Epidural Glucocorticoid Injections in Patients with Lumbar Spinal Stenosis
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Epidural injections are common. An estimated 10 million to 11 million injections (2.2 million in the Medicare population) are administered annually in the United States. Although many injections are used for indications other than spinal stenosis, epidural injections have become almost an expected part of a comprehensive nonoperative treatment protocol in patients with this condition. Yet, evidence to support this practice is incomplete and conflicting. In a January 2013 review and recommendation statement, the North American Spine Society concluded that “there is insufficient evidence to make a recommendation for or against the efficacy of transforaminal epidural steroid injections in the treatment of lumbar radicular pain in the setting of foraminal stenosis” or “in the setting of central stenosis.” Similarly, a recent Cochrane review of nonsurgical treatment for spinal stenosis with neurogenic claudication concluded that supportive evidence for glucocorticoid injections was limited to “low-quality evidence.”

In this issue of the Journal, Friedly et al. report the results of a randomized trial comparing epidural injections containing a combination of a glucocorticoid and lidocaine with injections containing lidocaine only in patients who had lumbar central spinal stenosis and associated leg pain and disability.

Patients in both treatment groups had decreased pain and improved function at 3 and 6 weeks, with at most minor differences between the groups. Small but significant differences favored glucocorticoids at 3 weeks, but there were no significant differences in disability and ratings of the intensity of leg pain at 6 weeks (the coprimary outcomes of the study). With adjustment for the duration of pain (which was longer in the glucocorticoid–lidocaine group), there was a statistically significant but small difference between the groups in favor of glucocorticoids at 6 weeks in physical function, but no significant difference in leg pain. At 6 weeks, more patients in the glucocorticoid–lidocaine group than in the lidocaine-only group were satisfied with their treatment (67% vs. 54%), and the glucocorticoid–lidocaine group had greater improvement with respect to symptoms of depression.

Studies of spinal stenosis are difficult because stenosis includes many different subtypes. Most patients with stenosis have degenerative stenosis, as was the case in this study. Some patients have congenital stenosis with superimposed degenerative changes that are often present at multiple levels. Lumbar spinal stenosis is also classified on the basis of location (either central or lateral), but often stenosis exists in both places at the same time. In the present study, all patients had central stenosis, but we do not know whether some of these patients also had lateral stenosis or how many levels were stenotic in each patient. All patients in this study had leg pain, but we do not know whether the leg pain was present in the distribution of a nerve root (radicular) or more diffuse (consistent with neurogenic claudication). Whereas randomization would be expected to result in similar proportions of patients with various types of stenosis in both treatment groups, individual differences in the type and extent of stenosis as well as in the severity of stenosis may explain
why some patients have a response to treatment, whereas others do not. Overall results may not be generalizable to all subgroups.

Since this trial lacked a sham control group, it is impossible to know whether the observed improvements in the two groups reflect a therapeutic effect of the injections. Improvements may also be due to a placebo effect. Moreover, symptoms of stenosis are known to vary over time. In the short term, glucocorticoids appeared to confer a small benefit as compared with lidocaine alone, but the longer-term benefits anticipated with glucocorticoids did not occur. It is unclear why more patients in the glucocorticoid–lidocaine group reported that they were satisfied with their treatment. A systemic effect of glucocorticoids is a possible explanation. The glucocorticoid–lidocaine group had higher rates of cortisol suppression at 3 and 6 weeks; this indicated some systemic absorption.

Epidural glucocorticoid injections for lumbar spinal stenosis are generally considered to be safe, with minor transient side effects. However, serious or even catastrophic complications may occur (including paralysis, nerve damage, or death), as was recently highlighted in a safety announcement by the Food and Drug Administration (FDA), which added a warning to the label for these products. In the present study, there was a higher rate of complications in the glucocorticoid–lidocaine group than in the lidocaine-only group, but the adverse effects were generally minor and reversible.

Certainly, this study raises serious questions about the benefits of epidural glucocorticoid injections for spinal stenosis. In patients who nonetheless proceed with an epidural glucocorticoid injection, repeat injections should be avoided if there is no effect. This recommendation is consistent with recommendations of the North American Spine Society. At present, many insurance companies require epidural injections as part of nonsurgical treatment before surgery is approved. The current trial and the FDA safety announcement suggest that this requirement should be reconsidered.

On the basis of the largely negative results of the present trial and the lack of other rigorous data to support the use of glucocorticoid injections in these patients, I will remain cautious in prescribing epidural glucocorticoid injections for patients with lumbar spinal stenosis. Patients should be informed that the current best available data have not provided support for a clinically significant long-term benefit overall and that complications are possible.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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DOI: 10.1056/NEJMe1405475
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