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Second Prize

The Effectiveness of Physical Modalities Among Patients With Low Back Pain Randomized to Chiropractic Care: Findings From the UCLA Low Back Pain Study

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ABSTRACT

Background: Although chiropractors often use physical modalities with spinal manipulation, evidence that modalities yield additional benefits over spinal manipulation alone is lacking.

Objective: The purpose of the study was to estimate the net effect of physical modalities on low back pain (LBP) outcomes among chiropractic patients in a managed-care setting.

Methods: Fifty percent of the 681 patients participating in a clinical trial of LBP treatment strategies were randomized to chiropractic care with physical modalities (n = 172) or without physical modalities (n = 169). Subjects were followed for 6 months with assessments at 2, 4, and 6 weeks and at 6 months. The primary outcome variables were average and most severe LBP intensity in the past week, assessed with numerical rating scales (0-10), and low back–related disability, assessed with the 24-item Roland-Morris Disability Questionnaire.

Results: Almost 60% of the subjects had baseline LBP episodes of more than 3 months' duration. The 6-month follow-up was 96%. The adjusted mean differences between groups in improvements in average and most severe pain and disability were clinically insignificant at all follow-up assessments. Clinically relevant improvements in average pain and disability were more likely in the modalities group at 2 and 6 weeks, but this apparent advantage disappeared at 6 months. Perceived treatment effectiveness was greater in the modalities group.

Conclusions: Physical modalities used by chiropractors in this managed-care organization did not appear to be effective in the treatment of patients with LBP, although a small short-term benefit for some patients cannot be ruled out. (J Manipulative Physiol Ther 2002;25:10–20)

Key Indexing Terms: Low Back Pain; Chiropractic; Physical Therapy; Randomized Controlled Trial; Managed Care

INTRODUCTION

Low back pain (LBP) is the most common reason for initiating chiropractic care,[1] and chiropractic is the "unconventional" or alternative therapy used most often for back pain in the United States.[2,3] In fact, most visits for LBP are to chiropractors,[4] and because managed care predominates in many parts of the United States,[5] these visits are increasingly in managed-care settings. Back-related health care expenditures have been rising dramatically, primarily the result of escalating costs associated with disabling LBP.[6] Back pain is also a leading cause of lost work days, resulting in almost $9 billion in work-related low-back claims and billions of dollars in additional indirect costs.[7,8]

Low back pain is treated with a variety of therapies by a number of different health care providers.[9,10] Physical modalities, such as heat therapy, ultrasound, and electrical muscle stimulation (EMS) are specific treatments that many chiropractors commonly use in conjunction with spinal manipulation.[11,12] Although there is little evidence that physical modalities alone are effective therapies for LBP,[13,14] there have been no published studies, to our knowledge, that address the relative benefit of modalities applied to patients with LBP who are receiving chiropractic care.

The purpose of the study was to estimate the net effect of physical modalities used at the discretion of chiropractors in managed care.

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METHODS

Study Design

Persons with LBP seeking care were randomized in a balanced design to 4 treatment groups, 2 of which included chiropractic care: chiropractic care with physical modalities and chiropractic care without physical modalities. Follow-up questionnaires were sent to subjects at 2 and 6 weeks and at 6 months, and a telephone interview took place at 4 weeks.

Source Population

The source population was the approximately 100,000 members of a multispecialty network of health care providers based in Southern California. The network is primarily a prepaid group practice of salaried chiropractors and other providers in which the group accepts capitated payments for more than 90% of its patients. Members receive all their outpatient health care through one or more of its offices or contract providers. This study was conducted at 3 of the group's outpatient care facilities that have chiropractors on staff.

Subject Selection

Inclusion and Exclusion Criteria. Patients were eligible for the study if they met the following criteria: (1) they were health maintenance organization (HMO) members with the medical group chosen as their health care provider; (2) they sought care at one of the 3 study sites from October 30, 1995 through November 9, 1998; (3) they had a complaint of LBP (defined as pain in the region of the lumbosacral spine and its surrounding musculature); (4) they had not received treatment for LBP within the past 1 month; and (5) they were at least 18 years old.

Potential subjects were excluded if any of the following applied: (1) their LBP involved third-party liability or workers' compensation; (2) they had back pain caused by fracture, tumor, infection, spondyloarthropathy, or other nonmechanical cause; (3) they had severe comorbidity; (4) they were being treated by electrical devices (eg, pacemaker); (5) they had a blood coagulation disorder or were using corticosteroids or anticoagulant medications; (6) they had progressive, unilateral lower limb muscle weakness; (7) they had current symptoms or signs of cauda equina syndrome; (8) they had plans to move out of the area; (9) they were not easily accessible by telephone; or (10) they lacked the ability to read English.

Patient Screening Protocol. Patients who had LBP were met by the field coordinator, who conducted the screening interview to determine potential eligibility. Patients received an information sheet that described the study's purpose, protocols, and requirements of participation and explained that subjects would be assigned at random to different treatment plans. A history and physical examination were conducted on each patient who initially agreed to participate, and radiographs and laboratory tests were ordered if necessary.

Informed Consent and Randomization. The study protocol and informed consent form were approved by the institutional review boards from UCLA and the health care network. Those patients agreeing to participate and meeting all eligibility criteria were asked to read and sign an informed consent form, which was administered by the field coordinator and witnessed by a third party. The field coordinator was available to answer any study-related questions during the informed consent process.

A computer program written by our statistician generated blocks of 12 site-stratified randomized assignments that were placed in site-specific, sequentially numbered and sealed security envelopes. For each consenting patient, the field coordinator opened the site-specific envelope in sequence and documented the patient for whom the assignment was made. Subjects completed the baseline questionnaire and received their initial chiropractic treatment the same day. Study subjects received $20 to compensate them for their time and to offset their copayments, which ranged from $5 to $20 depending on the patient's specific health plan.

Treatment Protocols

Chiropractic Care Without Physical Modalities (DC Group). Subjects assigned to this group received spinal manipulation involving high-velocity thrusts or other spinal adjusting techniques (eg, mobilization) directed at one or more specific vertebral or lumbosacral joints, instruction in strengthening and flexibility exercises, and instruction in proper back care.

Chiropractic Care With Physical Modalities (DCPm Group). Subjects assigned to this group received chiropractic care as described previously, as well as one or more of the following at the discretion of the chiropractor: applications of heat or cold therapy, ultrasound, and EMS. Subjects in both groups received care from one of 4 chiropractors, each with at least 5 years of chiropractic clinical experience. The chiropractors used diversified technique, which is the general type of full spine high-velocity manipulation taught in the vast majority of US chiropractic schools and is the most frequently used form of spinal manipulation.[11,12]

The use of specific therapies, exercises, instructions, and recommendations within each treatment group and visit frequency were at the discretion of the chiropractor.

Data Collection and Variables

Sources of data were the baseline history, physical examination and questionnaire, follow-up questionnaires at 2 and 6 weeks and at 6 months, telephone interview at 4 weeks, and computerized health information system.

Baseline Data. Sociodemographic variables included age, sex, race/ethnicity, education, household income, marital status, and current employment status. Specific questions addressed the number of previous episodes of LBP, age at first episode, duration of the current and longest episodes, time between last and current episodes, type of onset (injury-related or not), and disability, health care, and medication use associated with past and current LBP.

Disability from LBP was assessed by the 24-item Roland-Morris adaptation of the Sickness Impact Profile.[15,16] Pa-

tients responded by answering "yes" or "no" to indicate whether each statement described their current disability from LBP. Possible scores range from 0 (indicating no disability from LBP) to 24 (indicating severe disability from LBP). This instrument has been validated in previous studies of LBP[15,16] and chronic pain[17] and has been shown to be more responsive to change than other functional status instruments.[18-22] Numerical rating scales were used to assess intensity of pain (most severe pain and average level of pain for the past week), where 0 equals "no pain" and 10 equals "unbearable pain." The reliability and validity of these scales for measuring back pain have been shown to be excellent.[23,24]

Psychological, physical, and general health status were assessed with the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).[25] Five of the 8 scales of this previously validated instrument were used: (1) limitations in physical activities because of physical or emotional problems; (2) limitations in usual role activities because of physical health problems; (3) limitations in usual role activities because of emotional health problems; (4) general health perceptions; and (5) general mental health.[26] All 5 measures were scored on scales of 0 to 100. The reliability, validity, and psychometric properties of the SF-36 have been shown to be excellent in both general and LBP populations.[27]

Follow-up Data. The follow-up questionnaires at 2 weeks, 6 weeks, and 6 months covered LBP severity and related disability, cut-down days and bed days caused by LBP, and use of over-the-counter (OTC) and prescription medication for LBP. Low back-related disability was measured by repeated Roland-Morris Low-Back Disability Questionnaires, and the most severe and average level of LBP were measured by repeated numerical rating scales (0-10).

A 5- to 10-minute telephone interview conducted with each participant 4 weeks after his or her initial visit included questions about amount of time the chiropractor spent with the patient, advice given on exercises and other activities, compliance with advice, explanation of diagnosis and treatment plan, and specific treatment modalities applied during the course of care. Pain status and limitations in daily activities were assessed with 5-point scales of global improvement ("a lot worse" to "a lot better"). Data on patient satisfaction with back care were obtained with a numerical rating scale (0-10), in which 0 indicated "extremely dissatisfied" and 10 indicated "extremely satisfied" with LBP care. Subjects were also asked about their level of agreement ("strongly agree" to "strongly disagree") with the statement, "The treatment the chiropractor prescribed for my back problem was effective" and whether they would seek similar care for future LBP.

Data on number of visits and cost of low back care for each subject were extracted from the organization's computerized health information system. By using a standardized fee schedule, the total cost of low back care during the 6-month follow-up period was estimated by assigning values to separate units of service identified by CPT-4 codes from billing records.

Outcome Variables

The primary outcome variables were changes in average and most severe LBP intensity in the past week, assessed with numerical rating scales (0-10), and low back-related disability, assessed with the 24-item Roland-Morris Disability Questionnaire. Outcomes were treated as continuous and dichotomous variables in separate analyses. Cut-points of 2 or more points (vs less than 2 points) on the 0 to 10 numerical rating scales and 3 or more points (vs less than 3 points) on the Roland-Morris scale were used as dichotomous outcomes. These cut-points were chosen because they most strongly associated with patients' global assessment of their improvement ("better" or "a lot better" vs "no improvement"), and previous studies have shown reductions of 3 or more points on the Roland-Morris scale to be clinically meaningful.[28,29]

Secondary outcome variables were perceived change in low-back symptoms, satisfaction with care, perception of treatment effectiveness at 4 weeks, and number of LBP cut-down days, bed days, and pain medication–use days.

Statistical Methods

The primary comparison was chiropractic care with physical modalities (DCPm) versus chiropractic care without physical modalities (DC). All analyses were based on intention to treat. SAS version 8 (SAS Institute, Cary, NC) was used for all analyses.[30]

Descriptive statistics were used to summarize and compare each treatment group according to sociodemographic and baseline health characteristics. Means, SDs, and medians were computed by treatment group for continuous variables and frequency distributions generated for categorical variables. Normality was assessed for each continuous variable, time trends of continuous outcome variables within each treatment group were graphed, and differences from baseline measurements were computed and plotted by time.

Two analytic strategies were used to estimate treatment effects: (1) ordinary least squares regression models were used to estimate differences in mean change on each continuous outcome variable from baseline to each follow-up assessment; and (2) logistic regression modeling was used to estimate and test the effects of treatments on 2-point and 3-point reductions in pain and disability, respectively. Age, sex, LBP–episode duration, and baseline value of the outcome measure were included as covariates in the models. Given that chiropractors may spend more time per visit with patients assigned to receive modalities, and because time may be predictive of outcomes, average self-reported amount of time spent with the chiropractor was a covariate in a subset of models.

RESULTS

Screening, Enrollment, and Follow-up

Figure 1 shows the flow of patients from screening to follow-up. We screened a total of 2355 patients. Eight

hundred eighty-six (37.6%) screened patients were excluded for the following reasons (frequency in parentheses): treatment for LBP in the past 1 month (270), pain not primarily in the lumbosacral area (144), fee-for-service or no health insurance (119), Medi-Cal or Medicare coverage only (80), third party liability or workers' compensation case (55), inability to read English (46), under 18 years old (43), LBP caused by fracture, tumor, or infection (40), severe coexisting disease (37), plans to move out of the area (18), use of anticoagulant medications (13), ankylosing spondylitis or other rheumatic disease (7), treatment with electrical device (5), not easily accessible by telephone (4), progressive or severe unilateral lower limb muscle weakness (2), abdominal aortic aneurysm (1), and symptoms or signs of cauda equina syndrome (1), and blood coagulation disorder (1).

Of the 1469 patients who were eligible, 788 (53.6%) refused to participate. Participation in the study was declined for the following reasons (frequency in parentheses): not interested (345), inconvenient (137), preferred medical care (116), preferred chiropractic care (105), did not want to be limited to one treatment mode (45), and could not afford multiple copayments (31). Nine otherwise eligible and willing potential subjects were not enrolled because their understanding of the informed consent form was deemed questionable. Out of 1469 eligible patients, 681 were enrolled in the study, and 341 were randomized to one of the 2 chiropractic treatment groups.

Two-week and 6-week follow-up questionnaires with complete outcome data were returned by 340 (99.7%) and 338 (99.1%) chiropractic subjects, respectively, and 328 (96.2%) completed the 6-month follow-up questionnaire. The 4-week interview was completed by 335 (98.2%) subjects. Data on utilization and costs of low-back care during the 6-month follow-up period were available for 326 (95.6%) of the chiropractic subjects.

Baseline Characteristics

Tables 1 and 2 show the baseline distributions of sociodemographic, health status, and LBP characteristics by chiropractic treatment group. Forty-five percent of the subjects had been in pain for longer than 1 year, and 45% had been in pain for less than 3 months. Seventy-eight percent had been treated previously for LBP. Fifty-eight percent reported having leg pain in the past week. Baseline distributions of most demographic and health-status variables appeared comparable between treatment groups. Subjects in the physical modalities group were somewhat more likely to report more physical dysfunction and low-back disability at baseline; however, the differences were not clinically relevant. Groups were comparable on expectation of treatment success, and pain prognosis was expected to be similar.

Treatments

Eighty-five percent of each treatment group received high-velocity spinal manipulation within the initial 4 weeks. Thirty-two percent of each group received both manipulation and mobilization, whereas 15% received only mobilization or other nonthrust manual therapy. The physical modalities most often given to subjects in the modalities group were heat therapy alone (28%); heat and EMS (25%); heat, EMS, and ultrasound (23%); and heat therapy and ultrasound (15%). Four percent of subjects in the modalities group were not treated with any modalities, and 13% of subjects in the chiropractic-only group received EMS or ultrasound.

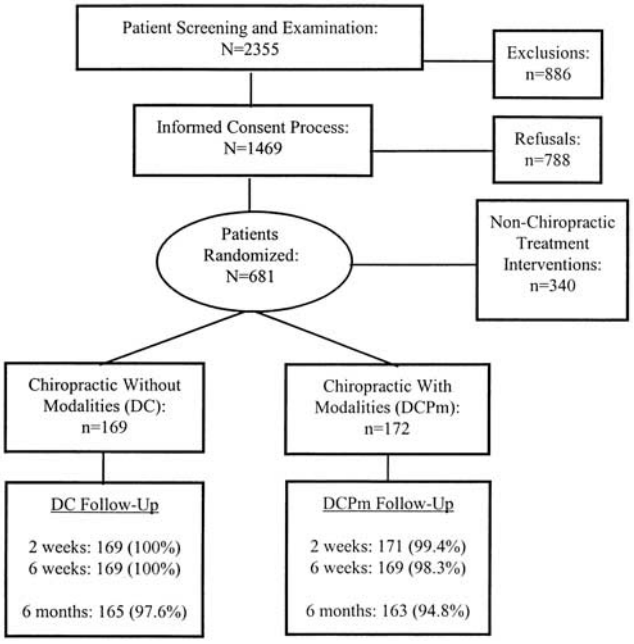

Fig 1. *Flow diagram of patient screening, enrollment, and follow-up.*

There were no appreciable differences between treatment groups with respect to exercise instruction, health advice, recommendations, compliance with advice, or other information given about diagnosis and treatment of LBP. However, chiropractors spent an average of 2 minutes more per visit with patients in the physical modalities group (16 vs 14 minutes).

Primary Outcomes

Intensity of LBP. The greatest unadjusted mean reduction in the most severe level of LBP occurred in the first 2 weeks (Fig 2). A reduction of 2 or more points occurred in 38% of all subjects at 2 weeks and in 52% at 6 weeks (Fig 3). Although almost 60% of subjects had reductions of 2+ points in most severe pain after 6 months, 80% reported having some degree of LBP in the preceding week. The adjusted mean reduction in most severe pain from baseline to 6 weeks was about 2 points, and 2.5 points after 6 months, with little difference between groups at any follow-up assessment (Table 3). The odds of 2+ point improvement was similar in each group (Table 4).

At the 2-week and 6-week follow-up assessments, greater proportions of the physical modalities group improved by 2+ points in the average level of LBP. By 6 months,

Table 1. *Characteristics of enrolled subjects by sociodemographic or health-status variable and treatment group (N = 341)*

Variable	DC group (n = 169)	DCPm group (n = 172)
Age (y)		
<30	8.9	8.1
30-39	20.1	22.1
40-49	16.6	12.8
50-59	19.5	18.6
60-69	16.6	14.5
≥70	18.3	23.8
Mean (SD)	51.8 (16.5)	53.4 (16.8)
Median	51	53
Sex		
Male	50.9	42.4
Female	49.1	57.6
Race/ethnicity		
White/non-Hispanic	62.1	65.7
Latino/Hispanic	27.2	25.6
Asian/Pacific Islander	6.5	2.9
African American/Black	3.0	2.9
Other	1.2	2.9
Education		
Some high school or less	9.5	8.1
High school graduate	22.5	23.3
Some college	46.2	38.4
College degree	12.4	20.3
Professional or graduate degree	9.5	9.9
Household income		
<$20,000	13.9	14.6
$20,000-$39,999	35.8	29.9
$40,000-$59,999	27.3	23.8
$60,000-$79,999	12.1	16.5
≥$80,000	10.9	15.2
Marital status		
Married	69.2	74.4
Widowed	5.3	8.1
Divorced/separated	14.2	9.9
In relationship	3.0	1.2
Never married	8.3	6.4
Current employment status		
Employed full-time	59.4	52.1
Employed part-time	7.3	8.3
Employed, on leave	1.8	1.2
Unemployed	6.1	7.7
Retired	25.5	30.8
General health status		
Excellent	7.1	8.1
Very good	36.7	35.5
Good	44.4	42.4
Fair	10.7	13.4
Poor	1.2	0.6
SF-36 Physical function		
Mean (SD)	65.8 (25.1)	59.7 (24.1)
Median	70	65
SF-36 Role-physical		
Mean (SD)	43.9 (41.0)	36.3 (39.1)
Median	25	25
SF-36 Role-emotional		
Mean (SD)	75.4 (38.5)	66.1 (40.7)
Median	100	100
SF-36 Mental health		
Mean (SD)	72.1 (16.6)	72.8 (15.8)
Median	76	76
SF-36 General health		
Mean (SD)	68.1 (17.3)	69.0 (17.2)
Median	70	70

Figures are percentages unless noted otherwise. *DC*, Chiropractic care without physical modalities; *DCPm*, chiropractic care with physical modalities.

Table 2. *Characteristics of enrolled subjects by baseline LBP variable and treatment group (N = 341)**

Variable	DC group (n = 169)	DCPm group (n = 172)
Duration of back-pain episode		
<3 weeks	21.9	30.2
3 weeks to 3 months	17.8	13.4
3 months to 1 year	14.8	12.8
>1 year	45.6	43.6
Roland-Morris disability score (0-24 scale)		
≤5	22.5	13.4
6-10	33.1	35.5
11-15	23.7	28.5
>15	20.7	22.7
Mean (SD)	10.3 (5.6)	11.3 (5.0)
Median	9	11
Most severe LBP (past week, 0-10 scale)		
Mean (SD)	6.5 (2.0)	6.7 (2.1)
Median	7	7
Average LBP (past week, 0-10 scale)		
Mean (SD)	4.5 (1.9)	4.7 (1.8)
Median	4	5
Cut-down days from LBP (past month)		
Mean (SD)	6.3 (7.4)	7.5 (8.0)
Median	4	5
>0 days (%)	74.4	80.8
Bed days from LBP (past month)		
Mean (SD)	0.7 (1.5)	0.8 (2.5)
Median	0	0
>0 days (%)	24.4	19.8
OTC pain medication use (past week)		
Yes	77.5	80.8
No	22.5	19.2
Prescription pain medication use (past six months)		
Yes	18.3	27.3
No	81.7	72.7
Leg pain or symptoms (past week)		
Yes	60.9	57.0
No	39.1	43.0
History of previous LBP episodes		
Yes	84.0	83.7
No	16.0	16.3
History of traumatic back injury		
Yes	28.4	24.4
No	71.6	75.1
History of previous LBP treatment		
Yes	73.4	83.7
No	26.6	16.3
Confidence in treatment success (0-10 scale)		
Mean (SD)	6.9 (2.4)	7.0 (2.3)
Median	7	7

Figures are percentages unless noted otherwise. *DC*, Chiropractic care without physical modalities; *DCPm*, chiropractic care with physical modalities.

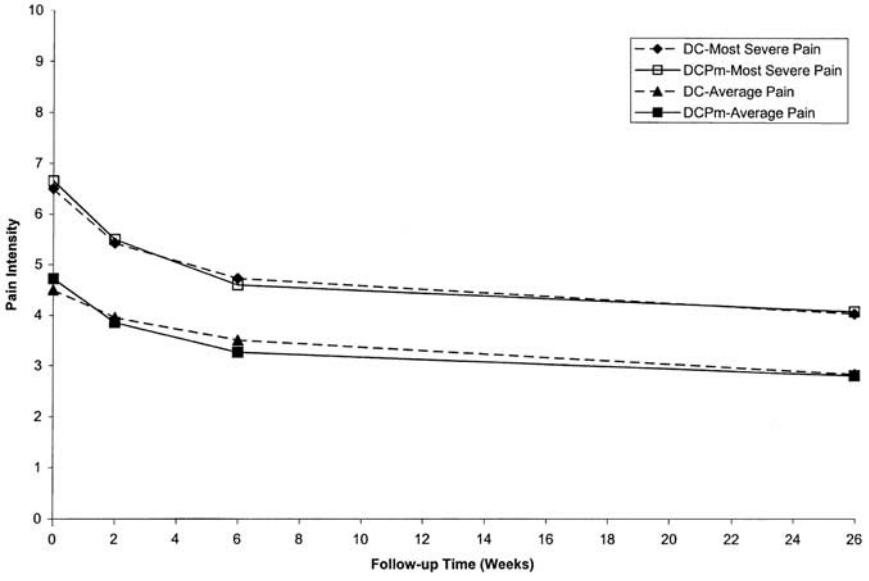

Fig 2. *Unadjusted mean scores on numerical rating scales (0-10) of most severe and average LBP in past week.*

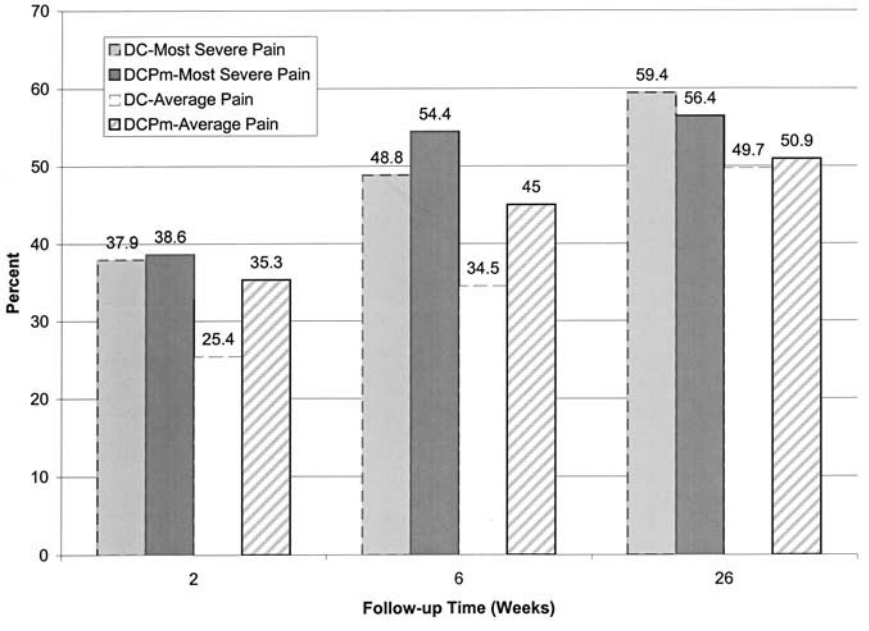

Fig 3. *Percent of subjects (unadjusted) improved by 2+ points on numerical rating scales (0-10) of most severe and average LBP from baseline to 2-week, 6-week, and 6-month follow-up assessments.*

however, 50% of both groups had improvements in average pain of 2 points or greater (Fig 3). Although the modalities group had larger adjusted mean reductions from baseline to 2 and 6 weeks in average pain level, these clinically insignificant differences disappeared by 6 months (Table 3). The odds of improvement by 2+ points in average pain was about 50% greater in the modalities group at 2 and 6 weeks, but no effect was observed at 6 months (Table 4). Treatment effects on pain outcomes did not change when models included average time per visit spent with the chiropractor.

Low Back Pain Disability. The unadjusted mean reduction in Roland-Morris Disability score from baseline was about 2 points at 2 weeks, 3 points at 6 weeks, and 4 points at 6 months (Fig 4). A reduction of 3+ points in disability score was observed in 37% of subjects at 2 weeks, 48% at 6 weeks, and 55% at 6 months, when two thirds of patients reported disability scores of at least 3 points. Proportions improved were somewhat greater in the modalities group at 2 and 6 weeks but not at 6 months (Fig 5). At all follow-up assessments, both groups had clinically indistinguishable adjusted mean reductions in disability (Table 3) and similar odds of improving by 3+ points on the Roland-Morris Disability scale (Table 4). Models with and without covariates for time spent with the chiropractor yielded similar effect estimates.

Table 3. *Results of ordinary least squares regression analyses**

Follow-up interval	Outcome variable†	N	DCPm group		DC group		DCPm-DC difference‡	95% CI
			Change‡	95% CI	Change‡	95% CI		
Baseline to 2 weeks	Most severe pain	340	1.08	0.77, 1.39	1.15	0.84, 1.46	−0.06	−0.51, 0.38
	Average pain	339	0.80	0.53, 1.06	0.61	0.34, 0.87	0.19	−0.19, 0.56
	Disability score	340	2.13	1.51, 2.75	1.77	1.14, 2.39	0.36	−0.53, 1.25
Baseline to 6 weeks	Most severe pain	337	1.95	1.59, 2.32	1.83	1.47, 2.20	0.12	−0.40, 0.64
	Average pain	337	1.35	1.05, 1.66	1.04	0.74, 1.35	0.31	−0.13, 0.75
	Disability score	338	3.16	2.46, 3.86	3.18	2.48, 3.88	−0.02	−1.02, 0.97
Baseline to 6 months	Most severe pain	328	2.51	2.09, 2.93	2.51	2.09, 2.93	0.00	−0.60, 0.59
	Average pain	328	1.82	1.49, 2.16	1.73	1.39, 2.06	0.10	−0.38, 0.58
	Disability score	328	3.68	2.94, 4.42	4.41	3.67, 5.15	−0.73	−1.79, 0.32

DCPm, Chiropractic care with physical modalities; *DC*, chiropractic care without physical modalities.

*Estimated adjusted mean changes and differences in improvement of chiropractic with physical modalities and chiropractic without physical modalities on most severe and average pain intensity in the past week and in disability score from baseline to each follow-up assessment.

†Most severe and average LBP in the past week assessed with numerical rating scales (0-10); low back–related disability assessed with the Roland-Morris Disability Questionnaire (0-24).

‡Estimated mean changes and differences adjusted for age, sex, duration of LBP episode, and baseline value of the outcome.

Table 4. *Results of logistic regression analyses**

Follow-up interval	Outcome variable†	N	OR‡	95% CI
Baseline to 2 weeks	Most severe pain	340	0.93	0.58, 1.51
	Average pain	339	1.56	0.92, 2.63
	Disability score	340	1.08	0.66, 1.77
Baseline to 6 weeks	Most severe pain	337	1.20	0.75, 1.93
	Average pain	337	1.52	0.93, 2.48
	Disability score	338	1.27	0.80, 2.01
Baseline to 6 months	Most severe pain	328	0.83	0.51, 1.35
	Average pain	328	0.98	0.60, 1.61
	Disability score	328	0.80	0.50, 1.30

*Estimated effects (adjusted odds ratios [ORs] and 95% CIs of chiropractic care with physical modalities versus chiropractic care without physical modalities on 2+ point reductions in most severe pain and average pain intensity in the past week and on 3+ point reducation in disability score from baseline to each follow-up assessment.

†Most severe and average LBP in past week assessed with numerical rating scales (0-10); low back-related disability assessed with Roland-Morris Disability Questionnaire (0-24).

‡Estimated effects (ORs) adjusted for age, sex, duration of LBP episode, and baseline value of outcome measure.

Secondary Outcomes

Perceived Change in Symptoms and Satisfaction. Perceptions of change in low-back symptoms at 4 weeks were similar in both groups. Seventy-eight percent of subjects in the physical modalities group versus 75% in the nonmodalities group perceived their LBP to be "better" or "a lot better" at 4 weeks. Although there was no difference between groups in satisfaction with care as measured with the 0 to 10 numerical rating scale (DC, mean [SD]: 7.1 [2.3]; DCPm, mean [SD]: 7.2 [2.1]), 22% of DCPm subjects versus 12% of DC subjects strongly agreed that the treatment was effective (unadjusted risk ratio [RR], 1.83; 95% CI, 1.11 to 3.03). Subjects assigned to receive modalities were also more likely to seek similar care for future LBP (79% vs 71%; unadjusted RR, 1.11; 95% CI, 0.98 to 1.25). Effect estimates from models that included time spent with the chiropractor and prognostic factors were comparable to the unadjusted estimates.

Medication Use and Disability Days. No differences between groups were detected in reported OTC or prescription medication use, and the numbers of cut-down days and bed days caused by LBP were not appreciably different between the groups at any of the follow-up assessments (Table 5).

Utilization and Cost of Low Back Care. Visit frequency over the 6-month follow-up did not vary appreciably by treatment group; however, the cost of care was somewhat higher in the physical modalities group (Table 6).

Adverse Events. No study-related adverse events requiring institutional review board notification were reported.

DISCUSSION

The effectiveness of physical modalities among patients with LBP randomized to chiropractic care was assessed in a managed-care practice setting. During 6 months of follow-up in this population of patients with primarily subacute and chronic pain, chiropractic care with or without physical modalities yielded mostly similar pain and disability outcomes. Most patients in both treatment groups had clinically meaningful reductions in pain severity and disability, although the majority of subjects reported at least

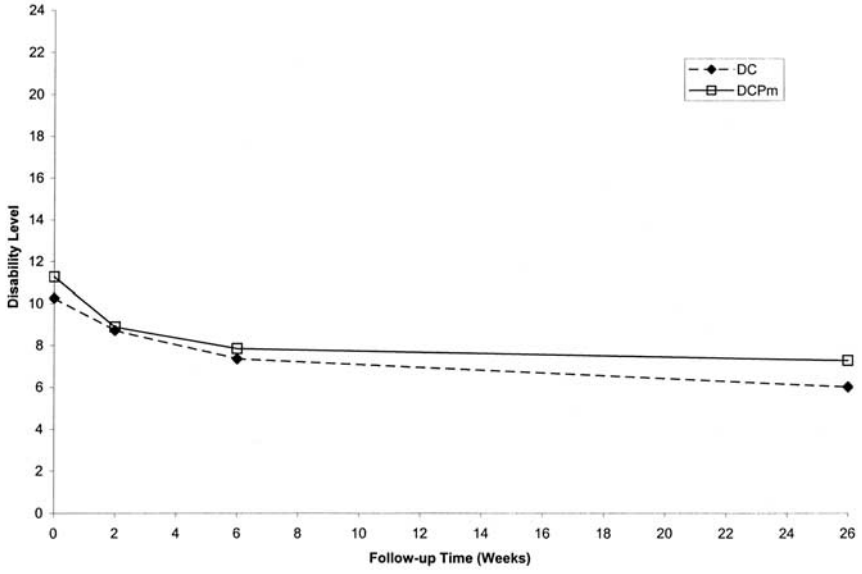

Fig 4. *Unadjusted mean score on Roland-Morris Disability Questionnaire (0-24).*

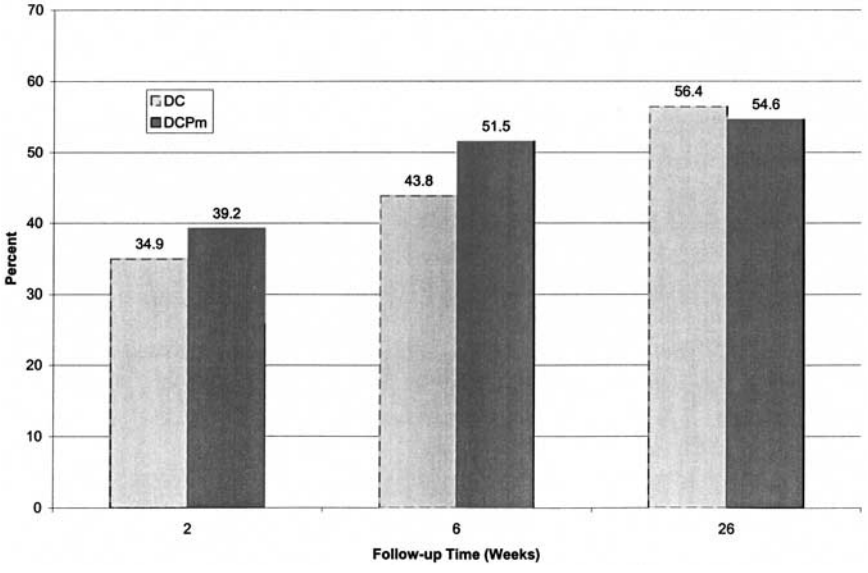

Fig 5. *Percent of subjects (unadjusted) improved by 3+ points on Roland-Morris Disability Scale (0-24) from baseline to 2-week, 6-week, and 6-month follow-up assessments.*

some pain and impaired function from back pain at 6 months. These findings add to the evidence showing that physical modalities provide, at best, minimal short-term benefit for patients with LBP who are receiving chiropractic care. Specific agents or modalities might, however, be effective in certain patients or in other settings.

Satisfaction with chiropractic care was equally high in both treatment groups, yet patients assigned to receive modalities were more likely to strongly agree that the treatment they received was effective and more likely to seek similar care for future back pain episodes. Because patients were not blinded, these findings illustrating greater perceived benefit do not necessarily reflect greater clinical benefit. For example, patients may simply equate the applications of additional treatments (eg, ultrasound, EMS) as better care regardless of their therapeutic value. Alternatively, modalities may offer patients transient symptomatic relief or improvements in other unmeasured health outcomes that we failed to consider. As a discrete therapy, spinal manipulation as routinely used by chiropractors in the United States and elsewhere has been shown to be beneficial for patients with acute LBP, at least in the short term,[9,31] and may be an effective treatment for chronic pain.[10] Current evidence does not support the use of EMS, ultrasound, and other passive modalities for acute or chronic LBP.[9,31,32] Exercise and other active physical therapeutic interventions may be of some benefit.[9,10,14] Harm resulting from spinal manipulation or physical modalities for LBP is remote.[9,31,32]

We are unaware of other randomized clinical trials (RCTs) that have compared chiropractic with and without

Table 5. *Mean (SD) and median number of cut-down days and bed days caused by LBP and days of over-the-counter and prescription pain medication use among enrolled subjects*

Variable	Interval	Statistic	DC group (n = 169)	DCPm group* (n = 172)
Cut-down days	Baseline to 2 weeks	Mean (SD)	2.6 (4.0)	2.7 (4.2)
		Median	0	0
		% >0 days	47.3	49.7
	2 weeks to 6 weeks	Mean (SD)	3.0 (5.6)	3.2 (6.1)
		Median	0	0
		% >0 days	43.8	45.0
Bed days	Baseline to 2 weeks	Mean (SD)	0.3 (1.0)	0.4 (1.6)
		Median	0	0
		% >0 days	10.1	9.9
	2 weeks to 6 weeks	Mean (SD)	0.3 (1.4)	0.2 (0.9)
		Median	0	0
		% >0 days	7.1	5.3
OTC pain medication days	Baseline to 2 weeks	Mean (SD)	3.6 (4.7)	3.7 (4.7)
		Median	2	2
		% >0 days	57.4	58.5
	2 weeks to 6 weeks	Mean (SD)	5.5 (8.5)	6.0 (8.7)
		Median	2	2
		% >0 days	55.0	58.0
Prescription pain medication days	Baseline to 2 weeks	Mean (SD)	0.8 (2.6)	1.1 (3.4)
		Median	0	0
		% >0 days	14.9	15.8
	2 weeks to 6 weeks	Mean (SD)	1.4 (4.2)	1.7 (5.6)
		Median	0	0
		% >0 days	16.6	16.0

DC, Chiropractic care without physical modalities; *DCPm*, chiropractic care with physical modalities.
*n = 171 for baseline to 2-week figures and n = 169 for 2-week to 6-week figures because of missing follow-up data.

Table 6. *Mean (SD) and median number of visits and cost of LBP care of subjects enrolled in the study*

Variable	Follow-up interval	Statistic	DC group* (n = 163)	DCPm group† (n = 163)
Number of visits	Baseline to 6 weeks	Mean (SD)	2.96 (1.53)	3.34 (1.64)
		Median	3	3
	6 weeks to 6 months	Mean (SD)	1.78 (2.57)	1.84 (2.12)
		Median	1	1
	Baseline to 6 months	Mean (SD)	4.74 (3.40)	5.18 (3.15)
		Median	4	5
Cost (US$)	Baseline to 6 weeks	Mean (SD)	295 (164)	387 (201)
		Median	256	346
	6 weeks to 6 months	Mean (SD)	189 (327)	195 (243)
		Median	56	112
	Baseline to 6 months	Mean (SD)	484 (410)	581 (358)
		Median	345	516

DC, Chiropractic care without physical modalities; *DCPm*, chiropractic care with physical modalities.
*n = 163 because of missing visit and cost data on 6 subjects in the DC group.
†n = 163 because of missing visit and cost data on 9 subjects in the DCPm group.

physical modalities, although 4 RCTs comparing chiropractic care with physical therapy for LBP have been published. Outcomes from chiropractic and hospital outpatient (physiotherapy) care were clinically similar in the Meade et al trial,[33,34] yet chiropractic patients reported greater satisfaction. Postacchini et al[35] and Skargren et al[36,37] also found little difference between outcomes from chiropractic and physical therapy at 6 or 12 months, although chiropractic patients' expectations were more likely to have been fulfilled in the latter trial. During 2 years' follow-up of patients randomized to chiropractic or McKenzie physical therapy,[38] satisfaction and pain and disability outcomes were similar.

The findings from prior studies are consistent with our results showing the ineffectiveness of physical modalities.[9,10,14] Active rather than passive interventions, however, may be of benefit for some patients with subacute and chronic LBP. Supervised exercise classes were found to be more effective than primary medical care for patients with subacute LBP after 6 and 12 months,[39] and supervised exercise interventions led to greater reductions in pain,

disability, and costs than self exercise among patients with chronic pain after 12 months.[40] The value of supervised exercise (vs self exercise) for patients with chronic LBP is also supported by another recent trial that followed patients for 2 years.[41] However, the authors of an RCT that compared low-impact aerobics with active physical therapy and muscle reconditioning among patients with chronic LBP found equivalent pain and disability outcomes with much less cost in the aerobics group after 6 months.[42]

The major limitation of our study is its potential lack of generalizability to other practice settings and patient populations. Given that the trial was conducted within 1 managed-care organization, extrapolating our findings to patients with LBP in other settings may be inappropriate. Patients under other reimbursement models, such as fee-for-service, workers' compensation, and third party liability, may differ in ways that affect treatment outcomes. In addition, chiropractors practicing in other environments may differ in their relations with patients, manipulative techniques, the frequency and duration of visits, the length and intensity of LBP care, and in their overall approach to patients. Findings from a recent study of chiropractic utilization in North America, for example, documented wide geographic variation in the frequency of visits during episodes of back-pain care.[1] Despite possible differences, other ambulatory LBP patient populations are similar to ours in terms of back-pain severity[38,43,44] and disability,[15,43,45-47] and most chiropractors in the United States are taught and use the same general types of spinal manipulation used by the chiropractors at our study site.[11,12]

CONCLUSION

Physical modalities used at the discretion of chiropractors in this managed-care setting do not appear to be more effective than chiropractic care without modalities in the treatment of patients with LBP, although a small short-term benefit for some patients cannot be ruled out. Given the added expense of office-based modalities, chiropractors may deliver equally effective and more cost-effective care by withholding modalities, educating patients, and perhaps recommending at-home applications of agents for the temporary relief of symptoms. However, the discrepancy between effects on pain and disability outcomes and perceptions of treatment effectiveness suggests that modalities may enhance the real or perceived effectiveness of chiropractic care among some patients. The perceptions of patients with LBP regarding treatment effectiveness and how these perceptions relate to clinical outcomes and costs and to preferences for subsequent care should be investigated in future studies.

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