Research Paper Review

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Symptomatic magnetic resonance imaging-confirmed lumbar disk herniation patients: A comparative effectiveness prospective observational study of 2 age- and sex-matched cohorts treated with either high-velocity, low-amplitude spinal manipulative therapy or imaging-guided lumbar nerve root injections

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Peterson CK, Leeman S, Lechmann M, et al.

ABSTRACT

OBJECTIVES: The purpose of this study was to compare self-reported pain and "improvement" of patients with symptomatic, magnetic resonance imaging-confirmed, lumbar disk herniations treated with either high-velocity, low-amplitude spinal manipulative therapy (SMT) or nerve root injections (NRI).

METHODS: This prospective cohort comparative effectiveness study included 102 age- and sex-matched patients treated with either NRI or SMT. Numerical rating scale (NRS) pain data were collected before treatment. One month after treatment, current NRS pain levels and overall improvement assessed using the Patient Global Impression of Change scale were recorded. The proportion of patients, "improved" or "worse," was calculated for each treatment. Comparison of pretreatment and 1-month NRS scores used the paired t test. Numerical rating scale and NRS change scores for the 2 groups were compared using the unpaired t test. The groups were also compared for "improvement" using the $\chi(2)$ test. Odds ratios with 95% confidence intervals were calculated. Average direct procedure costs for each treatment were calculated.

RESULTS: No significant differences for self-reported pain or improvement were found between the 2 groups. "Improvement" was reported in 76.5% of SMT patients and in 62.7% of the NRI group. Both groups reported significantly reduced NRS scores at 1 month ($P = .0001$). Average cost for treatment with SMT was Swiss Francs 533.77 (US $558.75) and Swiss Francs 697 (US $729.61) for NRI.

CONCLUSIONS: Most SMT and NRI patients with radicular low back pain and magnetic resonance imaging-confirmed disk herniation matching symptomatic presentation reported significant and clinically relevant reduction in self-reported pain level and increased global perception of improvement. There were no significant differences in outcomes between NRI and SMT. When considering direct procedure costs, the average cost of SMT was slightly less expensive.

ANALYSIS

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Background Information
Lumbar disc herniations (LDH) represent a common and disabling low back injury that is often associated with concurrent leg pain (sciatica). The natural history of sciatica in LDH cases trends toward resolution within two to three months. However, treatment can potentially help reduce that span and the impact during that period. Still, the most effective treatment for LDH remains largely unknown to date, although it is generally agreed that a course of conservative treatment should be undertaken before surgery is considered.

This study compared two commonly employed interventions for patients with LDH – spinal manipulative therapy (SMT) and nerve root injections, in terms of their effects on pain and perceived symptomatic improvement in patients with MRI confirmed LDHs.

PERTINENT RESULTS

- The average age of the 102 included patients was 47.6 years; 62.7% were male.
- The injection group had a significantly higher average initial Numerical Rating Scale (NRS) score when compared with the SMT group.
- The average number of SMT treatments was 11.2 (ranging from 5 to 20).
- Only 1 SMT patient reported being worse after treatment compared with 3 injection patients.
- No SMT patients required surgery during the study period, while 3 injection patients received a second injection and 3 had surgery.
- In the SMT group, 76.5% of patients were "improved" (Odds Ratio = 1.93, 95% Confidence Interval of 0.82-4.56), while 62.7% of the injection patients were "improved" (OR = 0.52, 95% CI: 0.22-1.23).
- There was no statistically significant difference between groups in terms of the proportion reporting clinically important improvements. The SMT and injection groups each had significant decreases in NRS scores at one month, with an average pain reduction of 60% in the SMT group and 53% (NRS score) in the injection group.
- Between groups at one month there were no significant differences in NRS scores, Patient Global Impression of Change (PGIC, a 7 point scale) scores or NRS change scores.
- The average cost in the SMT group was 533.8 Swiss Francs, while the average cost in the injection group was a total of 697 Swiss Francs.

CLINICAL APPLICATION & CONCLUSIONS

While there were no significant differences between groups, both nerve root injections and SMT produced statistically significant and clinically important improvements in pain and perceived change in symptoms after 1 month of treatment for patients with symptomatic MRI-proven LDH. The average cost of SMT treatment was slightly lower than nerve root injections. The patients averaged 11 treatments over the course of a month. No mention was made of the use of other treatments during the study period including or excluding exercise therapies, electrical modalities, or analgesic or other medications.

From a clinical standpoint, most clinicians who utilize SMT on patients with LDH can be reassured that their treatment is at least as effective and potentially more cost effective when compared with nerve root injections for this condition. Previous research (see Additional Reference 1 below) has indicated the overwhelming safety of SMT for patients with LDH. Another interesting take home point is that the authors employed certain types of manipulations for certain disc herniation locations and this may be advisable for manual therapists to consider when seeing patients with LDH, particularly in light of the largely positive results in this study, and how few of the SMT group patients were "worse" after 1 month of treatment (only 1, as mentioned above). As a reminder, patients with intraforaminal LDHs (as noted on MRI) received a modified push adjustment with a kick, whereas patients with paramedian LDHs receive a pull adjustment with a kick.

EDITOR'S NOTE: Below is an excerpt from an article I (Dr. Thistle) wrote with Dr. Mark Erwin, a chiropractor/PhD who is one of the world's leading experts on disc pathology. This article was written for the Canadian Chiropractic Association and discussed this paper, and the other cohort on cervical disc herniation patients. The information below provides some additional food for thought to go along with this review:

The clinical decision process surrounding the use of high-velocity, low-amplitude (HVLA) spinal manipulation (SMT) in patients with suspected (or confirmed) cervical (CDH) or lumbar disc herniation (LDH) has traditionally been difficult. Clinicians naturally wish to help their patients, yet medicolegal concerns about iatrogenesis or worsening of the patient's condition while under care are particularly prevalent for these patients. Similar to most spinal conditions, a variety of interventions are commonly employed in the treatment of CDH/LDH. The most effective treatment for CDH and LDH remains largely unknown to date, although it is generally agreed that a course of conservative treatment should be undertaken before surgery is considered. Regarding SMT specifically, the existing clinical evidence has been unable to provide a consistent level of guidance. In the real world, there have certainly been successes and failures.

The genesis of the herniated nucleus pulposus (HNP) is a multifactorial process and the clinician ought to bare these differences in mind when faced with a patient suffering from a HNP. Degenerative changes affecting the intervertebral disc (IVD) include loss of extracellular matrix integrity with the nucleus of the IVD as well as the progressive cell death of NP cells. Tears and fissures also occur throughout the annulus that likely lead to changes in tolerance of applied loads. However, one wonders what the ramifications of these changes are, particularly with respect to the choice of manual therapies.

If the hypothesis is that SMT is beneficial to some patients with HNP, what is the mechanism? What does SMT accomplish in the presence of a torn annulus and herniated nucleus pulposus? Or, does this study (and their cervical spine cohort) actually suggest that the SMT accomplishes anything with respect to the HNP as opposed to manual therapy for 'mechanical neck pain' in general (which is reasonable, as many patients did improve under care)? Is any benefit of SMT superior to a placebo? Radiculopathy caused by a herniated NP involves an inflammatory cytokine-induced neuropathy as well as a host of other biochemical and cellular events with the process requiring hours, days, weeks, months or even years to occur. Therefore, we cannot know how long the HNP was present prior to treatment commencing? What might occur through the provision of SMT that could resolve this pathology? These are important questions concerning possible therapeutic efficacy of SMT.

Legal actions have commenced against chiropractors treating patients presenting with neck and low back pain (with or without radiculopathy) with claims that SMT caused the HNP. These cases are always complex, with very grey areas amidst the patient's treatment history and evolution of the ultimate result. Most of the time there are no pre-treatment MRI or CT images available, making it impossible to determine exactly when the HNP occurred. Further, many of these cases include a

patient with a lengthy history of off and on neck or back +/- radicular pain. Such a history is consistent with the gradual evolution of the HNP and radiculopathy, further muddying the waters of causation. It is not to say that SMT may not be helpful with certain cases of HNP, however it is important for the clinician to be aware of the unpredictable nature of this ailment. Even when SMT is delivered with the greatest of care, there is the possibility that the patient's condition could be exacerbated. Therefore, one must ask one's self what the potential 'downside' may be in such a condition. It is very likely that in many of these cases the HNP was already present or in process due to the biology of disc degeneration. However, the reader must reconcile how a treatment thought by some to potentially cause a HNP could at the same time effectively treat the same condition.

It is important to learn if there were any particular, unique patient characteristics shared by the responders in both trials reported by Peterson et al. that may set them apart from others (if there was any particular therapeutic benefit)? It should be emphasized that treatment performed on a patient with a known HNP with well-defined parameters is a different thing from the usual clinical setting where such information is rarely available; therefore, the clinician ought to exercise good judgment extrapolating the results of this study to the clinic. On the other hand, when the clinician encounters a patient with neck and or low back pain with or without radiculopathy, what is one to do? The studies by Peterson et al. suggest that SMT may be an effective treatment for patients suffering from known and quantified disc herniation. It would be interesting to obtain post-treatment data concerning objective evidence for changes in the herniated disc (MRI) or neurological status of the patients post treatment such as EMG. Current guidelines maintain that an acutely herniated disc with progressive neurological compromise is an absolute contraindication to SMT treatment and the over-riding concern of 'first, do no harm' must be paramount.

The evolution of radiculopathy or neurological embarrassment usually occurs gradually over days, weeks or even months. Therefore, until we understand these pathologies better, perhaps the best approach with these patients should begin with a thorough, meticulous history and examination and patient education. If the patient presents within the developmental phase of a HNP that may progress to radiculopathy (or even myelopathy), conservative treatments such as traction, soft tissue therapy and perhaps acupuncture will pose the least potential for harm, but at the same time provide the clinician with valuable feedback over the course of a few clinic visits. Also, education about the potential for the condition to change over time will fully inform the patient with respect to potential important changes in their symptoms. The HNP may, left to its own devices, progress towards overt spinal cord compromise (in the cervical or lumbar spine) due simply to natural history or trivial trauma.

SMT is arguably the most formidable treatment option available to the chiropractor; thoughtful, reasonable and informed consideration ought to dictate its use. It may be that SMT is an effective and safe therapy for some cases of HNP as detailed within the Peterson et al. studies and there is a need for much for research in this area. However, it is imperative that the clinician be aware that the natural history of some patients suffering from a HNP is to develop frank neurological embarrassment simply due to natural history. The chiropractor needs to manage these cases very carefully for the benefit of all since neither the patient nor the clinician wants to be on the wrong side of Mother Nature or the legal system.

STUDY METHODS

This was a prospective cohort study of patients with MRI-proven and clinically correlated LDH that compared the effectiveness of the two treatments: manual SMT and imaging-guided nerve root injections. Data was obtained from two separate databases, one for each treatment group respectively. From each group, 51 age and gender matched patients were selected for analysis by a blinded researcher (for a total of 102 patients). Nerve root injection patients had not received SMT

and vice-versa. Manual Diversified style lumbar SMT was employed, but the type of adjustment utilized depended on the location of the LDH: patients with intraforaminal LDHs (as noted on MRI) received a modified push adjustment with a kick, whereas patients with paramedian LDHs receive a pull adjustment with a kick. The nerve root injection group received contrast fluoroscopy- or CT-fluoroscopy guided injections of Kenacort and Ropivacaine.

Baseline Numerical Pain Rating Scales (NRS) values were obtained, and after one-month of treatment a telephone interview obtained NRS values and Patient Global Impression of Change (PGIC, a seven-point scale), which was considered the primary outcome measure. The clinically meaningful change for NRS scores was deemed to be 30%. For the PGIC, only responses of 'much better' (1 on the scale) and 'better' (2 on the scale) were taken to mean "improvement" of a patient's condition, whereas scores of 5 through 7 ('slightly worse', 'worse', 'much worse' respectively) would lead to the patient being categorized as "worse". Student t tests were used to compare NRS scores and NRS change scores within groups. Unpaired t tests were used to compare between groups for NRS and NRS change scores. The Mann-Whitney U test was used to compare group average PGIC scores, while the chi square test was used to compare the groups for "improvement". Odds ratios with 95% CIs were calculated as were average direct procedure costs for each treatment.

STUDY STRENGTHS/WEAKNESSES

The biggest weakness of this study was that it was not actually a randomized controlled trial. As such, patient preference and other confounding factors may have influenced the results. It was a well-designed and well-executed cohort trial nonetheless, even though the sample sizes were relatively small. This study should help provide the impetus for future RCTs on patients with LDH to include an SMT arm. The authors did have issues with the injection group database as it did not contain as much demographic information, making additional group matching (such as chronicity of condition) beyond age and gender not feasible. The injection group had significantly higher initial pain levels, indicating that there may be differences between the two groups of patients, particularly as they had already self-selected their treatments. The authors also mention that telephone administered outcome measures often have more positive responses when compared with postal questionnaires.

An additional weakness is that only 1-month outcome measurement took place and there was no additional follow-up. Having additional outcome data such as Oswestry disability questionnaire scores or other indications of disability or quality of life would have been informative.

The only treatments utilized in this study were the nerve root injections or SMT. There were no additional interventions that were included for either group such as home exercises, over the counter medications, patient education, and so on. The study could have been more clinically applicable (or pragmatic) if one or more such treatments were included/allowed. However, as mentioned, the study did provide direction as to how they decided on the type of SMT to administer based on LDH location, as well as reporting an average of 11 SMT treatments over the course of a month. Both of these factors could assist practitioners with treatment planning for patients for LDH.

Finally, all of the patients had MRI-confirmed LDH, and frequently in primary care practice clinicians will have to proceed with treatment for LDH patients based on history and physical examination findings, due to waiting time constraints for MRI (at least in Canada). Again, that could represent a difference between the study population and those seen in practice.

Additional References

1. Oiphant D. Safety of spinal manipulation in the treatment of lumbar disc herniations: a systematic review and risk assessment. J Manipulative Physiol Ther 2004; 27:197-210.
2. Leininger B, Bronfort G, Evans R, Reiter T. Spinal manipulation or mobilization for radiculopathy: a systematic review. Phys Med Rehabil Clin N Am 2011; 22:105-25.