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Spinal High-Velocity Low Amplitude Manipulation in Acute Nonspecific Low Back Pain: A Double-Blinded Randomized Controlled Trial in Comparison With Diclofenac and Placebo

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Spine: April 01, 2013 - Volume 38 - Issue 7 - p 540–548

doi: 10.1097/BRS.0b013e318275d09c

Randomized Trial

[Abstract](#) [In Brief](#) [Author Information](#) [Authors](#) [Article Metrics](#) [Metrics](#)

Study Design. A randomized, double-blinded, placebo-controlled, parallel trial with 3 arms.

Objective. To investigate in acute nonspecific low back pain (LBP) the effectiveness of spinal high-velocity low-amplitude (HVLA) manipulation compared with the nonsteroidal anti-inflammatory drug diclofenac and with placebo.

Summary of Background Data. LBP is an important economical factor in all industrialized countries. Few studies have evaluated the effectiveness of spinal manipulation in comparison to nonsteroidal anti-inflammatory drugs or placebo regarding satisfaction and function of the patient, off-work time, and rescue medication.

Methods. A total of 101 patients with acute LBP (for <48 hr) were recruited from 5 outpatient practices, exclusion criteria were numerous and strict. The subjects were randomized to 3 groups: (1) spinal manipulation and placebo-diclofenac; (2) sham manipulation and diclofenac; (3) sham manipulation and placebo-diclofenac. Outcomes registered by a second and blinded investigator included self-rated physical disability, function (SF-12), off-work time, and rescue medication between baseline and 12 weeks after randomization.

Results. Thirty-seven subjects received spinal manipulation, 38 diclofenac, and 25 no active treatment. The placebo group with a high number of dropouts for unsustainable pain was closed praecox. Comparing the 2 active arms with the placebo group the intervention groups were significantly superior to the control group. Ninety subjects were analyzed in the

collective intention to treat. Comparing the 2 intervention groups, the manipulation group was significantly better than the diclofenac group (Mann-Whitney test: $P = 0.0134$). No adverse effects or harm was registered.

Conclusion. In a subgroup of patients with acute nonspecific LBP, spinal manipulation was significantly better than nonsteroidal anti-inflammatory drug diclofenac and clinically superior to placebo.

In a randomized controlled trial with patients with acute nonspecific low back pain and no other comorbidities spinal high-velocity low-amplitude manipulation was compared with diclofenac and rescue medication. The placebo group had to be closed earlier for ethical reasons (pain). The final evaluation showed manipulation being significantly better than nonsteroidal anti-inflammatory drug and clinically superior to placebo.

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Acknowledgment date: April 9, 2012. First revision date: May 29, 2012. Second revision date: August 9, 2012. Acceptance date: September 14, 2012.

The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

Funds to support this work were received from: Deutsche Gesellschaft für Manuelle Medizin (DGMM) - Aerzteseminar für Manuelle Wirbelsäulen- und Extremitaetentherapie (MWE).

Relevant financial activities outside the submitted work: support for travel to meetings.

W.v.H. is member of the board of the DGMM. All other authors declare no conflict of interest regarding any medical measures tested in this clinical trial.

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