

PAPER 11

Usage Trends and Safety Profile of Recombinant Human Bone Morphogenetic Protein-2 for Spinal Column Tumor Surgery: A National Matched Cohort Analysis

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Background:

Achieving arthrodesis after spinal tumor surgery remains a significant challenge. Patients in this vulnerable cohort commonly experience poor bone quality, malnutrition, and concurrent use of chemotherapy or radiotherapy – all of which interfere with proper bone formation and healing. To augment fusion efforts, recombinant human bone morphogenetic protein-2 (rhBMP-2) emerged as a powerful osteogenic factor after its FDA approval for anterior lumbar interbody fusion in 2002. While off-label has since dramatically exploded, its safety profile remains controversial – particularly within the spinal oncology subcohort.

Purposes:

The purpose of this study is to investigate national rates of rhBMP-2 utilization in spinal tumor surgery and examine its association with postoperative complications, revisions, and carcinogenicity.

Patients and Methods:

A retrospective query of Medicare, Medicaid, and commercial administrative claims from 2005 to 2020 was performed using PearlDiver. All patients diagnosed with primary or metastatic spinal tumors with subsequent surgical intervention involving a spinal fusion procedure were identified. Patients were 1:1 matched into two cohorts according to rhBMP-2 usage. Utilization trends were compared via Pearson correlation across calendar years. Postoperative complications and revisions were examined at 1 month, 3 months, 6 months, and 1 year after spinal fusion. New cancer incidence following spinal tumor surgery was assessed until 5 years postoperatively. Post hoc comparisons were characterized using chi-squared analysis and threshold for significance was established at $p < 0.05$.

Results:

A total of 11,198 patients underwent fusion surgery after resection of spinal tumors between 2005 and 2020, with 909 cases reporting the use of rhBMP-2 (8.1%). An annualized analysis revealed that the proportion of spine tumor fusion procedures utilizing rhBMP-2 has been significantly decreasing ($R^2 = 0.859$, $p < 0.001$), with the most recent annual utilization rate at 1.1%. The final matched cohorts each comprised 894 patients. At least 3 months after surgery, significantly increased incidences of surgical site (11.4% vs. 3.3%, $p = 0.03$) and systemic infections (8.1% vs. 1.6%, $p = 0.02$) were observed in patients who underwent fusion with rhBMP-2. Across all time points, no significant differences were observed in survival, implant removal, or revision rates. In addition, new cancer incidence after fusion surgery was comparable between the two groups.

Conclusion:

This analysis demonstrated significantly declining national utilization rates, and while rhBMP-2 usage was not associated with new cancer incidence postoperatively, its impact on local and metastatic progression requires further investigation. Compared with nonusers, spinal tumor cases utilizing rhBMP-2 sustained greater rates of surgical site and systemic infections. Furthermore, rhBMP-2 usage did not significantly reduce the risk of mortality, implant failure, or reoperation – suggesting it may not be essential to fulfilling the needs of this specific patient population.