Results of comprehensive medical management of lumbar disorders questioned

TO THE EDITOR: Parker et al.11 presented results of the 2-year comprehensive medical management of degenerative lumbar spine disease for lumbar spondylolisthesis, stenosis, or disc herniation with a value analysis of cost, pain, disability, and quality of life. They concluded that surgery was strikingly cost-effective, as compared with comprehensive medical management, whose 2-year total cost ranged from $6600 to $7747 depending on the pathology assessed. They also discussed cost-effectiveness, citing a value of $78,856–$110,671 per quality-adjusted life year (QALY) for medical management, compared with a value of $53,914–$62,995 per QALY for surgery. These figures were based on their own cost-effectiveness studies.

The authors did not follow appropriate methodology in their assessment. Quality-adjusted life year details are not shown for comprehensive medical management. The authors boldly state that they are comparing apples to apples; however, that is the case, they may be comparing sweet apples to tart apples. More accurately, they have compared apples to oranges. They included patients who initially did not respond favorably to conservative therapy and for whom surgery was chosen as the next option. Patients in whom conservative management initially fails often do not improve at a later date. This has been shown repeatedly for epidural injections, where patients who report at least 3 weeks of improvement following the initial two epidural injections tend to show improvement superior to that in patients who do not respond to the first two injections.4,8,10,11

Further, this strategy has been utilized to select a control group for percutaneous adhesiolysis and consistently produced poor results in those who had repeat caudal epidural injections after having failed to respond to epidural injections.5,29

Most importantly, the authors did not describe the types of conservative management provided to patients. Significant bias exists in surgeon-directed conservative management compared with interventional pain management and compared with conservative management using a multidisciplinary approach. In fact, a cost utility analysis of caudal epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, and post–lumbar surgery syndrome using only the direct medical expenses showed an average cost per QALY of around $2200.9 The cost-effectiveness of spinal cord stimulation compared to conventional medical management was £5624 per QALY.12

Among the most quoted assessments of surgical interventions and conservative management are those from the Spine Patient Outcomes Research Trial (SPORT). Its results showed that the cost per QALY gained for surgery relative to nonoperative care was $69,403 for disc herniation, $77,600 for spinal stenosis, and $115,600 for degenerative spondylolisthesis.13,34 Thus, it is inappropriate to assess patients in whom conservative management failed, to subsequently provide them with the same failed treatment, and then to conclude that this treatment somehow translates as not being cost-effective. No credible physician would continue conservative management after its failure for 2 years. The details of conservative management, including the types of modalities utilized (for example, were epidural injections utilized; if so, how many; what were the reasons for using them), leads to a cost of approximately $2000 for health care visits and from $3233 to $4340 for medications/injections, with total direct costs making up a significant proportion of the overall costs. In addition, no injection treatment for spondylolisthesis demonstrating any type of efficacy has been described in the literature. Consequently, the authors may have utilized treatments that were not proven to be effective.1,2 Epidural injections have significant Level II evidence supporting their use, specifically, high-quality randomized controlled trials for caudal and lumbar interlaminar epidural injections for disc herniation and for central spinal stenosis, for caudal injections used in post–lumbar surgery syndrome, and for lumbar transforaminal epidural injections for disc herniation.1,2 In fact, carefully conducted systematic reviews have shown evidence favoring each of these three approaches (interlaminar, caudal, transforaminal) in the management of low-back pain with a radicular component.

Thus, this analysis of cost, pain, disability, and quality of life does not follow sound scientific principles and, despite the authors’ assertions, does not compare apples to apples.

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Response

We thank Manchikanti and colleagues for their comments on the overall value of medical therapies for lumbar pathologies. Medical treatment modalities are highly effective for a variety of nonspecific low-back diseases and a multitude of structural lumbar spinal disorders. A number of physical therapies, medications, and spinal injection therapies have proven to be valuable and cost-effective for many structural and surgically relevant lumbar spine pathologies. However, in a subset of patients with structural spine pathology, comprehensive multimodal therapies remain only mildly effective or even ineffective. It is this small subset of medically refractory patients in whom surgery is most relevant and the cohort that we chose to study. We believe that there is some truth to Manchikanti and colleagues’ statement that “no credible physician would continue conservative management after its failure.” Indeed, it was our a priori hypothesis that continuing prolonged medical treatments in refractory patients has a low likelihood of providing delayed health benefit. In fact, the primary purpose of our study was to confirm exactly that: there is little health economic value or patient benefit in continuing ineffective treatments in the subset of patients with medically refractory structural spine disease. Our findings validate the comments in the editorial by Manchikanti et al. and are not intended to comment on the value of conservative management for a broader spectrum of spine patients.

It is reasonable to ask why one would solely study this subset of patients with initially medically refractory spine pathology. The primary reason is that it is exactly this subset of patients with structural lumbar pathology in which surgery is most relevant and most appropriately indicated. It is also the subset that is left to engage in further medical management when they are denied access to much-needed surgery by policymakers or third party payers. While Manchikanti et al., our group, and the findings of our prospective cohort study all suggest that continuing failed nonoperative spine care over the long term makes little sense, this practice continues to occur every day in the United States when patients are dissuaded by public opinion, financial disincentives, or payer policy from undergoing surgery.

Another reason to study longitudinal cost and outcomes of continued medical treatment in initially refractory patients is because obtaining a measurable cohort of surgically comparable patients is challenging. In the SPORT intent-to-treat analysis, the analyzable medical cohort had
a substantial number of surgical outcomes included. In the SPORT “as treated” cohort analysis, the analyzable medical cohort included only those patients who stayed with medical treatment after those most refractory to it crossed over to surgical care, artificially elevating the cohort’s mean effectiveness of care. Lower-level comparative effectiveness studies assessing the value of surgery often include patients in whom single modality treatments of 4–6 weeks have failed. However, this is less relevant to real-world care, as patients simply failing to respond to conservative treatment after 4–6 weeks have many other multimodality options to consider, which can improve their pain-related disability and quality of life. In our analysis and practice, only patients who have gone on to fully engage in at least several weeks of multimodality medical, injection, and physical therapies are eligible and recommended for surgery. In a registry format, we were able to capture those patients who were recommended for surgery but chose against it despite the failure of prior medical treatment. In most payer policies and real-world care paradigms, only patients in whom medical treatment has clearly failed for 3 or more months are offered surgery as the last option. For the reasons mentioned above, measuring the cost and benefit of nonsurgical care in this surgically relevant cohort has been a challenge and was the principal motivation for our study.

Elective lumbar surgery is only relevant for patients who have proven that they will not have meaningful improvement with prolonged medical treatments. Our cohort study is precisely this, an outcomes analysis of that small subset of low-back disease patients in which continued medical management has the lowest value and surgery has the highest relevance and potential value. Our results are not meant to comment on the broad value of medical treatment modalities for structural lumbar diseases, but rather to demonstrate in health economic terms that for patients who best meet the criteria for surgery (that is, those refractory to medical treatment) continued medical alternatives to surgery may be of little value.

In this health care reform era when the health economic value of lumbar surgery is being targeted, even for patients refractory to medical management, it is important for all health care stakeholders to understand that continuing cheaper care after it has proven to be ineffective may not be in the long-term best interest of the patient or the payer.

TO THE EDITOR: I was struck by the handsome yet inaccurate illustrations appearing on the cover of the August 2014 issue of the Journal, corresponding to Fig. 5 in the article by Young et al. 1 (Young RM, Sherman JH, Wind JJ, et al: Treatment of craniocervical instability using a posterior-only approach. Report of 3 cases. J Neurosurg Spine 21:239–248, August 2014). These illustrations depict a mid-sagittal view of the cervical spine in which bone screws appear to have been inserted into spinous processes at C-2 and below. In fact, the text of the article makes it clear that the authors used conventional pars or laminar placement at C-2 and lateral mass placement at C-3 and below. A more accurate representation appears in Fig. 7 of the article. The error only minimally detracts from this otherwise excellent technical article on posterior management of craniocervical instability. However, the prominent display of this illustration on the cover of the Journal requires acknowledgment and clarification of the inaccuracy by the authors.

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neurophysiological monitoring is not available for all patients with kyphosis. However, this technique cannot be performed in patients with congenital cranio cervical malformations, precluding the use of C-1 lateral mass or even C-2 pedicle screws.

We congratulate the authors for this outstanding manuscript.

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DISCLOSURE
The author reports no conflict of interest.

References

Response
We would like to thank Dr. Joaquim for his thoughtful and accurate commentary on our paper. His observation that reduction maneuvers result in cranio cervical kyphosis has also been observed in our experience. However, we will point out that for most patients, slight downward gaze is desirable for activities of daily living such as eating or going down stairs. Cervical sagittal alignment is becoming a topic of active research, but our feeling is that the C2–7 sagittal vertical axis is probably more important than slight cranio cervical kyphosis.

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Reference

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