Health Policy Opinion

Safeguards to Prevent Neurologic Complications after Epidural Steroid Injections: Analysis of Evidence and Lack of Applicability of Controversial Policies

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After extensive debate and investigation by the Food and Drug Administration (FDA), Rathmell et al (1) published the final document of *Safeguards to Prevent Neurologic Complications after Epidural Steroid Injections.* This is a product of consensus by 13 national organizations known as the Multisociety Pain Workgroup (MPW), excluding the American Society of Intervention Pain Physicians (ASIPP), an organization with mission and objectives to promote the development and practice of safe, high quality, cost-effective interventional pain management techniques. This article follows the warning issued by the FDA on April 23, 2014 that the injection of corticosteroids into the epidural space of the spine may result in rare, but serious adverse events, including "loss of vision, stroke, paralysis, and death" (2). This warning was issued without consensus or consultation of the safe use initiative (SUI) established by the FDA (3). Following this, significant controversy with multiple manuscripts and a citizen petition opposing the warning along with communication to the FDA, members of Congress, and, finally, a letter signed by 1,040 interventional pain physicians to withdraw the FDA warning and a request not to implement regulations emerged (3-7). The final version of Rathmell et al's (1) article which appeared in press is slightly different than the MPW's press release (8). The final version published and considered by MPW failed to meet consensus of FDA SUI (9). In fact, these were considered by MPW which ceased to develop LCDs.

Publication of Safeguards from the MPW

Rathmell et al (1) described this work as a collaboration undertaken by the U.S. FDA SUI, an expert multidisciplinary working group, and 13 specialty stakeholder societies. The goal of this collaboration was to review the existing evidence regarding neurologic complications associated with epidural corticosteroid injections and produce consensus procedural clinical considerations aimed at enhancing the safety of these injections. Consequently, 17 clinical considerations aimed at improving safety were produced by the stakeholder societies. Safeguards include specific clinical considerations for performing transforaminal and interlaminar injections including the use of nonparticulate steroids, anatomic considerations, and use of radiographic guidance. The manuscript (1) states that they have provided the existing scientific evidence for each clinical consideration.

This manuscript (1) described well the background information including anatomic laboratory and animal studies, possible mechanisms of injury, and the role of the FDA SUI. However, the methodology and results suffer with inaccuracies

and a lack of evidence. This manuscript (1) states that the SUI convened and facilitated teleconferences conducted by the working group, which drafted, discussed, and formulated a set of clinical consideration designed to minimize the risk of complications, and clinical considerations were formulated with reference to the best available scientific evidence or expert opinion from leading scientific societies or associations or experts in the subject of epidural injections. The manuscript also states that once clinical considerations were drafted, representatives from a number of national pain organizations were invited to review and vote on them.

The Role of FDA Safe Use Initiative

However, from our personal experience with participation in SUI (Laxmaiah Manchikanti, MD. and Frank Falco, MD) and based on the publication from the FDA (3), this information may not be quite accurate. In short, the FDA created the SUI in 2009 to create and facilitate public and private collaborations within the health care community. The SUI facilitated the organization of an expert working group of key stakeholders created to understand the causes of neurologic injuries associated with epidural steroid injections and devise strategies to mitigate the risk. This was initiated by Rathmell and the working group included Drs. Benzon, Aprill, Bogduk, Dreyfuss, Huntoon, Riew, Rosenquist, Rost, and Wallace (3). The working group drafted, discussed, and formulated a set of 20 clinical considerations to minimize the risk of catastrophic neurological injury associated with epidural steroid injections. Subsequent to this, the FDA invited other organizations to participate in the SUI in 2012. The organizations participating in SUI were different from the MPW. Participants in SUI included Weistroffer from American Academy of Orthopedic Surgeons (AAOS); Lamer from American Academy of Pain Medicine (AAPM); Sullivan from American Academy of Physical Medicine and Rehabilitation (AAPM&R);; Miguel from American Society of Anesthesiologists (ASA); Falco from American Society of Interventional Pain Physicians (ASIPP); Buvanendran from American Society of Regional Anesthesia (ASRA); Dreyfuss and Duszynski from Interventional Spinal Intervention Society (ISIS); and Rathmell from Massachusetts General Hospital; Kreiner, Hayden, and Rosolowski from North American Spine Society (NASS); Benzon from Northwestern University/Feinberg School of Medicine; Enterline and Prince from Society of Interventional Radiology (SIR); Huntoon from Vanderbilt Department of Anesthesiology; and Wallace from University of California San Diego (UCSD) (9). There were multiple meetings of SUI and the final one was held on January 31, 2013. There were significant disagreements on portions of each safeguard developed by the working group of the SUI. Subsequently, comments were sent, and after the appropriate responses at the end of 2013, it was clear that there was no consensus among the SUI. Importantly, the SUI consisted of 8 of the 13 societies on the MPW. ASIPP was part of the MPW, but exited on May 27, 2013, due to the unscientific collation and controversial consensus basis with a Google doc process to approve or disapprove the statements. This decision was made by ASIPP's Executive Committee to facilitate discussions, as organizations participating in federal guidance shall not oppose or request modifications. The consideration of safeguards by MPW was long after the exit of ASIPP and also after the activities of the MPW were suspended by Noridian. However, ASIPP continues to be part of the SUI and expressed its disappointment at the decision to hand over the epidural

Assessment of Evidence to the MPW

Rathmell et al (1) stated that recommendations are based on the available best scientific evidence, and when evidence was lacking, expert opinion was sought both within the working group and from leading scientific societies or associations with interest or expertise in the subject of epidural injections. ASIPP has provided abundant literature; however, none of this appeared to have been considered in theirrecommendations.

Rathmell et al's (1) recommendations for cervical and lumbar interlaminar epidural injections are to use fluoroscopy with appropriate lateral or oblique views in addition to anteroposterior views to gauge the depth of needle insertion to avoid penetration of the spinal cord. They provide 2 manuscripts by Landers et al (10) describing geometry of fluoroscopic views for cervical interlaminar epidural injections and Furman et al (11) describing a technical note of fluoroscopic contralateral oblique view in interlaminar interventions. Further, they state that relying on loss of resistance or on anteroposterior views alone does not predict accurate needle placement and avoid the risk of spinal cord injection with either air, saline, contrast medium, or other solutions. Landers et al (10) published their manuscript with review of illustrations, cadaver models, and deriving a mathematical model to demonstrate the utility of the contralateral oblique fluoroscopic view during the performance of cervical interlaminar epidural injections. The technical note by Furman et al (11) also

describes the value of the contralateral oblique view in performing cervical, thoracic, and lumbar interlaminar procedures. However, neither of the references defined the need for the oblique or lateral view in each and every case, instead they described the contralateral oblique view. The authors (1) have not considered significant literature and discussions of the contralateral oblique view which was the subject of Furman et al's manuscript (11-18). More importantly, the authors (1?) have not discussed or even mentioned the difficulties of assessing the depth of the cervical epidural space based on cervical anatomy and body surface area (19). Fujinaka et al (19) showed that accurate depth was measured within plus or minus 0.5 cm of actual depth in only 69% of the patients, whereas in others, the prediction was inaccurate by as much as 1.6 cm or 1.7 cm.

Overall, it is essential to determine the necessity of the lateral or oblique view prior to mandating it universally for these procedures. In an overwhelming majority of the cases with careful advancement of the needle under fluoroscopy in the posteroanterior view with loss of resistance technique in conjunction with contrast injection, illustrating appropriate positioning with spread into the epidural space and even nerve roots confirming the appropriate position, the need for the lateral or oblique view is eliminated. These mandated views can be associated with difficult positioning, increased radiation exposure, increased time, and potential for increased dural puncture. Further, many physicians have not been trained in these techniques and are unaware of them. The literature and discussions mandating the use of a lateral or oblique view in lumbar epidurals are even less convincing (16-24).

Rathmell et al (1) essentially mandate needle entry for cervical interlaminar epidural injections at C7-T1, with a caveat of not higher than the C6-C7 level. This guidance does not take into consideration the fact that the ultimate choice of what approach or technique to use should be made by the treating physician after balancing potential risks versus benefits, as described in Rathmell et al (1). To support this assertion of C7-T1 entry, they provide literature on the narrow epidural space, making the dural sac and spinal cord more susceptible to penetration and injury above C7-T1 (25-28). They (1) also provided a recommendation on inspection of adequate epidural space at the segmental level to admit a needle safely. Ironically, one of the manuscripts the authors quoted (29) showed that magnetic resonance imaging (MRI) did not improve treatment outcomes in patients with a wide range of spinal disorders. Thus, this indirectly mandates, without any evidence, that the treating physician and review the MRI without crediting a radiologist's opinion in each and every case. Further, Hodges et al (25) described epidural steroid injection with intrinsic spinal cord damage in 2 patients with dural puncture at C5-C6. This was due to heavy intravenous sedation, which resulted in a diminution (30) of the patient's ability to experience the expected pain and paresthesias at the time of spinal cord irritation. Further, they injected bupivacaine, fentanyl, and particulate steroid. The authors (25) concluded that the patient should be fully awake during the administration of cervical epidural steroid injection. Rathmell et al (1) also used Aldrete et al's (26) manuscript describing skin to cervical epidural space distances as read from MRI films, essentially stating that such estimations may not be reliable. This, however, does not support the assumption that procedures should be performed at C7-T1. Hogan (27) showed the lack of posterior epidural space above the C7-T1 level, implicating the potential for 100% dural puncture at C6-C7 and above. This study included 26 adult bodies frozen in total with examination of cryomicrotome sections. Finally, manuscript by Goel and Pollan (28) described contrast flow characteristics in the cervical epidural space with an analysis of cervical epidurograms. Goel and Pollan (28) hypothesized that lower levels, C6-C7 and C7-T1, were thought to be safer due to the large epidural space, as compared with higher levels. In fact, Lirk et al (31), in a publication after Hogan et al's publication (27), with cryomicrotome sections, showed that cervical and high thoracic ligamentum flavum variably fails to fuse in the midline. The described gaps in the ligamentum flavum were 11% at T2-T3, 21% at T1-T2, 51% at C7-T1, 64% at C6-C7, 74% at C5-C6, 58% at C4-C5, and 66% at C3-C4 (31). Essentially this study showed that there is substantial risk at C7-T1 also. The risk increases from 21% of gaps at T1-T2 to 51% at C7-T1 (31). Ironically at C4-C5 there seems to be less incidence of absent midline gaps with 58% compared to 74% at C5-C6. Additionally, significant variations have been described in cervical neural canal diameters (32,33). In fact, this variation in cervical canal dimension has precluded the definition of spinal stenosis, even though it may be important in administration of interlaminar epidural injections. Based on these studies, cervical anterior-posterior diameter was narrowest at the C4 level for African-Americans and C6 for Caucasians, ranging from 13.16 mm to 21.9 mm. Cervical transverse ligaments ranged from 18.89 mm to 24.02 mm. In addition, the studies

also have shown that the actual size of the posterior epidural space is greatest with 5 mm to 6 mm in the mid lumbar spine and gradually decreases to 3 – 5 mm in the mid thoracic region, 3 – 4 mm at T2, and 1.5 – 2 mm at C7 (33).

Thus, the available data affirms that the restriction at C7-T1 is not based on evidence, and may increase the risk, specifically with multiple maneuvers of the fluoroscopic unit, to not only the physician, but also to the patient and personnel. Further, none of the studies have shown the prevalence of incidence of subarachnoid placement of the needle anywhere near to the incidence of midline gaps. Manchikanti et al (34), in an assessment of 2,376 fluoroscopically directed cervical interlaminar epidurals, reported dural puncture in 1% or 24 patients. In addition, a recent manuscript (35), describing 4,398 cervical interlaminar epidurals performed with 1,228 at C7-T1, 1,835 at C6-C7, and 1,335 at C5-C6, showed subarachnoid placement of the needle in 1.4% total with 1.7% at C7-T1, 0.87% at C6-C7, and 1.79% at C5-C6. Many experienced interventionalists, performing a large number of these procedures, have utilized C6-C7 and C5-C6 as a preferred level based on the anatomy, contrast flow patterns, and location of the pathology and reported minimal or similar complications as when it is performed at C7-T1 or C6-C7. Ironically, the recent manuscript (35) showed a lesser incidence of subarachnoid placement when performed at C6-C7 with 0.87% (statistically insignificant) compared to 1.7% and 1.79% at C7-T1 and C5-C6. There was no difference between C5-C6 and C7-T1 level; further, performance at C5-C6 facilitates an easier lateral view without embarking on numerous alternate techniques and with minimal scatter radiation exposure. In a series of recent manuscripts in *Anesthesia & Analgesia,* it was clearly shown that patients managed by low performance anesthesiologists (corresponding to the twenty-fifth percentile of the distribution of anesthesiologist risk adjusted outcomes) experienced almost twice the rate of death or serious complications (36-41).

Authors (1) describe appropriately the causes of complications with cervical interlaminar as being related to the sedation and intraarterial injection with cervical and lumbar transforaminal epidural injections. They recommended dexamethasone for transforaminal epidural injections and to avoid particulate steroids; however, there are no safety studies of cervical and lumbar transforaminal injections in relation to particulate steroids or nonparticulate steroids. The recommendation to use dexamethasone does not take into consideration the four deaths reported to the FDA from injections done using dexamethasone. Further, the FDA describes no significant benefit with nonparticulate steroids in relation to complications. Based on the comments of the manuscript (1), the studies utilized to support the efficacy of nonparticulate steroids (42,43) appear to have been considered after the conclusions were drawn. Among these, Kennedy et al (43) assessed 78 consecutive patients with acute unilevel disc herniation with unilateral radicular pain. The follow-up was short-term and there was a relatively small number of patients for a multicenter trial. They showed surgical rates of 14.6% in the dexamethasone group and 18.9% of triamcinolone group. Based on this small study with short-term follow-up, they concluded that dexamethasone appears to possess reasonably similar effectiveness when compared with triamcinolone. The second manuscript, by El-Yahchouchi et al (42), was a retrospective noninferiority analysis of dexamethasone relative to particulate steroids which included 3,645 lumbar transforaminal epidural injections performed on 2.634 patients; however, the follow-up was only at 2 weeks and 2 months. They concluded that dexamethasone was noninferior to the particulate steroids in pain relief and functional improvement at 2 months. However, the efficacy of local anesthetic has been shown to be similar to particulate steroids in all spinal conditions except disc herniation (44-58). Rathmell et al (1) have omitted multiple other manuscripts, not only the ones comparing various types of steroids, but also those comparing local anesthetics with steroids, which basically showed the equal effectiveness of local anesthetics except in disc herniation during initial period of treatment (44-58). Further, Park et al (59) showed the superiority of triamcinolone compared to dexamethasone in a randomized, controlled trial with 53 patients in each group; however, again with a short-term follow-up. In addition, they also have not included the manuscript by 3 of the authors of the safeguards which showed a greater effect of triamcinolone in a short-term follow-up in a small sample size (60).

Majority of the authors endorsed digital subtraction angiography (DSA) for transforaminal injections on the grounds that it significantly increases the detection of vascular uptake of contrast medium (61-63). They (2) also claim that it requires less contrast medium to detect vessels; however, it requires significant investment, increased time, and substantially increased radia-

tion (64). They (1) have quoted the sensitivity of DSI to be only 60% compared with 20% with aspiration (63). Instead, others have emphasized the disadvantages of DSAand its lack of accuracy (65-67). A recent systematic review (66) has concluded that DSA had a 32% improvement (OR = 1.32) for detection of intravascular penetration with epidural steroid injection when compared to real time fluoroscopy. Thus, there is a greater than 30% "missed-events" rate for detection of vascular penetration when using real time fluoroscopy, which does not correlate with the generally reported cumulative rate of complications (1%). The authors concluded that this discrepancy suggests that factors other than vascular events also play a role in complications. Candido (67), in a commentary, elaborated numerous issues with the accuracy and disadvantages of DSA.

Other safeguards such as extension tubing has not been based on any scientific basis. More importantly, the authors (1) appear to have not considered the placement of the needle at the inferior aspect of the intervertebral foramina instead of the superior foramina (supraneural approach or safe triangle approach) as advocated by International Spine Intervention Society (ISIS) (68,69), while at the same time they have nominally considered other approaches (70-72). In considering these approaches, they utilized a manuscript by Windsor et al (72) describing cervical transforaminal injections; however, alternate approaches for cervical epidural injections may be irrelevant considering that radicular arteries are present in all quadrants anterior, ventral, and posterior dorsal (73-82). They quote the references by Park et al (83) showing the equivalent results of the Kambin triangle versus the supraneural approach for the treatment of lumbar radicular pain. In addition, in a comprehensive review (70), Atluri et al (70) analyzing the needle position data of paralysis from transforaminal epidurals showed that in all patients complications resulted after performing the procedures with a safe triangle approach. Further, based on Atluri et al's (70) review there is overwhelming literature illustrating that the distribution of radicular arteries can be avoided with almost certainty with alternate approaches in lumbar transforaminal epidural injections. Even then, caution must be exercised considering multiple risk factors in each and every patient. They considered this as an untested safeguard similar to a specific needle tip type. It appears that these alternate approaches and type of needle tips have even more evidence than many of the other safeguards assimilated. However, Rathmell et al (1) do not discuss the role of blunt needles in systematically changing the technique by which transoforaminal injections are done, thus removing the risk of intraarterial injection. Further, there were no discussions in reference to caudal epidural injections which are performed with the same frequency as interlaminar epidural injections.

Apart from neurological complications of intraarterial injections, arachnoiditis has been a major issue. We believe that arachnoiditis is secondary to not only particulate steroids with preservatives, but with repeated injections of steroids into the compromised epidural space after surgery with scar tissue, inadvertently entering the subarachnoid space (3,4,8,84,85). In addition, lack of identification of epidural space is aided by injection of high dose steroids and saline without local anesthetic to facilitate subarachnoid entry and injection (3,4,8,84,85). In fact, the Department of Phamacovigilance II (DPV) identified 131 FDA Adverse Event Reporting System (FAERS) cases of neurologic fatalities, which also included 41 cases of arachnoiditis (3). In addition, the outbreak of fungal meningitis included 751 cases with 64 deaths due to contaminated methylprednisolone acetate (86).

The greatest risk of neurologic comprise arises from cervical transforaminal injections. Safety considerations for cervical transforaminal epidural injections have been extended to all procedures. The statistics show that transforaminal epidurals injections have increased substantially in the cervical/thoracic regions and lumbosacral regions. There was an astonishing 577% increase per 100,000 fee-for-service Medicare recipients with an annual increase of 16% from 2000 to 2013 for lumbosacral transforaminal epidural injections (87,88). In contrast, for cervical and thoracic transforaminal epidural injections, the increase has been 84% with an annual increase of 5%, and for caudal and lumbar interlaminar epidural injections, the increase has been 11% with an annual increase of 1%. Cervical and thoracic interlaminar epidural injections have increased 119% with an annual increase of 6% (87,88). As authors of safeguards (1) accurately described that the injection of particulate steroids in transforaminal epidural injections is associated with devastating complications with infarctions of the spinal cord, brain stem, cerebrum, or cerebellum (1,4,8,73,80-82). However, it is not justifiable to transfer these complications to all epidural injections. The authors also quote the survey by Scanlon et al (82) who surveyed 1,340 physicians with

an overall response rate of 21.4% (287 of 1340). In all, 78 complications were reported, including 16 vertebrobasilar brain infarcts, 12 cervical spinal cord infarcts, and 2 combined brain/spinal cord infarcts. They (82) concluded that their study demonstrated a significant risk of serious neurologic injury after cervical transforaminal epidural steroid injections. Engel et al (73) in a subsequent publication reported similar results of serious complications, including 13 deaths and many catastrophic neurological injuries.

A growing body of evidence supports an embolic mechanism, whereby inadvertent intra-arterial injection of particulate corticosteroid causes a distal infarct. Embolism to the distal basilar artery region can cause midbrain, pons, cerebellum, thalamus, temporal, and occipital lobe infarctions. Other potential mechanisms of infarction include needle-induced vasospasm and vertebral artery perforation causing dissection/thrombosis and needle-induced vasospasm (73,80,82). In reference to the mechanisms, Rathmell et al (1) state that circumstantial evidence and some direct evidence implicates a variety of possible mechanisms for these complications. They describe injection into the radicular medullary artery as the major culprit (81). They also described the mechanism of particulate formation; however, none of the studies thus far have assessed the mechanism and pathoetiology of particle formation when combined with plasma or blood products (80,89,90). This is an area being investigated. Even though the authors state that injection of particulate steroids in experimental settings (91) did not show significant damage after injection of dexamethasone, the FDA has described that the damage is caused by both particulate and nonparticulate steroids (3). Rathmell et al (1) have minimized other potential mechanisms of injury, including perforation (92) and traumatic aneurysm caused by penetration with the needle (93), arterial spasm, and creation of an intimal flap, coming to the conclusion that there is a lack of direct evidence for these alternate mechanisms of neurologic injury (89). Despite these assertions, literature supports these alternate theories (74,75,94,95).

Preventive Strategies

Thus, overall the manuscript (1) reflects a lack of appropriate assessment of evidence, despite a high profile project started in 2009, with substantial resource allocation and anguish among interventional pain management community, the manuscript is based on conjuncture, creating confusion about the recommendation of safeguards. We suggest the following 5 simple measures to prevent neurological complications of not only intraarterial injections, but also arachnoiditis :

1. Establish appropriate medical necessity and indications with appropriate route and drugs of administration.
2. Understand prevalence of complications, pathoanatomy, and mechanism of injury.
3. Mandate fluoroscopy for all procedures, however, without mandating multiple views. Do not inject through scar tissue after surgery with or without steroids and with or without fluoroscopy.
4. Utilize alternate approaches to lumbar transforaminal epidural injections considering the multiple risk factors in each patient with evidence showing that local anesthetic may be as effective as either particulate or nonparticulate steroids (44,45,54,70,74,75,83,84,93-97).
5. Do not perform cervical transforaminal epidural injections with or without steroids due to the lack of accuracy and efficacy until either their accuracy for diagnostic purposes or efficacy for therapeutic purposes is proven in high quality diagnostic or randomized controlled trials (73,80-82,84,96-116).

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