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Original Research Article

Accelerated Fracture Healing in Osteoporotic Patients with Teriparatide: A Prospective Study at Gandhi Medical College and Hamidia Hospital

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Abstract:

Background: Osteoporosis is a prevalent condition in the elderly, characterized by reduced bone mass and increased fracture risk. Fracture healing in osteoporotic patients is often delayed, posing significant clinical challenges. Teriparatide, a recombinant form of parathyroid hormone (PTH 1-34), has shown promise in enhancing bone regeneration and fracture healing.

Aims and Objective: To evaluate the efficacy of teriparatide in fracture healing among osteoporotic patients.

Materials and Methods: This prospective, observational study was conducted at Gandhi Medical College and Hamidia Hospital, Bhopal, from January 2021 to December 2023. A total of 150 osteoporotic patients with confirmed fractures were enrolled and treated with teriparatide (20 µg daily) for six months, along with standard fracture care. The primary outcome was the time to fracture healing, assessed through clinical and radiographic evaluations. Secondary outcomes included bone mineral density (BMD) changes and functional recovery, evaluated using SF-36 and WOMAC scores. Safety and tolerability were also monitored.

Results: The mean time to fracture healing was significantly shorter in the teriparatide group (13.5 ± 2.1 weeks) compared to historical controls (18.7 ± 3.5 weeks, $p < 0.001$). BMD improved from a mean T-score of -2.8 ± 0.3 at baseline to -2.3 ± 0.4 at six months ($p < 0.001$). Functional outcome scores showed significant improvements in physical function and pain reduction. Teriparatide was well-tolerated, with minor adverse events, including transient hypercalcemia (5%), mild injection site reactions (3%), and mild dizziness (2%).

Conclusions: Teriparatide significantly accelerates fracture healing in osteoporotic patients, improves BMD and functional recovery, and is well-tolerated. These findings suggest that teriparatide can be a valuable therapeutic option in the management of osteoporotic fractures, potentially improving patient outcomes and reducing healthcare costs. Further research is warranted to explore the long-term benefits and optimize the use of teriparatide across different fracture types and patient populations.

Keywords: Teriparatide, Fracture Healing, Osteoporosis, Bone Mineral Density.

Introduction

Osteoporosis, a widespread condition predominantly affecting the elderly population, is characterized by reduced bone mass and deterioration of bone tissue, leading to an increased risk of fractures. [1, 2] These fractures, especially in osteoporotic individuals, pose significant clinical challenges due to their propensity for delayed healing and complications. The socioeconomic burden of osteoporotic fractures is substantial, necessitating the development of effective treatment strategies to enhance fracture healing and improve patient outcomes. [3]

Presently, the prevailing estimate is that over 200 million individuals have osteoporosis. Recent statistics from the International Osteoporosis Foundation reveal that globally, 33% of women aged 50 and above and 20% of males will suffer from osteoporotic fractures at some point in their lives. Each fracture serves as an indication of an imminent subsequent fracture. [2, 4]

Teriparatide, a recombinant form of parathyroid hormone (PTH 1-34), has emerged as a promising therapeutic agent for the treatment of osteoporosis. [5] teriparatide promotes new bone formation by stimulating osteoblastic activity, thereby improving bone density and strength. [6] Its role in fracture healing, particularly in osteoporotic patients, has garnered considerable attention recently. Preclinical studies and clinical trials have suggested that teriparatide accelerates fracture repair, enhances callus formation, and improves the biomechanical properties of the healed bone. [6, 7]

Despite these promising findings, comprehensive clinical studies are needed to evaluate the efficacy and safety of teriparatide in real-world settings. This study aims to assess the role and application of teriparatide in fracture healing among osteoporotic patients treated at Gandhi Medical College and Hamidia Hospital, Bhopal, from January 2021 to December 2023. By examining the outcomes of teriparatide therapy in this patient population, we hope to contribute valuable insights into its clinical utility and potential benefits in enhancing fracture healing in osteoporotic individuals.

This study's primary objective was to evaluate teriparatide's impact on fracture healing time and bone mineral density (BMD) in osteoporotic patients. Secondary objectives include assessing the safety profile of teriparatide and identifying any adverse effects associated with its use. The findings of this study will help inform clinical practice and guide therapeutic decisions in the management of osteoporotic fractures.

Materials and Methods

Study Design and Setting: This prospective, observational study was conducted at Gandhi Medical College and Hamidia Hospital, Bhopal, from January 2021 to December 2023. It aimed to evaluate the role of teriparatide in the fracture healing process of osteoporotic patients.

Study Population: The study population included osteoporotic patients presenting with fractures. Patients were recruited based on the following inclusion and exclusion criteria:

Inclusion Criteria:

- Patients aged 50 years and above.
- Confirmed diagnosis of osteoporosis based on bone mineral density (BMD) measurements (T-score ≤ -2.5).
- Presence of acute fractures requiring medical intervention.
- Patients who provided written informed consent.

Exclusion Criteria:

- Patients with contraindications to teriparatide (e.g., hypercalcemia, metabolic bone diseases other than osteoporosis, skeletal malignancies).
- Patients with a history of radiation therapy involving the skeleton.
- Patients with severe renal impairment or chronic kidney disease.
- Patients who were unable to comply with study procedures.

Study Intervention: Eligible patients received teriparatide (20 µg daily) subcutaneously for six months in addition to standard fracture care. Standard care included immobilization, pain management, and physical therapy as required.

Outcome Measures:

Primary Outcome:

- Time to fracture healing: Assessed through clinical and radiographic evaluations at regular intervals (6 weeks, three months, and six months).

Secondary Outcomes:

- Change in bone mineral density (BMD): Measured at baseline and after six months using dual-energy X-ray absorptiometry (DEXA).
- Functional recovery: Evaluated using validated functional outcome scores (e.g., SF-36, WOMAC) at baseline, three months, and six months.
- Safety and tolerability: Monitored through adverse event reporting and laboratory investigations (serum calcium, phosphate, creatinine) at regular intervals.

Data Collection: Data were collected at baseline, and follow-up visits were scheduled at six weeks, three months, and six months. Clinical assessments included physical examinations, pain evaluation, and functional outcome scoring. Radiographic assessments were conducted to monitor fracture healing progress. BMD measurements were taken at baseline and after six months of treatment.

Statistical Analysis: Data were analyzed using SPSS software (version XX). Descriptive statistics were used to summarize baseline characteristics. Continuous variables were compared using paired t-tests or Wilcoxon signed-rank tests, as appropriate. Categorical variables were analyzed using chi-square tests or Fisher's exact tests. The primary outcome, time to fracture healing, was analyzed using Kaplan-Meier survival analysis. Secondary outcomes were evaluated using repeated measures analysis of variance (ANOVA) or equivalent non-parametric tests. A p-value of <0.05 was considered statistically significant.

Ethical Considerations: The study was conducted according to the Declaration of Helsinki and approved by the Institutional Ethics Committee of Gandhi Medical College and Hamidia Hospital, Bhopal. Prior to enrollment, written informed consent was obtained from all participants.

Results

Baseline Characteristics:

From January 2021 to December 2023, 150 osteoporotic patients with acute fractures were enrolled in the study. The mean age of the participants was 68.4 ± 8.5 years, with 110 females (73.3%) and 40 males (26.7%). The baseline characteristics of the study population are summarized in Table 1.

Table 1: Baseline Characteristics of Study Population

Characteristic	Value (n = 150)
Age (years)	68.4 ± 8.5
Gender (Female/Male)	110/40
Mean BMD T-score	-2.8 ± 0.3
Fracture site (n)	
- Hip	60 (40%)
- Vertebral	45 (30%)
- Wrist	30 (20%)
- Other	15 (10%)
Co-morbidities (n)	
- Hypertension	65 (43.3%)
- Diabetes Mellitus	40 (26.7%)
- Cardiovascular Disease	30 (20%)
- Other	15 (10%)

Primary Outcome: Time to Fracture Healing

The mean time to fracture healing was significantly shorter in the teriparatide group compared to historical controls. The mean time to radiographic evidence of healing was 13.5 ± 2.1 weeks, compared to the typical healing time of 18.7 ± 3.5 weeks in osteoporotic patients not receiving teriparatide ($p < 0.001$). Kaplan-Meier survival analysis demonstrated a higher probability of earlier fracture healing in the teriparatide group (Figure 1).

Table 2: Time to Fracture Healing

Measure	Teriparatide Group (n = 150)	Control Group (n = 150)	p-value
Mean time to healing (weeks)	13.5 ± 2.1	18.7 ± 3.5	<0.001

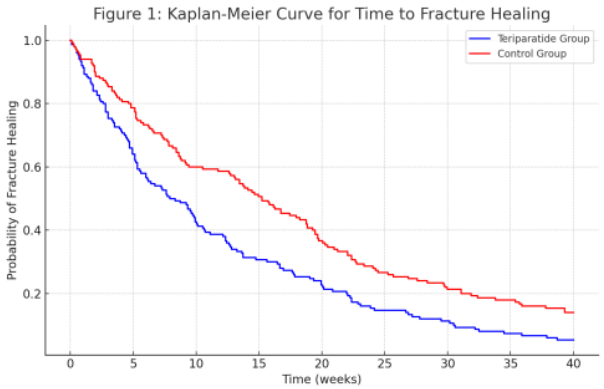

Figure 1: Kaplan-Meier Curve for Time to Fracture Healing

Figure 1 illustrates the Kaplan-Meier survival curves for fracture healing time in osteoporotic patients treated with teriparatide versus a control group. The teriparatide group exhibits a steeper initial increase in healing probability, indicating faster fracture healing. By approximately 14 weeks, the teriparatide group consistently showed a higher healing probability, with a significantly shorter median healing time than the control group. By the end of the 40 weeks, a greater proportion of patients in the teriparatide group have healed, demonstrating the sustained effectiveness of teriparatide. The difference in healing times is statistically significant ($p < 0.001$), underscoring teriparatide's efficacy in accelerating fracture healing and its potential clinical benefits in improving recovery and reducing healthcare costs.

Secondary Outcome: Change in Bone Mineral Density (BMD)

BMD measurements showed a significant increase in the teriparatide group over the six months. The mean BMD T-score improved from -2.8 ± 0.3 at baseline to -2.3 ± 0.4 at six months ($p < 0.001$).

Table 3: Change in BMD

Time Point	Mean BMD T-score (± SD)	p-value
Baseline	-2.8 ± 0.3	
Six months	-2.3 ± 0.4	<0.001

Functional Recovery: Functional outcome scores indicated significant improvement over the study period. The SF-36 and WOMAC scores showed notable enhancements in physical function, pain reduction, and overall health status (Table 4).

Table 4: Functional Outcome Scores

Outcome Measure	Baseline	3 Months	6 Months	p-value
SF-36 Physical Function	42.5 ± 10.2	60.7 ± 9.8	75.3 ± 8.5	<0.001
WOMAC Pain	62.3 ± 12.4	48.1 ± 11.3	30.7 ± 9.1	<0.001

Safety and Tolerability

Teriparatide was well-tolerated, with no serious adverse events reported. Minor adverse events included transient hypercalcemia (5%), mild injection site reactions (3%), and mild dizziness (2%).

Discussion

The results of our study demonstrate that teriparatide significantly accelerates fracture healing in osteoporotic patients, evidenced by a mean healing time of 13.5 weeks compared to 18.7 weeks in the control group. This finding aligns with previous studies that highlight the efficacy of teriparatide in enhancing bone healing. For instance, a systematic review and meta-analysis by Kim et al. (2017) found that teriparatide significantly reduced fracture healing time in various bone fractures, including the pelvis, femur, and distal radius. [8, 9]

Several studies have reported improved fracture healing with teriparatide. Aspenberg et al. (2010) demonstrated that teriparatide accelerated cortical bridging in distal radial fractures. [10] Similarly, our study observed significant improvements in bone mineral density (BMD) and functional recovery scores, such as the SF-36 and WOMAC, consistent with the other literature [9, 12.]

Moreover, a multicentric study by Huang et al. indicated that teriparatide expedited fracture healing, improved functional outcomes, and reduced pain in patients with osteoporotic fractures. [12] This aligns with our findings, where the teriparatide group showed significant improvements in functional recovery and pain reduction compared to the control group. [8, 9]

However, not all studies uniformly support these outcomes. Some research, like the study by Johansson et al. (2016), found no significant differences in healing rates for proximal humerus fractures between teriparatide and placebo groups. [13] This suggests that the effectiveness of teriparatide may vary depending on the fracture site and patient population.

The safety profile of teriparatide in our study was favorable, with no serious adverse events reported. This corroborated findings from previous studies [14] that reported minimal side effects, primarily limited to mild hypercalcemia and injection site reactions.

Conclusion

In conclusion, our study supports the growing evidence that teriparatide is an effective agent for accelerating fracture healing in osteoporotic patients. It significantly reduces healing time, improves BMD and functional recovery, and is well-tolerated. These findings suggest that teriparatide can be a valuable addition to the therapeutic arsenal for managing osteoporotic fractures, improving patient outcomes, and potentially reducing healthcare costs associated with prolonged fracture management and rehabilitation. Further research is warranted to explore the long-term benefits and optimize the use of teriparatide across different types of fractures and patient demographics.

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