The Risk of Getting Worse: Predictors of Deterioration After Decompressive Surgery for Lumbar Spinal Stenosis: A Multicenter Observational Study

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■ OBJECTIVE: **To investigate the frequency and predictors of deterioration after decompressive surgery for single and 2-level lumbar spinal stenosis.**

■ METHODS: **Prospectively collected data were retrieved from the Norwegian Registry for Spine Surgery. Clinically significant deterioration was defined as an 8-point increase in Oswestry disability index (ODI) between baseline and 12 months' follow-up.**

■ RESULTS: **There were 2181 patients enrolled in the study. Of 1735 patients with complete 12 months follow-up, 151 (8.7%) patients reported deterioration. The following variables were significantly associated with deterioration at 12 months' follow-up; decreasing age (odds ratio [OR] 1.02, 95% confidence interval [95% CI] 1.00–1.04, $P = 0.046$), tobacco smoking (OR 2.10, 95% CI 1.42–3.22, $P = 0.000$), American Society of Anesthesiologists grade ≥3 (OR 1.80, 95% CI 1.07–2.94, $P = 0.025$), decreasing preoperative ODI (OR 1.05, 95% CI 1.02–1.07, $P = 0.000$), previous surgery at the same level (OR 2.00, 95% CI 1.18–3.27, $P = 0.009$), and previous surgery at other lumbar levels (OR 2.10, 95% CI 1.19–3.53, $P = 0.009$).**

■ CONCLUSIONS: **Overall risk of clinically significant deterioration in patient-reported pain and disability after decompressive surgery for lumbar spinal stenosis is approximately 9%. Predictors for deterioration are decreasing age, current tobacco smoking, American Society of Anesthesiologists grade ≥3, decreasing preoperative ODI, and previous surgery at same or different lumbar level. We suggest that these predictors should be emphasized and discussed with the patients before surgery.**

INTRODUCTION

Lumbar spinal stenosis is the most frequent indication for spinal surgery in elderly patients, and its prevalence is likely to increase (8, 12, 17). Evidence is growing that decompressive surgery offers an advantage over nonsurgical management for selected patients with persistent severe symptoms (1, 3, 4, 23, 40). Moreover, a recent study has shown that the effectiveness of microdecompression is equivalent to laminectomy in the surgical treatment of central lumbar spinal stenosis with favorable outcomes at 1 year in both groups (26). Improvement in radiating pain, neurogenic claudication, functional status, and quality of life are common treatment goals.

For functional assessment, the Oswestry Disability Index (ODI) is a patient-reported outcome measure commonly used in lumbar spine surgery and included in several spine registries. Because

Key words
- Quality of life
- Spinal stenosis
- Spondylosis

Abbreviations and Acronyms
ASA: American Society of Anesthesiologists
CI: Confidence interval
EQ-5D: EuroQol-5D
MCID: Minimum clinically important difference
MRI: Magnetic resonance imaging
NORSpine: Norwegian Registry for Spine Surgery
NRS: Numerical Rating Scale
ODI: Oswestry Disability Index
OR: Odds ratio
ZCQ: Zürich Claudication Questionnaire

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most studies, however, focus on symptomatic or functional improvement the risk of deterioration seems unclear. Registry-based studies report success rates of surgery in the range of 30%–84% in terms of improvement in pain and about 55% for functional improvement (27, 37). One study reported that 9%–11% of patients experienced worsening of pain, but no data on functional deterioration were provided (37). Thus, the proportion of patients experiencing a clinically significant deterioration in pain and disability after surgery remains to be elucidated.

The aim of this prospective registry-based study was to evaluate the risk of clinically significant worsening of pain and disability, defined as an increase in ODI $\geq$8 at 12 months and to explore possible predictors for clinically significant deterioration after decompressive surgery for central lumbar spinal stenosis. Using data from the Norwegian Registry for Spine Surgery (NORspine), we included patients operated on with laminectomy or microdecompression at 1 or 2 lumbar levels without instrumentation.

MATERIALS AND METHODS

Study Population

Data for this registry based cohort study were collected from NORspine, which was established in 2006 and is a comprehensive clinical registry for quality control and research. Participation in NORspine by either providers or patients is not mandatory, nor is participation required as a necessary condition for a patient to gain access to health care or for a provider to be eligible for payment for the health care service. Follow-up time from the date of the operation (baseline) in this study was 12 months. Both first time operations and patients who had previous lumbar surgery were included.

Inclusion Criteria

Inclusion criteria were as follows: 1) diagnosis of central lumbar spinal stenosis; 2) operation at $\leq$2 lumbar levels with either open laminectomy or microdecompression in the time period between October 2006 and December 2011; and 3) included in the NORspine registry.

Exclusion Criteria

Exclusion criteria were as follows: 1) discectomy as part of the decompression; 2) spinal instrumentation as part of the procedure; and 3) other conditions in the lumbar spine (tumor, infection, or hemorrhage) verified by magnetic resonance imaging (MRI) and/or computed tomography.

Ethical Approval

The study was evaluated and approved by the regional committee for medical research in Central-Norway (ID 2013/643), and all participants provided written informed consent. The Data Inspectorate of Norway approved the registry protocol.

Primary Outcome Measure

We used version 2.0 of the ODI (13) as the measure of main outcome. ODI is a widely accepted outcome measure in lumbar spinal stenosis surgery (26, 40). This version has been translated into Norwegian and tested for psychometric properties (15). This disease-specific measure of functional status contains 10 questions on limitations of activities of daily living. The ODI questionnaire is used to quantify disability for degenerative conditions of the lumbar spine and covers intensity of pain, ability to lift, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. Each variable is rated on a 0- to 5-point scale, summarized, and converted into a percentage score. Scores range from 0 to 100, with a lower score indicating less severe pain and disability. For this patient population, the minimum clinically important difference for change in the mean ODI score is considered to be in the range of 8 to 10 points (6, 19, 21). The change in ODI score between baseline and 12 months after operation was classified as "deterioration" (increased ODI score of at least 8 points) or "no deterioration" (decreased, unchanged, or increased ODI score less than 8 points).

Data Collection and Registration by the NORspine Registry Protocol

Data were collected through the NORspine registry. In total 36 of 40 centers performing lumbar spine surgery in Norway report to NORspine. NORspine is linked to the National Registry and Statistics Norway, which contain information concerning everyone who either is or has been a resident in Norway. According to the Norwegian Directorate of Health, approximately 65% of all patients who undergo lumbar spine surgery in Norway are included in NORspine. This inclusion rate is presumably greater for lumbar spinal stenosis surgery, because the majority of these procedures are scheduled surgeries.

On admission for surgery, the patients completed the baseline questionnaire, which included questions about demographic and lifestyle issues in addition to the outcome measures. Information about marital status, educational level, employment status, body mass index, and tobacco smoking also was recorded. Intensity of pain was graded in 2 separate 0–10 Numerical Rating Scales (NRS) for back pain and leg pain where 0 equals no pain (20).

During the patient's hospital stay, using a standard registration form, the surgeon recorded data concerning diagnosis, previous lumbar spine surgery, comorbidity (including rheumatic diseases, hip/knee osteoarthritis, depression/anxiety, musculoskeletal pain, neurologic disorder, cerebrovascular disease, cardiovascular disease, vascular claudication, lung disease, cancer, osteoporosis, hypertension, endocrine disorders), American Society of Anesthesiologists (ASA) grade, duration of symptoms, treatment, and image findings.

The surgeons provided the following complications and adverse events to the NORspine registry: intraoperative hemorrhage requiring blood replacement, postoperative hematoma requiring repeated surgery, unintentional durotomy, cardiovascular complications, respiratory complications, anaphylactic reactions, and wrong-level surgery. Patients reported the following complications if they occurred within 3 months of surgery: wound infection, urinary tract infection, pneumonia, pulmonary embolism, and deep venous thrombosis.

A questionnaire was distributed to patients by regular mail 3 and 12 months after surgery, completed at home by the patients, and returned in the same way. The patients who did not respond received one reminder with a new copy of the questionnaire.