Adjuncts in Posterolateral Lumbar Spine Fusion: Comparison of Complications and Efficacy

INTRODUCTION:
Solid osseous posterolateral fusion is an integral component of surgical management of degenerative lumbar spine diseases. Iliac crest bone autograft (ICBG) is considered the gold standard for bone graft and fusion procedures. Pseudarthrosis can lead to persistent pain, fusion failure, and revision surgery. Autograft pseudarthrosis rates of 55% have been reported. Donor site morbidity is problematic. Despite instrumentation optimizing mechanical variables, the biological variables are also warranted. Therefore, surgeons are still looking for the ultimate enhancer effect. Today, a wide array of bone graft materials is commercially available. These materials fall into one of two major groups: bone void fillers or extenders without osteoinductive potential and osteobiologics or replacements with osteoinductive potential.

Allograft from fresh frozen bone has similar properties compared to ICBG but includes the risk for disease transmission. Processing allograft bone by acid extraction results in loss of the mineralized components (demineralized bone matrix, DBM). Collagen and non-collagenous proteins, including growth factors are persevered. DBM offers growth factors, including Bone Morphogenetic Proteins (BMP) in varying concentrations.

Recombinant human Bone Morphogenetic Proteins (rhBMP) have been reported as potent osteoinductors which increase fusion rates. BMP utilization in spinal fusions increased to 25% nationally (2006).

The purpose of this study was to compare fusion/nonunion rates as well as complication rates of rhBMP-2, DBM, and autograft alone in patients undergoing posterior lumbar spine fusion.

METHODS:
This study was an IRB approved retrospective cohort review of 2549 patients undergoing instrumented lumbar posterolateral fusion at a single spine center. Consecutive patients were identified that had initial treatment from 2002 through 2009. Surgical indications and treatment were performed in accordance with the surgeons’ best knowledge. Bone graft and bone graft extenders were used at the surgeons’ discretion. We retrospectively reviewed the operative reports and patient charts at our institution.

Demographic data and comorbidities were recorded. Surgical data included fusion levels, number of levels fused, grafting material, adjuncts, operative time, estimated blood loss, and hospital length of stay (LOS). Patients < 18 years, follow up < 6 months, with additional bone stimulator, anterior lumbar interbody fusion, and combination of DBM and rhBMP-2 or ICBG/bone marrow aspirate and rhBMP-2 were excluded. We included 1398 patients in our study, which were grouped into 3 groups: rhBMP-2 only, DBM, and Autograft. Allograft, local autograft and ceramic were included in the mixed group. We included all patients with DBM and all types of autograft in the DBM group. The Autograft group includes all patients without rhBMP-2 or DBM. All patients underwent decompression and fusion. The surgeon determined the amount or number of rhBMP-2 utilized per surgery. The mean total rhBMP-2 dose implanted was 12.7 mg per patient (range 4.2-48.0). The mean dosage per level was 7.8 mg (range 1.33 - 24.0). DBM was used according to manufacturer’s recommendation.

Platelet enriched plasma or bone marrow aspirate was added at the surgeons’ discretion. 43 patients had additional platelet enriched plasma and 35 patients underwent additional bone marrow aspiration.

Patients were followed for at least 6 months or until clinically stable. During that time radiographic evaluation was performed as well as CT scan and MRI if necessary. Complications due to the performed procedure and the redo surgeries performed, if necessary, were recorded.

RESULTS:
We identified 1398 cases with 575 (41.1%) males and 823 (58.9%) females of posterolateral lumbar fusions with supplementation of rhBMP-2, DBM, or autograft between 2002 and 2009. Average age was 60 years and BMI was 30.6 kg/m². Mean LOS was 5.1 days for all groups combined. There was a significant difference in LOS between patients who underwent rhBMP-2 only fusion compared to the autograft group (4.9 vs. 5.8 days, respectively; p=0.006). The average number of levels fused was 2.1 levels per patient. No significant differences between the three groups were found (p>0.05). Follow up was 22.54 months (range 6-183 months). Patients with autograft had a mean blood loss of 756 ml (average number of levels fused 2.0). Patients with BMP had a higher average blood loss (799 ml) whereas the average number of levels fused was higher (2.1) (p=0.548). The overall infection rate was 2.1%. No significant differences were found between the three groups. The incidence of seroma formation was higher in the BMP group (3.2%) than in the DBM or autograft group (2.0% and 1.4%, respectively) but this was not significant (χ²=0.286 and χ²=0.245, respectively).

One hundred and three patients (7.4%) underwent redo surgery for clinically significant nonunion. We found significantly fewer nonunions in the rhBMP-2 group (4.3%) compared to the DBM or autograft group (13.1% and 15.2%, respectively; χ²<0.001).

DISCUSSION:
Spinal surgeons currently are presented with a variety of bone void fillers and osteobiologics. Most bone substitutes have been developed and are promoted to avoid ICBG donor site morbidity. DBM has been discussed as a safe and effective graft extender and offers growth factors, including BMP in varying concentrations. Similar radiographic fusion rates for DBM and autograft have been described. The efficacy of DBM is influenced by the amount of BMP present. In our study, we could show no negative effect of DBM in posterolateral fusions compared to autograft alone. We found no significant differences in nonunion rate, infection, or seroma formation.

The efficacy of rhBMP-2 in posterolateral lumbar fusion has been studied previously. The combination of rhBMP-2 with compression-resistant bone void filler has been shown advantageous. Our data supports previous suggestion of the literature that rhBMP-2 does not increase complication rates compared to ICBG.

Reduced blood loss and shorter inpatient stay have been attributed as an advantage to osteobiologics. No significant difference was found between patients with or without ICBG concerning blood loss but LOS was significantly shorter in the BMP group. To our knowledge, this is the first comparison of autograft alone posterolateral lumbar fusions to procedures using DBM or rhBMP-2. In our findings nonunion rates utilizing rhBMP-2 for posterolateral lumbar spine fusion were significantly lower (χ²<0.001) compared to autograft alone or additional DBM. Comparing other adverse events (although not statistically significant), the rhBMP-2 associated seroma formation was more common. And, infection rates were lowest in the DBM group.

SIGNIFICANCE:
When determining the graft composition for a posterolateral spine fusion, orthopaedic spine surgeons should be cognizant that rhBMP-2 results in a significantly better fusion rate as compared to DBM and ICBG.