Bone Agent Linked To Problems In Neck Surgeries

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CHICAGO (AP) — A bone growth agent used in thousands of spinal fusion surgeries for neck pain has been linked to complications and higher cost, according to the first nationwide study of the product.

Safety questions arose last year about the protein product, BMP, when used in fusion surgeries in the neck region, a use not approved by federal regulators.

"Some of these complications are life-threatening because the neck is such a sensitive area," said lead author Dr. Kevin Cahill of Harvard-affiliated Brigham and Women's Hospital in Boston. The study appears in Wednesday's Journal of the American Medical Association.

Smaller studies have shown BMP promotes better healing of the bone and fewer repeat surgeries to fix failed spinal fusions. The product also makes it unnecessary to surgically harvest the patient's own bone from the shin or hip for a graft.

However, the powerful protein can make bone grow in unwanted places if it's incorrectly used. There are no official guidelines for its use.

Surgeons have rapidly adopted BMP since the Food and Drug Administration approved it in 2002 for back surgeries. Doctors used it in 17,623 spinal fusions in 2006, nearly 1 in 4 cases, the researchers found.

"It's a new product and use is taking off right now," Cahill said.

Last year, the FDA warned doctors about 38 reports of complications when the treatment was used in the neck region of the spine. For unknown reasons, some patients had swelling after surgery, and that caused problems with breathing and swallowing.

BMP is produced by two companies, Minneapolis-based Medtronic and Kalamazoo, Mich.-based Stryker.

Medtronic spokeswoman Marybeth Thorsgaard said that company added a label warning about neck complications in 2005. She said the company has a study under way that may help address how the product could be safely used in the neck region.

In an e-mailed statement, Stryker said doctors should use its BMP product only for approved uses, which do not include spinal fusions in the neck.

Spinal fusion is one option for people with back and neck pain, although some

researchers have questioned how well it works.

In a spinal fusion, a surgeon removes the shock-absorbing disc between two vertebrae and replaces it with the patient's own bone, BMP or another product. Ideally, new bone grows and fuses the vertebrae into one piece, stabilizing the spine.

Medtronic's BMP is in a liquid solution, which is implanted on a collagen sponge in a titanium cage. Stryker's product has the consistency of wet sand.

For the new study, researchers looked at records of more than 325,000 spinal fusions from 2002 to 2006. When BMP was used in the front of the neck region of the spine, there were complications in 7 percent of patients before they left the hospital, a 50 percent higher rate compared to when the product wasn't used.

Elsewhere in the spine, however, BMP led to no more complications than other spinal fusion treatments.

In all spinal fusions, average hospital charges were higher when BMP was used, compared to when it wasn't. Without BMP, fusion surgeries in the neck region cost about $31,000; with BMP, the cost is roughly $46,000. The product itself costs between $3,600 and $5,200.

The study looked only at problems right after surgery, and didn't include repeat surgeries as complications.

"This paper doesn't address one of the biggest issues: Does BMP in fact improve fusion rates?" said neurosurgeon Dr. Allan Levi of University of Miami's Miller School of Medicine, who wasn't involved in the new study but has written about BMP.

Without large studies on fusion rates, surgeons should "think twice before using it, in recognition of the complications and costs," Levi said. "We have a product that probably works, but is very expensive."

The study was funded by the Brain Science Foundation.

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