Does fusion improve the outcome after decompressive surgery for lumbar spinal stenosis?

A TWO-YEAR FOLLOW-UP STUDY INVOLVING 5390 PATIENTS

Whether to combine spinal decompression with fusion in patients with symptomatic lumbar spinal stenosis remains controversial. We performed a cohort study to determine the effect of the addition of fusion in terms of patient satisfaction after decompressive spinal surgery in patients with and without a degenerative spondylolisthesis.

The National Swedish Register for Spine Surgery (Swespine) was used for the study. Data were obtained for all patients in the register who underwent surgery for stenosis on one or two adjacent lumbar levels. A total of 5390 patients fulfilled the inclusion criteria and completed a two-year follow-up. Using multivariable models the results of 4259 patients who underwent decompression alone were compared with those of 1131 who underwent decompression and fusion. The consequence of having an associated spondylolisthesis in the operated segments pre-operatively was also considered.

At two years there was no significant difference in patient satisfaction between the two treatment groups for any of the outcome measures, regardless of the presence of a pre-operative spondylolisthesis. Moreover, the proportion of patients who required subsequent further lumbar surgery was also similar in the two groups.

In this large cohort the addition of fusion to decompression was not associated with an improved outcome.

Cite this article: Bone Joint J 2013;95-B:960–5.

Lumbar spinal stenosis (LSS) is the most common indication for spinal surgery in patients aged > 65 years and it is the most common diagnosis in patients requiring spinal surgery in Sweden. Decompression has been the treatment of choice for severe spinal stenosis and gives better results than non-operative treatment. The potential development of instability following decompression has long been the subject of debate.

Biomechanical studies have shown a correlation between the extent of decompression and post-operative instability. Decompression without concomitant fusion may lead to spondylolisthesis. The effect of spinal instability on the outcome following decompression is controversial: some authors suggest it is less favourable with a post-operative slip whereas others have questioned this. Some authors recommend concomitant fusion of the decompressed segment, especially in patients with a pre-operative degenerative spondylolisthesis, and a better outcome under these circumstances has been reported. Although these results have not been reproduced in other studies, the number of fusions being undertaken continues to increase.

However, in elderly patients with a high incidence of comorbidities, the addition of fusion can lead to an increased risk of life-threatening complications and a higher mortality rate. There is also the risk of accelerated degenerative changes adjacent to a lumbar fusion, which particularly affects older patients who undergo surgery for spinal stenosis. The main purpose of this study was to compare satisfaction at two years after decompression alone with that following decompression and fusion in patients with spinal stenosis with and without a pre-operative degenerative spondylolisthesis.

Patients and Methods

The National Swedish Register for Spine Surgery (Swespine) was used for the study. This register was started in 1993 and is a prospective registration of surgery for spinal disorders. It includes > 80% of the total number of operations undertaken for degenerative lumbar spinal disorders in Sweden. Pre-operatively, patients complete various questionnaires, including the Oswestry Disability Index (ODI), EuroQol Five Dimensions (EQ-5D), back and leg pain according to the visual
analgesics, estimated walking distance, working conditions and time taken off work. The same questionnaires and those recording global assessment\textsuperscript{28} are completed one, two, five and ten years post-operatively. The current protocol of the register has been validated.\textsuperscript{2,29} The postal questionnaires are not related to a hospital visit and are self-completed without the assistance of any other person involved in their treatment. Only surgical details, diagnosis and peri-operative complications are recorded by the surgeon.

Data were obtained for all patients in the register aged \textgreater{} 50 years at the time of surgery who underwent surgery for lumbar stenosis on one or two adjacent levels between L2 and L5 between 1 January 1998 and 1 July 2008. Both patients with and those without spondylolisthesis pre-operatively were included. In all, 8785 patients fulfilled these criteria. The surgery was undertaken in 48 hospitals. In seven of these the follow-up procedures had failed, and none of their 643 patients were assessed two years post-operatively. This left 8142 patients for analysis, and of these, 5390 had been assessed at two years. The 2752 patients who were not assessed at this time did not differ from the patients with complete follow-up data. A flow-chart of the participants in the study is shown in Figure 1.

The diagnosis of spinal stenosis is recorded by the surgeon and pre-operative spondylolisthesis is defined as a slip \textgreater{} 3 mm on pre-operative radiographs. A validation of the incidence of pre-operative degenerative spondylolisthesis using the radiographs of 167 patients from three hospitals was undertaken by two of the authors (PF and BS), who were blinded to the data in the register. The last radiological examination (MRI, CT or plain radiographs) before surgery was analysed. The assessments of the two observers were concordant in 84\% of patients and the information in the register agreed with the assessment of at least one of the observers in 87\%.

We defined a further operation as a second operation at the same level as the index procedure, a subsequent operation in another part of the lumbar spine for spinal stenosis, or an operation for post-operative instability. We did not have ethical permission to use patients’ full identification in the calculation of clinical outcome unlike for the analysis of subsequent operations. Thus the number and type of further operations were not known for exactly the same (number) cohort of patients as the patient-reported outcomes at the two-year follow-up. These criteria were fulfilled by 9651 patients, who were then used for the estimation of the rate of further surgery. This cohort was similar to, and included, the patients used for the other variables. All patients in the register aged \textgreater{} 50 years who underwent surgery for spinal stenosis before 1 July 2008 were used in the calculation of the rate of further surgery, regardless of operated levels or whether they had completed the two-year follow-up. The study had ethical approval.

**Statistical analysis.** The statistical calculations were performed using SAS v9.1 (SAS Institute, Cary, North Carolina). For continuous dependent variables, adjusted means were estimated using the MIXED procedure in the SAS package. For dichotomous dependent variables, multivariable logistic regression (PROC GENMOD) was used to assess odds ratios (OR) with 95\% confidence intervals (CI). The models were adjusted for age (continuous), gender, smoking, duration of symptoms, previous spinal surgery, baseline analgesic use, and in addition baseline values for the studied variable. In order to compensate for possible differences in patient selection and surgical technique between the hospitals, a frailty component was included in all models to handle within-hospital dependencies.

**Results**

A total of 4259 patients (79\%) were treated with decompression alone and 1131 (21\%) had combined decompression and fusion. Pre-operatively the fusion group had a higher proportion of women, more back pain and a higher percentage of degenerative spondylolisthesis (Table I). Most fusions were instrumented (n = 933, 82.5\%) and the remainder were not.

A total of 1306 patients (24\%) had a spondylolisthesis pre-operatively. A total of 651 patients (50\%) with spondylolisthesis and 480 (12\%) without had a fusion. More patients with a pre-operative spondylolisthesis were female (n = 956, 73\%) than those without (n = 2101, 51\%). The mean VAS for back pain was similar in patients with and without a pre-operative spondylolisthesis (58 vs 55). Table I shows the pre-operative characteristics of the patients.

At the two-year follow-up significant improvements were noted for all outcome measures regardless of surgical method or the presence of degenerative spondylolisthesis.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{flow_diagram}
\caption{Flow diagram showing the patients included in the study.}
\end{figure}
There were no differences in the mean EQ-5D or ODI after both forms of surgical treatment, regardless of the presence of a spondylolisthesis pre-operatively (Table II).

In the two subgroups with and without pre-operative spondylolisthesis there were no differences in the mean scores for back or leg pain between the two treatment groups at the two-year follow-up (Table II), and no differences in analgesic use: 32% of the patients in both groups regularly used analgesics (1343 in the decompression group and 362 in the decompression + fusion group). However when the subgroups are pooled together the large sample size gives a significant value for difference in back pain ($p = 0.04$) but with minimal difference in VAS and with overlapping confidence intervals, with 34.6 to 36.7 for decompression vs 31.3 to 35.2 for decompression + fusion.

**Mobility and overall satisfaction.** There were no differences in the odds of improvement of mobility or overall satisfaction between the two treatment groups. Compared with decompression only, those treated with decompression and fusion had an adjusted OR of 1.01 (95% CI 0.85 to 1.19) for having improved mobility and OR of 1.08 (95% CI 0.94 to 1.24) for a self-evaluated satisfactory result from the surgery.

**Fusion technique.** There was no difference between the results following instrumented and non-instrumented fusion.
(95% CI 0.55 to 1.74) when instrumented was compared with non-instrumented fusion. The same comparison rendered an adjusted OR for the regular use of analgesics of 1.01 (95% CI 0.73 to 1.40).

**Further operations.** The rate of further surgery for spinal stenosis or post-operative instability was 7.0% (95% CI 6.4 to 7.6) after decompression (n = 7407), and 8.1% (95% CI 7.0 to 9.2) after decompression and fusion (n = 2337). The mean time between the first and the second procedures was 27 months (4 days to 11 years).

**Discussion**

We found no patient-reported differences two years postoperatively when the patients treated with decompression only were compared with those treated with decompression and fusion and all had significant improvements in outcome measures. This applied to all the variables regardless of the presence of a degenerative spondylolisthesis pre-operatively.

When only decompression was carried out, the improvement in back pain was similar to the improvement in leg pain, irrespective of any pre-operative spondylolisthesis.

Due to the large sample size when all patients are pooled and analysed, regardless of the presence of pre-operative spondylolisthesis, statistical significance (p = 0.04) could be achieved regarding back pain. However, the confidence intervals are overlapping, and the difference in VAS is minimal and not clinically relevant. In the annual report of SWESPINE, the minimal clinically important difference (MCID) for VAS after spine surgery was estimated to be 14 points.

The hypothesis that patients with spinal stenosis might suffer from instability after decompression has been suggested by several authors. Some clinical studies have reported unchanged or worsened back pain after decompression without fusion, suggesting that decompression should be accompanied by fusion. Others, however, have observed improvement in both leg and back pain after decompression without fusion.

The evidence comparing decompression to decompression with fusion is scarce in patients with spinal stenosis but without pre-operative spondylolisthesis. In a study by Grob et al, 45 patients were randomly selected to undergo decompression or decompression and fusion, and there were no differences in outcome at a mean follow up of 28 months. Similar findings were reported in a meta-analysis by Niggemeyer et al, including 1668 patients with a mean follow-up of 4.7 years. There are also few previous studies comparing decompression only with decompression and fusion in patients with pre-operative spondylolisthesis.

In a study by Herkowitz and Kurz 50 patients were followed prospectively for between two and four years (mean three years). Of the 25 patients who had undergone fusion, 96% had a good or excellent outcome, compared to 44% of those who had undergone decompression. The fusion group also had significantly less leg and back pain. A meta-analysis by Mardjetko et al including 391 patients, and a retrospective study by Lombardi et al including 47 patients followed for between two and seven years (mean 2.7 years), as well as a systematic review by Martin et al, all came to the conclusion that patients with spinal stenosis and a degenerative spondylolisthesis who underwent decompression and fusion fared better than those who underwent decompression alone. In our study, patients with and without a degenerative spondylolisthesis had the same degree of back pain pre-operatively. Pearson et al described the baseline values of back and leg pain and ODI were similar in patients with and without a degenerative spondylolisthesis. We suspect that the role of degenerative spondylolisthesis has been overestimated. Nevertheless, in our work the higher proportion of patients with a degenerative spondylolisthesis in the fusion group is assumed to reflect the widespread practice of fusing a slipped segment when performing decompression for spinal stenosis. Klein-stueck et al recently found better results when fusion was added to decompression in patients with spinal stenosis and a degenerative spondylolisthesis. However, when analysing back pain and leg pain, the amount of pain-reduction for the two methods was compared. The reduction in back pain was greater after fusion, but since these patients had more back pain pre-operatively, the level of back pain was similar in the two groups at one-year follow-up.

Several observational studies have compared decompression alone to decompression with fusion in patients with and without a pre-operative spondylolisthesis. A retrospective study by Postacchini and Cinotti on 40 patients concluded that fusion gave better results, partly because of reduced bone regrowth and further stenosis after decompression without fusion eight years post-operatively. In a prospective study that included 124 patients and a mean follow-up of 5.8 years, Fox et al reported a better outcome in patients with combined decompression and fusion. However, no differences between the two groups could be detected in prospective studies of eight and two years’ follow-up, by respectively Rompe et al, who included 117 patients, and Katz et al, who included 272 patients. In a prospective study by Jansson et al, 285 patients from the Swedish Spine Register demonstrated no differences in health-related quality of life (EuroQol) one year after surgery. Cornefjord et al performed a retrospective study on 96 patients with a mean follow-up of 7.1 years and found no differences in outcome those patients who had decompression alone and those who had decompression and fusion.

Despite our relatively broad definition of further surgery, the rate of these procedures in this study is lower than in others. We included not only a second operation at the same level but also any subsequent lumbar decompression or fusion for stenosis or instability. A register study by Martin et al including 5699 patients showed a rate of further surgery of 17% after decompression and 20% after fusion. Jansson et al included 9664 patients from the Swedish National Inpatient Register and showed a rate of further surgery of 11%, with a slightly – albeit not significantly – lower risk when fusion was performed. In other studies on
smaller populations of patients the rate of further surgery varied from 5% to 24%, 30,40-42

A possible reason for the low rate of further surgery in our study was the higher mean age of the patients compared with that in other studies. Martin et al. 38 describes patients who are younger and found that insurance issues about workers’ compensation were important predictors of a higher risk of further surgery. We conclude that the definition of further surgery is not clear among surgeons, and the data in the register relating to further surgery are difficult to evaluate.

We did not assess the complications of surgery. It has recently been reported that the complications are poorly identified and under-recorded in the Swedish Register. 43 In a study by Deyo et al, 19 which included 32 152 patients with Medicare claims after surgery for spinal stenosis, the OR of having a life-threatening complication was 2.6 after simple fusion compared to decompression alone. Further, the risk of readmission within 30 days was higher after fusion than after decompression, with an OR of 1.9. 19

Our study has limitations. The number of patients lost to follow-up was high, with 2752 (34%) not completing the two-year milestone. However, the pre-operative characteristics and the proportions of the two surgical methods among patients lost to follow-up did not differ from the studied group. Solberg et al. 44 evaluated the outcome in patients lost to follow-up in a prospective study of patients who underwent surgery for degenerative lumbar disorders and found that non-responders had the same result as responders. Thus, we can assume that loss to follow-up does not affect the conclusions of this study.

Another limitation was that there may have been selection bias in an individual surgeon’s interpretation of the patient’s problem and choice of treatment. Those treated with fusion might theoretically have a worse prognosis because of their pre-operative status, and thereby gain more in absolute post-operative improvement. We observed only modest differences, however, in baseline characteristics of pain and function between the categories of patients, and such pre-operative differences were considered in our multivariable models.

We also acknowledge that the pre-operative radiological data in the register rely on the surgeon’s assessment of the radiographs and are not standardised. The identification of spondylolisthesis might be inaccurate, and the limit of 3 mm is close to the accuracy achieved by many radiological techniques. 45,46 However, the validation of the incidence of pre-operative degenerative spondylolisthesis that we performed led us to conclude that this information allows an analysis of this group of patients as a whole.

Our results question whether there is a need for more extensive surgery in the form of fusion when decompression is undertaken. Although this was not a randomised study, we consider our results to make a valuable contribution, with the main strength being the large sample size and the nationwide population-based design. Several authors have pointed out the validity of observational studies and their ability to explore databases rich in clinical information. 47,48 We have limited this study to the most common cases of spinal stenosis, i.e. those involving one or two lumbar levels in older patients. The conclusions cannot be extended to include the treatment of patients with multi-level stenosis, congenitally narrow spinal canals and poor spinal balance, as in those with a degenerative scoliosis.

Our conclusion is that, in elderly patients with one- or two-level lumbar spinal stenosis, with or without a degenerative spondylolisthesis, surgery can probably be limited to the less invasive procedure of decompression alone in order to avoid unnecessary complications.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

This article was primarily edited by J. Scott and first-proof edited by D. Rowley.

References

DOES FUSION IMPROVE THE OUTCOME AFTER DECOMPRESSIVE SURGERY FOR LUMBAR SPINAL STENOSIS?


