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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

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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’’