Letters to the Editor

NEUROSURGICAL FORUM

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 [Parker SL, Godil SS, Mendenhall SK, et al: Two-year comprehensive medical management of degenerative lumbar spine disease (lumbar spondylolisthesis, stenosis, or disc herniation): a value analysis of cost, pain, disability, and quality of life. *J Neurosurg Spine* 21:143–149, August 2014]. They concluded that surgery was strikingly cost-effective, as compared with comprehensive medical management, whose 2-year total cost ranged from \$6606 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, if 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.^{3,4,8,10,11} 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.^{5,7,9}

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 \$2200.⁶ 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.^{13,14} 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.

Laxmaiah Manchikanti, MD

University of Louisville, Louisville, Kentucky

Kenneth D. Candido, MD

Advocate Illinois Masonic Medical Center, Chicago, IL

Ramsin M. Benyamin, MD

Medical Director, Millennium Pain Center, Bloomington, IL
University of Illinois, Urbana-Champaign, IL

Joshua A. Hirsch, MD

Massachusetts General Hospital, Boston, MA
Harvard Medical School, Boston, MA

DISCLOSURE

The authors report no conflict of interest. Dr. Benyamin is a consultant for Kimberly Clarke and Boston Scientific and owns stock in Integral Spine Solutions.

References

1. Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, et al: An update of comprehensive evidence-based guidelines for interventional techniques of chronic spinal pain. Part II: guidance and recommendations. **Pain Physician 16 (2 Suppl):S49–S283**, 2013
2. Manchikanti L, Benyamin RM, Falco FJ, Kaye AD, Hirsch JA: Do epidural injections provide short- and long-term relief for lumbar disc herniation? A systematic review. **Clin Orthop Relat Res** [epub ahead of print], 2014
3. Manchikanti L, Cash KA, McManus CD, Damron KS, Pampati V, Falco FJE: A randomized, double-blind controlled trial of lumbar interlaminar epidural injections in central spinal stenosis: 2-year follow-up. **Int J Phys Med Rehab** [epub ahead of print], 2014
4. Manchikanti L, Cash KA, McManus CD, Pampati V, Fellows B: Results of 2-year follow-up of a randomized, double-blind, controlled trial of fluoroscopic caudal epidural injections in central spinal stenosis. **Pain Physician 15:371–384**, 2012
5. Manchikanti L, Cash KA, McManus CD, Pampati V, Singh V, Benyamin RM: The preliminary results of a comparative effectiveness evaluation of adhesiolysis and caudal epidural injections in managing chronic low back pain secondary to spinal stenosis: a randomized, equivalence controlled trial. **Pain Physician 12:E341–E354**, 2009
6. Manchikanti L, Falco FJE, Pampati V, Cash KA, Benyamin RM, Hirsch JA: Cost utility analysis of caudal epidural injections in the treatment of lumbar disc herniation, axial or discogenic low back pain, central spinal stenosis, and post lumbar surgery syndrome. **Pain Physician 16:E129–E143**, 2013
7. Manchikanti L, Rivera JJ, Pampati V, Damron KS, McManus CD, Brandon DE, et al: One day lumbar epidural adhesiolysis and hypertonic saline neurolysis in treatment of chronic low back pain: a randomized, double-blind trial. **Pain Physician 7:177–186**, 2004
8. Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV: Effect of fluoroscopically guided caudal epidural steroid or local anesthetic injections in the treatment of lumbar disc herniation and radiculitis: a randomized, controlled, double blind trial with a two-year follow-up. **Pain Physician 15:273–286**, 2012
9. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S: Assessment of effectiveness of percutaneous adhesiolysis and caudal epidural injections in managing lumbar post surgery syndrome: 2-year follow-up of randomized, controlled trial. **J Pain Res 5:597–608**, 2012
10. Manchikanti L, Singh V, Cash KA, Pampati V, Falco FJE: A randomized, double-blind, active-control trial of the effectiveness of lumbar interlaminar epidural injections in disc herniation. **Pain Physician 17:E61–E74**, 2014
11. Parker SL, Godil SS, Mendenhall SK, Zuckerman SL, Shau DN, McGirt MJ: Two-year comprehensive medical management of degenerative lumbar spine disease (lumbar spondylolisthesis, stenosis, or disc herniation): a value analysis of cost, pain, disability, and quality of life. **J Neurosurg Spine 21:143–149**, 2014

12. Taylor RS, Ryan J, O'Donnell R, Eldabe S, Kumar K, North RB: The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. **Clin J Pain 26:463–469**, 2010
13. Tosteson AN, Lurie JD, Tosteson TD, Skinner JS, Herkowitz H, Albert T, et al: Surgical treatment of spinal stenosis with and without degenerative spondylolisthesis: cost-effectiveness after 2 years. **Ann Intern Med 149:845–853**, 2008
14. Tosteson AN, Skinner JS, Tosteson TD, Lurie JD, Andersson GB, Berven S, et al: The cost effectiveness of surgical versus nonoperative treatment for lumbar disc herniation over two years: evidence from the Spine Patient Outcomes Research Trial (SPORT). **Spine (Phila Pa 1976) 33:2108–2115**, 2008

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.

Matthew J. McGirt, MD

Carolina Neurosurgery and Spine Associates, Charlotte, NC

Scott L. Parker, MD

Vanderbilt Medical Center, Nashville, TN

INCLUDE WHEN CITING

Published online December 19, 2014; DOI: 10.3171/2014.6.SPINE14605.

©AANS, 2015

Craniocervical instability

TO THE EDITOR: I was struck by the handsome yet inaccurate illustrations appearing on the cover of the Au-

gust 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.

Peyman Pakzaban, MD

Houston MicroNeurosurgery, Pasadena, TX

DISCLOSURE

The author reports no conflict of interest.

Reference

1. Young RM, Sherman JH, Wind JJ, Litvack Z, O'Brien J: Treatment of craniocervical instability using a posterior-only approach. Report of 3 cases. *J Neurosurg Spine* 21:239–248, 2014

Response

We thank Dr. Pakzaban for making the point that in our illustrative Fig. 5 the posterior screw fixation appears to be entering the spinous process as opposed to the C-2 pars/lamina, and that the other subaxial screws are not depicted as being in the lateral mass. We agree that Fig. 5 may be inaccurate in that sense; however, it is our hope that the general concept of the instrumentation is conveyed and that the technique can be learned by reading the *Methods* section in our article.

Richard M. Young, MD

Joseph O'Brien, MD, MPH

George Washington University Medical Center, Washington, DC

INCLUDE WHEN CITING

Published online January 2, 2015; DOI: 10.3171/2014.8.SPINE14820.

©AANS, 2015

Treatment of craniocervical instability using a posterior-only approach

TO THE EDITOR: We found the article by Young et al.⁶ (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) very interesting and well illustrated. The authors reported a posterior-only approach based on modern hardware instrumentation that allows intraoperative reduction techniques and avoids the need for an additional anterior approach to treat craniocervical junction instabilities. They also stated the important point that basilar invagination (BI) was harder to reduce with preoperative traction than cranial settling, because degeneration of the joints and ligaments can make reduction with traction easier in the latter.

We have some comments regarding intraoperative reduction using posterior-only approaches for craniocervical junction instabilities. In 2010, Jian et al. published a report of 29 patients with BI and atlantoaxial dislocation successfully treated with distraction between the occipital plate and C-2.² They did not perform preoperative traction or the maneuver for anterior reduction of C-2 relative to the foramen magnum. Since the publication of that article, we have tried to apply intraoperative posterior reduction techniques without preoperative traction, using the maneuver suggested by Jian et al. (distraction between the occipital plate and C-2) and also adding in some cases the anterior dislocation of the axis (pushing the cervical spine anteriorly) as proposed by Young et al. in this current manuscript. However, some of our patients who underwent just intraoperative reduction presented with a mild degree of postoperative craniocervical kyphosis (the horizontal gaze was slightly displaced downward and there was a reduction of the clivus-canal angle) because these maneuvers may favor cranial flexion. Because of that, we strongly recommend that patients with craniocervical instabilities, except for those with BI secondary to clivus hypoplasia, should undergo preoperative traction in a neutral position or even mild extension, which allows a gentle and gradual reduction of craniocervical misalignment.^{3–5} Especially in developing countries where neurophysiological monitoring is not available for all patients, preoperative reduction can be safely performed with assessment of the patient's neurological status in real time and can also decrease the duration of surgery (because the alignment will already have been corrected). Although preoperative traction is uncomfortable, unstable injuries generally reduce in the first 24 hours, and our practice is to perform traction the day before surgery. Another point observed in our practice is that using C-2 laminar screws for intraoperative reduction maneuvers results in more craniocervical kyphosis than the use of C-2 pedicle screws, probably because the latter can reach the anterior portion of the axis. Finally, the use of C1–2 spacers, as proposed by Goel et al., is also an alternative to direct intraoperative reduction, which does not result in any degree of craniocervical kyphosis.¹ However, this technique cannot be performed in all patients, because vertebral artery and bone anomalies are commonly found in patients with congenital craniocer-

vical malformations, precluding the use of C-1 lateral mass or even C-2 pedicle screws.

We congratulate the authors for this outstanding manuscript.

Andrei F. Joaquim, MD, PhD

State University of Campinas, Campinas, Brazil

DISCLOSURE

The author reports no conflict of interest.

References

1. Goel A: Basilar invagination, Chiari malformation, syringomyelia: a review. *Neurol India* 57:235–246, 2009
2. Jian FZ, Chen Z, Wrede KH, Samii M, Ling F: Direct posterior reduction and fixation for the treatment of basilar invagination with atlantoaxial dislocation. *Neurosurgery* 66:678–687, 2010
3. Joaquim AF: Basilar invagination. *J Neurosurg Pediatr* 10:355–356, 2012 (Letter)
4. Joaquim AF: Management of basilar invagination. *J Bras Neurocirurg* 24:53–59, 2013
5. Joaquim AF, Ghizoni E, Almeida JPC, Anderle DV, Tedeschi H: Basilar invagination secondary to hypoplasia of the clivus—is there indication for craniocervical fixation? *Coluna* 13:69–70, 2014
6. Young RM, Sherman JH, Wind JJ, Litvack Z, O'Brien J: Treatment of craniocervical instability using a posterior-only approach. Report of 3 cases. *J Neurosurg Spine* 21:239–248, 2014

Response

We would like to thank Dr. Joaquim for his thoughtful and accurate commentary on our paper. His observation that reduction maneuvers result in craniocervical 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 axis¹ is probably more important than slight craniocervical kyphosis.

Richard M. Young, MD

Joseph O'Brien, MD, MPH

George Washington University Medical Center, Washington, DC

Reference

1. Scheer JK, Tang JA, Smith JS, Acosta FL Jr, Protosaltis TS, Blondel B, et al: Cervical spine alignment, sagittal deformity, and clinical implications. A review. *J Neurosurg Spine* 19:141–159, 2013

INCLUDE WHEN CITING

Published online January 2, 2015; DOI: 10.3171/2014.9.SPINE14853.

©AANS, 2015