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Medical-Legal Review

A Medical-Legal Review Regarding the Standard of Care for Epidural Injections, with Particular Reference to a Closed Case

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Interventional pain management is an evolving field, with a primary focus on the safety of the patient. One major source of risk to patients is intraarterial or intraneural injections. Interventional pain physicians have considerable interest in identifying techniques which avoid these complications. A recent article has reviewed complications associated with interventional procedures and concluded that the complications were due to deviation from a specific prescribed protocol. One of the cases reviewed went to jury trial and the record of that case is in the public domain. Two of the authors of the recent review were expert witnesses in the trial. They provided conflicting testimony as to alleged violations of the standard of care. Their criticisms also differed from a third criticism contained in the article as well as the protocol being advocated in the article, thus contravening the claim that there is one prescribed protocol which must be followed.

The definition of standard of care varies amongst jurisdictions, but is generally defined as either that care which a reasonably well-trained physician in that specialty would provide under similar circumstances or as what would constitute reasonable medical care under the circumstances presented. Analysis of the case which went to trial indicates that there is not one prescribed protocol which must be followed; the definition of standard of care is broader than that. Interventional pain management is an evolving field and the standard of care is broadly defined.

Key words: Spine injection, complications, medical legal, standard of care, transforaminal injections, compression fracture, low back pain

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The field of interventional pain management rests upon 3 pillars: patient access to appropriate care, provision of services supported by scientific evidence, and the safe provision of these services. Interventional pain management is defined as, "the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment" (1). Further, interventional techniques have been defined by

MedPAC as, "minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain" (2).

It is expected that interventional pain management is practiced on the basis of evidence-based medicine (EBM) and comparative effectiveness research (CER) (3-11). CER is defined by the Institute of Medicine (IOM) (12) as, "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care." In contrast, EBM is defined (13) as, "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." Consequently, physicians are expected to provide effective treatments in a safe environment. Of these, safety takes pride of place as it rests upon the medical bedrock of "Firstly, do no harm." Interventional pain management procedures are widely acknowledged to have favorable risk/benefit ratios, especially in comparison to surgical interventions, in the treatment of chronic benign pain (14-51). Even then, the use of interventional techniques is exploding with practices at times that are questionable, along with various other modalities of treatments (14,51-55). However, the numerator in the ratio is certainly not zero as complications continue to be reported in the literature despite the fact that the injections were performed utilizing techniques which were accepted and regarded as appropriate at the time. Interest in the safety of IPM procedures has increased over the last several years because of the growing awareness that rare, but often times serious, complications can occur after injections (56-68). These investigations currently theorize that a critical cause of serious neurological complications has been intraarterial or intraneural injection.

As a result of this awareness of the risk of adverse outcomes after injections, many authors have focused upon the safety of these procedures (68-72). Recently, an article was published which reviewed a series of complications following interventional pain management procedures (68). Utilizing post hoc analysis of the cases, the authors claimed to be able to deduce what they considered to be the cause of the complications. In many cases, the complications were assigned by the authors to a specific error by the physician in not following a prescribed protocol.

One of the cases in which the prescribed protocol was, by specific report, not followed, was Glaser (67) and Bogduk et al (68) provide a detailed explanation as to how care deviated from the prescribed protocol. Interestingly, deposition and trial testimony in the public record by 2 of the authors of Bogduk et al (68) indicate that the opinions in the 2 reviews differed from each other and from the opinions presented in the published article. This lack of consistency in evaluating alleged failure to conform with protocol indicates that there is not one prescribed protocol but rather a variety of techniques that can be used as long as the techniques prevent or minimize intraarterial or intravascular injection.

The medical-legal case involved a 67-year-old woman with persistent pain after a T12 compression fracture. She did not respond to conservative treatment and a T12-L1 transforaminal epidural steroid injection was attempted on September 7, 2000. This injection was aborted as injection of contrast dye not only showed intravenous injection, but extravasation of contrast dye obscured the view of the foramen, making it impossible to safely place the needle. The patient returned one week later for the planned injection. The needle was placed in the ventral cranial aspect of the foramen. Injection of contrast showed venous runoff, but no extravasation of dye. The needle was therefore repositioned and a repeat contrast dye injection showed good outlining of the exiting left T12 nerve root, with contrast dye flow cephalad medial to the T12 pedicle. Lateral and AP views were obtained and contrast dye injected a total of 4 times. Local anesthetic and steroid were injected; within 5 minutes, the patient had a profound and persistent paraplegia with incontinence of bowel and bladder.

Bogduk et al (68) indicate that the procedure was faulty because

> the injections… were performed under lateral fluoroscopic imaging and with the needle at the upper end of the [fluoroscopy] screen. Both factors limit the ability of the operator to see a small artery passing medially and upwards to the spinal cord. Radicular arteries are small vessels that *may* be only fleetingly evident. (Emphasis added.) For optimal visualization and recognition, the vessel should be seen along a substantial length of its course. This requires centering the needle on an AP image, leaving an ample field of view medially and

> cephalad, across which any artery will be evident. Furthermore, it is critical that any artery be identified during the first injection of contrast medium. Once larger volumes of contrast medium have been injected, to outline the target nerve, they may obscure slender vessels that accompany the nerve.

This opinion ignores both the evidence contained in the trial testimony and evidence contained in the medical records. In addition, 2 of the authors of Bogduk et al (68) were expert witnesses for the plaintiff in this case. The case went to a jury trial and their testimony is part of the public record. That testimony provides 2 other explanations as to what occurred during the procedure that was a violation of the standard of care.

In contradistinction to the view presented in Bogduk et al (68) that the contrast dye injection was done under the wrong fluoroscopic positioning, one of the expert witnesses/authors testified that the deficiency violation of the standard of care in the case was related to the fact that the needle was not in the dorsal aspect of the foramen. A claim was made that the there was a ventral placement of the needle which was below the standard of care.

The second expert witness/author directly contravened the first, indicating that ventral placement of the needle was acceptable. The second expert noted that there was contrast seen on a lateral view, that an AP view was obtained showing contrast with the needle and injectate at the cranial aspect of the screen and then a repeat AP view obtained with the area of interest centered. Based upon the language of the operative report, this expert assumed that no contrast dye injection was made in the AP view with the fluoroscope centered and hence the procedure was below standard of care. The expert stated that it was below the standard of care because if more contrast dye had been injected with the fluoroscope centered, then the artery of Adamkiewicz would have been detected as it traveled cephalad to anastomose with the anterior spinal artery. This assumption was made despite the fact, as pointed out by defense experts, that more contrast dye was present with the needle centered on the fluoroscope image than when the needle was at the cranial aspect of the fluoroscope.

Thus, although Bogduk et al (68) attempt to present one prescribed protocol that, if deviated from, represents a departure from the standard of care, we present a case in which the authors of Bogduk et al (68) have provided 3 explanations as to how the subject case was below the standard of care. Firstly, the injection should be done in the AP view; secondly, that only 2 injections of contrast dye were made and these were made initially in the lateral view; and thirdly, the injection of the medication was made in the ventral epidural space.

This disagreement undermines that notion that there is one true method of performing procedures. The overarching and universally supported goal is patient safety. A major step towards patient safety is the avoidance of intraarterial and intraneural injections. We do not have a prescribed protocol that is the only way to avoid complications. Indeed, as noted by one expert witness/author in his deposition, failure to comply with the guidelines does not imply failure to meet the standard of care.

The exact definition of the standard of care utilized in courtrooms in the United States can vary somewhat from state to state. However, most states define the standard of care either as that care which a reasonably well-trained physician in that specialty would provide under similar circumstances or merely as what would constitute reasonable medical care under the circumstances presented (70). In theory, a technique or procedure should not be described as the "standard of care" unless it has become widely accepted as such among specialists in that field. Expert opinions are not supposed to be expressions of personal opinions or personal preferences (71,72) but, unfortunately, that occurs frequently in courtrooms by experts who couch their opinions in terms of the standard of care. Even more concerning are experts who, with the benefit of hindsight, manufacture theories as to deviations from the standard of care by misrepresenting the facts in the records or testimony or by distorting the medical principles involved to suit their theory and to justify their expert fees. Jurors are potentially vulnerable to being misled as they are typically instructed that they must rely on expert testimony in deciding if a defendant physician has complied with the standard of care and they do not personally have the expertise to assess the credibility of the expert testimony they are hearing. That is particularly difficult for jurors when they hear conflicting expert testimony and medical subjects which are highly technical.

One can see the folly of attempting to definitively testify to the standard of care in the Glaser case (67) as 3 "experts" could not come to a consensus regarding this issue, much less merely reasonably well trained physicians. This lack of consensus and variability of

opinion regarding the "correct" way to perform a procedure is indicative of the difficulty in honestly defining the standard of care in every clinical situation. It also strengthens the argument that the standard of care in medicine is an evolving concept as new information surfaces regarding the risks and efficacy of treatments. That was particularly true for the Glaser case as the complication which this patient experienced had never previously been reported in the medical literature and yet the testifying experts ignored that fact in coming up with their criticisms. It is also a concept that allows for variations in practice unless and until those practices can be deemed to definitively endanger the patient or have no significant benefit. In fact, the concept of the "standard of care" as used by courts in the United States allows for the proposition that several different medical techniques can be utilized in performing an injection and all be within the standard of care since all are "reasonable."

We have demonstrated that even the authors of procedural guidelines interpret alleged variations from these guidelines differently amongst themselves and also over time. Thus, while guidelines are useful and training paramount, there does not exist currently any one way of doing procedures. In fact, interventional pain management techniques, like other medical treatments, continue to evolve. What is important is ensuring that injections are not made into nerves or arteries. A detailed understanding of the anatomy of the foramen, the locations of the radiculomedullary arteries and the nerve roots, and the blood supply of the spinal cord is vitally important in reducing complications. Multiple techniques have been proposed and recommended to prevent these occurrences but avoidance of these vital structures is paramount (73,74). The final truth is that if there is any question as to the safety of the procedure, one should abort the procedure. As correctly pointed out by Bogduk et al (68), "Rescheduling is an inconvenience. A complication can be a catastrophe."

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