

## **Study questions cancer link with bone growth factor for spinal surgery**

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Adding to previous evidence, a study based on a statewide cancer database shows no increase in cancer risk in patients undergoing spinal fusion surgery with the bone-promoting growth factor recombinant human bone morphogenetic protein (rhBMP). The study appears in *Spine*.

At least through the first several years, <u>patients</u> who receiving rhBMP during <u>spinal fusion</u> surgery are at no higher risk of <u>cancer</u> than those undergoing spinal fusion without rhBMP, according to the new research by Joseph R. Dettori, PhD, of Spectrum Research, Inc, in Tacoma, Wash. However, additional follow-up is needed to rule out any longerterm increase in <u>cancer risk</u>.

## No Difference in Cancer Rates after Spinal Fusion with or without rhBMP

Using a Washington State hospital database, the researchers identified approximately 17,000 patients who underwent <u>spinal fusion surgery</u> for degenerative spine disease between 2002 and 2010. In about 4,250 patients, rhBMP was used to promote new bone growth to stabilize the spine in the fused area.

The state cancer registry was used to compare rates of subsequent cancers between patients who had spinal fusion with versus without rhBMP. The two groups were matched in terms of age, sex, and



treatment year. The patients averaged 55 years old; none had a previous history of cancer.

At an average follow-up time of about five years, the percentage of patients diagnosed with cancer was almost identical between groups: 2.76 percent in patients undergoing spinal fusion with rhBMP versus 2.62 percent without rhBMP.

For every 1,000 years of patient follow-up, there were 9.5 cancers in the rhBMP group and 9.0 in the no-rhBMP group. There was also no significant difference in the risk of death from cancer, based on death certificate data.

The results were similar in subgroups based on the site of the fusion (upper or lower spine) or the surgical method used. Although a few types of cancers were more common in patients receiving rhBMP (uterine, mouth, and liver cancer), the numbers were small and the associations were "within the limits of chance."

Introduced in 2002, rhBMP has become widely used to stimulate new bone formation in patients undergoing spinal fusion: a common procedure to treat spinal pain or instability. Subsequent reports have raised concerns about potential safety issues—including the possibility that rhBMP might increase the risk of cancer development or progression.

Previous analyses of data from randomized trials have suggested a twoto three-fold increase in cancer risk among rhBMP recipients. However, those studies had some important limitations, including the relatively small number of patients, short-term follow-up, and the likely incomplete detection of subsequent cancers.

Meanwhile, other studies analyzed data from larger patient



cohorts—including one published last year in *Spine*—have not supported the increase in cancer risk in patients receiving rhBMP. "In our view," Dr. Dettori and coauthors write, "the largely negative results regarding rhBMP administration and cancer incidence that have been obtained in various cohort studies are more compelling than the corresponding positive results obtained in the randomized trials."

However, all of the studies performed to date share one important limitation: the relatively short duration of follow-up in patients undergoing spinal fusion with rhBMP. Dr. Dettori and colleagues conclude: "While the collective results available are somewhat reassuring, the examination of cancer incidence in patients who have received rhBMP must continue beyond just the first several years in order to assess the potential of rhBMP to influence the occurrence of one or more types of malignancy."

**More information:** Joseph R. Dettori et al. The Risk of Cancer with the Use of Recombinant Human Bone Morphogenetic Protein in Spine Fusion, *SPINE* (2016). DOI: 10.1097/BRS.00000000001671

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