

## Do We Have an Alternative to Transforaminal Injections to Provide Safe and Effective Lumbar Epidural Steroid Injections to Our Patients While Minimizing the Burden to the Healthcare System?

*To the Editor:*

We read with interest the safe-use steroid consensus of opinions from 13 societies in the most recent issue of *ANESTHESIOLOGY*.<sup>1</sup> We applaud the multidisciplinary working group (MWG) on formulating safety guidelines for clinicians of the multiple specialties involved with neuraxial steroid injections. This consensus is perhaps a reflexive response to the U.S. Food and Drug Administration (FDA) safety concerns regarding the use of corticosteroid injections for the management of spine-related pain,<sup>2</sup> even though epidural steroid injections have been safely administered for over 50 yr. We agree with working group's statements designed to decrease the catastrophic neurological events after cervical epidural steroid injections, listed as numbers 1, 3, 4, 5, 6, and 7.

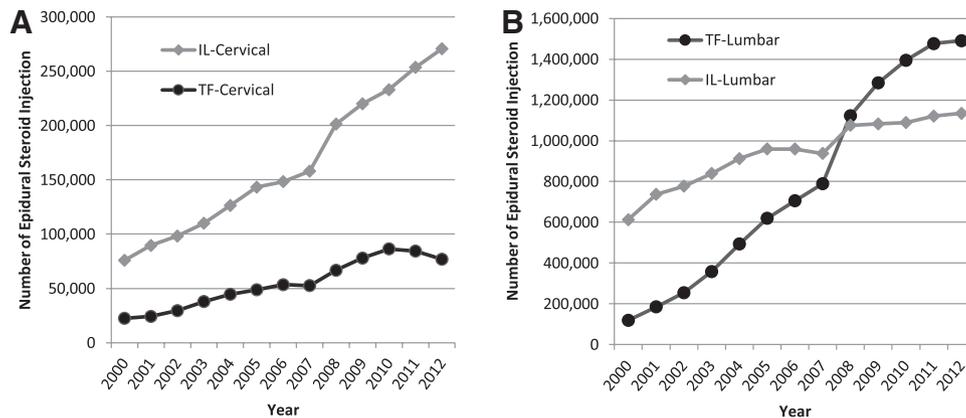
However, we would like to provide evidence of perhaps even safer alternatives to lumbar transforaminal injections (TF-LESI [transforaminal lumbar epidural steroid injections]) for readers and clinicians to MWG's statement no. 10. We think that the MWG recommendation that an initial TF-LESI should be performed with nonparticulate corticosteroids is controversial and not supported by solid scientific literature. MacVicar *et al.*<sup>3</sup> performed a systematic analysis of 39 publications that explored the efficacy of TF-LESI for various lumbar pain conditions. They found that in 24 of 26 studies that reported some degree of effectiveness of TF-LESI, the authors used different particulate (insoluble) steroids, and dexamethasone (soluble steroid) was used only in two studies. Kim and Brown<sup>4</sup> compared the efficacy of TF-LESI with dexamethasone and methylprednisolone and observed a nonsignificant trend of dexamethasone's shortcomings to sustain long-term pain relief and provide adequate efficacy of pain relief as provided by methylprednisolone. Kennedy *et al.*<sup>5</sup> examined a total of 78 patients during a 6-month period after an initial TF-LESI with either dexamethasone or triamcinolone for treating lumbar radiculopathy. Seven of 41 (17%) patients who received dexamethasone required three injections within 6 months.<sup>5</sup> However, only 1 of 37 (2.7%) patients who received triamcinolone required three injections within the same time period.<sup>5</sup>

When choosing between soluble and insoluble steroids, we must further consider a current state of healthcare reforms in an effort to control soaring healthcare costs. In considering the results from the study by Kennedy *et al.*<sup>5</sup> with a six-time greater use of the third TF-LESI among patients

receiving dexamethasone, we believe that MWG statement no. 10 would further burden an already strained healthcare system because more patients would be using more expensive therapy more regularly.

Analysis of interventional neuraxial procedure utilization data accessed from the Part B National Summary Data by the Center for Medicare and Medicaid Services showed a steady upward trend for epidural injections at cervical and lumbar regions between 2000 and 2012 (fig. 1).<sup>6</sup> It appears that clinicians are exercising reasonable judgment and appropriately assess risk–benefit ratios when selecting cervical epidural steroid injections, as cervical interlaminar (interlaminar epidural steroid injections) procedures are performed progressively more frequently than are cervical transforaminal epidural steroid injections (TF-ESI) (fig. 1A). However, a steadfast escalating trend is observed for TF-LESI when compared with IL-LESI among Medicare patients (fig. 1B). Grossly examining reimbursement payments for TF-LESI and IL-LESI in our city, we observe a concerning trend of greater reimbursement rates approximately 1.55 to 2.02 times for the transforaminal approach over the interlaminar approach, which might be one of the primary reasons for the observed overutilization of TF-LESI procedures. This overutilization occurs even in light of no strong evidence whatsoever favoring the analgesic efficacy of TF-LESI over interlaminar epidural steroid injections for treating lumbar radicular pain.<sup>7</sup>

We agree with MWG's statement no. 14, which allows for clinician's judgment to choose an appropriate lumbar epidural approach. However, we continue to be vexed by MWG's inability to consider evidence that clearly indicates the published efficacy of parasagittal interlaminar epidural steroid injections.<sup>8–11</sup> Bonica<sup>12</sup> (John J. Bonica, M.D., February 16, 1917 to August 15, 1994; Professor Emeritus at University of Washington, Seattle, Washington) first described a lateral parasagittal epidural approach in 1956 that provided a safer needle passage, which bypassed blood-vessel–rich lateral epidural regions and allowed for medication delivery to the targeted lesions.<sup>8</sup> Prospective randomized studies that compared the parasagittal approach with TF-LESI<sup>8,9</sup> in 119 patients showed at least the same if not better analgesic outcomes for the parasagittal group of patients with lumbar radicular pain. Furthermore, prospective, randomized double-blinded studies that compared a parasagittal with a midline interlaminar approach with 137 patients<sup>10,11</sup> showed that the parasagittal approach has a statistically significantly better outcome than the classical midline approach that was considered by MWG (see figs. 2 and 4 in Rathmell *et al.*<sup>1</sup>). If we take into consideration both the facts that TF-LESI injections are the subject of the FDA's advisory warning,<sup>2</sup> wherein the FDA cited 17 references supporting their warning, almost exclusively targeting TF-ESI procedures, along with reported higher complication rates, the parasagittal interlaminar approach



**Fig. 1.** Utilization of epidural steroid injections in the Medicare population from 2000 to 2012 according to the Current Procedural Terminology (CPT) codes.<sup>6</sup> (A) Cervical interlaminar (IL) (CPT code: 62310) and cervical transforaminal (TF) (CPT codes: 64479, 64480). (B) Lumbar IL (CPT code: 62311) and lumbar TF (CPT codes: 64483, 64484).

should be considered as a safer, effective, and cost-reducing alternative to TF-ESI. These injections are proven to be safe and efficient, and their more frequent utilization by pain management physicians will decrease healthcare costs because insoluble (triamcinolone and methylprednisolone) steroids can continue to be used with that approach without fear of causing catastrophic vascular compromise.

Regarding MWG statement no. 9 that digital subtraction angiography (DSA) could be used to prevent intravascular injections during TF-LESI, we disagree with adopting DSA for routine use because there is no supportive evidence in favor of its use. Isolated studies and meta-analysis showed that DSA use was not capable of distinguishing between an arterial and a venous injection.<sup>13–15</sup> In addition, adoption of DSA would expose patients and physicians to greater levels of radiation of up to three to four times per case, the cumulative effect of which could be catastrophic long term. TF-LESI using DSA and using soluble steroids will likely escalate healthcare costs due to the added expense incurred by purchasing the DSA equipment, as emphasis continues to be on cost containment.

We applaud the efforts of the MWG to create evidence-based recommendations for practicing interventional pain physicians that may improve the safety of epidural steroid injections. We do not believe that a push toward advocating for the observed trend of increasing TF-ESI use for managing lumbar radicular pain is the answer as literature support for doing so is marginal, at best. It is our hope that interventional pain societies, MWG, and regulatory governmental agencies will accept our evidence-based statements with a consideration for future deliberation on improving the guidelines pertaining to lumbar epidural corticosteroid injections.

### Competing Interests

The authors declare no competing interests.

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## The Devil Is in the Details

*To the Editor:*

In a consensus opinion by the multidisciplinary group regarding the safeguards to prevent neurological complications after epidural steroid injections, Rathmell *et al.*<sup>1</sup> correctly point out that the number of cases with catastrophic neurological injury related to epidural steroid injection is not trivial. Whereas spinal cord and brain infarction secondary to particulate steroid embolization is an important concern, it is to be noted that in a recent analysis of malpractice closed claims, neurological injuries related to direct needle trauma outnumbered the injuries related to spinal cord or brain embolic infarction.<sup>2</sup> In this analysis, fluoroscopy was used in 76% of cases in which neurological injury occurred; hence, mere use of fluoroscopy does not guarantee safety.<sup>2</sup> In the current consensus, the authors correctly point out that in addition to the anteroposterior view, the lateral or the contralateral oblique (CLO) view may be used to gauge needle depth.

Given that devastating injuries continue to occur despite the use of fluoroscopy, an important safety question is, “does a lateral fluoroscopic view reliably visualize the needle tip and estimate the depth of insertion particularly at the C7-T1 level?” The limitation of the lateral view in providing good needle tip visualization when accessing cervical or cervicothoracic epidural space by the interlaminar approach was highlighted by our study where the needle tip was not visualized or not well visualized in the lateral view in 16 of 24 cases in the low cervical and upper

cervicothoracic spine.<sup>3</sup> Furthermore, the lateral view did not provide consistent location of the needle tip in the epidural space with respect to bony landmarks.<sup>3</sup> These limitations of the lateral view could account for some cases of spinal cord injury despite the use of fluoroscopy. In contrast to this, the CLO view provided crisp visualization of the needle tip and less variability in needle tip location when visualized at an angle of 50 degrees. Based on this, we propose that the preferred use of the CLO view for depth of insertion during interlaminar epidural access has the potential of reducing complications related to direct spinal cord injury. This is likely to be especially true in cases where the needle tip is not well visualized in the lateral view. Correct use of the CLO view as well as the pitfalls of the lateral view should be taught routinely in fellowships and in society educational workshops to promote the safe access to the epidural space.

### Competing Interests

The authors declare no competing interests.

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## Insufficient Clarity of Statement 6 in the Consensus Opinions to Prevent Neurologic Complications after Epidural Steroid Injections

*To the Editor:*

I read with interest the consensus opinions to prevent neurologic complications after epidural steroid injections in the May 2015 issue.<sup>1</sup>

The working group deserves the thanks of practitioners of interventional pain medicine. The statements serve to direct