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#### Association between chiropractic spinal manipulation and lumbar discectomy in adults with lumbar disc herniation and radiculopathy: retrospective cohort study using United States' data

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# Association between chiropractic spinal manipulation and lumbar

# discectomy in adults with lumbar disc herniation and

radiculopathy: retrospective cohort study using United States'

# data

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# Abstract

Objectives: Chiropractic spinal manipulative therapy (CSMT) and lumbar discectomy are both used for lumbar disc herniation (LDH) and lumbosacral radiculopathy (LSR); however, limited research has examined the relationship between these therapies. We hypothesized adults receiving CSMT for newly diagnosed LDH or LSR would have reduced odds of lumbar discectomy over 1- and 2 years' follow-up compared to those receiving other care.

Design: Retrospective cohort study.

Setting: 105-million-patient United States health records network (TriNetX), queried August 3, 2022, yielding data from 2012-query.

Participants: Adults age 18-49 with newly-diagnosed LDH or LSR were included. Exclusions were prior lumbar surgery, absolute indications for surgery, trauma, spondylolisthesis, and scoliosis. Propensity score matching controlled for variables associated with the likelihood of discectomy (e.g., demographics, medications).

Interventions: Patients were divided into cohorts according to receipt of CSMT.

Primary and secondary outcome measures: Odds ratios (ORs) for lumbar discectomy; calculated by dividing odds in the CSMT cohort by odds in the cohort receiving other care.

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Results: After matching, there were 3093 patients per cohort (mean age 36.5±8.5). The ORs [95% CI] for discectomy were significantly reduced in the CSMT cohort compared to the cohort receiving other care over 1-year (0.61 [0.40 to 0.95], *P*=0.028) and 2-years' follow-up (0.65 [0.43 to 0.99], *P*=0.045). E-value sensitivity analysis estimated the strength in terms of risk ratio an unmeasured confounding variable would need to account for study results, yielding point estimates for each follow-up (1-year: 2.66; 2-year: 2.45), which no variables in the literature reached.

Conclusions: Our findings suggest receiving CSMT compared to other care for newly diagnosed LDH/LSR is associated with significantly reduced odds of discectomy over 2-years' follow-up. Given socioeconomic variables were unavailable and an observational design precludes inferring causality, the efficacy of CSMT for LDH/LSR should be examined via randomized controlled trial to eliminate residual confounding.

Keywords: Discectomy, Lumbar Disc Disease, Radiculopathy, Sciatica, Spinal Manipulation, Chiropractic, Low Back Pain

# **Article Summary**

#### Strengths and limitations of this study

• This study was based on an a priori protocol developed by a multidisciplinary research team with the intention of reducing bias.

	This study included patients with newly diagnosed lumbar disc herniation or
	lumbosacral radiculopathy and excluded those with absolute indications for surgery to
	make cohorts more comparable.
	While an extensive propensity matching model was utilized to control for confounding
	variables, socioeconomic variables were not available within the study dataset.
	While this study examined a large population, only large, academically affiliated
	healthcare organizations in the United States were included, thus results may not be
	broadly generalizable.
	As this study is observational, a randomized controlled trial would be needed to
	eliminate possible residual confounding.
Inti	roduction
A lu	mbar disc herniation (LDH) is a focal displacement of intervertebral disc material beyond
the	normal limit of the disc margin, <sup>1</sup> which may compress one or more nerve roots, causing
lum	bosacral radiculopathy (LSR). The clinical features of LSR include radicular (radiating) lower
extr	emity pain, predictable sensory disturbances, weakness, and/or diminished muscle stretch
refle	exes. <sup>2</sup> LDH and LSR are common reasons for patients to receive chiropractic care or undergo
surg	ery to remove LDH material, a procedure called discectomy. However, limited research has
exar	nined the association between chiropractic care and discectomy.

In the United States (US), chiropractors are portal-of-entry providers that often manage low back pain, including LDH/LSR.<sup>3,4</sup> While chiropractors may utilize soft tissue or exercise therapies

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for these patients,<sup>5</sup> they most often employ chiropractic spinal manipulative therapy (CSMT).<sup>4</sup> Prior studies have documented the benefits of CSMT for LDH/LSR, including randomized prospective studies.<sup>6,7</sup> In a meta-analysis, spinal manipulation was found to be one of the most effective treatments for discogenic LSR.<sup>8</sup> Accordingly, US and international clinical practice guidelines have recommended spinal manipulation for low back pain and LSR.<sup>9–13</sup>

Prior studies examining the association between chiropractic care and lumbar spine surgery have examined a broader population and/or outcome.<sup>14–20</sup> Two studies identified a significant reduction in odds of lumbar surgery among individuals receiving early chiropractic care, with one examining surgical fusion or decompression among patients with an occupational back injury,<sup>18</sup> and another examining discectomy and fusion among patients with back pain.<sup>14</sup> The current study differs by examining a narrower range of LBP conditions (i.e., LDH/LSR) with an outcome specific to discectomy.

Several factors may influence whether a patient undergoes a discectomy, including clinical features, patient preferences, and the response to conservative care.<sup>21–23</sup> While the presence of severe or "red flag" neurologic deficits and/or cauda equina syndrome are absolute indications for lumbar discectomy, continued pain despite conservative treatment that affects quality of life is considered a relative indication.<sup>24</sup> For patients without absolute indications, early discectomy can provide short-term benefits for LDH with LSR, however, long-term outcomes are similar at 1-2 years in those receiving conservative care.<sup>25</sup>

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This study was conducted considering that CSMT and lumbar discectomy are both viable treatment options for LDH and LSR, yet there has been limited research examining the relationship between these care pathways.

#### Objectives

 This study aimed to examine the association between receipt of CSMT for newly diagnosed LDH and/or LSR and odds of lumbar discectomy, with the hypothesis that adults receiving CSMT would have reduced odds of lumbar discectomy over 1- and 2year follow-up windows after index diagnosis compared to those receiving other care.

# Methods

## Study design

This study followed an a priori protocol registered with the Open Science Framework (https://osf.io/2gkcd),<sup>26</sup> and incorporated a retrospective, new-user, active-comparator design<sup>27</sup> to compare recipients and nonrecipients of CSMT from age 18-49 of any sex (Figure 1). The study included data within a range of 10 years prior to the query date (i.e., August 3, 2012, to August 3, 2022), to capture more recent data, considering the treatment of LDH and LSR may have changed over time. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline structure was followed.<sup>28</sup>

Figure 1: Study design. The vertical gray arrow represents the date of index diagnosis of lumbar disc herniation (LDH) or lumbosacral radiculopathy (LSR). Assessment windows to the left of this arrow represent time periods occurring before this date over a span of days [#,#]. The follow up window occurs after the index diagnosis and is represented by a green rectangle representing 1- and 2-years' follow-up. Figure created by RT using Creative Commons template from Schneeweiss et al.<sup>29</sup>

## Setting and data source

This study utilized a 105-million patient population within the TriNetX network (TriNetX Inc., Cambridge, MA, US).<sup>30</sup> Data in this network is de-identified, aggregated, and frequently updated from the health records of multiple health care organizations, which are typically large, academically affiliated health centers and their ambulatory offices. This network includes insured and uninsured patients across the US.<sup>31</sup>

Queries of this dataset are performed using standardized nomenclatures such as the ICD-10 procedural classification system (ICD-10-PCS), Current Procedural Terminology (CPT), and Veterans Health Administration National Drug File (VANDF), and others. International Classification of Diseases (ICD-10) codes may also be used which are interconverted automatically to older ICD-9 codes using general equivalence mappings.<sup>30</sup> At University Hospitals of Cleveland, the Clinical Research Center manages all use of the TriNetX platform.

As of January 2022, there were 10 healthcare organizations within the TriNetX network that had providers administering CSMT.<sup>32</sup> In accordance with of privacy regulations, these institutions remain anonymous. Although this study only examined a fraction of US chiropractic providers, integration of chiropractors into hospitals is a growing trend, with 5% of US chiropractors reporting a hospital affiliation in 2019.<sup>3</sup> Integrated chiropractors are most often employed within physical medicine, rehabilitation, or physical therapy settings and on average have at least 6 years' experience in practice.<sup>33</sup>

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#### Participants

#### Eligibility criteria

This study identified patients with LDH and/or LSR by querying the TriNetX dataset with a custom set of codes (Supplemental Table 1). Patients with diagnoses of lumbar or sacral radiculopathy or sciatica were included as these diagnoses often reflect underlying LDH or LSR,<sup>34</sup> and evidence suggested that these diagnosis codes are often utilized by clinicians.<sup>35</sup> **Error! Reference source not found.**The age bracket of 18-49 years was used as LDH is more common in younger patients aged 30-50.<sup>36</sup> Conversely, lumbar stenosis is a more prevalent cause of LSR in older patients.<sup>37</sup> Accordingly, the upper age cutoff was intended to exclude patients with lumbar stenosis from our study.

Patients with serious spine pathology or absolute indication for surgery, such as cauda equina syndrome (CES), signs of CES such as bowel or bladder incontinence, fracture, infection, and malignant neoplasms were excluded over 365 days preceding and including the date of index diagnosis (Supplemental Table 2).<sup>38</sup> Patients with conditions that could alter the CSMT or surgical approach and/or increase the odds of lumbar surgery were also excluded: lumbar fusion, arthrodesis or postlaminectomy syndrome,<sup>39,40</sup> lumbar spine trauma,<sup>41</sup> and degenerative lumbar scoliosis and spondylolisthesis.<sup>42</sup> As an additional measure of ensuring patients had no previous discectomy, any prior occurrence of discectomy was excluded over an infinite time window preceding and including the date of index diagnosis.

Diagnoses of lumbar spondylosis (e.g., ICD-10: M47.26) were not utilized in our inclusion criteria given these are not specific to LDH. In addition, codes specifying lumbar disc disorders

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with myelopathy (e.g., ICD-10: M47.16) were not utilized as myelopathy has different clinical features and management strategies than LDH/LSR. Diagnosis codes specifying lumbar or lumbosacral disc degeneration were not included, as a strategy to create more uniformity between cohorts. Disc degeneration is not associated with radicular symptoms, unlike LDH, which has a strong association with radicular symptoms.<sup>43</sup>

Included patients were divided into 2 cohorts according to receipt of CSMT (Supplemental Table 3). The CPT codes 98940, 98941, and 98942 for CSMT were included in the "CSMT" cohort and excluded in the "other care" cohort. These 9894\* codes are almost exclusively utilized by chiropractors in the US.<sup>44</sup>

#### Variables

#### Discectomy

A definition for the outcome of lumbar discectomy was developed based on discussion amongst co-authors and comparison with previous publications (Supplemental Table 4).<sup>35,38,45,46</sup> This definition included multiple procedure codes for discectomy, as well as the ICD-10-PCS code OSB4\* which includes open, percutaneous, and percutaneous endoscopic approaches to excise lumbosacral disc material,<sup>47</sup> and the Healthcare Common Procedure Coding System (HCPCS) code C9757 for lumbar discectomy with implantation of an annular closure device.<sup>46</sup> Feasibility testing was conducted in June, 2021, to ensure these codes were represented in the TriNetX database. Two follow-up windows of 1-year and 2-year were used in this study to allow for comparisons to prior similar studies also using long-term endpoints.<sup>16,18</sup>

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#### Potential confounders

Propensity score matching is a method of balancing confounding variables between cohorts to improve their comparability.<sup>27</sup> Based on previous recommendations, confounders were propensity matched when having evidence of an association with the outcome of interest (i.e. lumbar discectomy).<sup>48</sup> Variables present within a 365-day window preceding the index diagnosis of LDH and/or LSR were eligible for propensity matching (Supplemental Table 6). Demographic variables associated with the likelihood of lumbar surgery were propensity matched including increasing age,<sup>23,49</sup> male sex,<sup>23,49,50</sup> and race.<sup>49</sup> Other factors associated with increased likelihood of lumbar surgery were matched including obesity,<sup>23,49</sup> being a nonsmoker,<sup>23</sup> psychological disorders,<sup>49</sup> a history of lumbar injections,<sup>23,51</sup> and prior treatment with opioids<sup>41</sup> or prescription pain medications.<sup>23</sup> Radicular symptoms or radiculopathy are also predictors of lumbar surgery in those with low back pain,<sup>23,51</sup> and were matched via the ICD-10 codes for LSR and sciatica.

#### Study size

A required sample size of 198 was calculated using G\*Power<sup>52</sup> z-tests for logistic regression, with an alpha error 0.05, power of 0.95, probability of the outcome in the null hypothesis of 0.02, and odds ratio (OR) of 0.18, assuming a normal distribution and a moderate interaction between covariates (R2 = 0.5). Probabilities were taken from a prior similar study that examined surgical rates in recipients vs. nonrecipients of chiropractic care.<sup>16</sup> This sample was deemed to be feasible given the large patient population within the TriNetX network.

## Statistical methods

Statistical analysis was performed using built-in statistical functions available in the TriNetX software platform in real-time. Baseline characteristics were compared using a Pearson chisquared test for categorical variables and independent-samples t-test for continuous variables. Propensity scores for each cohort were calculated using logistic regression. Propensity scores were matched 1:1 using a greedy nearest-neighbor algorithm and a caliper of 0.01 pooled standard deviations. A visual diagnostic was used to assess the balance between cohorts following propensity score matching. Odds of discectomy in each cohort were calculated by dividing the number of patients undergoing discectomy by the number of patients not undergoing discectomy. ORs for discectomy for each follow-up window were calculated by dividing odds in the CSMT cohort by odds in the other care cohort.

A sensitivity analysis was conducted by computing E-values for both follow-up windows after propensity matching.<sup>53</sup> The E-value is defined as the minimum strength of association an unmeasured confounder would need to account for an association between the outcome (i.e. CSMT) and exposure (lumbar discectomy).<sup>54</sup>

Patient and Public Involvement

No patient or public involvement.

# Results

## Participants

Patients meeting selection criteria were identified from 66 health care organizations, 11 of which included CSMT services. A large sample size was identified for each cohort (Table 1). Before propensity matching, there were 3,093 patients in the CSMT cohort and 747,594 in the other care cohort. After propensity matching, which discarded non-matching patients in the larger other care cohort, there were 3,093 patients in each cohort (mean age 36.5±8.5 years). Before matching, there were several differences between cohorts. Most notably, the CSMT cohort had a significantly lower percentage of patients who were Black/African American or Hispanic/Latino, and patients who were prescribed opioid analgesics or central nervous system medications. The frequency of LDH/LSR codes also varied between cohorts. All differences between cohorts were no longer statistically significant after propensity matching, aside from the procedure code for spinal injections. However, this difference was minimal, being less than 1% different between cohorts.

Table 1: Baseline characteristics before and after propensity score matching

Characteristic	Before Ma	atching		After Matching		
	CSMT	Other care	<i>P</i> - value	CSMT	Other care	<i>P</i> - value
N	3,093	747,594		3,093	3,093	
Age	36.5±8.5	37.2±8.2	<0.001	36.5±8.5	36.5±8.5	0.957
Sex						

Female	1,795 (58%)	435,364 (58%)	0.821	1,795 (58%)	1,820 (59%)	0.51
Male	1,297 (42%)	312,120 (42%)	0.836	1,297 (42%)	1,272 (41%)	0.51
Race						
Black or African American	161 (5%)	136,985 (18%)	<0.001	161 (5%)	161 (5%)	1
White	2,317 (75%)	482,228 (65%)	<0.001	2,317 (75%)	2,324 (75%)	0.83
Asian	50 (2%)	16,749 (2%)	<0.019	50 (2%)	47 (2%)	0.75
Unknown Race	553 (18%)	107,048 (14%)	<0.001	553 (18%)	555 (18%)	0.94
Ethnicity						
Hispanic/Latino	74 (2%)	65,150 (9%)	<0.001	74 (2%)	56 (2%)	0.11
Not Hispanic/Latino	2,525 (82%)	469,221 (63%)	<0.001	2,525 (82%)	2,530 (82%)	0.86
Conditions (ICD-10)						
Mental, Behavioral & Neurodevelopmental Disorders (F01-F99)	846 (27%)	214,005 (29%)	0.118	846 (27%)	844 (27%)	0.95
Lumbosacral root disorders, not elsewhere classified (G54.4)	18 (1%)	961 (<1%)	<0.001	18 (1%)	10 (<1%)	0.13
Radiculopathy, lumbar region (M54.16)	816 (26%)	220,562 (30%)	<0.001	816 (26%)	806 (26%)	0.77
Radiculopathy, lumbosacral region (M54.17)	930 (30%)	107,065 (14%)	<0.001	930 (30%)	942 (31%)	0.74
Radiculopathy, sacral and sacrococcygeal region (M54.18)	52 (2%)	1,457 (<1%)	<0.001	52 (2%)	36 (1%)	0.08
Sciatica (M54.3)	725 (23%)	224,052 (30%)	<0.001	725 (23%)	728 (24%)	0.92
Lumbago with sciatica (M54.4)	611 (20%)	250,242 (34%)	<0.001	611 (20%)	631 (20%)	0.52
Procedure (ICD-10-PCS)						
Introduction of Anesthetic Agent into Spinal Canal, Percutaneous Approach Medications (VANDF)	10 (<1%)	1,273 (<1%)	0.040	10 (<1%)	0 (0%)	0.00

Opioid Analgesics (CN101)	651 (21%)	220,511 (30%)	<0.001	651 647 (21%)	647 (21%)	0.901
Central Nervous System Medications (CN000)	1,565 (51%)	408,947 (55%)	<0.001	1,565 (51%)	1,556 (50%)	0.819
BMI (kg/m²)	30.1±6.7	30.6±7.2	0.003	30.1±6.7	30.5±7.1	0.105

Abbreviations: chiropractic spinal manipulative therapy (CSMT), International Classification of Disease (ICD), International Classification of Disease Procedure Coding System (ICD-10-PCS), body mass index kg/m<sup>2</sup> (BMI measured by kilogram per square meter), Veterans Health Administration National Drug File (VANDF)

#### Descriptive data

The average number of data points per patient was high in both cohorts (CSMT 1659, other care 1158), which suggested there was no difference between cohorts with respect to missing data. A visual propensity score density graph revealed that cohorts were comparable after propensity matching (see online supplemental figure 1).

#### Key results

Discectomy was less frequent in the CSMT cohort throughout 1-year and 2-year follow-up windows before and after propensity matching. After matching, 1.0% of patients (CSMT) and 1.7% (other care) underwent discectomy over 1-year follow-up, while 1.2% (CSMT) and 1.8% (other care) underwent discectomy over 2-years (Table 2). After matching, odds of discectomy were significantly lower in the CSMT compared to other care cohort, with an OR (95% CI) of 0.61 (0.40-0.95; *P*=0.028) over 1-year and 0.65 (0.43-0.99; *P*=0.045) over 2 years' follow-up from index diagnosis.

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#### Table 2: Key results before and after propensity score matching

	Before mate	ching	After matching		
	CSMT	Other care	CSMT	Other care	
	n = 3,093	n = 747,594	n = 3,093	n = 3,093	
1 year					
Discectomy No.	32 (1.0%)	10,487 (1.4%)	32 (1.0%)	52 (1.7%)	
(%)					
OR (CI)	0.74 (0.52-	(reference)	<b>0.61</b> (0.40,	(reference)	
	1.04)		0.95)*		
2 years					
Discectomy No.	36 (1.2%)	11,332 (1.5%)	36 (1.2%)	55 (1.8%)	
(%)					
OR (CI)	0.77 (0.55,	(reference)	<b>0.65</b> (0.43-	(reference)	
	1.06)		0.99)*		
Abbreviations: chi	ropractic spir	nal manipulativ	e therapy (C	SMT), odds	
ratio (OR), 95% co	• •			•	
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\* Indicates a *P*-value of < 0.05.

**Bold** indicates results pertinent to the study hypotheses

## Sensitivity analysis

After propensity matching, ORs for the current study allowed calculation<sup>53</sup> of an E-value for the point estimate of 2.66 with an E-value for the lower confidence interval of 1.29 for the 1-year follow-up, and an E-value for the point estimate of 2.45 with an E-value for the lower confidence interval of 1.11 for the 2-year follow-up. While our protocol suggested patients have a small increase in likelihood of visiting a chiropractor if they have higher income (i.e., risk ratio of 1.23),<sup>55</sup> this was based on data from the 1990s,<sup>56,57</sup> which has been contradicted by more recent data. A more recent study found

that income, education level, and insurance coverage are not associated with patients' initial

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choice of provider for spinal pain (i.e., chiropractor, physical therapist, or medical physician).<sup>58</sup> Regardless, the risk ratio from the earlier study suggesting income was a predictor is less than the E-value point estimates for our study (i.e., 1.23 < 2.45 and 2.66).

An unmeasured variable associated with both likelihood of visiting a chiropractor and likelihood of undergoing discectomy would require a risk ratio greater than the study E-value point estimates, 2.45 and 2.66, to fully explain away our results of a significant reduction in odds of discectomy from the 2-years and 1-year follow-up outcomes, respectively.<sup>54</sup> We are unaware of any socioeconomic or other variable that were not measured in the current study that could fully explain away our results based on the E-value estimates.

## Discussion

This retrospective cohort study was the first to examine the association between receiving CSMT for newly diagnosed LDH and/or LSR and odds of lumbar discectomy and included a large US sample of over 3,000 patients per cohort after several exclusions and propensity matching to improve cohort comparability. These real-world results support our hypothesis that patients initially receiving CSMT for LDH/LSR have reduced odds of discectomy over 1- and 2-years' follow-up.

The frequency of discectomy in this study (i.e., 1-2% over 1 year) is comparable to previous studies, and suggestive that our methods of capturing this outcome were valid. One prior study which examined 2.5 million adults in the US with low back and/or lower extremity pain and no red flag diagnosis found that 1.2% of patients underwent surgery over a 1-year follow-up

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period.<sup>59</sup> While smaller studies have reported a higher frequency of discectomy of 5% or greater,<sup>43,60–62</sup> our study had a relatively young population and several exclusions, which could explain the frequency of discectomy being on the lower end of the range of prior studies. Further, most discectomies occurred in the 1<sup>st</sup> year of follow-up in our study, with only a small increase during the 2-year follow-up window. This is in agreement with a previous systematic review that reported the majority of patients undergo surgery within 2 and 12 months from onset of symptoms.<sup>24</sup>

The overall rate of surgery over 2-years' follow-up including both cohorts combined in our study was 1.7%, whereas in previous similar studies examining CSMT this value was 5%<sup>14</sup> and 9%.<sup>18</sup> The lower frequency of discectomy in our study could relate to a declining rate of lumbar surgery in the US.<sup>63</sup> While our study included the most recent data, from 2012-2022, the 5% value derived from data from 2012-2018,<sup>14</sup> and 9% value derived from older data from 2002-2004.<sup>18</sup> Finally, it is possible the final 2 years of our data included a lower frequency of discectomy related to the COVID-19 pandemic, as studies have reported delays and cancellations in elective spine surgeries during this time.<sup>64,65</sup>

Previous studies have reported a reduction in surgery among patients receiving CSMT. In one study, the reduction in odds of lumbar spine surgery was of a greater magnitude than our study (i.e., 0.22), however this study focused on a population with occupational back injury.<sup>18</sup> Another study examining a broader population identified a reduction in likelihood of surgery of greater magnitude than our study (i.e., risk ratio of 0.30).<sup>14</sup> A third similar study found a reduction in surgery among CSMT recipients, which was not statistically significant, likely due to small sample size.<sup>16</sup> While the current study reinforces these previous findings, the smaller

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magnitude of our ORs could be explained by the extensive selection criteria, narrow age bracket, propensity matching methods, and differences in patient population.

Our sensitivity analysis suggested that an unmeasured confounder associated with both CSMT and discectomy would require a risk ratio associated with patients' initial choice of CSMT for LDH/LSR of a magnitude of 2.45 to 2.66 to fully explain our results at 2- and 1-years' follow-up, respectively. While we are unaware of any unmeasured confounder of this magnitude based on recent research on this topic,<sup>58</sup> it is possible that one will be elucidated in future studies. Although the data in the current study includes insured and uninsured patients, socioeconomic variables were not included in the dataset, which remain potentially important unmeasured confounders.

These results provide real-world evidence that CSMT is effective in reducing the likelihood of discectomy among adults with LDH/LSR, and support previous studies showing efficacy in reducing pain related to LDH and LSR.<sup>6–8</sup> Considering the current study excluded absolute indications for surgery and serious pathology, we suggest our findings may be explained by pain relief afforded by CSMT. Previous studies have shown that LDH/LSR have good prognosis with at least half of patients experiencing significant relief in the first 3-12 months.<sup>66,67</sup> As most patients will undergo surgery within 2-12 months of symptom onset,<sup>24</sup> we suggest initial pain relief afforded by CSMT could allow patients to avoid surgery during this early critical period.

trial could eliminate residual sources of confounding such as socioeconomic variables. In such a study, several outcomes could be measured in tandem including pain severity, disability, cost of

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care, and pain medication utilization, in addition to the rate of lumbar discectomy. The current study provides preliminary data to justify such a study, which would be more costly and time consuming to conduct yet provide a higher level of evidence. Further, given our selection criteria focused on younger adults undergoing discectomy for LDH/LSR, a follow-up study could examine the likelihood of lumbar fusion surgery among older adults with lumbar stenosis.

## Limitations

First, because of its observational design, this study is unable to conclude that CSMT is causative in reducing the odds of lumbar discectomy. There are several variables unavailable in the TriNetX dataset that could lead to unmeasured confounding such as those relating to socioeconomic status, clinical examination findings,<sup>22</sup> detailed spinal imaging data such as measures of disc herniation,<sup>68</sup> and patient-reported outcome measures.

Second, data entered into a patient medical record may not be accurate, leading to an information bias in the aggregated health records data.<sup>69</sup> Certain comorbidities, prior diagnoses, treatments, medications, or other patient variables could be absent, incorrect, or outdated,<sup>70</sup> which could affect propensity matching or impact a patient's eligibility for the current study. It was not feasible to validate our query against a gold standard of chart review given data was de-identified and sourced from outside healthcare organizations.

Third, we are unable to determine the techniques of CSMT employed by chiropractors for each patient, which may have differing efficacy.<sup>71</sup> Knowledge of techniques performed such as mobilization, low-force, or high-velocity, low-amplitude CSMT could allow us to standardize the CSMT cohort to include a more uniform treatment, or enable subgroup analysis according to

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technique (e.g., flexion-distraction, lumbar HVLA manipulation, instrument-assisted, etc.). In addition, the number of visits in which CSMT was utilized likely varied between patients in the CSMT cohort, and this variable cannot be tracked in the study dataset.

Fourth, we were unable to examine the likelihood of visiting a surgeon due to a lack of provider codes in the dataset. Previous research has found that patients who initiate care for low back pain with a chiropractor have significantly reduced odds of visiting a surgeon.<sup>16</sup> Accordingly, it is unclear if a difference in surgical visits between cohorts mediates the association observed in our study.

Finally, as the study results derived from large, academically affiliated healthcare institutions they may not be generalizable to patients seeking chiropractic care in private facilities.<sup>72</sup> These results also may not be generalizable to healthcare settings outside of the US.

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# Conclusion

These findings suggest that patients receiving CSMT for newly diagnosed LDH and/or LSR without serious pathology, spinal deformity, or absolute indications for surgery have significantly reduced odds of discectomy through 2-years' follow-up after index diagnosis compared to those receiving other care. While socioeconomic variables were unavailable in the dataset, current data suggests these unmeasured variables would not completely explain our findings. However, given the possibility of residual confounding, the efficacy of CSMT for LDH/LSR should be explored further using a randomized controlled trial.

# Competing interests

Dr. Trager reports he has received book royalties as the author of two texts on the topic of

sciatica. No other authors reported conflicts.

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## Disclaimer

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## Data availability

We are unable to make the data used in this study publicly available. This data was obtained via a data use agreement with the TriNetX network that does not allow release or sharing of this data. Those interested in accessing this network may contact TriNetX (https://www.trinetx.com/).

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## Ethics

This study was determined Not Human Subjects Research by the University Hospitals Institutional Review Board (Cleveland, Ohio, USA; STUDY20220571).

## Author contributions

RT, CD, RC, AP, and JD conceived of and designed the study. RC and AP were responsible for data collection and management of the study software and database. RT, CD, AP, and JD were responsible for data analysis and interpretation. JD provided supervision and mentorship. RT drafted the manuscript while all authors critically revised and approved the final manuscript.

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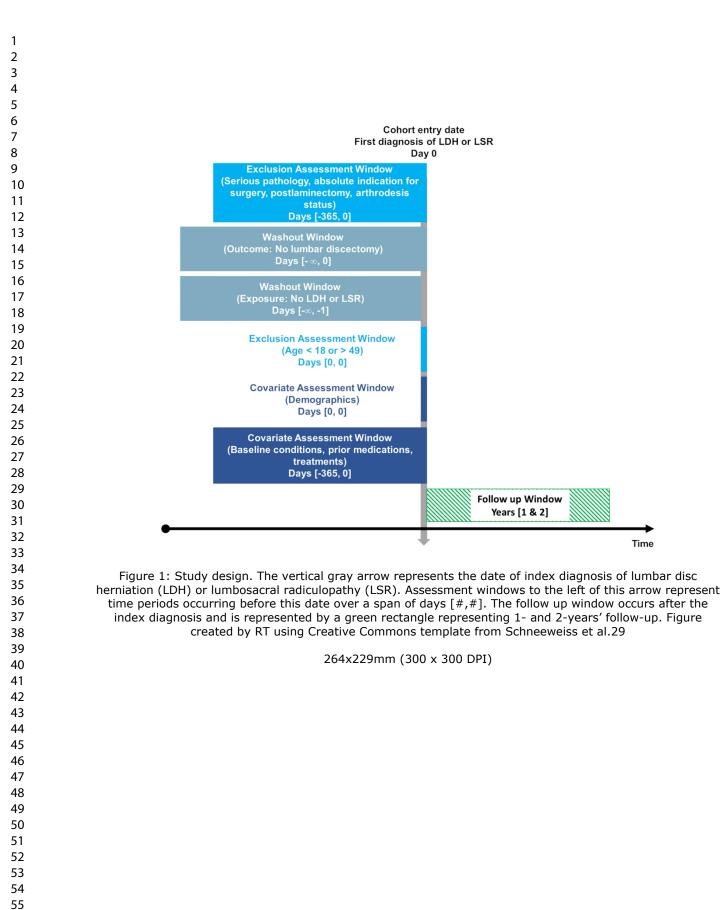
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# Supplemental File

Table 1: Inclusion codes for both cohorts for patients with lumbar disc herniation and/or lumbosacral radiculopathy

Definition
Lumbosacral root disorders, not elsewhere classified
Other intervertebral disc displacement, lumbar region
Other intervertebral disc displacement, lumbosacral region
Radiculopathy, lumbar region
Radiculopathy, lumbosacral region
Radiculopathy, sacral and sacrococcygeal region
Sciatica
Lumbago with sciatica
ication of Diseases (ICD-10)
cohorts

#### Table 2: Exclusions for both cohorts

Diagnosis codes*	Definition (excluded days -365 to 0)
C00-C96	Malignant neoplasm
G83.4	Cauda equina syndrome 🥢
M41	Scoliosis
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M48.0	Spinal stenosis
M48.46	Fatigue fracture of vertebra, lumbar region
M48.56	Collapsed vertebra, not elsewhere classified, lumbar region
M48.57	Collapsed vertebra, not elsewhere classified, lumbosacral region
M84.40	Pathological fracture, unspecified site
M84.48	Pathological fracture, other site
M84.58	Pathological fracture in neoplastic disease, other specified site
M84.60	Pathological fracture in other disease, unspecified site
M96.1	Postlaminectomy syndrome, not elsewhere classified
N31	Neuromuscular dysfunction of bladder, not elsewhere classified
R15	Fecal incontinence
R32	Unspecified urinary incontinence
S22.08	Fracture of T11-T12 vertebra
S30-S39	Injuries to the abdomen, lower back, lumbar spine, pelvis and externa genitals
S32.0	Fracture of lumbar vertebra
Z98.1	Arthrodesis status
Lumbar discectomy codes	Definition (excluded any time to day 0)
Multiple	See Supplemental File Table 4
* International Class	ification of Diseases (ICD-10)

Table 3: Additional selection criteria according to receipt of chiropractic spinal manipulative therapy

CPT code	Description	CSMT recipients	CSMT non- recipients
98940	CSMT; 1-2 regions	Included	Excluded
98941	CSMT; 3-4 regions	Included	Excluded
98942	CSMT; 5 regions	Included	Excluded
Abbreviations:	Chiropractic spinal manipulative th	nerapy (CSMT)	

#### Table 4: Lumbar discectomy outcome definition codes

Procedure code	Definition
Current Procedural	Terminology (CPT)
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral
	disc, any method utilizing needle-based technique to remove disc material under
	fluoroscopic imaging or other form of indirect visualization, with the use of an
	endoscope, with discography and/or epidural injection(s) at the treated level(s),
	when performed, single or multiple levels, lumbar
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve
	root(s) (eg, herniated intervertebral disc), single segment; lumbar (including
	transfacet, or lateral extraforaminal approach) (eg, far lateral herniated
	intervertebral disc)
Healthcare Commo	n Procedure Coding System (HCPCS)
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and excision of herniated intervertebral disc,
	and repair of annular defect with implantation of bone anchored annular closure
	device, including annular defect measurement, alignment and sizing assessment
	and image guidance; 1 interspace, lumbar
ICD-10 Procedural	Classification System (PCS)
0SB4*	Lumbosacral Disc (includes open, percutaneous, and percutaneous endoscopic
	surgical excision of lumbosacral disc)

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Table 5: Variables to be controlled for in propensity score matching

Variable	Description
Demographics	Patient age, sex, race, and ethnicity
Logical Observation	n Identifiers Names and Codes
39156-5	BMI – Body mass index
Lumbosacral radicu	Ilopathy diagnoses (ICD-10)
G54.4	Lumbosacral root disorders, not elsewhere classified
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.3	Sciatica
M54.4	Lumbago with sciatica
Comorbidities (ICD	-10)
F01-F99	Mental, Behavioral and Neurodevelopmental disorders
Z72.0	Tobacco use
Medications (VAND	OF Classes)
CN101	Opioid analgesics
CN000	Central nervous system medications
Procedures (ICD-10	0-PCS)
3E0R3BZ	Introduction of anesthetic agent into spinal canal, percutaneous approach
	y mass index (BMI) calculated as kg/m <sup>2</sup> , International Classification of dural Classification System (ICD-10-PCS); Veterans Health Administration

National Drug File (VANDF)

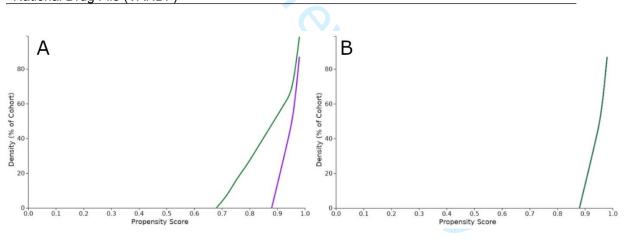


Figure 1: Propensity scores before (A) and after (B) matching. The purple line represents the cohort receiving chiropractic spinal manipulative therapy (CSMT) while the green line represents the cohort receiving other care. In image B, the propensity score densities overlap and only a single line is visible, suggesting that the cohorts are well matched.

# STROBE Statement

## -Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Pag #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the	1
		title or the abstract	
		(b) Provide in the abstract an informative and balanced summary of	2
		what was done and what was found	
Introduction	0	4	
Background/rationale	2	Explain the scientific background and rationale for the investigation	4
		being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods	6
		of recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of	7
		selection of participants. Describe methods of follow-up	
		(b) For matched studies, give matching criteria and number of	7
		exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential	9
		confounders, and effect modifiers. Give diagnostic criteria, if	
		applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of	6
measurement		methods of assessment (measurement). Describe comparability of	
		assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	10

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(a) Describe all statistical methods, including those used to control	11
		for confounding	
		(b) Describe any methods used to examine subgroups and	NA
		interactions	
		(c) Explain how missing data were addressed	14
		(d) If applicable, explain how loss to follow-up was addressed	NA
		( <u>e</u> ) Describe any sensitivity analyses	11
Results	•	6	
Participants	13*	(a) Report numbers of individuals at each stage of study—eg	12
		numbers potentially eligible, examined for eligibility, confirmed	
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	Figu
			1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic,	14
		clinical, social) and information on exposures and potential	
		confounders	
		(b) Indicate number of participants with missing data for each	NA
		variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over	14
		time	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-	14
		adjusted estimates and their precision (eg, 95% confidence	
		interval). Make clear which confounders were adjusted for and why	
		they were included	

categorized         (c) If relevant, consider translating estimates of rabsolute risk for a meaningful time period         Other analyses       17         Report other analyses done—eg analyses of subjuinteractions, and sensitivity analyses         Discussion         Key results       18         Summarise key results with reference to study or potential bias or imprecision. Discuss both direct	groups and
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Interpretation 20 Give a cautious overall interpretation of results of	onsidering
objectives, limitations, multiplicity of analyses, re	esults from similar
studies, and other relevant evidence	
Generalisability 21 Discuss the generalisability (external validity) of	he study results
Other information	
Funding22Give the source of funding and the role of the funding	
present study and, if applicable, for the original	tudy on which the
present article is based	

# **BMJ Open**

## Association between chiropractic spinal manipulation and lumbar discectomy in adults with lumbar disc herniation and radiculopathy: retrospective cohort study using United States' data

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# Association between chiropractic spinal manipulation and lumbar

# discectomy in adults with lumbar disc herniation and

radiculopathy: retrospective cohort study using United States'

# data

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Word count: 3,538

# Abstract

Objectives: Chiropractic spinal manipulative therapy (CSMT) and lumbar discectomy are both used for lumbar disc herniation (LDH) and lumbosacral radiculopathy (LSR); however, limited research has examined the relationship between these therapies. We hypothesized adults receiving CSMT for newly diagnosed LDH or LSR would have reduced odds of lumbar discectomy over 1- and 2 years' follow-up compared to those receiving other care.

Design: Retrospective cohort study.

Setting: 101-million-patient United States health records network (TriNetX), queried October 24, 2022, yielding data from 2012-query.

Participants: Adults age 18-49 with newly-diagnosed LDH/LSR (first date of diagnosis) were included. Exclusions were prior lumbar surgery, absolute indications for surgery, trauma, spondylolisthesis, and scoliosis. Propensity score matching controlled for variables associated with the likelihood of discectomy (e.g., demographics, medications).

Interventions: Patients were divided into cohorts according to receipt of CSMT.

Primary and secondary outcome measures: Odds ratios (ORs) for lumbar discectomy; calculated by dividing odds in the CSMT cohort by odds in the cohort receiving other care.

Results: After matching, there were 5785 patients per cohort (mean age 36.9±8.2). The ORs [95% CI] for discectomy were significantly reduced in the CSMT cohort compared to the cohort receiving other care over 1-year (0.69 [0.52 to 0.90], *P*=0.006) and 2-years' follow-up (0.77 [0.60 to 0.99], *P*=0.040). E-value sensitivity analysis estimated the strength in terms of risk ratio an unmeasured confounding variable would need to account for study results, yielding point estimates for each follow-up (1-year: 2.26; 2-year: 1.92), which no variables in the literature reached.

Conclusions: Our findings suggest receiving CSMT compared to other care for newly diagnosed LDH/LSR is associated with significantly reduced odds of discectomy over 2-years' follow-up. Given socioeconomic variables were unavailable and an observational design precludes inferring causality, the efficacy of CSMT for LDH/LSR should be examined via randomized controlled trial to eliminate residual confounding.

Keywords: Discectomy, Lumbar Disc Disease, Radiculopathy, Sciatica, Spinal Manipulation, Chiropractic, Low Back Pain

# **Article Summary**

### Strengths and limitations of this study

• This study was based on an a priori protocol developed by a multidisciplinary research team with the intention of reducing bias.

•	This study included patients with newly diagnosed lumbar disc herniation or
	lumbosacral radiculopathy and excluded those with absolute indications for surgery to
	make cohorts more comparable.
•	While an extensive propensity matching model was utilized to control for confounding
	variables, socioeconomic variables were not available within the study dataset.
•	While this study examined a large population, only large, academically affiliated
	healthcare organizations in the United States were included, thus results may not be
	broadly generalizable.
•	As this study is observational, a randomized controlled trial would be needed to
	eliminate possible residual confounding.
Intro	oduction
A lum	bar disc herniation (LDH) is a focal displacement of intervertebral disc material beyond
the n	ormal limit of the disc margin, <sup>1</sup> which may compress one or more nerve roots, causing
lumb	osacral radiculopathy (LSR). The clinical features of LSR include radicular (radiating) lower
extre	mity pain, predictable sensory disturbances, weakness, and/or diminished muscle stretch
reflex	es. <sup>2</sup> LDH and LSR are common reasons for patients to receive chiropractic care or undergo
surge	ry to remove LDH material, a procedure called discectomy. However, limited research has
exam	ined the association between chiropractic care and discectomy.
	United States (US), chiropractors are portal-of-entry providers that often manage low

back pain, including LDH/LSR.<sup>3,4</sup> While chiropractors may utilize soft tissue or exercise therapies

for these patients,<sup>5</sup> they most often employ chiropractic spinal manipulative therapy (CSMT).<sup>4</sup> Prior studies have documented the benefits of CSMT for LDH/LSR, including randomized prospective studies.<sup>6,7</sup> In a meta-analysis, spinal manipulation was found to be one of the most effective treatments for discogenic LSR.<sup>8</sup> Accordingly, US and international clinical practice guidelines have recommended spinal manipulation for low back pain and LSR.<sup>9–13</sup>

Prior studies examining the association between chiropractic care and lumbar spine surgery have examined a broader population and/or outcome.<sup>14–20</sup> Two studies identified a significant reduction in odds of lumbar surgery among individuals receiving early chiropractic care, with one examining surgical fusion or decompression among patients with an occupational back injury,<sup>18</sup> and another examining discectomy and fusion among patients with back pain.<sup>14</sup> The current study differs by examining a narrower range of LBP conditions (i.e., LDH/LSR) with an outcome specific to discectomy.

Several factors may influence whether a patient undergoes a discectomy, including clinical features, patient preferences, and the response to conservative care.<sup>21–23</sup> While the presence of severe or "red flag" neurologic deficits and/or cauda equina syndrome are absolute indications for lumbar discectomy, continued pain despite conservative treatment that affects quality of life is considered a relative indication.<sup>24</sup> For patients without absolute indications, early discectomy can provide short-term benefits for LDH with LSR, however, long-term outcomes are similar at 1-2 years in those receiving conservative care.<sup>25</sup>

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This study was conducted considering that CSMT and lumbar discectomy are both viable treatment options for LDH and LSR, yet there has been limited research examining the relationship between these care pathways.

## Objectives

 This study aimed to examine the association between receipt of CSMT for newly diagnosed LDH and/or LSR and odds of lumbar discectomy, with the hypothesis that adults receiving CSMT would have reduced odds of lumbar discectomy over 1- and 2year follow-up windows after index diagnosis compared to those receiving other care.

# Methods

## Study design

This study followed an a priori protocol registered with the Open Science Framework (https://osf.io/2gkcd),<sup>26</sup> and incorporated a retrospective, new-user, active-comparator design<sup>27</sup> to compare recipients and nonrecipients of CSMT from age 18-49 of any sex (Figure 1). The study included patients meeting selection criteria from October 24, 2012, to October 24, 2020 to capture more recent data, considering the treatment of LDH and LSR may have changed over time. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline structure was followed.<sup>28</sup>

Figure 1: Study design. The vertical gray arrow represents the date of index diagnosis of lumbar disc herniation (LDH) or lumbosacral radiculopathy (LSR). Assessment windows to the left of this arrow represent time periods occurring before this date over a span of days [#,#]. The follow up window occurs after the index diagnosis and is represented by a green rectangle representing 1- and 2-years' follow-up. Figure created by RT using Creative Commons template from Schneeweiss et al.<sup>29</sup>

# Setting and data source

This study utilized a 101-million patient population within the TriNetX US research network (TriNetX Inc., Cambridge, MA, US).<sup>30</sup> Data in this network is de-identified, aggregated, and frequently updated from the health records of multiple health care organizations in the US, which are typically large, academically affiliated health centers and their ambulatory offices. This network includes insured and uninsured patients.<sup>31</sup> The TriNetX dataset routinely undergoes automated and manual assessments to ensure data conformance, completeness, and plausibility.<sup>30,32</sup> One previous study estimated a completeness of at least 87% for medications in the TriNetX dataset,<sup>33</sup> however the completeness of other variables has not been examined to our knowledge.

Queries of this dataset are performed using standardized nomenclatures such as the ICD-10 procedural classification system (ICD-10-PCS), Current Procedural Terminology (CPT), and Veterans Health Administration National Drug File (VANDF), and others. International Classification of Diseases (ICD-10) codes may also be used which are interconverted automatically to older ICD-9 codes using general equivalence mappings.<sup>30</sup> At University Hospitals of Cleveland, the Clinical Research Center manages all use of the TriNetX platform.

As of January 2022, there were 10 healthcare organizations within the TriNetX network that had providers administering CSMT.<sup>34</sup> In accordance with of privacy regulations, these institutions remain anonymous. Although this study only examined a fraction of US chiropractic providers, integration of chiropractors into hospitals is a growing trend, with 5% of US chiropractors reporting a hospital affiliation in 2019.<sup>3</sup> Integrated chiropractors are most often

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employed within physical medicine, rehabilitation, or physical therapy settings and on average have 21 years' experience in practice.<sup>35</sup>

#### Participants

#### Eligibility criteria

This study identified patients with newly-diagnosed LDH and/or LSR by querying the TriNetX dataset with a custom set of codes (Supplemental Table 1). These patients were identified at the index date of diagnosis, which we defined as the first instance of LDH or LSR codes appearing in the medical record. This requirement created an infinite washout period preceding the index date in which patients had no previous diagnosis of LDH or LSR. Patients were required to be represented in the dataset for at least two years after the index diagnosis date to be eligible.

Patients with diagnoses of lumbar or sacral radiculopathy or sciatica were included as these diagnoses often reflect underlying LDH or LSR,<sup>36</sup> and evidence suggested that these diagnosis codes are often utilized by clinicians.<sup>37</sup> The age bracket of 18-49 years was used as LDH is more common in younger patients aged 30-50.<sup>38</sup> Conversely, lumbar stenosis is a more prevalent cause of LSR in older patients.<sup>39</sup> Accordingly, the upper age cutoff was intended to exclude patients with lumbar stenosis from our study.

Patients with serious spine pathology or absolute indication for surgery, such as cauda equina syndrome (CES), signs of CES such as bowel or bladder incontinence, fracture, infection, and malignant neoplasms were excluded over 365 days preceding and including the date of index

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diagnosis (Supplemental Table 2).<sup>40</sup> Patients with conditions that could alter the CSMT or surgical approach and/or increase the odds of lumbar surgery were also excluded: lumbar fusion, arthrodesis or postlaminectomy syndrome,<sup>41,42</sup> lumbar spine trauma,<sup>43</sup> and degenerative lumbar scoliosis and spondylolisthesis.<sup>44</sup> As an additional measure of ensuring patients had no previous discectomy, any prior occurrence of discectomy was excluded over an infinite time window preceding and including the date of index diagnosis.

Diagnoses of lumbar spondylosis (e.g., ICD-10: M47.26) were not utilized in our inclusion criteria given these are not specific to LDH. In addition, codes specifying lumbar disc disorders with myelopathy (e.g., ICD-10: M47.16) were not utilized as myelopathy has different clinical features and management strategies than LDH/LSR. Diagnosis codes specifying lumbar or lumbosacral disc degeneration were not included, as a strategy to create more uniformity between cohorts. Disc degeneration is not associated with radicular symptoms, unlike LDH, which has a strong association with radicular symptoms.<sup>45</sup>

Included patients were divided into 2 cohorts according to receipt of CSMT (Supplemental Table 3). The CPT codes 98940, 98941, and 98942 for CSMT were included in the "CSMT" cohort and excluded in the "other care" cohort. These 9894\* codes are almost exclusively utilized by chiropractors in the US.<sup>46</sup> Patients in the CSMT cohort were required to receive CSMT on the date of index date of diagnosis of LDH or LSR (i.e., the first instance of the diagnosis in the medical record), while those in the cohort receiving other care could not receive CSMT on the index date of diagnosis.

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## Variables

#### Discectomy

A definition for the outcome of lumbar discectomy was developed based on discussion amongst co-authors and comparison with previous publications (Supplemental Table 4).<sup>37,40,47,48</sup> This definition included multiple procedure codes for discectomy, as well as the ICD-10-PCS code OSB4\* which includes open, percutaneous, and percutaneous endoscopic approaches to excise lumbosacral disc material,<sup>49</sup> and the Healthcare Common Procedure Coding System (HCPCS) code C9757 for lumbar discectomy with implantation of an annular closure device.<sup>48</sup> Feasibility testing was conducted in June, 2021, to ensure these codes were represented in the TriNetX database. Two follow-up windows of 1-year and 2-year were used in this study to allow for comparisons to prior similar studies also using long-term endpoints.<sup>16,18</sup>

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## Potential confounders

Propensity score matching is a method of balancing confounding variables between cohorts to improve their comparability.<sup>27</sup> Based on previous recommendations, confounders were propensity matched when having evidence of an association with the outcome of interest (i.e. lumbar discectomy).<sup>50</sup> Variables present within a 365-day window preceding the index diagnosis of LDH and/or LSR were eligible for propensity matching (Supplemental Table 6). Demographic variables associated with the likelihood of lumbar surgery were propensity matched including increasing age,<sup>23,51</sup> male sex,<sup>23,51,52</sup> and race.<sup>51</sup> Other factors associated with increased likelihood of lumbar surgery were matched including obesity,<sup>23,51</sup> being a nonsmoker,<sup>23</sup> psychological disorders,<sup>51</sup> a history of lumbar injections,<sup>23,53</sup> and prior treatment with opioids<sup>43</sup> or prescription pain medications.<sup>23</sup> Radicular symptoms or radiculopathy are also predictors of lumbar surgery in those with low back pain,<sup>23,53</sup> and were matched via the ICD-10 codes for LSR and sciatica.

#### Study size

A required sample size of 198 was calculated using  $G^*Power^{54}$  z-tests for logistic regression, with an alpha error 0.05, power of 0.95, probability of the outcome in the null hypothesis of 0.02, and odds ratio (OR) of 0.18, assuming a normal distribution and a moderate interaction between covariates (R2 = 0.5). Probabilities were taken from a prior similar study that examined surgical rates in recipients vs. nonrecipients of chiropractic care.<sup>16</sup> This sample was deemed to be feasible given the large patient population within the TriNetX network.

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## Statistical methods

Statistical analysis was performed using built-in statistical functions available in the TriNetX software platform in real-time. Baseline characteristics were compared using a Pearson chi-squared test for categorical variables and independent-samples t-test for continuous variables. We did not perform any imputations for missing data.

Propensity scores for each cohort were calculated using logistic regression. Propensity scores were matched 1:1 using a greedy nearest-neighbor algorithm and a caliper of 0.01 pooled standard deviations. A visual diagnostic was used to assess the balance between cohorts following propensity score matching. Odds of discectomy in each cohort were calculated by dividing the number of patients undergoing discectomy by the number of patients not undergoing discectomy. ORs for discectomy for each follow-up window were calculated by dividing odds in the CSMT cohort by odds in the other care cohort.

A sensitivity analysis was conducted by computing E-values for both follow-up windows after propensity matching.<sup>55</sup> The E-value is defined as the minimum strength of association an unmeasured confounder would need to account for an association between the outcome (i.e. CSMT) and exposure (lumbar discectomy).<sup>56</sup>

### Patient and Public Involvement

No patient or public involvement.

# Results

# Participants

Patients meeting selection criteria were identified from 70 health care organizations, 10 of which included CSMT services. A large sample size was identified for each cohort (Table 1). Before propensity matching, there were 5785 patients in the CSMT cohort and 482704 in the other care cohort. After propensity matching, which discarded non-matching patients in the larger other care cohort, there were 5785 patients in each cohort (mean age 36.9±8.2 years). Before matching, there were several differences between cohorts. Most notably, the CSMT cohort had a significantly lower percentage of patients who were Black/African American or Hispanic/Latino, and significantly higher percentage of patients who were prescribed central nervous system medications. The frequency of LDH/LSR codes also varied between cohorts. All differences between cohorts were no longer statistically significant after propensity matching, aside from body mass index. However, this difference was minimal, varying only 0.5 kilograms per square meter between cohorts.

Table 1: Baseline characteristics before and after propensity score matching

	Before Ma	atching		After Mato	hing	
Characteristic	CSMT	Other care	<i>P</i> - value	CSMT	Other care	<i>P</i> - value
N	5,785	482,704		5,785	5,785	
Age	36.9±8.2	37.4±8.2	<0.001	36.9±8.2	36.9±8.2	0.972
Sex						

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<b>F</b> arra da	0.505	000.004	0.000	0.505	0.500 (040()	0.00
Female	3,535 (61%)	288,061 (60%)	0.028	3,535 (61%)	3,539 (61%)	0.93
Male	2,250 (39%)	194,587 (40%)	0.029	2,250 (39%)	2,245 (39%)	0.92
Race						
Black or African American	431 (8%)	90,838 (19%)	<0.001	431 (8%)	433 (8%)	0.94
White	4,389 (76%)	313,938 (65%)	<0.001	4,389 (76%)	4,368 (76%)	0.64
Asian	99 (2%)	9,913 (2%)	0.068	99 (2%)	100 (2%)	0.94
Ethnicity						
Hispanic/Latino	157 (3%)	37,715 (8%)	<0.001	157 (3%)	154 (3%)	0.86
Not Hispanic/Latino	4,839 (84%)	311,836 (65%)	<0.001	4,839 (84%)	4,808 (83%)	0.43
Conditions (ICD-10)		~				
Mental, Behavioral & Neurodevelopmental Disorders (F01-F99)	2,177 (38%)	145,444 (30%)	<0.001	2,177 (38%)	2,158 (37%)	0.71
Lumbosacral root disorders, not elsewhere classified (G54.4)	24 (<1%)	878 (<1%)	<0.001	24 (<1%)	16 (<1%)	0.20
Radiculopathy, lumbar region (M54.16)	1,713 (30%)	138,388 (29%)	0.115	1,713 (30%)	1,666 (29%)	0.33
Radiculopathy, lumbosacral region (M54.17)	1,420 (25%)	73,363 (15%)	<0.001	1,420 (25%)	1,375 (24%)	0.32
Radiculopathy, sacral and sacrococcygeal region (M54.18)	62 (1%)	1,052 (<1%)	<0.001	62 (1%)	58 (1%)	0.71
Sciatica (M54.3)	1,432 (25%)	150,984 (31%)	<0.001	1,432 (25%)	1,407 (24%)	0.58
Lumbago with sciatica (M54.4)	1,411 (24%)	158,467 (33%)	<0.001	1,411 (24%)	1,360 (24%)	0.26
Procedure (ICD-10-PCS)						
Introduction of Anesthetic Agent into Spinal Canal, Percutaneous Approach	10 (<1%)	991 (<1%)	0.588	10 (<1%)	10 (<1%)	1
Medications (VANDF)						
Opioid Analgesics (CN101)	1,883 (33%)	156,838 (33%)	0.925	1,883 (33%)	1,881 (33%)	0.96

Central Nervous System Medications (CN000)	3,619 (63%)	279,764 (58%)	<0.001	3,619 (63%)	3,603 (62%)	0.759
BMI (kg/m²)	30.6±6.9	30.6±7.2	0.571	30.6±6.9	30.1±7.2	0.005
Abbreviations: chiropractic spinal manipulative therapy (CSMT), International Classification of Disease (ICD), International Classification of Disease Procedure Coding System (ICD-10-PCS), body mass index kg/m <sup>2</sup> (BMI measured by kilogram per square meter), Veterans						

Health Administration National Drug File (VANDF)

# Descriptive data

The average number of data points per patient was high in both cohorts (CSMT 2442, other care 1527). After propensity matching, the frequency of unknown demographic variables was the same both cohorts, with 15% having unknown race, 14% having unknown ethnicity, and 0% having unknown sex or age. These findings suggested there was no difference between cohorts with respect to missing data. A visual propensity score density graph revealed that cohorts were comparable after propensity matching (see online supplemental figure 1).

## Key results

Discectomy was less frequent in the CSMT cohort throughout 1-year and 2-year follow-up windows before and after propensity matching. After matching, 1.5% of patients (CSMT) and 2.2% (other care) underwent discectomy over 1-year follow-up, while 1.9% (CSMT) and 2.4% (other care) underwent discectomy over 2-years (Table 2). After matching, odds of discectomy were significantly lower in the CSMT compared to other care cohort, with an OR (95% CI) of 0.69 (0.52-0.90; *P*=0.006) over 1-year and 0.77 (0.60-0.99; *P*=0.040) over 2 years' follow-up from index diagnosis.

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# Table 2: Key results before and after propensity score matching

	Before mate	ching	After matching	
	CSMT	Other care	CSMT	Other care
	n = 3,093	n = 747,594	n = 3,093	n = 3,093
1 year				
Discectomy No.	89 (1.5%)	8,854 (1.8%)	89 (1.5%)	129 (2.2%)
(%)				
OR (CI)	0.84 (0.68-	(reference)	<b>0.69</b> (0.52,	(reference)
	1.03)		0.90)*	
2 years				
Discectomy No.	108 (1.9%)	9,749 (2.0%)	108 (1.9%)	140 (2.4%)
(%)				
OR (CI)	0.92 (0.76,	(reference)	<b>0.77</b> (0.60-	(reference)
	1.12)		0.99)*	
Abbreviations: chi	ropractic spir	nal manipulativ	ve therapy (C	SMT), odds
ratio (OR), 95% co	nfidence inte	ervals (CI), num	iber (No.) and	l percentage
(%) of patients wit			. ,	. 0
* Indicates a P-val	-			

\* Indicates a *P*-value of < 0.05. **Bold** indicates results pertinent to the study hypotheses

## Sensitivity analysis

After propensity matching, ORs for the current study allowed calculation<sup>55</sup> of an E-value for the point estimate of 2.26 with an E-value for the lower confidence interval of 1.46 for the 1-year follow-up, and an E-value for the point estimate of 1.92 with an E-value for the lower confidence interval of 1.11 for the 2-year follow-up. While our protocol suggested patients have a small increase in likelihood of visiting a chiropractor if they have higher income (i.e., risk ratio of 1.23),<sup>57</sup> this was based on data from the 1990s,<sup>58,59</sup> which has been contradicted by more recent data. A more recent study found that income, education level, and insurance coverage are not associated with patients' initial

choice of provider for spinal pain (i.e., chiropractor, physical therapist, or medical physician).<sup>60</sup> Regardless, the risk ratio from the earlier study suggesting income was a predictor is less than the E-value point estimates for our study (i.e., 1.23 < 1.92 and 2.26).

An unmeasured variable associated with both likelihood of visiting a chiropractor and likelihood of undergoing discectomy would require a risk ratio greater than the study E-value point estimates, 1.92 and 2.26, to fully explain away our results of a significant reduction in odds of discectomy from the 2-years and 1-year follow-up outcomes, respectively.<sup>56</sup> We are unaware of any socioeconomic or other variable that were not measured in the current study that could fully explain away our results based on the E-value estimates.

# Discussion

This retrospective cohort study was the first to examine the association between receiving CSMT for newly diagnosed LDH and/or LSR and odds of lumbar discectomy and included a large US sample of over 3000 patients per cohort after several exclusions and propensity matching to improve cohort comparability. These real-world results support our hypothesis that patients initially receiving CSMT for LDH/LSR have reduced odds of discectomy over 1- and 2-years' follow-up.

The frequency of discectomy in this study (i.e., 1.5-2.2% over 1 year) is comparable to previous studies, and suggestive that our methods of capturing this outcome were valid. One prior study which examined 2.5 million adults in the US with low back and/or lower extremity pain and no red flag diagnosis found that 1.2% of patients underwent surgery over a 1-year follow-up

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period.<sup>61</sup> While smaller studies have reported a higher frequency of discectomy of 5% or greater,<sup>45,62–64</sup> our study had a relatively young population and several exclusions, which could explain the frequency of discectomy being on the lower end of the range of prior studies. Further, most discectomies occurred in the 1<sup>st</sup> year of follow-up in our study, with only a small increase during the 2-year follow-up window. This is in agreement with a previous systematic review that reported the majority of patients undergo surgery within 2 and 12 months from onset of symptoms.<sup>24</sup>

The overall rate of surgery over 2-years' follow-up including both cohorts combined in our study was 2.1%, whereas in previous similar studies examining CSMT this value was 5%<sup>14</sup> and 9%.<sup>18</sup> The lower frequency of discectomy in our study could relate to a declining rate of lumbar surgery in the US.<sup>65</sup> While our study included the most recent data, from 2012-2022, the 5% value derived from data from 2012-2018,<sup>14</sup> and 9% value derived from older data from 2002-2004.<sup>18</sup> Finally, it is possible the final 2 years of our data included a lower frequency of discectomy related to the COVID-19 pandemic, as studies have reported delays and cancellations in elective spine surgeries during this time.<sup>66,67</sup>

Previous studies have reported a reduction in surgery among patients receiving CSMT. In one study, the reduction in odds of lumbar spine surgery was of a greater magnitude than our study (i.e., 0.22), however this study focused on a population with occupational back injury.<sup>18</sup> Another study examining a broader population identified a reduction in likelihood of surgery of greater magnitude than our study (i.e., risk ratio of 0.30).<sup>14</sup> A third similar study found a reduction in surgery among CSMT recipients, which was not statistically significant, likely due to small sample size.<sup>16</sup> While the current study reinforces these previous findings, the smaller

magnitude of our ORs could be explained by the extensive selection criteria, narrow age bracket, propensity matching methods, and differences in patient population.

Our sensitivity analysis suggested that an unmeasured confounder associated with both CSMT and discectomy would require a risk ratio associated with patients' initial choice of CSMT for LDH/LSR of a magnitude of 1.92 to 2.26 to fully explain our results at 2- and 1-years' follow-up, respectively. While we are unaware of any unmeasured confounder of this magnitude based on recent research on this topic,<sup>60</sup> it is possible that one will be elucidated in future studies. Although the data in the current study includes insured and uninsured patients, socioeconomic variables were not included in the dataset, which remain potentially important unmeasured confounders.

Considering the current study excluded absolute indications for surgery and serious pathology, we suggest our findings may be explained by pain relief afforded by CSMT. Previous studies have shown that LDH/LSR have good prognosis with at least half of patients experiencing significant relief in the first 3-12 months.<sup>68,69</sup> As most patients will undergo surgery within 2-12 months of symptom onset,<sup>24</sup> we suggest initial pain relief afforded by CSMT could allow patients to avoid surgery during this early critical period.

Further research is needed to expand on the current study. Chiefly, a randomized controlled trial could eliminate residual sources of confounding such as socioeconomic variables. In such a study, several outcomes could be measured in tandem including pain severity, disability, cost of care, and pain medication utilization, in addition to the rate of lumbar discectomy. The current study provides preliminary data to justify such a study, which would be more costly and time

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consuming to conduct yet provide a higher level of evidence. Further, given our selection criteria focused on younger adults undergoing discectomy for LDH/LSR, a follow-up study could examine the likelihood of lumbar fusion surgery among older adults with lumbar stenosis.

#### Limitations

First, because of its observational design, this study is unable to conclude that CSMT is causative in reducing the odds of lumbar discectomy. There are several variables unavailable in the TriNetX dataset that could lead to unmeasured confounding such as those relating to socioeconomic status, clinical examination findings,<sup>22</sup> detailed spinal imaging data such as measures of disc herniation,<sup>70</sup> self-reported pain severity and impact, and measures of catastrophizing, self-efficacy, and disability.

Second, data entered into a patient medical record may not be accurate, leading to an information bias in the aggregated health records data.<sup>71</sup> Certain comorbidities, prior diagnoses, treatments, medications, or other patient variables could be absent, incorrect, or outdated,<sup>72</sup> which could affect propensity matching or impact a patient's eligibility for the current study. We were also unable to examine data completeness for all variables at an individual patient level. It was not feasible to validate our query against a gold standard of chart review given data was de-identified and sourced from outside healthcare organizations.

Third, we are unable to determine the techniques of CSMT employed by chiropractors for each patient, which may have differing efficacy.<sup>73</sup> Knowledge of techniques performed such as mobilization, low-force, or high-velocity, low-amplitude CSMT could allow us to standardize the CSMT cohort to include a more uniform treatment, or enable subgroup analysis according to

technique (e.g., flexion-distraction, lumbar HVLA manipulation, instrument-assisted, etc.). In addition, the number of visits in which CSMT was utilized likely varied between patients in the CSMT cohort, and this variable cannot be tracked in the study dataset.

Fourth, we were unable to examine the likelihood of visiting a surgeon due to a lack of provider codes in the dataset. Previous research has found that patients who initiate care for low back pain with a chiropractor have significantly reduced odds of visiting a surgeon.<sup>16</sup> Accordingly, it is unclear if a difference in surgical visits between cohorts mediates the association observed in our study.

Finally, as the study results derived from large, academically affiliated healthcare institutions they may not be generalizable to patients seeking chiropractic care in private facilities.<sup>74</sup> These results also may not be generalizable to healthcare settings outside of the US.

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# Conclusion

These findings suggest that patients receiving CSMT for newly diagnosed LDH and/or LSR without serious pathology, spinal deformity, or absolute indications for surgery have significantly reduced odds of discectomy through 2-years' follow-up after index diagnosis compared to those receiving other care. While socioeconomic variables were unavailable in the dataset, current data suggests these unmeasured variables would not completely explain our findings. However, given the possibility of residual confounding, the efficacy of CSMT for LDH/LSR should be explored further using a randomized controlled trial.

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## Competing interests

Dr. Trager reports he has received book royalties as the author of two texts on the topic of sciatica. No other authors reported conflicts.

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## Disclaimer

The views expressed are those of the authors and do not necessarily reflect the official policy or position of the US Department of Veterans Affairs or the US Government.

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### Data availability

We are unable to make the data used in this study publicly available. This data was obtained via a data use agreement with the TriNetX network that does not allow release or sharing of this data. Those interested in accessing this network may contact TriNetX (https://www.trinetx.com/).

## Ethics

This study was determined Not Human Subjects Research by the University Hospitals Institutional Review Board (Cleveland, Ohio, USA; STUDY20220571).

# Author contributions

RT, CD, RC, JP, and JD conceived of and designed the study. RC and JP were responsible for data collection and management of the study software and database. RT, CD, JP, and JD were responsible for data analysis and interpretation. JD provided supervision and mentorship. RT drafted the manuscript while all authors critically revised and approved the final manuscript.

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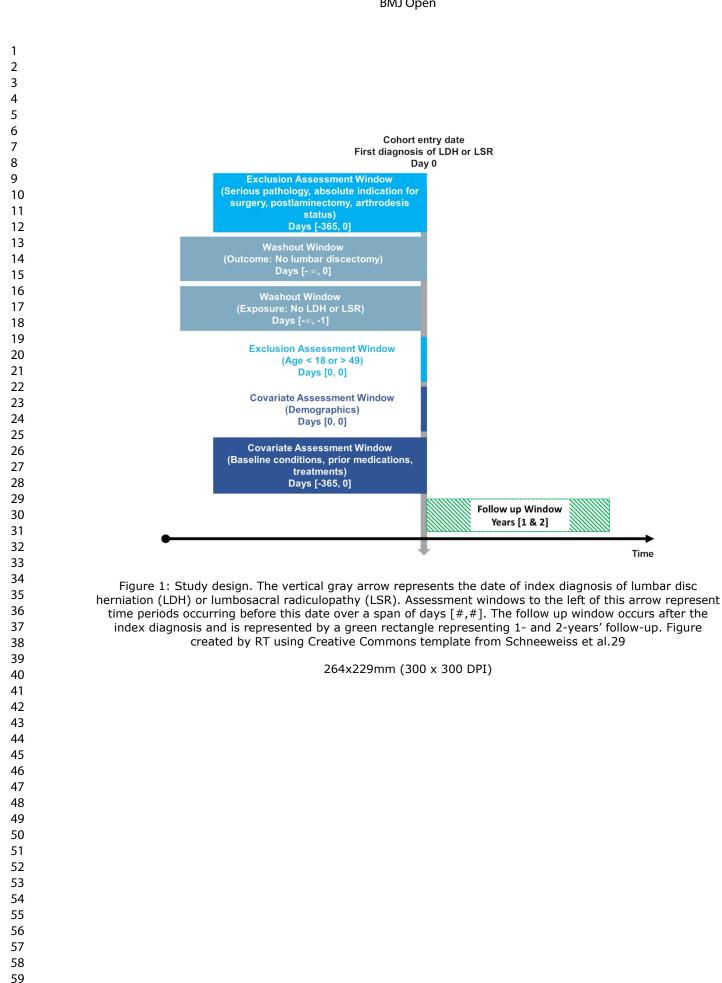
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Follow up Window

Years [1 & 2]

Time



# Supplemental File

Table 1: Inclusion codes for both cohorts for patients with lumbar disc herniation and/or lumbosacral radiculopathy

Diagnosis Codes*	Definition
G54.4	Lumbosacral root disorders, not elsewhere classified
M51.26	Other intervertebral disc displacement, lumbar region
M51.27	Other intervertebral disc displacement, lumbosacral region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.3	Sciatica
M54.4	Lumbago with sciatica
* International Classif	fication of Diseases (ICD-10)

# Table 2: Exclusions for both cohorts

Diagnosis codes*	Definition (excluded days -365 to 0)
C00-C96	Malignant neoplasm
G83.4	Cauda equina syndrome
M41	Scoliosis
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M48.0	Spinal stenosis
M48.46	Fatigue fracture of vertebra, lumbar region
M48.56	Collapsed vertebra, not elsewhere classified, lumbar region
M48.57	Collapsed vertebra, not elsewhere classified, lumbosacral region
M84.40	Pathological fracture, unspecified site
M84.48	Pathological fracture, other site
M84.58	Pathological fracture in neoplastic disease, other specified site
M84.60	Pathological fracture in other disease, unspecified site
M96.1	Postlaminectomy syndrome, not elsewhere classified
N31	Neuromuscular dysfunction of bladder, not elsewhere classified
R15	Fecal incontinence
R32	Unspecified urinary incontinence
S22.08	Fracture of T11-T12 vertebra
S30-S39	Injuries to the abdomen, lower back, lumbar spine, pelvis and external genitals
\$32.0	Fracture of lumbar vertebra
Z98.1	Arthrodesis status
Lumbar	Definition (excluded any time to day 0)
discectomy codes	
Multiple	See Supplemental File Table 4
* International Classi	fication of Diseases (ICD-10)

Table 3: Additional selection criteria according to receipt of chiropractic spinal manipulative therapy

CPT code	Description	CSMT recipients	CSMT non- recipients
98940	CSMT; 1-2 regions	Included	Excluded
98941	CSMT; 3-4 regions	Included	Excluded
98942	CSMT; 5 regions	Included	Excluded
Abbreviations:	Chiropractic spinal manipulative th	nerapy (CSMT)	

#### Table 4: Lumbar discectomy outcome definition codes

Procedure code	Definition
	I Terminology (CPT)
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral
	disc, any method utilizing needle-based technique to remove disc material under
	fluoroscopic imaging or other form of indirect visualization, with the use of an
	endoscope, with discography and/or epidural injection(s) at the treated level(s),
	when performed, single or multiple levels, lumbar
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve
	root(s) (eg, herniated intervertebral disc), single segment; lumbar (including
	transfacet, or lateral extraforaminal approach) (eg, far lateral herniated
	intervertebral disc)
Healthcare Commo	on Procedure Coding System (HCPCS)
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and excision of herniated intervertebral disc,
	and repair of annular defect with implantation of bone anchored annular closure
	device, including annular defect measurement, alignment and sizing assessment
	and image guidance; 1 interspace, lumbar
ICD-10 Procedural	Classification System (PCS)
0SB4*	Lumbosacral Disc (includes open, percutaneous, and percutaneous endoscopic
	surgical excision of lumbosacral disc)

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Variable	Description
Demographics	Patient age, sex, race, and ethnicity
Logical Observation	n Identifiers Names and Codes
39156-5	BMI – Body mass index
Lumbosacral radicu	ulopathy diagnoses (ICD-10)
G54.4	Lumbosacral root disorders, not elsewhere classified
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.3	Sciatica
M54.4	Lumbago with sciatica
Comorbidities (ICD	-10)
F01-F99	Mental, Behavioral and Neurodevelopmental disorders
Z72.0	Tobacco use
Medications (VANE	OF Classes)
CN101	Opioid analgesics
CN000	Central nervous system medications
Procedures (ICD-1	0-PCS)
3E0R3BZ	Introduction of anesthetic agent into spinal canal, percutaneous
	approach
	y mass index (BMI) calculated as kg/m <sup>2</sup> , International Classification of
	dural Classification System (ICD-10-PCS); Veterans Health Administration
National Drug File	(VANDF)

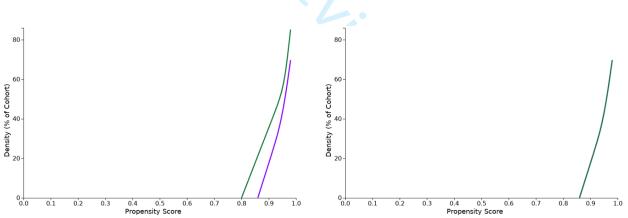


Figure 1: Propensity scores before (A) and after (B) matching. The purple line represents the cohort receiving chiropractic spinal manipulative therapy (CSMT) while the green line represents the cohort receiving other care. In image B, the propensity score densities overlap and only a single line is visible, suggesting that the cohorts are well matched.

# STROBE Statement

## -Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Pag #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the	1
		title or the abstract	
		(b) Provide in the abstract an informative and balanced summary of	2
		what was done and what was found	
Introduction	-0	4	
Background/rationale	2	Explain the scientific background and rationale for the investigation	4
		being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods	6
		of recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of	7
		selection of participants. Describe methods of follow-up	
		(b) For matched studies, give matching criteria and number of	7
		exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential	9
		confounders, and effect modifiers. Give diagnostic criteria, if	
		applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of	6
measurement		methods of assessment (measurement). Describe comparability of	
		assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	10

			-
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(a) Describe all statistical methods, including those used to control	11
		for confounding	
		(b) Describe any methods used to examine subgroups and	NA
		interactions	
		(c) Explain how missing data were addressed	14
		(d) If applicable, explain how loss to follow-up was addressed	NA
		(e) Describe any sensitivity analyses	11
Results		0	
Participants	13*	(a) Report numbers of individuals at each stage of study—eg	12
		numbers potentially eligible, examined for eligibility, confirmed	
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	Figur
			1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic,	14
		clinical, social) and information on exposures and potential	
		confounders	
		(b) Indicate number of participants with missing data for each	NA
		variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over	14
		time	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-	14
		adjusted estimates and their precision (eg, 95% confidence	
		interval). Make clear which confounders were adjusted for and why	
		they were included	

		(b) Report category boundaries when continuous variables were	NA
		categorized	
		(c) If relevant, consider translating estimates of relative risk into	NA
		absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and	NA
		interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	16
Limitations	19	Discuss limitations of the study, taking into account sources of	19
		potential bias or imprecision. Discuss both direction and magnitude	
		of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering	20
		objectives, limitations, multiplicity of analyses, results from similar	
		studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	20
Other information			
Funding	22	Give the source of funding and the role of the funders for the	21
		present study and, if applicable, for the original study on which the present article is based	

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### Association between chiropractic spinal manipulation and lumbar discectomy in adults with lumbar disc herniation and radiculopathy: retrospective cohort study using United States' data

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# Association between chiropractic spinal manipulation and lumbar

# discectomy in adults with lumbar disc herniation and

radiculopathy: retrospective cohort study using United States'

## data

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Word count: 3,568

## Abstract

Objectives: Chiropractic spinal manipulative therapy (CSMT) and lumbar discectomy are both used for lumbar disc herniation (LDH) and lumbosacral radiculopathy (LSR); however, limited research has examined the relationship between these therapies. We hypothesized adults receiving CSMT for newly diagnosed LDH or LSR would have reduced odds of lumbar discectomy over 1- and 2 years' follow-up compared to those receiving other care.

Design: Retrospective cohort study.

Setting: 101-million-patient United States health records network (TriNetX), queried October 24, 2022, yielding data from 2012-query.

Participants: Adults age 18-49 with newly-diagnosed LDH/LSR (first date of diagnosis) were included. Exclusions were prior lumbar surgery, absolute indications for surgery, trauma, spondylolisthesis, and scoliosis. Propensity score matching controlled for variables associated with the likelihood of discectomy (e.g., demographics, medications).

Interventions: Patients were divided into cohorts according to receipt of CSMT.

Primary and secondary outcome measures: Odds ratios (ORs) for lumbar discectomy; calculated by dividing odds in the CSMT cohort by odds in the cohort receiving other care.

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Results: After matching, there were 5785 patients per cohort (mean age 36.9±8.2). The ORs [95% CI] for discectomy were significantly reduced in the CSMT cohort compared to the cohort receiving other care over 1-year (0.69 [0.52 to 0.90], *P*=0.006) and 2-years' follow-up (0.77 [0.60 to 0.99], *P*=0.040). E-value sensitivity analysis estimated the strength in terms of risk ratio an unmeasured confounding variable would need to account for study results, yielding point estimates for each follow-up (1-year: 2.26; 2-year: 1.92), which no variables in the literature reached.

Conclusions: Our findings suggest receiving CSMT compared to other care for newly diagnosed LDH/LSR is associated with significantly reduced odds of discectomy over 2-years' follow-up. Given socioeconomic variables were unavailable and an observational design precludes inferring causality, the efficacy of CSMT for LDH/LSR should be examined via randomized controlled trial to eliminate residual confounding.

Keywords: Discectomy, Lumbar Disc Disease, Radiculopathy, Sciatica, Spinal Manipulation, Chiropractic, Low Back Pain

## **Article Summary**

#### Strengths and limitations of this study

• This study was based on an a priori protocol developed by a multidisciplinary research team with the intention of reducing bias.

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4	<ul> <li>This study included patients with newly diagnosed lumbar disc herniation or</li> </ul>
5 6 7	lumbosacral radiculopathy and excluded those with absolute indications for surgery to
8 9	make cohorts more comparable.
10 11 12	While an extensive propensity matching model was utilized to control for confounding
13 14	variables, several variables were unavailable in the dataset including those relating to
15 16 17	socioeconomic status, examination and imaging findings, pain severity and impact,
18 19	catastrophizing, self-efficacy, and disability.
20 21 22	While this study examined a large population, only large, academically affiliated
23 24	healthcare organizations in the United States were included, thus results may not be
25 26 27	broadly generalizable.
28 29	<ul> <li>As this study is observational, a randomized controlled trial would be needed to</li> </ul>
30 31 32	eliminate possible residual confounding.
33 34 35 36 37	Introduction
38 39	A lumbar disc herniation (LDH) is a focal displacement of intervertebral disc material beyond
40 41 42	the normal limit of the disc margin, <sup>1</sup> which may compress one or more nerve roots, causing
43 44 45	lumbosacral radiculopathy (LSR). The clinical features of LSR include radicular (radiating) lower
45 46 47	extremity pain, predictable sensory disturbances, weakness, and/or diminished muscle stretch
48 49 50	reflexes. <sup>2</sup> LDH and LSR are common reasons for patients to receive chiropractic care or undergo
50 51 52	surgery to remove LDH material, a procedure called discectomy. However, limited research has
53 54 55	examined the association between chiropractic care and discectomy.

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In the United States (US), chiropractors are portal-of-entry providers that often manage low back pain, including LDH/LSR.<sup>3,4</sup> While chiropractors may utilize soft tissue or exercise therapies for these patients,<sup>5</sup> they most often employ chiropractic spinal manipulative therapy (CSMT).<sup>4</sup> Prior studies have documented the benefits of CSMT for LDH/LSR, including randomized prospective studies.<sup>6,7</sup> In a meta-analysis, spinal manipulation was found to be one of the most effective treatments for discogenic LSR.<sup>8</sup> Accordingly, US and international clinical practice guidelines have recommended spinal manipulation for low back pain and LSR.<sup>9–13</sup>

Prior studies examining the association between chiropractic care and lumbar spine surgery have examined a broader population and/or outcome.<sup>14–20</sup> Two studies identified a significant reduction in odds of lumbar surgery among individuals receiving early chiropractic care, with one examining surgical fusion or decompression among patients with an occupational back injury,<sup>18</sup> and another examining discectomy and fusion among patients with back pain.<sup>14</sup> The current study differs by examining a narrower range of LBP conditions (i.e., LDH/LSR) with an outcome specific to discectomy.

Several factors may influence whether a patient undergoes a discectomy, including clinical features, patient preferences, and the response to conservative care.<sup>21–23</sup> While the presence of severe or "red flag" neurologic deficits and/or cauda equina syndrome are absolute indications for lumbar discectomy, continued pain despite conservative treatment that affects quality of life is considered a relative indication.<sup>24</sup> For patients without absolute indications, early discectomy can provide short-term benefits for LDH with LSR, however, long-term outcomes are similar at 1-2 years in those receiving conservative care.<sup>25</sup>

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This study was conducted considering that CSMT and lumbar discectomy are both viable treatment options for LDH and LSR, yet there has been limited research examining the relationship between these care pathways.

#### Objectives

 This study aimed to examine the association between receipt of CSMT for newly diagnosed LDH and/or LSR and odds of lumbar discectomy, with the hypothesis that adults receiving CSMT would have reduced odds of lumbar discectomy over 1- and 2year follow-up windows after index diagnosis compared to those receiving other care.

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## Methods

#### Study design

This study followed an a priori protocol registered with the Open Science Framework (https://osf.io/2gkcd),<sup>26</sup> and incorporated a retrospective, new-user, active-comparator design<sup>27</sup> to compare recipients and nonrecipients of CSMT from age 18-49 of any sex (Figure 1). The study included patients meeting selection criteria from October 24, 2012, to October 24, 2020 to capture more recent data, considering the treatment of LDH and LSR may have changed over time. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline structure was followed.<sup>28</sup>

## Setting and data source

This study utilized a 101-million patient population within the TriNetX US research network (TriNetX Inc., Cambridge, MA, US).<sup>30</sup> Data in this network is de-identified, aggregated, and frequently updated from the health records of multiple health care organizations in the US, which are typically large, academically affiliated health centers and their ambulatory offices. This network includes insured and uninsured patients.<sup>31</sup> The TriNetX dataset routinely undergoes automated and manual assessments to ensure data conformance, completeness, and plausibility.<sup>30,32</sup> One previous study estimated a completeness of at least 87% for medications in the TriNetX dataset,<sup>33</sup> however the completeness of other variables has not been examined to our knowledge.

Queries of this dataset are performed using standardized nomenclatures such as the ICD-10 procedural classification system (ICD-10-PCS), Current Procedural Terminology (CPT), and Veterans Health Administration National Drug File (VANDF), and others. International Classification of Diseases (ICD-10) codes may also be used which are interconverted automatically to older ICD-9 codes using general equivalence mappings.<sup>30</sup> At University Hospitals of Cleveland, the Clinical Research Center manages all use of the TriNetX platform.

As of January 2022, there were 10 healthcare organizations within the TriNetX network that had providers administering CSMT.<sup>34</sup> In accordance with of privacy regulations, these institutions remain anonymous. Although this study only examined a fraction of US chiropractic providers, integration of chiropractors into hospitals is a growing trend, with 5% of US chiropractors reporting a hospital affiliation in 2019.<sup>3</sup> Integrated chiropractors are most often

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employed within physical medicine, rehabilitation, or physical therapy settings and on average have 21 years' experience in practice.<sup>35</sup>

#### Participants

#### Eligibility criteria

This study identified patients with newly-diagnosed LDH and/or LSR by querying the TriNetX dataset with a custom set of codes (Supplemental Table 1). These patients were identified at the index date of diagnosis, which we defined as the first instance of LDH or LSR codes appearing in the medical record. This effectively required that patients had no previous instance of LDH or LSR diagnosis occurring over any time available in the dataset preceding the index date. As the length of time patients were available in the dataset prior to inclusion varied, this washout window also varied per patient. Patients were required to be represented in the dataset for at least two years after the index diagnosis date to be eligible.

Patients with diagnoses of lumbar or sacral radiculopathy or sciatica were included as these diagnoses often reflect underlying LDH or LSR,<sup>36</sup> and evidence suggested that these diagnosis codes are often utilized by clinicians.<sup>37</sup> The age bracket of 18-49 years was used as LDH is more common in younger patients aged 30-50.<sup>38</sup> Conversely, lumbar stenosis is a more prevalent cause of LSR in older patients.<sup>39</sup> Accordingly, the upper age cutoff was intended to exclude patients with lumbar stenosis from our study.

Patients with serious spine pathology or absolute indication for surgery, such as cauda equina syndrome (CES), signs of CES such as bowel or bladder incontinence, fracture, infection, and

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malignant neoplasms were excluded over 365 days preceding and including the date of index diagnosis (Supplemental Table 2).<sup>40</sup> Patients with conditions that could alter the CSMT or surgical approach and/or increase the odds of lumbar surgery were also excluded: lumbar fusion, arthrodesis or postlaminectomy syndrome,<sup>41,42</sup> lumbar spine trauma,<sup>43</sup> and degenerative lumbar scoliosis and spondylolisthesis.<sup>44</sup> As an additional measure of ensuring patients had no previous discectomy, we excluded patients with any instance of discectomy occurring over any time available in the dataset preceding and including the index date of diagnosis.

Diagnoses of lumbar spondylosis (e.g., ICD-10: M47.26) were not utilized in our inclusion criteria given these are not specific to LDH. In addition, codes specifying lumbar disc disorders with myelopathy (e.g., ICD-10: M47.16) were not utilized as myelopathy has different clinical features and management strategies than LDH/LSR. Diagnosis codes specifying lumbar or lumbosacral disc degeneration were not included, as a strategy to create more uniformity between cohorts. Disc degeneration is not associated with radicular symptoms, unlike LDH, which has a strong association with radicular symptoms.<sup>45</sup>

Included patients were divided into 2 cohorts according to receipt of CSMT (Supplemental Table 3). The CPT codes 98940, 98941, and 98942 for CSMT were included in the "CSMT" cohort and excluded in the "other care" cohort. These 9894\* codes are almost exclusively utilized by chiropractors in the US.<sup>46</sup> Patients in the CSMT cohort were required to receive CSMT on the date of index date of diagnosis of LDH or LSR (i.e., the first instance of the diagnosis in the medical record), while those in the cohort receiving other care could not receive CSMT on the index date of diagnosis.

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### Variables

#### Discectomy

A definition for the outcome of lumbar discectomy was developed based on discussion amongst co-authors and comparison with previous publications (Supplemental Table 4).<sup>37,40,47,48</sup> This definition included multiple procedure codes for discectomy, as well as the ICD-10-PCS code OSB4\* which includes open, percutaneous, and percutaneous endoscopic approaches to excise lumbosacral disc material,<sup>49</sup> and the Healthcare Common Procedure Coding System (HCPCS) code C9757 for lumbar discectomy with implantation of an annular closure device.<sup>48</sup> Feasibility testing was conducted in June, 2021, to ensure these codes were represented in the TriNetX database. Two follow-up windows of 1-year and 2-year were used in this study to allow for comparisons to prior similar studies also using long-term endpoints.<sup>16,18</sup>

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### Potential confounders

Propensity score matching is a method of balancing confounding variables between cohorts to improve their comparability.<sup>27</sup> Based on previous recommendations, confounders were propensity matched when having evidence of an association with the outcome of interest (i.e. lumbar discectomy).<sup>50</sup> Variables present within a 365-day window preceding the index diagnosis of LDH and/or LSR were eligible for propensity matching (Supplemental Table 5). Demographic variables associated with the likelihood of lumbar surgery were propensity matched including increasing age,<sup>23,51</sup> male sex,<sup>23,51,52</sup> and race.<sup>51</sup> Other factors associated with increased likelihood of lumbar surgery were matched including obesity,<sup>23,51</sup> being a nonsmoker,<sup>23</sup> psychological disorders,<sup>51</sup> a history of lumbar injections,<sup>23,53</sup> and prior treatment with opioids<sup>43</sup> or prescription pain medications.<sup>23</sup> Radicular symptoms or radiculopathy are also predictors of lumbar surgery in those with low back pain,<sup>23,53</sup> and were matched via the ICD-10 codes for LSR and sciatica.

#### Study size

A required sample size of 198 was calculated using  $G^*Power^{54}$  z-tests for logistic regression, with an alpha error 0.05, power of 0.95, probability of the outcome in the null hypothesis of 0.02, and odds ratio (OR) of 0.18, assuming a normal distribution and a moderate interaction between covariates (R2 = 0.5). Probabilities were taken from a prior similar study that examined surgical rates in recipients vs. nonrecipients of chiropractic care.<sup>16</sup> This sample was deemed to be feasible given the large patient population within the TriNetX network.

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### Statistical methods

Statistical analysis was performed using built-in statistical functions available in the TriNetX software platform in real-time. Baseline characteristics were compared using a Pearson chi-squared test for categorical variables and independent-samples t-test for continuous variables. We did not perform any imputations for missing data.

Propensity scores for each cohort were calculated using logistic regression. Propensity scores were matched 1:1 using a greedy nearest-neighbor algorithm and a caliper of 0.01 pooled standard deviations. A visual diagnostic was used to assess the balance between cohorts following propensity score matching. Odds of discectomy in each cohort were calculated by dividing the number of patients undergoing discectomy by the number of patients not undergoing discectomy. ORs for discectomy for each follow-up window were calculated by dividing odds in the CSMT cohort by odds in the other care cohort.

A sensitivity analysis was conducted by computing E-values for both follow-up windows after propensity matching.<sup>55</sup> The E-value is defined as the minimum strength of association an unmeasured confounder would need to account for an association between the outcome (i.e. CSMT) and exposure (lumbar discectomy).<sup>56</sup>

#### Patient and Public Involvement

No patient or public involvement.

# Results

## Participants

Patients meeting selection criteria were identified from 70 health care organizations, 10 of which included CSMT services. A large sample size was identified for each cohort (Table 1). Before propensity matching, there were 5785 patients in the CSMT cohort and 482704 in the other care cohort. After propensity matching, which discarded non-matching patients in the larger other care cohort, there were 5785 patients in each cohort (mean age 36.9±8.2 years). Before matching, there were several differences between cohorts. Most notably, the CSMT cohort had a significantly lower percentage of patients who were Black/African American or Hispanic/Latino, and significantly higher percentage of patients who were prescribed central nervous system medications. The frequency of LDH/LSR codes also varied between cohorts. All differences between cohorts were no longer statistically significant after propensity matching, aside from body mass index. However, this difference was minimal, varying only 0.5 kilograms per square meter between cohorts.

Table 1: Baseline characteristics before and after propensity score matching

	Before Ma	Before Matching After Matching				
Characteristic	CSMT	Other care	<i>P</i> - value	CSMT	Other care	<i>P</i> - value
N	5,785	482,704		5,785	5,785	
Age	36.9±8.2	37.4±8.2	<0.001	36.9±8.2	36.9±8.2	0.972
Sex						

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<b>F</b> arra da	0.505	000.004	0.000	0.505	0.500 (040()	0.00
Female	3,535 (61%)	288,061 (60%)	0.028	3,535 (61%)	3,539 (61%)	0.93
Male	2,250 (39%)	194,587 (40%)	0.029	2,250 (39%)	2,245 (39%)	0.92
Race						
Black or African American	431 (8%)	90,838 (19%)	<0.001	431 (8%)	433 (8%)	0.94
White	4,389 (76%)	313,938 (65%)	<0.001	4,389 (76%)	4,368 (76%)	0.64
Asian	99 (2%)	9,913 (2%)	0.068	99 (2%)	100 (2%)	0.94
Ethnicity						
Hispanic/Latino	157 (3%)	37,715 (8%)	<0.001	157 (3%)	154 (3%)	0.86
Not Hispanic/Latino	4,839 (84%)	311,836 (65%)	<0.001	4,839 (84%)	4,808 (83%)	0.43
Conditions (ICD-10)		~				
Mental, Behavioral & Neurodevelopmental Disorders (F01-F99)	2,177 (38%)	145,444 (30%)	<0.001	2,177 (38%)	2,158 (37%)	0.71
Lumbosacral root disorders, not elsewhere classified (G54.4)	24 (<1%)	878 (<1%)	<0.001	24 (<1%)	16 (<1%)	0.20
Radiculopathy, lumbar region (M54.16)	1,713 (30%)	138,388 (29%)	0.115	1,713 (30%)	1,666 (29%)	0.33
Radiculopathy, lumbosacral region (M54.17)	1,420 (25%)	73,363 (15%)	<0.001	1,420 (25%)	1,375 (24%)	0.32
Radiculopathy, sacral and sacrococcygeal region (M54.18)	62 (1%)	1,052 (<1%)	<0.001	62 (1%)	58 (1%)	0.71
Sciatica (M54.3)	1,432 (25%)	150,984 (31%)	<0.001	1,432 (25%)	1,407 (24%)	0.58
Lumbago with sciatica (M54.4)	1,411 (24%)	158,467 (33%)	<0.001	1,411 (24%)	1,360 (24%)	0.26
Procedure (ICD-10-PCS)						
Introduction of Anesthetic Agent into Spinal Canal, Percutaneous Approach	10 (<1%)	991 (<1%)	0.588	10 (<1%)	10 (<1%)	1
Medications (VANDF)						
Opioid Analgesics (CN101)	1,883 (33%)	156,838 (33%)	0.925	1,883 (33%)	1,881 (33%)	0.96

Central Nervous System Medications (CN000)	3,619 (63%)	279,764 (58%)	<0.001	3,619 (63%)	3,603 (62%)	0.759
BMI (kg/m²)	30.6±6.9	30.6±7.2	0.571	30.6±6.9	30.1±7.2	0.005
Abbreviations: chiropractic spinal manipulative therapy (CSMT), International Classification of Disease (ICD), International Classification of Disease Procedure Coding System (ICD-10-PCS), body mass index kg/m <sup>2</sup> (BMI measured by kilogram per square meter), Veterans						

Health Administration National Drug File (VANDF)

## Descriptive data

The average number of data points per patient was high in both cohorts (CSMT 2442, other care 1527). After propensity matching, the frequency of unknown demographic variables was the same both cohorts, with 15% having unknown race, 14% having unknown ethnicity, and 0% having unknown sex or age. These findings suggested there was no difference between cohorts with respect to missing data. A visual propensity score density graph revealed that cohorts were comparable after propensity matching (see online Supplemental Figure 1).

## Key results

Discectomy was less frequent in the CSMT cohort throughout 1-year and 2-year follow-up windows before and after propensity matching. After matching, 1.5% of patients (CSMT) and 2.2% (other care) underwent discectomy over 1-year follow-up, while 1.9% (CSMT) and 2.4% (other care) underwent discectomy over 2-years (Table 2). After matching, odds of discectomy were significantly lower in the CSMT compared to other care cohort, with an OR (95% CI) of 0.69 (0.52-0.90; *P*=0.006) over 1-year and 0.77 (0.60-0.99; *P*=0.040) over 2 years' follow-up from index diagnosis.

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## Table 2: Key results before and after propensity score matching

	Before matching		After matching	
	CSMT	Other care	CSMT	Other care
	n = 3,093	n = 747,594	n = 3,093	n = 3,093
1 year				
Discectomy No.	89 (1.5%)	8,854 (1.8%)	89 (1.5%)	129 (2.2%)
(%)				
OR (CI)	0.84 (0.68-	(reference)	<b>0.69</b> (0.52,	(reference)
	1.03)		0.90)*	
2 years				
Discectomy No.	108 (1.9%)	9,749 (2.0%)	108 (1.9%)	140 (2.4%)
(%)				
OR (CI)	0.92 (0.76,	(reference)	<b>0.77</b> (0.60-	(reference)
	1.12)		0.99)*	
Abbreviations: chi	ropractic spir	nal manipulativ	ve therapy (C	SMT), odds
ratio (OR), 95% co	nfidence inte	ervals (CI), num	iber (No.) and	l percentage
(%) of patients wit			. ,	. 0
* Indicates a P-val	-			

\* Indicates a *P*-value of < 0.05. **Bold** indicates results pertinent to the study hypotheses

## Sensitivity analysis

After propensity matching, ORs for the current study allowed calculation<sup>55</sup> of an E-value for the point estimate of 2.26 with an E-value for the lower confidence interval of 1.46 for the 1-year follow-up, and an E-value for the point estimate of 1.92 with an E-value for the lower confidence interval of 1.11 for the 2-year follow-up. While our protocol suggested patients have a small increase in likelihood of visiting a chiropractor if they have higher income (i.e., risk ratio of 1.23),<sup>57</sup> this was based on data from the 1990s,<sup>58,59</sup> which has been contradicted by more recent data. A more recent study found that income, education level, and insurance coverage are not associated with patients' initial

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choice of provider for spinal pain (i.e., chiropractor, physical therapist, or medical physician).<sup>60</sup> Regardless, the risk ratio from the earlier study suggesting income was a predictor is less than the E-value point estimates for our study (i.e., 1.23 < 1.92 and 2.26).

An unmeasured variable associated with both likelihood of visiting a chiropractor and likelihood of undergoing discectomy would require a risk ratio greater than the study E-value point estimates, 1.92 and 2.26, to fully explain away our results of a significant reduction in odds of discectomy from the 2-years and 1-year follow-up outcomes, respectively.<sup>56</sup> We are unaware of any socioeconomic or other variable that were not measured in the current study that could fully explain away our results based on the E-value estimates.

## Discussion

This retrospective cohort study was the first to examine the association between receiving CSMT for newly diagnosed LDH and/or LSR and odds of lumbar discectomy and included a large US sample of over 3000 patients per cohort after several exclusions and propensity matching to improve cohort comparability. These real-world results support our hypothesis that patients initially receiving CSMT for LDH/LSR have reduced odds of discectomy over 1- and 2-years' follow-up.

The frequency of discectomy in this study (i.e., 1.5-2.2% over 1 year) is comparable to previous studies, and suggestive that our methods of capturing this outcome were valid. One prior study which examined 2.5 million adults in the US with low back and/or lower extremity pain and no red flag diagnosis found that 1.2% of patients underwent surgery over a 1-year follow-up

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period.<sup>61</sup> While smaller studies have reported a higher frequency of discectomy of 5% or greater,<sup>45,62–64</sup> our study had a relatively young population and several exclusions, which could explain the frequency of discectomy being on the lower end of the range of prior studies. Further, most discectomies occurred in the 1<sup>st</sup> year of follow-up in our study, with only a small increase during the 2-year follow-up window. This is in agreement with a previous systematic review that reported the majority of patients undergo surgery within 2 and 12 months from onset of symptoms.<sup>24</sup>

The overall rate of surgery over 2-years' follow-up including both cohorts combined in our study was 2.1%, whereas in previous similar studies examining CSMT this value was 5%<sup>14</sup> and 9%.<sup>18</sup> The lower frequency of discectomy in our study could relate to a declining rate of lumbar surgery in the US.<sup>65</sup> While our study included the most recent data, from 2012-2022, the 5% value derived from data from 2012-2018,<sup>14</sup> and 9% value derived from older data from 2002-2004.<sup>18</sup> Finally, it is possible the final 2 years of our data included a lower frequency of discectomy related to the COVID-19 pandemic, as studies have reported delays and cancellations in elective spine surgeries during this time.<sup>66,67</sup>

Previous studies have reported a reduction in surgery among patients receiving CSMT. In one study, the reduction in odds of lumbar spine surgery was of a greater magnitude than our study (i.e., 0.22), however this study focused on a population with occupational back injury.<sup>18</sup> Another study examining a broader population identified a reduction in likelihood of surgery of greater magnitude than our study (i.e., risk ratio of 0.30).<sup>14</sup> A third similar study found a reduction in surgery among CSMT recipients, which was not statistically significant, likely due to small sample size.<sup>16</sup> While the current study reinforces these previous findings, the smaller

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magnitude of our ORs could be explained by the extensive selection criteria, narrow age bracket, propensity matching methods, and differences in patient population.

Our sensitivity analysis suggested that an unmeasured confounder associated with both CSMT and discectomy would require a risk ratio associated with patients' initial choice of CSMT for LDH/LSR of a magnitude of 1.92 to 2.26 to fully explain our results at 2- and 1-years' follow-up, respectively. While we are unaware of any unmeasured confounder of this magnitude based on recent research on this topic,<sup>60</sup> it is possible that one will be elucidated in future studies. Although the data in the current study includes insured and uninsured patients, socioeconomic variables were not included in the dataset, which remain potentially important unmeasured confounders.

Considering the current study excluded absolute indications for surgery and serious pathology, we suggest our findings may be explained by pain relief afforded by CSMT. Previous studies have shown that LDH/LSR have good prognosis with at least half of patients experiencing significant relief in the first 3-12 months.<sup>68,69</sup> As most patients will undergo surgery within 2-12 months of symptom onset,<sup>24</sup> we suggest initial pain relief afforded by CSMT could allow patients to avoid surgery during this early critical period.

Further research is needed to expand on the current study. Chiefly, a randomized controlled trial could eliminate residual sources of confounding such as socioeconomic variables. In such a study, several outcomes could be measured in tandem including pain severity, disability, cost of care, and pain medication utilization, in addition to the rate of lumbar discectomy. The current study provides preliminary data to justify such a study, which would be more costly and time

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consuming to conduct yet provide a higher level of evidence. Further, given our selection criteria focused on younger adults undergoing discectomy for LDH/LSR, a follow-up study could examine the likelihood of lumbar fusion surgery among older adults with lumbar stenosis.

#### Limitations

First, because of its observational design, this study is unable to conclude that CSMT is causative in reducing the odds of lumbar discectomy. There are several variables unavailable in the TriNetX dataset that could lead to unmeasured confounding such as those relating to socioeconomic status, clinical examination findings,<sup>22</sup> detailed spinal imaging data such as measures of disc herniation,<sup>70</sup> self-reported pain severity and impact, and measures of catastrophizing, self-efficacy, and disability.

Second, data entered into a patient medical record may not be accurate, leading to an information bias in the aggregated health records data.<sup>71</sup> Certain comorbidities, prior diagnoses, treatments, medications, or other patient variables could be absent, incorrect, or outdated,<sup>72</sup> which could affect propensity matching or impact a patient's eligibility for the current study. We were also unable to examine data completeness for all variables at an individual patient level. It was not feasible to validate our query against a gold standard of chart review given data was de-identified and sourced from outside healthcare organizations.

Third, we are unable to determine the techniques of CSMT employed by chiropractors for each patient, which may have differing efficacy.<sup>73</sup> Knowledge of techniques performed such as mobilization, low-force, or high-velocity, low-amplitude CSMT could allow us to standardize the CSMT cohort to include a more uniform treatment, or enable subgroup analysis according to

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technique (e.g., flexion-distraction, lumbar HVLA manipulation, instrument-assisted, etc.). In addition, the number of visits in which CSMT was utilized likely varied between patients in the CSMT cohort, and this variable cannot be tracked in the study dataset.

Fourth, we were unable to examine the likelihood of visiting a surgeon due to a lack of provider codes in the dataset. Previous research has found that patients who initiate care for low back pain with a chiropractor have significantly reduced odds of visiting a surgeon.<sup>16</sup> Accordingly, it is unclear if a difference in surgical visits between cohorts mediates the association observed in our study.

Finally, as the study results derived from large, academically affiliated healthcare institutions they may not be generalizable to patients seeking chiropractic care in private facilities.<sup>74</sup> These results also may not be generalizable to healthcare settings outside of the US.

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## Conclusion

These findings suggest that patients receiving CSMT for newly diagnosed LDH and/or LSR without serious pathology, spinal deformity, or absolute indications for surgery have significantly reduced odds of discectomy through 2-years' follow-up after index diagnosis compared to those receiving other care. While socioeconomic variables were unavailable in the dataset, current data suggests these unmeasured variables would not completely explain our findings. However, given the possibility of residual confounding, the efficacy of CSMT for LDH/LSR should be explored further using a randomized controlled trial.

# Figure legends

Figure 1: Study design. The vertical gray arrow represents the date of index diagnosis of lumbar disc herniation (LDH) or lumbosacral radiculopathy (LSR). Assessment windows to the left of this arrow represent time periods occurring before this date over a span of days [#,#]. The " $\sim$ " indicates that the time window extends as far as data are available in the dataset for each patient. The follow up window occurs after the index diagnosis and is represented by a green rectangle representing 1- and 2years' follow-up. Figure created by RT using Creative Commons template from Schneeweiss et al.<sup>29</sup>

## Competing interests

Dr. Trager reports he has received book royalties as the author of two texts on the topic of

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sciatica. No other authors reported conflicts.

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Disclaimer

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## Data availability

We are unable to make the data used in this study publicly available. This data was obtained via a data use agreement with the TriNetX network that does not allow release or sharing of this data. Those interested in accessing this network may contact TriNetX

(https://www.trinetx.com/).

## Ethics

This study was determined Not Human Subjects Research by the University Hospitals Institutional Review Board (Cleveland, Ohio, USA; STUDY20220571).

## Author contributions

RT, CD, RC, JP, and JD conceived of and designed the study. RC and JP were responsible for data collection and management of the study software and database. RT, CD, JP, and JD were responsible for data analysis and interpretation. JD provided supervision and mentorship. RT drafted the manuscript while all authors critically revised and approved the final manuscript.

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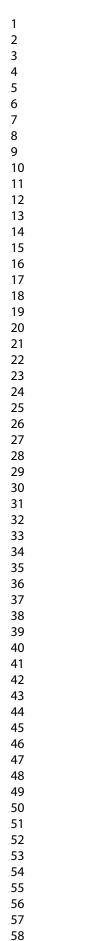
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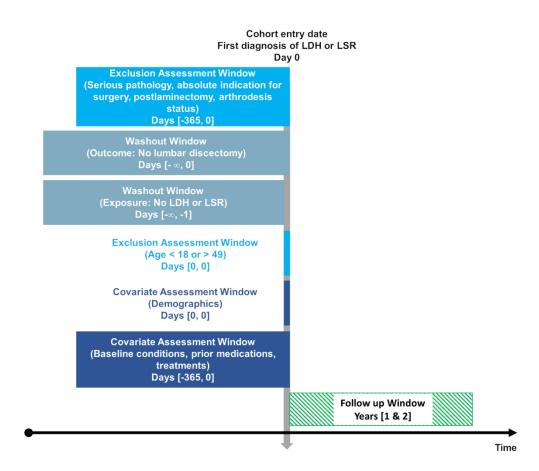


Figure 1: Study design. The vertical gray arrow represents the date of index diagnosis of lumbar disc herniation (LDH) or lumbosacral radiculopathy (LSR). Assessment windows to the left of this arrow represent time periods occurring before this date over a span of days [#,#]. The "∞" indicates that the time window extends as far as data are available in the dataset for each patient. The follow up window occurs after the index diagnosis and is represented by a green rectangle representing 1- and 2-years' follow-up. Figure created by RT using Creative Commons template from Schneeweiss et al.29

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# Supplemental File

Table 1: Inclusion codes for both cohorts for patients with lumbar disc herniation and/or lumbosacral radiculopathy

Diagnosis Codes*	Definition
G54.4	Lumbosacral root disorders, not elsewhere classified
M51.26	Other intervertebral disc displacement, lumbar region
M51.27	Other intervertebral disc displacement, lumbosacral region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.3	Sciatica
M54.4	Lumbago with sciatica
* International Classif	fication of Diseases (ICD-10)

# Table 2: Exclusions for both cohorts

Diagnosis codes*	Definition (excluded days -365 to 0)
C00-C96	Malignant neoplasm
G83.4	Cauda equina syndrome
M41	Scoliosis
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M48.0	Spinal stenosis
M48.46	Fatigue fracture of vertebra, lumbar region
M48.56	Collapsed vertebra, not elsewhere classified, lumbar region
M48.57	Collapsed vertebra, not elsewhere classified, lumbosacral region
M84.40	Pathological fracture, unspecified site
M84.48	Pathological fracture, other site
M84.58	Pathological fracture in neoplastic disease, other specified site
M84.60	Pathological fracture in other disease, unspecified site
M96.1	Postlaminectomy syndrome, not elsewhere classified
N31	Neuromuscular dysfunction of bladder, not elsewhere classified
R15	Fecal incontinence
R32	Unspecified urinary incontinence
S22.08	Fracture of T11-T12 vertebra
S30-S39	Injuries to the abdomen, lower back, lumbar spine, pelvis and externa genitals
S32.0	Fracture of lumbar vertebra
Z98.1	Arthrodesis status
Lumbar	Definition (excluded any time to day 0)
discectomy codes	
Multiple	See Supplemental File Table 4
* International Classi	fication of Diseases (ICD-10)

Table 3: Additional selection criteria according to receipt of chiropractic spinal manipulative therapy

CPT code	Description	CSMT recipients	CSMT non- recipients
98940	CSMT; 1-2 regions	Included	Excluded
98941	CSMT; 3-4 regions	Included	Excluded
98942	CSMT; 5 regions	Included	Excluded
Abbreviations:	Chiropractic spinal manipulative th	nerapy (CSMT)	

#### Table 4: Lumbar discectomy outcome definition codes

Procedure code	Definition
	I Terminology (CPT)
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral
	disc, any method utilizing needle-based technique to remove disc material under
	fluoroscopic imaging or other form of indirect visualization, with the use of an
	endoscope, with discography and/or epidural injection(s) at the treated level(s),
	when performed, single or multiple levels, lumbar
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve
	root(s) (eg, herniated intervertebral disc), single segment; lumbar (including
	transfacet, or lateral extraforaminal approach) (eg, far lateral herniated
	intervertebral disc)
Healthcare Commo	on Procedure Coding System (HCPCS)
C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including
	partial facetectomy, foraminotomy and excision of herniated intervertebral disc,
	and repair of annular defect with implantation of bone anchored annular closure
	device, including annular defect measurement, alignment and sizing assessment
	and image guidance; 1 interspace, lumbar
ICD-10 Procedural	Classification System (PCS)
0SB4*	Lumbosacral Disc (includes open, percutaneous, and percutaneous endoscopic
	surgical excision of lumbosacral disc)

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Variable	Description
Demographics	Patient age, sex, race, and ethnicity
Logical Observation	n Identifiers Names and Codes
39156-5	BMI – Body mass index
Lumbosacral radicu	ulopathy diagnoses (ICD-10)
G54.4	Lumbosacral root disorders, not elsewhere classified
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.3	Sciatica
M54.4	Lumbago with sciatica
Comorbidities (ICD	-10)
F01-F99	Mental, Behavioral and Neurodevelopmental disorders
Z72.0	Tobacco use
Medications (VANE	OF Classes)
CN101	Opioid analgesics
CN000	Central nervous system medications
Procedures (ICD-1	0-PCS)
3E0R3BZ	Introduction of anesthetic agent into spinal canal, percutaneous
	approach
	y mass index (BMI) calculated as kg/m <sup>2</sup> , International Classification of
	dural Classification System (ICD-10-PCS); Veterans Health Administration
National Drug File	(VANDF)

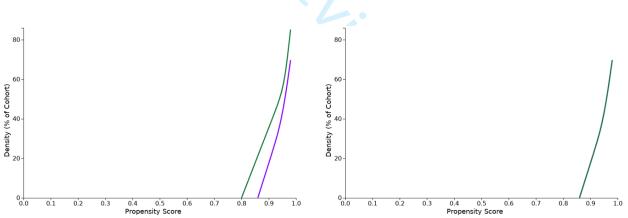


Figure 1: Propensity scores before (A) and after (B) matching. The purple line represents the cohort receiving chiropractic spinal manipulative therapy (CSMT) while the green line represents the cohort receiving other care. In image B, the propensity score densities overlap and only a single line is visible, suggesting that the cohorts are well matched.

# **STROBE Statement**

## -Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Pag #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the	1
		title or the abstract	
		(b) Provide in the abstract an informative and balanced summary of	2
		what was done and what was found	
Introduction	-0	4	
Background/rationale	2	Explain the scientific background and rationale for the investigation	4
		being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods	6
		of recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of	7
		selection of participants. Describe methods of follow-up	
		(b) For matched studies, give matching criteria and number of	7
		exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential	9
		confounders, and effect modifiers. Give diagnostic criteria, if	
		applicable	
Data sources/	8*	For each variable of interest, give sources of data and details of	6
measurement		methods of assessment (measurement). Describe comparability of	
		assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	10

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Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(a) Describe all statistical methods, including those used to control	11
		for confounding	
		(b) Describe any methods used to examine subgroups and	NA
		interactions	
		(c) Explain how missing data were addressed	14
		(d) If applicable, explain how loss to follow-up was addressed	NA
		(e) Describe any sensitivity analyses	11
Results		0	
Participants	13*	(a) Report numbers of individuals at each stage of study—eg	12
		numbers potentially eligible, examined for eligibility, confirmed	
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	Figur
			1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic,	14
		clinical, social) and information on exposures and potential	
		confounders	
		(b) Indicate number of participants with missing data for each	NA
		variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over	14
		time	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-	14
		adjusted estimates and their precision (eg, 95% confidence	
		interval). Make clear which confounders were adjusted for and why	
		they were included	

Discussion Key results Limitations Interpretation Generalisability Other information	17 18 19 20 21	categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses Summarise key results with reference to study objectives Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Discuss the generalisability (external validity) of the study results	NA NA 16 19 20
Discussion Key results Limitations Interpretation Generalisability Other information	18 19 20	<ul> <li>absolute risk for a meaningful time period</li> <li>Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses</li> <li>Summarise key results with reference to study objectives</li> <li>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</li> <li>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</li> </ul>	NA 16 19
Discussion Key results Limitations Interpretation Generalisability Other information	18 19 20	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses         Summarise key results with reference to study objectives         Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias         Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Discussion Key results Limitations Interpretation Generalisability Other information	18 19 20	interactions, and sensitivity analyses Summarise key results with reference to study objectives Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Key results Limitations Interpretation Generalisability Other information	19 20	Summarise key results with reference to study objectives Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19
Key results Limitations Interpretation Generalisability Other information	19 20	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19
Limitations Interpretation Generalisability Other information	19 20	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19
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Other information	21	studies, and other relevant evidence	
Other information	21		
Other information	21	Discuss the generalisability (external validity) of the study results	
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Funding			
	22	Give the source of funding and the role of the funders for the	21
		present study and, if applicable, for the original study on which the	
		present article is based	
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