

# Commentary on: Laminectomy plus fusion versus laminectomy alone for lumbar spondylolisthesis by Ghogawala Z, Dziura J, Butler WE, Dai F, Terrin N, Magge SN, *et al.* NEJM 2016;374 (15):1424-34

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Received: 25 April 16 Accepted: 16 May 16 Published: 22 September 16

## Abstract

**Background:** How does an article involving only 66 patients randomized into two spinal surgical groups get into the New England Journal of Medicine? Nevertheless, this one did. The article by Ghogawala *et al.* entitled Laminectomy plus fusion versus laminectomy alone for lumbar spondylolisthesis, compared the efficacy/outcomes of pedicle/screw/rod instrumented posterolateral lumbar fusions vs. decompressions alone for treating lumbar stenosis with grade I degenerative spondylolisthesis (DS).

**Methods:** They designed a randomized controlled study involving only 66 patients between the ages of 50–80 (average age: 67) with lumbar stenosis and “stable” DS (3–14 mm). Outcomes were measured utilizing the physical measures from the Short Form 36 (SF-36) up to 4 postoperative years, and the Oswestry Disability Index (ODI) up to 2 postoperative years. Data were available for 86% of patients at 2, but only for 68% of the patients at 4 postoperative years.

**Results:** At 2 postoperative years, SF-36 scores were higher for the instrumented patients (28 patients) vs. decompressed (29 patients) patients. However, the scores were comparable for both groups using the ODI at 4 years. SF-36 scores, however, remained higher for the 19 remaining instrumented patients. Additionally, reoperation rates were 14% for fusions and a staggering 34% for decompressions alone.

**Conclusions:** The authors concluded; laminectomy with fusion offered a “slightly greater but clinically meaningful improvement in overall physical health-related quality of life vs. laminectomy alone.” Rather, it should have read there were no statistically significant differences between the two groups and an insufficient number of patients were included in the study at all stages.

**Key Words:** Efficacy study, fusion, laminectomy, lumbar spondylolisthesis

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10.4103/2152-7806.191061

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**How to cite this article:** Epstein NE. Commentary on: Laminectomy plus fusion versus laminectomy alone for lumbar spondylolisthesis by Ghogawala Z, Dziura J, Butler WE, Dai F, Terrin N, Magge SN, *et al.* NEJM 2016;374 (15):1424-34. Surg Neurol Int 2016;7:S644-7.

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## INTRODUCTION

How does an article involving only 66 patients randomized into two spinal surgical groups get into the *New England Journal of Medicine* (NEJM)? Nevertheless, this one did. The article by Ghogawala *et al.* entitled Laminectomy plus fusion versus laminectomy alone for lumbar spondylolisthesis, compared the efficacy/outcomes of pedicle/screw/rod instrumented posterolateral lumbar fusions versus decompressions alone for treating lumbar stenosis with grade I degenerative spondylolisthesis (DS). The question was whether fusion would offer greater improvement/outcomes versus decompression alone.

## MATERIALS AND METHODS

The authors designed a randomized controlled study that ended up involving just 66 patients between the ages of 50–80 (average age: 67) with lumbar stenosis and "stable" DS (3–14 mm). Originally, the authors wanted to enroll 100 patients and to randomly assign at least 64, along with maintaining 40 patients in an observational cohort. However, here, the original 66 patients declined by 2 years to 57 patients (86%) and by 4 years to only 45 (68%) patients. Of interest, the study was originally scheduled to run for 5 years, but the dropout rate was too high.

### Proposed surgery

The surgical procedures offered to address stenosis/DS included decompression alone versus decompression with posterolateral lumbar instrumented pedicle screw/rod fusion. Decompressions reportedly included; "complete laminectomy with partial removal of the medial facet joint." Those undergoing fusion had laminectomy with pedicle/screw/rod instrumentation and iliac crest autograft applied over the transverse processes.

### Surgeon enrollment criteria

Notably, for surgeons to enroll their patients in the study, they had to have performed only 100 laminectomies and 100 laminectomies with posterolateral instrumented fusions. This meant that a number of the surgeons were neophytes, and/or just out of residency. Certainly, it might help explain the high reoperation rate for laminectomy alone wherein they likely inadvertently removed much more than the medial facet, thus resulting in a higher rate of postoperative instability.

### Outcome assessment

Outcomes were measured utilizing the physical measures of the Short Form 36 (SF-36) and Oswestry Disability Index (ODI: Secondary measure) at 2 years postoperatively; 4 year outcomes were reported utilizing the SF-36. They also reported complications and the reoperation rates for each operative group. Notably, data were collected by study coordinators who also but "not

explicitly" collected information on blood loss, operative time, and length of hospital stay (LOS).

## RESULTS

The authors devoted most of the first paragraph of the results section to reviewing the number of patients not included in the study. Originally, 130 patients were identified; 66 (average age: 67) consented to become randomized (1 never underwent surgery), but 40 did not (agreed to be in the observational group).

### Outcomes

At 2 postoperative years, SF-36 scores were higher for the instrumented patients (28 patients) versus decompressed (29 patients). Conclusions for the SF-36 outcomes at 2 postoperative years were based on the following analysis; 24 of 28 in the fusion group and 20 of 29 in the decompression groups had "a prespecified minimal clinically important difference of 5 points in the SF-36 physical component summary score." It appears that with such small numbers and the complex statistical analysis performed that the authors were markedly "over-reaching" the given limitations of their data. They also observed that at 4 postoperative years, SF-36 scores still remained higher for instrumented patients (19 patients) vs. decompressed patients (26 patients); again, "over-reaching" would be my opinion, particularly considering the much reduced number of patients left in each cohort. Of interest, the ODI data failed to show any differences for the low back pain scores at 2, 3, and 4 postoperative years. Perhaps, this is why they considered the ODI their "secondary" outcome measure (e.g. in an attempt to ignore these findings).

### Reoperation rates

The reoperation rate was 14% for those undergoing fusions, and predominantly addressed adjacent level disease.

Notably, a staggering, unprecedented 34% reoperation rate was observed for those undergoing decompressions alone (e.g. requiring reoperations predominantly at the index level). For this latter group, one has to again ask, were neophytes performing these decompressions and was the reoperation rate so high because they were sacrificing more than the medial facet on a regular basis?

### Longer length of stay and blood loss for fusion procedures

As anticipated, longer lengths of stay (LOS) and greater estimated blood loss were noted for patients undergoing instrumented fusions.

## DISCUSSION

Many would agree with Weinstein *et al.* who reported that patients with spinal stenosis/DS undergoing surgery have better outcomes at 2 postoperative years versus

those not undergoing any surgery.<sup>[10]</sup> However, there is a long-standing controversy as to whether lumbar stenosis with DS is better managed with or without fusion.<sup>[6,9]</sup> In the study by Herkowitz and Kurz in 1991, involving only 50 patients, the authors determined that at 2.4 postoperative years, better outcomes were associated with those undergoing laminectomy with non-instrumented posterolateral intertransverse process fusions vs. laminectomy alone.<sup>[6]</sup> In a very biased analysis without adequate documentation Resnick *et al.* in 2014 noted that the majority of studies indicate superior outcomes for patients undergoing “some type of lumbar fusion procedure.”<sup>[9]</sup>

Nevertheless, other multiple other studies have demonstrated comparable outcomes with/without fusion for treating spinal stenosis with DS.<sup>[1,7,8]</sup> Utilizing a minimally invasive surgical technique (MIS) for focal decompression of stenosis with/without DS in 75 consecutive patients, Kelleher *et al.* in 2010 concluded that MIS decompression alone was “clinically effective” for most patients with stenosis/DS.<sup>[7]</sup> Chang *et al.* in 2014 concluded that stenosis/DS treated with unilateral laminotomy with bilateral decompression did well, and that lumbar fusion was often unnecessary.<sup>[1]</sup> Rampersaud *et al.* in 2014 specifically examined the management of lumbar stenosis with DS (grade I) treated with “anatomy-preserving decompression” versus decompression/fusion; at 2 postoperative years, SF-36 results were comparable.<sup>[8]</sup>

### Increased risks of adjacent level disease with instrumented lumbar fusion

Many studies have cited the increased risk of adjacent level disease following instrumented lumbar fusions performed for degenerative lumbar disease/stenosis with/without DS. In this study, Ghogawala *et al.* cited a 14% reoperation rate following decompressive laminectomy with instrumented posterolateral pedicle/screw fusions to address new adjacent level disease.<sup>[5]</sup> In Epstein’s 2015 and 2016 reviews of the old and new literature, adjacent level disease occurred in up to 30% of patients undergoing instrumented lumbar fusions, and reoperation rates following instrumented fusions approached 80% at 5 postoperative years.<sup>[2,3]</sup> Furthermore the addition of instrumentation did not “correlate with improved outcomes.” One study cited that the frequency of adjacent level disease warranting reoperation was 18.5% for instrumented fusions but was reduced to 5.6% for non-instrumented fusions.<sup>[2]</sup> Epstein found that for 336 patients undergoing initial average 4.7 level lumbar laminectomies with average 1.4 level non-instrumented fusions (mean follow-up of 7.1 years) addressing spinal stenosis with grade I (195 patients) or grade II spondylolisthesis (67 patients); the frequency of reoperations was only 2.7% (9 patients).<sup>[4]</sup>

### Limitations of this study

Ghogawala *et al.* tried very hard to avoid confronting the marked limitations of this study and its lack of statistical significance. They repeatedly stated that they originally screened 130 patients, enrolled 106, but unfortunately, only 66 remained to be randomly assigned to the treatment groups.<sup>[5]</sup> This was an extremely small number of total patients to start with, and was even smaller when broken into two groups that continued to diminish with time [2 years: 57 patients total (28 and 29 patients/group), 4 years: 45 patients total (19 and 26 patient/group)]. They based their main conclusion regarding the superiority of laminectomy with fusion for stenosis/DS on the SF-36. However, they only studied 3 of the 8 SF-36 outcomes measures, namely, Physical Function, Bodily Pain, and Vitality. They should certainly have included Physical Role Functioning even if they omitted General Health, Emotional Role, Social Role, and Mental Health. Furthermore, they were clearly “over-reaching” in their interpretation of the data. For instance, they concluded at 2, 3, and 4 postoperative years that the SF-36 physical component “suggests a sustained difference between treatments over time.” They then add “The between-group differences in the increase in SF-36 physical component summary score were small but clinically meaningful.” That does not actually sound scientific at all. Furthermore, they attempted to dismiss the ODI findings as just secondary: “We did not observe significant between group differences with respect to reductions in the ODI score.”

### CONCLUSIONS

Ghogawala *et al.* concluded that for patients with spinal stenosis and DS, laminectomy with fusion offered a “slightly greater but clinically meaningful improvement in overall physical health-related quality of life vs. laminectomy alone.” Rather, it should have read that there were no statistically significant differences between the two treatment groups, and that the number of patients in the study was insufficient at all stages. In short, I would again ask: How did this article involving only 66 patients randomized into two spinal surgical groups get into the NEJM?

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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