

BMJ Open Comparative effectiveness of microdecompression and laminectomy for central lumbar spinal stenosis: study protocol for an observational study

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ABSTRACT

Introduction: This observational study is designed to test the equivalence between the clinical effectiveness of microdecompression and laminectomy in the surgical treatment of central lumbar spinal stenosis. Lumbar spinal stenosis is the most frequent indication for spinal surgery in the elderly, and as the oldest segment of the population continues to grow its prevalence is likely to increase. However, data on surgical outcomes are limited. Open or wide decompressive laminectomy, often combined with medial facetectomy and foraminotomy, was formerly the standard treatment. In recent years a growing tendency towards less invasive decompressive procedures has emerged. At present, many spine surgeons perform microdecompression for central lumbar spinal stenosis.

Methods and analysis: Prospectively registered treatment and outcome data are obtained from the Norwegian Registry for Spine Surgery. The primary outcome measure is change in Oswestry disability index between baseline and 12-month follow-up. Secondary outcome measures are changes in health-related quality of life measured by the Euro-QoL-5D between baseline and 12-month follow-up, perioperative complications, and duration of surgical procedures and length of hospital stay.

Ethics and dissemination: The study has been evaluated and approved by the regional committee for medical research in central Norway and all participants provided written informed consent. The findings of this study will be disseminated through peer-reviewed publications.

Trial registration number: Clinicaltrials.gov (NCT02006901).

BACKGROUND

Lumbar spinal stenosis most often results from a gradual, degenerative ageing process. It is the most frequent indication for spinal surgery in the elderly, and as the oldest segment of the

Strengths and limitations of this study

- The main limitation of this study is that analyses are not based on randomised treatment assignments.
- Another potential weakness of the present study is the expected loss to follow-up of approximately 22%.
- The results are strengthened by the use of specific inclusion and exclusion criteria, the large sample size and the re-evaluation of the pre-operative diagnostic imaging.

population continues to grow its prevalence is likely to increase.^{1–3} Management of spinal stenosis can be challenging and requires the integration of patients' symptoms, clinical findings and diagnostic imaging. There is growing evidence that decompressive surgery offers an advantage over non-surgical management for selected patients with persistent severe symptoms.^{4–8} Currently it is generally accepted that surgery is indicated if conservative or non-surgical management fails. Improvement in radiating pain, neurogenic claudication, functional status and quality of life are the main treatment goals. Open or wide decompressive laminectomy, often combined with medial facetectomy and foraminotomy, was formerly the standard treatment.³ However, in recent years a growing tendency towards less invasive decompressive procedures has emerged. In a study from 2005, unilateral microdecompression for bilateral decompression, and bilateral microdecompression were shown to be promising treatment alternatives when compared with open decompressive laminectomy.⁹ Since then unilateral and bilateral microdecompression have been adopted by many spine surgeons, and as is the case in Norway, more frequently among neurosurgeons than orthopaedic surgeons. However,



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there is still a need to evaluate the benefits and risks of different decompressive surgical procedures for lumbar spinal stenosis.

AIMS OF THE STUDY

The primary aim of this observational study is to test the equivalence of changes in functional outcomes measured with the Oswestry disability index (ODI) between baseline and 12-month follow-up after decompressive laminectomy and microdecompression with unilateral or bilateral approach in patients with single and two-level central lumbar spinal stenosis using data from the Norwegian Registry for Spine Surgery (NORspine). Secondary outcome measures are changes in health-related quality of life (HRQL) measured with the Euro-Qol-5D (EQ-5D) between baseline and 12-month follow-up, perioperative complications, duration of surgical procedures and length of hospital stays.

METHODS AND MATERIALS

Study population

Data for this cohort study will be collected through the NORspine, which was established in 2006 and is a comprehensive clinical registry for quality control and research. Participation in the registration by either providers or patients is not mandated, nor is participation required as a necessary condition for a patient to gain access to healthcare or for a provider to be eligible for payment for the healthcare service. Patients operated between October 2006 and December 2011 will be screened for study eligibility. Follow-up time from the date of the operation (baseline) in this study is 12 months.

Inclusion criteria

1. Diagnosis of central lumbar spinal stenosis.
2. Operation in ≤ 2 lumbar levels with either open decompressive laminectomy, bilateral microdecompression or unilateral microdecompression for bilateral decompression in the time period between October 2006 and December 2011.
3. Included in the NORspine registry.

Exclusion criteria

1. History of lumbar fusion.
2. Previous surgery in the lumbar spine.
3. Discectomy as part of the decompression.
4. Associated pathological entities such as disc herniation, spondylolisthesis or scoliosis.

Primary outcome measure

The primary outcome measure is change in functional outcome between baseline and 12-month follow-up measured with V.2.0 of ODI,¹⁰ translated into Norwegian and tested for psychometric properties by Grotle *et al.*¹¹ ODI is one of the principal condition-specific outcome

measures used in the management of spinal disorders. It has been extensively tested, has shown good psychometric properties, and is considered applicable in a wide variety of settings. ODI contains 10 questions on limitations of activities of daily living. Each variable is rated on a 0–5-point scale, summarised and converted into a percentage score. Scores range from 0 to 100, with lower score indicating less severe pain and disability.

Secondary outcome measures

Secondary outcome measures are:

1. Changes in HRQL measured with the EQ-5D between baseline and 12-month follow-up;
2. Perioperative complications;
3. Duration of surgical procedures and hospital stays.

EQ-5D is a generic and preference-weighted measure of HRQL.¹² The Norwegian version of EQ-5D has shown good psychometric properties.¹³ EQ-5D evaluates five dimensions: mobility, self-care, activities of daily living, pain, and anxiety and/or depression. For each dimension, the patient describes three possible levels of problems (none, mild-to-moderate and severe). This descriptive system therefore contains $3^5=243$ combinations or index values for health status. EQ-5D has been validated for patient populations similar to that in our study.¹³ Total score ranges from -0.6 to 1 , where 1 corresponds to perfect health and 0 to death. Negative values are considered to be worse than death.

Surgeons provide the following complications and adverse events to the NORspine registry: intraoperative haemorrhage requiring blood replacement, unintentional durotomy, nerve injury, cardiovascular complications, respiratory complications, anaphylactic reactions and wrong level surgery. Patients report the following complications if they occur within 3 months of surgery: wound infection, urinary tract infection, pneumonia, pulmonary embolism and deep vein thrombosis.

Data collection and registration by the NORspine registry protocol

On admission for surgery, patients complete the baseline questionnaire, which includes questions about demographics and lifestyle issues in addition to the outcome measures. Information about marital status, educational level, employment status, body mass index and tobacco smoking is available in the NORspine registry. During the hospital stay, using a standard registration form, the surgeon records data concerning diagnosis, comorbidity, *American Society of Anesthesiologists* (ASA) grade, duration of symptoms, treatment and image findings. A questionnaire is distributed by regular mail 3 and 12 months after surgery, completed at home by patients, and returned in the same way. Patients who do not respond receive one reminder with a new copy of the questionnaire. Patients complete preoperative questionnaire data and postal follow-up questionnaires without any assistance from the surgeon.

Diagnostic imaging

In the NORspine registry surgeons provide data concerning preoperative diagnostic imaging and the results of these investigations. For patients with available preoperative MRI we review the images and perform a morphological grading of the severity of spinal stenosis as described by Schizas *et al.*¹⁴ This morphological grading from A to D is based on the cerebrospinal fluid/rootlet ratio as seen on axial T2-weighted MRI. The original publication defines four subgroups of grade A. We will not use these subgroups since they all are defined as no or minor stenosis. In the morphological grading A–D, we define grade A as no stenosis, grade B as relative stenosis and grades C and D as significant stenosis. The clinicians who review the preoperative MRI and perform the morphological grading of the severity of spinal stenosis will be blinded with regard to treatment allocation (laminectomy or microdecompression).

Surgical procedures

There is variation in the surgical management of lumbar spinal stenosis, and in the following only a general description is provided for each procedure. When a decompressive laminectomy (group 1) is performed the spinous process and the laminae of the involved level(s) as well as the medial aspects of the facet joints are resected.⁹ Microdecompression (group 2) can be performed using a bilateral or unilateral approach depending on the surgeon's preference and the individual patient's anatomy and symptoms. Unlike a decompressive laminectomy, the spinous process and the supraspinous and interspinous ligaments are left intact when performing a microdecompression.⁹ Bilateral microdecompression means resection of the bone from the inferior aspect of the cranial lamina, and, occasionally, from the superior aspect of the subjacent lamina. Resection of the medial aspect of the facet joint is performed to alleviate the lateral recess. Flavectomy is performed to expose the spinal canal. The same procedure is then repeated on the contralateral side. When performing a unilateral microdecompression for bilateral decompression, the spinous process is undercut in addition to the ipsilateral decompression. By angling the microscopic view and occasionally tilting the operating table following ipsilateral decompression, resection of the contralateral ligamentum flavum and the medial aspects of the contralateral facet joints are possible.⁹

Statistical analyses

This study will use mixed linear models to test the equivalence of the clinical effectiveness of microdecompression and laminectomy. If the population effect of treatment on changes is ≤ 8 , the treatments are considered equal with respect to effectiveness. The minimal clinical important difference for change in the mean ODI score is considered to be in the range of 8–10 points.^{15–17} Assuming a correlation of 0.5 between

baseline and follow-up measurements and an SD of 18 for the individual measurements, the study will have 90% power with 132 patients in each treatment group. The minimal clinical important difference for ODI in patients with lumbar spinal stenosis in the same study population will be analysed in a separate ongoing study. In the analyses of primary and secondary outcome measures adjustments for the number of levels operated (one or two), age, body mass index and preoperative ODI will be made. Supplementary analyses with adjustments for baseline covariates and for the propensity to receive microdecompression will be performed. We plan to conduct subgroup analyses to compare the clinical effectiveness of microdecompression and laminectomy in patients aged ≥ 70 years. In addition, we plan to conduct subgroup analyses to compare the clinical effectiveness of microdecompression and laminectomy in obese patients (body mass index ≥ 30). Statistical significance level is defined as $p \leq 0.05$ with no adjustments made for multiple comparisons. Baseline and follow-up measurements will be assumed to be normally distributed provided this assumption is confirmed by Q–Q plots. To evaluate the magnitude of change in EQ-5D score, effect sizes will be estimated according to the method of Kazis *et al.*¹⁸ An effect size of 0.8 or more is considered to be large.

Missing data

For the primary outcome (change in ODI between baseline and 12-month follow-up) we will perform a complete case analysis and a full information analysis using mixed linear models. In the complete case analysis for the primary outcome patients with missing ODI data at 12-month follow-up will be excluded. A study on an equivalent patient population showed no difference in outcomes between responders and non-responders.¹⁹

Study limitations

The main limitation of this study is that analyses are not based on randomised treatment assignments. However, the results are strengthened by the use of specific inclusion and exclusion criteria, the large sample size and the re-evaluation of the preoperative diagnostic imaging.²⁰ Another potential weakness of the present study is the expected loss to follow-up of approximately 22%, which is relatively high.¹⁹ A third possible limitation is the growing tendency towards microdecompression, especially among neurosurgeons, during the study period.

CONCLUSION

In this article, we present a protocol for an observational study designed to test the equivalence between the clinical effectiveness of microdecompression and laminectomy in the surgical treatment of central lumbar spinal stenosis. Prospectively registered treatment and outcome data are obtained from the NORspine. We have

discussed some of the methodological issues pertinent to the successful execution of this surgical observational study.

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Contributors All authors read and approved the final manuscript. SG is the guarantor and gave the original concept of the study. USN and SG were involved in the study design, collection of the data, statistics and writing of the manuscript. ASJ and SMC took part in the study design, statistics and writing. OS and ØPN contributed in the study design and writing. CW, VR and GL participated in the collection of data. TKS was involved in the study design, collection of the data and writing of the manuscript. ØS contributed in the study design and statistics.

Competing interests None.

Patient consent Obtained.

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