

A Blinded, Multi-Center Clinical and Radiological Study to Evaluate the Use of OsteoAMP versus rhBMP-2 in TLIF/LLIF Procedures

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Introduction

Adverse events and complications related to use of rhBMP-2 have raised many ethical, legal, and reimbursement concerns for surgeons. OsteoAMP® bone graft is an allograft derived growth factor available on the market rich in osteoinductive, angiogenic, and mitogenic proteins. The following data displays a blinded, multi-center study evaluating and comparing fusion outcomes between rhBMP-2 and OsteoAMP® bone graft.

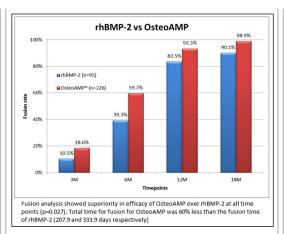
Methods

A total of 321 consecutive patients (485 total levels) were treated with TLIF or LLIF spine fusion procedures. A group of 95 patients (54.3 \pm 10.9 y/o) were treated with rhBMP-2 (Infuse®, Medtronic) and local bone with an average of 1.35 levels per surgery. A group of 226 patients (60.0 \pm 13.0 y/o) were treated with OsteoAMP® (Advanced Biologics) and local bone with an average of 1.58 levels per surgery. Fusion assessments were made by a blinded independent radiologist based on radiograph and CT images at 6w, 3m, 6m, 12m, and 18m follow up.

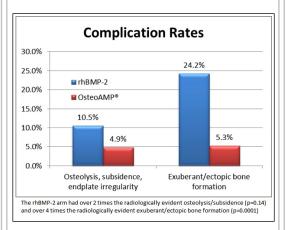
Characteristic	OsteoAMP®	rhBMP-2
	(n=226)	(n=95)
Age, mean ± SD	60.0 ± 13.0	54.3 ± 10.9
emale, n	131 (58.0%)	56 (58.9%)
Avg Levels/Case	1.58	1.35
.evels, n		
One	147 (65.0%)	75 (78.9%)
Two	58 (25.7%)	14 (14.7%)
Three	10 (4.4%)	1 (1.1%)
Four	4 (1.8%)	3 (3.2%)
Five	3 (1.3%)	2 (2.1%)
Six	1 (0.4%)	0 (0.0%)
Seven	1 (0.4%)	0 (0.0%)
Eight	1 (0.4%)	0 (0.0%)
Twelve	1 (0.4%)	0 (0.0%)

Results

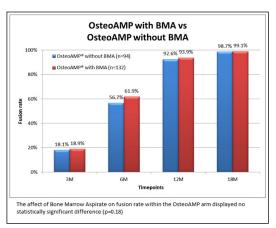
Fusion analysis showed superiority in efficacy of OsteoAMP® over rhBMP-2 at all time points (p=0.027). Use of rhBMP-2 produced limited early fusions at 6 months (39.3%) yet improved at 1 year (83.5%). OsteoAMP® facilitated fusion for the majority of patient by 6 months (59.7%) and nearly all patients within 1 year (93.3%). At 18 months, 98.9% of OsteoAMP® patients had fused while the rhBMP-2 arm had an 90.1% fusion rate. Total time for fusion for OsteoAMP® was 60% less than rhBMP-2 at 207.9 and 333.9 days respectively.



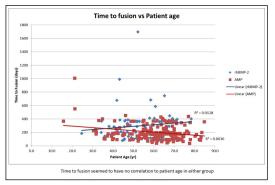
The rhBMP-2 arm had over 2 times the radiologically evident osteolysis/subsidence (p=0.14) and over 4 times the radiologically evident exuberant/ectopic bone formation (p=0.0001)



Analysis of the affect of Bone Marrow Aspirate on fusion rate within the OsteoAMP arm displayed no statistically significant difference (p=0.18)



Time to fusion had no correlation to patient age in either group.



Conclusions

Despite its use with an older patient population and a higher number of levels per surgery, OsteoAMP® has shown great promise as a faster and safer alternative to rhBMP-2.

Learning Objectives

Identify an effective alternative for rhBMP-2 in lumbar spine fusions.

References

Infuse, rhBMP-2, rh-BMP2, biologic, osteobiologic, OsteoAMP, bone graft, growth factor, dbm, TLIF, LLIF, spine, spine fusion, spinal fusion, arthrodesis