

Two Year Prospective, Multicenter Analysis of Consecutive Adult Spinal Deformity (ASD) Patients Demonstrates Higher Fusion Grade, Lower Implant Failures and Greater Improvement in SRS-22r Scores for Patients Treated with Recombinant Human Bone Morpho

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Learning Objectives

By the conclusion of this session, participants should be able to: (1) Appreciate that, compared with adult spinal deformity patients whose surgery did not include rhBMP-2, those with rhBMP-2 demonstrated higher fusion grade, fewer implant failures, similar major complications, and greater health-related quality of life improvement at 2 year follow-up; (2) Appreciate that further research is needed to evaluate the potential long-term effects of rhBMP-2.

Introduction

Theoretical advantages of rhBMP-2 (BMP) use include high fusion rates and improved outcomes, however little data exists evaluating fusion grade, complications and health related quality of life (HRQOL) for ASD patients treated with BMP. The purpose of this study was to evaluate fusion grade, complications and HRQOL associated with BMP versus no BMP use in a prospective, multicenter, consecutive ASD cohort, with a minimum 2 years follow-up.

Methods

This is a multicenter, prospective analysis of consecutive ASD patients receiving rhBMP-2 (BMP) or no BMP (NOBMP). Inclusion criteria: ASD, age=18 years, spinal fusion=4 levels, complete demographic and radiographic data, and minimum two-year follow up. ASD is defined as scoliosis equal to or greater than 20 degrees, sagittal vertical axis greater than or equal to 5cm, pelvic tilt greater than or equal to 25 degrees, or thoracic kyphosis greater than or equal to 60 degrees.

Methods (cont'd)

Spine fusions were evaluated using the Lenke grade. Complications were noted at each visit and as reported by patients. Baseline and 2 year postoperative HRQOL (SRS-22r, SF-36, ODI) were analyzed for comparison.

Results

141 of 189 patients had complete two year data (75% follow-up). Mean follow up 35.8 months (range 24.1-47.9). For the 110 BMP patients, mean rhBMP-2 dose for posterolateral fusions was 2.6mg/level and 5.3mg/level for interbody fusions. The 31 NOBMP patients had similar preop deformity, baseline HRQOL, and total posterior fusion levels to BMP (BMP=11.6, NOBMP=12.9). BMP was older (56 vs. 49 years), had more anteroposterior surgery (25% vs. 6.5%), and fewer pedicle subtraction osteotomies/patient (0.12 vs. 0.3) than NOBMP ($p<0.05$). BMP had more minor complications (61% vs. 29%) and fewer implant failures (1.8% vs. 13%) than NOBMP, respectively ($p<0.05$). Mean BMP fusion grade was greater than NOBMP (1.9 vs. 1.5; $p<0.05$). BMP had greater 2 year improvement in SRS-22r total (0.9 vs. 0.5), mental (0.4 vs. -0.02), and pain (1.0 vs. 0.4) scores than NOBMP, respectively ($p<0.05$).

Conclusions

BMP use in ASD, at reported BMP dose/level, demonstrated higher fusion grade, fewer implant failures, similar major complications, and greater HRQOL improvement at 2 year follow-up than NOBMP. Research is needed evaluating long term complications and outcomes.

References

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HRQOL Data

	NOBMP (N= 31)	BMP (N= 110)	p-value
ODI preoperative; mean (range)	38.2 (0 to 92)	41.3 (2 to 82)	N/S
ODI two year postoperative; mean (range)	29.2 (0 to 73.3)	25.2 (0 to 82.2)	N/S
Δ ODI; mean (range)	-9.0 (-50 to 34)	-16.1 (-60.2 to 26)	N/S
Δ ODI reaches MCID (15 points)*	NO	YES	
SF-36 PCS preoperative; mean (range)	36.5 (13.1 to 64.8)	32.5 (10.0 to 57.7)	N/S
SF-36 PCS two year postoperative; mean (range)	39.9 (17.4 to 62.9)	42.1 (15.4 to 60.1)	N/S
Δ SF-36 PCS	3.4 (-16.5 to 34.9)	9.6 (-17.8 to 31.1)	N/S
Δ SF-36 PCS reaches MCID (5.2 points)*	NO	YES	
SF-36 MCS preoperative; mean (range)	46.6 (29.5 to 68.2)	46.1 (10.6 to 71.2)	N/S
SF-36 MCS two year postoperative; mean (range)	44.7 (17.7 to 65.6)	50.9 (12.2 to 67.3)	0.0260
Δ SF-36 MCS	-1.9 (-35.6 to 21.5)	4.5 (-25.3 to 36.0)	0.0044
Δ SF-36 MCS reaches MCID	NA	NA	
SRS-22r Function preoperative; mean (range)	3.0 (1.2 to 5)	3.0 (1.2 to 4.8)	N/S
SRS-22r Function two year postoperative; mean (range)	3.4 (1.6 to 5)	3.7 (1.2 to 5)	N/S
Δ SRS-22r Function	0.4 (-1.8 to 2.2)	0.7 (-2 to 2.6)	N/S
Δ SRS-22r Function reaches MCID (0.375 points)*	YES	YES	
SRS-22r Pain preoperative; mean (range)	2.7 (1 to 4.8)	2.5 (1 to 4.6)	N/S
SRS-22r Pain two year postoperative; mean (range)	3.2 (1 to 4.8)	3.5 (1 to 5)	N/S
Δ SRS-22r Pain	0.5 (-2.4 to 3)	1.0 (-1.4 to 3.4)	0.0066
Δ SRS-22r Pain reaches MCID (0.587 points)*	NO	YES	
SRS-22r Self-image preoperative; mean (range)	2.4 (1 to 4.2)	2.5 (1 to 4.6)	N/S
SRS-22r Self-image two year postoperative; mean (range)	3.5 (1 to 5)	3.9 (1.2 to 5)	N/S
Δ SRS-22r Self-image	1.1 (-1 to 3)	1.4 (-2.2 to 3.8)	N/S
Δ SRS-22r Self-image reaches MCID (0.8)*	YES	YES	
SRS-22r Mental health preoperative; mean (range)	3.5 (1 to 5)	3.5 (1.4 to 5)	N/S
SRS-22r Mental health two year postoperative; mean (range)	3.4 (1.2 to 5)	3.9 (1.0 to 5)	0.0068
Δ SRS-22r Mental health	-0.1 (-3 to 1.6)	0.4 (-1.4 to 2.2)	0.0014
Δ SRS-22r Mental health reaches MCID (0.42)*	NO	NO	
SRS-22r Total score preoperative; mean (range)	2.9 (1.3 to 4.6)	2.9 (1.3 to 4.3)	N/S
SRS-22r Total score two year postoperative; mean (range)	3.4 (1.7 to 4.9)	3.8 (1.6 to 5)	0.0285
Δ SRS-22r Total score	0.5 (-1.2 to 1.7)	0.9 (-1.0 to 2.5)	0.0046
Δ SRS-22r Total score reaches MCID	NA	NA	
SRS-22r Satisfaction two year postoperative; mean (range)	4.1 (1 to 5)	4.3 (1.5 to 5)	N/S

BMP vs. NOBMP HRQOL data (NA=Not Applicable, N/S=Not Statistically Significant)