11-1-2002

A comprehensive study of patients with surgically treated lumbar spinal stenosis with neurogenic claudication

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A COMPREHENSIVE STUDY OF PATIENTS WITH SURGICALLY TREATED LUMBAR SPINAL STENOSIS WITH NEUROGENIC CLAUDICATION

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Background: The relationship between objective measurements and subjective symptoms of patients with spinal stenosis and the degree of narrowing of the spinal canal is not clear. The purpose of this study was to evaluate patients undergoing surgery for lumbar spinal stenosis and intermittent neurogenic claudication with functional testing, quantitative imaging, and patient self-assessment.

Methods: Sixty-two patients with lumbar spinal stenosis and neurogenic claudication were prospectively enrolled in the study. All underwent preoperative magnetic resonance imaging and/or computed tomography myelography, and all were treated with decompressive surgery and were followed for a minimum of two years. The evaluation included treadmill and bicycle exercise tests as well as patient self-assessment with use of the Oswestry Disability Index and a visual analog pain scale preoperatively and postoperatively.

Results: Preoperatively fifty-eight (94%) of the patients had a positive result (provocation of symptoms) on the treadmill test and twenty-seven (44%) had a positive result on the bicycle test, whereas postoperatively six and twelve, respectively, had positive results. The mean preoperative scores on the Oswestry Disability Index and visual analog pain scale were 58.4 and 7.1, respectively. Postoperatively, these scores decreased to 21.1 and 2.3, respectively, and both decreases were significant ($p < 0.05$). Forty-seven (76%) of the patients were seen to have central stenosis on the preoperative imaging studies; forty-one of them had a cross-sectional area of the dural tube of <100 mm^2 at at least one level and twelve had a cross-sectional area of <100 mm^2 at at least two levels.

Conclusions: A positive treadmill test was consistent with a diagnosis of spinal stenosis and neurogenic claudication in >90% of the patients preoperatively. Following surgical decompression of the lumbar spinal stenosis, more functional improvement was demonstrated by the treadmill test than by the bicycle test. The scores on the Oswestry Disability Index and visual analog pain scale also improved postoperatively. The severity of central canal narrowing at a single level does not appear to limit the postoperative improvement in either functional ability or patient self-assessment. Patients with multilevel central stenosis were, on the average, older and walked a shorter distance preoperatively and postoperatively, although the improvement in their postoperative self-assessment scores was similar to that of patients with single-level stenosis.

Patients with lumbar spinal stenosis have narrowing of the central portion of the spinal canal, the lateral recesses, and/or the intervertebral foramina. The most prominent clinical symptom is neurogenic claudication, which is defined by pain, aching, and cramping associated with paresthesias in the lower limbs when the patient walks or exercises in an erect position. Neurogenic claudication may lead to debilitating deterioration in the quality of life, and decompressive surgery is commonly performed in patients with lumbar spinal stenosis. While surgical results generally have been reported to be good[1-5], objective measures of surgical outcome are limited. Exercise testing has been used to differentiate vascular from neurogenic claudication, and it has been

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used for neurological assessment of patients with lumbar spinal stenosis. Functional status has been assessed with use of a bicycle[6-9] and a treadmill[8,10-12].

We are not aware of any study focusing on the relationship among objective functional measurements, subjective symptoms, and the degree of narrowing of the spinal canal in patients treated surgically for lumbar spinal stenosis. Since 1992, we have prospectively evaluated patients with lumbar spinal stenosis and suspected neurogenic claudication with a functional assessment that included both treadmill and bicycle exercise testing[13,14]. The patients were also assessed with imaging studies and on the basis of self-reporting of symptoms with use of both the Oswestry Disability Index[15,16] and a clinical pain scale (visual analog pain scale).

We had several hypotheses before starting the study. The initial hypothesis was that patients with more severe symptoms would be seen to have more severe stenosis on the imaging study and more difficulty with walking. The second hypothesis was that these patients would have more trouble exercising on a treadmill (during which the lumbar spine is in extension) than on a bicycle (during which the lumbar spine is in flexion). The purpose of the present study was to (1) determine whether it is possible to evaluate patients with lumbar spinal stenosis more objectively by using treadmill and bicycle exercise testing along with a neuroradiographic imaging study; (2) to determine whether treadmill and bicycle testing provide quantitative measures that demonstrate the result of surgery; and (3) to determine whether there are correlations among the results of functional evaluations including both treadmill and bicycle testing, patient self-reported assessment with use of the Oswestry Disability Index and visual analog pain scale, and neuroradiographic imaging.

Materials and Methods

Sixty-two patients with symptomatic lumbar spinal stenosis were studied prospectively. All patients gave their informed consent to participate in this study, which had been approved by the Human Studies Committee of our School of Medicine. All patients had intractable neurogenic claudication and neuroradiographically confirmed lumbar spinal stenosis. There were twenty-four men and thirty-eight women, and their mean age (and standard deviation) was 63.2 ± 9.4 years. The concomitant diagnoses causing the spinal stenosis were degenerative spondylolisthesis (≥5 mm in the sagittal plane) in thirty-three patients, isthmic spondylolisthesis in seven patients, lumbar spondylosis in thirteen patients, and degenerative scoliosis (>15° in the coronal plane) in nine patients. Nine patients had had previous surgery on the lumbar spine. Seven of them underwent revision surgery to treat recurrent stenosis at the same levels. Patients with peripheral vascular disease or with a severe cardiopulmonary or musculoskeletal condition that would limit their exercise capacity during functional testing were excluded.

Posterior decompressive surgery was performed in all patients. A mean of 1.8 ± 0.9 levels (range, one to four levels) were decompressed. Forty-six patients (74%) with preoperative instability in the coronal and/or sagittal plane also underwent posterolateral arthrodesis of the spine with instrumentation. We defined spinal instability as ≥5 mm of sagittal translation on the upright lateral lumbar radiograph or on the flexion-extension lateral lumbar radiograph. In the coronal plane, it was defined as any angular malalignment of ≥10° between vertebrae or any rotatory subluxation between two vertebrae producing ≥5 mm of coronal offset. In addition, there could be no evidence of stabilizing osteophytes in either the coronal or the sagittal plane.

All patients underwent preoperative magnetic resonance imaging (forty-two patients) and/or computed tomography myelography (twenty-four patients). These imaging studies were performed routinely with the patient lying supine with the hips and knees extended. All of the patients also performed treadmill and bicycle exercise tests preoperatively and postoperatively. Forty-one patients performed the postoperative tests at six months; thirty-six, at one year; and thirty-five, at two years. All patients were followed clinically and radiographically for a minimum of two years after the surgery. The mean follow-up period was 3.8 ± 1.4 years (range, two to seven years). Five patients underwent revision surgery following the index procedure because of pseudarthrosis (two patients), stenosis at an adjacent level (two patients), or recurrence of stenosis at the same level (one patient). These five patients performed the tests after the revision surgery.

Our prospective evaluation included (1) preoperative imaging (magnetic resonance imaging and/or computed tomography myelography) to measure the cross-sectional area of the dural tube at each intervertebral level with stenosis, (2) preoperative and postoperative treadmill exercise testing, (3) preoperative and postoperative bicycle exercise testing, (4) patient self-assessment with use of the Oswestry Disability Index (a scale of 0 to 100, with 0 indicating the best function) and a visual analog pain scale (a scale of 0 to 10, with 0 indicating no pain) preoperatively and on the day of the latest follow-up, and (5) preoperative and latest follow-up upright anteroposterior and lateral lumbar radiographs. These measurements and tests were done by independent examiners who were not part of the surgical teams.

Measurement of the Cross-Sectional Area of the Dural Tube

The transverse images of the lumbar spine were obtained with magnetic resonance imaging in thirty-eight patients and with computed tomography myelography in the remaining twenty-four[17-19]. The cross-sectional area of the dural tube was measured at the midpoint of each intervertebral level with stenosis; it was also measured at the level of the pars interarticularis in the patients who had isthmic spondylolisthesis. Forty-seven of the sixty-two patients were considered to have mainly central canal stenosis, and fifteen had isolated lateral recess stenosis. The measurements (anterior-to-posterior dimension in millimeters [A] and medial-to-lateral dimension in millimeters [B]) and calculation (A × B) were done by an independent spine surgeon with NIH Image software (a public domain image-processing and analysis program developed

TABLE I Comparison of Preoperative and Postoperative Results in All Sixty-two Patients

	Preop.	Postop.
No. of subjects	62	62
Oswestry Disability Index		
Score* *(points)*	58.4 ± 13.3	21.1 ± 18.9§
Rate of improvement *(%)*		63.7
Visual analog pain scale		
Score* *(points)*	7.1 ± 1.9	2.3 ± 2.3§
Rate of improvement *(%)*		57.3
Treadmill test		
Positive result†	58 (93.5%)	6 (9.7%)§
Test completed†	25 (40.3%)	48 (77.4%)§
Time‡ *(min)*	13.7 (14.8)	17.6 (20.0)§
Distance‡ *(mi [km])*	0.50 [0.80] (0.49 [0.79])	0.65 [1.0] (0.78 [1.3])§
Time to onset of symptoms‡ *(min)*	1.9 (1.0)	14.8 (20.0)§
Visual analog pain scale score* *(points)*		
Before test	2.9 ± 2.6	1.1 ± 2.0§
After test	7.3 ± 2.2	1.8 ± 2.8§
Change during test	4.4 ± 3.4	0.7 ± 2.1§
Bicycle test		
Positive result†	27 (43.5%)	12 (19.4%)§
Test completed†	43 (69.4%)	51 (82.3%)
Time‡ *(min)*	8.7 (10.0)	9.2 (10.0)
Distance‡ *(mi [km])*	2.2 [3.5] (2.4 [3.9])	2.3 [3.7] (2.5 [4.0])
Time of onset of symptoms‡ *(min)*	6.1 (8.3)	7.7 (10.0)
Visual analog pain scale score* *(points)*		
Before test	2.8 ± 2.6	0.9 (1.8)§
After test	4.1 ± 3.4	1.8 ± 2.9§
Change during test	1.3 ± 2.3	0.9 ± 2.2

*The values are given as the mean and standard deviation. †The values are given as the number of patients, with the percentage in parentheses. ‡The values are given as the mean, with the median in parentheses. §The difference between the preoperative and postoperative values was signifcant ($p < 0.05$).

by the Research Services Branch [RSB] of the National Institute of Mental Health [NIMH], which can be found at rsb.info.nih.gov/nih-image/). The measurement was performed twice with a one-month interval between measurements, and the mean of the two measurements was used for data analysis. The variability between the two measurements was 9.5% ± 8.3%. The narrowest cross-sectional area of the dural tube as well as the level or levels and the number of levels at which the cross-sectional area of the dural tube was <100 mm^2 were recorded.

Treadmill Exercise Protocol

The detailed protocol previously described by Tenhula et al.[8] was followed. First, the subject recorded the pretest symptoms and marked the visual analog pain scale. He or she then walked on a treadmill on a level surface at 2.0 mph (3.2 kph) for ten minutes, then at 2.5 mph (4.0 kph) for five minutes, and finally at 3 mph (4.8 kph) for five minutes. If the patient was unable to tolerate the standard speed and distance (time), the speed was reduced or the test was ended. Changes in symptoms were continually monitored during the test. The time when the symptoms began or increased and the total time and the total distance that the patient walked were recorded. At the end of the test, the patient recorded the symptoms and marked the visual analog pain scale again.

Bicycle Exercise Protocol

The patient pedaled on a stationary ergometer, seated with his or her preferred posture and holding the handlebar, with instructions to continue at a constant pedaling speed of 50 to 60 rpm throughout the entire test. No resistance was added for the first minute. Resistance was then increased to 20 W (~120 kpm/m) for another minute. After two minutes of warm-up, the resistance was increased to 50 W (~300 kpm/m) for an additional eight minutes. The patient recorded the symptoms and marked the visual analog pain scale before and after the test. The tester monitored the change in symptoms during the test, recording the time when the symptoms began or in-

creased and the reason for stopping the test. The total time and distance that the patient pedaled were also recorded.

Both the treadmill and the bicycle tests were stopped, or the work load was reduced, if the patient could not tolerate the protocol because of symptoms, an adverse medical response, exercise intolerance, or elevation of the blood pressure or heart rate beyond an acceptable level. If the patient performed several tests postoperatively, the latest test was used for data analysis. According to Tenhula et al., the postoperative test data are consistent whenever the test is performed[8].

Statistical Analysis

A standard StatView software package (SAS Institute, Cary, North Carolina) was used for the statistical analysis. Nonparametric analysis (Kruskal-Wallis) followed by the Mann-Whitney U test was used for evaluating the differences between two groups. Repeated-measures analyses of variance in the same group was performed with use of the Wilcoxon test. Chi-square analysis was performed on the categorical data regarding whether the test was completed and whether it was considered positive or negative. P values of <0.05 were considered significant.

Results

Patient Self-Assessments and Radiographic Outcomes

Compared with the preoperative data, the scores on the Oswestry Disability Index and visual analog pain scale were significantly improved at the time of final follow-up (at a minimum of two years) ($p < 0.05$). The mean rate of improvement ([(preoperative score − postoperative score)/preoperative score] × 100%) in the Oswestry Disability Index and visual analog pain scale scores were 63.7% and 57.3%, respectively (Table I). After the index operation, a pseudarthrosis developed in four of the forty-six patients who had had an arthrodesis. Two patients underwent revision surgery because of persistent symptoms, whereas the other two patients chose to be followed without revision surgery.

Treadmill Exercise Testing

There were significant differences ($p < 0.05$) between the preoperative and postoperative values for the time for which the subject walked, the distance that he or she walked, the time to the onset of symptoms, the scores on the visual analog pain scale before testing and after testing, and the change in the score on the visual analog pain scale after the test compared with the score before the test. Also, a significantly greater percentage of patients had a positive test (provocation of symptoms) and were unable to complete the test preoperatively compared with postoperatively (Table I). The data demonstrate that surgical treatment resulted in a significant improvement in all factors analyzed.

Bicycle Exercise Testing

There were no significant differences between the preoperative and postoperative values for riding time, riding distance, the time to onset of symptoms, the percentage of patients who were unable to complete the test, or the change in the score on the visual analog pain scale after the test compared with the score before the test. There was a significant difference between the preoperative and postoperative percentages of patients who had a positive result (provocation of symptoms) and between the preoperative and postoperative visual analog pain scale scores before and after the bicycle test ($p < 0.05$).

Compared with the twenty-four male patients, the thirty-eight female patients walked for significantly less time postoperatively, walked a significantly smaller distance preoperatively and postoperatively, and pedaled the bicycle for significantly less time preoperatively and for a significantly smaller distance preoperatively and postoperatively ($p < 0.05$).

Relationship Between Findings on Neuroimaging and Results of Functional Testing and Patient Self-Assessment

The mean cross-sectional area of the dural tube at the narrowest level was 90.6 ± 55.0 mm^2. There was no significant difference in clinical status or functional ability between the forty-seven patients with mainly central stenosis and the fifteen with lateral recess stenosis, with the exception of the mean age and narrowest dural area (see Appendix).

Of the forty-seven patients with central stenosis, forty-one had a cross-sectional area of the dural tube of <100 mm^2 at at least one level and twelve had it at at least two levels. The narrowest level was between the second and third lumbar vertebrae in two patients, between the third and fourth lumbar vertebrae in eight, between the fourth and fifth lumbar vertebrae in thirty-six, and between the fifth lumbar and first sacral vertebrae in one. The mean cross-sectional area of the dural tube at the narrowest level was 68.9 ± 25.7 mm^2 in the forty-seven patients with central stenosis.

The forty-seven patients with central stenosis were divided in two groups according to whether the narrowest cross-sectional area of the dural tube was <70 mm^2 (twenty-five patients) or >70 mm^2 (twenty-two patients). The patients with more severe stenosis (a cross-sectional area of <70 mm^2) had a significantly lower mean postoperative score on the Oswestry Disability Index ($p < 0.05$); however, they had similar results in all of the other comparisons, including the treadmill and bicycle tests (see Appendix).

The twelve patients with central stenosis at two or more levels were compared with the thirty-five patients with central stenosis at only one level. There were significant differences between the two groups with regard to mean age as well as walking distance during the preoperative and postoperative treadmill tests ($p < 0.05$). However, there was no significant difference in the duration of the preoperative symptoms, score on the Oswestry Disability Index or visual analog pain scale, or rate of improvement in the score on the Oswestry Disability Index or visual analog pain scale (see Appendix).

The forty-six patients who were treated concomitantly with posterolateral spine arthrodesis and instrumentation were compared with the sixteen who were not. The former group had a significantly higher rate of improvement in the

score on the Oswestry Disability Index than the latter group ($p < 0.05$) (see Appendix).

The sixty-two patients were divided into four groups according to whether they had degenerative spondylolisthesis (thirty-three patients), isthmic spondylolisthesis (seven), degenerative scoliosis (nine), or spondylosis (thirteen). None of the patients with degenerative spondylolisthesis had a positive result during the postoperative treadmill test. This rate of positive results was significantly lower than that of two of the other three groups ($p < 0.05$) (see Appendix).

Patients who had had previous surgery walked on the treadmill and pedaled the bicycle for a shorter time and distance preoperatively than did patients without previous surgery ($p < 0.05$). Also, they had a higher mean visual analog pain scale score postoperatively ($p < 0.05$) (see Appendix).

In the series as a whole, age had a negative correlation with the narrowest cross-sectional area of the dural tube ($r = –0.38$, $p < 0.05$) and a positive correlation with the number of levels at which the cross-sectional area of the dural tube was <100 mm^2 ($r = 0.40$, $p < 0.05$). Also the number of levels with a cross-sectional area of <100 mm^2 had a negative correlation with the time ($r = –0.33$, $p < 0.05$) and distance ($r = –0.35$, $p < 0.05$) walked during the preoperative treadmill test. Comparison of the patients with less postoperative improvement (improvement rates in the scores on the Oswestry Disability Index and visual analog pain scale of <50%) with those with more postoperative improvement did not reveal any factors predicting the results of surgical management.

Discussion

This study demonstrated that the result of a treadmill test is consistent with symptoms of neurogenic claudication in >90% of patients treated surgically. The patients with multilevel central stenosis walked on the treadmill for a significantly shorter distance both preoperatively and postoperatively ($p < 0.05$), but their postoperative improvement in self-assessment scores was similar to that of the other patients. We also found correlations among patient age, the number of narrowed levels, and walking capacity during the treadmill test. To our knowledge, this is the first report demonstrating a quantitatively significant relationship between functional status and the degree of stenosis in patients with lumbar spinal stenosis.

Preoperatively, the patients had a substantial increase in symptoms during the treadmill test, but fewer had notable symptoms during the bicycle test. These results demonstrate and confirm that patients with lumbar spinal stenosis are able to tolerate bicycling (during which the lumbar spine is flexed) better than walking (during which the lumbar spine is extended)[6,12]. Postoperatively, the patients had marked improvement in the ability to walk on the treadmill and a little improvement in the ability to pedal the bicycle. Treadmill testing was more sensitive to the patients' symptoms than was bicycle testing. The patients also reported markedly improved self-assessment (Oswestry Disability Index and visual analog pain scale) scores at the time of final follow-up. Therefore, this study showed that surgical treatment improved both the patients' self-assessment of their condition as well as their walking ability on treadmill testing. Treadmill and bicycle tests have been used mainly to assess patients with central stenosis, but we also analyzed those with lateral recess stenosis (radicular claudication) as well as combined central and lateral recess stenosis. After surgery, the patients with isolated lateral recess stenosis also improved functionally as shown by the treadmill and bicycle testing. Finally, although men and women had similar postoperative improvement in the self-assessment scores, there were some significant ($p < 0.05$) differences between genders with regard to their ability to carry out the treadmill and bicycle testing. This gender variance should be considered when functional status is assessed.

We found that the patients with two or more stenotic levels walked for a significantly shorter distance preoperatively and postoperatively than did patients with stenosis at only one level, but the two groups had similar rates of postoperative improvement in the scores on the Oswestry Disability Index and the visual analog pain scale. This study also showed, unexpectedly, that the patients with severe central stenosis (a cross-sectional area of <70 mm^2) at a single level had a better postoperative score on the Oswestry Disability Index than did those with moderate stenosis (a cross-sectional area of >70 mm^2). A possible reason for this finding is that another comorbidity (for example, psychosomatic disease) might have been involved in the patients who had only moderate stenosis but progressive symptoms of neurogenic claudication.

Recently neuroradiographic measurements have been developed to quantify the degree of lumbar spinal stenosis. Both magnetic resonance imaging and computed tomography myelography are used for those measurements, and some studies have shown a high degree of correlation between the two studies with regard to the assessment of lumbar spinal stenosis[20,21]. Those studies showed a definite relationship between clinical features and radiographic findings[22,23], whereas others have demonstrated opposite results[1,15,24]. Hamanishi et al. measured the cross-sectional area of stenotic lumbar dural tubes with magnetic resonance imaging and concluded that a cross-sectional area of <100 mm^2 at two or more intervertebral levels was highly associated with intermittent claudication[23]. The results of our study support not only previous clinical research[23,25], but also previous experimental studies[26,27] indicating that two-level stenosis induces neurogenic claudication more frequently than does one-level stenosis.

Comprehensive assessment of patients with lumbar spinal stenosis and neurogenic claudication with functional testing and quantitative neuroimaging studies as well as the patient's self-assessment can be a useful tool in the decision-making process and evaluation for surgical treatment. These assessments may improve diagnostic accuracy and facilitate differentiation from other diseases, such as psychogenic disorders and vascular claudication, as well as confirm the beneficial outcomes of decompressive surgery.

Appendix

eA Six additional tables presenting comparisons of patients with central stenosis and lateral stenosis, severe and moderate central stenosis, single-level and multiple-level stenosis, arthrodesis or no arthrodesis, various types of spondylolisthesis, and with and without revision surgery are available with the electronic versions of this article, on our web site at www.jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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The authors did not receive grants or outside funding in support of their research or preparation of this manuscript. They did not receive payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

Read at the Annual Meeting of American Academy of Orthopaedic Surgeons, San Francisco, California, February 28 through March 4, 2001.

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