Introduction:
Percutaneous vertebroplasty and balloon kyphoplasty have been widely used to treat vertebral compression fractures due to osteoporosis, osteolytic metastasis, and myeloma. The most common material used for these procedures is polymethylmethacrylate (PMMA) mixed with barium sulfate, which is deposited into fractured vertebral bodies. Some of the most important complications of vertebral augmentation are radiculopathies and/or spinal cord compression caused by cement leakage. To avoid these complications, it is important to have good visualization of the injected cement under fluoroscopic image guidance. Other complications include cement extravasation and thermal necrosis. In this study, we compared the differences of biocompatibility and visualization between PMMA mixed with 10% and 30% Barium sulfate in a sheep vertebroplasty model.

Materials and Methods:

**Surgery**

Six skeletally mature female sheep of approximate equal size were used in this Institutional Animal Care and Use Committee approved study. Wool was removed from the left abdominal area and the sheep positioned in lateral recumbency on the operating table under general anesthesia. A lateral retroperitoneal approach through the oblique abdominal muscles to the plane ventral to the transverse processes was made. The ventral spinal muscles were cleared from the lateral vertebral body. A 3 mm drill hole was made over the lateral cortex of L4. Using a spoon curette, a cavity was created in the vertebral body. PMMA, approximately 0.5 cc’s, was deposited into the vertebral body. An identical procedure was performed at L5 and L6 using PMMA with either 10% or 30% barium sulfate, or no PMMA (control). At 12 days (3 animals) and 90 days (3 animals) following surgery, the sheep were euthanized. At necropsy, the lumbar vertebrae were harvested and the explanted vertebral bodies (L4, L5, L6) were evaluated using radiographs, histology, and CT scans.

**Radiographic analyses**

Radiographs of each vertebrae body were used to compare the visualization of 10% and 30% BaSO4/PMMA. Micro-CT images of the explanted vertebral bodies (L4, L5, L6) were collected at 50kV and 100 uA. The images were 512x512 with a resolution of 150 micrometers. Reconstructed images were scaled between 0 (black) to 255 (white). A region of interest within the cylinder was used to calculate average gray level intensity for each cement area. Statistical analysis was performed using Kruskal-Wallis test.

**Histologic Preparation**

The specimen were cut sagittally, radiographed and fixed in formalin. Half of each specimen was dehydrated slowly in alcohols without acetic to preserve PMMA and embedded in Spurr’s plastic (Polysciences, Inc., Warrington, PA) without decalcification. The remainder of each specimen was dehydrated in a graded series of alcohols, decalcified, and embedded in paraffin. Sections were stained with Giemsa (undecalcified) or hematoxylin and eosin (decalcified).

**Histologic analysis**

Microscope slides were reviewed with special reference to evidence of thermal necrosis, foreign-body reaction, and cement extravasation. Cement status (porosity, porous size, and fractures) was evaluated in undecalcified sections (Giemsa). Cellular and tissue response to the cement were evaluated in decalcified sections (H&E.).

**Results**:

**Radiographic findings**

Figure 1 shows the gross findings of undecalcified axial sections and A-P radiographs of vertebrae. The 30% BaSO4 cement could be visualized clearer than the 10% BaSO4 cement. Figure 2 shows the differences of CT value at the drill hole of each vertebra at 90 days. The average CT value of each group was 4.5 (Empty), 49.1 (10% BaSO4) and 119.8 (30% BaSO4). The CT value of the 30% BaSO4 group was 2.4 fold higher than the 10% BaSO4 group. The CT value among the three groups were significantly different (P=0.027).

**Histologic analysis**

In the 90 days group, residual cement particles in decalcified section were more easily recognized in the 30% BaSO4 group than the 10% group. Foreign body giant cells were recognized around the BaSO4 particles at 90 days in the 30% BaSO4 group (Fig. 3), while in the 12 days group, few particles were recognized in either the 10% or 30% group and no foreign body reaction was recognized. Thermal necrosis was not clearly identified at either time point. No cement extravasation was identified.

Discussion:

It is desirable to have clear visualization of cement during vertebroplasty or kyphoplasty in order to limit complications. Most surgeons have achieved adequate visualization by using higher concentrations of BaSO4 than are used for total joint arthroplasty. A previous report described thermally induced bone necrosis in rabbits1, but a human specimen retrieved after vertebral augmentation showed only rare foci of necrosis, suggesting that most necrotic bone must have been remodeled by the time of specimen retrieval2. Although we used a relatively small volume of cement, thermal necrosis was not obvious in this sheep model of vertebroplasty. Occasional cement particles and foreign body giant cells were recognized in this study, especially at 90 days in the 30% BaSO4 group (Fig. 3). This observation is similar to observations made in a human specimen retrieved after vertebral augmentation1, in which particles of BaSO4 were confirmed by scanning electron microscopy and energy dispersive spectroscopy. The clinical importance of these observations needs to be viewed in the appropriate context. In general, it seems undesirable to use a concentration of BaSO4 high enough to induce a foreign body giant cell reaction, but on the other hand, the consequences of poor cement visualization during injection may be more clinically significant. The material modification would be desirable for percutaneous vertebral augmentation procedures.

References: