

A Randomized Trial of Medical Care With and Without Physical Therapy and Chiropractic Care With and Without Physical Modalities for Patients With Low Back Pain: 6-Month Follow-Up Outcomes From the UCLA Low Back Pain Study

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Study Design.

A randomized clinical trial.

Objectives. To compare the effectiveness of medical and chiropractic care for low back pain patients in managed care; to assess the effectiveness of physical therapy among medical patients; and to assess the effectiveness of physical modalities among chiropractic patients.

Summary of Background Data. Despite the burden that low back pain places on patients, providers, and society, the relative effectiveness of common treatment strategies offered in managed care is unknown.

Methods. Low back pain patients presenting to a large managed care facility from October 30, 1995, through November 9, 1998, were randomly assigned in a balanced design to medical care with and without physical therapy and to chiropractic care with and without physical modalities. The primary outcome variables are average and most severe low back pain intensity in the past week, assessed with 0 to 10 numerical rating scales, and low back-related disability, assessed with the 24-item Roland-Morris Disability Questionnaire.

Results. Of 1,469 eligible patients, 681 were enrolled; 95.7% were followed through 6 months. The mean changes in low back pain intensity and disability of participants in the medical and chiropractic care-only groups were similar at each follow-up assessment (adjusted mean differences at 6 months for most severe pain, 0.27, 95% confidence interval, -0.32–0.86; average pain, 0.22, -0.25–0.69; and disability, 0.75, -0.29–1.79). Physical therapy yielded somewhat better 6-month disability outcomes than did medical care alone (1.26, 0.20–2.32).

Conclusions. After 6 months of follow-up, chiropractic care and medical care for low back pain were comparable in their effectiveness. Physical therapy may be marginally more effective than medical care alone for reducing disability in some patients, but the possible benefit is small. [Key words: low back pain, randomized trial, physical therapy, chiropractic, managed care] **Spine 2002;27:2193–2204**

Back pain is among the principal reasons for persons to seek medical care⁵² and the most common reason for initiating chiropractic care.²⁵ Chiropractic was the most common “unconventional” therapy used in the United States in 1996,¹⁷ and chiropractic is the most commonly used alternative therapy for back problems.¹⁸ Most visits for low back pain are to chiropractors,⁴¹ back pain is one of the most frequent reasons for physicians to refer patients to physical therapy,²⁰ and an increasing proportion of health care services is being delivered in managed care environments.⁵² Disabling low back pain is largely responsible for the estimated \$33 billion spent annually in direct health care costs associated with low back pain care.⁵⁰ Although the rate and duration of back-related disability claims have decreased in recent years,^{23,35} back pain remains a leading cause of worker absenteeism, resulting in \$8.8 billion in work-related low back claims in 1995.³⁵

Despite the high prevalence of low back pain, and the suffering, disability, health care, and economic costs associated with it, there remains a lack of consensus about how to treat and manage both acute and chronic low back pain. Although recent studies, including a randomized clinical trial,⁹ have compared medical, chiropractic care, and physical therapy for patients with low back pain, none has been conducted entirely within a managed care practice setting with salaried providers. The objectives of this study are 1) to compare the effectiveness of medical and chiropractic care for low back pain patients in managed care; 2) to assess the effectiveness of physical therapy among medical patients; and 3) to assess the effectiveness of physical modalities among chiropractic patients.

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This study was funded by grants from the Agency for Healthcare Research and Quality (AHRQ) (R01 HS07755) and the Southern California University of Health Sciences. Dr. Hurwitz was supported by a grant from the National Center for Complementary and Alternative Medicine (NCCAM) (K23 AT00055).

Acknowledgment date: October 8, 2001.

First revision date: January 23, 2002.

Acceptance date: April 10, 2002.

Device status/drug statement: This report does not contain information about medical device(s) drug(s).

Conflict of interest: Federal and foundation funds were received to support this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this report.

DOI: 10.1097/01.BRS.0000029253.40547.84

■ Materials and Methods

Study Design. Ambulatory low back pain patients were randomly assigned in a balanced design to four treatment groups: medical care with and without physical therapy and chiropractic care with and without physical modalities. Follow-up questionnaires were mailed to participants at 2 and 6 weeks and 6 months.

Source Population. The source population is approximately 90,000 to 110,000 members of a health care network based in southern California. The network is primarily a prepaid group practice of salaried providers in which the group accepts capitated payments for most of its patients. Members receive all their outpatient health care through one or more of the group's offices or contract providers. This study was conducted at three of the group's ambulatory care facilities.

Patient Selection

Inclusion and Exclusion Criteria. Patients were eligible for the study if they 1) were health maintenance organization members with the medical group chosen as their health care provider; 2) sought care from a health care provider on staff at one of the three study sites during the intake period from October 30, 1995, through November 9, 1998; 3) presented with a complaint of low back pain (defined as pain in the region of the lumbosacral spine and its surrounding musculature) with or without leg pain; 4) had not received treatment for low back pain within the previous month; and 5) were at least 18 years old.

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

Patient Screening Protocol. All patients presenting with low back pain were interviewed by the field coordinator to determine eligibility. Patients meeting the inclusion criteria were asked if they would be willing to participate in a study designed to assess the effectiveness of various treatment strategies for their condition. The eligible patients received an information sheet stating that each patient would be assigned at random to one of four treatment protocols; that it is not known which protocol is most beneficial; and the requirements of participation. A primary care provider conducted a history and physical examination on each patient who agreed to participate. Radiographs and lab tests were ordered if necessary.

Informed Consent and Randomization. Those patients agreeing to participate and meeting all eligibility criteria were asked to read and sign an informed consent form. The study protocol and informed consent form were approved by the institutional review boards from the University of California–Los Angeles (UCLA) and the health care network. The field coordinator administered the informed consent form and was

available to answer any questions patients may have had about the requirements of participation, the nature of the treatment protocols, risks and benefits of participation, and other study-related questions.

The study statistician ran a computer program to generate randomized assignments in blocks of 12, stratified by site. The statistician placed each treatment assignment in a numbered security envelope. A separate series of sequentially numbered sealed envelopes was provided for each of the three sites. When each patient consented to be in the study, the field coordinator opened the site-specific envelope in sequence and documented the patient for whom the assignment was made and the time of the assignment. After completing the baseline questionnaire, each patient reported to the assigned medical or chiropractic provider on the same day. Patients received \$10 on enrollment and \$10 after completing the final follow-up questionnaire. Patients were responsible for paying their co-payments, which ranged from \$5 to \$20, depending on the patient's specific health plan.

Treatment Protocols. The specific therapies received by patients varied within each treatment group, and our study protocol did not prescribe the type or amount of care that should be received by participating patients. Frequency of medical and chiropractic visits were at the discretion of the medical provider or chiropractor assigned to the patient. Frequency of physical therapy visits was at the discretion of the supervising physical therapist.

Medical Care Only. Patients assigned to this group received one or more of the following at the discretion of the medical provider: instruction in proper back care and strengthening and flexibility exercises; prescriptions for pain killers, muscle relaxants, anti-inflammatory agents, and other medications used to reduce or eliminate pain or discomfort; and recommendations regarding bedrest, weight loss, and physical activities.

Chiropractic Care Only. Patients assigned to this group received spinal manipulation or another spinal-adjusting technique (*e.g.*, mobilization), instruction in strengthening and flexibility exercises, and instruction in proper back care. Chiropractic practice at the study site is consistent with chiropractic philosophy and training throughout the United States. The chiropractors routinely use the diversified technique, which is the general type of spinal manipulation taught in most chiropractic schools and is the most frequently used form of manipulation.¹⁰

Medical Care with Physical Therapy. Patients assigned to this group received medical care as described above, instruction in proper back care from the physical therapist, plus one or more of the following at the discretion of the physical therapist: heat therapy, cold therapy, ultrasound, electrical muscle stimulation (EMS), soft-tissue and joint mobilization, traction, supervised therapeutic exercise, and strengthening and flexibility exercises. All physical therapy was administered in the medical group's physical therapy department and supervised by a licensed physical therapist.

Chiropractic Care with Physical Modalities. Patients assigned to this group received chiropractic care as described above plus one or more of the following at the discretion of the chiropractor: heat or cold therapy, ultrasound, and EMS.

Data Collection and Variables

Baseline Data

Low Back Pain and Related Disability. Disability resulting from low back pain was assessed by the 24-item Roland-Morris adaptation of the Sickness Impact Profile.^{13,39} Patients respond by answering “yes” or “no” to indicate whether or not each statement is a true description of their current disability resulting from low back pain. Possible scores range from 0 (indicating no disability) to 24 (indicating severe disability). This instrument has been validated in previous low back pain studies^{13,39} and in a study of chronic pain patients with and without low back pain,²⁶ and it is more responsive to change over time than most other functional status instruments.^{6,16,24,45}

Numerical rating scales were used to assess intensity of pain (most severe pain and average level of pain for the past week), in which 0 is no pain and 10 is unbearable pain. These scales have been shown to have excellent reliability and validity for measuring back pain.⁴⁶

Pain History. Specific questions addressed the number of previous low back pain episodes, age at first episode, duration of current and longest episodes, time between last and current episodes, type of onset (injury- or noninjury-related), and disability and healthcare associated with previous low back pain.

Psychological Distress and Well-Being. Psychological, physical, and general health status, in terms of functioning and well-being, was assessed by the Medical Outcomes Study 36-Item Short-Form Health Survey.⁵¹ Five of eight subscales 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 (psychological distress and well-being).³¹ All five measures are scored on scales of 0 to 100.

Sociodemographic Data. Sociodemographic variables included age, sex, race/ethnicity, education, household income, marital status, and current employment status.

Follow-Up Data. The follow-up questionnaires addressed low back pain severity, improvement, and related disability; cut-down days and bed days attributed to low back pain; and use of over-the-counter and prescription medication for low back pain. Functional status was measured by repeat Roland-Morris Low-Back Disability Questionnaires at every follow-up assessment. Pain status was measured by repeat numerical rating scales and scales of global pain improvement (“a lot worse” to “a lot better”) at every follow-up assessment. Health care use data were extracted from the organization’s computerized health information system. A brief telephone interview at 4 weeks’ postrandomization queried patients about their low back pain visits.

Outcome Variables. The primary outcome variables are changes in average and most severe low back pain intensity in the past week, assessed with 0 to 10 numerical rating scales, and low back-related disability, assessed with the 24-item Roland-Morris Disability Questionnaire. Each outcome is treated as a continuous variable and as a dichotomous variable. Cut-points of 2 or more points (*vs.* < 2 points) on the 0 to 10 numerical rating scales and 3 or more points (*vs.* < 3 points) on

the Roland-Morris scale were used as dichotomous outcomes. These cut-points were chosen on account of being 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 relevant.^{15,24,37} Differences between treatment groups of 2 or more points on the numerical rating scales and 3 or more points on the Roland-Morris scale were deemed to be clinically significant.

Statistical Methods. The primary comparisons are 1) medical care alone *versus* chiropractic alone, 2) medical care alone *versus* medical care plus physical therapy, and 3) chiropractic alone *versus* chiropractic plus physical modalities. Intention-to-treat analyses were performed throughout. All *P* values are two-sided.

Descriptive statistics were used to summarize the patient characteristics measured at baseline for each treatment group. Means, standard deviations, and medians were computed by treatment group for continuous variables, and frequency distributions were 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.

Three 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; 2) logistic regression was used to estimate and test the effects of treatments on dichotomous outcomes; and 3) mixed effects linear models were used to show changes in each outcome over the 6-month follow-up period by treatment group. Age (continuous), sex, low back pain episode duration (< 3 weeks, 3 weeks–1 year, > 1 year), and baseline value of the outcome measure were included as covariates in the ordinary least squares regression and logistic models. The logistic model results were used to estimate risk ratios and 95% confidence limits for each treatment contrast by setting the model covariates to sample means for continuous covariates, female sex, and chronic pain (> 1 year duration). Age, sex, and low back pain episode duration were included as covariates in the mixed effects linear models.

■ Results

Screening, Enrollment, and Follow-Up

Figure 1 shows the flow of patients from screening to follow-up. We screened a total of 2,355 patients. Eight hundred eighty-six (37.6%) screened patients were excluded for the following reasons, in descending order of frequency (in parentheses): low back pain treatment in the past month (*n* = 270), pain not primarily in the lumbosacral area (*n* = 144), fee-for-service or no health insurance (*n* = 119), Medi-Cal or Medicare coverage only (*n* = 80), third-party liability or workers’ compensation case (*n* = 55), inability to read English (*n* = 46), age younger than 18 years old (*n* = 43), plans to move out of the area (*n* = 18), and not easily accessible by telephone (*n* = 4). In addition, patients were excluded for the following medical reasons: low back pain caused by fracture, tumor, or infection (*n* = 40); severe coexist-

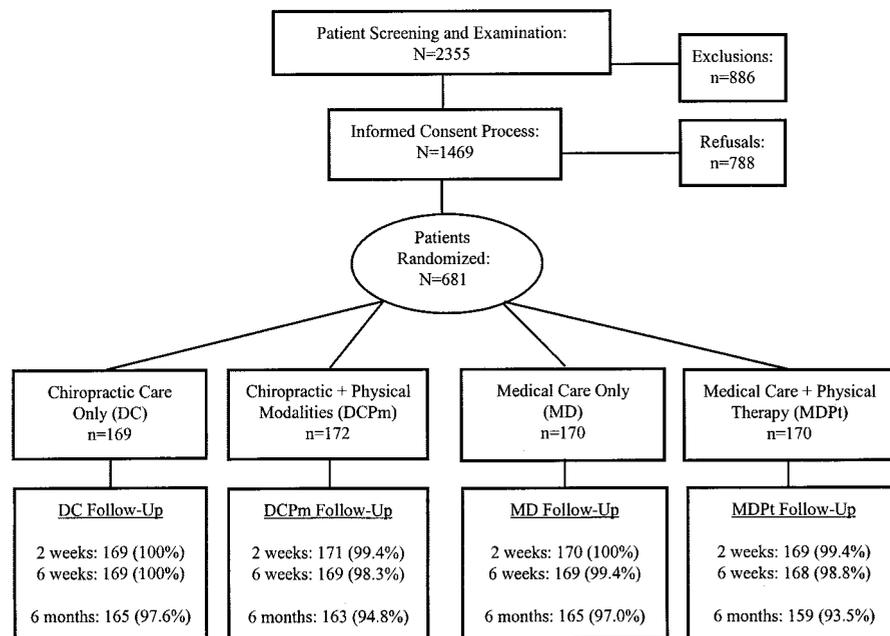


Figure 1. Flow diagram of patient screening, enrollment, and follow-up.

ing disease ($n = 37$); use of anticoagulant medications ($n = 13$); ankylosing spondylitis or other rheumatic disease ($n = 7$); treatment with an electrical device ($n = 5$); progressive or severe unilateral lower limb muscle weakness ($n = 2$); abdominal aortic aneurysm ($n = 1$); symptoms or signs of cauda equina syndrome ($n = 1$); and blood coagulation disorder ($n = 1$).

Of the 1,469 patients who were eligible, 788 (53.6%) refused to participate. Participation in the study was declined for the following reasons, in descending order of frequency (in parentheses): is not interested ($n = 345$), finds it inconvenient ($n = 137$), prefers medical care ($n = 116$), prefers chiropractic care ($n = 105$), does not want to be limited to one treatment mode ($n = 45$), and cannot afford multiple co-payments ($n = 31$). In addition, nine otherwise eligible and willing potential participants were not enrolled because the patient enrollment coordinator felt that they did not understand the informed consent form. Of 1,469 eligible patients, 681 were enrolled in the study.

Two- and 6-week follow-up questionnaires with complete outcome data were returned by 679 (99.7%) and 675 (99.1%) patients, respectively, and 652 patients (95.7%) completed the 6-month follow-up questionnaire.

Baseline Characteristics

Tables 1 and 2 show the baseline distributions of sociodemographic, health status, and low back pain characteristics by treatment group. Fifty-two percent of the patients are female, half are younger than 50, and 40% are nonwhite. Forty-seven percent of the patients had been in pain for longer than 1 year, 26% had been in pain for less than 3 weeks, and 27% had been in pain for 3 weeks to 1 year. Seventy-eight percent had been treated previously for low back pain. Thirty-four percent reported

having leg pain below the knee in the past week. There are relatively small differences between treatment groups in the baseline distributions of sociodemographic and health status variables. Although there are minor differences between the groups with respect to low back pain severity and related disability, the differences are clinically insignificant. Overall, there do not appear to be systematic differences between groups in expected prognosis.

Utilization and Treatments

Table 3 shows the frequency of low back pain visits and the percent of patients with at least one visit to each type of provider, by treatment group. Ninety-nine percent of patients had at least one visit to their assigned chiropractic or medical provider; however, about one-third of patients randomly assigned to medical care with physical therapy had no physical therapy visits. About 20% of patients in the chiropractic groups received concurrent medical care, whereas 7% of patients in the medical groups received concurrent chiropractic care in the first 6 weeks. Chiropractors and medical providers spent an average of 15 minutes with patients at each visit, whereas physical therapy providers averaged 31 minutes per patient visit.

Eighty-five percent of patients in the chiropractic groups received high-velocity spinal manipulation. The physical modalities most often given to patients in the methods group were heat therapy alone (28%); heat and EMS (25%); heat, EMS, and ultrasound (23%); and heat therapy and ultrasound (15%). Four percent of patients in the modalities group were not treated with any modalities, and 13% of patients in the chiropractic-only group received modalities. The most common interventions in the physical therapy group were heat or cold

Table 1. Frequency Distributions (in percent) and/or Means (Standard Deviations [SDs]) and Medians of Selected Socio-demographic and Health-status Variables, by Treatment Group* (n = 681)

Variable	Category	Treatment Group				Total
		DC (n = 169)	DCPm (n = 172)	MD (n = 170)	MDPt (n = 170)	
Age (Years)	<30	8.9	8.1	9.4	11.2	9.4
	30–39	20.1	22.1	22.9	22.9	22.0
	40–49	16.6	12.8	22.9	20.6	18.2
	50–59	19.5	18.6	17.1	17.1	18.1
	60–69	16.6	14.5	11.2	14.1	14.1
	≥70	18.3	23.8	16.5	14.1	18.2
	Mean (SD)	51.8 (16.5)	53.4 (16.8)	49.4 (16.5)	49.3 (16.7)	51.0 (16.7)
	Median	51	53	47	48	50
Sex	Male	50.9	42.4	52.9	45.9	48.0
	Female	49.1	57.6	47.1	54.1	52.0
Race/ethnicity	White/Non-Hispanic	62.1	65.7	60.0	53.5	60.4
	Latino/Hispanic	27.2	25.6	31.8	34.7	29.8
	Asian/Pacific Islander	6.5	2.9	4.1	4.7	4.5
	African American/Black	3.0	2.9	1.8	3.5	2.8
	Other	1.2	2.9	2.4	3.5	2.5
Education	Some high school or less	9.5	8.1	7.6	7.6	8.2
	High school graduate	22.5	23.3	16.5	23.5	21.4
	Some college	46.2	38.4	38.8	34.7	39.5
	College degree	12.4	20.3	25.3	22.4	20.1
	Prof. or graduate degree	9.5	9.9	11.8	11.8	10.7
Household Income	Less than \$20,000	13.9	14.6	11.4	14.9	13.7
	\$20,000 to \$39,999	35.8	29.9	23.5	30.4	29.9
	\$40,000 to \$59,999	27.3	23.8	32.5	26.2	27.5
	\$60,000 to \$79,999	12.1	16.5	13.3	11.9	13.4
	\$80,000 or more	10.9	15.2	19.3	16.7	15.5
Marital Status	Married	69.2	74.4	70.6	64.7	69.8
	Widowed	5.3	8.1	3.5	7.1	6.0
	Divorced/Separated	14.2	9.9	11.2	14.1	12.3
	Not married, in relationship	3.0	1.2	1.2	1.8	1.8
	Never married	8.3	6.4	13.5	12.4	10.1
Current Employment Status	Employed full time	59.4	52.1	61.3	62.3	58.7
	Employed part time	7.3	8.3	8.3	8.4	8.1
	Employed, but on leave	1.8	1.2	1.2	1.8	1.5
	Unemployed	6.1	7.7	6.0	4.2	6.0
	Retired	25.5	30.8	23.2	23.4	25.7
General Health Status	Excellent	7.1	8.1	9.4	7.6	8.1
	Very good	36.7	35.5	44.1	31.8	37.0
	Good	44.4	42.4	32.9	48.2	42.0
	Fair	10.7	13.4	12.4	10.6	11.7
	Poor	1.2	0.6	1.2	1.8	1.2
SF-36 Physical Function	Mean (SD)	65.8 (25.1)	59.7 (24.1)	63.9 (22.8)	59.4 (25.9)	62.2 (24.6)
	Median	70	65	65	60	65
SF-36 Role-Physical	Mean (SD)	43.9 (41.0)	36.3 (39.1)	43.8 (39.8)	41.2 (40.5)	41.3 (40.1)
	Median	25	25	50	25	25
SF-36 Role-Emotional	Mean (SD)	75.4 (38.5)	66.1 (40.7)	68.4 (38.4)	70.0 (39.0)	70.0 (39.2)
	Median	100	100	100	100	100
SF-36 Mental Health	Mean (SD)	72.1 (16.6)	72.8 (15.8)	70.6 (17.1)	69.3 (16.7)	71.2 (16.6)
	Median	76	76	72	72	76
SF-36 General Health	Mean (SD)	68.1 (17.3)	69.0 (17.2)	67.6 (18.3)	66.6 (19.1)	67.8 (18.0)
	Median	70	70	70	70	70

* DC = chiropractic care only; DCPm = chiropractic care with physical modalities; MD = medical care only; and MDPt = medical care with physical therapy.

therapy (71%), supervised therapeutic exercise (59.5%), ultrasound (45%), EMS (33.6%), and mobilization (19.9%). Prescription pain medications (58.5%), muscle relaxants (48.5%), and nonprescription pain medications (25.9%) were the most frequent interventions in the medical groups.

Outcomes

Low Back Pain Intensity. The mean reduction in most severe pain from baseline to 6 weeks is at least 1.5 points

at 6 weeks and greater than 2 points at 6 months in all treatment groups ($P < 0.001$ for the time trend in mean pain score in each follow-up interval: baseline to 2 weeks, 2–6 weeks, and 6 weeks to 6 months). Most patients in all treatment groups had 2-point or greater reductions in most severe pain by 6 months. The greatest mean pain reduction occurred in the first 2 weeks, with no apparent differences between groups at this point. On average, patients in the medical care-only group improved less than patients in the other groups from base-

Table 2. Frequency Distributions (in percent) and/or Means (Standard Deviations [SDs]) and Medians of Baseline Low-Back Pain Variables, by Treatment Group* (n = 681)

Variable	Category	Treatment Group				Total
		DC (n = 169)	DCPm (n = 172)	MD (n = 170)	MDPt (n = 170)	
Duration of back-pain episode	<3 weeks	21.9	30.2	27.1	25.3	26.1
	3 weeks–3 months	17.8	13.4	17.1	14.1	15.6
	3 months–1 year	14.8	12.8	7.1	11.8	11.6
	>1 year	45.6	43.6	48.8	48.8	46.7
Roland-Morris Disability score (0–24 scale)	≤5	22.5	13.4	20.0	14.1	17.5
	6–10	33.1	35.5	31.2	26.5	31.6
	11–15	23.7	28.5	27.6	31.8	27.9
	>15	20.7	22.7	21.2	27.6	23.1
	Mean (SD)	10.3 (5.6)	11.3 (5.0)	10.5 (5.6)	11.7 (5.4)	10.9 (5.4)
	Median	9	11	10	12	11
Most severe low-back pain (past week, 0–10 scale)	Mean (SD)	6.5 (2.0)	6.7 (2.1)	6.5 (2.2)	7.0 (2.1)	6.7 (2.1)
	Median	7	7	7	7	7
Average low-back pain (past week, 0–10 scale)	Mean (SD)	4.5 (1.9)	4.7 (1.8)	4.4 (1.9)	4.9 (2.0)	4.6 (1.9)
	Median	4	5	5	5	5
Cut-down days due to low-back pain (past month)	Mean (SD)	6.3 (7.4)	7.5 (8.0)	6.2 (8.0)	7.4 (8.4)	6.9 (8.0)
	Median	4	5	3	5	4
	>0 days (%)	74.4	80.8	74.1	78.2	76.9
Bed days due to low-back pain (past month)	Mean (SD)	0.7 (1.5)	0.8 (2.5)	1.0 (3.5)	1.2 (3.0)	0.9 (2.7)
	Median	0	0	0	0	0
	>0 days (%)	24.4	19.8	22.6	31.2	24.5
Over the counter pain medication use (past week)	Yes	77.5	80.8	80.6	78.2	79.3
	No	22.5	19.2	19.4	21.8	20.7
Prescription pain medication use (past six months)	Yes	18.3	27.3	20.6	24.1	22.6
	No	81.7	72.7	79.4	75.9	77.4
Leg pain below the knee (past week)	Yes	34.9	33.1	32.9	35.9	34.2
	No	65.1	66.9	67.1	64.1	65.8
Most severe leg pain (past week, 0–10 scale)	Mean (SD)	5.4 (2.9)	6.3 (2.6)	5.5 (2.8)	6.5 (2.4)	5.9 (2.7)
	Median	5	7	5.5	7	6
Average leg pain (past week, 0–10 scale)	Mean (SD)	3.9 (2.4)	4.6 (2.2)	3.5 (2.4)	5.0 (2.3)	4.3 (2.4)
	Median	4	4	3	5	4
History of previous low-back pain episodes	Yes	84.0	83.7	81.8	79.4	82.2
	No	16.0	16.3	18.2	20.6	17.8
History of traumatic back injury	Yes	28.4	24.4	25.3	31.2	27.3
	No	71.6	75.1	74.7	68.8	72.7
History of previous low-back pain treatment	Yes	73.4	83.7	78.8	77.6	78.4
	No	26.6	16.3	21.2	22.4	21.6

* DC = chiropractic care only; DCPm = chiropractic care with physical modalities; MD = medical care only; and MDPt = medical care with physical therapy.

line to 6 weeks and 6 months, but the differences are clinically insignificant.

At all follow-up assessments, the physical therapy and physical modalities groups had the largest mean reductions from baseline in average and most severe low back pain; however, there are no clinically meaningful differences between any of the groups (Figures 2 and 3; Table 4). Compared with medical care-only patients, physical therapy patients had a 20% to 30% greater risk at 6 weeks and 6 months of a 2-point or more reduction in most severe pain and in average pain. Although the risk of a 2-point or more reduction in average pain is more than a third greater in the physical modalities group (*vs.* chiropractic care only) at 2 and 6 weeks, the earlier positive effect disappears at 6 months (Table 5).

Low Back Pain Disability. The mean reduction in Roland-Morris Disability score from baseline is greater than 2 points at 6 weeks and greater than 3 points at 6 months in all treatment groups ($P < 0.001$ for the time trend in mean disability score in each follow-up interval: baseline

to 2 weeks, 2–6 weeks, and 6 weeks to 6 months). Mean reductions in disability were greatest during the first 2 weeks in all groups except physical therapy, which had the greatest disability reduction between 6 weeks and 6 months (Figure 4). At the 2- and 6-week follow-up assessments, all groups had similar mean reductions in disability, whereas at 6 months, the medical care with physical therapy group had the largest mean disability score reduction. Compared with the medical care-only group, the estimated risk of improving by 3 points or more is almost 30% greater in the physical therapy group at 6 months (Table 5).

Medication Use and Disability Days. At the 2- and 6-week follow-up assessments, patients in the medical care groups were much more likely to report prescription pain medication use than were patients in the chiropractic groups (69% *vs.* 15% at 2 weeks; 46% *vs.* 16% at 6 weeks). The difference is less pronounced at 6 months (32% *vs.* 24%). Nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and narcotic analgesics

Table 3. Mean (Standard Deviation [SD]) and Median Number of Low-Back Pain Visits, and Percent of Subjects with at Least One Visit to Each Type of Provider, by Followup Interval and Treatment Group

Followup Interval	Variable	Treatment Group*			
		DC† (n = 163)	DCPm‡ (n = 163)	MD§ (n = 162)	MDPt¶ (n = 167)
Baseline to 6 weeks	Number of back-related visits				
	Mean (SD)	3.2 (1.5)	3.7 (1.7)	1.7 (1.1)	3.7 (2.7)
	Median	3	4	1	3
	Range	0–8	1–10	1–8	1–13
	Percent with 1+ medical visits	22.7	20.3	98.8	100.0
Baseline to 6 months	Percent with 1+ chiropractic visits	99.4	98.2	9.3	5.4
	Percent with 1+ physical therapy visits	0.0	0.6	2.5	64.1
	Number of back-related visits				
Baseline to 6 weeks	Mean (SD)	5.3 (3.8)	5.7 (3.3)	2.9 (3.3)	5.4 (4.6)
	Median	4	5	2	4
	Range	0–21	1–18	1–23	1–21
	Percent with 1+ medical visits	36.2	32.5	98.8	100.0
	Percent with 1+ chiropractic visits	99.4	98.2	19.1	10.8
Baseline to 6 months	Percent with 1+ physical therapy visits	3.7	1.8	4.9	68.3

† n = 163 because of missing visit data on 6 subjects in the DC group.

‡ n = 163 because of missing visit data on 9 subjects in the DCPm group.

§ n = 162 because of missing visit data on 8 subjects in the MD group.

¶ n = 167 because of missing visit data on 3 subjects in the MDPt group.

* DC = chiropractic care without physical modalities; DCPm = chiropractic care with physical modalities; MD = medical care without physical therapy; MDPt = medical care with physical therapy.

were the types of medications most frequently prescribed. Chiropractic patients were somewhat more likely than medical care patients to report over-the-counter pain medication use at each follow-up assess-

ment (58% vs. 50% at 2 weeks; 56% vs. 51% at 6 weeks; and 56% vs. 49% at 6 months). There were no statistically discernible differences in reported medication use either between medical care with and without

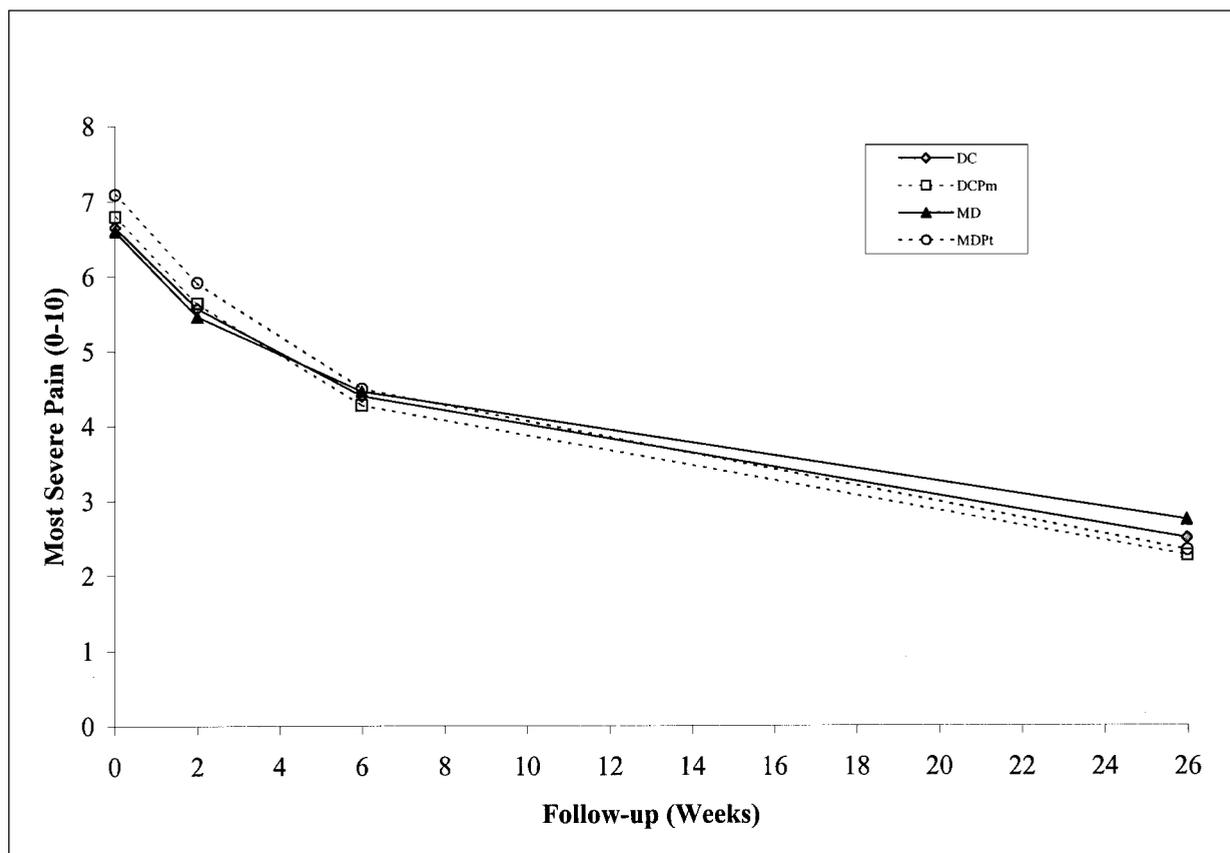


Figure 2. Mean level of most severe pain (0–10 scale) in the past week, by follow-up assessment and treatment group: results from a mixed effects linear model with age, sex, and low-back pain episode duration included as covariates.

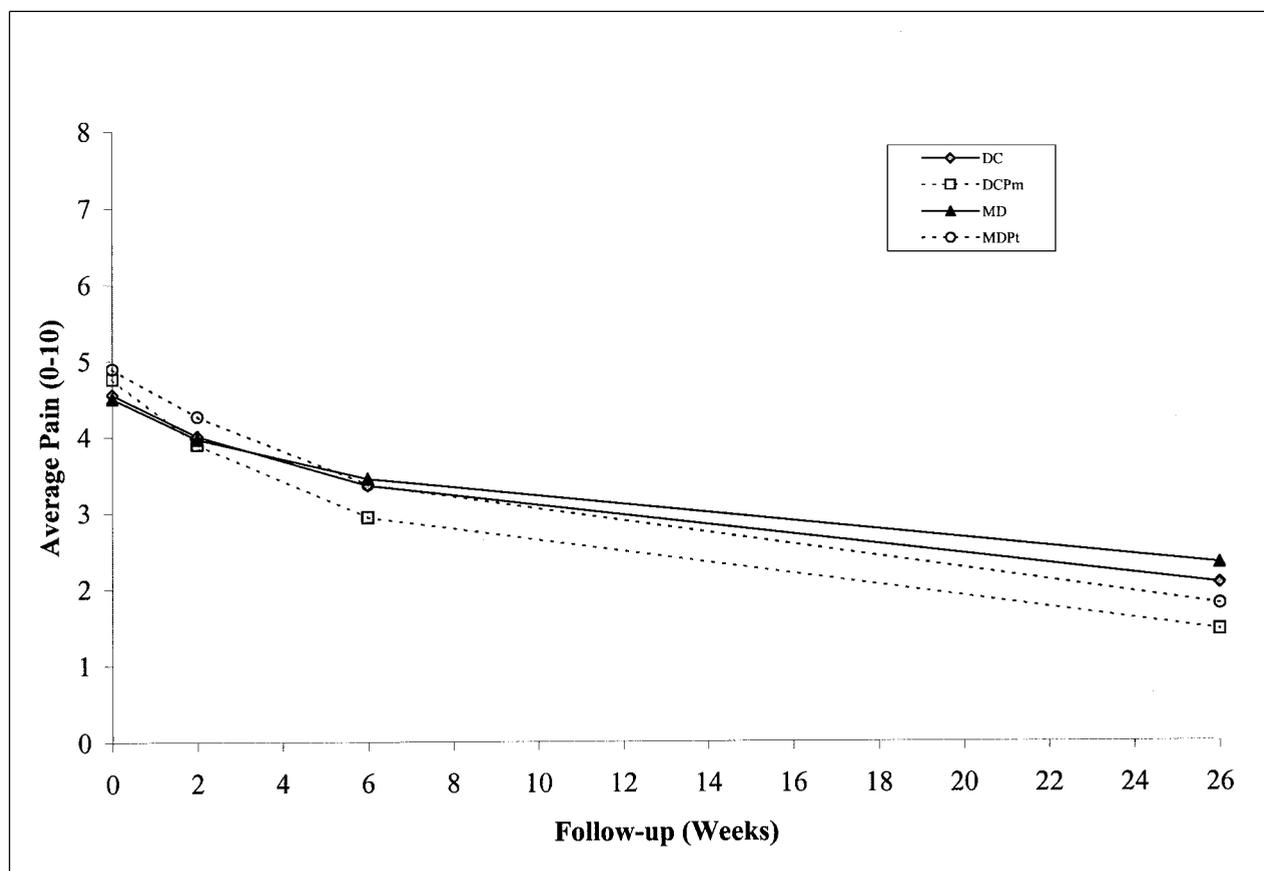


Figure 3. Mean level of average pain (0–10 scale) in the past week, by follow-up assessment and treatment group: results from a mixed effect linear model with age, sex, and low-back pain episode duration included as covariates.

physical therapy or between chiropractic care with and without physical modalities.

The numbers of cut-down days and bed days resulting from low back pain were not appreciably different between the treatment groups at any of the follow-up assessments. No known study-related adverse events requiring institutional review board notification were experienced by patients in any of the treatment groups.

Discussion

This is the first randomized clinical trial to address the relative effectiveness of primary medical *versus* chiropractic care and the effectiveness of physical therapy or physical modalities for patients with low back pain within a managed care practice setting with salaried providers. Medical and chiropractic care without physical

Table 4. Estimated Effects by Followup Interval and Treatment Contrast of DC vs. MD, MDPt vs. MD, and DCPm vs. DC on Most Severe Pain and Average Pain Intensity in the Past Week and in Disability Score from Baseline to Each Followup Assessment: Results of Ordinary Least Squares Regression Analyses

Followup Interval	Treatment Contrast	Most Severe Pain		Average Pain		Disability Score	
		Mean Difference*	95% CI	Mean Difference*	95% CI	Mean Difference*	95% CI
0–2 weeks	DC vs. MD	–0.02	–0.47, 0.43	0.00	–0.37, 0.37	0.21	–0.69, 1.11
	MDPt vs. MD	–0.18	–0.63, 0.27	–0.08	–0.45, 0.29	0.18	–0.72, 1.08
	DCPm vs. DC	–0.07	–0.52, 0.38	0.17	–0.20, 0.54	0.36	–0.54, 1.26
0–6 weeks	DC vs. MD	0.33	–0.20, 0.86	0.22	–0.21, 0.65	0.57	–0.43, 1.57
	MDPt vs. MD	0.34	–0.19, 0.87	0.35	–0.08, 0.78	0.06	–0.94, 1.06
	DCPm vs. DC	0.13	–0.40, 0.66	0.31	–0.12, 0.74	0.00	–1.00, 1.00
0–6 months	DC vs. MD	0.27	–0.32, 0.86	0.22	–0.25, 0.69	0.75	–0.29, 1.79
	MDPt vs. MD	0.27	–0.34, 0.88	0.35	–0.12, 0.82	1.26	0.20, 2.32
	DCPm vs. DC	–0.02	–0.63, 0.59	0.10	–0.37, 0.57	–0.78	–1.82, 0.26

* Estimated effects (mean differences in improvement and 95% confidence intervals [CIs]) adjusted for age, sex, low-back pain episode duration, and baseline value of the outcome measure. Positive values indicate more improvement in the first treatment group listed in each treatment contrast. DC = chiropractic care only; MD = medical care only; MDPt = medical care with physical therapy; DCPm = chiropractic care with physical modalities.

Table 5. Estimated Effects by Followup Interval and Treatment Contrast of DC vs. MD, MDPt vs. MD, and DCPm vs. DC on 2+ Point Reductions in Most Severe Pain and Average Pain Intensity in the Past Week, and on 3+ Point Reduction in Disability Score from Baseline to Each Followup Assessment: Results of Logistic Regression Analyses

Followup Interval	Treatment Contrast	Most Severe Pain		Average Pain		Disability Score	
		RR*	95% CI	RR*	95% CI	RR*	95% CI
0-2 weeks	DC vs. MD†	0.95	0.69, 1.31	0.79	0.51, 1.22	1.08	0.77, 1.53
	MDPt vs. MD†	0.85	0.61, 1.19	0.76	0.49, 1.18	1.01	0.71, 1.43
	DCPm vs. DC†	0.96	0.69, 1.33	1.42	0.93, 2.16	1.05	0.75, 1.46
0-6 weeks	DC vs. MD†	1.18	0.87, 1.60	1.09	0.75, 1.59	1.10	0.82, 1.48
	MDPt vs. MD†	1.26	0.93, 1.70	1.28	0.89, 1.84	1.06	0.79, 1.43
	DCPm vs. DC†	1.11	0.84, 1.47	1.35	0.95, 1.90	1.15	0.88, 1.51
0-6 months	DC vs. MD†	1.18	0.91, 1.53	1.15	0.84, 1.59	1.17	0.90, 1.50
	MDPt vs. MD†	1.20	0.92, 1.56	1.25	0.91, 1.72	1.28	0.99, 1.64
	DCPm vs. DC†	0.90	0.69, 1.16	0.98	0.71, 1.34	0.88	0.68, 1.13

* Estimated effects (adjusted risk ratios [RRs] and 95% confidence intervals [CIs]) adjusted for age, sex, low-back pain episode duration, and baseline value of the outcome measure.

† Reference group. DC = chiropractic care only; MD = medical care only; MDPt = medical care with physical therapy; DCPm = chiropractic care with physical modalities.

therapy or physical modalities yielded similar improvements in pain severity and disability after 6 months of follow-up. Physical therapy appears to be more effective than medical care alone for reducing disability in some patients after 6 months, but the magnitude of this possible benefit is not large. Overall, there are only small differences in low back pain outcomes between the treat-

ment groups in this population of largely subacute and chronic pain patients.

Our study is one of many in recent years to compare various treatment approaches for patients with low back pain. The authors of review papers and treatment guidelines have concluded that acetaminophen,^{5,14} NSAIDs,^{5,11,14,28,49} muscle relaxants,^{11,49} conditioning exercises and certain aerobic

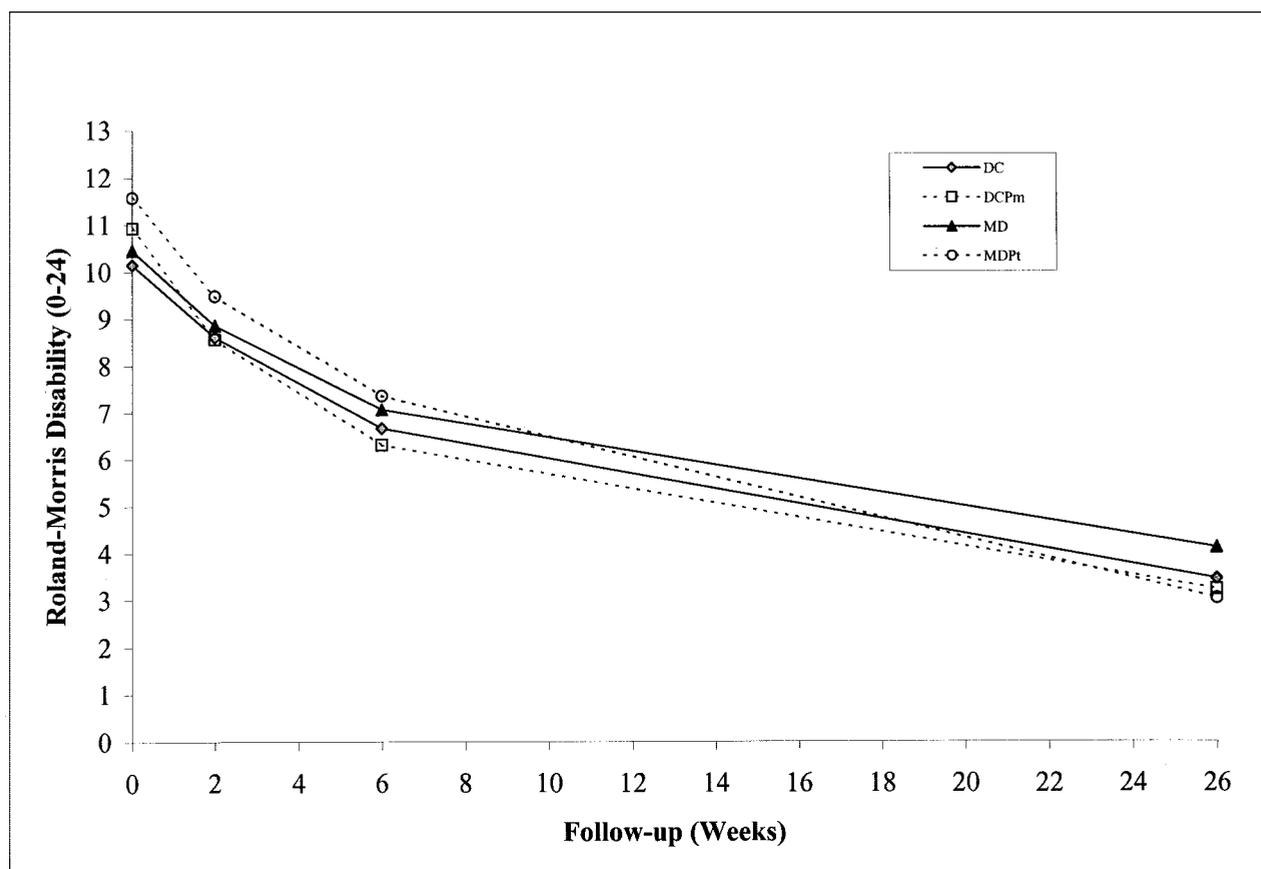


Figure 4. Mean level of low-back-pain related disability (0-24 Roland-Morris scale), by follow-up assessment and treatment group: results from a mixed effects linear model with age, sex, and low-back pain episode duration included as covariates.

activities,⁵ and spinal manipulation^{5,40} may provide short-term benefit for patients with acute low back pain; NSAIDs,⁴⁹ exercise therapy,^{19,49} and spinal manipulation⁴⁹ may be of some benefit for patients with chronic low back pain. There is little evidence to support the use of bedrest for acute pain^{5,49} or physical agents or modalities for acute^{5,36,49} or chronic low back pain.^{36,49} Adverse reactions are much more frequent in patients taking medications than in patients receiving nonmedication comparison treatments.^{5,11,28} Side effects and complications resulting from spinal manipulation for low back pain are extremely rare.^{2,3,40}

Four randomized controlled trials have compared chiropractic with physical therapy for low back pain. No clinically significant differences in outcomes between chiropractic and hospital outpatient care were found in the Meade et al^{32,33} trial. Postacchini et al³⁸ concluded that acute pain patients were better with chiropractic at 3 weeks; chronic patients were better with physical therapy at 3 weeks; and there were no differences between groups at 6 months. Skargren et al^{42,43} reported no differences between chiropractic and physical therapy patients at 6 months or 1 year in terms of pain, function, cost, or sick leave, although chiropractic was slightly more favorable for patients with episodes of less than a week and physical therapy more favorable for patients with episodes of more than a month. Cherkin et al⁹ reported no differences between chiropractic and McKenzie physical therapy groups during 2 years of follow-up in terms of pain and disability, and these groups had only slightly better outcomes and much greater costs than did patients in the control group receiving only an educational booklet.

A recent randomized clinical trial comparing osteopathic care with standard medical care in a managed care setting found equivalent pain and disability outcomes among patients with subacute (3 weeks to 6 months) low back pain after 12 weeks of care, but there was greater prescription medication use in the medical care group.¹ The authors of a well-designed observational study concluded that among patients with low back pain of less than 10 weeks' duration seen by primary care physicians, chiropractors, and orthopedic surgeons, pain and functional status outcomes were similar at 6 months, and costs were higher for patients of orthopedic surgeons and chiropractors.⁸

The findings from prior studies are consistent with our results showing relatively small differences between medical, chiropractic, and physical therapy care. The slightly better 6-month disability outcomes observed for physical therapy patients in our study are consistent with findings reported recently from physical therapy intervention studies for subacute and chronic low back pain. An intervention with physical therapist-led exercise classes was found to be more effective than primary medical care for patients with subacute low back pain after 6 and 12 months.³⁴ In patients with chronic pain, physical therapy and medically supervised exercise were found to be bet-

ter than unsupervised exercise in terms of pain intensity, functional status, and cost per sick day after 12 months following 3 months of therapy in Norway.⁴⁸ The greater value of supervised exercise for patients with chronic low back pain is also supported by another recent trial that followed patients for 2 years.²¹ Because many of the medical care with physical therapy patients in our study did not receive physical therapy, the intention-to-treat analysis may have underestimated the magnitude of this effect.

Because our study was conducted within one managed care organization, generalization of our findings to patients in other settings should be viewed with caution. Medical providers, chiropractors, and physical therapists outside this network may differ in their approaches to low back pain care; and patients under fee-for-service, workers' compensation, personal injury, and other reimbursement models may differ in ways that affect treatment outcomes. Also, patients who chose not to be randomly assigned may differ from participants on factors that modify treatment effects. Nevertheless, our study population is similar to other outpatient low back pain populations in terms of average baseline level of back pain^{9,29,30} and baseline level of disability resulting from back pain.^{7,29,39,44,47} However, differences on other unmeasured factors and treatment effects that may be relatively larger in certain patient subgroups could potentially limit the study's generalizability.

Chiropractors at the study site use the same general type of spinal manipulation taught in most chiropractic schools and used by most chiropractors in the United States.^{10,12} The medical providers prescribe NSAIDs, muscle relaxants, and narcotic analgesics, which is the typical treatment approach used by primary care physicians for patients with low back pain.^{11,14} The physical therapists emphasize therapeutic exercise and other active care strategies, rather than passive methods that are de-emphasized in modern physical therapy training and practice.²² The active approach used by the physical therapy staff may be responsible for the relatively better 6-month disability outcomes experienced by the physical therapy patients. Findings from a national network of physical therapy practices showed that the combination of modalities and exercise is the most frequently used treatment strategy for patients with lumbar impairments.²⁷ Although this study also showed managed care and fee-for-service reimbursement do not appreciably affect utilization patterns,²⁷ an earlier survey of physical therapists demonstrated differences in treatment preferences and visit frequency by practice setting.⁴

■ Conclusions

Medical and chiropractic care without physical therapy or physical modalities yielded similar improvements in pain severity and disability after 6 months of follow-up. The findings suggest that physical therapy patients may have greater reductions in disability, on average, than do patients in the medical care-only group from 6 weeks to

6 months, resulting in relatively better 6-month disability outcomes; however, these small differences may be chance findings and may not persist with continued follow-up. Assessment of the costs and potential risks associated with each treatment strategy would be helpful in more fully understanding the roles of medical providers, chiropractors, and physical therapists in the treatment of low back pain.

■ Key Points

- A randomized clinical trial was conducted among low back pain patients to compare the effectiveness of medical and chiropractic care; to assess the effectiveness of physical therapy among medical patients; and to assess the effectiveness of physical modalities among chiropractic patients.
- Six hundred eighty-one patients presenting to a managed care facility were randomly assigned to medical care with and without physical therapy and chiropractic care with and without physical modalities; 95.7% were followed up through 6 months.
- Medical and chiropractic care without physical therapy or physical modalities yielded similar improvements in pain severity and disability after 6 months of follow-up. Physical therapy appears to be more effective than medical care alone for reducing disability in some patients, but the magnitude of this possible benefit is minimal.
- Overall, there are only small differences in low back pain outcomes between the treatment groups in this population of largely subacute and chronic pain patients.

Acknowledgments

We thank Friendly Hills HealthCare Network's executive officers for their initial interest, support, and commitment of resources; Gary Pirnat, former chairman of chiropractic services and manager of rehabilitation services, as well as the medical, chiropractic, and physical therapy providers for their cooperation during the study; and the clinic management teams from La Habra, Brea, and Buena Park and their front office help and health information personnel for their help with patient enrollment. We also wish to acknowledge UCLA personnel Karen Hemmerling and Stan Ewald for coordinating patient recruitment and follow-up efforts; Emerlinda Gonzalez and Silvia Sanz for assistance with patient enrollment and tracking; and He-Jing Wang for providing data management services at UCLA.

This study was funded by grants from the Agency for Healthcare Research and Quality (AHRQ) (R01 HS07755) and the Southern California University of Health Sciences. Dr. Hurwitz was supported by a grant from the National Center for Complementary and Alternative Medicine (NCCAM) (K23 AT00055).

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