

# SYMPTOMATIC, MAGNETIC RESONANCE IMAGING– CONFIRMED CERVICAL DISK HERNIATION PATIENTS: A COMPARATIVE-EFFECTIVENESS PROSPECTIVE OBSERVATIONAL STUDY OF 2 AGE- AND SEX-MATCHED COHORTS TREATED WITH EITHER IMAGING-GUIDED INDIRECT CERVICAL NERVE ROOT INJECTIONS OR SPINAL MANIPULATIVE THERAPY

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## ABSTRACT

**Objective:** The purpose of this study was to compare the outcomes of overall improvement, pain reduction, and treatment costs in matched patients with symptomatic, magnetic resonance imaging–confirmed cervical disk herniations treated with either spinal manipulative therapy (SMT) or imaging-guided cervical nerve root injection blocks (CNRI).

**Methods:** This prospective cohort comparative-effectiveness study included 104 patients with magnetic resonance imaging–confirmed symptomatic cervical disk herniation. Fifty-two patients treated with CNRI were age and sex matched with 52 patients treated with SMT. Baseline numerical rating scale (NRS) pain data were collected. Three months after treatment, NRS pain levels were recorded and overall “improvement” was assessed using the Patient Global Impression of Change scale. Only responses “much better” or “better” were considered “improved.” The proportion of patients “improved” was calculated for each treatment method and compared using the  $\chi^2$  test. The NRS and NRS change scores for the 2 groups were compared at baseline and 3 months using the unpaired *t* test. Acute and subacute/chronic patients in the 2 groups were compared for “improvement” using the  $\chi^2$  test.

**Results:** “Improvement” was reported in 86.5% of SMT patients and 49.0% of CNRI patients ( $P = .0001$ ). Significantly more CNRI patients were in the subacute/chronic category (77%) compared with SMT patients (46%). A significant difference between the proportion of subacute/chronic CNRI patients (37.5%) and SMT patients (78.3%) reporting “improvement” was noted ( $P = .002$ ).

**Conclusion:** Subacute/chronic patients treated with SMT were significantly more likely to report relevant “improvement” compared with CNRI patients. There was no difference in outcomes when comparing acute patients only. (*J Manipulative Physiol Ther* 2016;39:210-217)

**Key Indexing Terms:** *Cervical Spine; Disk Herniation; Nerve Root; Injections; Manipulation, Spinal; Outcomes Assessment; Comparative-Effectiveness Research; Radiculopathy*

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**C**ervical nerve root compression (radiculopathy) can be severely disabling in some patients and is caused by either disk herniation or more commonly spinal degeneration affecting the intervertebral foramina and subsequent exiting nerve root.<sup>1</sup> The most common nerve roots to be involved are the C6 and C7 levels, with the symptoms arising because of compression of the nerve root, inflammation of the nerve root, or both.<sup>1,2</sup> Typical clinical signs and symptoms of cervical radiculopathy include pain in the distribution of the involved nerve root, paresthesias in a dermatomal pattern, weakness of the muscles innervated by the involved nerve root, and/or a decrease in the reflex.<sup>3</sup> In some patients, arm pain predominates over the neck pain.<sup>3,4</sup>

The diagnosis of cervical nerve root compression is made with magnetic resonance imaging (MRI) scans. It is important, however, to recognize that disk protrusions seen on MRI are not always symptomatic, so it is critical that imaging abnormalities are linked to patient symptoms to determine whether or not the imaging findings are clinically relevant.<sup>5-7</sup> However, more severe disk herniations such as extruded disks with compression of the spinal cord are uncommon in asymptomatic people.<sup>7</sup>

Patients with symptomatic cervical disk herniations are initially treated conservatively, with surgery reserved for those cases that remain unresponsive to conservative care.<sup>2-4,8</sup> A variety of different conservative treatments are used for these patients, including pain medications, physiotherapy treatment, lifestyle changes, nerve root injections, or even spinal manipulative therapy (SMT). However, most treatments, other than cervical transforaminal epidural steroid injections (cervical nerve root injections [CNRI]), are not well documented with research evidence.<sup>2,3,8-13</sup> Recently, the use of imaging-guided CNRI has come under scrutiny because of rare but extremely serious adverse events in some patients including ischemic myelopathy, transient or permanent tetraplegia, brain infarctions leading to death, and arterial dissections or cortical blindness.<sup>14,15</sup> Because of the risk of such serious adverse events, a few institutions have modified the procedure to significantly reduce these risks to the new procedure called the *imaging-guided indirect CNRI*.<sup>14,16</sup> Comparing short-term outcomes of this new indirect approach with the traditional direct nerve root injection showed no significant differences in the level of pain reduction.<sup>16</sup>

The research evidence for SMT as a treatment for patients with symptomatic cervical disk herniations is sparse but slowly increasing, with a recent cohort outcomes study showing that more than 3/4 of patients with subacute and chronic symptoms reported clinically relevant improvement at 3 months after start of treatment.<sup>10-13,17</sup> However, SMT to the cervical spine is not without controversy either. The issue of vertebral artery dissection and stroke after manipulation is often quoted.<sup>18,19</sup> Unfortunately, accurate estimations of the frequency of this

association cannot be calculated because of its rarity but are estimated at 1 of 200,000 treatments to 1 in several million treatments.<sup>18,19</sup>

It is also important to recognize that the natural history for patients with acute symptoms from disk herniation (less than 4-8 weeks) is reported to be favorable, and thus, it is difficult to determine whether or not improvement in acute patients undergoing various treatments including CNRI or SMT is due to the treatment or to the natural history of the condition.<sup>19,20</sup> Randomized, controlled, clinical trials (RCTs) would be considered the "criterion standard" to compare specific treatments with patients not treated at all. However, subacute and especially chronic patients should have passed the time point for the effects of natural history to have occurred. Thus, evaluating the outcomes of these patients treated with various conservative therapies could provide useful evidence for clinicians.

Recently, *comparative-effectiveness* research has been promoted rather than RCTs to compare treatment outcomes for similar patients using databases from prospective cohort studies.<sup>21,22</sup> It is argued that patients in prospective cohort outcomes databases may be more representative of patients seen in daily clinical practice as compared with patients included in RCTs. Based on this premise, the purpose of this study is to compare the outcomes of overall improvement, pain reduction, and treatment costs in age- and sex-matched patients with symptomatic, MRI-confirmed cervical disk herniations who were treated with either SMT or CNRI using a comparative-effectiveness prospective cohort design.

## METHODS

This is a comparative-effectiveness observational outcomes study on patients with symptomatic, MRI-confirmed cervical disk herniations. This study follows the same research protocol as done in a similar study using lumbar disk herniation patients.<sup>23</sup> One cohort of patients was from the radiology database for imaging-guided indirect CNRI, and the other cohort was from the chiropractic medicine database for cervical SMT in cervical disk herniation patients. Both databases were started to monitor treatment outcomes as part of the research and quality assurance projects at this specialized orthopedic/rheumatology university hospital.

The CNRI patients were all treated in the radiology department at this hospital. The SMT patients were all treated by 1 of 3 different chiropractors in a single chiropractic practice which is involved in research studies with the university chiropractic medicine department. There was no crossover of patients switching treatments or having both interventions. Data for the CNRI patients were collected between January 2010 and August 2013. Data for the SMT patients were collected between October 2010

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