Outcomes of Acute and Chronic Patients With Magnetic Resonance Imaging–Confirmed Symptomatic Lumbar Disc Herniations Receiving High-Velocity, Low-Amplitude, Spinal Manipulative Therapy: A Prospective Observational Cohort Study With One-Year Follow-Up

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Abstract

Objective: The purposes of this study were to evaluate patients with low-back pain (LBP) and leg pain due to magnetic resonance imaging–confirmed disc herniation who are treated with high-velocity, low-amplitude spinal manipulation in terms of their short-, medium-, and long-term outcomes of self-reported global impression of change and pain levels at various time points up to 1 year and to determine if outcomes differ between acute and chronic patients using a prospective, cohort design.

Methods: This prospective cohort outcomes study includes 148 patients (between ages of 18 and 65 years) with LBP, leg pain, and physical examination abnormalities with concordant lumbar disc herniations. Baseline numerical rating scale (NRS) data for LBP, leg pain, and the Oswestry questionnaire were obtained. The specific lumbar spinal manipulation was dependent upon whether the disc herniation was intraforaminal or paramedian as seen on the magnetic resonance images and was performed by a doctor of chiropractic. Outcomes included the patient's global impression of change scale for overall improvement, the NRS for LBP, leg pain, and the Oswestry questionnaire at 2 weeks, 1, 3, and 6 months, and 1 year after the first treatment. The proportion of patients reporting "improvement" on the patient's global impression of change scale was calculated for all patients and acute vs chronic patients. Pretreatment and posttreatment NRS scores were compared using the paired *t* test. Baseline and follow-up Oswestry scores were compared using the Wilcoxon test. Numerical rating scale and Oswestry scores for acute vs chronic patients were compared using the unpaired *t* test for NRS scores and the Mann-Whitney *U* test for Oswestry scores. Logistic regression analysis compared baseline variables with "improvement."

Results: Significant improvement for all outcomes at all time points was reported ($P < .0001$). At 3 months, 90.5% of patients were "improved" with 88.0% "improved" at 1 year. Although acute patients improved faster by 3 months, 81.8% of chronic patients reported "improvement" with 89.2% "improved" at 1 year. There were no adverse events reported.

Conclusions: A large percentage of acute and importantly chronic lumbar disc herniation patients treated with chiropractic spinal manipulation reported clinically relevant improvement. (J Manipulative Physiol Ther 2014;xx:1-9)

Key Indexing Terms: *Intervertebral Disc Displacement; Lumbar Vertebrae Manipulation, Spinal; Chiropractic*

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Approximately 70% of the population will have back pain at some point in time.[1] Low-back pain (LBP) with associated leg pain due to a herniated intervertebral disc is one of the most severe and disabling forms of back pain.[1-4] Many treatment options are available that can be grouped into 2 categories: surgical and conservative care. Conservative care may include medication, corticosteroid nerve root or epidural infiltrations, bed rest, physical therapy, flexion/distraction therapy, and spinal manipulation.

The first meta-analysis comparing the effectiveness of spinal manipulative therapy (SMT) for LBP patients with disc herniations with other therapies concluded that SMT was neither more nor less effective than other kinds of conservative care.[5] Although a later systematic review concluded that SMT is a very safe and cost-effective option for treating symptomatic lactate dehydrogenase (LDH), little research was cited to support that conclusion.[6] A 2006 randomized controlled trial (RCT) comparing active SMT with simulated SMT in disc herniation patients showed that patients treated with active SMT had greater pain relief and consumed fewer drugs compared with those receiving the simulated SMT.[7] However, only disc herniations with an intact peripheral annulus were included. A later systematic review as well as an extensive literature synthesis also evaluating the effectiveness of conservative treatments for patients with lumbar radiculopathy stated that no conclusion could be drawn whether physical therapy, medication, bed rest, or manipulation should be prescribed.[8,9]

A recent pilot study evaluated chronic lumbar disc herniation patients having radiculopathy for over 3 months who had failed 3 months of nonoperative and non-SMT treatment. These patients were randomly assigned to receive SMT or microdiskectomy.[10] Although 60% of the patients benefited from SMT to the same degree as those having surgical intervention, it is hard to determine precisely what was considered "benefit" in this study as, although many valid outcome measures were used, it is not specifically stated what was the primary outcome measure and how much change was considered "benefit." It appears that any improvement from baseline was considered a benefit. The most recent systematic review evaluating both manipulation and mobilization as treatments for patients having radiculopathy stated that there is moderate evidence that SMT is better than sham SMT in the short and long terms but that the evidence comparing SMT with other therapies is of low quality.[11]

Despite the fact that there is only moderate evidence in the literature supporting the use of spinal manipulation to treat LDH, it is widely used by manual therapists.[12] Therefore, the purposes of this study are (1) to evaluate patients with LBP and leg pain due to magnetic resonance imaging (MRI)–confirmed disc herniation who are treated with high-velocity, low-amplitude spinal manipulation in terms of their short-, medium-, and long-term outcomes of self-reported global impression of change and pain levels at various time points up to 1 year and (2) to determine if outcomes differ between acute and chronic patients using a prospective, cohort design.

Methods

Ethics approval was obtained from the Canton of Zürich Ethics Committee and Balgrist Hospital Ethics Committee, and all patients provided informed consent. Patients came from a single chiropractic practice (3 doctors of chiropractic [DCs]), which works closely with the university chiropractic medicine program. All patients were between ages of 18 and 65 years, experiencing back pain and moderate to severe leg pain in a dermatomal pattern, and at least one of the following: (*a*) decreased straight leg raise test, (*b*) deficit in detection of cold, (*c*) reduced response to pinprick; (*d*) decreased muscle strength in a corresponding myotome, (*e*) decreased or absent deep tendon reflex corresponding to the involved segment.[13] Magnetic resonance imaging–proven LDH at the corresponding symptomatic spinal segment was also required (Fig 1).

Patients with pathologies of the lumbar spine that are contraindications to chiropractic manipulative treatment, including tumors, infections, inflammatory spondylarthropathies, acute fractures, Paget disease, and severe osteoporosis, were excluded. Also excluded were patients with previous spinal surgery, signs of cauda equina syndrome, body mass index more than 30, spondylolisthesis, neurogenic claudication, and pregnancy.

Before the first treatment, demographic information was provided by the DC including patient age, sex, duration of complaint, marital status, working status, number of previous episodes, pain medication usage, whether the patient was a smoker, and general overall health. The patients also completed a questionnaire before treatment consisting of two 11-point numeric rating scales (NRS), one for LBP and one for leg pain (0, no pain and 10, worst pain imaginable), and an Oswestry pain and disability questionnaire (OPDQ) that has been validated in German. At 2 weeks, 1, 3, and 6 months, and 1 year after the initial consultation, the patients were contacted by telephone by a research assistant from the university hospital who was independent from the practice, and the patient answered the same OPDQ, patient's own global impression of change (PGIC), and rated his or her pain intensity on an NRS for both the LBP and leg pain. The PGIC scale is a 7-point verbal scale, including much worse, worse, slightly worse, no change, slightly better, better, and much better. Only the scores of "much better" or "better" were considered clinically relevant "improvement." This was the primary outcome. "Slightly worse," "worse," and "much worse" were all considered worsening of the condition. This is the same format used in other recent studies.[14,15]

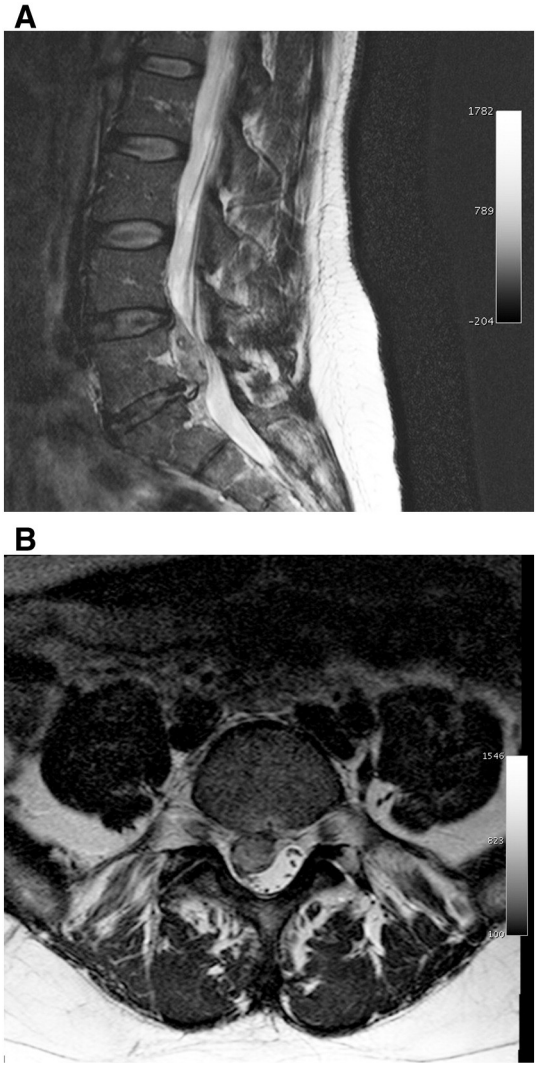

Fig 1. *A and B, T2-weighted sagittal and axial MRI slices showing one of the patients included in this study who presented with a large right posterior disc prolapse and effacement of the thecal sack.*

Table 1. *Patient Demographic Information and Baseline Variables*

Sex	
Male	110 (74.3%)
Female	38 (25.7%)
Mean age (y ± SD)	43.18 (10.29)
Duration category	
Acute (0-4 wks)	79 (53.4%)
Subacute (4-12 wks)	31 (20.9%)
Chronic (>12 wks)	37 (25.0%)
Marital status	
Single	(26.4%)
Married	(60.8%)
Divorced	(8.1%)
Separated	(1.4%)
Unknown	(3.4%)
Working status	
Paid employed	115 (77.7%)
Unemployed	3 (2%)
Medical leave	18 (12.2%)
Student	4 (2.7%)
Housewife	3 (2%)
Retired	3 (2%)
Pain medication	
Yes	57 (38.5%)
No	89 (60.1%)
Unknown	2 (1.4%)
No. of previous episodes	
None	72 (48.6%)
1-3	46 (31%)
4 or more	30 (20%)
Smoker	
Yes	32 (21.6%)
No	115 (77.7%)
General health	
Good	134 (90.5%)
Average	14 (9.5%)
Poor	0

Demographic variables were dichotomized with the exception of duration of complaint and number of previous episodes (Table 1). For purposes of the statistical analysis, working status was categorized as "paid employment," yes or no, and marital status was categorized as "married," yes or no.

All patients underwent a neurologic assessment consisting of checking deep tendon reflexes (L4, L5, and S1), dermatomal sensory testing, and motor function testing of the lower limb. A baseline orthopedic examination was also performed with special interest in nerve tension signs such as straight leg raising, Bowstring, Braggards, and a Valsalva maneuver. This was repeated at every follow-up visit.

Spinal Manipulation Procedure

The specific lumbar spinal manipulation was dependent upon whether the disc herniation was intraforaminal or paramedian as seen on the magnetic resonance images. All SMT procedures were high-velocity, low-amplitude side posture thrusts as described below (Fig 2).

Intraforaminal Disc Herniation: Modified Push Adjustment With a Kick. The patient lies on the affected side with the top leg bent similar to a push position. The DC contacts over the mammillary process on the downside of the superior vertebra of the involved motion segment. By using his index or middle finger, the DC applies pressure taking out joint and tissue slack and uses his knee to stabilize the patient's spine with downward pressure. Rotation is minimized. The thrust is delivered by the contact hand and body drop. This thrust is aided by a kicking maneuver of the DC's knee over the patient's flexed leg. The force is directed at the mammillary process of the superior vertebra of the involved motion segment in a posterior to anterior direction.

Paramedian Disc Herniation: Pull Adjustment With a Kick. The patient lies on the nonaffected side with the top leg bent. The DC hooks the spinous process of the inferior vertebra of the involved motion segment and applies traction to take out tissue and joint slack. This part of adjustment is assisted by downward pressure applied through the DC's knee to

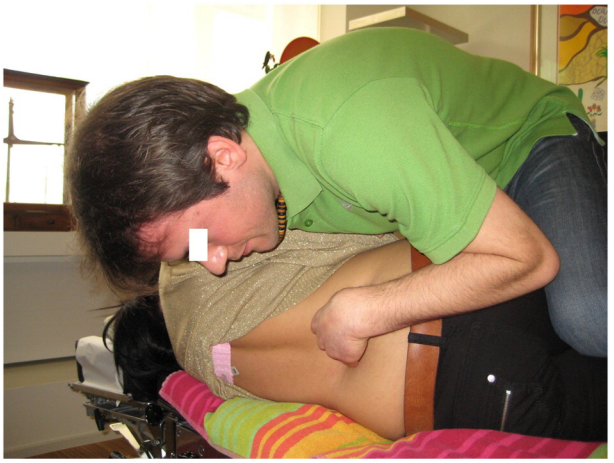

Fig 2. *Set-up for the high-velocity, low-amplitude spinal manipulative procedure to the level of disc herniation.*[15] *Symptomatic MRI-confirmed lumbar disk herniation patients: a comparative effectiveness prospective observational study of 2 age- and sex-matched cohorts treated with either high-velocity, low-amplitude spinal manipulative therapy or imaging-guided lumbar nerve root injections. (J Manipulative Physiol Ther 2013;36:218–25.)*

help stabilize the patient's spine. A body drop through the contact and a pull is performed by the DC's contact hand over the patient's spinous process.

Statistical Methods

Patients responding "better" or "much better" were categorized as "improved," and all other patients as "not improved." "Improved" was the primary outcome measure. "Slightly improved" was not considered clinically relevant improvement. The proportion (%) of patients "improved" or "worse" was calculated for each time point. In addition to descriptive statistics, the NRS scores at pretreatment and posttreatment were compared using the paired Student *t* test. The OPDQ baseline and posttreatment scores were compared using the Wilcoxon test for matched pairs. Comparisons were made at each time point with the baseline scores. Change scores for the NRS and Oswestry questionnaire at all data collection time points were also calculated. Subgroup analysis was carried out on chronicity of complaint comparing only acute (symptoms, <4 weeks) with chronic (symptoms, >12 weeks) patients. The NRS mean and change scores and the OPDQ change scores for acute vs chronic patients were compared at the various time points using the unpaired *t* test. Baseline demographic factors were compared between acute and chronic patients using the χ^2 test for categorical variables. In addition, logistic regression analysis was done comparing the various baseline factors with the primary outcome of "improvement" for all of the data collection time points in a univariate model for all patients. The mean number of chiropractic treatments during the first month (+ standard deviation [SD]) was also calculated. IBM SPSS version 20 (Chicago, IL) was used for all data analyses.

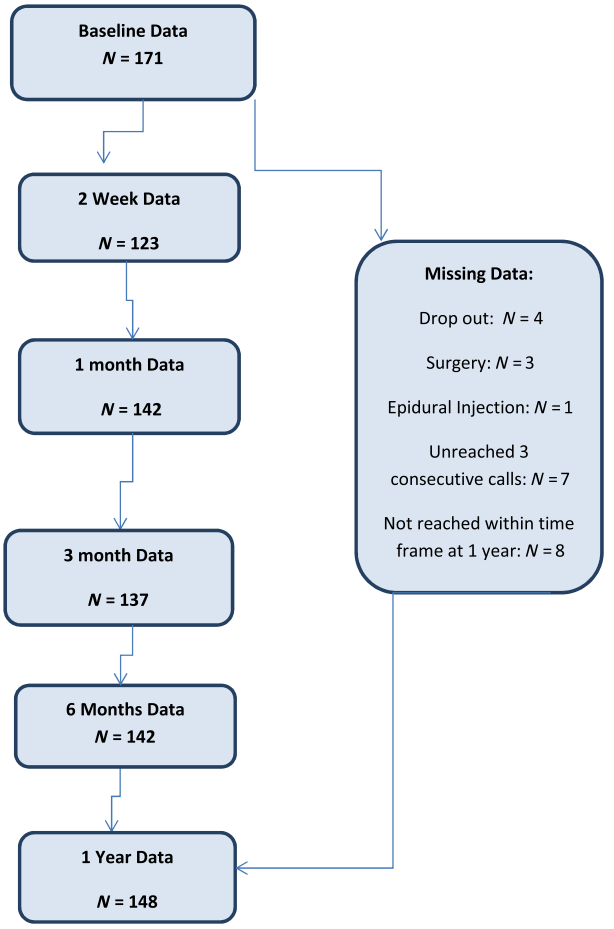

Fig 3. *Flowchart showing patient numbers at the various data collection time points. N, number of patients.*

Results

There were 148 patients with baseline and 1 year data (110 males). Figure 3 shows the number of patients for each data collection time point and the reasons for missing data between baseline and 1 year. The main reason for the smaller sample sizes at the various time points is due to missed telephone calls during the time window agreed for each call. However, unless 3 consecutive telephone calls were missed, the patient remained in the study. To obtain 148 patients with 1 year data, 171 patients with baseline data were enrolled.

Table 1 shows the proportion of patients within the various categories of the baseline variables. There was no significant age difference between the sexes nor was there a significant difference between the sexes for baseline NRS LBP or leg pain scores, duration of complaint, or baseline Oswestry scores. Of the 148 patients, 79 had symptoms of

Table 2. *Baseline and Outcome Data for All Patients at the Various Time Points*

	Baseline Data (148 pts)	2 Wks (123 pts)	1 Mo (142 pts)	3 Mos (137 pts)	6 Mos (142 pts)	1 Y (148 pts)
PGIC		69.9%, Much better or better 1.6%, Slightly worse	79.6%, Much better or better 1.4%, Slightly worse	90.5%, Much better or better 2.1%, Slightly worse or worse	88.7%, Much better or better 2.8%, Slightly worse	88.0%, Much better or better 2.8%, Worse
NRS back (mean)	5.67 (2.98)	2.94 [a] (2.28)	2.12 [a] (1.80)	1.67 [a] (1.71)	1.50 [a] (1.78)	1.42 [a] (1.73)
Change (SD)		2.73 (3.00)	3.59 (2.83)	4.07 (2.98)	4.28 (3.14)	4.35 (3.28)
NRS leg (mean [SD])	5.68 (3.12)	3.00 [a] (2.50)	2.08 [a] (2.16)	0.91 [a] (1.48)	0.94 [a] (1.58)	0.91 [a] (1.67)
Change (SD)		2.68 (2.93)	3.20 (2.87)	4.50 (3.23)	4.51 (3.23)	4.87 (3.47)
Oswestry (mean [SD])	18.75 (10.24)	12.86 [a] (6.63)	10.13 [a] (6.73)	6.19 [a] (5.08)	5.25 [a] (5.54)	4.82 [a] (5.12)
Change (SD)		5.82 (8.87)	8.29 (9.26)	12.23 (10.76)	13.53 (11.69)	13.92 (11.83)

Abbreviations: *NRS*, numerical rating system; *PGIC*, patient's global impression of change; *PTS*, patients.
[a] $P < .0001$ compared with baseline score.

Table 3. *Comparison of Disc Herniation Patients With Symptoms 4 Weeks or Less With Those Having Symptoms 3 Months or Longer (Acute vs Chronic)*

	Baseline	2 Wks	1 Mo	3 Mos	6 Mos	1 Y
NRS back						
Acute	(n = 80)	(n = 66)	(n = 76)	(n = 74)	(n = 76)	(n = 80)
Mean (SD)	6.23 (2.90)	2.61 (2.19)	2.21 (1.91)	1.49 (1.56)	1.33 (1.69)	1.27 (1.73)
Change (SD)		3.54 [a] (2.91)	4.05 (2.87)	4.60 (2.90)	4.87 (2.99)	4.99 (3.43)
Chronic	(n = 37)	(n = 30)	(n = 34)	(n = 33)	(n = 35)	(n = 37)
Mean (SD)	5.78 (2.49)	3.68 [a] (2.23)	2.68 (1.90)	2.08 (1.84)	1.90 (2.15)	1.99 (1.86)
Change (SD)		2.05 [a] (2.88)	3.24 (2.47)	4.05 (2.99)	3.85 (3.15)	3.79 (2.67)
NRS leg						
Acute						
Mean	5.89 (3.26)	2.93 (2.46)	2.07 (2.30)	0.78 (1.33)	0.75 (1.49)	0.81 (1.62)
Change	4.56 [a] (3.08)	3.11 [a] (2.89)	3.76 [a] (3.08)	5.10 [a] (3.36)	5.04 (2.27)	5.14 [a] (3.49)
Chronic						
Mean		3.36 (2.70)	2.35 (2.07)	0.88 (1.19)	0.85 (1.36)	1.24 (2.01)
Change		1.39 [a] (2.48)	2.03 [a] (2.21)	3.67 [a] (2.78)	3.96 (3.07)	3.27 [a] (3.59)
Oswestry						
Acute						
Mean	21.25 (11.04)	12.50 (6.60)	9.93 (6.78)	5.55 (5.31)	4.69 (5.87)	4.51 (5.00)
Change	15.41 (7.03) [a]	8.24 [a] (9.86)	10.98 [a] (10.13)	14.93 [a] (11.65)	16.45 [a] (12.69)	16.74 [a] (12.78)
Chronic						
Mean		12.57 (5.16)	10.48 (5.81)	7.26 (4.60) [a]	6.34 (4.95) [a]	5.93 (5.79)
Change		3.51 [a] (5.62)	4.65 [a] (6.54)	8.42 [a] (5.62)	9.31 [a] (7.32)	9.48 [a] (7.99)
PGIC						
Acute		80.6%, Much better or better (1.5% worse)	84.6%, Much better or better (1.3% worse)	94.5%, Much better or better (1.4% worse)	90.9%, Much better or better (1.3% worse)	86.3%, Much better or better (3.8% worse)
Chronic		46.7%, Much better or better (3.3% sl. worse)	70.6%, Much better or better (0% worse)	81.8%, Much better or better (0% worse)	88.6%, Much better or better (2.9% slightly worse)	89.2%, Much better or better (2.7% worse)

Abbreviations: *NRS*, numerical rating system; *PGIC*, patient's global impression of change; *sl*, slightly.
All mean results are statistically significant compared with the baseline figures at $P < .0001$.
[a] $P < .05$ comparing the acute with the chronic patients.

less than 4 weeks and were labeled as "acute," whereas 37 had symptoms of 3 months or longer and were labeled as "chronic." Subacute patients (n = 31) were not included in the subgroup analysis. There was no significant age difference between the acute and chronic patients.

Table 2 shows the baseline data and outcomes data for all patients (acute, subacute, and chronic) at all data collection time points. At 2 weeks after the start of treatment, a large proportion of patients reported substantial "improvement," with the percentage reporting "improvement" increasing at 1 (79.6%) and 3 (90.5%) months. This then stabilized at the 6-month and 1-year data collection time points. There was statistically significant improvement ($P < .0001$) in NRS and OPDQ scores at each time point

Table 4. *Significant Predictors of "Improvement" From Logistic Regression Analysis at the Various Time Points*

Predictor Variable/Data Collection Time Point	Unadjusted OR (95% CI)	*P*
Duration category: 2 wks	0.73 (0.21-2.58)	.004
NRS leg: 2 wks	0.64 (0.50-0.83)	.001
Pre-OPDQ total: 3 mos	1.17 (1.01-1.36)	.033
Pre-OPDQ total: 6 mos	1.20 (1.06-1.36)	.006

Abbreviations: *CI*, confidence intervals; *NRS*, numeric rating system; *OPDQ*, Oswestry pain and disability questionnaire; *OR*, odds ratio.

compared with baseline scores. A very small percentage of patients reported that they were "worse," and 3 went to surgery, although they had all reported "improvement" on their PGIC scores at 1 month. One patient had an epidural injection, and 11 patients reported a recurrence of symptoms between the 6-month and 1-year data collection points. No cases of cauda equina syndrome or other adverse events were reported, and no patients were excluded based on the type of disc herniation visualized on their MRI scans. The mean number of SMT treatments up to the 1-month data collection period was 11.20 (SD, 3.61).

A comparison of outcomes for acute and chronic patients is shown in Table 3. The mean duration of complaint for the chronic patients was 450.97 (SD, 624.82) days. The proportion of patients reporting "improvement" continued to increase up to the 3-month time point for acute patients. This then stabilized or slightly reduced for acute patients. However, the chronic patients continued to report higher percentages of "improvement" at both 6 months (88.6%) and 1 year (89.2%). The pain and disability scores continued to decrease substantially for both groups up to 3 months after the first treatment and then basically stabilized at the 6-month and 1-year time points. These changes were faster and more dramatic for the acute patients. There were no significant differences between acute and chronic patients for any of the categorical demographic factors, including number of previous episodes.

Prognostic Variables. Direct logistic regression analysis of potential predictors at baseline for improvement at 2 weeks is shown in Table 4. The only factors linked with "improvement" at this first data collection time point were "duration of complaint category" and "NRS leg pain." Acute patients were 73% more likely to "improve" at 2 weeks. For every 1 point increase in leg pain at baseline, the odds of the patient improving decreased by a factor of .644.

There were no significant predictors at baseline for "improvement" at 1 month. At both 3 and 6 months, the only predictor of "improvement" was the baseline OPDQ score (Table 4). The higher the baseline OPDQ score, the more likely the patient was to "improve." For every 1 point increase in the baseline OPDQ score, the odds of the patient improving increased by a factor of 1.17 at 3 months and a factor of 1.20 at 6 months (Table 4). "Improved" patients had a baseline to 3-month OPDQ change score of 14.25 (SD, 11.72) compared with 3.33 (SD, 5.91) for patients not improved. Similarly, at 6 months, the OPDQ change score was 15.21 (SD, 11.11) for "improved" patients, and only 0.96 (SD, 8.21) for patients who were not improved. There were no significant baseline factors that were predictors of "improvement" at 1 year. With so few factors associated with "improvement," no further detailed analyses were performed.

Discussion

The purpose of this study was to document outcomes of patients with confirmed, symptomatic lumbar disc herniations and sciatica who were specifically treated with side posture high-velocity, low-amplitude, spinal manipulation to the level of the disc herniation. It is important to emphasize that all patients in this study had clear abnormal physical examination findings of radiculopathy, as described in the methods section, corresponding to their MRI abnormalities. Although previous studies have identified the presence of "leg pain" in addition to LBP as a negative prognostic factor for improvement with chiropractic treatment compared with patients with LBP only, a recent, large, prospective outcome study found that the presence of radiculopathy was not a negative predictor of improvement in LBP patients being treated with chiropractic therapy.[14,16,17]

The proportion of patients reporting clinically relevant improvement in this current study is surprisingly good, with nearly 70% of patients improved as early as 2 weeks after the start of treatment. By 3 months, this figure was up to 90.5% and then stabilized at 6 months and 1 year. One may argue that most of the treatment effect is explained by natural history. This might contribute significantly to the outcomes in the acute patient subgroup. However, for the chronic patients, any positive effect due to natural history should already have occurred. The natural history of sciatica in acute disc herniation patients is normally quite favorable, with 36% reporting major improvement after 2 weeks and up to 73% having resolution of their leg pain by 12 weeks.[18,19] The acute patients in this current study reported more substantial improvement and improved more quickly than the chronic patients, with more than 80% reporting clinically relevant improvement as early as 2 weeks and 94.5% improved at 3 months. These results are better than the natural history figures cited above.[18,19]

Even the chronic patients in this study, with the mean duration of their symptoms being over 450 days, reported significant improvement, although this takes slightly longer. More than 81% reported being "improved" at 3 months, and the proportion reporting "improvement" at 1 year (89.2%) was slightly higher than the percentage for acute patients. This was due to the higher number of acute

patients reporting a recurrence. In addition, the LBP NRS levels for chronic patients significantly dropped from a baseline mean of 5.78 to 2.08 at 3 months, and their leg pain decreased from 4.56 at baseline to 0.88 at 3 months. This cannot be explained by natural history as a previous study found that duration of symptoms more than 30 days was predictive of an unfavorable outcome, at 3 months after start of treatment.[19] The results from this current study are better than the 60% of chronic patients who benefited from side posture SMT at 12 weeks reported by McMorland et al,[10] better than the 50% of chronic patients reporting improvement in an article by Cassidy et al,[20] and better than the 59% of subacute and chronic patients reporting success after manipulation by Petersen et al[21] The results in this current study are encouraging when considering that it is chronic LBP patients who are a large economic burden with greater use of prescription medications and increased use of other health care resources.[22]

Unfortunately, recurrences cannot be avoided completely because the genesis of this condition is multifactorial. In the acute patient group, 11 patients reported a recurrence between the 6-month and 1-year data collection periods. No chronic patients reported a recurrence however. A small proportion of patients reported being "worse" after the start of treatment with 2.1% of 137 patients reporting that they were "slightly worse" or "worse" at 3 months and 2.8% of patients reporting that they were "slightly worse" at 1 year. No patient reported being "much worse." One topic that needs to be addressed is the often stated fear that SMT applied to patients with disc herniation often causes cauda equina syndrome.[6,23] No cases of cauda equina syndrome or other serious adverse events were reported in this current study. Three patients did choose to have surgery, however, although they had reported significant improvement at 1 month, and one patient elected to have an epidural injection of anesthetic and corticosteroid.

It was not surprising that there were few predictors of "improvement" identified from the baseline variables as previous studies have also struggled to find reliable predictors of improvement in LBP patients.[14,17] However, chronicity of complaint was a predictor for early improvement with acute patients having better outcomes at 2 weeks, most likely due to the natural history of this condition as previously mentioned. Although patients reporting higher levels of leg pain at baseline were less likely to improve at 2 weeks, this factor was no longer predictive at all follow-up time points. This information is useful for patients as well as the clinicians treating these patients. Surprisingly, the baseline OPDQ total score was not prognostic for improvement until the 3- and 6-month time points with higher baseline scores associated with an increased likelihood of improvement. Certainly, acute patients have higher baseline disability and pain scores compared with chronic patients and improve more quickly than chronic patients as noted above, so this may be one reason for this result. However, it does not explain why the OPDQ was not prognostic until later in the course of the condition. Not until it was placed into the logistic regression model, controlling for other factors, did it became predictive.

The major criticism of this study may be that it is not an RCT using a control group which had no treatment. Although RCTs are traditionally the criterion standard for determining effective treatments, there has been recent criticism of this research methodology pointing out that their strict inclusion and exclusion criteria may result in study populations that do not represent real-world conditions, and thus, the results may be of limited use to clinicians and not generalizable to the intended population.[24,25] However, pragmatic RCTs, which use a broader selection criteria and observational studies, as in this prospective outcomes study, can include large and diverse populations and are more likely to reflect the patients routinely seen in clinical practice. The inclusion/exclusion criteria (and therefore the participants) in this study are no different from those that would be recruited in an RCT to address the same study hypotheses.

Treatment in this current study was standardized to 1 of the 2 possible manipulative procedures, based on the location of the disc herniation as seen on the MRI scans. Furthermore, patients whose herniations had penetrated through the peripheral annular fibers, the posterior longitudinal ligament or were sequestered were not excluded from being treated with SMT as was done in the RCT by Santilli et al[7] However, no studies have been conducted to determine whether there is a difference in outcome based on the choice of the specific manipulative procedure or the type and location of disc herniation.

The hypothetical rationale behind selecting one SMT procedure over the other based on the MRI and clinical findings is based on the mechanics of each lesion. First, by combined flexion and lateral bending, the side on which the patient lies is determined because it is not desired to treat into the pain. For foraminal hernias, it is preferred to gap the foramen on the affected side thereby inducing more normal movement patterns, decreasing the pressure on the disc and nerve, releasing adhesions, allowing efflux of chemical irritants, and stimulating the receptors in the surrounding tissues. For paramedian hernias, it is the unaffected side but with the same therapeutic goals in mind. The opening of the foramen seems to be of lesser importance for these disc herniations. Of course, this is all hypothetical and needs to be investigated further.

Limitations

As this is a cohort outcomes study rather than an RCT means that the outcomes cannot be directly attributed to the SMT treatment. Additional research comparing SMT with other treatments, for example, therapeutic nerve root

infiltrations needs to be done. All patients were examined and treated in a single chiropractic practice in Zürich, Switzerland using a standardized treatment approach. Therefore, the results obtained may not be representative of other chiropractic practices. The relatively small sample size for the subgroup of disc herniation patients whose symptoms were "chronic" (37 patients) is another limitation.

Conclusions

A large percentage of acute and importantly chronic lumbar disc herniation patients treated with high-velocity, low-amplitude side posture SMT reported clinically relevant "improvement" with no serious adverse events.

Practical Applications

- A large proportion of patients with symptomatic, MRI-confirmed, lumbar disc herniations reported statistically significant and clinically relevant improvement in all outcome measures as early as 2 weeks after start of treatment.
- The percentage of patients reporting clinically relevant improvement continued to increase up to 3 months after the first treatment and then stabilized up to the 1-year time point.
- More than 80% of chronic lumbar disc herniation patients who had symptoms over 3 months reported clinically relevant "improvement" at 3 and 6 months and 1 year after receiving chiropractic SMT.
- There were no adverse events reported due to SMT applied to the patients with MRI-confirmed, symptomatic lumbar disc herniations.

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Contributorship Information

Concept development (provided idea for the research): SL, CS, BA.

Design (planned the methods to generate the results): CP, KH, SL, CS, BA.

Supervision (provided oversight, responsible for organization and implementation, and writing of the manuscript): CP, KH.

Data collection/processing (responsible for experiments, patient management, organization, or reporting data): SL, CS, BA, CP.

Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): CP.

Literature search (performed the literature search): CP, SL.

Writing (responsible for writing a substantive part of the manuscript): CP, SL, CS.

Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): SL, KH, CP, CS, BA.

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