Clinical Study

Reoperation rate after surgery for lumbar spinal stenosis without spondylolisthesis: a nation-wide cohort study

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Abstract

BACKGROUND CONTEXT: Lumbar spinal stenosis is one of the most common degenerative spine diseases. Surgical options are largely divided into decompression only and decompression with arthrodesis. Recent randomized trials showed that surgery was more effective than nonoperative treatment for carefully selected patients with lumbar stenosis. However, some patients require reoperation because of complications, failure of bony fusion, persistent pain, or progressive degenerative changes, such as adjacent segment disease. In a previous population-based study, the 10-year reoperation rate was 17%, and fusion surgery was performed in 10% of patients. Recently, the lumbar fusion surgery rate has doubled, and a substantial portion of the reoperations are associated with a fusion procedure. With the change in surgical trends, the longitudinal surgical outcomes of these trends need to be reevaluated.

PURPOSE: To provide the longitudinal reoperation rate after surgery for spinal stenosis and to compare the reoperation rates between decompression and fusion surgeries.

STUDY DESIGN/SETTING: Retrospective cohort study using national health insurance data.

PATIENT SAMPLE: A cohort of patients who underwent initial surgery for lumbar stenosis without spondylolisthesis in 2003.

OUTCOME MEASURES: The primary end point was any type of second lumbar surgery. Cox proportional hazards regression modeling was used to compare the adjusted reoperation rates between decompression and fusion surgeries.

METHODS: A national health insurance database was used to identify a cohort of patients who underwent an initial surgery for lumbar stenosis without spondylolisthesis in 2003; a total of 11,027 patients were selected. Individual patients were followed for at least 5 years through their encrypted unique resident registration number. After adjusting for confounding factors, the reoperation rates for decompression and fusion surgery were compared.

RESULTS: Fusion surgery was performed in 20% of patients. The cumulative reoperation rate was 4.7% at 3 months, 7.2% at 1 year, 9.4% at 2 years, 11.2% at 3 years, 12.5% at 4 years, and 14.2% at 5 years. After adjusting for confounding factors, the reoperation rates for decompression and fusion surgery were compared.

FDA device/drug status: Not applicable.


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5 years. The adjusted reoperation rate was not different between decompression and fusion surgeries (p = .82). The calculated reoperation rate was expected to be 22.9% at 10 years.

CONCLUSIONS: The reoperation rate was not different between decompression and fusion surgeries. With current surgical trends, the reoperation rate appeared to be higher than in the past, and consideration of this problem is required. © 2013 Elsevier Inc. All rights reserved.

Keywords: Reoperation rate; Decompression; Fusion; Lumbar spine; Surgery

Introduction

Lumbar spinal stenosis is a common degenerative spinal disease. Recent randomized trials have shown that surgery is more effective than nonoperative treatment for carefully selected patients with lumbar stenosis [1–3]. Surgical options are largely divided into decompression only and decompression with arthrodesis. However, some patients require reoperation because of complications, failure of bony fusion, persistent pain, or progressive degenerative changes such as adjacent segment disease [4]. Fusion surgery had a higher probability of reoperation than decompression surgery during postoperative years 2 to 4 [4]. Additionally, although fusion surgery comprised only 10.6% of surgeries for lumbar spinal stenosis during 1990 to 1993, it increased 220% from 1990 to 2001 [5,6]. With the recent change in surgical trends, the longitudinal reoperation rate reflecting these changes needs to be reevaluated.

Population-based studies are less subject to selection or nonresponse biases than case-series studies, they do not miss reoperation events, and they have high statistical power [5]. The longitudinal reoperation rates should be determined using population-based data [4]. Martin et al. [5] analyzed patients operated on during 1990 to 1993 and showed that the reoperation rate was 17.1% more than 10 years of follow-up; moreover, there was no difference in outcome with the addition of fusion surgery. However, no population-based data are available reflecting this recent surgical trend, except for an analysis of elderly patients (>60 years) [4]. Deyo et al. [4] analyzed elderly patients (>60 years) operated on in 2004 with spinal stenosis, and the reoperation rate was 11% at 4 years.

The primary aim of the present study was to determine the effect of fusion surgery on the cumulative incidence of reoperation with population-based data for spinal stenosis without spondylolisthesis.

Materials and methods

The data source

All Korean citizens are beneficiaries of the Korean National Health Insurance (NHI) System [7]. All nationwide inpatient and outpatient data on diseases and services (procedures and operations) are coded and registered in the Korean National Health Insurance Corporation database, thus enabling the undertaking of population-based studies [7]. In addition, individual patients can be followed through use of their unique resident registration number, thereby making longitudinal analyses possible [7]. The data source was the same as previously published [7]. In Korea, a "fee-for-service" system has been the traditional route for reimbursement. Disease codes are standardized according to the Korean Classification of Disease, 4th version, which follows the International Classification of Disease, 10th version (ICD-10) [7]. The procedure codes were created by the Korean Health Insurance Review and Assessment Service (HIRA) to standardize the filing of claims for medical fees to HIRA. All health-care organizations in Korea use these standardized codes for disease and procedures, but recording of a more detailed surgical level and complexity of operation are not specified. The Korean Health Insurance Review and Assessment Service national database was used to identify a cohort of patients who underwent surgery.

Cohort

Patients who underwent lumbar spine surgery for spinal stenosis without spondylolisthesis between January 1, 2003, and December 31, 2003, were identified from the HIRA database. There were 47,316 patients who underwent spine surgery in 2003 [7]. Among them, those with a record of lumbar surgery in the preceding 5 years (1998–2002, n = 4,286), patients under 20 years (n = 1,305), and those with a concomitant disease code (fracture, neoplasm, or infection, n = 6,167) were excluded (Fig. 1) [5,7]. From the remaining 35,558 patients, 11,027 patients who underwent initial lumbar surgery in 2003 with a disease code of spinal stenosis and without a code of spondylolisthesis were selected and included in the present study (Fig. 1). The patients’ resident registration numbers were encrypted for privacy.

The surgical methods were divided into two categories: decompression and fusion surgery. The decompression category included discectomy, laminectomy, or both. Any procedure involving a fusion, with or without decompression, was classified as a fusion [5]. The Korean Health Insurance Review and Assessment Service provides general guidelines for fusion surgery in spinal stenosis. Those guidelines are symptomatic instability, intraoperative instability because of wide decompression, severe foraminal stenosis, and decreased disc height. Nearly all health-care organizations in Korea follow the NHI regulations to be reimbursed; so the guidelines could be regarded as a surgical indication for fusion.

All patients in the cohort were followed until December 31, 2008, by using their encrypted unique resident...
Potential confounding factors were age, gender, presence of comorbidity, diabetes, osteoporosis, and hospital type (tertiary-referral hospital [3rdH] vs. general hospital [GH] vs. hospital [H] vs. private clinic [C]). Medical comorbidity was assessed according to the “ICD-9 clinical modification and ICD-10 coding algorithms for Charlson Comorbidities” proposed by Quan et al. [8] If the primary or secondary diagnoses listed (as many as four diagnoses) at any hospital visit in 2003 included these disease codes, the patient was regarded as having comorbidity [9]. We analyzed diabetes separately from comorbidity because diabetes is a known predisposing factor for spinal stenosis [10] and is a known risk factor for complication [5,10–14]. Hospital type is defined by law according to the size and capability as 3rdH, GH, H, and C. In Korea, hospital type is defined by law [7]. General hospitals have at least eight departments, such as internal medicine, general surgery, obstetrics and gynecology, pediatrics, diagnostic radiology, anesthesiology, pathology, and laboratory medicine, with at least one board-certified doctor in each department and more than 99 beds [7]. Tertiary-referral hospitals are designated from among the GHs by the government. A 3rdH should have at least 20 departments and should include the basic requirements of a GH in addition to a residency training program, at least five operation rooms, and a variety of imaging/diagnostic tools used for computed tomography, magnetic resonance imaging, electromyography, angiography, gamma camera radiography, and Holter cardiac monitoring [7]. In addition, the portion of patients with difficult diseases (as designated by the Minister of Health and Welfare) should be more than 12% of the total number of annual inpatients [7]. Hospitals are the final type and are defined as lacking any of the essential departments or having between 30 and 99 beds [7]. Private clinics have less than 30 beds [7].
period. Fusion surgery was used as the reference standard. In each period, patients with an event (reoperation) and patients who died during the former period were excluded from the analysis. All graphs were plotted with SPSS software (version 18.0; IBM, Armonk, NY, USA), and statistical analysis was performed with SAS software (version 9.1.3; SAS Institute, Inc., Cary, NC, USA). A probability (p) value of less than .05 was regarded as significant.

Results

Overall outcome

The characteristics of the cohort are presented in Table 1. Decompression surgery was performed in 79.8% (8,795/11,027) of patients and fusion surgery comprised 20.2% (2,232/11,027) of patients. The most common age was 60s in both groups. Comorbidity was detected in 75.6% (8,338/11,027) of the patients (Tables 1 and 2). Fusion surgery was performed in 19.2%, 25.4%, 18.8%, and 11.4% of patients in 3rdH, GH, H, and C, respectively. During the 6-year follow-up, 14.8% (1,632/11,027) of the patients underwent reoperation. The cumulative reoperation rate was 4.7% at 3 months, 7.2% at 1 year, 9.4% at 2 years, 11.2% at 3 years, 12.5% at 4 years, and 14.2% at 5 years (Table 3 and Fig. 2). Among the surgical procedures, reoperation was needed in 1,307 (14.9%) patients after decompression and in 325 (14.6%) patients after fusion surgery. Male sex, presence of diabetes or comorbidity, and hospital type were significant risk factors for reoperation (Table 4). The adjusted reoperation rate was not different between decompression and fusion surgeries (p = .82, Table 4).

Early reoperation (within 90 days)

Reoperations were performed in 4.66% (514/11,027) of the patients during the first 90 days. During this period, 33 patients died. Among the reoperations, 67.1% (346/514) were performed within 30 days (Table 3). Male sex, presence of comorbidity, and hospital type were significant risk factors for reoperation (Table 4). The adjusted reoperation rate was not different between surgical procedures (p = .62) (Table 4).

Short-term reoperation (91–365 days)

For this analysis, the 514 patients who had an event (second lumbar surgery) within 90 days and the 33 dead patients were excluded; thus, 10,480 patients remained in the short-term reoperation cohort. Reoperations were performed in 2.6% (277/10,480) of these patients (Table 3). During the late period, 74 patients died. Male sex and the presence of diabetes or comorbidity were significant risk factors for reoperation (Table 4). The adjusted reoperation rate was not different between procedures (p = .40) (Table 4).

Midterm reoperation (1–6 years)

For this analysis, the 277 patients who had second lumbar surgery and 74 dead patients were excluded; thus, 10,129 patients remained in the midterm reoperation cohort. Reoperations were performed in 8.3% (841/10,129) of these patients (Table 3). During the late period, 390 patients died. The presence of diabetes or comorbidity and hospital type were significant risk factors for reoperation (Table 4). The adjusted reoperation rate was not different between procedures (p = .80) (Table 4).

Discussion

The present study provided nation-wide data regarding the longitudinal reoperation rate and a comparison of the reoperation rate between decompression and fusion surgeries for spinal stenosis without spondylolisthesis. In the present study, we included patients with spinal stenosis without concomitant diagnosis of spondylolisthesis because clinical outcomes differ with spondylolisthesis [5,6,16,17]. The longitudinal reoperation rate was 4.7% at 3 months, 7.2% at 1 year, 9.4% at 2 years, 11.2% at 3 years, 12.5% at 4 years, and 14.2% at 5 years. About half of all the reoperations were performed within 1 year after surgery (Table 3). Adding fusion surgery was not effective in reducing the reoperation rate during all periods (Table 4). Unfortunately, the reasons for performing the reoperations were not specified in the population-based data [7,18]. The cause of a reoperation in this cohort could be failure of the initial surgery or development of a new problem unrelated to the initial surgery [19]. Although the cause could not be specified, reoperation could be regarded as an unfavorable outcome [4–6,19,20]. However, reoperation cannot be
considered to directly reflect a poor outcome of the initial surgery without clinical data, which were not available with the administration data [5,6].

Reoperation rate with time

In the Spine Patient Outcome Research Trial for spinal stenosis (N=289, patients enrollment period 2000–2005), the reoperation rates were 8% and 13% for 2 and 4 years, respectively [1,2]. In the Maine Lumbar Spine Study (N=148, period 1990–1992), the reoperation rate reached 23% during 8 to 10 years [3,21]. Those data were obtained from a randomized controlled trial. We can also find the reoperation rate from population-based studies, although the causes were not specified (Table 5). Nation-wide population data from Sweden (Jansson et al. [20], N=9,644, cohort period 1989–1999) showed that the reoperation rate was 11% at 10 years. However, spondylolyisitis was not classified. Martin et al. [5] retrospectively analyzed population data for patients with spinal stenosis without spondylolyisitis (N=5,699, period 1990–1993), and their reoperation rate was 17.1% during the 10-year follow-up. The lumbar fusion surgery rate in the United States increased 220% from 1990 to 2001 [6], and reference data reflecting the recent surgical trend are required. Recently, Deyo et al. [4] showed that the reoperation rate was 10.6% among elderly patients (≥60 years, N=31,543, period 2004) with spinal stenosis during 4 years. In the present nation-wide study, we included all adults who underwent surgery during 2003. About half of all the reoperations occurred during the first year, and the annual increase in the reoperation rate showed a linear relationship (Fig. 3). A simple formula for calculating the crude reoperation rate at each time is as follows: reoperation rate = 5.75 + 1.71 × postoperative year (R^2 = 0.99, Fig. 3). If the reoperation rate increases in this way, the 10-year reoperation rate would be 22.9%; this figure is higher than that of the previous studies (11%–17%) [5,20]. Although the cause was not specified, the increased reoperation rate could be regarded as an increased number of patients with unfavorable outcomes [4–6,19,20]. We need to pay attention to the high reoperation rate during the first postoperative year (7.1%), comparing it with previous results (approximately 2%–5%) [5,20].
Is reoperation reduced by fusion surgery?

The present study showed that the reoperation rate was not reduced by adding fusion surgery. Previously, prospective trials had been performed to compare outcomes by adding fusion surgery for patients with spinal stenosis [22,23]. Better outcomes were obtained from patients who underwent fusion for degenerative stenosis and spondylolisthesis in 1991 [22]. However, the result of another randomized trial (1995) suggested no advantage of fusion over laminectomy alone in patients with spinal stenosis without instability [23]. Deyo et al. [24] showed that during 4 years postoperatively, patients who underwent fusion had a complication rate approximately 1.9 times higher and reoperation rates were no lower than in patients who had surgery without fusion. Martin et al. [5] were concerned that 62.5% of reoperations were associated with a diagnosis suggesting device complication or pseudarthrosis. Fusion surgery was performed in approximately 10% of patients in the previous population studies [5,20], but it has more than doubled (20%–27%) in recent studies, including the present one (Table 5) [4]. Recently, Deyo et al. [4] showed that the reoperation rate during 4 years did not differ when fusion surgery was added. The cohort comprised elderly patients...
patients (≥60 years), and fusion surgery was performed in 27% of patients [4]. A device-related complication was associated with 29.2% of reoperations [4]. In the present study, we included all ages above 20 years, and fusion surgery was performed in 20.2% of patients. Regardless of the recent increase of fusion surgery, the reoperation rate was not reduced according to the population-based studies including ours [4,5,25]. Moreover, the length of hospital stay, hospital charge, and postoperative complication were reported to be higher for patients with fusion surgery [19]. However, the result was obtained from the administration data without clinical/radiological information. The effectiveness of spinal arthrodesis needs to be verified with a randomized controlled clinical trial.

Other risk factors

Here, diabetes and comorbidities were risk factors for early or late reoperation (Table 5), as reported previously [5,11,26]. The low reoperation rate in female patients was exhibited a linear relationship to postoperative duration in years.

In population-based studies, including ours, such factors could not be controlled as strictly as is possible in a randomized clinical trial [4–6,19,29]. The study’s apparent lack of generalizability should be considered when interpreting the present results. Nonetheless, we showed longitudinal reoperation rates reflecting recent surgical trends, and the results obtained may be useful to the clinicians and patients.

Conclusions

The longitudinal reoperation rate was 4.7% at 3 months, 7.2% at 1 year, 9.4% at 2 years, 11.2% at 3 years, 12.5% at 4 years, and 14.2% at 5 years. The reoperation rate was not different between decompression and fusion surgeries.
With current surgical trends, the reoperation rate appeared to be higher than in the past, and consideration of this problem is required.

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