

# Research Paper Review

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Spinal manipulation and home exercise with advice for subacute and chronic back-related leg pain: a trial with adaptive allocation Annals of Internal Medicine 2014; 161: 381-391

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# **ABSTRACT**

**Background:** Back-related leg pain (BRLP) is often disabling and costly, and there is a paucity of research to guide its management.

**Objective:** To determine whether spinal manipulative therapy (SMT) plus home exercise and advice (HEA) compared with HEA alone reduces leg pain in the short and long term in adults with BRLP.

**Design:** Controlled pragmatic trial with allocation by minimization conducted from 2007 to 2011. (ClinicalTrials.gov: NCT00494065)

Setting: 2 research centers (Minnesota and Iowa).

Patients: Persons aged 21 years or older with BRLP for least 4 weeks.

Intervention: 12 weeks of SMT plus HEA or HEA alone.

**Measurements:** The primary outcome was patient-rated BRLP at 12 and 52 weeks. Secondary outcomes were self-reported low back pain, disability, global improvement, satisfaction, medication use, and general health status at 12 and 52 weeks. Blinded objective tests were done at 12 weeks.

**Results:** Of the 192 enrolled patients, 191 (99%) provided follow-up data at 12 weeks and 179 (93%) at 52 weeks. For leg pain, SMT plus HEA had a clinically important advantage over HEA (difference, 10 percentage points [95% CI, 2 to 19]; P = 0.008) at 12 weeks but not at 52 weeks (difference, 7 percentage points [CI, -2 to 15]; P = 0.146). Nearly all secondary outcomes improved more with SMT plus HEA at 12 weeks, but only global improvement, satisfaction, and medication use had sustained improvements at 52 weeks. No serious treatment-related adverse events or deaths occurred.

Limitation: Patients and providers could not be blinded.

**Conclusion:** For patients with BRLP, SMT plus HEA was more effective than HEA alone after 12 weeks, but the benefit was sustained only for some secondary outcomes at 52 weeks. **Primary Funding Source:** U.S. Department of Health and Human Services.

#### **ANALYSIS**

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#### **Background Information**

Back-related leg pain (BRLP) is a common and important symptom associated with low back pain (LBP); however, despite its incidence, it is relatively understudied. Leg pain tends to be associated with a poorer prognosis and quality of life and is associated with greater pain severity, more lost time at work and higher rates of surgery (1-6). Current treatment often includes prescription medications and/or surgery, although, with concerns regarding the adverse effects of these treatments mounting (7-15), conservative treatments such as spinal manipulative therapy (SMT) are increasingly being recommended (16).

The purpose of the current study was to determine whether a combination of SMT, home exercises and advice would be more effective than exercise and advice alone in decreasing BRLP.

#### PERTINENT RESULTS

#### **Participants**

1132 patients were initially screened for inclusion, with 192 ultimately being included in the study. Approximately 90% of included patients were experiencing chronic BRLP. There were no significant differences between the demographic and baseline characteristics of the intervention and control groups.

#### Study Treatments

Of 192 participants, 191 (99%) provided 12-week follow-up data; 179 (93%) provided 52-week follow-ups. Attendance at appointments was above 90% for each group. The mean number of HEA visits in the SMT plus HEA Group was 3.8 (SD, 0.6; median, 4.0) versus 3.6 (SD, 1.0; median, 4.0) in the HEA alone group. The mean number of SMT visits was 14.6 (SD, 3.8; median, 16) in the SMT plus HEA group.

#### Primary Outcome

BRLP was significantly lower in the SMT + HEA group after 12 weeks (10 percentage points [95% CI: 2 to 19]; p = 0.008) but not after 52 weeks (7 percentage points [CI: -2 to 15]; p = 0.146). Also at 12 weeks, 37% of patients receiving SMT plus HEA had at least a 75% reduction in leg pain, compared with 19% in the HEA group (further, 20% of patients receiving SMT plus HEA had a 100% reduction, compared with 5% in the HEA alone group).

#### Secondary Outcomes

At 12 weeks, the adjusted means in the SMT plus HEA group were better than those in the HEA group for:

- LBP (difference, 9 percentage points [CI: 3 to 16]; p = 0.005)
- Disability (difference, 11 percentage points [CI: 5 to 17]; p < 0.001)

- SF-36 physical component score (difference, 3.4 percentage points [CI: 1.0 to 5.8]; p = 0.006)
- Global improvement (difference, 10 percentage points [CI: 14 to 5];  $p \le 0.02$ )
- Satisfaction (difference, 13 percentage points [CI: 17 to 9]; p < 0.001)

At 52 weeks, the SMT plus HEA group sustained better:

- Global improvement (difference, 6 percentage points [CI: 11 to 1];  $p \le 0.02$ ),
- Satisfaction (difference, 10 percentage points [CI: 16 to 6]; p < 0.001), than did the HEA group.

## Medication Use

At 12 weeks, 56% of SMT + HEA patients were still using pain medication, compared with 63% of HEA alone patients. At 52 weeks, the values were 42% and 66% respectively.

Lastly, during the 12-week study period, 10 patients reported visiting non-study health care providers for their leg pain or LBP: 3 in the SMT + HEA group (2 chiropractor, 1 massage therapy) and 7 in the HEA alone group (3 multiple providers, 2 physician, 1 chiropractor, 1 massage therapist). By 52 weeks, 81 patients had sought additional health care since the end of the study treatment phase.

# **CLINICAL APPLICATION & CONCLUSIONS**

The addition of SMT to a home exercise and advice program resulted in a medium effect size (0.6) in patients suffering from back-related leg pain, indicating a positive effect of SMT when combined with home exercise and advice. This indicates that, for patients with subacute and chronic BRLP, SMT in addition to HEA is a safe and effective method of relieving pain in the first 12 weeks following injury. Clinicians should, however, continue to exercise caution and continual clinical judgment in these cases due to the potential for disc injury in patients with BRLP.

## **STUDY METHODS**

## **Design & Subjects**

This was a randomized, controlled trial with a parallel design. Patients were recruited from the surrounding population of 2 chiropractic educational institutions (Minneapolis, MN; Davenport, IA).

## Inclusion Criteria

- Age 21 years or older;
- BRLP based on Quebec Task Force on Spinal Disorders classifications 2, 3, 4, or 6 (radiating pain into the proximal or distal part of the lower extremity, with or without neurologic signs);
- BRLP severity of 3 or greater (on a scale of 0 to 10);
- A current episode length of 4 weeks or more; and
- A stable prescription medication plan in the previous month.

## Exclusion Criteria

- Quebec Task Force on Spinal Disorders classifications of 1, 5, 7, 8, 9, 10, and 11 (pain without radiation into the lower extremities, progressive neurologic deficits, the cauda equina syndrome, spinal fracture, spinal stenosis, surgical lumbar spine fusion, several incidents of lumbar spine surgery, chronic pain syndrome, visceral diseases, compression fractures or metastases, blood clotting disorders, severe osteoporosis, and inflammatory or destructive tissue changes of the spine);
- Receiving ongoing treatment of leg pain or LBP;

- Pregnant or nursing;
- Current or pending litigation for worker's compensation, disability, or personal injury;
- Unable to read or comprehend English; or
- Evidence of substance abuse.

#### Patient Allocation

A Web-based program assigned patients to treatment after the second baseline visit using a minimization algorithm based on the Taves method (17). Patients were assigned in a 1:1 ratio, stratified by site.

## Interventions

- *SMT* + *HEA group*: As many as 20 SMT visits were allowed, each lasting 10 to 20 minutes, including a brief history and examination. Patients assigned to SMT plus HEA also attended 4 HEA visits. The primary focus of SMT treatment was on manual techniques (including high-velocity, low amplitude thrust procedures or low-velocity, variable amplitude mobilization maneuvers to the lumbar vertebral or sacroiliac joints). Spinal level(s) treated and the number and frequency of treatments was left to the discretion of the treating chiropractor. Adjunct therapies to facilitate SMT, including light soft-tissue therapy and/or ice/hot packs, were used as needed.
- *HEA alone group*: Home exercise and advice were delivered in four 1-hour, one-on-one visits. Exercises were designed to provide participants with tools to manage their existing pain and prevent recurrences. Instruction and demonstration were provided for all exercises.

Positioning exercises incorporating flexion and extension motion cycles were utilized. Positioning exercises were performed 3 times per day, with 25 repetitions per episode. Stabilization exercises included pelvic tilt, quadruped, bridging, abdominal curl-ups, and side bridging with positional variations appropriate to patients' tolerance. Stabilization exercises were performed every other day, with 8-12 repetitions performed per episode.

Postural awareness was also addressed in the exercise program, via printed information about simple pain management techniques (e.g. heat, cold, movement).

#### Outcomes

Self-reported outcomes were collected at the baseline visit and at 3, 12, 26, and 52 weeks via questionnaires independent of study personnel influence. The primary outcome measure was patient-rated typical level of leg pain during the past week using an 11-point numerical rating scale. Endpoints were 12- and 52-weeks. Secondary outcomes included LBP, disability measured with the modified Roland–Morris Disability Questionnaire, physical and mental health status using the Short Form-36 Health Survey (SF-36), patient satisfaction, global improvement, and frequency of medication use for back and leg pain in the past week.

## Statistical Analysis

An intention-to-treat approach was used. The primary outcome variable, patient-rated leg pain, was modeled with mixed-effects regression over baseline. The secondary outcome variables were analyzed with the same methods as patient-rated leg pain but without controlling for multiple testing.

#### **STUDY STRENGTHS / WEAKNESSES**

## Strengths

- A rigorous design and interventions intended to be pragmatic in nature and reflective of clinical practice, patient needs, and the best available research were utilized, and
- Patients older than 65 years were included, thus enhancing generalizability.

## Limitations

- Participants and treating practitioners were not able to be blinded to treatment, and
- The study was not designed to evaluate the effectiveness of SMT alone for BRLP, instead being designed to be more pragmatic and reflect a more real-world setting in which patients would be treated but also provided with advice/exercises (therefore, this is more of a consideration than a limitation!).

## Additional References

- 1. Andersson GBJ. The epidemiology of spinal disorders. In: Frymoyer JW, Ducker TB, Hadler NM, Kostuik JP, Weinstein JN, Whitecloud TS, eds. The Adult Spine: Principles and Practice. New York: Raven Pr; 1997: 93-141.
- 2. Selim AJ, Ren XS, Fincke G et al. The importance of radiating leg pain in assessing health outcomes among patients with low back pain. Results from the Veterans Health Study. Spine 1998; 23: 470-4.
- 3. Kent PM, Keating JL. Can we predict poor recovery from recent-onset nonspecific low back pain? A systematic review. Man Ther 2008; 13: 12-28.
- 4. Hill JC, Konstantinou K, Egbewale BE et al. Clinical outcomes among low back pain consulters with referred leg pain in primary care. Spine 2011; 36: 2168-75.
- 5. Kongsted A, Kent P, Albert H et al. Patients with low back pain differ from those who also have leg pain or signs of nerve root involvement— a cross-sectional study. BMC Musculoskelet Disord 2012; 13: 236.
- 6. Konstantinou K, Hider SL, Jordan JL et al. The impact of low back-related leg pain on outcomes as compared with low back pain alone: a systematic review of the literature. Clin J Pain 2013; 29: 644-54.
- 7. Centers for Disease Control and Prevention (CDC). CDC grand rounds: prescription drug overdoses- a U.S. epidemic. MMWR Morb Mortal Wkly Rep. 2012; 61: 10-3.
- 8. Manchikanti L, Pampati V, Boswell MV et al. Analysis of the growth of epidural injections and costs in the Medicare population: a comparative evaluation of 1997, 2002, and 2006 data. Pain Physician 2010; 13: 199-212.
- 9. Bohnert AS, Valenstein M, Bair MJ et al. Association between opioid prescribing patterns and opioid overdose-related deaths. JAMA 2011; 305: 1315-21.
- 10.Dunn KM, Saunders KW, Rutter CM et al. Opioid prescriptions for chronic pain and overdose: a cohort study. Ann Intern Med 2010; 152: 85-92.
- 11.Martell BA, O'Connor PG, Kerns RD et al. Systematic review: opioid treatment for chronic back

pain: prevalence, efficacy, and association with addiction. Ann Intern Med 2007; 146: 116-27.

- 12.Gore M, Sadosky A, Stacey BR et al. The burden of chronic low back pain: clinical comorbidities, treatment patterns, and health care costs in usual care settings. Spine 2012; 37: E668-77.
- 13.Deshpande A, Furlan A, Mailis-Gagnon A et al. Opioids for chronic low-back pain. Cochrane Database Syst Rev 2007: CD004959.
- 14.Deyo RA, Mirza SK, Turner JA, Martin BI. Overtreating chronic back pain: time to back off? J Am Board Fam Med 2009; 22: 62-8.
- 15.Ohrn A, Elfström J, Tropp H, Rutberg H. What can we learn from patient claims? A retrospective analysis of incidence and patterns of adverse events after orthopaedic procedures in Sweden. Patient Saf Surg 2012; 6: 2.
- 16.Delitto A, George SZ, Van Dillen LR et al. Orthopaedic Section of the American Physical Therapy Association. Low back pain. J Orthop Sports Phys Ther 2012; 42: A1-57.
- 17. Taves DR. Minimization: a new method of assigning patients to treatment and control groups. Clin Pharmacol Ther 1974; 15: 443-53.

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