Clinical Outcomes and Cost-Effectiveness of Demineralized Bone Matrix-Augmented Vertebroplasty for Osteoporotic Vertebral Compression Fractures

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Introduction

- **Current Status of OVCF**: A major cause of pain and decreased mobility in the elderly population.
- **Percutaneous Vertebroplasty (PVP):** Standard treatment using PMMA bone cement; however, limitations include lack of biological activity and risk of adjacent segment fractures.
- **Role of Demineralized Bone Matrix (DBM):**
  - Possesses osteoinductive and osteoconductive properties.
  - Potential to combine biological healing capacity with the mechanical stability of PMMA.
- **Rationale:** Lack of empirical evidence regarding the clinical efficacy and economic viability of DBM-augmented PVP.

Study Objective & Hypothesis

- **Objective:** To compare the clinical and radiologic outcomes, as well as the cost-effectiveness, of DBM-augmented vertebroplasty (VPDBM) versus conventional bone cement vertebroplasty (VPBC).

- **Hypothesis:** Despite the initial higher cost, DBM augmentation will demonstrate superior cost-effectiveness by reducing treatment failure rates.

Materials and Methods

- **Study Design:**
  - Retrospective cohort study (Jan 2020 – Mar 2025)
- **Participants:** ≥ 60 years with acute OVCF (N=187)
  - **VPDBM Group:** n=103 (DBM + PMMA)
  - **VPBC Group:** n=84 (PMMA only)
- **Outcome Measures:**
  - VAS (Pain), Koval grade (Ambulatory function)
  - Vertebral Kyphotic Angle (VKA), Local Kyphotic Angle (LKA), Correction Angle
  - Incremental Cost-Effectiveness Ratio (ICER) per 1% increase in Deterioration-Free Survival (DFS)

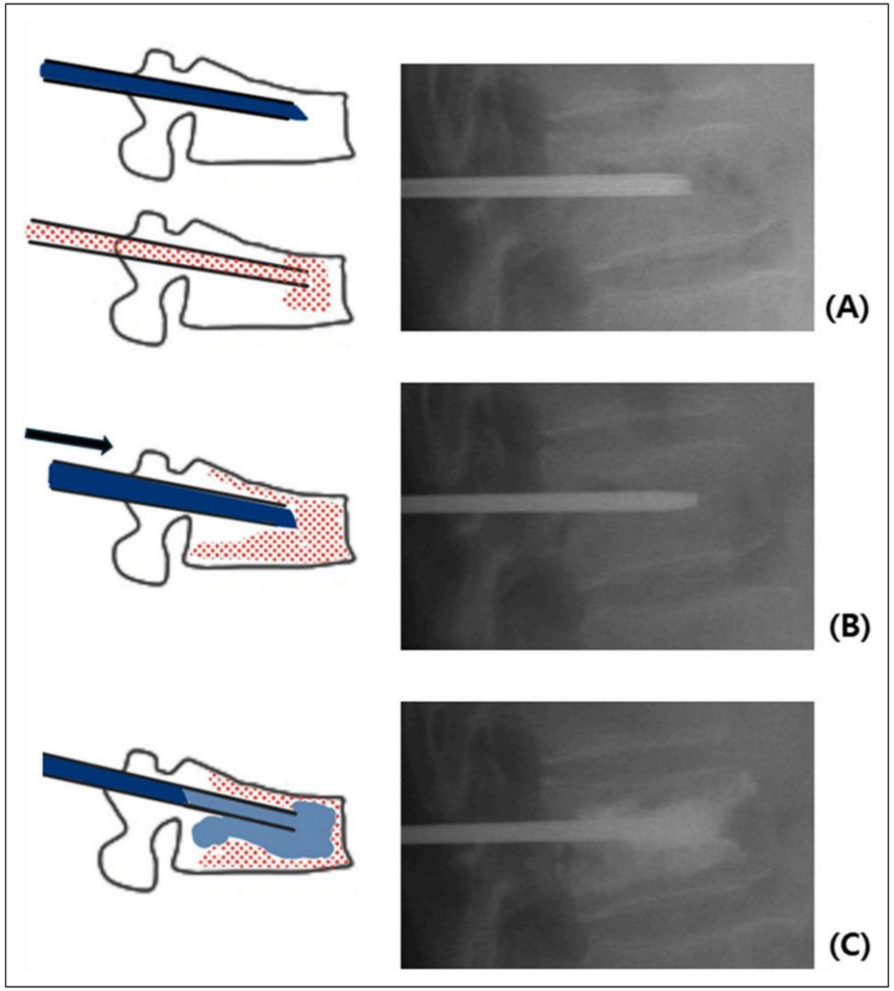

Figure 1. Operative workflow of PVP with adjunctive DBM, shown as paired intraoperative C-arm fluoroscopic images (left) and matching schematic diagrams (right). (A) Transpedicular access to the vertebral body with the stylet engaged in the cannula. After stylet withdrawal, DBM (red dots) is delivered through the sheath into the vertebral body; DBM itself is not radiopaque and is indicated in the schematic. (B) The stylet is fully reinserted to clear the sheath, leaving DBM within the vertebral body. (C) PMMA (gray shading) is injected during the doughy phase to achieve adequate vertebral fill while avoiding leakage

Demographic Data

Table 1. Comparison of Demographic Data Between the Two Groups

Factor	VPDBM (n = 103)	VPBC (n = 84)	*P*-value
Age (years)	80.6 ± 7.3	79.5 ± 8.1	.356
Sex (male/female)	21/82	17/66	.540
BMI (kg/m^2)	22.1 ± 3.6	22.1 ± 3.3	.987
Hospital days	11.8 ± 7.8	10.0 ± 8.6	.183
BMD (T-score)	−2.8 ± 0.5	−2.8 ± 0.7	.873
Fracture site (T/TL/L)	46/38/19	31/31/22	.379
Approach (unipedicular/bipedicular)	14/89	14/70	.704
CVD (n/%)	77/74.8	63/75	.531
DM (n/%)	24/23.3	23/27.4	.638
CKD (n/%)	5/4.9	4/4.8	.540
RD (n/%)	0/0	2/2.4	.390
Smoking history (n/%)	5/4.9	2/2.4	.443
Alcohol consumption history (n/%)	21/20.4	17/20.1	1.000
Steroid medication history (n/%)	10/9.7	2/2.4	1.000
Osteoporosis treatment before surgery (n/%)	27/26.2	12/14.3	.069
Osteoporosis treatment after surgery (n/%)	74/71.8	58/69	.798

Data are presented as mean ± standard deviation.
DBM, demineralized bone matrix; BMI, body mass index; BMD, bone mineral density; T/TL/L, thoracic/thoracolumbar/lumbar spine; CVD, cardiovascular disease; DM, diabetes mellitus; CKD, chronic kidney disease; RD, rheumatic disease.

Clinical & Radiologic Results

- **Clinical Outcomes:** Both groups showed significant improvement in VAS and Koval grades at 12-month follow-up (no significant intergroup differences).
- **Radiologic Outcomes:**
  - No significant differences in VKA or LKA between groups.
  - Correction Angle: VPBC showed initial superiority (***p*=0.041**), but the difference vanished by the 12-month mark.
- DBM augmentation <u>does not compromise</u> short-term analgesic efficacy.

Treatment Failure & Survival Analysis

- **Composite Treatment Failure Rate:**
  - VPDBM: 12.6% vs. VPBC: 27.4% (*p*=**0.010**)
  - Relative Risk: 0.46 (54% risk reduction); NNT: 6.8
- **Kaplan-Meier Analysis:**
  - VPDBM group demonstrated significantly higher DFS (*p*=**0.034**).
  - Most failure events occurred within the first 6 months postoperatively.

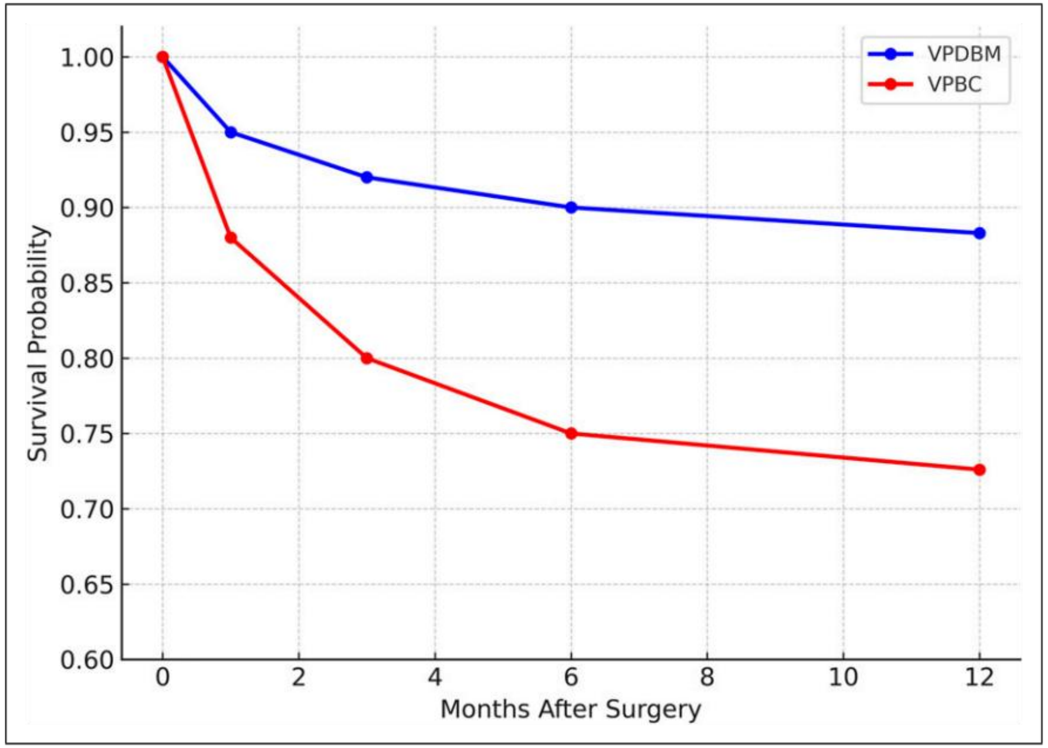

Figure 2. Kaplan–Meier curves for deterioration-free survival (DFS) through 12 months after percutaneous vertebroplasty for osteoporotic vertebral compression fractures. VPDBM (blue) and VPBC (red). Time zero is the day of surgery; patients were censored at last follow-up. Dots mark scheduled assessment time points (1, 3, 6, and 12 months). The VPDBM curve remains above VPBC throughout follow-up, with most failures in both groups occurring within the first 6 months

Cost-Effectiveness Analysis

- **Cost Analysis:** Higher initial cost in the VPDBM group due to DBM material expenses (₩883,200).
- **Effectiveness Metric:** Deterioration-Free Survival (DFS)
- **ICER Results:**
  - Additional cost per 1% increase in DFS: **₩43,978 ($32.0)**
  - The ratio is well below standard Willingness-to-Pay (WTP) thresholds, confirming high cost-effectiveness.

Discussion

- Both VPDBM and VPBC showed similar improvements in pain and function. However, VPDBM resulted in a lower treatment failure rate and improved DFS.
- This suggests that while short-term clinical outcomes are mainly driven by mechanical stabilization, DBM may enhance long-term structural durability through its biological effects.
- Most failures occurred within 6 months, indicating the need for early monitoring and optimized osteoporosis management.

- **Study Limitations:**

1. As a retrospective cohort study, there may be inherent selection bias despite efforts to standardize treatment.
2. The study was conducted at a single institution with a relatively small cohort, which may limit the generalizability of the findings to broader populations.
3. A 12-month follow-up period may not be sufficient to capture very long-term complications, such as late-onset adjacent segment fractures or delayed DBM remodeling.
4. The cost-effectiveness analysis was primarily focused on material costs and direct clinical outcomes; indirect costs (e.g., caregiver burden, loss of productivity) were not included.

Conclusion

- VPDBM is a **clinically effective and cost-effective strategy** for treating OVCF.
- It **reduces treatment failure and improves DFS** compared with conventional VPBC.
- **Further prospective, multicenter randomized studies** are required to validate these findings.