

Previous studies overstated evidence on Medtronic spinal fusion product, review finds

June 18 2013

An analysis by the Evidence-based Practice Center at Oregon Health & Science University has found that previously published clinical trial studies about a controversial bone growth product used in spinal surgeries overstated the product's effectiveness.

The OHSU analysis found the product offered no real benefit over bone grafts traditionally used in such surgeries and also found that previous studies had underreported harms that occurred in the studies. All but one of those studies were funded by the product's manufacturer, Medtronic.

The OHSU review is one of two independent reviews of the Medtronic product that will be published in the June 18 edition of the *Annals of Internal Medicine*. The other independent review, performed by a university in Great Britain, also found that the product offered little benefit over bone grafts and came with potential harms.

The bone growth product—called recombinant human bone morphogenetic protein-2, or rhBMP-2—is used in spinal fusion surgeries, where vertebrae in the back are permanently joined together to eliminate pain or correct a deformity.

But rhBMP-2 has been at the center of controversy in recent years. Questions have been raised in major newspapers and a major medical journal about the product's safety and efficacy. A panel of experts

writing in the summer 2011 edition of *The Spine Journal* found that study authors with financial ties to Medtronic reported many times fewer complications with the product than were found in Food and Drug Administration reports.

In late 2011, OHSU became part of a novel independent study on the patient data associated with the product. The Yale University Open Data Access Project, or YODA, chose OHSU's Evidence-based Practice Center and another group at the University of York in Great Britain to conduct systematic reviews and reanalyze the data associated with the use of the product in spine fusion. Medtronic supplied patient level data for the reviews and paid for the YODA-coordinated re-examination of the data. The independent reviews made up the first initiative of the YODA project. The project seeks to address the problem of unpublished and selectively published clinical evidence.

Each team analyzed the data independently. Neither team knew of the other team's findings until both manuscripts were accepted for the June 18 publication.

In their review, OHSU researchers found "no evidence that rhBMP-2 is more effective" than the bone grafts often used in [spinal fusion surgery](#). The review also found that at 24 months after surgery, rhBMP-2 was associated with an increased risk for cancer, though the overall cancer risk was low.

The review also found "substantial evidence of reporting bias" in the previous studies on the product. The review found that Medtronic-sponsored publications analyzed or reported results in biased ways to indicate that it was more effective. The OHSU review also found higher rates of adverse events in patients, both with and without the use of rhBMP-2, compared with the published studies.

"Based on our analysis, it is difficult for us to find a clear indication to use rhBMP-2 for spinal fusion surgeries," said Rongwei Fu, Ph.D., an associate professor of public health and preventive medicine at OHSU and the lead author on the OHSU review.

OHSU's evidence-based practice center was the Oregon Evidence-based Practice Center when it was chosen to conduct the analysis of the Medtronic product in 2011. The center was renamed the Pacific Northwest Evidence-based Practice Center in August 2012.

In an article accompanying the publication of the reviews, Christine Laine, M.D., M.P.H., editor-in-chief of the *Annals of Internal Medicine*, wrote that the fact that two independent groups armed with the same patient data arrived at essentially the same conclusions should temper enthusiasm for the Medtronic product. She wrote that beyond replicating results, the independent reviews demonstrated additional value in having different scientists tackle the same data. The YODA project "is a novel exercise that illustrates the value of evidence synthesis, data sharing, peer review and editing, and reproducible research in helping us get closer to the truth," she wrote.

Provided by Oregon Health & Science University

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