

New guidelines coming for intrathecal analgesia

Apr 16, 2007

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Health-System Edition



William Stuart

The 2007 Polyanalgesic Consensus Panel recently recommended major changes to the guidelines for treatment, via intraspinal infusion, of patients suffering from severe chronic pain. The guidelines will be published later this year in the journal *Neuromodulation*. They were previously updated in 2003.

Eric Grigsby, M.D., medical director of the Spectrum Care Pain Treatment Center in Napa, Calif., explained that the new algorithm includes ziconotide (Prialt, Elan Pharmaceuticals) as an alternative to first-line opioids morphine and hydromorphone. Ziconotide is recommended as a second-line treatment in combination with one of the two first-line opioids. In addition, fentanyl was moved from a fourth-line treatment option to a second-line option, Grigsby said. He noted that if ziconotide, morphine, hydromorphone, and fentanyl were used as second-line treatment options, it could possibly be in combination with clonidine and bupivacaine.

William Stuart, R.Ph., president of the Hartley Medical Center Pharmacy in Long Beach, Calif., said that published studies demonstrate ziconotide degradation within 30 days when combined with other intraspinal analgesics. The higher the concentration, the more profound the degradation, he added.

The panel recognized some variability in the recommended and observed effective dosages of ziconotide. Stuart said that "dosing guidelines recommend starting patients on 1.2 mcg/d to 2.4 mcg/d. Some clinicians consider starting at smaller doses, such as 0.5 to 1 mcg/d." Among the authors' recommendations was a 0.5 to 2.4 mcg/d starting dosage range, with a maximum dose of 19.2 mcg/d. The panel recommended slow dosage titration to reduce the risk for toxicities. Stuart recommended that dosage adjustments be made at least every two weeks.

Grigsby noted that the recommended daily concentration of morphine is 15 mg/cc, which can be titrated up to the maximum recommended daily concentration, 30 mg/cc, to minimize the risk of granuloma.

The panel removed midazolam and baclofen from its fourth-line treatment recommendations, and neostigmine, adenosine, and ketorolac from its fifth-line recommendations, because of a lack of adequate clinical evidence to support their general use for chronic pain. The authors recommended midazolam, ketamine, tetracaine/lidocaine (Synera, Endo Pharmaceuticals), and droperidol only for treating patients whose prognosis is four weeks or less. They designated baclofen for use only in those with spasticity.

When the panel last met four years ago, ziconotide had not yet been approved, explained Grigsby. "The availability of ziconotide is what led us to recognize the need for an update to these practice guidelines."

Ziconotide is a non-narcotic, selective calcium-channel blocker that is effective for the relief of pain, Stuart said. It is a synthetic copy of a naturally occurring conopeptide found in a marine snail, *Conus magus*. The major side effects of ziconotide are psychological and neurological in nature. Its predominant adverse effect is somnolence. Stuart mentioned, however, that the adverse effects usually dissipate when patients discontinue the drug. He advised that patients with preexisting psychosis should not be treated with ziconotide.

Pharmacists involved in the treatment of chronic pain utilizing the intrathecal route must fully understand the precise pharmacological properties of pharmaceuticals and the physiological nature of the intraspinal passage. According to Stuart, some of the drugs infused are very hydrophilic, which enables them to travel freely through the cerebral spinal fluid and affect many nerve roots.

Other drugs, such as fentanyl and sufentanil, are very lipophilic. They disperse less freely within the intraspinal space. In order to detect and avoid costly prescription errors, Stuart advised pharmacists to keep abreast of new developments in this field, study the currently available literature, and become intimately familiar with dosing regimens and distinguishing drug properties. He observed that with drugs considered viable candidates for intrathecal therapy, clinical comprehension and monitoring are even more critical to optimizing pain management.

While the panel's recommendations are very important to physicians, they are even more important to R.Ph.s, Stuart said. Pharmacists should understand the function of the algorithm and the dosing of drugs for proper patient care. Not every physician will be aware of or adhere to the panel's recommendations. "Often pharmacists are consulted by physicians who need prudent guidance to achieve optimal patient care," he concluded.

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