Re: A Systematic Review to Assess Comparative Effectiveness Studies in Epidural Steroid Injections for Lumbar Spinal Stenosis and to Estimate Reimbursement Amounts

To the Editor,

We read with great interest the systematic review by Bresnahan et al [1] in which they assessed comparative effectiveness studies in epidural steroid injections for lumbar spinal stenosis and also estimated reimbursement amounts. They concluded that there was no evidence for epidural injections and that they were not cost effective.

It appears that the authors have missed the purpose of a systematic review, which is to highlight the findings and provide clinicians and other stakeholders a coherent recommendation that uses clear-cut methodologies that are transparent and reproducible and to provide a clinical utility of the therapy in question. Although the authors claim that they evaluated the articles for the presence of bias, the final recommendations reek of personal bias.

Bresnahan et al [1] seemingly used appropriate search criteria but failed to find all the manuscripts that were included by some of the authors of this letter in the past. In the search criteria through August 2012, the authors missed 3 systematic reviews [2-4] and 2 randomized, double-blind controlled trials [5,6] in which investigators assessed the effectiveness of caudal and lumbar interlaminar approaches with 1-year follow-up with comparative effectiveness of a local anesthetic with or without steroids. Both of the studies are of high quality and report positive results on a long-term basis. In addition, the authors also have missed another randomized trial by Wilson-MacDonald et al [7], who found that the use of either an epidural steroid injection or an intramuscular injection of local anesthetic and steroids showed positive results in the short-term. However, the authors did include multiple poor-quality studies with small sample sizes and short-term follow-ups.

Assessment bias appears to be extremely confusing. The authors state that using the standard evidence-based criteria, 5 of the 6 randomized controlled trials were judged to have low risk of bias from insufficient blinding or loss of follow-up. However, it is confusing that they have quoted 3 references, 12, 15, 17, from the manuscript. In addition, the authors have not shown the table of bias assessment and the resultant scores. In multiple systematic reviews, all of the studies included in this manuscript were judged with less than high quality or low risk of bias except the manuscript by Fukusaki et al [2-4]. Further, the studies had a multitude of issues, including not being performed with fluoroscopy and short follow-up periods, and the study by El Zahaar used almost 40 mL of solution without fluoroscopy. Brown et al, as described in the manuscript, included only 38 patients with a follow-up period of 6 weeks. Comparing a surgical intervention with a single epidural injection does not meet criteria by any standards, even though the authors did conclude that it was of high-risk bias.

In reference to the cost utility analysis, the authors have used all the costs of initial evaluations and magnetic resonance imaging costs in a hospital setting. This may be overestimating the overall costs and does not represent only the costs for epidural injections. In fact, a recent analysis based on a 2-year follow-up of 100 patients receiving caudal epidural injections with or without steroids [8] showed cost utility of $2200 per 1-year of quality-adjusted life-year. If the authors wanted to estimate proper cost utility, they should have assessed it in multiple settings without inclusion of magnetic resonance imaging assessment or other costs. Finally, it is interesting to note that the cost utility of epidural injections is substantially better than surgical intervention and even physical therapy. Overall, we believe the authors have used inappropriate methodology in their literature search and performed an inappropriate assessment, leading to inappropriate conclusions.

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REPLY

To the Editor,

Thank you for the opportunity to respond to the letter from Dr Manchikanti and colleagues commenting on our article, in which we reviewed the clinical effectiveness and cost-effectiveness evidence for epidural steroid injections (ESIs) for spinal stenosis [1]. We believe that we were appropriately clear in our review of the literature, summary of findings, and suggestions for needing additional sufficiently high-quality evidence related to ESI as an intervention for spinal stenosis. Manchikanti et al suggested 3 main criticisms related to our manuscript: overall conclusions, methodology, and inclusion of studies. We will briefly address each sequentially.

OVERALL CONCLUSIONS

Contrary to the statements made by Manchikanti et al, our manuscript did not indicate that there were no effectiveness data for ESIs in spinal stenosis or that ESIs are not cost-effective in a spinal stenosis population. We clearly stated that “this systematic review of ESI for treating lumbar spinal stenosis found a limited amount of data that suggest ESI is effective in some patients for improving select short-term outcomes, but results differed depending on study design, outcome measures used, and comparison groups evaluated. Overall, there are relatively few comparative clinical or economic studies for ESI procedures for lumbar spinal stenosis in adults, indicating a need for additional evidence.” This conclusion statement is valid and is supported by the existing published evidence.

We made no specific claims related to cost-effectiveness of ESI, and we found no published evidence in which authors assessed the incremental cost-effectiveness of ESIs for patients with lumbar spinal stenosis. This statement applied at the time of our final manuscript submission to PM&R in May 2013 and remains the case today in terms of adequately transparent cost-effectiveness assessments that adhere to methodologic standards.

It seems the authors incorrectly interpreted the intention of our simplified unit-cost estimation for ESI procedures. As stated in the Materials and Methods, Additional Institutional Analysis of ESI Procedures section, “a descriptive analysis of resource use associated with ESI was performed.” During our evidence evaluation, we were unable to identify a published Centers for Medicaid & Medicare Services—based cost estimate for a typical ESI “event” in an outpatient setting; thus, we supplemented the comparative effectiveness research review with an institutional example of a simplified unit-cost evaluation for an ESI injection in Medicare patients. This estimate of reimbursed amounts for ESIs in an outpatient setting was not linked to outcomes or any effectiveness measures.

SEARCH METHODOLOGY

Manchikanti et al raise concerns about our methodology and cite studies not included in our systematic review. Our methods are reported transparently in the manuscript and were based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for reporting systematic reviews [2]. Our manuscript was subjected to substantial peer-review, which improved the quality of our review. We used multiple search tools (ie, PubMed, EMBASE, and CINAHL) to be more comprehensive in our evidence capture. We refer readers to our search strategy described in the first paragraph of Materials and Methods, Data Sources and Search subsection. Figure 1 presents our search strategy, terms used, and results for the number of studies identified.

Consistent with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement, we performed a standardized bias assessment of the included studies. Our bias assessment is described in the Methods section of our manuscript, and the details of this assessment tool are further described in The Cochrane Collaboration’s tool for assessing risk of bias in randomized trials [3]. We summarized these results in the text rather than in table format.

Unfortunately, there was a publishing error in the manuscript text in the first sentence of the first paragraph in the “Results of Assessment of Bias” on page 708. We are glad that this was identified, and we apologize for any confusion caused to readers. The sentence should read “standard evidence-based criteria, 5 [13-16,18] of the 6 RCTs were judged to have “low risk” of bias.”

STUDIES INCLUDED

We applied well-accepted methodologic standards in selecting studies, including whether clinical trial design, outcomes, and data collection methods were reported transparently and whether the study descriptions and/or data presented were consistent with the manuscript findings and conclusions.

Manchikanti et al state that we “seemingly used appropriate search criteria, but failed to find all the manuscripts