Summary

Some studies identify complications associated with off-label use of rhBMP-2 in the setting of TLIF. The dose-related efficacy of rhBMP-2 in the setting of short segment fusion has not been thoroughly investigated.

Hypothesis

Increasing dosages of rhBMP-2 in the setting of short segment fusion will improve fusion rates and outcomes, with no difference in rates of complications.

Design

Retrospective cohort study of prospectively collected data from a single surgical spine practice.

Introduction

The use of off-label rhBMP-2 remains the primary synthetic osteoinductive material used in spinal fusion surgery. It has been shown to be as effective as autograft. However, no optimal dosage of rhBMP-2 in the setting of TLIF for short segment fusion has been established. There is disagreement in the literature with regard to dosage-related complications. Therefore, the purpose of this study was to analyze the dose-related outcomes and complications in adults undergoing short segment fusion with TLIF using off-label rhBMP-2.

Methods

TLIF with rhBMP-2 was performed in 516 consecutive adults who underwent primary or revision short segment open posterior instrumented fusion with a minimum 2-year follow-up. The sample was divided into 3 cohorts based on dosage of rhBMP-2 received (0 mg, 2 mg, 4 mg). Patients who received any amount of rhBMP-2 for posterolateral fusion were excluded from this study. Complications including hardware failure, seroma, infection, and revision surgery within 2-years of the index surgery were recorded. Pre-operative VAS-BP, VAS-LP, and ODI were collected at 6 weeks, 3 months, 6 months, 1 year, and 2 years. Radiographic union was assessed based off of flexion and extension films. No industry funding was received for this study.

Results

Mean age of patients was 78.6 (sd = 33.0). The mean number of levels fused was 2.31 (sd= 1.08). There were no differences in baseline demographics, comorbidity burden, tobacco use, and number of levels fused between cohorts. At an average of 5 years follow -up, there was a total of 27 (5.2%) non-unions and no statistically significant differences in non-union rates amongst cohorts: 0 mg - 6.5%; 2 mg - 5.9%, 4 mg - 4.1%; p=0.577. There were no differences in overall peri-operative complications appreciated between the cohorts including post-operative seromas and infections. At the two-year post-operative visit, no significant differences in VAS-BP, VAS-LP, or ODI were appreciated between cohorts; all cohorts experienced significant improvement in pain and function from preoperative baseline.

Conclusion

This is the largest prospectively collected data series comparing BMP to local autograft in the setting of TLIF to date. Clinical outcomes, including rates of non-union, are no different when using local autograft versus increasing dosages of rhBMP-2. Furthermore, with use of our current BMP technique, complications rates are acceptably minimal.