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Chronic Spinal Pain

A Randomized Clinical Trial Comparing Medication, Acupuncture, and Spinal Manipulation

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Study Design. A randomized controlled clinical trial was conducted.

Objective. To compare medication, needle acupuncture, and spinal manipulation for managing chronic (>13 weeks duration) spinal pain because the value of medicinal and popular forms of alternative care for chronic spinal pain syndromes is uncertain.

Summary of Background Data. Between February 1999 and October 2001, 115 patients without contraindication for the three treatment regimens were enrolled at the public hospital's multidisciplinary spinal pain unit.

Methods. One of three separate intervention protocols was used: medication, needle acupuncture, or chiropractic spinal manipulation. Patients were assessed before treatment by a sports medical physician for exclusion criteria and by a research assistant using the Oswestry Back Pain Disability Index (Oswestry), the Neck Disability Index (NDI), the Short-Form-36 Health Survey questionnaire (SF-36), visual analog scales (VAS) of pain intensity and ranges of movement. These instruments were administered again at 2, 5, and 9 weeks after the beginning of treatment.

Results. Randomization proved to be successful. The highest proportion of early (asymptomatic status) recovery was found for manipulation (27.3%), followed by acupuncture (9.4%) and medication (5%). Manipulation achieved the best overall results, with improvements of 50% ($P = 0.01$) on the Oswestry scale, 38% ($P = 0.08$) on the NDI, 47% ($P < 0.001$) on the SF-36, and 50% ($P < 0.01$) on the VAS for back pain, 38% ($P < 0.001$) for lumbar standing flexion, 20% ($P < 0.001$) for lumbar sitting flexion, 25% ($P = 0.1$) for cervical sitting flexion, and 18% ($P = 0.02$) for cervical sitting extension. However, on the VAS for neck pain, acupuncture showed a better result than manipulation (50% *vs* 42%).

Conclusions. The consistency of the results provides, despite some discussed shortcomings of this study, evidence that in patients with chronic spinal pain, manipulation, if not contraindicated, results in greater short-term improvement than acupuncture or medication. However, the data do not strongly support the use of only manipulation, only acupuncture, or only nonsteroidal antiinflammatory drugs for the treatment of chronic spinal pain. The results from this exploratory study need confirmation from future larger studies. Key words: acupuncture, chiropractic spinal manipulation, clinical trial, medicine, spine] **Spine 2003;28:1490–1503**

A pathologic cause cannot be identified for most episodes of spinal pain,[66] and clinicians often have great difficulty establishing the underlying cause.[46] Only about 15% of patients receive a definitive diagnosis[45] because it often is impossible to reach specific diagnosis.[17] However, numerous studies have shown that patients with low back pain do exhibit abnormal spinal motion.[19,44,65] Psychosocial factors, ambiguous diagnoses, and lack of a clearly superior treatment have complicated the management of patients with chronic low back pain.[43] Similar difficulties are encountered in cases of neck and thoracic spine pain.

The proportion of primary care patients with uncomplicated spinal pain who have poor outcomes appears to be higher than generally recognized,[12] and the financial and resource implications of low back pain alone are extensive.[35,56] For example, the direct cost of medical examinations and therapies to the Australian community in 1993–1994 for low back pain was US$390 million, whereas neck pain cost approximately A$94 million.[53] The direct costs in Western countries for back pain were as follows: US$251.9 million for Finland in 1995[80] and US$24.3 billion for the United States in 1990.[28] Direct and indirect costs for spinal pain account for 0.8% to 2.1% of the gross domestic product in industrialized countries.[36] Much literature has emphasized acute low back pain[15,61,69,94] and chronic low back pain,[7,52,62,79] as compared with neck and thoracic spine pain.

Various attempts using randomized clinical trials (RCT) have been made to describe the effectiveness of medication, acupuncture, and spinal manipulation in helping patients with chronic spinal pain syndrome. However, the study design used for these RCTs has not enabled a definitive conclusion to be drawn in many cases, although the RCT is regarded as the most important instrument.[5,16] For example, Andersson *et al*[2] investigated the effect of one or more standard medical therapies as well as osteopathic spinal manipulation in 20- to 59-year-old patients with low back pain of at least 3 weeks but less than 6 months duration. These authors concluded that osteopathic manual care and standard

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medical care had similar clinical results in patients with subacute low back pain. However, no mention was made of radiologic investigation used to examine osseous spinal structures. Much effort has been expended to compare chiropractic spinal manipulation with physical therapy or an educational booklet.[11] However, because not all the studied patients underwent imaging, the authors were unable to say whether anomalies or various degenerative or pathologic changes were present or equally distributed among the treatment groups. Nonetheless, they concluded that the McKenzie method of physical therapy and chiropractic spinal manipulation provided only marginally better outcomes than the use of an educational booklet.

Another difficulty with the literature is that it does not consistently distinguish acute, subacute, and chronic low back pain or the duration defining each.[94] Some authors have defined acute as a 1- to 14-day episode,[27,49,67,96] whereas Carey *et al*[10] extend acute to episodes of "less than 10 weeks duration." More recently, Skouen *et al*[79] has suggested the following time frames for spinal pain: acute (<28 days duration), subacute (4–12 weeks duration), and chronic (>12 weeks duration). Thus a RCT study, in addition to describing the treatment method, should clearly define the duration of the spinal pain syndrome and report whether radiologic investigations were performed for all patients.

The literature on the efficacy and effectiveness of medication, acupuncture and spinal manipulation for chronic uncomplicated spinal pain syndrome treatment suggests the following concepts.

Medication

Patients with chronic spinal pain syndrome who repeatedly seek medical care report many unmet needs and expectations.[58] Furthermore, the possible adverse reactions to nonsteroidal antiinflammatory (NSAID) medication have been well documented.[71,73,76] Gastrointestinal toxicity induced by NSAIDs is one of the most common serious adverse drug events in the industrialized world.[48] The newer COX-2-selective NSAIDs are less than perfect, so it is imperative that contraindications be respected.[61] This is particularly noteworthy because there still is insufficient evidence for the use of NSAIDs to manage chronic low back pain, although they may be somewhat effective for short-term symptomatic relief.[90] In an observational study of patients with low back pain, Cherkin *et al*[14] found that patients prescribed medications, particularly muscle relaxants, reported less severe symptoms after 1 week than those receiving no medications. These authors concluded that randomized trials are needed to determine which medication or combination of medications is most effective.

Acupuncture

Smith *et al*[81] could not find any convincing evidence for using acupuncture to manage spinal pain, whereas Ezzo *et al*[24] found inconclusive evidence that acupuncture is more effective than placebo, sham acupuncture, or standard medical care. Furthermore, Cherkin *et al*[13] found traditional Chinese medical acupuncture to be relatively ineffective for chronic low back pain. These authors identified 20- to 70-year-old patients with low back pain who had visited a primary physician 6 weeks previously for low back pain. However, it does not appear that they examined all patients radiologically or had standardized medical diagnosis before randomization after a telephone call asking questions about "baseline data." In a systematic review and metaanalysis of 12 studies meeting inclusion and exclusion criteria, Ernst[21] concluded that reasonably good evidence supports the use of acupuncture for low back pain. However, Ernst[21] could not reach a definitive conclusion for the treatment of neck pain, although Ernst and White[23] had found that acupuncture is superior to various control interventions despite insufficient evidence to state whether it is superior to placebo. Irnich *et al*[41] found that acupuncture did help neck pain in the short term. In a paper summarizing the research evidence for the effectiveness of acupuncture, Vickers *et al*[93] concluded that current levels of evidence from RCTs of acupuncture for chronic spinal pain probably are sufficient to justify this practice.

Spinal Manipulation

Shekelle *et al*[78] concluded that although spinal manipulation is of short-term benefit for some patients with uncomplicated acute low back pain, insufficient data are available concerning the efficacy of spinal manipulation for chronic low back pain. In a study comparing the relative efficacy of spinal manipulation combined with trunk exercise or NSAID therapy combined with trunk exercise for chronic low back pain, Bronfort *et al*[7] concluded that all three therapeutic regimens were associated with similar and clinically important improvement over time that was considered superior to the expected natural history of longstanding low back pain. McMorland and Suter[57] found that spinal manipulation was beneficial for the treatment of neck and low back pain, although their study design did not account for the natural history of such pain. In a literature search to assess the evidence for the efficacy of cervical spine manipulation in the treatment of neck pain and headache, Hurwitz *et al*[39] concluded that cervical spine manipulation and mobilization probably provide at least short-term benefits for some patients with neck pain and headaches. Spinal manipulation was found to be favorably comparable with medical care in terms of long-term low back pain and disability outcomes,[64] and patients undergoing chiropractic treatment showed greater improvement and satisfaction at 1 month than patients treated by family physicians.[62] Stig *et al*[84] concluded that a large group of chiropractic patients with relatively long-lasting or recurrent low back pain reported "improvement" early in the course of treatment. The Meade *et al*[59,60] trial, proclaimed to be "one of the better trials in this field,"[3] showed that when chiropractors and hospital therapists treat patients with low back pain as they would in day-

to-day practice, those treated by chiropractic practice derive more benefit and long-term satisfaction. The Meade *et al*[59,60] trial was a "pragmatic" efficacy trial that tested what happens in day-to-day practice. In this trial, the details of the type, frequency, and duration of intervention were at the discretion of the treating clinician. Furthermore, studies such as those by Shekelle *et al*[77] and Manga *et al*[50] provide extensive literature overviews concerning the effectiveness of manipulation in managing mechanical spinal pain syndromes. Moreover, manipulation is considered useful for treating intervertebral joint lesions in general and has proved to be effective treatment for low back pain.[4,47]

Ernst and Pittler[22] found that expert opinion favors the effectiveness of osteopathy and chiropractic for acute uncomplicated low back pain and judged acupuncture to be of some value for chronic uncomplicated low back pain. In a pilot study to determine the feasibility of a RCT restricting treatment interventions to medication, acupuncture, or spinal manipulation in patients with chronic (>13 weeks duration) spinal pain syndrome, Giles and Muller[31] concluded that despite several discussed study shortcomings, the findings showed that spinal manipulation, if not contraindicated, results in greater improvement than acupuncture or medicine.

According to Gerster,[30] the assessment of therapy for low back pain using drugs (NSAIDs), locally injected corticosteroids, active physical therapy, back school, and chiropractic is difficult because clinical symptoms and signs are nonspecific and there is no good correlation of clinical signs with radiologic images. The high incidence of chronic spinal pain, its recurrent nature in many patients, and its contribution as a main cause of absence from work are documented beyond dispute.[59] It also is not disputed that long-term evaluation of treatment modality by medical and chiropractic physicians suggests that chronic low back pain is persistent and difficult to treat for both provider types.[63]

Thus, there still is sparse conclusive knowledge about the absolute and relative efficacy (*i.e.,* "scientific" or quantitative outcomes) and effectiveness (*i.e.,* "naturalistic" or qualitative outcomes) of different interventions for chronic spinal pain syndromes, although Giles *et al*[32] found a very high level of patient satisfaction with a multidisciplinary team approach to spinal pain syndromes. It should be noted that in addition to providing clinically meaningful care, managed care organizations are interested in providing care that is acceptable to their enrollees, and that this has greatly increased the importance of patient satisfaction as an outcome.[34]

From the preceding discussion, it is clear that a RCT must be very carefully standardized if any meaningful efficacy result is to be achieved when different therapies are compared.

Objectives

To assess the comparative efficacy of common treatment regimens, a controlled randomized clinical trial was conducted at the multidisciplinary spinal pain outpatient unit (MSPU) in an Australian public hospital that. Although based on the pilot study of Giles and Muller,[31] this RCT was greatly expanded and different. The study objective included more subjective questionnaires, a wide range of objective measurements (*vs* none in the pilot study), needle acupuncture alone (*i.e.,* without the low-volt electrical stimulation used in the pilot study), three types of medication (*vs* only one in the pilot study), and a different and larger group of patients for further evaluation of these treatment types. This "fastidious"[59] efficacy trial compared three separate interventions: medication, needle acupuncture, and spinal manipulation.

Ethical Approval

Ethical approval was granted by the Townsville Hospital's Northern Regional Health Authority's Ethics Committee (Reference 32/94).

■ Materials and Methods

Study Protocol. A randomized controlled clinical trial was conducted at the hospital's outpatient MSPU from February 1, 1999 to October 10, 2001 in cooperation with medical and other health practitioners who referred patients. Patients also were allowed to self-refer. Patients initially consulted the unit's sports medicine physician to receive a diagnostic workup, and to determine whether they met the inclusion criteria. Patients were included in the study if they had experienced uncomplicated (*i.e.,* mechanical) spinal pain syndrome for a minimum of 13 weeks and were at least 17 years of age. Subjects were excluded if they had nerve root involvement, spinal anomalies other than sacralization or lumbarization, pathology other than mild to moderate osteoarthrosis, spondylolisthesis of L5 on S1 exceeding Grade 1, previous spinal surgery, and leg length inequality greater then 9 mm with postural scoliosis. The patients were asked to complete a questionnaire requesting sociodemographic data and asking whether they were involved in pending litigation regarding their spinal pain. The recruitment and follow-up procedures are detailed in Figure 1.

Assignment. After informed written consent had been obtained, the patients were randomized in a balanced way. Each patient drew a sealed envelope from a box with 150 well-shuffled envelopes containing one of three possible treatment codes so that an efficacy comparison could be made between three active treatments: medication, needle acupuncture, and spinal manipulation. Each treatment acted as a control for the others.[37] This RCT did not include a group of untreated patients because placebo-controlled trials are considered unethical,[20,51] and because patients with long-standing (*i.e.,* chronic, lasting longer than 13 weeks) spinal pain syndromes are unlikely to have a self-limiting condition. In addition, patients requesting aid must be protected.[82]

Intervention Regimens. Patients randomized to acupuncture or spinal manipulation first underwent a physical examination by their treating clinician to determine, at their discretion, which form acupuncture needle placement and needling would take place (using the "near and far" technique[85]), or what type

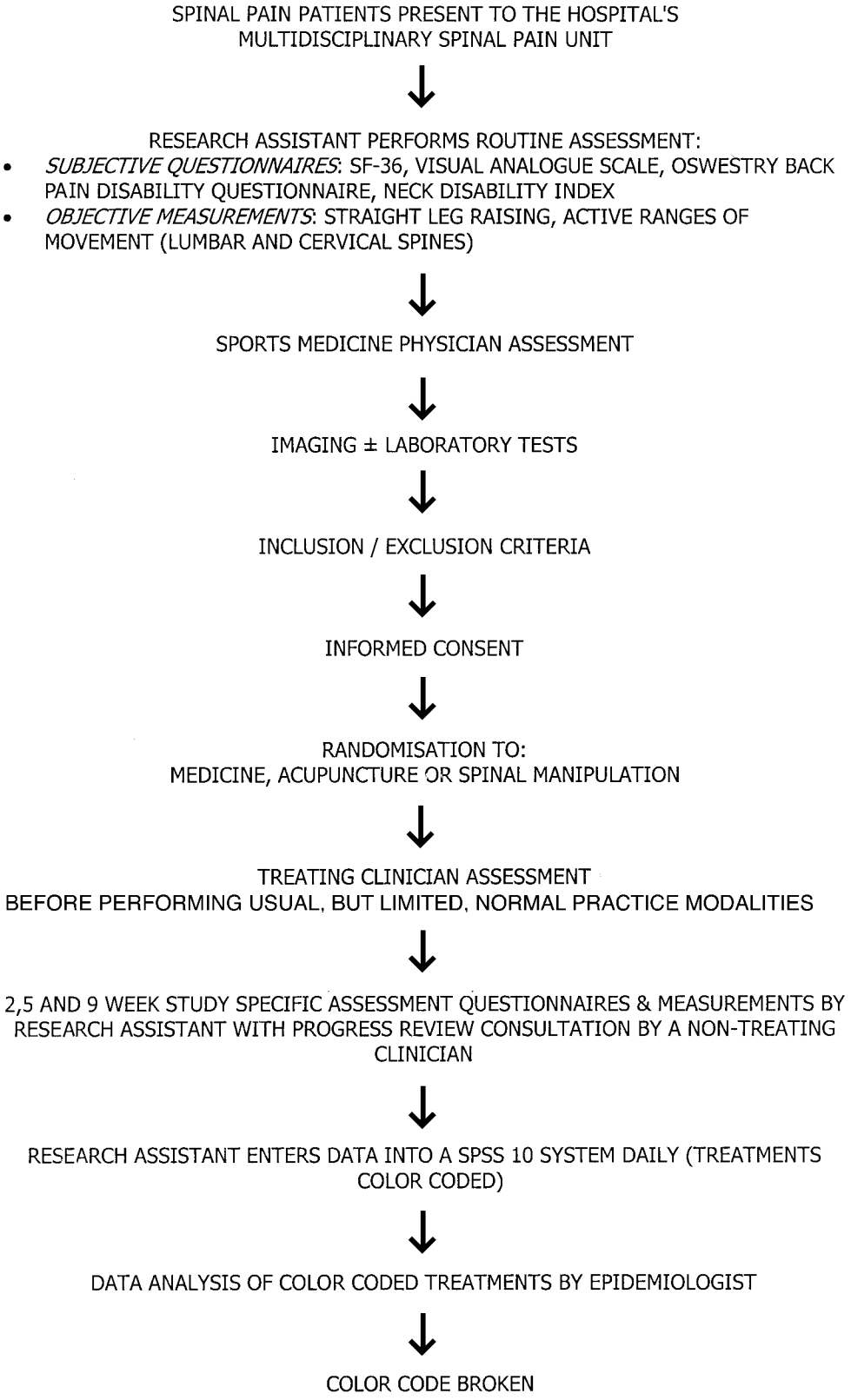

Figure 1. Recruitment and follow-up procedures.

of spinal manipulation would be performed to mobilize joints. Suitability for acupuncture and spinal manipulation was evaluated by the individual treating clinician applying examination criteria. This was followed by treatment, in which the participants practiced their everyday acupuncture or spinal manipulation such that the treatment would be generalizable outside the multidisciplinary spinal pain unit setting. However, only one therapeutic method was allowed: either needle acupuncture or spinal manipulation. Treatment times were standardized by arranging 20-minute appointments for all treatment visits to eliminate a potential placebo effect from different lengths of "exposure" to the clinician. At all the follow-up

visits, the patients were specifically asked about progress and any adverse reactions. They then were reassessed for appropriate ongoing treatment. Notes were made on the patient's chart by the acupuncturist or chiropractor at each visit. These procedures explain the 20-minute time requirement for each appointment.

Because all the patients had already tried some form of medication, it was necessary for the sports medicine practitioner to have a choice of three drugs, so a medication could be selected that had not already been tried by a patient randomized into the medication arm of the study. There was no point in again prescribing an ineffective drug. The patients randomized to medication normally were given Celebrex (200–400 mg/day) unless it had previously been tried. The next drug of choice was Vioxx (12.5–25 mg/day), followed by paracetamol (up to 4 g/day). Doses, left to the sports physician's discretion, were related particularly to the patient's weight, with the severity of symptoms playing a minor role. This enabled generalizability of medical treatment to normal practice outside the MDSPU setting, although it was restricted to a NSAID or to an analgesic. Because the patients randomized to medication had previously tried medication without success, an attempt was made to overcome lower expectation bias by telling them that a very promising "new" medication would be tried. The treating sports physician also was allocated 20 minutes for follow-up visits for the reasons described earlier in relation to other clinicians.

Random interviews of the patients were conducted by a nontreating clinician to determine whether the treating clinician's notes corresponded with the patient's impressions of the results up to the defined maximum of 9 weeks treatment.

Acupuncture was performed by one of two experienced acupuncturists using sterile HWATO Chinese disposable acupuncture guide tube needles (length, 50 mm; gauge, 0.25 mm) during 20-minute appointments. For each patient, 8 to 10 needles were placed in local paraspinal intramuscular maximum pain areas, and approximately 5 needles were placed in distal acupuncture point meridians according to the "near and far" technique (upper limb, lower limb, or scalp)[85] depending on the spinal pain syndrome being treated. Once patients could tolerate the needles satisfactorily, needle agitation was performed by turning or "flicking" the needles at approximately 5-minute intervals for 20 minutes. The needles were inserted to a length of 20 to 50 mm, depending on the depth of muscle bulk, in the maximum pain area, and up to approximately 5 mm in the distal points. Two treatments per week defined this intervention.

High-velocity, low-amplitude thrust spinal manipulation to a joint[8,59] was performed as judged to be safe and usual treatment by the treating chiropractor for the spinal level of involvement to mobilize the spinal joints. Two treatments per week defined this intervention.

Outcome Measures. The patients were assessed at four time points: at the initial visit and then at weeks 2, 5, and 9 after the initial treatment. All the outcome assessments were performed exclusively by the research assistant providing subjective questionnaires and performing objective measurements, except for an additional assessment for patients who experienced early recovery or an adverse reaction. Such additional assessment was performed by a nontreating clinician. The individual end point of the study was defined as either early recovery (symptoms no longer present at the week 2 or week 5 assessment) or the final assessment at week 9, whichever occurred earlier. It was not possible to blind the treating or nontreating clinicians.

For the subjective measurements, the following validated questionnaires were self-administered: the Oswestry Questionnaire[25] for low back and thoracic spine pain ("back" pain), the Neck Disability Index (NDI)[91] for neck pain, and the Short-Form-36 Health Survey questionnaire (SF-36).[72,95] The Oswestry and NDI questionnaires[25,91] have been well validated,[26,55,68] consist of 10 different items (*e.g.,* pain intensity, lifting, and traveling), and result in a disability percentage. If some single items are not answered, the overall score is computed from the available information.[25] The SF-36 questionnaire, a well-tested and established questionnaire[29] that fulfills stringent criteria of reliability and validity,[6,42] was used as a generic indicator of general health status.[55]

Visual analog scales (VAS),[40] as well-tested and established instruments,[54,75] were used to assess subjective pain intensity. The VAS pain scale consisted of a horizontal 10-cm line with the words "no pain" at the one end and "pain as bad as it could be" at the other end.

Pain frequency was recorded for each region of the spine on a scale with six ordered categories: 1 (no pain), 2 (once per month), 3 (once per week), 4 (once per day), 5 (more frequently), 6 (constant).

The objective measurements for straight leg raising were recorded using a protractor with a plumb-bob to measure the straight leg raise angle. Lumbar spine ranges of movement were measured using a calibrated perspex device,[33] and cervical spine ranges of movement were measured using a cervical range of motion instrument (CROM) shown to have very good validity.[9,86]

Each assessment after treatment began recorded whether patients had to be crossed over to another intervention because of treatment ineffectiveness or side effects, or whether they were asymptomatic and could be discharged.

Data Handling and Statistical Analysis. The patients' data were color coded to ensure that no one involved with data analysis would be aware of the treatment provided. Data were analyzed using SPSS version 10.

Because the frequency distributions of the main outcome measures proved to be skewed, medians were used as measures of central tendency and quartiles as measures of dispersion. Consequently, nonparametric test procedures were used for numeric variables. Pre- and postintervention changes within the treatment groups were tested using an exact version of the paired Wilcoxon signed-rank test. For comparison between the groups, an exact version of the Mann–Whitney *U* test was used. All tests relating to categorical variables were assessed with exact χ^2 type tests. Checking for possible confounding effects and interactions was performed by multiple regression models and logistic regression approaches. For all the tests, a P value less than 0.05 was regarded as statistically significant. An additional intention-to-treat analysis was performed for the main outcome measures.

Because the nature of the study was exploratory, testing a wide range of outcome measures, an adjustment of the alpha error, as would be necessary in a confirmative study of the Bonferroni–Holm type, was not performed.

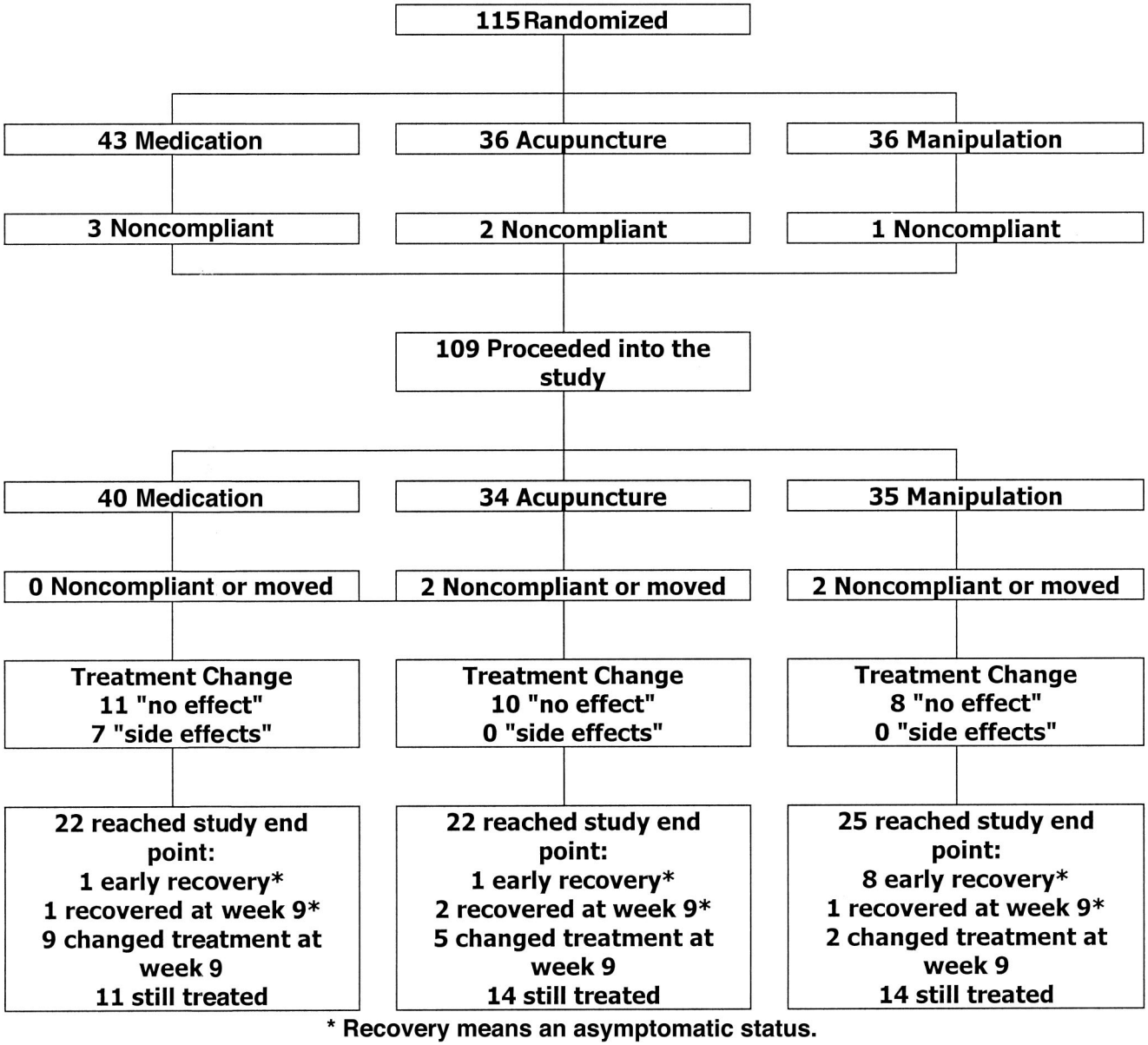

Figure 2. Patient flow chart.

To investigate whether the censored observations biased the results, an additional intention-to-treat analysis was performed for the main outcome measures. All the patients who had to be crossed over to another intervention because of treatmentineffectiveness or side effects were incorporated into this analysis (n = 109). Their last assessment while still in the original treatment arm was used as their "study endpoint." Only those who were not compliant and those who left the city before any assessment other than the baseline was performed were not included.

To exclude any "financial bias" against a specific intervention, the Queensland State Government provided a grant for costs not covered by Medicare rebates.

■ Results

Participants and Follow-up Evaluation

During the study period, 533 patients were seen. Besides self-referrals (n = 157, 32%), there were 339 medical referrals (63.6%) from 141 different medical practitioners and 37 referrals (4.4%) from other health professionals. Of the 533 patients, 418 (78.4%) had to be excluded, mainly for pathology other than mild to moderate osteoarthrosis or spondylolisthesis of L5 on S1 greater than Grade 1. Consequently, 115 patients were eligible to participate in the study: 54 referrals from medical practitioners, 47 self-referrals, and 14 referrals from specialists. Of these participants, no patient refused to give informed consent. In the following randomization 43 (37.4%) were assigned to medication, 36 (31.3%) to acupuncture, and 36 (31.3%) to spinal manipulation (Figure 2). Of the 43 patients randomized to medication, 27 (63%) received Celebrex, 11 (26%) received Vioxx, and 5 (11%) received paracetamol (Table 1).

Of the 21 litigants in the study sample, there were 9 (8.3%) in the medication group, 4 (3.7%) in the acu-

Table 1. Medication

No. of Patients	Medication *Doses relate to patient weight with the severity of symptoms playing a minor role*
27	Celebrex 200–400 mg per day In 4 cases that had 200 mg per day doses, the sports medicine physician increased the dose to 400 mg per day when indicated by symptoms at review and if there had been no adverse reaction.
11	Vioxx 12.5 mg per day or 25 mg per day
5	Paracetamol 500 mg tablets 2–6 per day

puncture group, and 8 (7.3%) in the manipulation group. The average duration of spinal pain symptoms was 8.3 years for the spinal manipulation group, 6.4 years for the medication group, and 4.5 years for the acupuncture group (Figure 3).

Figure 2 details the patients' flow chart. All 10 cases of noncompliance occurred before the first review. All the noncompliant patients were contacted, and all their reasons were found to be unrelated to the outcome (*e.g.*, traveling problems because of distance, moved location).

A total of 69 patients (63.3%) reached the 9-week end point of the study (Figure 2). Altogether, 36 patients (31.3%) had to change treatment during the study because they felt the allocated treatment was ineffective (n = 29; 25.2%) or resulted in side effects such as indigestion, abdominal pain, or skin rash (n = 7; 6.1%). The observed proportions of patients wishing to change treatment did not differ significantly ($P = 0.14$) between the treatment regimens: manipulation (n = 8, 7%), acupuncture (n = 10, 8.7%), and medication (n = 18, 15.7%).

Main Analysis

Control of Randomization. Table 2 details the patient characteristics and the initial subjective and objective assessments. The treatment groups proved to be very similar in all respects except standing flexion, for which the manipulation group had better initial measurements.

Main Outcome Measures. Overall, an asymptomatic status was reported by 14 patients (12.2%) (Figure 2). The highest proportion of asymptomatic patients before or at the week 9 assessment was found in the manipulation group (n = 9, 27.3%) followed by the acupuncture group (n = 3, 9.4%) and the medication group (n = 2, 5%) ($P = 0.05$). Tables 3 and 4 detail the results of the main subjective and objective measures.

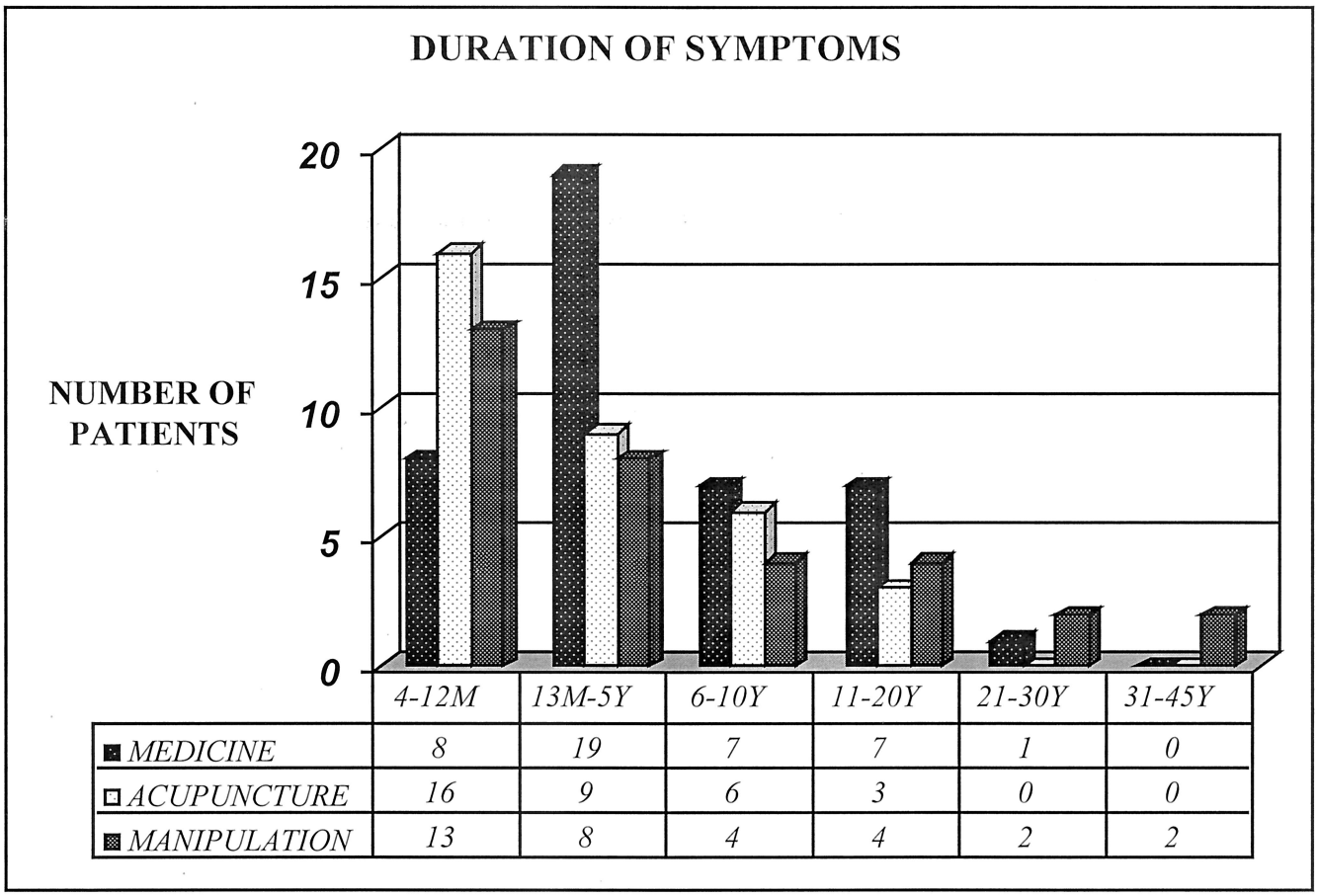

Figure 3. Duration of spinal pain symptoms.

Table 2. Control of Randomization; Patient Characteristics at Initial Assessment*

Variable	Total (n = 109)	Manipulation (n = 35)	Acupuncture (n = 34)	Medication (n = 40)	P Value
Gender Male	55.0% (n = 60)	51.4% (n = 18)	55.9% (n = 19)	57.5% (n = 23)	0.86
Socioeconomic					0.35
Skilled trade	29.4% (32)	31.4% (11)	29.4% (10)	27.5% (11)	
Pensioner/unemployed	20.2% (22)	25.7% (9)	5.9% (2)	27.5% (11)	
Manager/clerk/sales	20.2% (22)	20.0% (7)	20.6% (7)	20.0% (8)	
Professional	11.9% (13)	11.4% (4)	14.7% (5)	10.0% (4)	
Other	18.3% (20)	11.4% (4)	29.4% (10)	15.0% (6)	
Age (quartiles)	27/39/43	25/39/50	23.8/37.5/44	29.5/39/41.8	0.66
BMI	25.8 (23.2–28.7) 1m	25.8 (23.7–29.6)	25.8 (23.6–27.9)	25.8 (21.8–29) 1m	0.90
Pain Frequency: Back (scale 0–5)	5 (4–5) 1m	5 (4–5)	4 (4–5)	5 (4–5) 1m	0.83
Pain Frequency: Neck (scale 0–5)	3.5 (0–4) 1m	4 (0–5)	4 (0–4)	2 (0–4) 1m	0.71
Pain Intensity: Back (scale 0–10)	6 (3–8) 2m	6 (3–7)	6 (4.5–8) 1m	5 (3–8) 1m	0.32
Pain Intensity: Neck (scale 0–10)	3 (0–8) 2m	5 (0–7)	4 (1–8) 1m	3 (0–8) 1m	0.45
Oswestry Disability Back (in %)	28 (16–47) 1m	22 (8.9–40)	30 (22–45) 1m	32 (24–49)	0.06
Neck Disability Index (in %)	23 (0–44) 1m	20 (0–40)	28 (0–47) 1m	13 (0–48)	0.45
Lumbar Spine: Sitting Flexion	51 (40–58) 1m	50 (34–56)	49 (40–58)	54 (40–58) 1m	0.47
Lumbar Spine: Standing Flexion	52 (35–63) 1m	40 (29–60)	54 (49–65)	56 (36–68) 1m	0.01
Cervical Spine: Sitting Flexion	32 (20–50) 12m	40 (29–50) 3m	30 (20–50) 3m	32 (19–50) 6m	0.33
Cervical Spine: Sitting Extension	40 (20–50) 12m	40 (23–50) 3m	32 (14–50) 3m	40 (20–50) 6m	0.64
SF-36 Total	46 (32–59) 1m	54 (35–67)	47 (32–52) 1m	41 (28–57)	0.09

* (Displayed are percentages (n) for categorical variables and medians with interquartile ranges for numerical variables; m = missing; P Values refer to tests between the treatment groups).

Table 5 displays the changes in the main outcome measures as medians of individual percentage changes. Manipulation yielded the best results over all the main outcome measures except the NDI, for which acupuncture achieved a better result than manipulation.

For all the main outcome measures, additional analyses were performed to assess potential confounding of variables such as age, gender, body mass index, pain duration, and involvement in litigation. Bivariate analyses proved that none of the assessed variables were significantly correlated with the main outcome measures or with the treatment regimens. Multivariate models also disproved any influence of these variables on the outcome measures, corroborating the absence of any relevant confounding bias.

Intention-to-Treat Analysis. The results of the intention-to-treat analysis are displayed in Table 6. Because the "unsuccessful" cases (involving patients who had to change treatment because of treatment ineffectiveness or side effects) are included, the results display an overall decreased efficacy of the treatment regimens. The small relative superiority of spinal manipulation for spinal pain (except for neck pain, which responded better to acupuncture according to the VAS) was found to be quite consistent with the results from the main analysis (Tables

Table 3. Results of Subjective Measures*

Variable		Total (n = 69)	Manipulation (n = 25)	Acupuncture (n = 22)	Medication (n = 22)
Pain Frequency *Back*	T1	4 (4–5)	5 (4–5)	4 (4–5)	4 (4–5)
	T4	4 (3–5) P = 0.002	4 (0–5) P = 0.004	4 (3–5) P = 0.06	4 (3–5) P = 0.87
Pain Frequency *Neck*†	T1	4 (2–5)	4 (3–5)	4 (2–4)	4 (2–5)
	T4	4 (2–4) P = 0.18	4 (0–4) P = 0.07	3 (1–4) P = 0.42	4 (4–5) P = 0.38
Pain Scale (VAS) *Back*	T1	5 (4–8)	5 (4–8)	6 (4–8)	5 (3–8)
	T4	4 (2–7) P = 0.003	3 (0–7) P = 0.005	4 (2–7) P = 0.07	5 (2–7) P = 0.77
Pain Scale (VAS) *Neck*†	T1	6 (3–8)	6 (3–7)	6 (4–9)	6 (3–9)
	T4	4 (1–6) P = 0.01	3 (1–6) P = 0.14	3 (1–6) P = 0.04	6 (3–8) P = 0.53
Oswestry *Back*	T1	26 (16–44)	24 (10–36)	27 (21–46)	32 (23–49)
	T4	22 (4–37) P < 0.001	12 (0–29) P = 0.01	24 (11–36) P = 0.02	32 (11–46) P = 0.22
Neck Disability	T1	37 (20–50)	26 (16–42)	36 (20–50)	47 (33–53)
Index†	T4	27 (10–44) P = 0.002	17 (0–36) P = 0.08	28 (14–42) P = 0.03	42 (20–51) P = 0.23
SF-36‡	T1	46 (31–62)	57 (35–66)	46 (31–52)	37 (27–61) P < 0.001
	T4	62 (41–81) P<0.001	70 (48–100) P <0.001	53 (39–69) P = 0.006	57 (32–77)

* (Displayed are medians with interquartile ranges; P Values refer to tests between initial (T1) and study end point (T4) assessments).
† Analysis relates only to patients who recorded one or more episodes of neck problems during the study period. Overall n = 50; manipulation n = 18; acupuncture n = 19; medication n = 13.
‡ Please note that for the SF-36 measurements, *increasing* values reflect improvement in general health status; for all other variables, a *decrease* indicates improvement in pain and disability.

Table 4. Results of Objective Measures*

Variable		Total (n = 69)	Manipulation (n = 25)	Acupuncture (n = 22)	Medication (n = 22)
Straight	T1	30 (13–50) 1m	40 (18–60)	28 (7–43)	25 (12–56) 1m
Leg Raising (Lt)	T4	38 (15–67) 1m P = 0.09	60 (23–70) P = 0.04	33 (10–46) P = 0.96	35 (15–60) 1m P = 0.67
Straight	T1	30 (15–50) 1m	45 (15–65)	33 (10–46)	26 (17–45) 1m
Leg Raising (Rt)	T4	40 (17–70) 1m P = 0.08	64 (24–70) P = 0.03	32 (10–49) P = 0.79	30 (17–54) 1m P = 0.62
Lumbar	T1	51 (40–58)	49 (33–57)	48 (41–61)	54 (46–58)
Sitting Flexion†	T4	45 (32–54) 2m P <0.001	32 (10–45) P < 0.001	47 (43–57) 1m P = 0.4	47 (38–54) 1m P < 0.001
Lumbar	T1	52 (35–61)	45 (29–61)	53 (49–63)	56 (34–67)
Standing Flexion†	T4	42 (18–58) 1m P < 0.001	20 (10–38) P < 0.001	55 (36–64) P = 0.46	52 (31–62) 1m P = 0.14
Lumbar Lateral	T1	58 (52–62)	55 (51–60)	59 (55–65)	59 (44–62)
Bending (Lt)†	T4	53 (47–59) P < 0.001	47 (45–52) P = 0.002	56 (54–62) P = 0.008	55 (47–62) 1m P = 0.82
Lumbar Lateral	T1	56 (51–61)	55 (48–59)	56 (53–62)	58 (48–63)
Bending (Rt)†	T4	53 (47–58) 3m P = 0.007	49 (45–53) 2m P = 0.009)	57 (52–64) P = 0.36	54 (47–59) 1m P = 0.39
Cervical	T1	32 (21–50) 4m	40 (30–50) 2m	30 (20–50)	31 (10–50) 2m
Sitting Flexion	T4	42 (30–50) 8m P = 0.02	38 (22–50) 3m P = 0.1	41 (21–50) 2m P = 0.11	40 (28–50) 3m P = 0.6
Cervical	T1	38 (20–50) 4m	38 (22–50) 2m	34 (19–51)	40 (19–50) 2m
Sitting Extension	T4	48 (30–56) 8m P = 0.08	50 (32–60) 3m P = 0.02	44 (16–50) 2m P = 0.54	40 (28–52) 3m P = 0.95
Cervical Lateral	T1	30 (20–40) 4m	32 (20–40) 2m	30 (26–40)	30 (13–40) 2m
Bending (Lt)	T4	34 (21–45) 8m P = 0.36	40 (22–45) 3m P = 0.59	32 (24–44) 2m P = 0.46	32 (20–42) 3m P = 0.77
Cervical Lateral	T1	30 (20–38) 4m	34 (22–38) 2m	30 (20–37)	28 (16–32) 2m
Bending (Rt)	T4	36 (20–45) 8m P = 0.04	41 (26–45) 3m P = 0.28	37 (23–40) 2m P = 0.24	30 (20–44) 3m P = 0.28
Cervical	T1	48 (27–60) 4m	42 (30–60) 2m	47 (17–53)	49 (25–60) 2m
Rotation (Lt)	T4	52 (35–68) 8m P = 0.04	60 (48–80) 3m P = 0.003	50 (23–64) 2m P = 0.39	42 (22–62) 3m P = 0.62
Cervical	T1	48 (20–60) 4m	48 (38–58) 2m	47 (20–69)	44 (10–60) 2m
Rotation (Rt)	T4	52 (32–72) 8m P = 0.02	62 (49–80) 3m P = 0.004	47 (24–68) 2m P = 0.62	50 (24–64) 3m P = 0.79

* (Displayed are medians with interquartile ranges; m = missing; P Values refer to tests between initial (T1) and study end point (T4) assessments).
† Please note that for the measurements of lumbar sitting and standing flexion, and lumbar lateral bending, *decreasing* values reflect an improved range of movement. For all other variables, an *increase* indicates an improved range of movement.

3 and 4), disproving any relevant selection bias introduced by those who had to change treatment.

■ Discussion

The search to find effective conservative treatments for acute and chronic nonspecific low back pain has been largely inconclusive,[88,89] as is the case with neck and thoracic spine pain. Conflicting claims exist for nearly every form of conservative therapy used to manage low back disorders, probably because studies have been performed among widely differing types of patients with back pain, or because of methodologic problems.[18] Therefore, the current RCT was designed with a rigorous protocol, a broad range of outcome measures, and the use of three treatment regimens acting as controls for each other (from a treatment and placebo perspective) in an attempt to overcome these methodologic problems and to provide the tools that can be used to draw valid inferences of cause and effect.[1] Notably, Hrobjartsson and Gotzsche[38] found little evidence that placebos had powerful clinical effects, notwithstanding their possible small benefits for the treatment of pain. It therefore is likely that any

Table 5. Main Outcome Measures: Percentage changes of Initial Assessment*

Variable	Total (n = 69)	Manipulation (n = 25)	Acupuncture (n = 22)	Medication (n = 22)
VAS *Back*	−13 (−60;+23)	−50 (−100;0)	−15 (−57;+15)	0 (−41;+51)
VAS *Neck*†	−28 (−70;+31)	−42 (−74;+28)	−50 (−78;0)	0 (−42;+50)
Oswestry Back Disability	−13 (−75;0)	−50 (−100;−2)	−5 (−55;+2)	−4 (−56;+12)
Neck Disability Index†	−16 (−61;+11)	−38 (−100;+15)	−16 (−60;0)	−8 (−24;10)
Lumbar Sitting Flexion	−7 (−27;+2) 2m	−20 (−75;+2)	−2 (−12;+8) 1m	−7 (−23;−1) 1m
Lumbar Standing Flexion	−11 (−45;+9) 1m	−38 (−66;+2)	−2 (−25;+15)	−4 (−24;+10) 1m
Cervical Sitting Flexion§	+20 (−12;+79) 11m	+25 (−7;+40) 5m	+20 (−5;+90) 2m	+8 (−17;+100) 4m
Cervical Sitting Extension§	+4 (−18;+46) 12m	+18 (−5;+95) 5m	+2 (−27;+43) 2m	0 (−41;+33) 5m
SF-36‡	+23 (+2;+62)	+47 (+2;+76)	+15 (+1;+60)	+18 (+8;+54)

* (Displayed are medians with interquartile ranges of individual percentage changes; m = missing).
† Analysis relates only to patients who recorded one or more episodes of neck problems during the study period. Overall n = 50; manipulation n = 18; acupuncture n = 19; medication n = 13.
‡ Please note that for the SF-36 measurements, *increasing* values reflect improvement in general health status.
§ For cervical sitting flexion and extension, *increasing* values reflect improvement in ranges of movement; for all other variables *a decrease* indicates an improvement in ranges of movement, pain and disability.

Table 6. Results of Intention to Treat Analysis*

Variable		Total (n = 109)	Manipulation (n = 35)	Acupuncture (n = 34)	Medication (n = 40)
VAS Back	T1	6 (3–8) 2m	6 (3–7)	6 (5–8) 1m	5 (3–8) 1m
	T4	5 (2–8) 2m P = 0.06	3 (0–7) P = 0.015	7 (2–9) 1m P = 0.48	5 (2–7) 1m P = 0.96
VAS† Neck†	T1	6 (3–8)	6 (4–8)	6 (2–9)	5 (3–9)
	T4	5 (2–8) P = 0.11	5 (2–7) P = 0.12	4 (2–8) P = 0.30	6 (2–8) P = 0.91
Oswestry Back Disability	T1	28 (16–46) 1m	22 (9–40)	30 (22–45)	32 (24–50)
	T4	24 (6–44) 1m P = 0.002	14 (0–33) P = 0.045	26 (13–41) P = 0.059	32 (14–46) P = 0.17
Neck Disability Index†	T1	38 (20–50)	28 (16–42)	37 (20–51)	47 (26–55)
	T4	31 (15–50) P = 0.06	22 (2–44) P = 0.29	30 (16–47) P = 0.21	42 (20–51) P = 0.36
Lumbar Sitting Flexion	T1	51 (40–58) 1m	50 (34–56)	49 (40–58)	54 (40–58) 1m
	T4	46 (36–55) 1m P = 0.0001	39 (10–54) P = 0.001	47 (42–56) P = 0.12	51 (41–58) 1m P = 0.04
Lumbar Standing Flexion	T1	52 (35–63) 1m	40 (29–60)	54 (49–65)	56 (36–68) 1m
	T4	47 (25–61) 1m P = 0.003	30 (10–52) P = 0.12	56 (37–66) P = 0.19	52 (33–62) 1m P = 0.22
Cervical Sitting Flexion§	T1	32 (20–50) 13m	40 (28–50) 4m	30 (20–50) 3m	32 (19–50) 6m
	T4	40 (25–50) 13m P = 0.087	40 (32–50) 4m P = 0.44	40 (20–50) 3m P = 0.054	38 (26–50) 6m P = 0.73
Cervical Sitting Extension§	T1	39 (20–50) 13m	40 (22–50) 4m	32 (14–50) 3m	40 (20–50) 6m
	T4	40 (21–50) 13m P = 0.229	42 (30–60) 4m P = 0.09	40 (14–50) 3m P = 0.13	35 (19–50) 6m P = 0.46
SF-36 Total‡	T1	46 (32–59) 1m	54 (35–66)	47 (32–52) 1m	41 (28–57)
	T4	54 (40–74) 1m P < 0.0001	68 (40–90) P = 0.002	49 (37–68) 1m P = 0.029	49 (31–73) P = 0.001

* (Displayed are medians and interquartile ranges; m = missing; P Values refer to tests between initial (T1) and study end point (T4) assessments).
† Analysis relates only to patients who recorded one or more episodes of neck problems during the study period. Overall n = 50; manipulation n = 18; acupuncture n = 19; medication n = 13.
‡ Please note that for the SF-36 measurements, *increasing* values reflect improvement in general health status.
§ For cervical flexion sitting and extension, *increasing* values reflect improvement in ranges of movement; for all other variables a *decrease* indicates improvement in ranges of movement, pain and disability.

small possible placebo effect would have been distributed equally across the three treatment regimens in this study, not imparting any advantage to one group.

The results of this efficacy study suggest that spinal manipulation, if not contraindicated, may be superior to needle acupuncture or medication for the successful treatment of patients with chronic spinal pain syndrome, except for those with neck pain. The NDI showed that for neck pain acupuncture achieved a better result than manipulation. Considering that the patients in this study had experienced chronic spinal pain syndrome for an average of 4.5 years in the medication group, 6.4 years in the acupuncture group, and 8.3 years in the spinal manipulation group, it is notable that manipulation, during a maximum treatment duration of 9 weeks, achieved asymptomatic status for every fourth patient (27%). This result is superior to the percentages for acupuncture (9.4%) and medication (5%) for short-term outcomes.

A pilot study[31] using different patients and different methodology (fewer subjective questionnaires, no objective measurements, needle acupuncture with low-voltage electrical stimulation, only one NSAID for medication [tenoxicam (20 mg) plus ranitidine (50 mg × 2)] per day, and a 4-week end point instead of 9 weeks), found that in patients with chronic spinal pain syndromes, spinal manipulation, if not contraindicated, results in greater short-term improvement than acupuncture or medicine. The results of the pilot study[31] that used only subjective outcomes corroborates the findings of this 9-week outcome study.

In the current study, acupuncture played a role in improving neck disability, as shown by the VAS score, indicating that needle acupuncture is a useful treatment method for neck disability and pain. This supports the findings of Irnich *et al*[41] and Vickers *et al.*[92,93]

Medication apparently did not achieve a marked improvement in chronic spinal pain and caused adverse reactions in 6.1% of the patients. The adverse symptoms disappeared once medication was stopped. Interestingly, although "new" medication (*i.e.*, not previously tried by patients) showed no significant improvement for the subjective pain and disability measures or the objective measures, the SF-36 did show an improvement of 18% for general health status, as compared with 15% for acupuncture and 47% for spinal manipulation. This is difficult to explain, but may reflect some satisfaction that the inconvenience of attending twice-weekly treatment was not needed. It also may suggest that medication did not act as a nocebo (*i.e.*, something that induces a feeling of ill health).[70]

It should be strongly emphasized that this study was exclusively concerned with chronic spinal pain, and that consequently, no statement whatsoever can be made about the potential role of medication in treating acute spinal pain syndromes.

The validity of the study does not seem to be compromised by any obvious bias. Randomization was successful, and there was strict adherence to both the treatment regimens and the follow-up protocols. The nature of the interventions made general blinding impossible. However, all data handling and analyses were performed before the treatment color code was broken, thus minimizing information bias and ensuring that blinding for data analysis was successful.[74] The treating and assessing clinicians were not made aware of the results from the pre- and posttreatment subjective questionnaires or objective measurements, so they were effectively blinded to the results of these color-coded data. No volunteer bias was involved because no person declined the informed consent. Selection bias caused by patients who changed

treatment was disproved by the intention-to-treat analysis, which returned relative results quite similar to those of the main analysis. Selection bias from the 10 noncompliers is unlikely because all the individual reasons for dropping out were unrelated to the illness. Detection bias was minimized by recording information exclusively at the set intervals of weeks 2, 5 and 9. Confounding bias seems improbable because much care was taken to record all potential confounders, randomization proved to be successful, and additional bivariate and multivariate analyses showed no influence of potential confounders on the outcome (also true for the 21 litigants).

Because the patients had chronic spinal pain syndromes, it is unlikely that improvement resulted from "self-limiting" spinal pain, as could be the case with acute spinal pain.[83] The patients were not seen at their worst and, in general, had long histories of seeking pain relief.

Although the absolute sample size may seem small, it seems worth reiterating that statistical testing takes the sample size into account, and that the observed effects proved to be both medically relevant and statistically significant. Also, the results seem to support the finding of Manga *et al*[50] that manipulation is beneficial for the treatment of mechanical spinal pain syndromes.

The results of this study can be generalized because the study sample had a broad socioeconomic background and a wide age range. Furthermore, each treating clinician was able to use usual treatment regimens that would be used in their private practices, although treatments were limited to only one procedure for each group in this study (*i.e.,* medication only, needle acupuncture only, and spinal manipulation only). Clinicians were allowed to treat neck and back pain syndromes if patients presented with these combined conditions because this would be done in private practice, and it enhanced the concept of generalizability of treatment outside a spinal pain unit.

In summary, the significance of the study is that for chronic spinal pain syndromes, it appears that spinal manipulation provided the best overall short-term results, despite the fact that the spinal manipulation group had experienced the longest pretreatment duration of pain. This is consistent with the suggestion of Nyiendo *et al.*[62–64] Acupuncture provided the best VAS improvement for neck pain, and all three treatments improved the general health status, as measured by the SF-36 questionnaire.

According to Turk and Rudy,[87] no clinical study can be completely valid, because of the complexities of RCTs. However, the current authors attempted to conduct a well-executed and well-documented RCT with a rigorous protocol. The main weaknesses of the study were that the patients and treating clinicians could not be blinded, and that it did not provide data on 12-month follow-up questionnaires. This data, however, will be collected and analyzed in approximately 1 year from this writing.

■ Key Points

- Spinal manipulation appears to provide the best short-term benefit for some patients with chronic spinal pain syndrome.
- Acupuncture appeared to be more efficacious for neck pain on the VAS.
- All three forms of treatment showed some positive response according to the SF-36 general health status questionnaire.

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Point of View

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The major objective of the study conducted by Giles and Muller[1] was to compare the relative effectiveness of medication, needle acupuncture, and spinal manipulation for managing chronic spinal pain. Although these investigators themselves have noted a number of weaknesses in the investigation, such as the study being nonblinded and the lack of long-term follow-up evaluation, they are to be commended for attempting a more scientific evaluation of two complementary and alternative medicine (CAM) approaches: acupuncture and spinal manipulation. Eisenberg *et al*[2,3] have noted that the general population is becoming more aware of CAM approaches, with the result that these are now more widely used. Examples of such approaches include acupuncture, chiropractic, massage, and various herbal remedies. The National Institutes of Health now has an Office of Complementary and Alternative Medicine, which focuses on helping to stimulate new research in this area of medicine. Conventional medicine has been historically slow to embrace new concepts and treatment approaches. Complementary and alternative medicine exemplifies a new area of medicine that is slowly being embraced. Indeed, there is now a national trend in which some third-party payers authorize alternative therapies in the form of "expanded benefits."[2]

Clinicians are beginning to use a number of CAM approaches for the treatment of pain. Berman *et al*[4] have reviewed research on the efficacy of CAM procedures such as acupuncture, chiropractic, and various mind–body techniques for treating various chronic pain syndromes. One of the traditional approaches has been biofeedback. It should be kept in mind, however, that these approaches often cannot be used as the sole treatment method. Rather, they should be used with other conventional treatments as "complementary" or adjunctive approaches. Other CAM approaches that health providers in the area of pain management are beginning to be use include hypnosis, massage therapy, and herbalism.

As Giles and Muller noted, Ernst *et al*[5] concluded that there is reasonably good evidence supporting the use of acupuncture for low back pain. It should be noted that there are different types of acupuncture. Giles and Muller indicated that in a pilot investigation they conducted, needle acupuncture with low-voltage electrical stimulation was used. They abandoned this type of acupuncture and used needle acupuncture alone in the current study. This was unfortunate. A study by Ghoname *et al*[6] compared the effectiveness of percutaneous electrical nerve stimulation (PENS), a form of acupuncture including electrical stimulation, with transcutaneous electrical nerve stimulation (TENS) and low back exercise therapies in patients with chronic low back pain. A sham

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PENS procedure also was included in the design to control for possible placebo effects. A pre- to post-treatment assessment randomized design was used. The results clearly demonstrated that the PENS treatment, as compared with the other three conditions, was significantly more effective in decreasing self-reported pain and medication use, and in improving physical activity, quality of sleep, and a sense of "well-being." Moreover, 81% of the patients stated that they would be willing to pay money "out of pocket" to receive PENS therapy, as compared with only 4% to 9% who responded in kind to the other treatment methods. It would be worthwhile for Giles and Muller to continue evaluating acupuncture with electrical stimulation as a potentially more effective method than needle acupuncture alone. This treatment may exceed the outcomes produced by manipulation therapy.

Finally, one somewhat confusing aspect of the data analyses in this study was the intention-to-treat analysis. The authors indicate that the "patients who had to change treatment because of ineffectiveness of treatment or side effects" were included in this analysis. However, it was never clear what treatment group actually was included in the final follow-up measures, although the final results did not substantially change the results generated from the main analyses. Again, however, Giles and Muller should be applauded for their attempt to conduct a systematic and rigorous evaluation of potentially useful CAM procedures for spinal patients. More research such as this is needed to advance the field further. For the readers interested in further reviews of CAM, there is a growing list of publications available. In the area of pain management, for example, Davis[7] has presented a number of CAM methods that can be used by physical therapists and other healthcare professionals in the management of patients with chronic pain.

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