Bone Marrow Concentration vs. Iliac Crest Bone Graft: 2-Year Results in a Single-Blinded Randomized Controlled Trial on Thoracolumbar Spinal Fusion Bone Grafts in Multi-Level Adult Spinal Deformity

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Background

• Biologic therapies enhance spinal fusion, prevent nonunion and complications which may result in significant pain and disability.¹,²,³

• The “gold standard” is autologous bone graft obtained from the iliac crest (ICBG)⁴,⁵
  – Pros: osteoconductive scaffold, osteogenic factors, and cellular elements that promote arthrodesis.
  – Cons: limited supply, significant donor site pain, postoperative morbidity

• Alternative techniques to enhance spinal fusion have been studied, resulting in the development of bone marrow concentrate (BMC).⁶
Study Objective

• Previous literature has found BMC to display comparable angiogenic, osteoinductive, osteoconductive, and osteogenic properties as ICBG.\(^7\)

• Several recent studies have proposed utilizing BMC combined with allograft cancellous bone chips (BMC+Allograft).\(^8–10\)

• The major advantage of BMC+Allograft is the ability to obtain a greater volume of osteogenic bone precursor cells without the morbidity of iliac crest harvest (ICBG).

• BMC+allograft has been shown to improve fusion rates compared to allograft alone, and has equivalent fusion rates compared to ICBG,\(^8,10\) the only in vivo study performed was reported on 1 to 3 level fusions.

• Our goal was to examine the differences between BMC+Allograft and ICBG during posterior lumbar or lumbosacral multi-level spinal fusions.
Materials & Methods

• Design
  – Prospective single center randomized clinical trial.

• Inclusion Criteria:
  – Age >18 years w Adult Spinal Deformity, Failed at least 6 weeks of conservative care with
    – Posterior spinal fusion: Thoracolumbar spine or lumbar spine
    – Oswestry Disability Index (ODI) score >30%

• Exclusion criteria:
  – Spondylolisthesis grade ≥3, Metabolic bone disease, Use of medications that may interfere with bone healing. Active malignancy

• Patient Groupings
  – Randomized in a 2:1 ratio:
    • BMC+allograft
    • ICBG

• Collected data:
  – Demographics, medical comorbidities, surgical details, and treatment complications
  – Baseline to 2-Years postop
  – HRQL: ODI, Short Form 12 (SF-12), Numeric Pain Rating Scale (NRS-Pain)
  – Aspirate data of both BMC and ICBG groups (assessed by an independent laboratory).
    • Total nucleated cell concentration
    • Platelet Concentration
Materials & Methods

- **Intervention Technique**
  - All patients received *open posterior lumbar fusion*. ≥4 level fusions with sacrum extensions also received *interbody fusions* at L5-S1 and *bilateral iliac fixation*.

- **(BMC+Allograft Harvesting)**
  - Bone marrow aspirate (*BMA*) was aspirated from the posterior iliac crests.
  - *BMA* was pooled with anticoagulant citrate dextrose solution, concentrated via centrifuge (*BMC*), and then packed with cancellous bone chips yielding 10 mL bone logs (*BMC+Allograft*).
Materials & Methods

• Fusion Assessment
  – Performed by two independent radiologists.
  – Fusion status was classified according to Tan et al:
    1. Complete Fusion
    2. Partial Fusion
    3. Unipolar Pseudarthrosis
    4. Bipolar Pseudarthrosis

• Statistical Analysis
  – **Frequencies**: assessed Demographics
  – **Non-parametric Mann Whitney U and Wilcoxon Signe-Rank tests**: compared complications, fusion grading, biologic quality, HRQLs within and between groups.
  – Level of Significance was set to $P = 0.05$
Results

• 27 Patients included
  – 17 BMC+Allograft
  – 10 ICBG

• Demographics [Overall Cohort]
  – Mean age 56 years old (range: 35-77)
  – 60% Female
  – 44% Unemployed
  – 48% Smokers
  – 40.7% History of Spinal Surgery
  – No significant differences between BMC+Allograft and ICBG (all p>0.05)
Results

• Complications
  – No significant differences in overall complications ($p=0.935$), reoperations ($p=0.201$).
  – ICBG patients had significantly greater incidence of rod breakage ($p=0.024$).
  – No significant intraoperative complications related to BMC+Allograft or ICBG protocol.
  – Complication Details: within the 2-year follow-up period
    • BMC+Allograft
      – 7 complications (41.1%)
      – 3 re-operations (17.6%)
        • 1 non-union, 1 persistent radiculopathy, 1 hardware removal.
    • ICBG
      – 4 complications (40%)
      – 4 re-operations (40%)
        • 3 hardware failure (two rod breakage), 1 patient fall.
## Results

**Surgical Details:** All clinical values for interventions were similar due to cohort randomization (*All P* > 0.05).

<table>
<thead>
<tr>
<th>BMC+Allograft</th>
<th>ICBG</th>
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<tbody>
<tr>
<td>Avg. levels fused: 6.0</td>
<td>Avg. levels fused: 6.2</td>
</tr>
<tr>
<td>Estimated Blood Loss (EBL): 2542 ±1425</td>
<td>Estimated Blood Loss (EBL): 2102.9 ±1201</td>
</tr>
<tr>
<td>Avg. OR time: 7:26 ±2:20</td>
<td>Avg. OR time: 8:15 ±2:49</td>
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**Techniques (Prevalence)**

- Osteotomy: 62.5% ±51.8%
- 3-Column Osteotomy: 11.7% ±33.2%
- Decompression: 85.7% ±37.8%
- Osteotomy: 70.6% ±47.0%
- 3-Column Osteotomy: 20% ±42.2%
- Decompression: 86.7% ±35.2%
Results

• Post-Operative Fusion Evaluation
  – 88.2% of BMC patients were graded ‘fused’ at 1-year follow-up, and 60% of ICBG patients (p=0.088)
  – Based on the described Lenke 1-4 classification, BMC patients trended towards better fusion scores, but insignificantly (BMC average: 1.5 vs. ICBG average: 2.3, p=0.062).

• Effect of Smoking Status on Arthrodesis
  – 61.5% of patients with a history of smoking were graded ‘fused’ at 1-year follow-up, and 92.9% of non-smoking patients were graded ‘fused’ (p=0.05).
Results

• Aspirate Analysis - Biologic Quality
  – **No significant associations** were observed between number of nucleated cells, number of platelets, reaching threshold of >1500 BMC cells x10^6 per cm³ (Threshold proposed by Herigou et al), and improved fusion scores (all \(P>0.05\)).

• 2-Year Outcome HRQLs:
  – Both Patient groups improved from baseline to 2-Year postop
  – No significant differences were observed between either group in baseline, changes to, or 2-year followup HRQLs (ODI, NRS Back, SF-12 MCS, SF-12 PCS) (\(p>0.05\)).
Conclusions

• Limitations:
  – Small patient population (n:27)
  – No ICBG data for nucleated cell and platelet count
  – Fusion score was assessed by the lowest score of any vertebra in the construct (not combined or individual levels).

• BMC+Allograft
  – Associated with less hardware failures
  – Trended towards better fusion scores
  – A viable alternative, with similar HRQL outcomes and overall complication rates compared to ICBG.
Thank You!
References

8. Edgar, Cory MD, PhD; Einhorn TAM: Treatment of Avascular Necrosis of the Femoral Head With Drilling and Injection of Concentrated Autologous Bone Marrow. Tech Orthop 28:218–222
11. https://stemcells.nih.gov/sites/all/themes/stemcells_theme/stemcell_includes/figure2_sm.jpg

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