Spinal Manipulation, Epidural Injections, and Self-Care for Sciatica: A Pilot Study for a Randomized Clinical Trial

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Abstract

Objective: To assess the feasibility of recruiting sciatica patients and to evaluate their compliance in preparation for a full-scale randomized clinical trial. We also aimed to determine the responsiveness of key outcome measures.

Methods: Thirty-two subjects were randomly assigned to spinal manipulation (n = 11), epidural steroid injections (n = 11), or self-care education (n = 10). No between-group comparisons were planned because of the small sample size.

Results: At week 12 (the end of the treatment phase), the outcome measures indicating the most improvement/change were the Oswestry disability score (mean, 22.9; SD, 19.9; effect size [ES], 1.8), leg pain severity (mean, 2.9; SD, 1.7; ES, 1.7), and if the symptoms were bothersome (mean, 25.2; SD, 16.0; ES, 1.6). Twenty-four patients were either "very satisfied" or "completely satisfied," and 22 of 32 patients reported 75% or 100% improvement. After 52 weeks, the outcome measure showing the most improvement/change was leg pain severity (mean, 2.3; SD, 2.6; ES, 1.35), followed by the Oswestry disability score (mean, 15.6; SD, 20; ES, 1.2) and if symptoms were bothersome (mean, 18.1; SD, 22.6; ES, 1.1). Eighteen patients were either "very satisfied" or "completely satisfied," and 15 of 32 patients reported 75% or 100% improvement.

Conclusions: The results of this pilot study suggest that it is feasible to recruit subacute and chronic sciatica patients and to obtain their compliance for a full-scale randomized clinical. (J Manipulative Physiol Ther 2004;27:503-508)

Key Indexing Terms: *Chiropractic Manipulation; Drug Therapy; Spine; Sciatica*

Back-related leg pain, or sciatica, is one of the common variations of low-back pain.[1,2] Sciatica sufferers have been identified as an important subgroup of low-back pain patients with potentially different prognoses and responses to treatment.[3,4] Often disabling, sciatica accounts for more work loss than uncomplicated low-back pain[5] and is associated with more recurrences and an increased need for surgery.[6]

Sciatica is commonly equated with lumbar radiculopathy caused by mechanical root compression secondary to a disk herniation. However, there is a substantial amount of research indicating that radiating pain to the leg often exists in the absence of disk herniation. Discography studies have shown that internal disruption associated with annular tears in the posterior part of the disk, when provoked by irritating dye injections, can reproduce pain radiation into the lower limb.[7] These leg symptoms thus occur in the absence of direct nerve compression or irritation by a disk fragment in the epidural space. It has also been shown that breakdown products from degenerating nucleus pulposus tissue may leak into the epidural space and result in inflammatory changes involving the nerve root.[8,9]

Surgery is a costly treatment strategy for sciatica and is only indicated for patients with progressive neurologic deficits or unmanageable pain. Nonsurgical treatment such as spinal manipulation, epidural steroid injections, and self-care advice are prescribed for many sciatica patients.[10] Despite their common use, however, there is still uncertainty regarding the efficacy of these interventions and a need for randomized clinical studies.[11-13]

The purposes of this pilot study were to assess the feasibility of recruiting patients, to evaluate their compliance in preparation for a full-scale randomized clinical trial, and to determine the responsiveness of key outcomes. A previous pilot study with more restrictive inclusion and exclusion criteria indicated recruitment of acute and

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subacute sciatica patients would not be possible in our setting.[14] However, through the first pilot study, we identified a broader population of patients who had suffered with sciatica for longer periods of time. Subsequent design changes, specifically the addition of a self-care education group, also required further testing. Would patients with chronic sciatica be willing to accept a minimal intervention such as self-care education? Furthermore, could chronic sciatica patients comply with the proposed study protocols including questionnaires, objective testing, and random assignment to 1 of 3 treatments? Finally, given the limited available scientific literature regarding sciatica of longer duration, it was necessary to assess the performance of our outcome measures and obtain variability estimates for new sample size calculations.

Methods

Recruitment

Study recruitment began in January 2000 by using a list of individuals disqualified from a previous sciatica study,[14] metropolitan and community newspaper advertisements, mailed postcards, and posters in local businesses. Interested individuals completed a phone-screening questionnaire to establish eligibility. Those who qualified attended 2 baseline evaluation visits, which included informed consent, health history, physical examination, and patient-rated outcome questionnaires. A trained and certified research technician performed straight leg raise and lumbar range of motion at both visits. Before randomization, participants were asked to rate how they expected their condition to change for each of the study treatments (1 = worse, 2 = no change, 3 = better, 4 = much better). Participants were randomly assigned to 1 of 3 treatment groups by study staff blinded to the treatment allocation scheme.

Inclusion/Exclusion Criteria

To be included in the study, patients had to be 18 to 65 years of age with a current sciatica episode that had lasted 4 weeks or longer. Sciatica was defined as unilateral or bilateral radiating pain of lumbar origin into the buttock, thigh, or calf. To qualify, patients had to have Quebec Classification Category 2, 3, 4, or 6,[15,16] which included low-back pain patients with radiating pain into the proximal or distal part of the lower extremity, with or without neurologic signs.

Individuals were excluded from the study if they had spinal fracture, spinal stenosis, or other diagnoses, including visceral diseases, compression fractures, and metastases. Other exclusion criteria included progressive neurological deficits, cauda equina syndrome, surgical lumbar spine fusion, contraindications to study treatments, a leg pain score of less than 3 (on a 0-10 scale), current or pending litigation, or ongoing treatment for low back and leg pain from other health care providers. Pregnant or nursing women were also excluded from participating.

Randomization

At the second baseline visit, individuals who had given their informed consent were randomly allocated to 1 of the 3 treatment groups using sequentially numbered, sealed opaque envelopes. The allocation scheme was kept concealed from the study staff.

Interventions

Patients in the chiropractic and epidural injection treatment groups received care based on protocols from the previous pilot study.[14] Chiropractic treatment took place at the outpatient clinic at Northwestern Health Sciences University and was limited to low-amplitude, high-velocity, manual spinal manipulation and mobilization; flexion distraction procedures; light soft tissue massage; heat; and cold. The number of chiropractic treatments was determined by the provider. Epidural steroid injections were provided on an outpatient basis at the Center for Diagnostic Imaging by experienced, Board-certified radiologists. Patients in the injection group received up to 3 epidural steroid injections over a 12-week period. The epidural steroid injection was performed under fluoroscopic control. Patients in the self-care education group attended two 60-minute sessions with a physical therapist at Northwestern Health Sciences University. Treatment consisted of advice regarding postural instructions and practical demonstrations of proper body mechanics performed with patient participation. In addition, patients were given a self-care booklet for low-back pain and sciatica patients.[17]

Prescription strength rescue medications were available during the 12-week treatment period for patients experiencing severe pain. These were prescribed as needed by a medical physician blinded to treatment assignment.

Outcome Measures

Self-report questionnaires, straight leg raise, and lumbar spinal motion were assessed twice at baseline and at 3 and 12 weeks after randomization. Patients were also mailed self-report questionnaires 52 weeks postrandomization.

The typical level of leg pain and low back pain for the past week were each rated using separate 11-box ordinal scales (0 = no symptoms, 10 = worst pain possible).[18] Low back–specific disability was measured by using the Modified Roland Morris Disability Scale and Oswestry Disability Questionnaire. Both were converted to a percentage of the maximal scores with higher values representing greater disability.[19,20]

Five symptoms (back pain, buttock pain, leg pain, numbness or tingling in leg(s) and/or feet, and weakness in leg(s) and/or feet) were rated on 0 to 5 scales to quantify

Table 1. *Baseline demographic and clinical characteristics of randomized patients*

Characteristics	Chiropractic	Injections	Self-Care	All patients
Number of patients	11	11	10	32
Sex (no. female)	5	4	5	14
Age (yr)	43.6 (9.2)	51.9 (5.5)	51.7 (10.1)	49.0 (9.1)
Height (in)	67.6 (3.7)	68.3 (4.6)	67.9 (4.3)	67.9 (4.1)
Weight (lbs)	183.4 (55.4)	186.0 (45.5)	197.6 (54.3)	188.7 (50.8)
Income				
<$25,000/year	1	2	1	4
$25,000-49,000/year	2	6	6	14
≥$50,000/year	8	3	3	14
Smoker (no.)	1	4	3	8
QTF Diagnostic Classification				
Pain+radiation to proximal extremity (QTF 2)	5	4	4	13
Pain+radiation to distal extremity (QTF 3)	5	6	5	16
Pain+radiation to extremity with neurologic signs (QTF 4)	1	1	1	4
Duration of leg pain (no.)				
1-3 months	2	2	2	6
4-6 months	1	1	0	2
7-12 months	2	0	1	3
>12 months	7	7	7	21
Cause of leg pain				
Unknown (no.)	5	5	7	17
Automobile accident (no.)	1	2	1	4
Work or leisure related (no.)	3	1	1	5
Other (no.)	2	3	1	6
Leg pain (0-10)	5.8 (1.8)	5.1 (1.7)	5.1 (1.6)	5.3 (1.7)
Low-back pain (0-10)	4.3 (2.3)	5.5 (1.8)	5.0 (2.3)	4.9 (2.1)
Roland Morris Disability Scale (0-100)	42.5 (21.2)	55.5 (18.2)	40.7 (23.1)	46.4 (21.3)
Oswestry Disability Scale (0-100)	39.6 (12.7)	44.9 (12.9)	39.7 (13.2)	41.5 (12.7)
Bothersomeness of symptoms (0-100)	44.9 (15.1)	48.0 (16.7)	39.8 (16.8)	44.4 (16.0)
Frequency of symptoms (0-100)	46.7 (14.4)	46.6 (16.3)	44.8 (21.1)	46.1 (16.8)
Cut back on activities (no. of days) (NHIS)	7.5 (7.3)	10.6 (9.02)	4.1 (9.3)	7.5 (8.7)
Stayed in bed (no. of days) (NHIS)	0.8 (1.5)	1.9 (3.9)	0.9 (1.5)	1.2 (2.5)
Missed work or school (no. of days) (NHIS)	1.9 (2.4)	5.1 (7.2)	2.7 (5.3)	3.2 (5.4)
Depression (0-100) (CES-D)	7.3 (5.8)	8.9 (6.5)	6.2 (4.8)	7.5 (5.8)
Lumbar range of motion (°)				
Flexion/extension	65.9 (17.1)	59.8 (14.2)	58.7 (13.8)	61.6 (15.0)
Rotation	45.7 (14.1)	46.2 (18.8)	36.0 (12.8)	42.9 (15.7)
Lateral bending	57.6 (16.8)	59.8 (15.9)	48.5 (13.7)	55.2 (15.8)

Values are means and standard deviations (SD) unless otherwise noted.
OTF, Quebec Task Force; *NHIS,* National Health Interview Survey; *CES-D,* Center for Epidemiologic Studies-Depression.

the "bothersomeness" and "frequency" of patients' symptoms.[14,19] These scores were combined and expressed as a percentage for analyses. To gauge overall change or improvement, patients were asked how much their sciatica had changed since they started treatment in the study.[21] Disability days were assessed by using 3 questions from the National Health Interview Survey.[22] Medication use was measured by asking patients how often they took nonprescription or over-the-counter pain-relieving medication for low back and/or leg pain during the past week by using a 5-point scale (0 = none, 4 = every day).[21]

Patients were also asked to rate how satisfied they were with the care they received for their leg and back pain on a 7-point scale (0 = completely satisfied, 6 = could not be worse).[21]

Dynamic lumbar spine motion was assessed by using the CA6000 Spine Motion Analyzer (Orthopedic Systems Inc., Haywood, Calif).[23] Each patient performed the motions in the following order: flexion/extension, left and right rotation, and left and right lateral flexion. Each motion was performed between 2 and 6 times in succession without any verbal prompts or cues.

It was determined a priori that 30 individuals were required for the pilot study. The sample size was based on our previous experience and deemed adequate to determine the feasibility of a full-scale randomized clinical trial. Data analysis was performed by using SPSS PC for Windows, version 10.0 (SPSS, Chicago, Ill). Descriptive statistics were performed for recruitment data, baseline characteristics, and outcome measures. Effect sizes were calculated

Table 2. *Mean changes from basline in patient-rated outcome measures for all patients*

Outcome	3 weeks (SD)	Effect size	12 weeks (SD)	Effect size	52 weeks (SD)	Effect size
Leg pain (0-10)	1.8 (1.7)	1.1	2.9 (1.7)	1.71	2.3 (2.6)	1.35
Low-back pain (0-10)	0.9 (2.1)	0.4	1.7 (2.1)	0.8	1.9 (2.7)	0.9
Roland Morris (0-100)	13.7 (17.0)	0.6	22.7 (21.2)	1.1	19.6 (21.0)	0.9
Oswestry (0-100)	11 (12.7)	0.9	22.9 (19.9)	1.8	15.6 (20.0)	1.2
Bothersome symptoms (0-100)	14.6 (16.0)	0.91	25.2 (16)	1.58	18.1 (22.6)	1.13
Frequency of symptoms (0-100)	12.4 (16.8)	0.74	23.0 (16.8)	1.37	17.5 (23.1)	1.04
Cut back on activities (no. of days) (NHIS)	3.3 (7.3)	0.38	5.3 (7.2)	0.61	5.3 (8.1)	0.61
Stayed in bed (no. of days) (NHIS)	0.2 (3.9)	0.08	1.2 (2.5)	0.47	0.5 (4.0)	0.20
Missed work or school (no. of days) (NHIS)	0.8 (4.1)	0.15	1.9 (3.5)	0.35	2.3 (5.1)	0.43

NHIS, National Health Interview Survey.

by using the following formula: (endpoint score-baseline score)/ baseline standard deviation for all randomized patients. No between-group comparisons were performed because of the insufficient sample size and the risk of committing Type II errors.

Results

A total of 344 persons were screened by telephone to determine initial eligibility (198 from new recruitment efforts and 146 from a list from the previous pilot study).[14] Of these, 101 declined to complete the questionnaire after hearing a short description of the study. The most common reason for declining to complete the questionnaire (26 of 101) was the patient did not want to receive injections as a study treatment. Of the 344 individuals who expressed interest in the study, 120 did not qualify (the most common reason for disqualification being history of low-back surgery), and an additional 55 individuals were placed on a wait list because the study became full. A total of 68 patients qualified for a baseline evaluation appointment, of which 32 qualified and were randomly assigned to 1 of the study treatments: spinal manipulation (n = 11), epidural steroid injections (n = 11), and self-care education (n = 10). One patient in the injection group refused treatment and did not complete subsequent follow-up questionnaires or evaluations. All other patients completed the treatment phase as well as the 3-week and 12-week follow-up evaluations. Four individuals failed to complete the 52-week follow-up.

Baseline demographic and clinical characteristics are outlined in Table 1. As expected, the treatment groups were slightly different because of the small sample size. Almost half of the patients (n = 16) had low-back pain with radiation to the distal extremity, and 21 had experienced the current episode of sciatica for more than a year. As a group, the patients had moderate leg pain severity (mean = 5.3), moderate low-back pain severity (mean = 4.9), and moderate leg and back pain disability (Roland Morris mean = 46.3, Oswestry mean = 41.5).

The average number of injections received by patients in the epidural injection group was 2.1. The average number of treatments in the chiropractic group was 15.4. Each patient in the self-care education group attended 2 visits. No serious adverse effects were reported in any of the groups. All patients who received treatment in the injection group (n = 10) reported flushing, and 6 of 11 patients in the chiropractic group reported soreness after their treatment. No side effects were reported in the self-care education group. Two patients required a short course of rescue medications (1 in the chiropractic group and the other in the self-care education group).

Patient-Rated Outcomes and Responsiveness of Outcome Measures

No group comparisons were planned or performed because of the small sample size. Descriptive statistics and effect sizes (where applicable) are presented in Tables 2 and 3 for data collected at weeks 3, 12, and 52. Generally, the data for all patients showed the most improvement in outcomes at the 12-week evaluation (the end of the treatment phase). At week 12, the outcome measures indicating the most change were the Oswestry questionnaire (mean, 22.9; SD, 19.9; effect size [ES], 1.8), leg pain severity (mean, 2.9; SD, 1.7; ES, 1.7), and how symptoms bothersome were (mean, 25.2; SD, 16.0; ES, 1.6). After 12 weeks, 24 patients were either "very satisfied" or "completely satisfied" with the care they received in the study, and 22 patients reported 75% or 100% improvement. Two patients reported no change and another 2 patients reported a 25% worsening of their sciatica. Questions from the National Health Interview Survey regarding the number of days that patients missed work or school, spent in bed, or cut down on normal activities showed the least change over the treatment period (ES, 0.35-0.61). After 52 weeks, the outcome measure showing the most change was leg pain severity (mean, 2.3; SD, 2.6; ES, 1.35), followed by the Oswestry questionnaire (mean, 15.6; SD, 20; ES, 1.2) and how bothersome symptoms were (mean, 18.1; SD, 22.6; ES, 1.1). Further, after 52 weeks, 18 patients were either "very satisfied" or "completely satisfied" with the care they

Table 3. *Patient-rated satisfaction and improvement at 12 and 52 weeks for all patients*

Outcome measure	12 weeks n = 31 (frequency of responses)	52 weeks n = 27 (frequency of responses)
Overall satisfaction with care		
Completely satisfied	11	9
Very satisfied	13	9
Somewhat satisfied	2	6
Neither satisfied or dissatisfied	4	2
Somewhat dissatisfied	1	1
Very dissatisfied	0	0
Completely dissatisfied	0	0
	12 weeks n = 31 (frequency of responses)	**52 weeks n = 28 (frequency of responses)**
Overall improvement		
100% Improvement	5	5
75% Improvement	17	10
50% Improvement	1	1
25% Improvement	4	6
0% Improvement	2	3
25% Worse	2	1
50% Worse	0	1
75% Worse	0	1
100% Worse	0	0

received in the study, and 15 patients reported 75% or 100% improvement. One patient reported no change in his sciatica, and the same 2 patients who reported a worsening of their sciatica at 12 weeks also reported this after 1 year (1 was 25% worse, and 1 was 50% worse).

Range of Motion

The mean change in flexion/extension motion for all patients over the 12-week treatment period was 3.09° (SD, 12.81), 6.52° (SD, 9.89) for total axial rotation, and 3.58° (SD, 10.23) for lateral bending.

Discussion

One of the most critical aspects of conducting a randomized clinical trial is the ability to recruit qualified and willing participants. In our previous pilot study of acute and subacute sciatica patients, the recruitment rate during a 1-year period was less than 3% (20 individuals randomized of 706 individuals initially screened by telephone). Consequently, we determined that recruitment for a full-scale study was not feasible in our setting. However, we did identify a substantial number of chronic sciatica sufferers seeking relief, which led to this second pilot study. The recruitment rate for the current study was approximately 10% (32 randomized of 344 initially screened), which was more than 3 times what was observed in the first pilot study. Further, this recruitment rate is likely an underestimation due to the fact that 56 patients had to be wait-listed because the study became full.

Although our recruitment efforts for the second pilot study were successful, we also identified barriers to recruitment for future full-scale trials. Almost a one-third (101 of 344) of those interviewed were not interested in participating in this study. The most common reason given for declining participation was not wanting to accept the chance of receiving epidural steroid injections (26 of 101). Thus, future recruitment efforts will need to take into account the general public's preconceived opinions regarding the study therapies and perhaps adopt a more educational approach.

Patient compliance with the treatment and data collection protocols in this study was high, with only 1 of 32 patients refusing treatment (injection group) and 31 of 32 patients completing the week 12 evaluations. Data were also successfully collected 1 year after treatment, with 28 of 32 randomized patients returning the mailed self-report questionnaires. A concern in this study was whether chronic sciatica patients would perceive the self-care education group as a legitimate treatment approach. Nine of 32 study patients expected they would experience "no change" with self-care, compared with 3 patients expecting no change with chiropractic treatment and 0 patients expecting no change with injections. However, those that received the self-care treatment seemed to tolerate it well, with all patients randomized to that group completing the treatment and follow-up visits. Furthermore, more than half the patients in the self-care group were highly satisfied with the care they received and half of them reported 50% to 100% improvement 12 weeks after treatment and 1 year later. These results suggest that the self-care education group is a feasible "minimal intervention" group for randomized clinical trials assessing patients with subacute and chronic sciatica. However, because of expectation differences and their potential effect on outcomes, pretreatment expectations should be measured and factored into the statistical analyses.

The Oswestry Disability Questionnaire, leg pain, and how bothersome symptoms were were the most responsive outcome measures in this sample of subacute and chronic sciatica patients. These were also the most responsive outcomes in the previous pilot study of acute and subacute sciatica sufferers,[14] although the magnitude of effect sizes was somewhat larger in the previous study. This may be related to the chronicity of sciatica experienced by individuals in the current study, who may be more prone to smaller degrees of improvement, which is then reflected in the outcome measures. Future studies of chronic sciatica patients may want to consider the use of questionnaires that measure coping and fear avoidance behaviors to reflect some of the other dimensions of the chronic pain experience.

The costs associated with this second pilot study were substantial in terms of financial resources, effort, and time. High-quality clinical research is an arduous and costly process with few quick answers. To proceed with a full-scale randomized clinical trial without critical information regarding recruitment feasibility and study protocols raises the potential for squandered finances, immense frustration, and wasted effort on the part of patients and personnel should the study be unsuccessful. Two recent pilot studies[14,24] have successfully shown the usefulness of pilot studies to identify areas in which the subsequent full-scale randomized trials would have failed. Although patients, clinicians, and health care policy makers clamor for scientific evidence now, investigators and funding agencies have a responsibility to ensure that the appropriate steps are taken to ensure the successful conduct and completion of high-quality clinical research. This includes establishing the feasibility and likelihood of success through well-designed pilot studies.

Conclusion

The results of this pilot study suggest that it is feasible to recruit subacute and chronic sciatica patients for a randomized clinical trial to compare chiropractic care, epidural steroid injections, and self-care education. Furthermore, subacute and chronic sciatica patients appear willing and able to comply to with the study protocols, as described in this article. Appropriate outcome measures have been identified, and variability estimates have been obtained to inform the sample size of future full-scale trials. Although this second pilot study required substantial time and resources, the lessons learned and conclusions drawn are valuable for the successful conduct of future research.

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