Pain Management and End-of-Life Care CME Program

Module 10

Registration: The registration page and test questions are at the end of this article. The 10 questions must be answered and submitted to the CSA in order to receive the CME credit. The full text of each module of this CME program, along with references, will be accessible through the CSA Web Site, **www.csahq.org**, in the *Bulletin*/Online CME section and as part of the online *CSA Bulletin.*

Fees: This is a free service for CSA members. Non-members will be charged $25 per CME credit hour. Your CME certificate will be mailed from the CSA office.

Availability: This module is available from June 30, 2006, until June 30, 2009.

Target Audience: California law now requires that every licensed physician complete 12 credit hours in pain management and end-of-life care by the end of 2006. This module fulfills one credit hour of CME toward that requirement. This program is intended for all licensed physicians, including anesthesiologists, residents, and physicians with an interest in pain management.

Faculty and Disclosures for Module 10:

Ann Lofsky, M.D.
Saint John's Hospital, Santa Monica

All faculty participating in continuing medical education activities sponsored by the California Society of Anesthesiologists are required to disclose any real or apparent conflict(s) of interest related to the content of their presentation(s) or any of the industry sponsors of the meeting. In addition, speakers must disclose when a product is not labeled for the use under discussion or when a product is still investigational.

For this program, Dr. Lofsky has disclosed that she has received a salary from The Doctors Company for her role as a medical consultant.

CME Sponsor/Accreditation: The California Society of Anesthesiologists is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

The California Society of Anesthesiologists Educational Programs Division designates this educational activity for a maximum of 1 AMA PRA Category 1 Credit™.

Evaluation: An evaluation of Module 10 of this series is offered after the test questions. Please fill in your responses and return them to the CSA office.

Objectives: At the conclusion of this course, participants should be able to:

- describe the techniques that expert pain reviewers feel will lessen the incidence of neurologic complications after interscalene brachial plexus blocks;
- list four risk management suggestions to avoid complications while performing cervical epidural steroid injections.

Resources: These materials, including questions, are offered online at the CSA Web Site at www.csahq.org. Instructions for the Bulletin version are on the registration page.

Improving Patient Safety for Pain Blocks:

Lessons Learned from Medical Malpractice Claims Reviews

By Ann Lofsky, M.D.

Dr. Lofsky completed both internal medicine and anesthesiology residencies at U.C.L.A. before entering private practice in anesthesiology. She is currently a partner in the anesthesia group at Saint John's Hospital in Santa Monica. She has previously served on the board of the CSA as director for District 11. For 13 years, Dr. Lofsky served on the board of governors of The Doctors Company, a physician-owned medical malpractice insurer. In this capacity, she has published and lectured extensively on risk management and patient safety concerns for anesthesiologists. She is currently a governor emeritus and anesthesia consultant for The Doctors Company.

Joshua P. Prager, M.D., M.S.
Editor, CSA Pain Management and End-of-Life Care Program

Anesthesiologists who practice pain management fall along a broad spectrum, ranging from physicians who see pain patients exclusively to those who work primarily in operating rooms, performing occasional epidural steroid injections or blocks for the express purpose of relieving postoperative pain. Reviews of malpractice claims relating to pain blocks reveal

that while there are different risks involved when compared with anesthesiology claims in general (virtually no dental damage!), the injuries that are seen still may be quite severe, often involving permanent disabilities. Evaluations of pain claims from a risk management standpoint have led to a number of suggestions to minimize patient injury and to help anesthesiologists protect themselves from unnecessary liability.

Documentation

Record keeping and informed consent issues are frequent concerns in malpractice claims for pain. Procedures performed to prevent or relieve pain are, generally speaking, elective. When complications develop, attention inevitably focuses on what the patient was told prior to the procedure regarding the risks. A determination will then be made as to whether or not the procedure was performed according to currently acceptable standards. A significant number of pain cases must be settled because of inadequate documentation of either the informed consent process or the procedure itself.

Patients need to receive adequate information and understanding of planned procedures in order to make their own informed decisions about whether or not to proceed. When blocks are performed for postoperative pain, patients should be aware that their blocks are elective choices, and that there are other alternatives available for pain relief. A statement that "The surgeon asked me to do it" is never a substitute for a patient's informed consent.

Common risks of the procedure to be performed should be mentioned as well as the possibility of an exceedingly rare but catastrophic outcome. This can still be phrased in a reassuring light: "I have to tell you that very rarely patients have died because of unusual complications of procedures like this, but I certainly don't anticipate any problems." This is very important from a medical/legal standpoint. Fortunately, rarely have patients suffered cardiopulmonary arrests during block placements as a result of accidental intravascular injections of local anesthetics or anaphylaxis. In addition to informing patients of such risks, physicians should always be prepared to manage such emergencies whenever and wherever blocks are performed.

The documentation of pain blocks in medical records reviewed for malpractice claims typically runs the gambit from minutely detailed and dictated procedure notes to simple preprinted check-off sheets. Anesthesiologists should make sure that however the procedure is documented, sufficient information is provided to demonstrate that acceptable standards of care were met. What interspace was injected? What size needle was used? What was its length? Were there any paresthesias? Did you use fluoroscopy? Did you use a nerve stimulator?

These are all questions anesthesiologists have been asked in depositions for malpractice claims whose defense depended on the answers. If this information was documented in writing shortly after the procedure was performed, that is likely to be much more credible to a jury. Memory alone may be unreliable for events that occurred several years in the past.

Postoperative Pain

Interscalene Brachial Plexus Blocks

Invasive procedures performed to relieve postoperative pain sometimes seem to be treated almost as an afterthought. In medical records reviewed, they may not even be mentioned in the documentation of the informed consent and may be only briefly noted on the anesthesia record itself. They are not infrequently, however, the main reason for medical malpractice claims. A significant number of claims alleging neurologic injuries have involved brachial plexus blocks performed to provide postoperative pain relief for patients undergoing shoulder procedures.

Alon Winnie, M.D., described the use of single injection brachial plexus blocks in the 1960s. Since then he has published extensively on this subject and is considered one of the leading experts in this field. Winnie suggests the use of 22-gauge beveled needles, stating that when smaller gauge needles are used, the force of the injectate may be too attenuated to push nerves out of the way, potentially increasing the chance of intraneural injections.[1] Expert witnesses in malpractice claims have also argued that smaller gauge needles are floppier and therefore more difficult to precisely control. Winnie strongly advocates the use of needles 1½ inches in length or less, stating simply that longer needles "should never be used."[1] Since pain is a warning sign of neurological injury, injection should be abandoned immediately if severe pain results. Medical malpractice claims involving deviations from widely accepted practices are often more difficult to defend.

A prospective study of interscalene blocks showed that short- and long-term neurological complications, while rare, do occur.[2] A total of 521 patients had elective shoulder surgeries performed with interscalene blocks prior to general anesthetics; 234 had brachial plexus catheters placed; the remainder of the blocks were accomplished with single shot injections. The blocks were all performed using 21- or 22-gauge "short" beveled needles attached to nerve stimulators. On the tenth post-op day, 14 percent of patients reported either paresthesias, dysesthesias, or pain deemed unrelated to the surgery itself. At one month, 8 percent had persistence of these symptoms, although they had normal EMGs. At three months, 4 percent of patients were still symptomatic,

but at nine months, only one patient (0.2 percent) had persistent complaints. The authors concluded that while the incidence of transient neurological complaints is high, very few patients experience long-term complications. Still, it would appear prudent to warn all patients in whom interscalene blocks are planned that postoperative neurological symptoms are within the risks of this procedure.

A 2000 article by Jonathan Benumof, M.D., described four cases of spinal cord trauma associated with interscalene blocks.[3] The blocks described in the article were all performed on patients who were heavily sedated or under general anesthesia for shoulder surgery at the time of the needle placement and injections. These patients developed evidence of high spinals followed by motor and sensory impairment of the upper extremities. In each case, there was MRI evidence of direct damage to the spinal cord at C6, the level of the needle insertion for the block. One of Benumof's conclusions was that general anesthesia should be considered a relative contraindication for interscalene brachial plexus blocks since patients under general anesthesia are not be able to complain of pain or paresthesias in the event of intraneural injections. The blocks ideally should be placed on lightly sedated patients in advance of the induction of general anesthesia for surgery.

Benumof also concluded that because the spinal cord usually is less than two inches from the interscalene groove skin line, while the brachial plexus is often less than half that distance from the skin, a needle one and a half inches or less in length should be used for interscalene blocks.[3] As Winnie also advised, this should help minimize the chances of inserting it too far. Another risk management recommendation from experts is that the needle should maintain a caudad direction at C6. This will help minimize the possibility of inserting it through an inter-vertebral foramen and into the epidural or subarachnoid space.[3,4] Extra care should be exercised when performing interscalene blocks on obese patients, as the landmarks may be obscure and the depth of the brachial plexus from the skin increased.[3]

Estimates of the incidence of post-procedure phrenic nerve block, with transient ipsilateral diaphragmatic paralysis, run as high as 100 percent in patients receiving interscalene brachial plexus blocks—regardless of the technique used.[5] For many patients, this may be completely asymptomatic, but special care should be taken in deciding whether or not to perform the block in the obese, the elderly and in those with COPD, as respiratory reserve in these patients may be compromised and hypoxia might result. Patients who are forewarned about the possibility of temporary respiratory symptoms related to hemidiaphragmatic paralysis may be less alarmed should this occur.

Chronic Pain

Cervical Epidurals

Epidural steroid injections are one of the most commonly performed blocks for chronic pain, yet they are not without risks. A report of the American Society of Anesthesiologists Closed Claims Project revealed that 114 out of the 276 claims for invasive pain procedures involved epidural steroids.[6] This study, however, combined data from blocks performed at all levels (cervical, thoracic, lumbar and caudal).

The Doctors Company recently reported on an alarming incidence of major injuries relating to cervical epidural steroid injections.[7] In this malpractice carrier's experience, the number of claims for cervical epidurals consistently exceeds the combined total of claims for steroid blocks performed at all other levels. Because it does not appear that cervical blocks are performed at a substantially higher rate than blocks at other levels, they may, therefore, be associated with a true higher incidence of significant complications. The narrowing of the epidural space in the cervical area and its increased proximity to the spinal cord are factors that might contribute to a higher injury rate when the dural space is entered unintentionally.

The latter series reviewed 13 medical malpractice claims relating to cervical epidural steroid injections. Allegations included arachnoiditis, paralysis, anoxic brain damage and death. The blocks were all performed at C5-6 or C6-7 and were done in either the sitting or prone positions with the neck flexed. Standard #22 or #18 gauge epidural needles were employed and fluoroscopy was used in all but one case.[7]

Cervical Spinal Cord Injury: There were seven claims involving cervical spinal cord trauma with resultant neurological injuries. All of the patients in these claims had MRI evidence of trauma to the cord at or near the level of the attempted epidurals. Imaging descriptions included cord edema, abnormal signals consistent with blood, fluid or contrast material within the cord, cord syrinx or scarring. Most of the patients had pre-procedure MRIs or CT scans confirming that the findings were new.

The medical records recorded that these patients complained immediately or during the recovery period of pain, weakness or numbness in one or both arms and hands, and in two cases, one arm and the ipsilateral leg. Most of these patients were treated with steroids. The symptoms tended to improve with time, but all of the patients alleged some permanent residual disability.

Four of the patients received intravenous sedation/analgesia before the block—usually a combination of midazolam and fentanyl, with propofol added in two of the claims. Excessive sedation/analgesia was an allegation in some of these claims during the litigation process. The issue of sedation during epidural steroid blocks remains controversial. While many anesthesiologists do use IV medications to increase patient comfort and relieve anxiety, it has been suggested by some authors that this might leave patients unable—or less able—to complain about pain or paresthesias, which can serve as early warning signs of nerve trauma, before more serious damage is done.[8,9] The authors of a large series of epidural steroid injections, including 669 cervicals, performed uneventfully using minimal or no sedation, explained that: "Heavily sedated patients are unable to respond with the expected pain and paresthesias due to spinal cord irritation in the event of errant needle placement."[8]

Sudden jerking movements during needle insertion or during the injection of dye or medication were reported in four of these claims. It was the conclusion of some reviewers that the sudden movement had likely caused the needle to dislocate and perforate the cord. An alternative explanation offered is that because cord trauma reportedly is quite painful, the patients might have moved because of needle injuries and not just prior to them.[7] In three of these claims, when the patients moved or complained of severe pain, the injections were still performed, resulting in dye or fluid visible by MRI within the cord. Reviewers suggested that, in retrospect, it would have been preferable to remove the needles entirely and replace them or to have aborted the procedures rather than proceed.[7]

Respiratory Arrest: All three of the patients who had respiratory arrests in The Doctors Company report received intravenous sedation with midazolam and fentanyl, with one patient receiving additional propofol.[7] All of these patients received injections of bupivacaine in addition to steroids. The authors of the large study of uncomplicated cervical epidural blocks performed them by injecting only steroids into the epidural space, explaining that "Anesthetic agent is not injected into the cervical epidural space to avoid the risk of respiratory suppression resulting from high cervical anesthesia."[8]

Respiratory arrests resulting from unintentional dural puncture may not happen immediately. Two of the arrests occurred in recovery rooms when the anesthesiologists were no longer in attendance. One of the patients arrested while an anesthesiologist was performing the block, while a second anesthesiologist administered the sedation.

Epidural Hematoma: The one patient in this series who developed a cervical epidural hematoma following epidural steroid placement was not on any

anti-coagulating drugs. During the evening following the block, the patient noted progressive weakness of all four extremities and an MRI demonstrated a large hematoma compressing the cervical cord. Surgical decompression was accomplished with a substantial improvement in neurological function. Because time is always of the essence in determining functional improvement after cord compression, patients should be made aware of the symptoms and signs and should know how to contact a physician immediately, if necessary.

Spinal Cord Infarction: In the one claim involving a vascular injury to the cord, the patient complained of pain and "tingling" on needle insertion. The needle was withdrawn 2 mm and local with steroid was injected. The patient immediately complained of ringing in the ears, but according to the anesthesiologist, by that time the block was already complete. In the recovery room, the patient could move neither arms nor legs. An MRI showed ischemia and infarction of the spinal cord in the cervical area and the neurological diagnosis was probably intra-arterial injection with spasm or occlusion of a vertebral artery branch.

Because arterial injections are more likely to occur with a transforaminal approach to the cervical epidural space, reviewers recommended that particulate steroid injections be avoided whenever that approach is used. Injections should be given slowly enough to allow patients to report any unusual sensations, and patients should always be questioned if they appear uncomfortable.

Risk Management: The study reviewing the large number of cervical epidural steroid injections reported that patients found the procedure to be relatively painless.[8] Therefore, complaints of pain or paresthesias, or sudden "jerking" movements should be considered significant warning signs of potential nerve injury and the procedure should be stopped immediately. Strong consideration should be given to removing or completely repositioning the needle before proceeding with any injections, including epidurography. The advisability of continuing with the block after a known wet tap should also be considered because the risk that injected substances might spread into the CSF may be increased.[7]

Injections should be given slowly, following negative aspiration for blood or CSF. Fluoroscopy, while providing a measure of safety, cannot alone prevent neurologic injury and should not provide a false sense of security.[7] Cadaver evidence has shown that the ligamentum flavum, the major landmark for the loss of resistance technique, frequently fails to fuse in the midline over the cervical interspaces, and midline gaps were observed in more than 50 percent of specimens.[10,11] Because these gaps are more common at the higher interspaces, it follows that injections should be made into the most caudad interspace

possible. Minimal complications were seen in the large series of blocks all performed at C7-T1.[8] The epidural space above that level may be diminutive and, therefore, associated with a higher risk of dural puncture.[8] Because epidurally injected substances spread up to four interspaces above the site of injection, most of the cervical discs spaces may be reached from the C7–T1 interspace while lessening the risk of cord damage.[7]

The monitoring of patients undergoing cervical epidural blocks is important both during the procedure and in the recovery period, especially when sedation or local anesthetics are used. Some authors suggest routine monitoring for 30-45 minutes after completion of the block.[8] Resuscitation equipment and drugs should be readily available throughout this period, as should personnel trained in their use. Physicians should be aware of the concerns regarding sedation and should make an individualized decision for the specific patient regarding the need for (and, if so, the amount of) sedation.

As baby boomers age, the incidence of back and neck pain is increasing and the demand for cervical epidural steroid injections likely will continue to increase.[12] As with any invasive procedure, the risks must be weighed against the potential benefits to patients in deciding appropriateness. Knowledge of the complications encountered in medical malpractice claims will hopefully serve to make this a more informed decision for both physicians and their patients.

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Pain Management and End-of-Life Care

CSA Educational Program

California law now requires that every licensed physician complete 12 credit hours in pain management and end-of-life care by the end of 2006. The CSA Educational Programs Division is providing a 12-module program to satisfy this requirement. Each article is written by a current or former director of a university-based pain management program in California. The full text of each article, along with references, will be accessible through the CSA Web Site. Joshua P. Prager, M.D., M.S., of the David Geffen School of Medicine at UCLA is the Coordinator of this series.

One module worth one CME credit hour is presented in each quarterly issue of the CSA *Bulletin* for Volumes 53-55 and it is also offered online through the end of 2006 at **www.csahq.org**.

In this issue of the *Bulletin*, Module 10 is available. Modules 1 through 10 are available on the CSA Web Site now. You may also contact the CSA office at (800) 345-3691, and we will send you the materials by fax or mail.

Module 11 will be published in the Fall 2006 issue and the final module, Module 12, will be available online by October or November 2006 to finish the series. It will also appear in the Winter 2007 issue for those who are still interested.

Watch for Module 11 in the Fall 2006 issue.

Registration

To register for the CSA CME Course in Pain Management and End-of-Life Care, Module 10, fill out this form. Then complete the test and the evaluation, and **mail or fax** all three to the CSA office at:

951 Mariner's Island Boulevard #270
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Questions

1. When obtaining informed consent for pain procedures you should:
    a. Mention primarily those risks with a demonstrated incidence greater than 5 percent in published studies.
    b. Mention that catastrophic outcomes such as permanent neurological injury or death, although fortunately rare, have occurred.
    c. Avoid mentioning anything that might alarm or stress a patient beforehand.
    d. Rely on the surgeon or referring physician to explain the procedure for you.

2. Which of the following is *true* concerning the needle used to perform interscalene brachial plexus injections?
    a. It is preferable to use #25 or #27 gauge needles because they are associated with a lower incidence of neurological injuries.
    b. Blunt rather than beveled needles are preferable as they provide more tactile feedback during insertion.
    c. Use of a 2.5 inch needle is advised as the plexus may lie deeper than expected.
    d. Most experts suggest the use of #22 or #21 gauge 1.5 inch beveled needles.

3. Why should the needle in an interscalene brachial plexus block be directed at a caudad angle?
    a. It decreases the likelihood of passing through an intervertebral foramen and unintentionally injecting into the epidural or subarachnoid space.
    b. It has been shown in prospective studies to be associated with the highest success rate.
    c. It avoids most paresthesias and direct nerve trauma.
    d. It decreases the possibility of phrenic nerve blockade.

4. When performing interscalene brachial plexus blocks for postop pain relief in shoulder surgeries, evidence indicates that:
    a. It is preferable to use the block as the main anesthetic for surgery, as the addition of general anesthesia increases the complication rate unnecessarily.
    b. Patients who have the blocks performed while they are under the effects of general anesthesia report a higher satisfaction rate with the procedure overall.
    c. Cases of serious permanent injury to the spinal cord have occurred when the blocks were performed after general anesthesia was induced.
    d. The success rate of the block is increased when patients are given moderate or heavy sedation prior to needle insertion.

5. Which of the following is *not* true concerning diaphragmatic paralysis and interscalene brachial plexus blocks?
    a. Published incidences of hemidiaphragm paralysis after interscalene blocks run as high as 100 percent.
    b. Patients with preexisting pulmonary disease are more likely to complain of symptoms related to paralyzed diaphragms after interscalene blocks.
    c. Adherence to correct technique will minimize the incidence of diaphragmatic paresis after the block.
    d. Patients may be reassured that although they might develop minor shortness of breath or dyspnea on exertion after an interscalene block related to hemidiaphragm paralysis, this is a transient condition that should abate when the block dissipates.

6. Which of the following statements concerning the complication rate of cervical epidural steroid injections is *true*?
    a. They are disproportionately represented in medical malpractice claims because they are more commonly performed than blocks at all other levels.
    b. They accounted for 114 claims out of 276 in the ASA Closed Claims Project report.
    c. They may have a true higher incidence of complications than epidural steroid injections performed at other levels.
    d. They are exceeded in complication rate only by thoracic epidural steroid injections.

7. Which of the following complications have been reported following cervical epidural steroid injections?
    a. Death
    b. Permanent Neurological Injury
    c. Anoxic Brain Damage
    d. All of the Above

8. What is the major concern that claim reviews raise regarding sedation/analgesia used for cervical epidural procedures?
    a. Sedated patients might be unable to complain of pain or paresthesias that could serve as warning signs of impending nerve or cord trauma.
    b. Inadequately sedated patients may move unpredictably causing nerve trauma, including cord injury.
    c. Overly sedated patients may develop respiratory arrests while the anesthesiologist's attention is diverted in performing the block.
    d. Inadequately sedated patients may become extremely anxious and allege emotional distress.

9. When a patient complains of severe pain during insertion of the needle or injection of medication, the anesthesiologist should …
    a. Immediately inject contrast material and visualize by fluoroscopy to verify continued correct needle placement in the epidural space.
    b. Stop all injections and remove or replace the needle.
    c. Reassure the patient that the pain is transitory and will resolve with the completion of the injection
    d. Administer intravenous narcotics or propofol.

10. Which of the following is *not* a risk management suggestion for avoiding complications related to cervical epidurals?
    a. Consider placing only steroids rather than local anesthetic mixtures into the cervical epidural space and monitoring patients closely for signs of high spinals.
    b. Inject slowly, and encourage patients to describe any abnormal sensations they experience during the process.
    c. Use fluoroscopy to ensure accurate identification of the correct spinal level.
    d. Use the C5–C6 interspace whenever possible.
    e. Avoid particulate steroid injections when using a transforaminal approach.

Evaluation of Module 10

As part of the CSA Educational Programs Division's ongoing efforts to offer continuing medical education, the following evaluation of this program is requested. This is a useful tool for the EPD in preparing future CME programs.

1. How well were the learning objectives of this program met?

Very Well	5	Above Average	4
Average	3	Below Average	2
Not Well at All	1		

2. How relevant was the information in this program to your clinical practice?

Very Relevant	5	Above Average	4
Average	3	Below Average	2
Not Relevant	1		

3. How would you rate this program overall?

Excellent	5	Above Average	4
Average	3	Below Average	2
Poor	1		

4. Did you detect any commercial bias in this module?

Yes	No