over 14 weeks [49]. Our data support the investigation of a larger number of visits in future trials.

Disability outcomes further support a larger number of visits in future trials (Fig. 3). A linear dose-response was noted at 4 weeks for patients with and without PM. At 12 weeks, there was no evidence within this pilot study of any treatment effects. The considerable improvement observed at 12 weeks was independent of the quantity of care received in the range of visits under study. The data cannot distinguish a plateau effect from the absence of a threshold effect in terms of benefit accrued.

The majority of outside health care for LBP was limited to only 6 of 72 individuals. Because the remaining participants sought little care, it is unlikely that outside care impacted study findings significantly. It is not surprising that participants in the lowest study visit group were most likely to

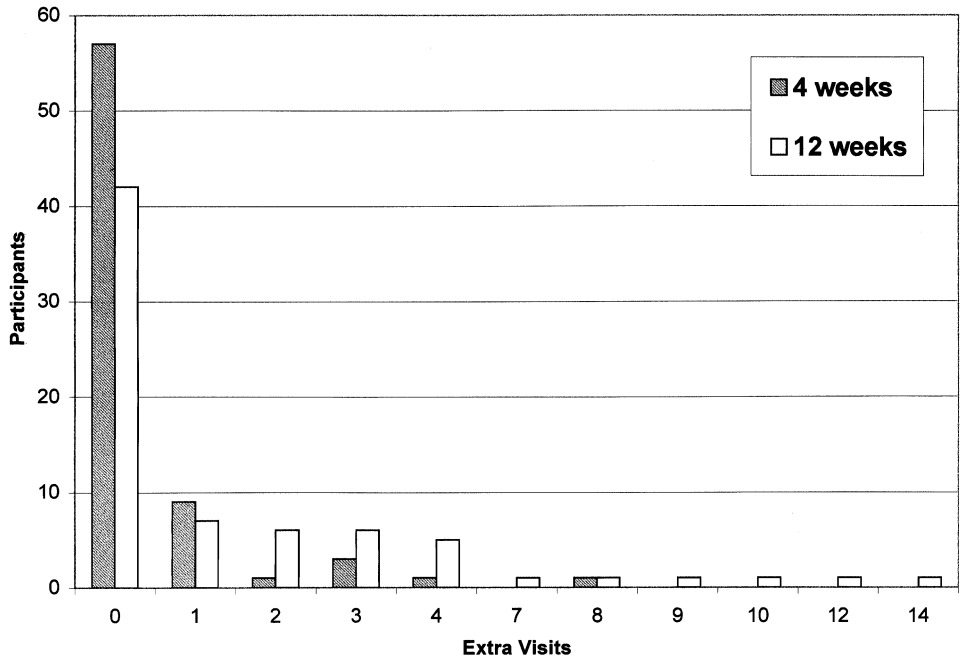

Fig. 4. The total number of visits made by the 72 participants outside the study protocol to any health-care provider for the treatment of low back pain by 4 weeks and by 12 weeks after randomization.

have additional care, but the motivation for care seeking is not clear. Possible reasons certainly include pain exacerbation between data collection points. However, expectation of the quantity of care required for pain relief may have played a role.

Clearly, the primary limitation of this study was the small sample size used in this pilot. Point estimates of the mean outcomes for the 8 groups could not be measured with precision (large confidence intervals). The observed effects may have resulted from sampling error causing unknown imbalance in unidentified confounding variables. Effects may have also depended on the root transformation used to normalize the disability data. These data were positively skewed, although the skewing was not as "severe" as for a log-normal distribution (ie, requiring a natural logarithm transform). Larger sample sizes may provide better assessment of the overall distribution and extent of skewness, as well as reveal additional significant higher-order interaction effects, including deviations from linearity.

A further limitation of the present study was that we did not control patient attention bias and expectation (more treatment is better). One alternative design to address this concern would require all participants to attend the same number of study visits. They would be blinded to group assignment by receiving sham therapy at nontreatment visits. However, blinding to sham manipulation/PM presents a challenge to investigators if the institutional review board requires disclosure of sham procedures in the study design. Patients aware of the existence of treatment alternatives might contrast and discern real from sham. A second alternative design might include assessment visits (rather than visits for sham treatment) to control attention bias, and include patient blinding to the mix of treatment and assessment visits to control, at least in part, the effects of expectation. Provider blinding to the number of treatment visits would require a different design.

Comprehensive assessment for chiropractic management of LBP requires systematic investigation of the effects on clinical outcomes of number and frequency of patient visits, intensity of therapeutic modality utilization (manipulation and PM) and duration of patient care [20,24,50]. Our study was a first step, looking at relief up to 2 months after completion of care. To date, there have been no trials on concentration of visits or duration of care. Only one case series found that patients, with constant, severe chronic LBP that was unresponsive to conservative/operative care, showed marked improvement following 2 weeks of daily manipulation [51]. The effect of treatment parameters on the durability of outcomes in the long term is also unknown.

Conclusions

There was a positive, clinically important effect of the number of chiropractic treatments on chronic LBP at 4 weeks. Relief was substantial for patients receiving care three to four times per week for 3 weeks. The sustainability of relief patterns to 12 weeks was not clear. A concentrated course of chiropractic care of up to 12 visits in 3 weeks appears appropriate for the treatment of chronic LBP.

The study findings should be generalizable to the practice of manual medicine providers who use high-velocity low-amplitude spinal manipulation and PM for the treatment of

LBP. However, the effect of additional care, such as exercise and different manipulation techniques, on the observed outcomes is unknown. The data show room for considerable improvement and suggest further study on regimens, including a greater number of visits for care. The effect of duration of care on outcomes and the durability of pain/disability relief in the long term remain to be investigated.

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Sixty-five years ago in spine

Chamberlain's [1] classic radiographic study of basilar invagination, reported in 1939, established abnormalities to the craniocervical junction as important clinical entities. He described the importance of a line drawn from the posterior edge of the hard palate to the posterior border of the foramen magnum, noting that symptoms may occur if the odontoid extends above that line, now known as Chamberlain's line. Modification in which the line is drawn from the posterior edge of the hard palate to the most caudal point of the occipital curve, described by McGregor [2], is more commonly used because it is more easily seen on lateral roentgenograms.

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