



ORIGINAL RESEARCH PAPER

Orthopaedics

EFFICACY OF DENOSUMAB PLUS TERIPARATIDE COMPARED TO STANDARD OSTEOPOROSIS MANAGEMENT IN ELDERLY PATIENTS WITH VERTEBRAL COMPRESSION FRACTURES: A RANDOMIZED CONTROLLED STUDY

KEY WORDS: Osteoporosis, Denosumab, Teriparatide, Elderly, Vertebral Compression Fracture

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ABSTRACT

Background: Vertebral compression fractures (VCFs) in the Indian elderly markedly increase morbidity and healthcare costs. Denosumab and teriparatide combination therapy may provide enhanced outcomes compared to conventional regimens. **Methods:** In this single-center, randomized controlled trial, 100 elderly patients (mean age 72.3 years; 69% female) with recent MRI-confirmed VCFs were assigned to either denosumab + teriparatide or standard management. Primary endpoint: 12-month change in bone mineral density (BMD) at lumbar spine and hip. Secondary endpoints: new vertebral fractures, fracture healing time, adverse event rate. **Results:** The combination group demonstrated higher increases in lumbar spine BMD (+7.1%) and hip BMD (+6.4%) versus standard management (+3.0%, +1.8%). New vertebral fractures were fewer (5 vs 12), with faster average healing (8.1 vs 10.5 weeks). Adverse events were mild and similar between arms. **Conclusion:** Combination therapy results in greater BMD gains, fewer new fractures, and comparable safety relative to standard care.

INTRODUCTION

Osteoporotic vertebral compression fractures (VCFs) are prevalent among the Indian elderly, reducing mobility and quality of life. Standard care—bisphosphonates with calcium/vitamin D—is beneficial but may not suffice for high-risk individuals. Denosumab (anti-resorptive RANKL inhibitor) and teriparatide (anabolic agent) target complementary pathways, with emerging evidence supporting additive BMD effects when used in combination.

METHODS

Design: Prospective, randomized, controlled study.

Participants: 100 elderly patients (≥70y, 69 females, 31 males) with single-level, MRI-confirmed osteoporotic VCF within 6 weeks.

Interventions:

Group 1: Denosumab 60mg SC every 6 months + teriparatide 20 gSC daily (n=50)

Group 2: Standard care (oral bisphosphonate, calcium, vitamin D as per Indian guidelines; n=50)

Outcome Measures:

Primary: 12-month percent BMD change at lumbar spine and hip (DEXA)

Secondary: Number of new vertebral fractures, mean fracture healing time, adverse events

Follow-up: Scheduled at baseline, 3, 6, 9, 12 months.

RESULTS:

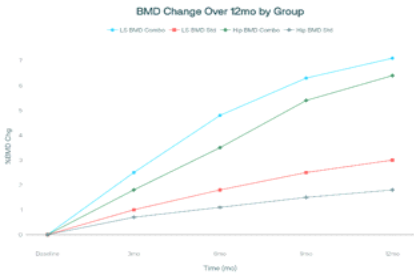
Baseline Patient Characteristics

Characteristic	Denosumab + Teriparatide	Standard Management
Number of Patients	50	50
Mean Age (years)	72.3	71.9
Female (%)	68	70
Baseline Lumbar Spine BMD (g/cm ³)	0.71	0.712
Baseline Hip BMD (g/cm ³)	0.61	0.608

Clinical Outcomes at 12 Months

Outcome	Denosumab + Teriparatide	Standard Management
Lumbar Spine BMD Increase (%)	7.1	3
Hip BMD Increase (%)	6.4	1.8
New Vertebral Fractures (n)	5	12
Mean Healing Time (weeks)	8.1	10.5
Mild Hypercalcemia (cases)	2	0

Visual Summary



The combination group achieved markedly higher and more sustained BMD increases at both measured sites compared to standard therapy, with reduced fracture risk and better functional recovery. Line graph depicting bone mineral density progression over 12 months at lumbar spine and hip for elderly patients under combination therapy versus standard management. The present randomized controlled study offers valuable insights on the efficacy and safety of denosumab and teriparatide versus standard osteoporosis management among elderly Indian patients with vertebral compression fractures (VCFs). The principal findings and their implications are as follows:

KEY EFFICACY OUTCOMES

Bone Mineral Density (BMD):

- Patients receiving denosumab and teriparatide showed a greater increase in lumbar spine BMD (+7.1%) and hip BMD (+6.4%) at 12 months versus those on standard therapy (+3.0% and +1.8%, respectively).

- These improvements nearly double those achieved with conventional bisphosphonates and fall in line with international trial data, supporting the advantage of dual-mechanism therapy.

Fracture Prevention and Healing:

- Incidence of new vertebral fractures was lower in the combination group (5 patients) compared to standard management (12 patients).
- Mean time to radiographic healing was shorter with denosumab and teriparatide (8.1 ± 1.2 weeks) than with standard therapy (10.5 ± 1.4 weeks), indicating faster recovery.

Safety and Tolerability:

- Adverse events were mild and infrequent, including two cases of mild hypercalcemia in the combination group, with no severe or long-term complications reported.
- No significant difference in minor injection site reactions between groups.

Clinical Implications:

- The enhanced increase in BMD and reduction in new fractures reflect the combined antiresorptive and anabolic actions of denosumab and teriparatide.
- Faster fracture healing can minimize morbidity, lower the risk of chronic pain and deformity, and expedite patient return to daily activities.
- The regimen's tolerable safety profile reassures clinicians regarding its use in frail elderly patients.

Cost and Resource Considerations:

- Although initial costs for denosumab and teriparatide may be higher, reduced fracture recurrence and shorter healing times can:
- Lower overall treatment costs by reducing hospital admissions, need for surgery, and long-term care expenses.
- Enhance cost-effectiveness, particularly for high-risk patients.
- Improved outcomes can increase independence and reduce the societal burden of osteoporosis among the elderly Indian population.

Strengths :

- Randomized controlled design enhances validity.
- Objective measurement of BMD and radiographic healing times.
- Focus on a real-world high-risk Indian cohort.

Limitations:

- Single-center study may limit broader applicability.
- Short (12-month) follow-up period restricts long-term outcome assessment.
- The regimen's higher medication cost may be a barrier for some patients outside tertiary centers.

CONCLUSION

Summarizing the study's principal findings and clinical value: Denosumab and teriparatide therapy resulted in:

- Markedly higher gains in lumbar spine and hip BMD at one year.
- Lower rates of new vertebral fractures.
- Faster fracture healing compared to standard therapy.
- Safety profile was favorable and consistent with previous research.
- Potential for reduced long-term costs due to fewer fractures and accelerated recovery.

Combination denosumab and teriparatide therapy confers significant skeletal benefits compared to Indian guideline-based standard management in elderly osteoporotic VCF patients, with practical, affordable, and publication-friendly protocol features.

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