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Chiropractic manipulation in the treatment of acute back pain and sciatica with disc protrusion: a randomized double-blind clinical trial of active and simulated spinal manipulations

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Abstract

BACKGROUND CONTEXT: Acute back pain and sciatica are major sources of disability. Many medical interventions are available, including manipulations, with conflicting results.

PURPOSE: To assess the short- and long-term effects of spinal manipulations on acute back pain and sciatica with disc protrusion.

STUDY DESIGN/SETTING: Randomized double-blind trial comparing active and simulated manipulations in rehabilitation medical centers in Rome and suburbs.

PATIENT SAMPLE: 102 ambulatory patients with at least moderate pain on a visual analog scale for local pain (VAS1) and/or radiating pain (VAS2).

OUTCOME MEASURES: Pain-free patients at end of treatment; treatment failure (proportion of patients stopping the assigned treatment for lack of effect on pain); number of days with no, mild, moderate, or severe pain; quality of life; number of days on nonsteroidal anti-inflammatory drugs; number of drug prescriptions; VAS1 and VAS2 scores; quality of life and psychosocial findings; and reduction of disc protrusion on magnetic resonance imaging.

METHODS: Manipulations or simulated manipulations were done 5 days per week by experienced chiropractors, with a number of sessions which depended on pain relief or up to a maximum of 20, using a rapid thrust technique. Patients were assessed at admission and at 15, 30, 45, 90, and 180 days. At each visit, all indicators of pain relief were used.

RESULTS: A total of 64 men and 38 women aged 19–63 years were randomized to manipulations (53) or simulated manipulations (49). Manipulations appeared more effective on the basis of the percentage of pain-free cases (local pain 28 vs. 6%; $p<.005$; radiating pain 55 vs. 20%; $p<.0001$), number of days with pain (23.6 vs. 27.4; $p<.005$), and number of days with moderate or severe pain (13.9 vs. 17.9; $p<.05$). Patients receiving manipulations had lower mean VAS1 ($p<.0001$) and VAS2 scores ($p<.001$). A significant interaction was found between therapeutic arm and time. There were no significant differences in quality of life and psychosocial scores. There were only two treatment failures (manipulation 1; simulated manipulation 1) and no adverse events.

CONCLUSIONS: Active manipulations have more effect than simulated manipulations on pain relief for acute back pain and sciatica with disc protrusion.

Keywords: Manipulation; Chiropractic manipulation; Back pain; Sciatica; Intervertebral disc; Randomized controlled trial

Introduction

Acute back pain and sciatica are major sources of disability, with impairment of daily living activities. Many medical interventions are available but the results are conflicting [1]. Spinal manipulations are widely used [2]. The rationale for manipulation includes reduction of a bulging disc, correction of disc displacement, release of adhesive

FDA device/drug status: not applicable.

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fibrosis surrounding prolapsed discs or facet joints and entrapped synovial folds or plicae, inhibition of nociceptive impulses, relaxation of hypertonic muscles, and unbuckling displaced motion segments [3,4]. However, a systematic review of randomized clinical trials did not unanimously demonstrate the efficacy of spinal manipulations, some reports concluding that there is moderate evidence that spinal manipulations are effective for pain relief [5] and have better short-term efficacy than spinal mobilization and detuned diathermy [6], and others that there is no evidence that spinal manipulative therapy is superior to standard treatments [7]. Results are also conflicting for chronic spinal pain [5–9]. These contradictory findings can be partly explained by differences in study design and poor methodological quality [10,11]. In addition, some groups of patients seemed to benefit from manipulations, but these subgroups cannot be consistently identified. Also, the long-term effects of manipulation are poorly defined and the effects of spinal manipulations on the outcome of acute back pain and sciatica with protruding discs are unknown.

We therefore conducted a randomized double-blind clinical trial to assess the short- and long-term impact of spinal manipulations on acute back pain and sciatica in a cohort of patients with lumbar disc protrusion. The aim was to assess the benefit, if any, of spinal manipulations as opposed to sham manipulations in this target group, expressed in terms of pain reduction and treatment continuation.

Material and methods

Study population and selection criteria

Included were consecutive ambulatory patients age 18 to 65 years, seen between February 9, 1999 and October 27, 2000 in two medical rehabilitation centers in and near Rome (Celio Hospital and Istituto Chirurgico Ortopedico Traumatologico [ICOT]). To be included, each individual had to report acute low back pain (LBP) of moderate to severe intensity (5 or higher on a 10 cm visual analog scale [VAS]) [12], moderate to severe radiating pain to one leg (5 or higher on a VAS), and magnetic resonance imaging (MRI) evidence of disc protrusion with or without disc degeneration in the spinal segments involved in pain.

Acute LBP was defined as pain for less than 10 days in a patient who had been pain-free in the previous 3 months. Evoked local and radiating pain was assessed using the 10-point VAS (VAS1 and VAS2, respectively). We used a 10-cm line where 0 cm corresponded to ''no pain'' and 10 cm to ''unbearable pain''. The patients responded by placing a mark somewhere along the line. Local pain was identified by palpation and percussion on the lumbosacral spine and the sciatic notch in order to identify trigger points. Radiating pain was evoked by specific clinical tests, including straight leg raising [13] and Wasserman [14] maneuver (hyperextension of the hip with the patient in the prone position with the knee flexed at 90°; this maneuver evokes pain by stimulating the L2–L4 roots).

Disc abnormalities were classified according to the Modic classification [15] and subjects with 4A herniated disc (protrusion with an intact annulus) were included in the study.

A patient was excluded if at least one of the following conditions was satisfied: body mass index >30; lumbar scoliosis >20°; lower limb length difference more than 1.5 cm on plane X-rays; spondylolisthesis, previous spinal surgery, and diabetic neuropathy to rule out alternative pain sources; severe osteoporosis (bone mineral density [quantitative ultrasound on densitometry] more than 2.5 SD lower than the mean of normal age-matched individuals) and metabolic disease causing osteopenia, for which spinal manipulative therapy is contraindicated; clinical, electrophysiological, or radiological findings suggesting a lesion requiring surgery; herniated disc classified as 4B (extrusion with rupture of either the annulus or the posterior longitudinal ligament, or both) or 4C (rupture of the annulus and the posterior longitudinal ligament with sequestration of a disc fragment in the spinal canal); history of chronic LBP. Patients were also excluded if they had already received spinal manipulation, to avoid possible blinding failure, and if they refused to give written informed consent.

Electrophysiological tests were done only in diabetic patients in order to exclude diabetic neuropathy; bone mineral density was assessed only in patients with X-ray signs of osteoporosis.

Baseline assessment

At admission, every eligible patient was interviewed directly and given a complete physical examination and, where indicated, blood biochemical, hematological, electrophysiological, and radiological tests to check the exclusion criteria, and to collect the main demographic and clinical details. The interview included the collection of data about pain (site, number of segments, aggravating factors), VAS1 and VAS2 scores, the patient's psychological profile, and quality of life. The psychological profile was scored using the Italian translation of the Kellner rating scale [16]. The Italian version of the Rand 36-Item Health Survey (Short Form-36) [17] was used to assess quality of life.

MRI findings of disc protrusion were obtained at admission and verified at the end of the follow-up period using the same procedure and equipment. MRI readings were done by the same radiologist in each center. Disc protrusion changes were assessed using the Modic criteria [15]. Reduction of disc protrusion was measured by a shift to a lower Modic category.

Randomization and treatment modalities

The patients were randomized blindly to active or simulated manipulations using computer-generated lists. The allocation sequence was generated at the ''Mario Negri''

Institute in Milan, the trial coordinating center, using two lists, one for each center. Participants were enrolled by local investigators from the two centers. Each investigator informed the trial coordinating center by telephone of each eligible patient and received the assigned treatment immediately.

Individuals assigned active manipulations were treated according to a pre-planned 30-day protocol with a number of sessions that depended on pain relief or up to a maximum of 20. Sessions were scheduled 5 days per week, each lasting 5 minutes for active and simulated manipulations. *Active* manipulations consisted of examining the range of motion in the back, followed by soft tissue manipulations and brisk rotational thrusting away from the greatest restriction, as described by Herbst [18] and Plaugher [19]. The aim of manipulation of the spinal column was to restore the physiological motor unit movement (a motor unit consists of two vertebrae, disc, and surrounding structures). With the patient sitting, the pertinent segment of the spine was examined and assessed by motion palpation in order to determine the joint hypo-hypermobility. The patient was then laid on one side, with arms folded and thighs flexed. The chiropractor faced the patient and made contact with one hand at the level of the patient's shoulder and the other at the level of the vertebral motor unit to be mobilized. The slack was then taken up and a quick, precise, well-controlled movement was imparted with either a push or pull, always toward the pain-free direction.

Subjects randomized to simulated manipulations received soft muscle pressing apparently similar to manipulations but not following any specific patterns and not involving rapid thrusts. Active and simulated manipulations were done by two experienced chiropractors, one at each center, who both held U.S. Doctor of Chiropractic degrees and had received the same formal training.

Follow-up

After admission, each patient received an ad hoc diary in which to record the days of pain during the 30-day treatment period, number and type of nonsteroidal anti-inflammatory drugs, and number of drug prescriptions. Opiates and steroids were not allowed. In the diaries, pain days were indicated in separate categories according to severity, which was coded arbitrarily as absent, mild, moderate, or severe (the latter including severe, very severe, and unbearable pain) specifying any radiation to a leg. Patients were also assessed for pain relief with a series of clinical indicators (see below) at the scheduled visits (at 15, 30, 45, 90, and 180 days). Assessors (physiatrists), who were different from the investigators who enrolled the participants, were blind to the assigned treatments.

Outcome measures (Table 1)

The primary outcome measures included the number of patients becoming pain-free at the end of treatment and treatment failure, defined by the number of patients stopping the assigned treatment because of no benefit (no reduction of pain). Secondary outcome measures included number of days with pain of any severity, number of days with at least moderate pain, mean number of days on nonsteroidal anti-inflammatory drugs, mean number of drug prescriptions, number of patients experiencing less severe pain, number of patients becoming pain-free at each follow-up, changes in the VAS1 and VAS2 scores at each follow-up, mean SF-36 and Kellner scores, and mean number of cases experiencing at least a reduction of disc protrusion as shown by MRI (at 45 days).

Table 1
Outcome measures of spinal manipulations for acute back pain with disc protrusion

Primary
No. patients pain-free at end of follow-up (180 days)
Treatment failure (see text for explanation)
Secondary
No. days with pain (total, mild, moderate, severe)
No. days with nonsteroidal anti-inflammatory drugs
No. prescriptions of nonsteroidal anti-inflammatory drugs
No. patients with reduction of local pain (VAS1) or radiating pain (VAS2) on day 15, 30, 45, 90, 180
No. patients pain-free (VAS1 or VAS2) on day 15, 30, 45, 90, 180
Reduction of local pain (VAS1) or radiating pain (VAS2) on day 15, 30, 45, 90, 180
SF-36 score (quality of life)
Kellner score (psychological profile)
No. patients with reduction of disc protrusion (MRI).

VAS1=visual analog scale for local pain; VAS2=visual analog scale for radiating pain.

Statistical analysis

Statistical analysis was done using the chi-square or Fisher exact test, Student *t* test, or the Mann-Whitney test, and analysis of variance, as appropriate. The choice of parametric or nonparametric tests was dictated by the results of a test for normality of data. Multivariate repeated measures and analysis of variance was used to test the effect of time, treatment, and the interaction time by treatment on the VAS1 and VAS2 scores. All analyses were done on an intention-to-treat basis. Standard statistical software packages (SPSS 10.0 and SAS 6.09) were used. All reported p values are two-tailed. No adjustment for multiplicity of reporting was considered because it increases the type II errors for associations that are not null [20].

Sample size and power

Sample size was calculated under the assumption that 20% of patients randomized to simulated manipulations and 50% of those randomized to manipulations (30% absolute difference) would be pain-free at the end of treatment. The study was also powered to detect a 30% absolute difference in the proportion of treatment failures at the end

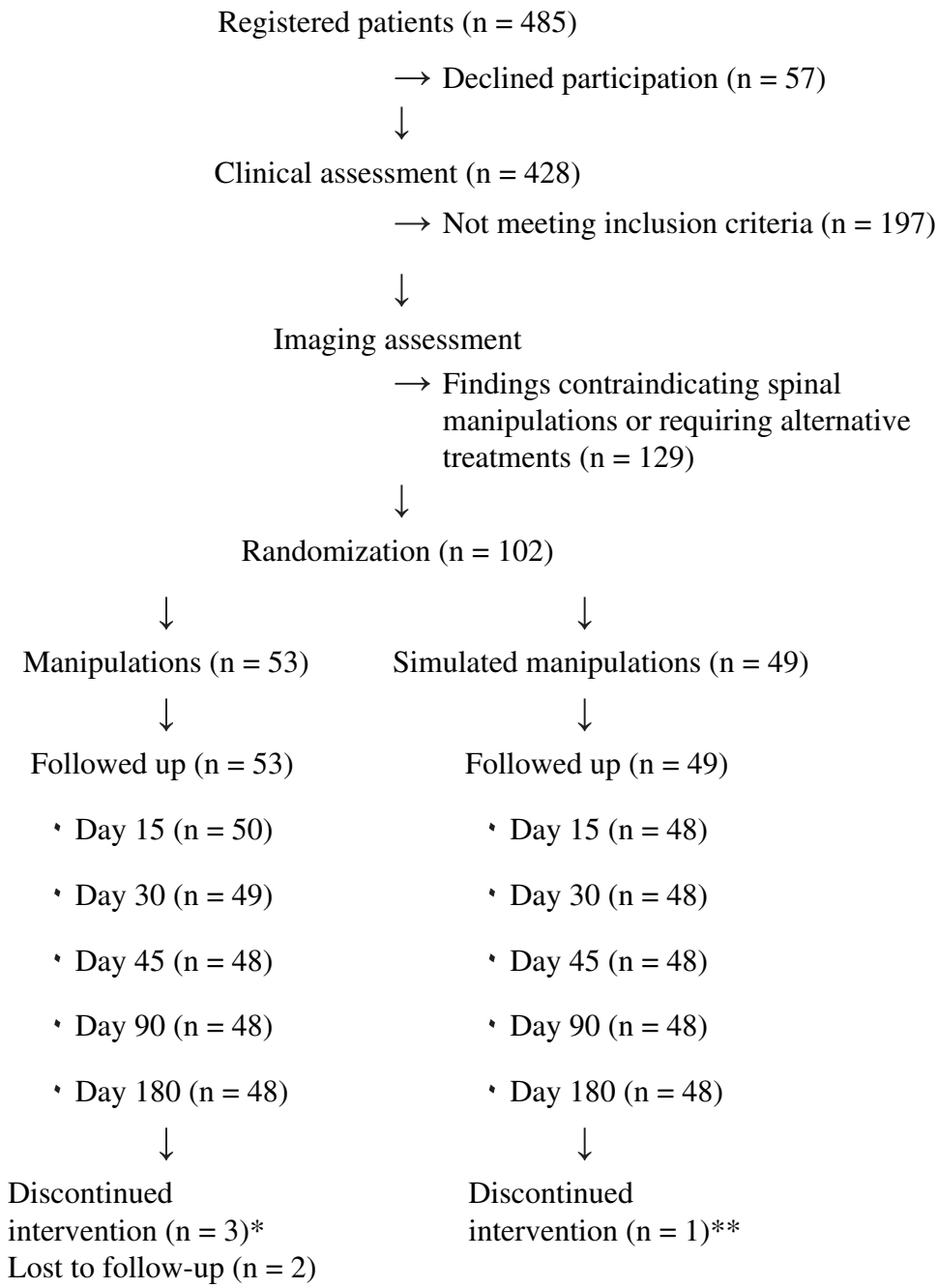

Fig. 1. Spinal manipulations for acute back pain caused by disc protrusion. Trial flow diagram. *Lack of efficacy (n=1); changed residence (n=1); car accident with leg fractures (n=1). **Lack of efficacy.

of follow-up (simulated manipulations 60%; manipulations 30%). On this basis, the minimum number of patients to be enrolled in each treatment arm would be 40 with at least 80% power and 5% significance. Allowing for a 20% drop-out rate, 100 patients had to be recruited.

Ethical and regulatory issues

The study was approved by the Institutional Review Board of the ''Centro Studi di Patologia Vertebrale'', a nonprofit orthopedic and rehabilitation institution. The procedures followed were in accordance with the ethical standards of the Committee on Human Experimentation of the institutions involved.

Results

During the study period, 485 ambulatory patients presented to the two study centers with at least moderate acute back pain. Of these, 383 were not randomized as they were

ineligible (326) or because they declined participation (Fig. 1). One hundred and two patients were randomized to manipulation (53) or simulated manipulation (49). The sample included 64 men and 38 women age 19 to 63 years (mean 43.1), who presented lumbar or lumbosacral pain caused by disc protrusion. The two treatment groups were fairly well balanced for local and referred pain intensity (VAS1 and VAS2) (Table 2). The mean (SD) number of sessions was 12.8 (4.8) for active manipulation and 13.0 (4.5) for simulated manipulation.

At the end of follow-up a significant difference was present between active and simulated manipulations in the percentage of cases becoming pain-free (local pain 28% vs. 6%, p<.005; radiating pain 55% vs. 20%, p<.0001) (Table 3).

There were only six patients discontinuing treatment or lost to follow-up (manipulation 5; simulated manipulation 1) (Fig. 1). Of these, only two (manipulation 1; simulated manipulation 1) were dissatisfied with treatment. There were no missing data from patients completing follow-up, who were fully compliant with the completion of their diaries.

Differences between active and simulated manipulations were also found for total number of days with pain (23.6 vs. 27.4; p<.005) and total number of days with moderate or severe pain (13.9 vs. 17.9; p<.05) (Table 3). Active manipulations were followed by reduction of radiating pain, with no significant trends, and by a lower (nonsignificant) number of days on, and prescriptions of, nonsteroidal anti-inflammatory drugs.

At first follow-up (day 15), patients receiving manipulation had a lower mean VAS1 score than patients given simulated manipulation (mean difference 0.8) (Fig. 2A). The mean difference increased slightly at subsequent visits, with peaks (1.8) at days 45 and 90. The pattern was the same for the VAS2 scores (Fig. 2B). These differences were significant by multivariate analysis both for VAS1 (F 17.6; p<.0001) and VAS2 (F 11.6; p<.001). A significant

Table 2
Population characteristics of the two samples

Variable	Active manipulations n	Active manipulations %	Simulated manipulations n	Simulated manipulations %
Total	53	100	49	100
Center				
ICOT	47	88.7	46	93.9
Celio Hospital	6	11.3	3	6.1
Sex				
Male	37	69.8	27	55.1
Female	16	30.2	22	44.9
Age (years)				
<40	24	45.3	16	32.7
40–49	14	26.4	16	32.7
50+	15	28.3	17	34.7
Pain				
Lumbar	49	96.1	49	100.0
Lumbosacral	2	3.9	—	—
No. segments with disc protrusion				
1	12	22.6	8	16.3
2	35	66.0	36	73.5
3	6	11.3	5	10.2
Aggravation				
Standing	42	79.2	40	81.6
Gait	40	75.5	36	73.5
Change of posture	34	64.2	38	77.6
VAS1, mean (SD)	6.4 (0.9)		6.4 (0.8)	
VAS2, mean (SD)	5.3 (1.4)		5.1 (1.3)	

ICOT=Istituto Chirurgico Ortopedico Traumatologico; VAS1=visual analog scale for local pain; VAS2=visual analog scale for radiating pain.

Table 3
Spinal manipulations for acute back pain caused by disc protrusion—Change in pain intensity

Variable	Active manipulations Mean (SD) (unless otherwise specified)		Simulated manipulations Mean (SD) (unless otherwise specified)	
Pain (no. days)				
Mild	9.6 (4.9)		9.5 (4.6)	
Moderate	9.2 (5.9)		11.6 (5.3)	
Severe	4.7 (3.9)		6.3 (4.7)	
Total*	23.6 (6.5)		27.4 (4.5)	
NSAID (no. days)	1.8 (2.9)		3.7 (7.1)	
NSAID (no. prescriptions)	2.6 (4.0)		4.6 (8.9)	
	No.	%	No.	%
Patients with reduction of local pain (VAS1)				
Day 15†	44	86	30	61
Day 30	47	94	41	85
Day 45	48	100	44	92
Day 90	47	98	43	90
Day 180	47	98	45	94
Patients with reduction of radiating pain (VAS2)				
Day 15*	42	82	26	53
Day 30‡	47	94	37	77
Day 45†	48	100	39	81
Day 90*	47	98	37	77
Day 180†	48	100	40	83
Patients becoming pain-free (VAS1)				
Day 15	0	0	0	0
Day 30	3	6	0	0
Day 45	9	17	3	6
Day 90‡	13	24	3	6
Day 180*	15	28	3	6
Patients becoming pain-free (VAS2)				
Day 15	7	13	2	4
Day 30	12	23	6	12
Day 45†	22	41	8	16
Day 90§	29	55	6	12
Day 180§	29	55	10	20

NSAID=nonsteroidal anti-inflammatory drugs; VAS1=visual analog scale for local pain; VAS2=visual analog scale for radiating pain.
* p<.005, Mann-Whitney test.
† p<.01, Fisher exact test.
‡ p<.05, Fisher exact test.
§ p<.0001, Fisher exact test.

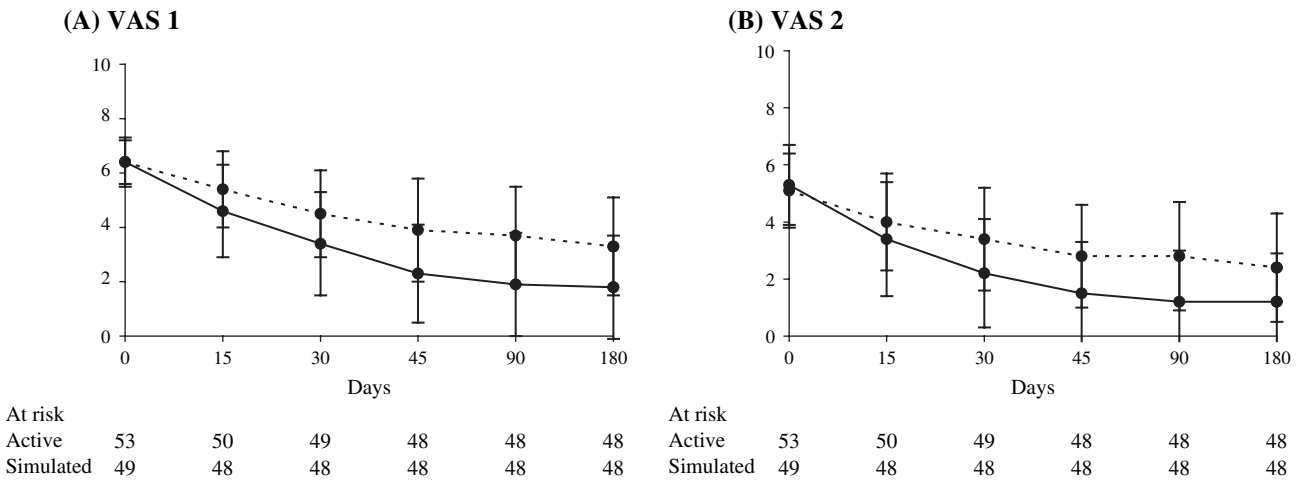

Fig. 2. Spinal manipulations for acute back pain caused by disc protrusion. Visual analog scales for local pain (VAS1) (A) and radiating pain (VAS2) (B) at entry and during follow-up. Continuous lines: active manipulations; dotted lines: simulated manipulations. Numbers are patients at entry and at each follow-up visit.

interaction was found between therapeutic arm and time for VAS1 (F 8.2; $p<.0001$) and VAS2 (F 8.9; $p<.0001$).

There were no statistically significant differences in the Kellner symptom scores and SF-36 scores in the two groups (Table 4). Follow-up MRI confirmed disc protrusion in all patients with signs of disc degeneration (34 patients receiving manipulations and 42 simulated manipulations). MRI findings were unchanged from baseline (see Table 1).

No adverse events were reported.

Discussion

Patients receiving active manipulations enjoyed significantly greater relief of local and radiating acute LBP, spent fewer days with moderate-to-severe pain, and consumed fewer drugs for the control of pain. However, only few patients withdrew from treatment, with no significant differences for active and simulated manipulations. We assigned a pragmatic a priori difference between treatment and control groups, on the basis that withdrawal before concluding treatment would be a robust measure of efficacy. On that basis, active manipulations did not appear superior to simulated manipulations. The low rate of withdrawal from treatment for both active and sham manipulations is important in this context, as simulated manipulations can be assimilated to massage, which may have some effect on LBP.

Although no adjustments were made for multiple observations, the possibility of chance findings can be excluded by the statistical significance of the results, even considering the variety of secondary outcome measures. These findings are in keeping with other reports comparing spinal manipulation to other or no treatment [21–26], but contrast with some well-conducted randomized clinical trials which did not find manipulations consistently better than other treatments in patients with acute back pain [27–30]. However, some found good results in selected subgroups, defined by the duration of symptoms [28] and the response to straight leg raising [31]. Thus, manipulations may relieve acute back pain and sciatica with disc protrusion, although the results of subgroup analyses must be interpreted with caution.

Interestingly, pain was also significantly reduced in patients given simulated manipulations, starting from day 30 (Fig. 2) with a smaller difference between treatments when comparing day 90 with day 180. Although, as noted above,

Table 4
Spinal manipulations for acute back pain and sciatica with disc protrusion—Quality of life (SF-36 Health Survey) and psychological profile (Kellner Rating Scale)

	Active manipulations (n=53)		Simulated manipulations (n=49)	
	mean	(SD)	mean	(SD)
SF-36 Health Survey				
Domain				
Physical functioning	67.4	(17.9)	60.5	(22.5)
Role, physical	31.1	(37.6)	29.1	(37.6)
Bodily pain	33.8	(12.5)	31.9	(13.6)
General health	53.8	(16.8)	57.5	(20.0)
Vitality	57.7	(14.1)	52.1	(16.4)
Social functioning	57.8	(13.5)	52.1	(16.4)
Role, emotional	44.6	(41.8)	37.4	(42.8)
Mental health	73.5	(16.9)	70.2	(14.7)
Kellner Rating Scale				
Item				
Anxiety	6.1	(3.6)	6.4	(3.8)
Anxiety symptoms	3.7	(2.7)	3.9	(3.0)
Relaxed	2.4	(1.6)	2.5	(1.6)
Depression	4.1	(3.1)	4.4	(2.8)
Depression symptoms	1.8	(2.0)	2.0	(1.9)
Contented	2.2	(1.7)	2.4	(1.6)
Somatic	9.7	(3.5)	9.2	(4.6)
Somatic symptoms	5.1	(3.2)	5.0	(4.2)
Somatic well-being	4.6	(1.5)	4.4	(1.7)
Anger-hostility	3.5	(3.1)	3.2	(2.9)
Anger-hostility	2.1	(2.5)	2.2	(2.4)
Friendly	1.2	(1.3)	1.1	(1.5)

simple massage may be helpful in relieving LBP, this finding supports the assumption that, even when disc protrusion appears unchanged at follow-up, as observed in the present study, acute back pain is self-limiting and its natural history is toward regression in a few weeks in a large proportion of cases [32,33]. This could also explain why the majority of patients continued the planned treatment (either true or simulated), despite unchanged psychiatric symptoms and quality of life measures, under the assumption of a perceived benefit.

Despite the positive findings, the study has two major limitations. First, in the absence of an exit interview there is no certainty that our patients were truly blinded as to group involvement. However, the exclusion of patients undergoing previous manipulations and the low rate of withdrawal in both treatment arms is against the possibility of unmasking. Second, the external validity of our results is limited by the fact that only two institutions were involved, and by the treatment of pain with disc protrusion. Thus, this study needs to be replicated in other settings to verify its findings.

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