A critical eye on Infuse use studies

A leading spine journal is casting a critical eye on industry-supported research that has led to widespread use of Medtronic’s controversial bone growth product Infuse. The June 2011 issue of Spine Journal carries a strongly worded editorial about the trial designs, reporting bias, and peer review shortfalls that the authors say have promoted the product’s widespread use, with “eventual life-threatening complications and deaths.”

The editorial says early studies underestimated risks of BMP-2, even though there were indications of a number of complications like inflammatory reactions, radiculitis, retrograde ejaculation, urinary retention, and bone resorption.

Some authors of these early trials had financial ties with Medtronic in amounts ranging to more than $26 million per study, the editorial notes.

Infuse, or bone morphogenic protein (BMP-2), approved by the Food and Drug Administration (FDA) in 2002 for limited application, is widely used in spinal surgery to induce bone growth. An estimated 30% to 50% of fusions used BMP-2 in 2007.

Despite the growing list of complications, BMP-2 may still be of great benefit to a small group of patients who have serious bone healing problems, writes one of the editors, Christopher M. Bono, MD.

The issue includes reviews of the early research plus clinical studies and commentaries.

A critical 21-page review of the 13 original industry-sponsored studies, led by Spine Journal’s editor in chief, Eugene J. Carragee, MD, finds the articles did not report a single adverse event. Yet FDA documents and subsequent studies found complication rates and adverse events 10 to 50 times the original estimates.

Also in the issue, a clinical study disputes a frequent justification for using BMP-2, less pain by avoiding harvest of the patient’s own bone. The study disputes the severity and frequency of this problem, placing it in perspective of the general pain patients have after lumbar fusion.

Other studies highlight effects of BMP-2 on the central and peripheral nervous system and look at osteolysis, a common side-effect.

‘Choirboy defense’
The editorial takes to task the “choirboy defense” among spine surgeons who contend the profession is honest, has “unimpeachable integrity,” and conflicts of interest that are only “potential.”

“Outside the echo chamber,” the authors say, “much of this rhetoric fails to pass the test of minimum credibility.

“We find ourselves at a precarious intersection of professionalism, morality, and public safety,” say the editorial writers, noting that spine surgery now “operates under a burden of suspicion.”

The journal’s editors pledge to make changes in editorial policy that they hope will achieve a better balance in critical manuscript review, conflict of in-
terest disclosure, and publication presentation.

*Spine Journal* is published by the North American Spine Society.

*A news release with links to the articles is at www.spine.org.*