

The Use of Bone Morphogenetic Protein in Cervical Spine Procedures: Analysis of the Marketscan Longitudinal Database

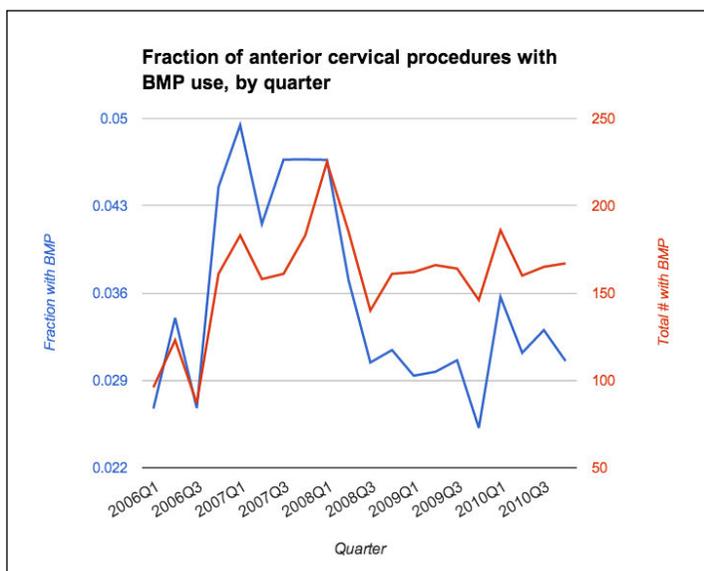
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Introduction

Recombinant human bone morphogenetic protein (BMP) is used within the lumbar spine at substantial rates, with most utilization off label. BMP use in anterior cervical discectomy and fusions (ACDF) is controversial. Studies suggest increased rates of dysphagia, soft-tissue hematoma, and severe airway compromise in cervical procedures using BMP. An FDA "black box" warning cautioning the use of BMP in cervical cases was issued in 2008. This study describes national utilization trends and incidence of complications associated with BMP use in anterior cervical spine procedures.

Methods

Between 2006-2010, 91,543 patients were recorded for ACDF and/or cervical corpectomy in the Thomson Reuters Marketscan database. Patient selection and outcome measures were ascertained using ICD-9 and CPT coding. 3,197 patients were treated with BMP intra-operatively. Mean follow-up was 588 days in the non-treated group and 591 days in the BMP-treated group. Comorbidities and demographics were used in multivariate regression to find adjusted OR between BMP-treated and non-treated groups.



Results

BMP was utilized at higher rates in multi-level (OR 1.2, CI 1.1-1.3, $p < 0.0001$) and instrumented cervical procedures (OR 1.7, CI 1.4-2.1, $p < 0.0001$). At 30-days post-operation and adjusted for demographic variables and multiple comorbidities, **BMP utilization increased the risk of**

- **any complication** (OR 1.4, CI 1.2-1.5, $p < 0.0001$)
- **wound hematoma** (OR 1.7, CI 1.3-2.3, $p = 0.0007$)
- **dysphagia** (OR 1.3, CI 1.1-1.6, $p = 0.002$)
- **new chronic pain** (OR 1.4, CI 1.0-1.9, $p = 0.04$)
- **any pulmonary complication** (OR 1.5, CI 1.2-1.8, $p = 0.0005$)

	Without BMP		With BMP		P	% increase with BMP	Cost increase with BMP
	Mean	StdErr	Mean	StdErr			
Payments: Hospital	\$20,275	\$72	\$24,606	\$440	<.001	21.36%	\$4,331.02
Payments: Physician	\$6,488	\$25	\$6,940	\$126	<.001	6.96%	\$451.73
Payments: Total (Case)	\$29,824	\$86	\$35,369	\$508	<.001	18.59%	\$5,545.51

There was no statistical difference in

- re-admission rates
- mortality
- referrals to pain management
- new malignancies
- overall re-operation rates

between the two groups. The BMP-treated group also demonstrated

- higher rates of pseudoarthrosis (OR 1.5, CI 1.3-1.8, $p < 0.0001$)
- mean increase in total case payment of **\$5,546** (19% increase, $p < 0.001$).

	No BMP	BMP	OR (95% CI)	P
30 day readmit	2809 (3.95%)	121 (4.66%)	1.19 (0.99-1.43)	0.073
Revision rate	5397 (6.11%)	200 (6.29%)	1.03 (0.89-1.19)	0.651
Pseudoarthrosis	3781 (4.28%)	203 (6.39%)	1.53 (1.32-1.77)	<0.0001
Time to revision	338 days (2.33%)	316 days (11.9%)	-	<0.0001
Pain mgmt	10664 (12.3%)	359 (11.5%)	0.93 (0.83-1.04)	0.183
Post op ESI	2889 (3.33%)	120 (3.84%)	1.16 (0.96-1.40)	0.129
Pre-op cancer	4114 (4.69%)	132 (4.18%)	0.885 (0.74-1.06)	0.184
Post-op cancer	2844 (3.24%)	96 (3.04%)	0.934 (0.76-1.15)	0.573

Conclusions

In this national database study on cervical spine procedures, we report higher rates of post-operative complications in ACDF patients receiving BMP. Adverse events including pseudoarthrosis, wound hematoma, and dysphagia were more common in the BMP cohort. BMP did not reduce the need for revision procedures. BMP effectiveness in the cervical spine remains controversial, although increased costs with its use appear clear.

Learning Objectives

By the conclusion of this session, participants should be able to discuss in small groups the pros and cons, as well as indications and complications, associated with BMP use in ACDF from national data.

Key References

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- Cahill, K. S.; Chi, J. H.; Day, A.; and Claus, E. B.:** Prevalence, complications, and hospital charges associated with use of bone-morphogenetic proteins in spinal fusion procedures. *JAMA*, 302(1): 58-66, 2009
- Carragee, E. J.; Hurwitz, E. L.; and Weiner, B. K.:** A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned. *Spine J*, 11(6): 471-91, 2011