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Consensus Panel Issues New Guidelines For Pain Management Via Intraspinal Infusion

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A panel of experts has recommended major changes to the guidelines used to determine treatment via intraspinal infusion for patients suffering from severe chronic pain. The 2007 Polyanalgesic Consensus Panel brought together a group of national leaders in chronic pain management for the purpose of updating their current algorithm. In making their new recommendations, the expert panel reviewed data published since its last meeting, as well as considered changes in FDA status and the clinical experience of the consensus panel members.

"Treating chronic pain via intraspinal drug delivery is a practice that is changing rapidly," said Timothy Deer, MD, of the Center for Pain Relief in Charleston, West Virginia. The group of nearly 20 experts was led by Deer and Samuel Hassenbusch, MD, PhD, of the University of Texas M.D. Anderson Cancer Center in Houston. The conference was held January 20 in Miami, FL.

Physicians treating patients with severe pain can now turn to increasingly sophisticated pump-and-catheter drug delivery systems. But they must choose from a growing number of novel drugs created for these systems, as well as existing drugs newly approved for intraspinal infusion. "The updated algorithm aids physicians by providing a foundation for clinical practice," Deer said.

The new algorithm includes ziconotide (PRIALT, Elan Corp.) as an alternative to first-line opioids, morphine and hydromorphone and as a second-line treatment in combination with one of the two first-line opioids. Additionally, fentanyl was moved from a fourth-line treatment option to a second-line option and clonidine was recommended for neuropathic pain as second-line single agent option. Lastly, several drugs were removed from line-four classification and designated as options only for patients receiving end-of-life care.

In previous years, the panel determined that preclinical and clinical trial data should include evidence of safety, efficacy, stability and compatibility with drug delivery systems, and, in the case of drug combinations, drug-drug stability. "The new guidelines reflect the most current and best available evidence for each of the drugs included in the algorithm--informed, as always, by our own collective experience of their use," Deer said.

The panel's conclusions are expected to be published later this year in a peer-reviewed journal. The original guidelines were published in 2000 in the *Journal of Pain and Symptom Management*. The guidelines were updated in 2003 and the panel's recommendations published the next year in the same journal.

At the time of the panel's 2003 meeting, ziconotide had not received FDA approval. It became commercially available in early 2005. Ziconotide, a non-narcotic synthetic based on a conopeptide found in neurotoxic marine snails, is an important addition to the list of options physicians have to treat severe chronic pain. Unlike intraspinal opioids, ziconotide is not associated with granuloma formation. "This is a real concern because granuloma formation means you have to stop therapy and evaluate the need for catheter removal and replacement," Deer said.

The panel did, however, recognize some variability in the recommended and observed effective dosages of ziconotide. Among its recommendations will be a 0.5 to 2.4 micrograms per day starting dosage range, with a maximum of 19.2 micrograms per day. Slow dosage titration was recommended to reduce the risk for toxicities. In addition, ziconotide can be combined with other line-three treatment options (morphine or hydromorphone, bupivacaine and clonidine).

The panel removed midazolam and baclofen from line-four and neostigmine, adenosine and ketorolac from line-five due to lack of adequate clinical evidence to support their general use for chronic pain. Four drugs, midazolam, ketamine, tetracaine and droperidol were recommended only for treating patients whose prognosis is four weeks or less. Baclofen was designated for use only in patients with spasticity.

The drug options for intraspinal drug delivery to treat severe pain are increasing rapidly. Periodic update of the guidelines for their selection is therefore necessary if physicians are to make treatment decisions that will most benefit their patients, Deer said. "We must evaluate new data as it becomes available and change our selection criteria accordingly," he added.

About the Polyanalgesic Consensus Panel

The PCP is an expert panel of leading pain management physicians from throughout the United States who meet periodically to evaluate the efficiency of various treatments. Members of the 2007 Panel include:

- Timothy R. Deer, MD (The Center for Pain Relief, Charleston, WV)
- Samuel Hassenbusch, MD (UT M.D. Anderson Cancer Ctr., Houston, TX)
- Allen W. Burton, MD (UT M.D. Anderson Cancer Ctr., Houston, TX)
- Stuart DuPen, MD (Overlake Medical Center Pain Medicine Clinic, Bellevue, WA)
- Michael A. Erdek, MD (Johns Hopkins University, Baltimore, MD)
- Kenneth A. Follett, MD (University of Nebraska Medical Center, Omaha, NE)
- Philip S. Kim, MD (Center for Pain Medicine, Wilmington, DE)
- Marc A. Huntoon, MD (Mayo Clinic, Rochester, NY)
- Robert M. Levy, MD, PhD (Northwestern University, Chicago, IL)
- Judith A. Paice, RN, PhD (Northwestern University Feinberg School of Medicine Chicago, IL)
- Joshua P. Prager, MD, MS (Ctr. For Rehabilitation of Pain Syndromes, Los Angeles, CA)
- Michael Saulino, MD, PhD (Moss Rehab Thomas Jefferson Univ. Elkins Parks, PA)
- B. Todd Sitzman, MD, MPH (Advanced Pain Therapy, Forrest General Cancer Ctr., Hattiesburg, MS)

- *K. Dean Willis, MD (Alabama Pain Center, Huntsville, AL)*
- *David Caraway, MD, PhD (The Center for Pain Relief Tri-State, Huntington, WV)*
- *James C. Eisenach, MD (Wake Forest University School of Medicine, Winston-Salem, NC)*
- *Eric Grigsby, MD (Spectrum Care Pain Treatment Ctr., Napa, CA)*
- *Elliot Krames, MD, DABPM (Pacific Pain Treatment Centers, San Francisco, CA)*
- *Gladstone C. McDowell, II, MD (Integrated Pain Solutions, Columbus, OH)*
- *Sunil J. Panchal, MD (COPE Foundation, Tampa, FL)*
- *Peter S. Staats, MD, MBA (Premier Pain/American Pain Medicine, Colts Neck, NJ)*
- *Michael Stanton-Hicks, MD (Cleveland Clinic, Cleveland, OH)*
- *Richard L. Rauck, MD (The Center for Clinical Research, Winston-Salem, NC)*
- *James Rathmell, MD (MGH Pain Center, Boston, MA)*
- *Lisa Jo Stearns, MD (Valley Cancer Pain Treatment Ctr., Division of Valley Anesthesiology Cons., Scottsdale, AZ)*
- *Mark Wallace, MD (University of California San Diego, Center for Pain Medicine, San Diego, CA)*
- *William D. Witt, MD (Interventional Pain Associates, Lexington, KY)*
- *Nagy Mekhail, MD, PhD (Cleveland Clinic, Cleveland, OH)*
- *Eric Buchser, MD (Center for Neuromodulation EHC, Morges, Switzerland)*
- *Michael Cousins, MD (Royal North Shore Hospital, Sydney, Australia)*

Source: *Polyanalgesic Consensus Panel*

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