

Pain Management and End-of-Life Care CME Program

Module 12

Registration: The registration page and test questions are at the end of this article. The 12 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 November 27, 2006, until November 27, 2009.

Target Audience: California law now requires that every physician licensed by 2002 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. Doctors licensed after 2002 have four years from the date of licensure to complete the 12 unit CME 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 12:

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Neuromodulation (cont'd)

For this program, Dr. Prager did not receive any support with regard to the preparation of this article. In the last two years, he has performed educational consulting for Medtronic, Advanced Bionics (a Boston Scientific Corporation), Pfizer and Lilly.

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 12 of this series is offered after the test questions. Please fill in your responses and return them to the CSA office.

Objectives: Upon completion of this activity, participants will be able to:

- Discuss the history and indications for spinal cord stimulation
- Discuss the history and indications for intrathecal medication therapy
- Explain the need for behavioral evaluation and adequate trial procedures before implanting neuromodulatory devices.

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

Summary of Pain Management and End-Of-Life Care Series, and Neuromodulation

By Joshua P. Prager, M.D., M.S.

Dr. Prager received his M.D. and M.S. (Management/Health Services Research) from Stanford in 1981. He is Board Certified in Internal Medicine and Anesthesiology and Doubly Board Certified in Pain Medicine, having completed his Internal Medicine Residency at UCLA and Anesthesia Residency at Massachusetts General Hospital. He has served on the full-time faculty at Harvard Medical School and at UCLA where he was the Director of the Pain Medicine Center. Currently, he is Director of the Center for the Rehabilitation of Pain Syndromes at 100 UCLA Medical Plaza, a multi-disciplinary program focused on the

Neuromodulation (cont'd)

functional rehabilitation of patients with complex regional pain syndrome. He is President of the North American Neuromodulation Society (NANS), the society of physicians who implant devices for the control of pain and spasticity and other nervous system disorders. Most recently, he formed a coalition of all 10 organizations whose physicians implant neuromodulatory devices, for the purpose of ensuring patients access to these valuable techniques. This module marks the completion of Dr. Prager's three-year tenure as Editor of the CSA Pain Management and End-of-Life CME Program, calling upon colleagues who are current or former directors of pain-related programs in California to contribute to this series.

In the last decade great advances have been made in the field of pain management and in neurosciences in general. The knowledge physicians attained during medical school with regard to this field is often obsolete if the physician training was more than 10 years ago. The legal case¹ that motivated the legislature to pass Assembly Bill 487, mandating 12 hours of pain management and end-of-life care training for physicians, underscores the all too common lack of current knowledge in this field.

The purpose of this series has not been to provide a comprehensive review of pain management. This task would have required more time than is mandated by the legislature to refresh a physician's knowledge. Rather, the goal has been to provide an interesting sampling of topics within pain management that illustrate the rapidly evolving changes that impact the field. Dr. Mackey's module² demonstrated the information gained about changes in activity in the nervous system as a consequence of untreated chronic pain, as seen through functional magnetic resonance imaging. The changes that occur in the nervous system as a consequence of untreated pain as described in modules 2 and 4 demonstrated that these changes produce symptomatology that fulfill the definition of a disease.^{3,4} Complex regional pain syndromes illustrate how pain syndromes become such diseases.⁵ Neurobiology allows us to now study receptors and understand them in ways previously unobtainable. Palmer's module viewed tolerance from a more modern perspective.⁶ Richeimer's module presented practical clinical knowledge gained by a better understanding of the difference between physical dependence, tolerance and addiction.⁷

Appropriate pain treatment has evolved to become a right of all suffering patients. Berger's module highlighted the rapidly expanding field of palliative care.⁸ Despite the advances that have occurred in the science of pain management, the role of those who provide pain management care should be to provide for the functional rehabilitation of patients as much as, if not more than, to alleviate the symptoms of pain itself. Dr. Pham's module integrated proven techniques with modern pain management knowledge.⁹

The evolving field of pain management has produced numerous medical-legal consequences. The modules of Fishman,¹⁰ Lofsky¹¹ and Richeimer⁷ all

demonstrated how a rapidly evolving field can produce a changing legislative and legal environment in which the pain management is practiced, and alerted us to the special caution that is necessary.

One area that utilizes the new technological abilities with regard to pain management involves neurosurgical approaches to pain, as discussed by Dr. DeSalles.¹² With better imaging and greater understanding, neurosurgical treatment of pain is progressing at an ever-increasing rate. We can now not only correct anatomical lesions, but we can perform neuromodulation to augment what we cannot change. Two areas of neuromodulation are discussed in the remainder of this article. Spinal cord stimulation and intrathecal drug delivery benefit from microprocessor technology to allow pain physicians to implant devices that modulate pain without causing any form of destruction. These procedures are fully reversible and nondestructive and can provide benefits that were inconceivable several decades ago.

Spinal Cord Stimulation

With the advent of the gate control theory of pain in 1965, a paradigm shift occurred in the thinking regarding chronic pain syndromes. According to this theory, stimulation of the low-threshold primary afferent fibers produces central suppression of nociceptive influences.¹³ The theory was applied to the treatment of peripheral nerve pain with potentially great results. In 1967, application of this theory suggested that stimulation of the dorsal columns of the spinal cord to control intractable lower extremity pain would “close the gate” at the level of *substantia gelatinosa*, thereby producing pain control over a wide region of the body.¹⁴ At first, spinal cord stimulation (SCS) surgeries were performed in an open fashion, by performing laminectomies, opening the dura, and placing the electrodes directly to the dorsal columns in the subarachnoid space. Numerous complications occurred, including subdural fibrosis as well as leakage of cerebrospinal fluid.¹⁴ In later years, it was suggested that epidural placement of the electrodes would provide comparable results.¹⁵ The earlier of these clinical results were encumbered by the cephalad placement of the electrodes, producing segmental side effects.

In recent years, the term “dorsal column stimulation” has been replaced by “spinal cord stimulation,” because it has become obvious that the dorsal columns are not stimulated in isolation. Rather, more pathways are being stimulated and more is occurring mechanistically in the spinal cord than was previously understood. It is difficult to understand the mechanism of spinal cord stimulation on the basis of conventional neurophysiological information.¹⁶ It is not known whether electrical stimulation activates specific axons inhibiting central information, or whether the stimulation inhibits

Neuromodulation (cont'd)

transmission directly in nociceptive fibers. The important concept regarding SCS is that it is a reversible neuroaugmentive technique distinguished from “ablative” procedures such as radiofrequency destruction, or “anatomic” procedures such as sympathectomy or decompression.

Efficacy has been established for SCS for neuropathic as opposed to nociceptive pain, supported mostly by case reports and case series. The long-term efficacy of SCS is suggested by extended follow-up evaluation, with the longest case series encompassing greater than 20 years.¹⁹ The predominant complication in these series has been lead migration, which—although it reduces or eliminates the efficacy of the system—causes no harm to the patient.

In the intervening years since the advent of SCS, numerous advances have been made. Leads can now be placed percutaneously through a needle. More efficient leads can be placed via laminotomy, using a paddle-type electrode. Systems have become totally implantable with application of pacemaker technology to internal pulse generator design. Over the last three years, more sophisticated technology has been approved and released utilizing rechargability, thereby reducing the need to manage power for more sophisticated programming configurations. With these new configurations, pain targets previously unobtainable are now being covered.

Paramount to successful application of spinal cord stimulation is the need for a proper evaluation of the patient. This includes review of the medical records, history, and physical examination, as well as a comprehensive behavioral evaluation. Following this, it is mandatory to perform a prolonged trial of the modality to determine its efficacy, as well as any unpleasant or unacceptable side effects to the patient. Only following this evaluative process should a permanent implantation be performed.

Accepted indications for spinal cord stimulation include radicular pain, complex regional pain syndrome, and pain of failed back surgery syndrome (FBSS). In Europe, the most common indications for spinal cord stimulation include treatment of refractory angina and peripheral vascular disease. Off-label commonly performed procedures in the United States include application for pelvic pain such as interstitial cystitis, headache, and visceral pain. Microprocessor technology will allow for progressively more complex stimulation arrays, and pulse generators are expected to become smaller in size with greater rechargability.

Numerous studies have been conducted regarding spinal cord stimulation for the treatment of chronic pain.^{17,18} A reference list can be found on the CSA

Neuromodulation (cont'd)

Web Site at http://www.csahq.org/pdf/cme/Supplemental_reference_list.pdf regarding the long-term efficacy of spinal cord stimulation

Spinal cord stimulation is most effective for regionalized pain. When a trial of stimulation is not successful, other neuromodulatory techniques such as intrathecal drug delivery can be considered.

Intrathecal Drug Delivery

The predominant benefit of intrathecal medication delivery is that medications delivered directly into the spinal fluid have 300 times the analgesic effect of the identical medication administered orally. Such a substantial reduction of the amount of medication administered eliminates much of the toxicity of pain medications, especially cognitive dysfunction. Higher analgesic equivalents can be administered, providing better pain relief without most of the systemic side effects.

The discovery of opioid receptors²⁰ provided a rational basis for the delivery of opioid drugs intraspinally. By 1979, reports of epidural and intrathecal opioid delivery in humans had entered the peer-reviewed literature. Intraspinally delivered drugs directly to opioid receptors, limited systemic exposure, and by decreasing the opioid dosage required for pain relief, generally reduced side effects—which, in turn, facilitated the provision of greater analgesia. The benefits of short-term spinal analgesia, primarily for patients with intractable cancer pain,²¹ led to investigation of longer-term continuous subarachnoid opioid infusions for the management of both cancer pain and noncancer pain, such as that produced by FBSS.²²

The key to appropriate treatment of pain is proper diagnosis. Pain can be characterized as nociceptive (e.g., somatic pain), neuropathic (pain from nerve injury), or idiopathic. Pure nociceptive pain usually responds well to systemic opioids. Neuropathic pain responds to opioids at higher doses and often is more responsive to a large number of antineuropathic medications. FBSS pain usually is a mixed type of pain that is both nociceptive and neuropathic.

In appropriately selected patients, intraspinal therapy has been refined through accumulated experience from treating tens of thousands of cases (more than 25,000 with implantable pumps), improved drug delivery systems, and new pharmacologic approaches, making it an effective technique for the control of intractable pain.

Intraspinal Drug Delivery Systems

Intraspinal drug delivery can be accomplished by a variety of means, including percutaneous catheter, percutaneous catheter with subcutaneous tunneling, implanted catheter with subcutaneous injection site, totally implanted catheter with implanted reservoir and manual pump, and totally implanted catheter with implanted infusion pump. The choice of the system depends on the indication for intraspinal therapy, the need for bolus versus continuous infusion, the patient's general medical condition, available support services, ambulatory status, life expectancy, and cost. In general, percutaneous tunneled catheters, external pumps, and implanted passive reservoirs can be more cost-effective when life expectancy is a matter of weeks to months. A fully implanted pump becomes economical if life expectancy is longer than three months.

Two types of implantable drug delivery systems are marketed currently in the United States. The first commercially available implanted pump delivered medication at a fixed rate and consisted of two chambers separated by a flexible bellows, in addition to a side port for bolus injections. Outflow was regulated by compressed Freon gas, so changes in altitude and temperature affected drug flow. Because the pump ran at a fixed rate, changes in the rate of medication delivery could be accomplished only by emptying the pump and refilling it with a different concentration of medication. A second fixed-rate pump is available.

The third type of implantable delivery system is a programmable electronic pump powered by batteries that last up to seven years, depending on flow rate. One pump model contains a 10- or 18-mL reservoir, with another model containing either 20-ml or 40-ml reservoirs, both models having a collapsible reservoir and a peristaltic pump that pushes medication through a bacteriostatic filter and catheter. This pump is FDA-approved for epidural or intrathecal infusion of preservative-free morphine sulfate for chronic, intractable pain; ziconotide²³ (a neuron-specific N channel Calcium blocker), which primarily acts in the dorsal horn of the spinal cord; and baclofen for chronic spasticity. The pump is programmed, using noninvasive telemetry, to control medication concentration, volume, and dosage. The programmable feature allows flexible dosing options over time and permits precise dose titration. A new development is the release of a patient activator which allows the patient to self-administer intrathecal boluses preprogrammed by the physician. Both pump types require refilling under sterile conditions at least every several months, depending on flow rate. In deciding whether to implant a programmable pump or a fixed-rate pump, several factors are to be considered. The programmable pump provides greater flexibility of medication delivery and clearly is more adjustable.

Neuromodulation (cont'd)

However, a programmable pump is more expensive and needs to be replaced when the battery fails. Hardware is but one component of the entire implantation cost, and the percentage difference in cost diminishes when all costs are aggregated. As a rule of thumb, programmable pumps are implanted when dosage titration and regulation is anticipated, and fixed-rate pumps may provide a cost-effective choice when dosage is expected to be stable. In practical terms for the patient with chronic pain of spinal origin, dosage regulation is anticipated. Thus, a programmable pump serves the patient better initially. If the patient stabilizes on a regimen, a fixed-rate pump may be considered for replacement to minimize expense. However, the current and future flexibility of programmable pumps makes them a superior choice for most important factors, excluding expense.

Patient Selection and Screening Trials

The literature is virtually unanimous in emphasizing the importance of appropriate patient selection if intraspinal pain therapy is to be successful.²⁴ Patients with chronic pain are subject to neurophysiologic, emotional, and behavioral influences, which govern their perception of pain and of pain relief. Therefore, treatment of chronic noncancer pain is multidisciplinary, drawing on cognitive and behavioral psychological therapies, functional rehabilitation, orthopedic and neurologic surgery, medications, nerve blockade, and neuroaugmentive and sometimes neurodestructive procedures.

Drug Selection

Intraspinal drugs must be preservative-free. Alcohol, phenol, formaldehyde, and sodium metabisulfite—common drug preservatives—all are toxic to the central nervous system. Any drug packaged in a multidose vial probably contains preservatives and should not be used for intraspinal administration. Preservative-free morphine sulfate and ziconotide are the only drugs approved by the FDA for intraspinal delivery for pain relief. Its long history of clinical use, long duration of action (12 to 24 hours), and relative ease of use explain why morphine was the gold standard for intraspinal therapy. If morphine is poorly tolerated, other opioids (hydromorphone, meperidine, methadone, fentanyl, and sufentanil) also can be used intraspinally. Care must be taken to ensure that the medication preparation is compatible with the pump tubing, and that the medication is pure and preservative-free. Drug admixtures may help patients who experience side effects or tolerance associated with the increasing doses of opioids required to provide analgesia. Combining drugs with different mechanisms of action can produce synergy, as in the case of morphine combined with bupivacaine. In theory, synergy reduces morphine-associated side effects by decreasing the opioid dose required for analgesia.

Neuromodulation (cont'd)

One caveat applies: Although use of admixtures is increasingly popular and often produces increased analgesia, safety data on many of the combinations is scarce. In fact, there is a paucity of literature even demonstrating the stability of various admixtures in the pump at body temperature up to three months. There have been two consensus meetings of experts related to treatment algorithms for off-label use of intrathecal medications, with results published in 2000²⁵ and 2003.²⁶

Future Challenges

During the past decade, intraspinal therapy for intractable pain has evolved into a useful clinical treatment. Nevertheless, many challenges remain. Large-scale, well-controlled studies could answer some perplexing questions regarding efficacy in patients with noncancer or neuropathic pain. Patient-selection criteria undoubtedly will be refined and validated as more patients are treated. In addition, further investigation of specifically targeted agents or drug combinations for intraspinal use could reduce side effects and expand indications. Basic science is elucidating pain mechanisms, providing a basis for the development of new medications and a rationale for new off-label uses of existing medications. With this in mind, clinicians planning new intrathecal catheter placement should consider a location close to the site where pain information enters the spinal cord so that lipophilic medications can achieve optimal effect. Vigilance must be exercised to observe long- and short-term side effects of medications introduced into the spinal fluid. New combinations of medications provide a huge potential for increased efficacy through additive effects and synergy, but the stability of these admixtures and their neurologic impact must be studied. Microprocessors and miniaturization have enhanced pump development. Programmable pumps are now limited by battery life constraints and size. Improvements in power sources will expand the lifespan of programmable pumps and decrease their size, allowing for larger reservoir volume. At this writing, only one implantable intrathecal system provides an element of patient control, and it is not FDA-approved for use in the United States. The current pumps are effective in treating baseline pain, but a system that allows patient control for breakthrough pain is essential. Finally, given the contrast in the pharmacokinetics and pharmacodynamics of the various medications that will be used simultaneously in pumps in the future, a system that can deliver different medications at different rates would be desirable. Neuraxial medication delivery is now a proven and sophisticated method for managing complex intractable pain. This treatment should be considered when other methods short of neurodestructive procedures have failed. With proper patient selection and medication trial, neuraxial medication delivery is a reversible, nondestructive technique that can benefit chronic pain patients by providing improved pain relief while reducing systemic side effects.

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Neuromodulation (cont'd)

Registration

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951 Mariner's Island Boulevard #270
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Questions

1. Neuromodulation techniques include:
 - a) Spinal cord stimulation
 - b) Radiofrequency neural ablation
 - c) Neuraxial intrathecal drug delivery
 - d) A and C above
 - e) A, B, and C above
2. Medications that are approved for chronic intrathecal administration by pump include all of the following EXCEPT:
 - a) Baclofen
 - b) Bupivacaine
 - c) Morphine
 - d) Ziconotide
3. All of the following are true EXCEPT:
 - a) Before implantation of a spinal cord stimulator for intrathecal drug delivery system, a behavioral evaluation is mandatory.
 - b) Before permanent implantation of a spinal cord stimulator system or intrathecal drug delivery system, a test trial is necessary.
 - c) Spinal cord stimulation is the most appropriate therapy for diffuse pain syndromes.
 - d) The most common application of spinal cord stimulation in Europe is for angina and peripheral vascular disease.
4. Which of the following is true: Ziconotide ...
 - a) Acts on the dorsal columns to inhibit transmission of pain information.
 - b) Is a neuron-specific N channel calcium blocker.
 - c) Is not yet FDA-approved for chronic intrathecal use.
 - d) Is a novel opiate.
5. Which may be appropriate for the pain of failed back surgery syndrome?
 - a) Spinal cord stimulation
 - b) Intrathecal drug administration
 - c) All the above
 - d) None of the above
6. Which is the more appropriate term for application of electrical signals in the epidural space to control chronic pain?
 - a) Spinal cord stimulation
 - b) Dorsal column stimulation
7. Admixtures of medications for chronic intrathecal use are:
 - a) FDA approved
 - b) Unacceptable practice
 - c) Off label use with algorithms that have been produced by two major consensus conferences
 - d) Not commonly used

Neuromodulation (cont'd)

8. Accepted applications for spinal cord stimulation include:
- Pain of failed back surgery syndrome
 - Radicular pain
 - Complex regional pain syndrome
 - All of the above
 - None of the above
9. All of the following are true EXCEPT:
- A device now exists to allow a patient to provide a preprogrammed bolus of intrathecal medications.
 - Spinal cord stimulator systems are now rechargeable.
 - Spinal cord stimulation is a neuro-destructive procedure that is not reversible.
 - Advances in microprocessing technology allow for more complex programming of spinal cord stimulator systems.
10. Intrathecal administration of opioids has an analgesic potency _____ greater than ORAL administration.
- 10X
 - 30X
 - 100X
 - 300X
11. All of the following are true, EXCEPT:
- Intrathecal pumps are now available with at least four different sizes of reservoir volume.
 - Both programmable and fixed-rate pumps exist for intrathecal use.
 - The way to change the rate of delivery of a fixed-rate pump is to change the concentration of medication in it.
 - Programmable pumps are more expensive than fixed-rate pumps and require replacement due to battery failure.
 - There are no advantages for programmable pumps relative to fixed-rate pumps.
12. All the following are true, EXCEPT:
- Pure nociceptive pain usually responds well to systemic opioids.
 - Neuropathic pain does not respond to opioids.
 - Neuropathic pain responds to opiates at higher doses and is often more responsive to a large number of antineuropathic pain medications.
 - Failed back surgery syndrome pain is a mixed type of pain that is both nociceptive and neuropathic.

Evaluation of Module 12

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	
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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 has been presented in each quarterly issue of the *CSA Bulletin* for Volumes 53-55, and it is also offered online at www.csaqh.org.

In this issue of the *Bulletin*, Module 12 is available. Modules 1 through 12 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.

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