

concentration. There does not appear to be any clinical evidence of a hyper-sensitivity reaction or other adverse response.

FDA DEVICE/DRUG STATUS: rhBMP-2: Approved for this indication.

doi: 10.1016/j.spinee.2007.07.017

13. The Natural History of Subsequent Adjacent Level Vertebral Compression Fractures

Bruce Frankel, MD¹, Alex Vandergrift, MD¹; ¹Medical University of South Carolina, Charleston, SC, USA

BACKGROUND CONTEXT: Osteoporotic vertebral compression fractures (VCF) are routinely treated with the vertebral augmentation procedures (VAP), vertebroplasty and kyphoplasty. Both are reported to be an effective means of pain relief; however, there may be an increased risk of developing subsequent VCFs after such procedures. The risk of subsequent VCF after 1 fracture is reported to be 19.2% at one year, and is widely reported as the benchmark figure to define the expected natural history of subsequent fractures in patients after VAPs. This number should not be used as the standard to compare to in order to determine whether or not VAPs result in an increased incidence of subsequent VCFs for several reasons. Firstly, it takes into account all subsequent fractures, not just the most relevant “adjacent level” fractures likely to result from the increased stiffness of augmented vertebrae. Secondly, it does not account for the fact that many patients undergoing VAPs are on bisphosphonate therapy, agents reported to reduce subsequent VCFs by 50%. Finally, it is not known whether or not bisphosphonate therapy reduces the incidence of adjacent-level VCFs.

PURPOSE: The purpose of this study was to determine the natural history of subsequent “adjacent-level” VCFs in patients with osteoporosis both with and without bisphosphonate therapy, and with and without VAPs.

STUDY DESIGN/SETTING: A retrospective review of the treatment and placebo arms from several large risedronate trials was analyzed to determine the natural history of subsequent “adjacent-level” VCFs for both bisphosphonate-treated and bisphosphonate-naïve patients. These figures were compared to those from patients with subsequent “adjacent-level” VCFs after undergoing VAPs.

PATIENT SAMPLE: 2000 patients with previous VCFs, enrolled in several large risedronate trials were studied for the occurrence of subsequent “adjacent-level” VCFs, and compared to those in patients undergoing VAPs.

OUTCOME MEASURES: The incidence of subsequent adjacent-level VCFs was determined as reported from radiographic analysis.

METHODS: Data sets were retrospectively reviewed to determine the subsequent fracture rate at adjacent levels (one level above or below a previous known fracture). This was performed for both the treatment and placebo arms of previous risedronate trials. As such, the natural history of subsequent “adjacent-level” VCFs for both bisphosphonate-treated and bisphosphonate-naïve patients was calculated and compared to those from patients after undergoing VAPs.

RESULTS: Of the 19% subsequent VCFs occurring in the year following a single fragility fracture, only approximately 50% appear at an adjacent-level regardless of whether or not the patient was on bisphosphonate therapy. Published series on VAPs indicate that the risk of subsequent fracture after a VAP ranges from 0–16% in vertebroplasty and 7–45% in kyphoplasty patients. If this lower natural history rate is compared to the rate of VCFs occurring after VAPs, a concern is raised that these procedures may be causing an increased incidence in adjacent-level fractures.

CONCLUSIONS: The rate of subsequent adjacent-level VCFs occurring after VAPs appears to be greater than the expected natural history of spontaneously occurring adjacent-level fractures. Efforts to identify and mitigate causative factors are warranted.

FDA DEVICE/DRUG STATUS: Vertebroplasty: Approved for this indication.

doi: 10.1016/j.spinee.2007.07.018

Wednesday, October 24, 2007

1:56–2:45 PM

Concurrent Session 1: Fusion Enhancement

14. Stem Cells from Human Fat as Cellular Delivery Vehicles in a Rat Posterolateral Spine Fusion Model

Wellington Hsu, MD¹, Jeffrey Wang, MD², Nancy Liu³, Lucie Krenek³, Patricia Zuk³, Mark Hedrick⁴, Prosper Benhaim³, Jay Lieberman, MD¹; ¹University of California, Los Angeles, Los Angeles, CA, USA; ²University of California, Los Angeles, Santa Monica, CA, USA; ³UCLA Medical Center, CA, USA; ⁴Macropore Biosurgery, CA, USA

BACKGROUND CONTEXT: Mesenchymal stem cells derived from human liposuction aspirates, termed processed lipoaspirate cells (PLAs), have been utilized in the induction of bone formation as cellular delivery vehicles for tissue engineering and gene therapy.

PURPOSE: This study seeks to evaluate the efficacy of BMP-2-producing adipose-derived stem cells (ADSC) in inducing a posterolateral spine fusion in an athymic rat model.

STUDY DESIGN/SETTING: Pre-clinical animal model.

OUTCOME MEASURES: Plain radiographs fusion scores from manual palpation microCT histologic analysis.

METHODS: A total of five groups of athymic rats were used (n=8): Group I: 5×106 adipose-derived stem cells transduced with Ad-BMP-2 adenoviral vector, Group II: 5×106 ADSCs treated with osteogenic media and exogenous BMP-2, Group III and IV: 10 ug and ug of rh-BMP2, respectively, and Group V: 5×106 ADSCs alone.

RESULTS: All animals in Group I demonstrated successful spinal fusion with large fusion masses four weeks postoperatively assessed by plain radiographs, fusion scores from manual palpation, quantifiable bone formation on microCT, and histologic analysis. In fact, Group I specimens consistently revealed spinal fusion at the proximal level where no fusion bed was prepared surgically. In contrast, Group II (ADSC-treated) animals demonstrated minimal bone formation even eight weeks after implantation. None of the negative control animals demonstrated successful spine fusion eight weeks after surgery.

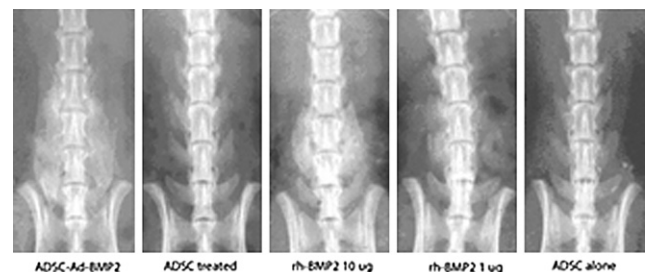


Figure 1.

CONCLUSIONS: ADSCs show great promise as cellular delivery vehicles for BMP-2 but further modifications of existing cell-based protocols are necessary before this type of strategy can be adapted for use in humans.

FDA DEVICE/DRUG STATUS: This abstract does not discuss or include any applicable devices or drugs.

doi: 10.1016/j.spinee.2007.07.020

15. The Adjunctive Effect of a Binding Peptide on Bone Morphogenic Protein in an Animal Spinal Fusion Model

Ahmet Alanay, MD¹, Chihui Chen², Sang-Hun Lee³, Masashi Miyazaki, MD¹, Elsa Brochman, PhD⁴, Samuel Murray, MD¹, Antonia Napoli,