Manipulation or Microdiskectomy for Sciatica? A Prospective Randomized Clinical Study

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Abstract

Objective: The purpose of this study was to compare the clinical efficacy of spinal manipulation against microdiskectomy in patients with sciatica secondary to lumbar disk herniation (LDH).

Methods: One hundred twenty patients presenting through elective referral by primary care physicians to neurosurgical spine surgeons were consecutively screened for symptoms of unilateral lumbar radiculopathy secondary to LDH at L3-4, L4-5, or L5-S1. Forty consecutive consenting patients who met inclusion criteria (patients must have failed at least 3 months of nonoperative management including treatment with analgesics, lifestyle modification, physiotherapy, massage therapy, and/or acupuncture) were randomized to either surgical microdiskectomy or standardized chiropractic spinal manipulation. Crossover to the alternate treatment was allowed after 3 months.

Results: Significant improvement in both treatment groups compared to baseline scores over time was observed in all outcome measures. After 1 year, follow-up intent-to-treat analysis did not reveal a difference in outcome based on the original treatment received. However, 3 patients crossed over from surgery to spinal manipulation and failed to gain further improvement. Eight patients crossed from spinal manipulation to surgery and improved to the same degree as their primary surgical counterparts.

Conclusions: Sixty percent of patients with sciatica who had failed other medical management benefited from spinal manipulation to the same degree as if they underwent surgical intervention. Of 40% left unsatisfied, subsequent surgical intervention confers excellent outcome. Patients with symptomatic LDH failing medical management should consider spinal manipulation followed by surgery if warranted. (J Manipulative Physiol Ther 2010;33:576-584)

Key Indexing Terms: *Manipulation, Spinal; Disk, Herniated; Sciatica; Diskectomy, Percutaneous; Chiropractic*

Introduction

The prevalence of sciatica caused by lumbar disk herniation (LDH) has been estimated to have a lifetime incidence of between 2% and 40%.[1] In a large population sample, a diagnosis of lumbar disk herniation with sciatica was present in 5.1% of men and 3.7% of women older than 30 years.[2] Physical workload factors appear related to the onset of sciatica, whereas psychosocial factors, heavy labor, and obesity seem related to adverse outcome.[3,4]

Initial intervention for the treatment of patients with sciatica is usually nonoperative given the spontaneous recovery seen in most patients.[5] Nonoperative management has been demonstrated to be beneficial in more than 50% of patients with sciatica[4,6]; however, there are no established guidelines for appropriate medical management strategies. A variety of regimens have been recommended, but recent guidelines have failed to show that any nonoperative treatment approaches have been subjected to high-quality clinical trials.[7,8] Those patients failing "conservative care" are frequently recommended for surgical assessment. Elective lumbar diskectomy is one of the most commonly performed surgical procedures in the United States, now exceeding 250,000 cases per year.[9-13] Studies comparing surgical management of LDH to different forms of conservative treatment tend to favor surgery with respect to short-term outcome.[10-14] However, there are less striking differences observed in long-term follow-up of 1 year or more.[15-17] Improvement in the patient's predominant symptom, return to work, and persisting disability tend to be similar regardless of treatment received.

The role of spinal manipulation in nonoperative care of sciatica is unestablished. Most studies define conventional nonoperative care as exercise, analgesics, and/or epidural

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injections without reference to active spinal manipulation. However, spinal manipulation for sciatica has been found to be related to positive patient and cost outcomes when compared to medical management.[18-23] Cassidy and colleagues[23] reported a clinical improvement in 50% of their study sample in a case series of patients with chronic sciatica treated with manipulation. In the only published controlled trial of manipulation for LDH, Nwuga[24] showed that manipulation was more effective than heat, exercise, and postural education.

Although surgical decompression and spinal manipulation are popular choices among patients with sciatica due to LDH, there are no controlled studies comparing patient outcome between these 2 treatments. The purpose of this pilot study was to compare quality of life and condition specific disability between surgical treatment vs spinal manipulation in patients with sciatica secondary to LDH using a randomized clinical design. The study further aimed to assess the feasibility of the recruitment and randomization process, choice of outcome measures, and effect size to inform a future large-scale clinical trial.

Methods

Study Design

Three participating spinal neurosurgeons (SC, SJD, RJH) screened patients between December 2000 and May 2004 for symptoms of unilateral lumbar radiculopathy secondary to LDH at L3-4, L4-5, or L5-S1. Detailed surgical histories and physical examinations were performed. Patients were considered eligible for inclusion if they presented with leg-dominant symptoms with objective signs of nerve root tethering ± neurologic deficit correlated with evidence of appropriate root compression on magnetic resonance imaging. These patients must also have failed at least 3 months of nonoperative management including treatment with analgesics, lifestyle modification, physiotherapy, massage therapy, and/or acupuncture. Patients receiving concurrent or previous spinal manipulation treatment were excluded. Figure 1 illustrates the detailed exclusion criteria.

An independent third party (nurse clinician, not blinded as to the randomization of patients) explained the purpose, risks, and potential benefits of the study to eligible patients during the intake assessment, and interested patients were asked to give written consent. For consenting patients, demographic details, neurologic examinations, and baseline data for all outcome measures were obtained. Subjects were then assigned to either the surgical arm or the spinal manipulation arm. The randomization process was carried out by a blinded, independent third party based on a computer-generated sequence of random numbers in balanced blocks of 10. Recruitment was stopped once 20 patients were randomized into each group.

- Radicular symptoms < 3 months duration
- Major neurological deficits such as:
  → Cauda equina syndrome
  → Rapidly progressing neurological symptoms (e.g. foot drop)
- Substance abuse
- Hospitalization for intravenous or intramuscular narcotics
- Systemic or visceral disease (e.g. auto-immune diseases, major system failure)
- Hemorrhagic disorders, anticoagulation therapy
- Previous surgery at symptomatic level
- Concurrent treatment involving spinal manipulation at time of enrollment
- Prolonged use of systemic corticosteroids
- Osteopenia/Osteoporosis
- Spondylolisthesis grade III or IV
- Unable to read or speak English
- Age < 18
- Pregnancy
- Dementia or other cognitive impairment
- Unavailable for follow-up (geographic barriers)

Fig 1. *Exclusion criteria for the study.*

Patients to be treated by microdiskectomy were booked for surgery in the next available operative slot, typically 6 to 8 weeks from the time of assessment. Patients to receive spinal manipulation commenced their therapy within 2 to 3 weeks of the initial surgical consultation.

Nonresponders to primary treatment were defined by no change over baseline scores in the outcome measures within 12 weeks of commencement of spinal manipulation or surgical intervention. Patients who felt they were not responding to the primary treatment intervention at the 12-week point were allowed to cross over immediately to the opposite treatment group and were observed for an additional 52 weeks. Response to treatment was measured with a general quality of life assessment tool (Short Form [SF-36]) as well as disease-specific questionnaires (McGill Pain Questionnaire, Aberdeen Back Pain Scale, and Roland-Morris Disability Index). The research assistant contacted participants in both treatment arms by phone at 3, 6, 12, 24, and 52 weeks after treatment was initiated to complete the follow-up surveys.

This study was approved by the Conjoint Research Ethics Board, University of Calgary, and Calgary Health Region. This trial was registered with the US National Institutes of Health, registration number: NCT00415220.

Description of Spinal Manipulative Therapy

All spinal manipulative therapies were provided by a single doctor of chiropractic (GM). The standardized intake history and physical examination was repeated at the initial chiropractic visit to ensure there were no contraindications to treatment. Spinal manipulative therapy consisted of side-posture, high-velocity, low-amplitude, short lever technique, which is commonly used for this type of condition.[18,19,22] The decision to administer manual spinal manipulation on each visit was based on that patient's ability

to tolerate the position they were to assume to receive the treatment as well as the discretion of the treating clinician. Generally speaking, peripheralization or significant exacerbation of the patient's leg symptoms when attempting to position them to receive the treatment were considered a contraindication to receive the treatment on that particular visit. Two of the 20 patients in the spinal manipulation group were not able to tolerate the treatment due to pain and subsequently crossed over to surgery. Cryotherapy or thermotherapy (ice or heat) were used on an "as-needed" basis during each treatment session to enhance patient ability to tolerate treatment. Best practices recommends graduating patients from passive care to active and finally, self-directed care so all patients undergoing spinal manipulative treatment were provided with an information/education package and were introduced to rehabilitative exercises. The educational material covered basic spinal hygiene ("do's and don'ts") and self-care (home) recommendations. The patients also participated in a supervised rehabilitative (core stability) exercise regimen.[25,26] Emphasis during rehabilitation sessions was on ensuring appropriate knowledge of the exercises and safeguarding performance with proper technique, oriented toward self-administration.[27,28] Treatments typically required 2 to 3 visits per week for the first 4 weeks reducing to 1 to 2 visits per week for the next 3 to 4 weeks. At the 8-week mark, follow-up visits were scheduled based on the patient's symptoms. An initial treatment holiday was given for 2 weeks. Upon follow-up, if the patient's symptoms had not deteriorated, no treatment was given on the follow-up visit and the next treatment holiday time was doubled with another follow-up visit scheduled for 1 month later. If, at the time of follow-up, the patient's symptoms had deteriorated, treatment was administered, and another treatment holiday of the same length of time was scheduled. This process of treatment withdrawal and follow-up visits was continued until the patient's symptoms were deemed stable (ie, no deterioration or flare up) with a 2-month treatment holiday.

Description of Surgical Care

Surgical microdiskectomies were performed with patients in a prone position supported by bolsters through a standard midline lumbar incision. All procedures were undertaken using microsurgical techniques with the aid of an operating microscope. Laminotomies were created as required at the level of the LDH. Both sequestrectomy and intraannular diskectomy were performed to ensure adequate nerve root decompression. All wounds were closed primarily without drainage. Postoperatively, patients were managed in hospital for 1 to 2 days before release from hospital. On discharge, they were given a prescription for oral analgesia for 10 days to 2 weeks and advised to avoid heavy lifting (>5 kg), bending or twisting until their follow-up appointment.

A single follow-up examination was performed by the attending neurosurgeon 6 to 8 weeks after surgery. After documentation of satisfactory improvement, patients were enrolled in the same supervised rehabilitation program as the spinal manipulation patients and given the same home-based self-care information/educational package at that time.

Statistical Analysis

Summary statistics were generated for demographic and outcome data and plotted on ordinal axes to look for apparent differences between groups, expressed as mean ± standard error where appropriate. Primary data comparisons to support or not support the null hypothesis of this study (ie, no difference between surgical and chiropractic arms) were focused on contrasting the primary outcome measures between the 2 treatment arms. Changes in primary outcome measure were assessed using a repeated measures analysis of variance, mixed model technique. An intention-to treat analysis was conducted with the primary groups (surgery, chiropractic) for the 12-week period. There was no missing data for that period. A secondary analysis was conducted with 4 groups over a 52-week period: (1) successful surgery patients, (2) successful spinal manipulation patients, (3) surgery crossover, and (4) spinal manipulation crossover. For the crossover patients, the outcomes measured at week 12 were used as a new baseline, and they were followed up over an additional 52 weeks. These results were examined separately from the primary intent to treat analysis. In the spinal manipulation arm, there were no missing data points up to and including the 24-week point; however, there were 2 missing data points at the 52-week mark. In the surgical arm, there were no missing data points up to and including the 24-week mark; however, there were 3 missing data points at the 52-week mark. In the crossover from manipulation to surgery, there were no missing data points up to the 24-week mark. There was one missing data point at the 52-week mark. In the crossover from surgery to manipulation, there were no missing data points up to the 24-week mark. There were 2 missing data points at the 52-week mark. All data were included in the analysis. To manage missing data over the 52-week follow-up period, a first-order autoregressive covariance structure was chosen that assumes correlation between adjacent time points is the same and that correlation decreases by the power of the number of time intervals between measures.[29,30]

Data were analyzed with SPSS version 11.5 for Windows (SPSS, Inc, Chicago, IL). Two-tailed significance testing was performed in all cases, and significance was defined as $P \leq .05$.

We conducted sample size calculations using the Aberdeen Back Pain Scale as key outcome measure because of its applicability to patients with both back and leg pain.[31] Sample size was calculated using preidentified across-

patient standard deviations of 15.9 and within-patient changes of 6.7 as approximations based on observations in a validation study with 568 patients.[31] Taking the mean difference of 6 to be relevant, with a standard deviation of 12, the study would require 63 patients in each arm to provide 80% power in a 2-sided test to obtain significance at the 5% level. Allowing for a 10% dropout rate, a trial would require 70 patients into each arm.

Results

The 3 neurosurgeons screened a total of 120 consecutive patients. Sixty patients met the inclusion criteria and were asked to consider study participation. After the verbal informed consent procedure, 20 patients refused participation. They stated that they had never been offered spinal manipulation as a treatment option and elected to enroll in the spinal manipulation to potentially avoid surgical treatment. Of the 40 consenting patients, 20 were randomized to receive spinal manipulative treatment for their sciatica and 20 were randomized to microdiskectomy. Demographics of the participants are described in Table 1. There were no systematic differences observed between primary treatment groups nor were there any disparities in pretreatment pain-specific and quality of life indicators ($P > .05$, 1-way analysis of variance).

Table 1. *Patient demographics*

	Chiropractic	Surgery
Male	11	13
Female	9	7
Mean age (years ± SE)		
Male	36.4	42.85
Female	48.33	40.1
Duration of complaint		
3-6 mo	6	3
6-12 mo	6	5
>12 mo	8	12
Level of LDH		
L3-4	0	1
L4-5	11	8
L5-S1	9	11
Medication at intake		
None	3	3
Over the counter only	2	1
Prescription nonnarcotics	12	13
Narcotics	3	3
Smokers	6	8
Employment mode		
N/A	0	3
Employee	17	13
Self-employed	3	4
Work status		
Employed	8	8
Medical leave	11	9
Unemployed	1	0
Work duties		
Sedentary	14	11
Manual labor	6	6
Insurance status		
Workers' compensation	1	1
3rd party disability insurance	0	0
Private/self-insured	19	19

Clinical Outcomes

Patients in the spinal manipulation group received an average of 21 treatment sessions and an additional 6 supervised rehabilitation sessions over the 52-week duration of the study. Patients in the surgical arm underwent a single microdiskectomy procedure followed by 6 supervised rehabilitation sessions over the 52-week duration of the study. No new neurologic deficits arose from either of the treatment protocols nor were there any significant adverse events reported. The most common minor adverse event reported in both groups was increased postprocedure soreness. This was self-limiting, requiring no additional intervention. No revisional surgeries were required. No additional treatment, such as increased medication or nerve root block procedures were used in the spinal manipulation group. At the end of 12 weeks (intention to treat period), 12 (60%) of 20 patients receiving spinal manipulative care demonstrated clear improvement in outcomes and continued to complete the 52-week follow-up period without crossover into the surgical arm. Eight patients failed to respond favorably to spinal manipulation treatment at the 12-week point of the treatment intervention and subsequently underwent surgery. Five of these patients crossed over immediately after completion of the 12-week spinal manipulation treatment. The remaining 3 patients crossed over within 3 months after completion of the spinal manipulation treatment. Of the 20 patients, 17 (85%) entering the surgical arm demonstrated clear improvements in outcomes and continued to complete the 52-week follow-up. Three patients failed to respond favorably to surgical management and subsequently enrolled in spinal manipulative care. Although they were allowed to cross over at the 12-week point after their surgery, these 3 patients crossed over to the spinal manipulation treatment 6 to 8 months after their surgical date. Representative magnetic resonance sequences from each group of patients can be found in Figure 2. The difference in crossover rates between the primary spinal manipulation group and the primary surgical group was notable in that more patients receiving spinal manipulation treatment felt compelled to pursue additional surgical intervention (40%) as opposed to surgical patients going on to spinal manipulative therapy (15%). Although this was not statistically significant ($\chi^2 = 3.135$; $df = 1$, $0.10 > P > .05$), a sample size of 49 patients per group would be required to accept the null hypothesis with a type II error rate of 0.2.

Intention to treat analysis for the primary surgical and primary spinal manipulation groups revealed improvement in all outcome parameters including the McGill PRI(R), Aberdeen, Roland Morris, and SF-36 total scores over the

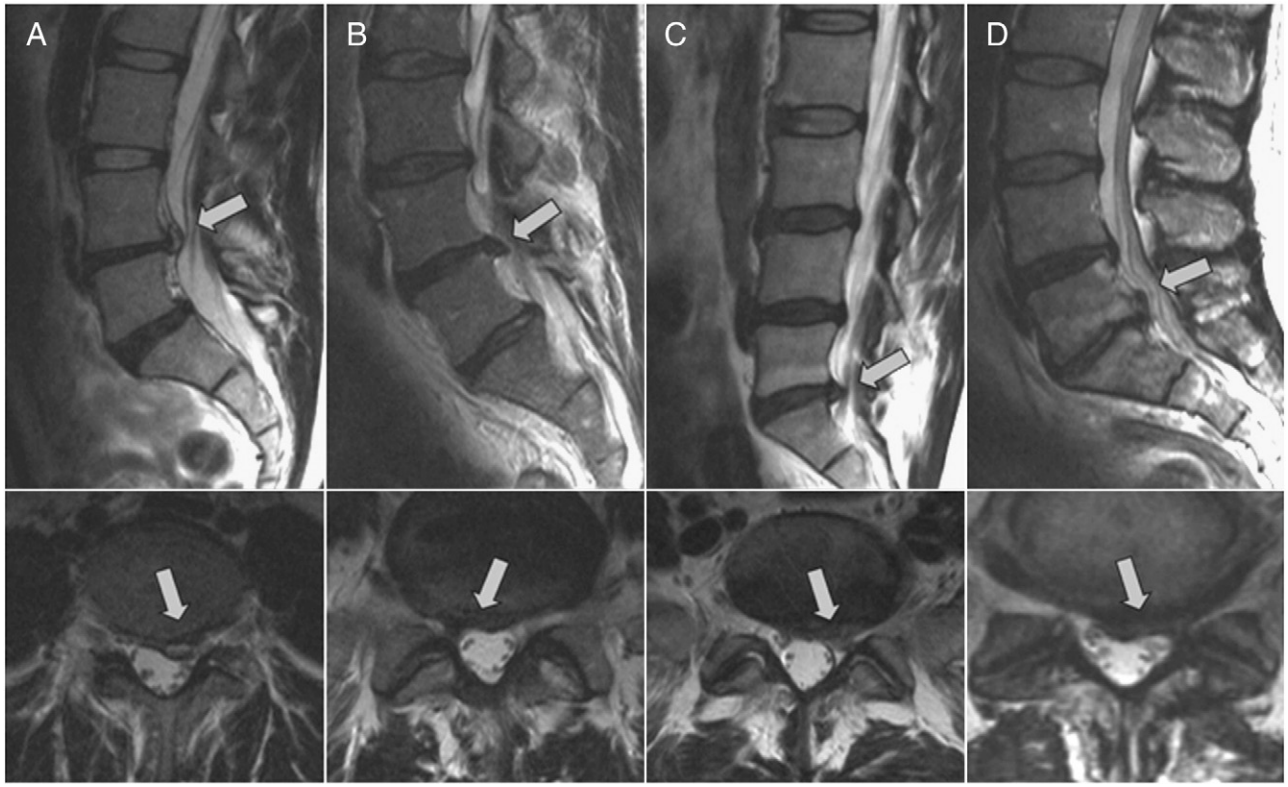

Fig 2. *Sagittal and axial T2-weighted magnetic resonance images from patients who are representative of each treatment group demonstrating lumbar disk herniation associated with radicular symptoms. (A) Primary spinal manipulation group. (B) Primary surgical group. (C) Spinal manipulation failure crossing over to surgery. (D) Surgical failure crossing over to spinal manipulation treatment.*

12-week period (Table 2). Overall magnitude of improvement and rate of recovery in each of these scales was similar for both treatment groups. Intent-to-treat repeated measures analysis of variance failed to reveal any significant differences in McGill pain, Roland Morris disability index, or SF-36 total scores based on type of treatment received (Table 2).

Similarity between the 2 primary treatment groups was also observed in each of the 8 SF-36 subscales (Table 2). With one exception, each of the subscales improved with time and most did so in a statistically significant manner. Only in the general health category there was no significant treatment effect ($P = .399$), not unexpectedly as reflected by the questions in this component.

Secondary analysis with the 4 treatment groups: successful surgery, successful spinal manipulation, surgery crossover, and spinal manipulation crossover revealed the following results over the 52-week period (Figs 3-6): clinical improvement for the 8 patients who crossed over from spinal manipulative therapy to surgery was very similar in tempo and degree to the improvement seen in the primary intent-to-treat analyses. However, patients unsatisfied with surgical outcome crossing over to spinal manipulation treatment (n = 3) performed worse in all clinical outcome measures compared to the other 3 groups throughout the duration of follow-up (Figs 3-6). McGill Pain Scores, Aberdeen Back Pain Scale, Roland Morris Disability Index, and SF-36 Total and Subscales consistently reflected the same pattern: equivalent improvement among primary spinal manipulation, primary surgical, and crossover to surgery groups in contrast to chronic poor performance of the surgical failures. In almost all comparisons, these differences were statistically significant despite the small number of patients making up this group. Post hoc analyses confirmed the poor outcomes to be most pronounced from weeks 12 through 52 after initiation of spinal manipulative care.

Discussion

Most health care providers would agree that first-line treatment of radiculopathy secondary to LDH should consist of nonoperative care in the form of lifestyle modification and analgesia for pain control. Additional options include careful use of antiinflammatory medications, physiotherapy, massage therapy, local injections, acupuncture, and chiropractic treatment. However, it is when these modalities fail over a period of 6 to 12 weeks

Table 2. *Repeated measures analysis of variance for clinical outcome tools (intention-to-treat over 12-week period)*

Outcome measure	Treatment	Mean (SD) Baseline	3 wk	6 wk	12 wk	*P* (time)	*P* (treatment)	*P* (time * treatment)
McGill Pain								
PRI(R)	Surgery	32.5 (12.9)	19.8 (13.8)	18.4 (16.3)	13.0 (16.3)	.013	.103	.754
	Chiropractic	28.7 (17.4)	24.9 (15.4)	21.7 (13.7)	19.4 (14.3)			
Number of words chosen	Surgery	13.2 (5.0)	10.1 (5.8)	8.8 (6.4)	5.7 (5.1)	.029	.080	.574
	Chiropractic	12.0 (5.5)	11.8 (5.9)	10.8 (6.1)	9.6 (6.3)			
Present pain intensity	Surgery	2.7 (1.0)	1.9 (1.2)	1.6 (1.3)	1.5 (1.3)	.010	.094	.736
	Chiropractic	2.4 (0.8)	2.2 (0.8)	1.8 (0.7)	1.6 (0.9)			
Aberdeen								
	Surgery	45.1 (17.8)	38.0 (23.7)	32.3 (22.2)	25.8 (23.7)	.017	.034	.836
	Chiropractic	44.7 (12.9)	37.5 (18.6)	34.8 (19.1)	35.6 (18.9)			
Roland Morris								
	Surgery	10.1 (5.7)	12.2 (6.7)	9.4 (6.4)	7.2 (6.9)	.033	.199	.760
	Chiropractic	12.0 (5.4)	10.5 (5.6)	9.5 (6.0)	9.0 (6.2)			
SF-36								
Total score	Surgery	379.5 (149.8)	380.4 (137.2)	429.1 (157.3)	500.3 (179.7)	.016	.382	.683
	Chiropractic	381.3 (161.9)	428.5 (139.7)	445.6 (142.8)	484.6 (148.9)			
Bodily pain	Surgery	27.3 (19.8)	31.5 (21.8)	41.4 (24.1)	57.4 (22.3)	.031	.341	.367
	Chiropractic	28.5 (21.8)	40.6 (22.6)	45.8 (21.3)	47.1 (18.4)			
Role physical	Surgery	17.5 (32.5)	6.3 (17.9)	15.0 (33.8)	28.8 (37.4)	.126	.719	.038
	Chiropractic	18.8 (26.7)	23.8 (35.8)	26.3 (37.6)	32.5 (38.1)			
Role emotional	Surgery	60.8 (41.0)	9.7 (28.6)	63.3 (47.0)	65.0 (43.9)	.034	.715	.410
	Chiropractic	53.4 (50.0)	28.8 (39.1)	66.7 (45.7)	74.5 (36.4)			
Vitality	Surgery	40.1 (21.0)	41.2 (22.7)	48.7 (24.4)	65.0 (19.6)	.006	.040	.854
	Chiropractic	41.5 (23.1)	42.1 (16.4)	52.5 (16.7)	56.8 (17.7)			
Physical function	Surgery	42.7 (22.7)	41.0 (23.6)	51.3 (28.2)	65.8 (27.6)	.034	.720	.448
	Chiropractic	47.4 (24.8)	52.8 (25.8)	54.8 (24.4)	59.0 (25.4)			
Social function	Surgery	50.2 (29.0)	47.9 (30.0)	54.1 (30.9)	67.3 (34.7)	.138	.938	.596
	Chiropractic	52.9 (33.0)	58.1 (28.9)	62.7 (20.0)	73.6 (19.7)			
Mental health	Surgery	69.2 (13.0)	79.5 (14.3)	77.7 (16.8)	83.2 (10.6)	.001	.905	.990
	Chiropractic	69.0 (21.3)	76.6 (12.5)	78.6 (11.6)	82.8 (8.7)			
General health	Surgery	71.8 (19.5)	82.7 (15.4)	77.6 (16.9)	83.2 (13.0)	.399	.119	.867
	Chiropractic	75.2 (18.0)	75.8 (17.4)	72.6 (14.9)	77.8 (15.3)			

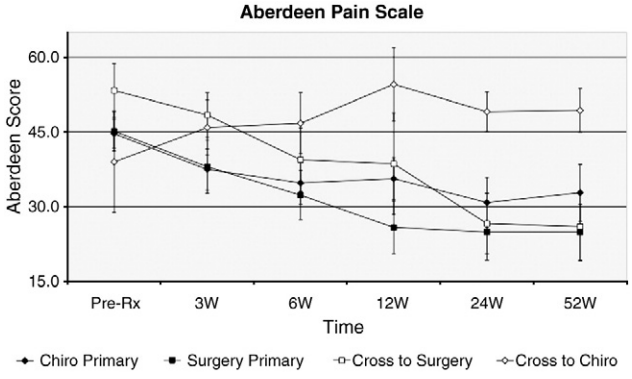

Fig 3. *Aberdeen Pain Scale primary clinical outcomes measured before and after treatment initiation through 1-year follow-up for the 4 groups.*

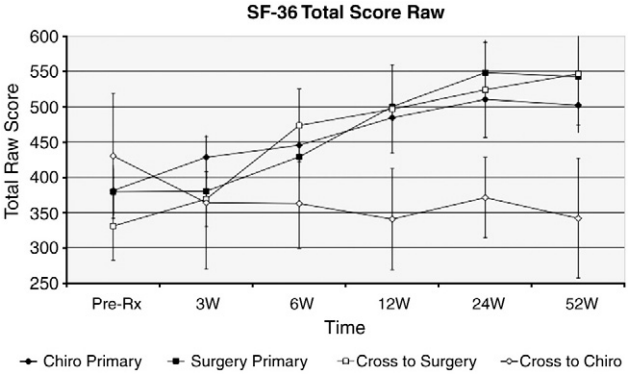

Fig 4. *SF-36 primary clinical outcomes measured before and after treatment initiation through 1-year follow-up for the 4 groups.*

that the more invasive and expensive option of surgery is often considered. Perhaps it is the attraction of immediate anatomical restoration and ensuing pain relief that sets surgical intervention apart from other treatment modalities, or perhaps it is recognition of the attendant and relatively unique risks associated with operative intervention. Whatever the reason, surgery is generally regarded as the final solution in what is in many cases a very long journey through failed medical management.

The purpose of this pilot study was to compare clinical outcomes among patients failing nonspecific conservative care (in which the common denominator was time elapsed from onset of symptoms) who were then subjected to a regulated spinal manipulation regimen or to a traditional

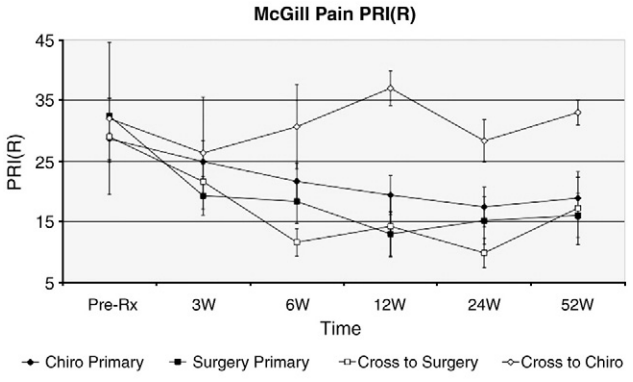

Fig 5. *McGill PRI(R) outcomes measured before and after treatment initiation through 1-year follow-up for the 4 groups.*

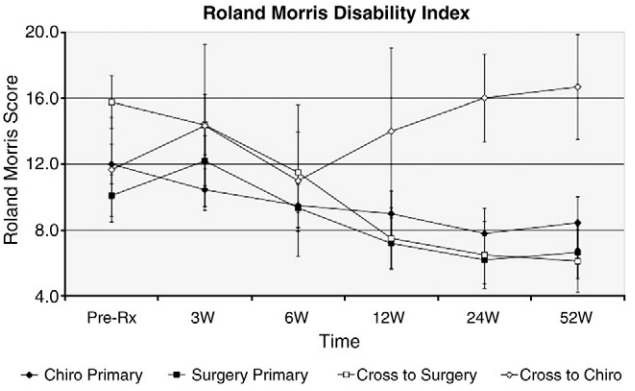

Fig 6. *Roland Morris Disability Index outcomes measured before and after treatment initiation through 1-year follow-up for the 4 groups.*

surgical microdiskectomy. To our knowledge, this is the first study to directly compare the efficacy of surgery against a standardized nonsurgical treatment.

It is well established that the failure rate of microdiskectomy in the relief of radiculopathy secondary to LDH is in the order of 10% to 20%.[32-34] Our observed surgical failure rate of 15% is in keeping with these previously published findings. Similarly, our observed spinal manipulation failure rate of 40% lies within the published range of 5% to 50%.[5,7,14,35,36] It is notable that our study is the first to report on manipulation treatment effects on a group of patients failing other medical management and with symptoms of more than 1 to 3 weeks in duration. Hence, it is not surprising for our patients to be perhaps more refractory to spinal manipulation therapy.

There is a large range of treatments that fall under the umbrella of "conservative" or "nonoperative" treatment. In this study's patient population, only 2 of the 120 screened had received spinal manipulation before presentation. Although guidelines have been established outlining appropriate care pathways for this patient population, our experience has been that standardized treatment approaches are not followed. The nature of conservative treatment for patients presenting for this study was largely passive in nature, consisting of medication and rest. Those patients who had undergone a course of physiotherapy had received treatment focused on pain relief (ie, modalities) as opposed to active rehabilitation. Of those patients reporting some attempts at active rehabilitation in their previous treatments, all related that any attempts at performing rehabilitative exercises were limited by pain. None of the 120 patients screened for this study had received intraspinal injections.

Using objective clinical indicators tested for validity and reliability, this study has found by intent-to-treat analyses that a relatively high number (60%) of patients failing initial medical management and deemed appropriate for surgical intervention can gain a similar amount of pain relief through spinal manipulative treatment as they might have gained from surgery. This observation appears to hold true for both rate and magnitude of recovery. Changes in clinical status were reflected in each of the measurement tools used. This consistency between the outcomes measured lends credibility to the reliable nature of the data and attest to the extremely small likelihood of study results being contaminated by random chance.

Although 40% of patients referred to spinal manipulative therapy for LDH-induced sciatica may fail to achieve satisfactory relief, the obvious risk and cost profile of operative care argues for serious physician and patient consideration of spinal manipulative therapy before surgical intervention. In the present study, 8 patients who failed primary spinal manipulative care and went on to surgical decompression ultimately benefited with clinical outcomes indistinguishable from the treatment successes. There was no evidence that delay in definitive treatment adversely affected degree of improvement. Nonetheless, further study is warranted to better identify factors predictive of spinal manipulative success and failure.

Finally, it appears that those patients who fail surgery do not benefit from further spinal manipulation intervention. Despite the small number of patients in this category, the results from the present study have shown a consistent failure of improvement in all clinical outcome measures with strong statistical significance. This observation tends to reinforce a general clinical impression that the surgical "failed back" tends to be a chronic condition refractory to other forms of intervention.

It can perhaps be argued that clinical improvement in both treatment groups was confounded by the benefits of natural history (ie, spontaneous improvement with time). However, all patients in this study had failed at least 3 months of conservative care. Approximately 80% of participating subjects (n = 32) experienced symptoms for greater than 6 months, whereas 65% (n = 26) of them experienced symptoms for greater than 1 year. These

figures suggest that most of the patient population in this study were not likely to improve from natural history alone.

Limitations

The main limitation of this study is its relatively small sample size (n = 40). However, statistical techniques have demonstrated it to be adequately powered in the ability to detect clinically significant differences between treatment groups. Nonetheless, for more robust conclusions with respect to the patients who failed surgical microdiskectomy, a larger sample size would be preferable. In addition, this trial was not designed to incorporate a "nontreatment" (natural history) control group; hence, the hypothesis that both surgery and spinal manipulation treatments are no different than the natural history of symptomatic LDH was not tested. Although follow-up in the present study was less than 2 years after final treatment, it is unlikely that any further significant changes would have been observed between 1- and 2-year follow-up points based on the experience of other recent prospective randomized trials.[15,17]

Conclusions

Most of the patients who were considered surgical candidates for the treatment of radiculopathy from LDH improved with standardized spinal manipulative care to the same degree as those who had undergone surgery. Of those who failed spinal manipulation treatment, subsequent surgical intervention provided excellent outcome. In contrast, the 3 patients who failed microdiskectomy did not benefit from further spinal manipulative care. Therefore, patients with symptomatic LDH failing medical management (failed at least 3 months of nonoperative management including treatment with analgesics, lifestyle modification, physiotherapy, massage therapy, and/or acupuncture) should consider chiropractic spinal manipulative treatment as a primary treatment, followed by surgery if unsuccessful.

Practical Applications

- Based upon this randomized clinical study, 60% of patients with sciatica and had failed other medical management benefited from spinal manipulation to the same degree as if they underwent surgical intervention.
- Of the 40% of patients that showed unsatisfactory results with spinal manipulation, subsequent surgical intervention conferred excellent outcome.
- The 3 patients who failed surgical treatment and crossed over to spinal manipulation did not gain further improvement.

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