Does Recombinant Human Bone Morphogenetic Protein-2 (BMP) Use in Adult Spinal Deformity (ASD) Increase Complications and Are Complications Dose Related? A Prospective, Multicenter Study of 257 Consecutive Patients

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Learning Objectives

(1) See that rhBMP-2 use in ASD surgery, at the reported doses, are not associated with increased rates of wound infections (superficial or deep) or return to the operating room (2) Appreciate that future research is still warranted to further clarify complications associated with specific rhBMP-2 dosing and to correlate rhBMP -2 use and complications with clinical outcomes.

Purpose

Evaluate complication types and rates associated with Recombinant Bone Morphogenetic Protein-2 (BMP) versus No BMP use in Adult Spinal Deformity (ASD) surgery.

Introduction

ASD is associated with the highest subspecialty complication rate - pseudoarthrosis accounting for the majority. Not long after its introduction, BMP use in ASD surgery increased in an attempt to reduce pseudoarthrosis rates. However, as BMP use has increased, scrutiny has been paid to previous studies showing low complication rates

Methods

This study is an analysis of complications following ASD surgery for BMP or no BMP (NOBMP). Data analyzed was from a multicenter, prospective, consecutive dataset.

Inclusion criteria:

- Age >=18 years
- ASD surgery (scoliosis >=20 degrees, sagittal vertical axis (SVA) >=5cm, pelvic tilt (PT) >=25 degrees, or thoracic kyphosis (TK)>=60 degrees)
- Complete data; demographic, radiographic, and operative data, and minimum 8 weeks follow-up

Rates of major and minor acute complications, and those requiring reoperation were compared and contrasted between the BMP and NOBMP groups. ANOVA was used to contrast BMP versus NOBMP. Correlations were made with BMP use (total BMP dose, BMP dose/level) and surgical data as independent variables and complication rates and types as dependent variables. Multivariate regression analysis performed with Multivariate Adaptive Regression Splines (MARS).

Results

257/316 patients met inclusion criteria. Mean followup was 20.3 months (range 2.2-38). BMP (n=155; avg PSF dose 2.4mg/level; range 0-12 mg/level; avg interbody dose 2 mg/level; range 0-18 mg) and NO BMP (n= 102) had similar age, BMI, smoking history, prior spine surgery, maximal scoliosis, SVA, levels fused, and estimated blood loss ($p>0.05$). BMP had greater Charlson comorbidity index, operative time, osteotomies/ patient, and anteroposterior surgery ($p<0.05$). Total complications per patient were greater for BMP vs. NOBMP (1.0 vs.0.5; $p<0.05$), however major complications, neurological and wound complications, superficial and deep infections, and complications requiring surgery were similar for BMP vs. NOBMP ($p>0.05$). Total posterior (PSF) BMP dose statistically correlated with total, major, and neurological complications ($p<0.05$), however r values indicated small correlations (0.32, 0.14 and 0.14, respectively). PSF BMP dose/level did not correlate with major, wound or neurological complications, deep infections or return to OR ($p<0.05$).

Conclusions

In general, patients with BMP had more total and minor complications than those without, but wound and neurological complications, deep infection, and onset of complication were similar between the groups. BMP use in ASD, at BMP dose/level reported, is not associated with wound, superficial or deep infections or return to OR. Further research is needed to evaluate long-term complications, complications associated dosing, and to evaluate how BMP use relates to outcomes measures.

References

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