EXPLORATORY ANALYSIS OF CLINICAL PREDICTORS OF OUTCOMES OF NONSURGICAL TREATMENT IN PATIENTS WITH LUMBAR SPINAL STENOSIS

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Abstract

Objective: The purpose of this study was to explore potential baseline physical examination and demographic predictors of clinical outcomes in patients with lumbar spinal stenosis.

Methods: This was a secondary analysis of data obtained from a pilot randomized controlled trial. Primary and secondary outcome measures were the Swiss Spinal Stenosis (SSS) Questionnaire and visual analog scale (VAS) for leg pain. Multiple regression models were used to assess 2 different outcomes: SSS at completion of care and VAS at completion of care. Separate regression models were built for each of the 2 outcomes to identify the best subset of variables that predicted improvement. Predictors with a significant contribution were retained in a final "best" model.

Results: Three variables were identified as having an association with SSS score at completion of care: baseline SSS score, qualitative description of leg pain, and age (adjusted $R^2 = 33.2$). Four variables were identified as having an association with VAS score at completion of care: baseline VAS score, qualitative description of leg pain, body mass index, and age (adjusted $R^2 = 38.3$).

Conclusion: This study provides preliminary evidence supporting an association between certain baseline characteristics and nonsurgical clinical outcomes in patients with lumbar spinal stenosis. (J Manipulative Physiol Ther 2015;xx:1-7)

Key Indexing Terms: Spinal Stenosis; Manipulation; Chiropractic; Low Back Pain; Complementary Therapies; Lumbar Vertebrae; Radiculopathy

Lumbar spinal stenosis (LSS) is a syndrome that is characterized by significant buttock or lower extremity pain—which may occur with or without back pain—associated with diminished space available for the neural and vascular elements in the lumbar spine. It is important to note that the diagnosis of the clinical syndrome of LSS requires both imaging evidence of bony narrowing as well as clinical evidence of significant buttock or leg pain. The hallmark symptom of LSS is pain that is typically worse with walking or standing and better with sitting or lying down. The leg pain associated with LSS often leads to significant impairment in ambulation and quality of life. Lumbar spinal stenosis is a significant public health concern due to the high prevalence of this condition in the senior population and the burden caused by its associated physical impairments. It has been cited as the...
most common reason for spine surgery in patients older than 65 years.\(^3\)

The fastest growth in lumbar surgery in the United States this past decade has occurred in older adults with LSS, and the rate of complex fusion procedures has increased 15-fold.\(^3\) These surgical procedures are associated with significant health care costs, risks and complications, and high rehospitalization rates.\(^3\) The natural history of patients with clinically mild to moderate LSS can be favorable in approximately one-third to one-half of patients, without any type of specific treatment. Therefore, the development of optimal nonsurgical management approaches for LSS is a high public health priority.

The largest randomized clinical trial and cohort study to date (SPORT trial) that compared surgical vs nonsurgical care for LSS concluded that patients with symptomatic LSS who were treated surgically had greater improvement in pain and function in the short term.\(^1\) This benefit seems to last for up to 4 years, after which the surgical and nonsurgical outcomes converge.\(^5,6\) The patients in the cohort study who chose surgery were younger; had higher baseline pain, greater disability, and dissatisfaction with their symptoms; and reported their symptoms as progressively worsening at baseline. However, the results from that same study also showed that approximately one-third of patients in the nonoperative group experienced significant improvement in pain and function lasting up to 4 years, with approximately one-fourth reporting a major improvement in their condition.\(^4\)

Nonsurgical care in the SPORT trial, both before and after randomization, was not standardized, being described as “usual care” (ie, whatever nonsurgical care each patient happened to have sought). More recently, Delitto et al\(^7\) published the results of their randomized trial of 169 LSS patients who were randomized to either physical therapy (PT) or surgical decompression. The primary outcome was physical function score on the Short Form-36 Health Survey at 2 years. Intention-to-treat analysis showed no difference between groups at 2 years, although there was a high rate of cross-over from PT to surgery.

There are few studies in the literature regarding the nonsurgical management of LSS by chiropractors, physical therapists, or medical physicians. There is 1 systematic review of epidural injections for the nonsurgical medical treatment of chronic low back pain that includes some studies related to treatment of LSS.\(^8\) This review found 10 randomized controlled trials (RCTs) and 11 observational studies; only 1 small RCT\(^9\) and 2 observational studies were specifically related to LSS that met the inclusion criteria. Significant relief of pain was noted in only 55% to 65% of the patients in the RCT.

A systematic review of chiropractic treatment for LSS revealed 6 relevant articles but no RCTs; these included 4 case reports, 1 case series, and 1 observational cohort study.\(^10\)

The chiropractic treatments in these studies included spinal manipulation, most often distraction manipulation. Numerous other interventions including exercise, activity of daily living modifications, and various passive care modalities were selectively used in the included studies. The 1 observational cohort study involved a case series of 57 consecutive patients with LSS treated with a combination of distraction manipulation and neural mobilization.\(^11\) A majority of the patients in that cohort study showed clinically meaningful improvement in pain and disability scores that were maintained for up to 18 months.

There is 1 narrative review of the physical therapy literature for LSS with a case series of 3 patients managed with PT.\(^12\) One RCT has been published that compared 2 types of PT for treatment of LSS.\(^13\) This trial showed that a majority of the patients experienced clinically significant improvements in both pain and function and that these gains were maintained for up to 18 months. A survey of LSS patients receiving PT treatment reported that the following nonsurgical PT options were most commonly used: strengthening and flexibility exercises, heat/ice, massage, joint mobilization, and acupuncture.\(^14\)

It would be valuable for patients and clinicians to know if there are baseline predictors of surgical and nonsurgical treatment outcomes for patients with LSS. However, most of the evidence about predictors is restricted to the surgical literature. Secondary analyses of the SPORT trial data\(^15,16\) found that duration of symptoms less than 12 months at baseline was a significant predictor of better outcome with either surgical or nonsurgical treatments and that diabetic patients did not do as well with nonsurgical treatments. However, diabetic patients who did have surgery for LSS showed more postoperative complications and less improvement in pain or function as compared to nondiabetic LSS patients.

A systematic review of preoperative predictors for LSS surgery\(^17\) found the following baseline predictors were associated with better postsurgical outcomes: male sex, younger age, better walking ability, better self-reported health, fewer comorbidities, and more pronounced canal stenosis. Negative predictors were depression, cardiovascular comorbidities, scoliosis, and other comorbid conditions affecting walking capacity. Smoking has also been associated with poorer outcomes in patients undergoing spine surgery, especially procedures that involve spinal fusions.\(^18\)

As noted above, better walking ability at baseline was associated with better postsurgical outcomes, but we do not know if this finding generalizes to nonsurgical treatment outcomes. Previous studies have reported the important and predictive value of leg symptoms and self-reported patient information in the differential diagnosis of LSS.\(^19-21\) These studies have shown that various lower extremity symptoms are highly associated with the diagnosis of LSS, including the inability to walk long distances without sitting down, improvement in leg symptoms when flexing the lumbar spine, and inability to stand due to leg symptoms. However,
there is a paucity of literature about the association of leg symptoms as predictors of response to nonsurgical treatment of LSS.

The literature is generally lacking with respect to good quality evidence informing which baseline characteristics are correlated with—or predictive of—LSS clinical outcomes with various nonsurgical treatment approaches.\(^22,23\)

Therefore, the purpose of this study was to explore potential baseline physical examination and demographic predictors of clinical outcomes in patients with LSS.

**METHODS**

This study analyzed the data and variables obtained from a previously implemented chiropractic clinical trial\(^24\) that randomized 60 LSS subjects into 4 groups; 3 of the groups received varying dosages of distraction manipulation and the fourth group received placebo care. All of the subjects recruited to the trial had both anatomical signs of spinal canal narrowing on magnetic resonance imaging scan and clinical symptoms of current leg pain (neurogenic claudication) for at least 6 months duration. The results of this parent clinical trial are described in detail in a separate publication.\(^24\) The parent trial was approved by the institutional review board at National University of Health Sciences and registered on ClinicalTrials.gov (identifier: NCT00527527).

The primary and secondary outcome measures used in the original trial were the Swiss Spinal Stenosis (SSS) Questionnaire\(^25,26\) and visual analog scale\(^27\) (VAS) for pain. Therefore, we decided to maintain these original outcome measures and use them as the dependent variables in our analyses. Both of these are validated instruments for assessing self-reported physical impairment from LSS and intensity of pain, respectively. The VAS used in this study was a 10-cm line which was anchored on the left end with the statement “no pain” and on the right end with the words “worst pain imaginable.” Patients were instructed to mark an “x” on the line which represented their self-reported level of pain. The SSS is a validated 12-item condition-specific outcome measure for patients with LSS. Seven of the items compose the symptom severity subscale and 5 items compose the physical function subscale. The symptom severity subscale is further divided into “pain” and “neuroischemic” domains. Total score is expressed as a percentage, with higher numbers representing higher levels of self-reported symptoms or impaired physical function.

The Oswestry (OSW) Low Back Pain Disability Index was also given to patients, as this is one of most widely used self-report instruments for low back pain research. The OSW is considered to be a valid and reliable measure of functional impairment, with a score range from 0 to 50 (converted to a percentage), with higher numbers representing higher levels of self-reported disability.\(^28\)

- **Age**
- **Duration of leg pain (months)**
- **Baseline severity of leg pain**
- **Baseline severity of back pain**
- **Body mass index**
- **Oswestry low back disability score**
- **Swiss Spinal Stenosis questionnaire score**
  - Total score
  - Neuro-ischemic subscore
  - Symptom severity subscore
- **Treadmill Test**
  - Total minutes walked
  - Unilateral or bilateral leg pain
  - Proximal or distal leg pain
  - Qualitative description of leg symptoms

The original data set contained more than 180 independent variables, representing a number of physical examination findings, signs and symptoms obtained from the case history, and sociodemographic information. As noted previously, a systematic review of RCTs that reported predictors associated with treatment response\(^17\) found that age, walking capacity, comorbidities affecting walking, general health status, and other baseline variables were associated with clinical outcomes. Using clinical reasoning and including many of these previously noted predictors, we hypothesized that 13 of the baseline variables that were collected in the parent trial were most likely to show a potential correlation with treatment outcomes (see Fig 1).

The most common impairment associated with LSS is walking intolerance due to severe leg pain (neurogenic claudication). In the parent trial, all subjects performed a treadmill test at baseline and were told to stop walking when their leg pain became intolerable. The researchers recorded the total minutes of walking time on the treadmill, as well as which one of the following 7 qualitative descriptions of the type of leg pain caused them to stop the treadmill test: (1) pain, (2) numbness, (3) tingling, (4) weakness, (5) burning, (6) heaviness, or (7) tightness/cramping.

We calculated the total number of patients who used each one of these descriptors. We found that approximately one-half of the subjects simply used the word “pain” because they had difficulty expressing a more specific quality of their leg pain. The remaining patients were mixed
in their use of the other 6 qualitative descriptive terms. Therefore, we dichotomized these 7 different qualitative descriptions of leg pain into 2 new independent variables: (1) “Pain” symptoms—which included only the leg “pain” response; and (2) “Other” symptoms—which included any of the other 6 qualitative descriptions of leg pain.

Before modeling, descriptive information and frequencies were generated for all variables to assess normality and associations between the potential predictors and outcome measures were explored using correlational methods. Multiple regression models were then used to assess 2 different dependent variables as outcomes: (1) SSS at completion of care and (2) VAS (leg pain) at completion of care. Separate regression models were built for each of the 2 outcomes to identify the best subset of variables that predicted pain improvement in patients with LSS using a stepwise (backward elimination) technique. Predictors with a significant contribution were retained for the final model. All statistical analyses were performed using SPSS (version 19) software, with α set at .05 unless otherwise specified.

### RESULTS

The final data set consisted of 59 patients (39 male) with a mean age of 62.2 years (SD, 8.0 years) (see Table 1). Table 2 reports the results of the regression analyses. In the regression model with the dependent variable as SSS score at completion of care (CC), 3 of the 13 predictors were identified as having an impact: baseline SSS, qualitative description of leg pain, and age. Among these variables, baseline SSS score had the highest influence on SSS score at CC. A higher baseline SSS score was associated with a higher SSS score at CC, indicating that those subjects starting out with more self-reported physical impairment from their LSS responded has less favorable clinical outcomes. The additional effects of qualitative description of leg pain and age were less influential. Qualitative description of leg pain as “other” and older age were also associated with higher SSS score at CC. These 3 predictors as a group explained 33.2% (adjusted \( R^2 \)) of the variability in SSS score at CC (\( F_{3,56} = 10.11; P < .001; R^2 = 0.368 \)).

The regression model with the dependent variable as VAS (leg pain) at CC contained 4 significant predictors: baseline VAS, qualitative description of leg pain, age, and body mass index (BMI). Visual analog scale baseline pain was the most influential; subjects with higher baseline pain scores experienced higher pain scores at completion of care which indicates less favorable clinical outcomes. In addition, description of leg pain as “other” and older age were associated with higher VAS score at CC. The negative correlation between BMI and the outcome indicated that, for this sample, lower BMI was associated with higher VAS scores at CC. These 4 predictors as a group explained 38.3% (adjusted \( R^2 \)) of the variability in VAS at CC (\( F_{4,53} = 9.86; P < .001; R^2 = 0.427 \)).

### DISCUSSION

The results of this analysis suggest that some of the baseline variables were predictive of clinical outcomes with the nonsurgical treatment (and placebo) used in the parent trial. The variables that accounted for most of the variation in clinical outcome measures were the baseline SSS and VAS scores, followed by age and qualitative description of leg symptoms. It is not surprising that patients with more self-reported physical impairment (SSS score) and pain (VAS) at baseline show less favorable responses to treatment. However, it was interesting to find that a number of expected baseline variables were not predictive of outcome, including amount of walking time on the treadmill, unilateral vs bilateral leg pain, proximal vs distal leg pain, duration of leg pain, and OSW score. The clinical relevance of the negative correlation between BMI and final VAS score, but not with final SSS score, is unknown.

One possible explanation for lack of correlation between clinical outcome and treadmill walking time is that treadmill testing may simply not be the best measure of walking capacity in patients with LSS. The performance of a treadmill test by older adults—especially those with no prior experience walking on a treadmill—can lead to unforeseen challenges in the research environment and

### Table 1. Baseline Characteristics of Research Participants in Parent Randomized Trial

<table>
<thead>
<tr>
<th></th>
<th>Total, N = 60</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>40 (67%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>20 (33%)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>37 (62%)</td>
<td></td>
</tr>
<tr>
<td>Unmarried</td>
<td>21 (38%)</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>53 (88%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>7 (12%)</td>
<td></td>
</tr>
<tr>
<td>Education*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ High school</td>
<td>11 (18%)</td>
<td></td>
</tr>
<tr>
<td>Post–high school</td>
<td>49 (82%)</td>
<td></td>
</tr>
<tr>
<td>Self-reported activity level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>14 (23%)</td>
<td></td>
</tr>
<tr>
<td>Inactive</td>
<td>8 (13%)</td>
<td></td>
</tr>
<tr>
<td>Somewhat active</td>
<td>38 (64%)</td>
<td></td>
</tr>
<tr>
<td>Leg symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Both</td>
<td>29 (48%)</td>
<td></td>
</tr>
<tr>
<td>Left only</td>
<td>19 (32%)</td>
<td></td>
</tr>
<tr>
<td>Right only</td>
<td>12 (20%)</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>41 (68%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19 (32%)</td>
<td></td>
</tr>
</tbody>
</table>

**Mean**

|                |       |
|                | 62.5 |
| Age (y)        |       |
| Duration of pain (mo) |     8.8  |
| Weight (lb)    | 203.3 |
| SSS: symptom severity | 3.2 |
| Treadmill test (min) | 10.4 |

SSS, Swiss Spinal Stenosis Questionnaire.
BMI, body mass index; SE, standard error; SSS, Swiss Spinal Stenosis Questionnaire; VAS, visual analogue scale.

Model 1 used the end-of-care SSS score, and model 2 used the end-of-care VAS as the dependent variables, respectively. Baseline dependent variable score, qualitative description of leg pain, and age were associated with both SSS and VAS at end of care. Body mass index was negatively associated with end-of-care VAS but not end-of-care SSS.

* Standardized β.

Table 2. Results of the Regression Analyses

<table>
<thead>
<tr>
<th>Variable</th>
<th>β</th>
<th>SE</th>
<th>β*</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression model 1: SSS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>-7.99</td>
<td>7.61</td>
<td>-1.05</td>
<td>.299</td>
<td></td>
</tr>
<tr>
<td>Baseline SSS</td>
<td>0.65</td>
<td>0.14</td>
<td>0.50</td>
<td>4.54</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Leg pain</td>
<td>3.67</td>
<td>1.42</td>
<td>0.27</td>
<td>2.58</td>
<td>.013</td>
</tr>
<tr>
<td>Age</td>
<td>0.21</td>
<td>0.09</td>
<td>0.36</td>
<td>2.30</td>
<td>.026</td>
</tr>
<tr>
<td>Regression model 2: VAS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intercept</td>
<td>-14.27</td>
<td>26.44</td>
<td>-0.54</td>
<td>.591</td>
<td></td>
</tr>
<tr>
<td>Baseline VAS</td>
<td>0.52</td>
<td>0.12</td>
<td>0.44</td>
<td>4.23</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Leg pain</td>
<td>17.30</td>
<td>4.80</td>
<td>0.39</td>
<td>3.61</td>
<td>.001</td>
</tr>
<tr>
<td>Age</td>
<td>0.73</td>
<td>0.29</td>
<td>0.27</td>
<td>2.52</td>
<td>.013</td>
</tr>
<tr>
<td>BMI</td>
<td>-1.11</td>
<td>0.55</td>
<td>-0.22</td>
<td>-2.01</td>
<td>.049</td>
</tr>
</tbody>
</table>

The limitations of this study were the small sample size, the reliance on subjective descriptions of leg pain, and logistical problems with measuring walking intolerance on the treadmill test. Our dichotomization of the 7 qualitative descriptions of leg pain into 2 groups was somewhat arbitrary, albeit based upon clinical reasoning and the distribution of the descriptive terms.

Another limitation may have been our decision to use only patient self-reported outcome measures (SSS and VAS) as the dependent variables in our analyses. It is possible that an objective measure of walking performance might have been a better outcome measure, such as time walked on the treadmill before the onset of leg symptoms. However, we found that even this “objective” measure of walking performance was clouded with subjectivity. Many patients would stop the treadmill test prematurely for reasons not related to leg symptoms, such as fear of falling or balance problems. Alternate measures of walking performance such as the self-paced walking test or use of accelerometers might prove to be better outcome measures in future LSS trials.

Despite these limitations, the results of this secondary analysis may help to inform better research study design in future nonsurgical LSS trials. We suggest that future LSS trials should include a qualitative description of leg pain that might be used as an independent predictor variable. It is also possible that other baseline characteristics could be potential predictors of clinical outcomes, but our analysis was limited to the 13 variables that we hypothesized were potentially significant predictors. Larger trials are necessary to more thoroughly explore this issue of potential predictors of clinical outcome with nonsurgical treatment methods.

CONCLUSION

This study provides preliminary evidence supporting an association between certain baseline characteristics and clinical outcomes in patients with LSS with a nonsurgical treatment or placebo. The qualitative description of leg symptoms is correlated with clinical outcome, but the neurophysiological mechanisms for this observation are unknown. Future clinical trials should consider the use of qualitative descriptors of leg symptoms as a potential predictor variable of clinical outcomes.

FUNDING SOURCES AND POTENTIAL CONFLICTS OF INTEREST

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No conflicts of interest were reported for this study.
CONTRIBUTORSHIP INFORMATION

Concept development (provided idea for the research): J.C., M.S., D.M.
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Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): M.S.
Data collection/processing (responsible for experiments, patient management, organization, or reporting data): J.C.
Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): LT, RH, DM
Literature search (performed the literature search): J.S.
Writing (responsible for writing a substantive part of the manuscript): M.S., J.C., L.T., D.M., J.S., R.H.
Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): M.S., J.C., L.T., D.M., J.S.

Practical Applications
- Qualitative description of leg symptoms was predictive of treatment outcome.
- Half the patients in study had bilateral leg symptoms, but this variable was not correlated with treatment outcome.
- Age, baseline leg pain, and function were predictive of treatment outcome.

REFERENCES


