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ORIGINAL RESEARCH

Effect of teriperatide in healing of intertrochanteric fractures in elderly persons

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ABSTRACT

Background: The present study aimed to assess the impact of teriparatide therapy on Bone Mineral Density, serum Bone Turnover Markers and Radiographic Union Score for Hip (RUSH) in a surgically stabilized osteoporotic intertrochanteric femur fractures and provide a foundation for future research in this domain. **Methods:** We conducted a prospective study of 40 patients diagnosed with osteoporosis and intertrochanteric fractures, divided into two groups: one managed with proximal femur nailing alone, and the other receiving teriparatide therapy in addition to standard treatment after obtaining informed consent. A comparative analysis was performed between the teriparatide-treated group and the control group receiving calcium supplementation alone. We assessed the influence of teriparatide on fracture union time, bone mineral density (BMD), bone turnover markers (BTMs), and other postoperative complications. Radiographic healing was evaluated using the Radiographic Union Score for Hip (RUSH). **Results:** All patients were followed for a 6-month period, during which complete fracture union was observed. However, the teriparatide group demonstrated a significantly accelerated fracture union, shortening the healing time by approximately 2 weeks compared to the control group. Additionally, the teriparatide group showed greater improvements in BMD and radiographic union scores. **Conclusion:** Our findings suggest that teriparatide therapy may promote faster fracture union and improve BMD outcomes in osteoporotic patients with surgically treated intertrochanteric fractures. Nonetheless, further high-quality randomized controlled trials are warranted to substantiate these preliminary findings.

Keywords: Intertrochanteric fractures, Teriparatide, Osteoporosis, Bone mineral density, Radiographic Union Score for Hip (RUSH)

INTRODUCTION

Osteoporosis is a systemic skeletal condition characterized by a decrease in bone mineral density (BMD) and changes in bone microarchitecture. The National Institutes of Health states that osteoporosis can develop when compromised bone strength increases the risk of fractures [1]. Typical fractures in osteoporotic individuals include spinal (vertebral) fractures, followed by hip fractures, wrist fractures, and fractures at the proximal end of the humerus [2]. Hip fractures are the most severe type of osteoporotic fracture, affecting 1.6 million people annually, with predictions that this number will rise to 4.5-6.3 million by 2050, according to the International Osteoporosis Foundation [3,4].

Hip fractures resulting from osteoporosis are becoming increasingly urgent public health issues. Trochanteric fractures are more common than femoral neck fractures in the elderly population. These fractures lead to discomfort and immobility, resulting in reduced quality of life and high morbidity and mortality rates.

Surgical intervention is recommended for elderly osteoporotic patients with trochanteric hip fractures to ease discomfort and accelerate mobilization as quickly as possible. Bone quality and fracture comminution determine

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the solidity of fracture fixation and the implant's benefits. These patients experience a higher rate of implant failure and reduction loss; thus, a modern approach focuses on a multimodal treatment strategy that addresses both fracture fixation and bone quality.

Teriparatide is used to treat osteoporosis in postmenopausal women and men with primary hypogonadal or idiopathic osteoporosis [5]. The receptors that this PTH analog acts upon are significantly different from those of antiresorptive medications[6]. TPTD promotes bone turnover by maintaining a positive balance between bone production and resorption, while antiresorptive medication reduces bone turnover by preventing resorption [7]. Liu A et al.[8] conveyed that injecting parathyroid hormone- related protein (PTHrP) subcutaneously fundamentally upregulates osteoblastic gene and protein expression, enhances endochondral osteogenesis, and increases osteoclastic bone activity. Recombinant human PTH (1-34) (teriparatide) is administered once daily via the subcutaneous route to accelerate bone remodeling, trabecular connectivity, and cortical bone thickness, promoting new bone formation
[9-12].

BMD alone fails to determine the treatment plan and evaluate osteoclastic bone resorption or the response to specific osteoporosis treatments; hence, it does not entirely represent the risk of osteoporotic fractures. Bone turnover markers have been found useful for predicting bone loss and fracture risk and monitoring osteoporosis treatment response. Bone turnover markers include osteoblast-derived bone formation markers and osteoclast-derived bone resorption markers. Some of the most frequently used bone formation markers are P1NP or procollagen type I N-propeptide, while the most commonly used bone resorption markers are C-telopeptide cross-linked type I collagen (CTx), also known as beta-cross Laps, and N- telopeptide cross-linked type I collagen (NTx), traceable in serum and urine. Biomarker concentrations in blood and urine reflect the body's bone-rebuilding process.

Our study's objective was to evaluate the effect of Teriparatide on fracture healing time in elderly patients with osteoporotic intertrochanteric fractures. We also analyzed improvements in bone mineral density, changes in bone turnover markers, and RUSH scores. We retrospectively registered our prospective randomized trial.

MATERIALS AND METHODS

Study Design

The ethical committee of Government Medical College, Patiala affiliated to Baba Farid University to Health Sciences, approved the study protocol. Written informed consent was obtained from all participants in the prospective randomized controlled study, which was conducted from July 2022 to June 2023 at Government Medical College, Patiala.

Patient Engagement

All patients above 50 years of age who presented to the orthopedic emergency department at Government Medical College, Patiala, between July 2022 and June 2023, with intertrochanteric femur fractures, were considered for inclusion. The study had no influence on the surgical plan or implant selection. Patients diagnosed with osteoporosis, according to a bone mass index (BMD) that was 2.5 SD below the normal peak bone mass [a T score of –2.5 or worse], and scheduled for surgical fixation were enrolled in the study. Routine blood work-ups were performed to rule out metabolic bone disease. The exclusion criteria were age less than 50 years, pathological fractures due to causes other than osteoporosis, patients already receiving teriparatide therapy, bisphosphonates, or hormonal therapy for osteoporosis, and incomplete medical records. The fractures were categorized as stable or unstable according to the AO/OTA classification of the proximal end of the femur fracture. Type 31A1 fractures were stable, whereas types 31A2 and 31A3 fractures were unstable.

Randomization

Patients were randomly assigned to two groups using a computer- generated random sequence. Patients in Group A were administered a daily subcutaneous dose of 20 mcg teriparatide starting from the first postoperative day, while patients in Group B received calcium and vitamin D supplementation post-surgery. Both patients and caregivers received training on the correct use of a pen-type device for drug administration. The administration process was closely monitored during the patient’s hospital stay to ensure accurate technique. After discharge, patient compliance with the treatment plan was assessed on the basis of the empty refills that were returned.

Rehabilitation Program and Follow-up Protocol

The rehabilitation program for patients began the day after surgery. Patients were monitored

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for suture site care after 2 weeks and thereafter at four-week intervals till six months. Partial weight-bearing was initiated at two weeks postoperatively, with progression to full weight-bearing guided by radiographic evidence of fracture site consolidation. A follow-up DEXA scan of the contralateral hip and lumbosacral spine was conducted at the six-month mark to assess bone mineral density.

Radiological assessment

Postoperative radiographic assessments were conducted for all patients on the first day following surgery and subsequently at four-week intervals over a six-month period to evaluate fracture site healing. The degree of radiographic union was quantified using the Radiographic Union Score for Hip (RUSH), a validated scoring system designed to improve interprofessional agreement between orthopedic surgeons and radiologists in the assessment of fracture healing. The obtained data were analyzed using Excel software for Windows, version 17.0, with a statistical power of 80%, an alpha error set at 0.05, an effect size of 4 weeks, and a standard deviation of 0.63 weeks. The minimum required sample size was calculated to be 40 participants. Student's t test was used for continuous variables, whereas Fisher's exact test or the chi-square test was used for categorical variables. Statistical significance was considered at a P value <0.05, highly statistical significance at a P value <0.001, and no statistical significance at a P value >0.05. The observations were depicted in tables and graphs.

RESULTS

Demographics

This prospective clinical study involved 40 patients diagnosed with osteoporotic intertrochanteric femur fractures, all of whom underwent reduction and internal fixation procedures. The patients were randomly assigned into two treatment groups: Group A received daily subcutaneous teriparatide, while Group B was administered calcium supplements. Each group consisted of 20 participants. Given the randomized group allocation, no statistically significant differences were observed between the groups in terms of sex distribution or age at the time of surgery. The bone mineral density (BMD) of the contralateral normal hip as well as serum biochemical markers—including serum calcium (Ca^{2+}), phosphate (PO_4^{3-}), alkaline phosphatase (ALP), procollagen type I N-terminal propeptide (P1NP), and C-terminal telopeptide of type I collagen (B-CTX)—were recorded and analyzed.

The mean age of the study participants was between 65 and 70 years. A higher proportion of female patients was noted, with 25 out of the 40 participants being female, while the remaining 15 were male. Fracture types were classified according to the AO/OTA classification system, with varied distributions across the two groups. The most prevalent fracture type was AO 31A1, observed in 23 patients. In addition, 10 patients had fractures classified as AO 31A2, and 7 patients were classified as AO 31A3.

There were no significant differences in the American Society of Anaesthesiologists (ASA) classification between the two groups, ensuring comparability in baseline health status.

This randomized study aims to provide insights into the efficacy of teriparatide versus calcium supplements in the treatment of osteoporotic fractures, with a focus on key biochemical and clinical outcomes (Table I).

Bone Turnover Markers

At baseline, there were no significant differences in the levels of procollagen type I N-terminal propeptide (P1NP) and C-terminal telopeptide of type I collagen (B-CTX) between the teriparatide and control groups. However, after six months of treatment, notable changes were observed. The teriparatide group exhibited a three-fold increase in serum P1NP levels, while the control group showed no significant change. This difference between the groups was statistically significant ($P < 0.001$) **(Table II) (Figure 1)**. Moreover, changes in serum P1NP levels over six months were positively correlated with increases in lumbar-sacral bone mineral density (BMD).

Similarly, the teriparatide group demonstrated a two-fold increase in the average ß-CTX level compared to baseline, a statistically significant change ($p = 0.001$). In contrast, the control group showed a slight, non- significant decrease in ß-CTX levels ($p = 0.446$) **(Table II) (Figure 2)**. These findings suggest a differential effect of teriparatide on bone turnover markers, particularly with respect to bone formation and resorption, as indicated by the changes in P1NP and ß-CTX levels.

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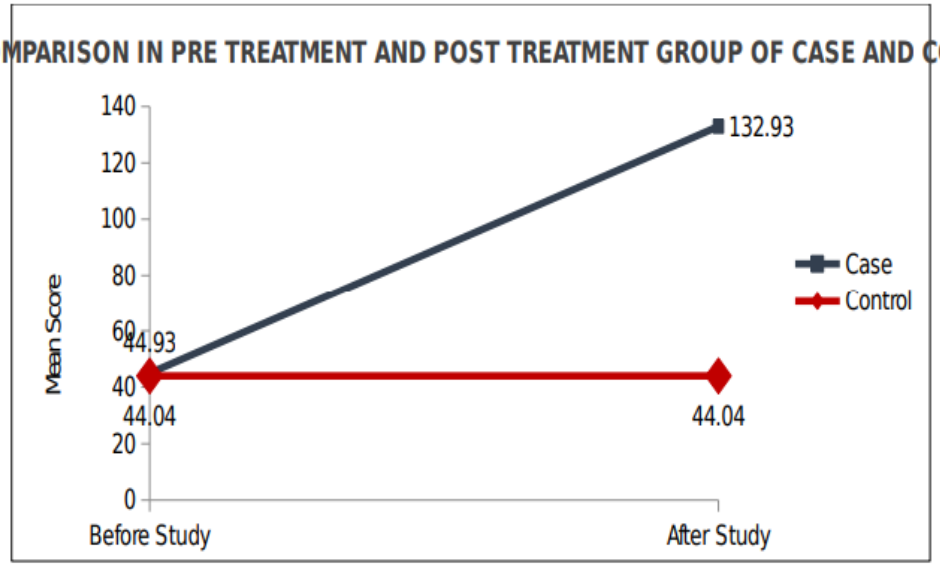

FIGURE 1: P1NP COMPARISON IN PRE-TREATMENT AND POST- TREATMENT GROUP OF CASE AND CONTROL

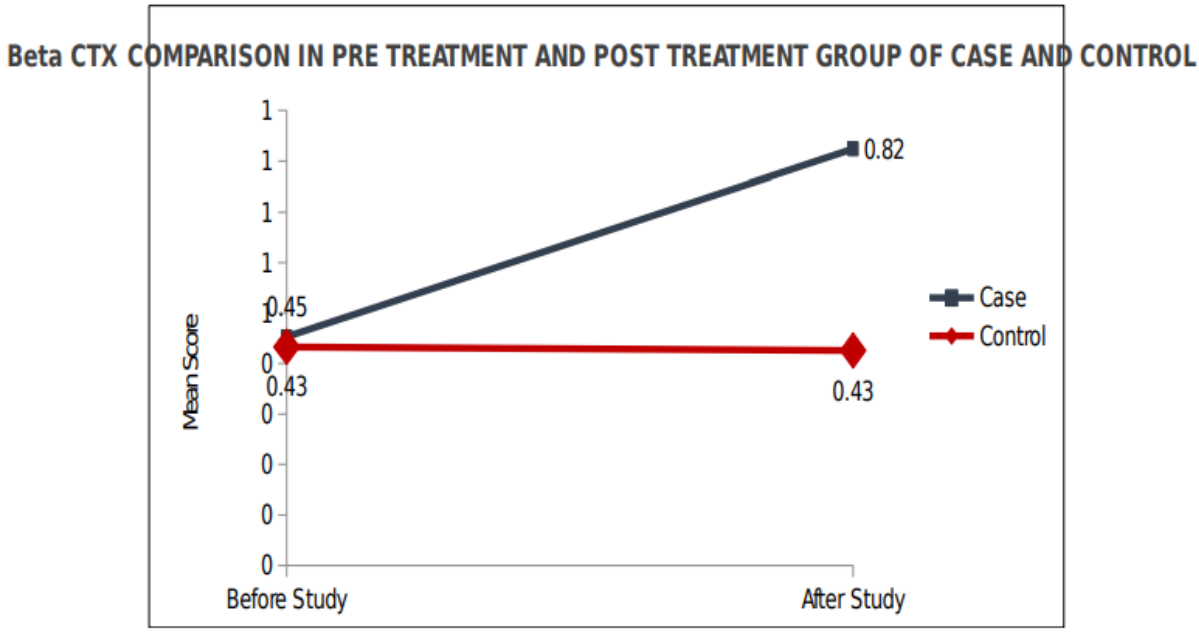

FIGURE 2: Beta CTX COMPARISON IN PRE-TREATMENT AND POST-TREATMENT GROUP OF CASE AND CONTROL

Radiological Outcomes

In this study, all 40 participants successfully achieved fracture union. However, the time to bone union differed significantly between the two groups. Patients in Group A, who received teriparatide treatment, experienced a shorter union time compared to those in Group B, who received standard calcium supplementation. Specifically, 50% of the patients in Group A achieved union within 8 to 12 weeks, whereas it was 15% of the patients in Group B who achieved union at same time. This difference in fracture union time between the groups was statistically significant.

At 12 weeks post-treatment, the mean Radiographic Union Score for Hip (RUSH) in Group A was 28.62 ± 1.64, while in Group B, it was 27.65 ± 1.47, with a statistically significant difference ($p = 0.039$) **(Table III)**. Additionally, patients receiving teriparatide demonstrated faster overall healing compared to those in the control group **(Figure 3)**. These findings indicate that teriparatide therapy may accelerate fracture healing and improve clinical outcomes in patients with osteoporotic fractures.

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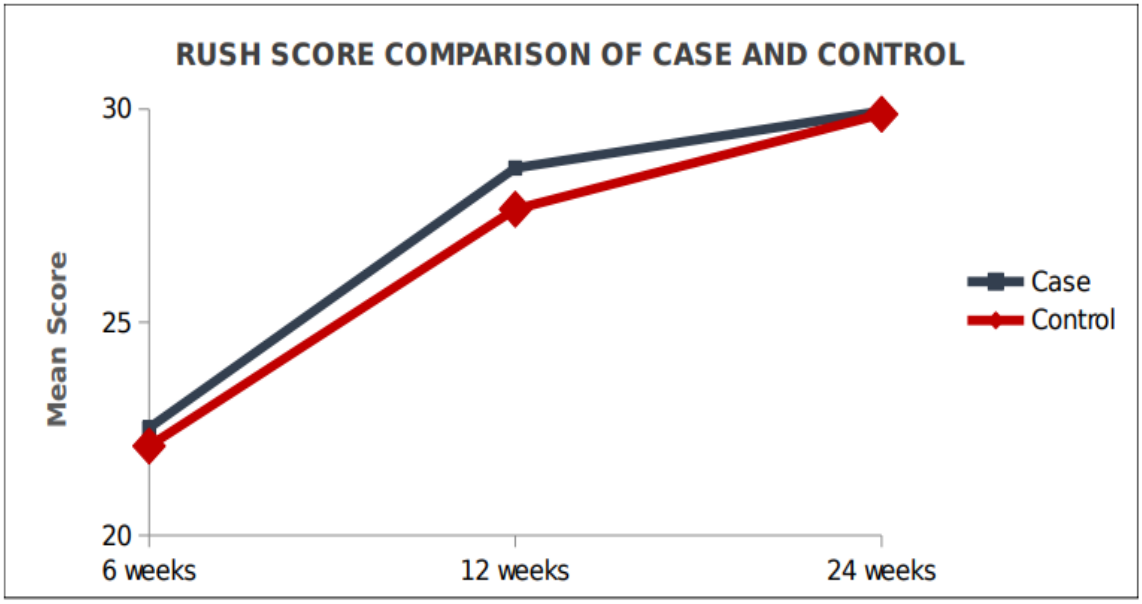

FIGURE 3: RUSH SCORE COMPARISON OF CASE AND CONTROL

Bone mineral density

Bone mineral density (BMD) and T-scores were evaluated using dual- energy X-ray absorptiometry (DEXA) at both baseline and the six-month follow-up. At the initiation of the study, the BMD and T-scores were comparable between the two groups. However, at the six-month follow-up, patients receiving teriparatide therapy (Group A) demonstrated a significant increase in BMD in the unaffected hip compared to the control group (Group B) **(Figure 4).**

By week 24, the T-score of patients in Group A improved from -3.04 ± 0.43 at baseline to -2.83 ± 0.43. In contrast, Group B showed minimal changes, with a T-score of -3.17 ± 0.73 at baseline and -3.15 ± 0.73 at the study's conclusion. These findings indicate that extended teriparatide therapy led to a significant improvement in bone quality, as reflected by the enhanced BMD and T-scores over time **(Figure 5)**.

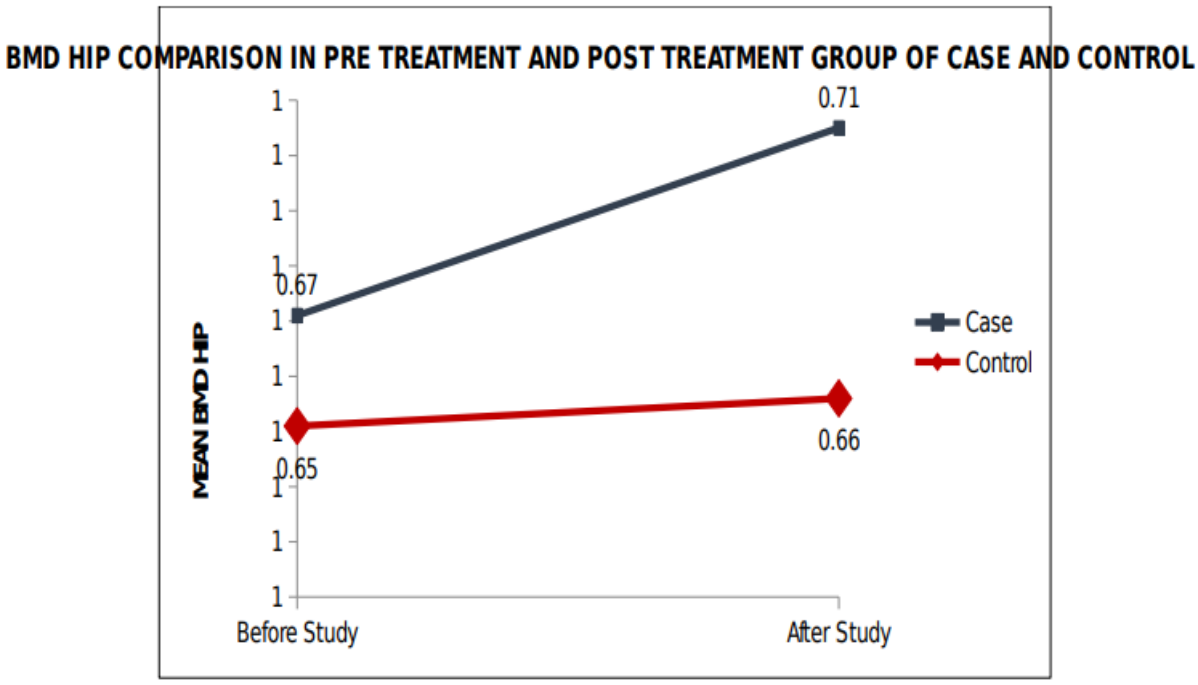

FIGURE 4: BMD HIP COMPARISON OF PRE-TREATMENT AND POST TREATMENT GROUP OF CASE AND CONTROL

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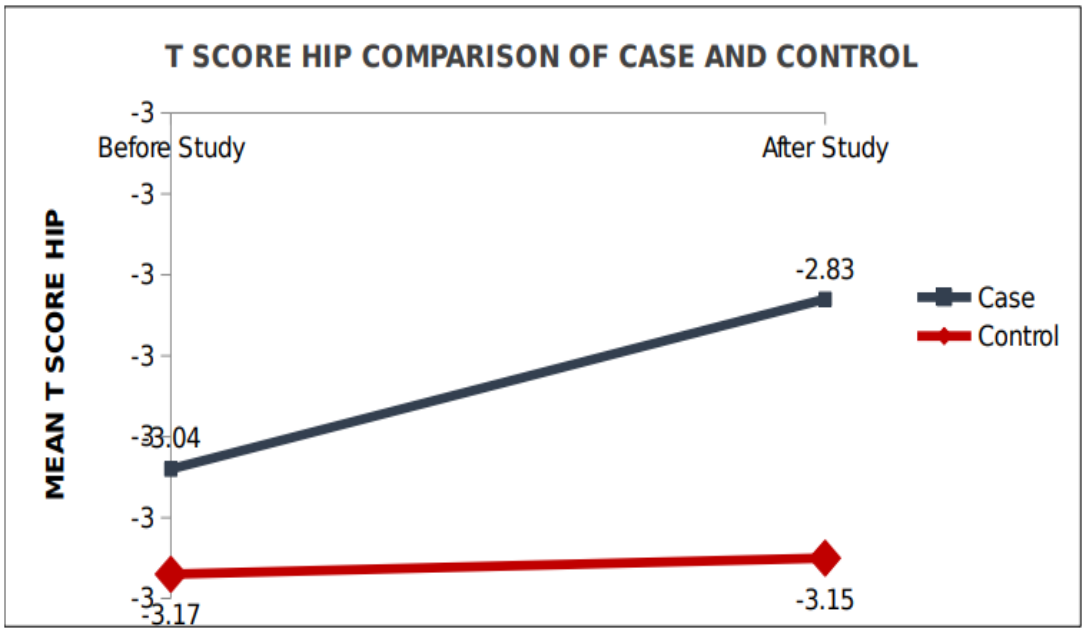

FIGURE 5: T-SCORE HIP COMPARISON OF CASE AND CONTROL

TABLE I: Table depicting demographic, fracture classification, serum profile, BMD of contralateral hip and T score of contralateral hips of patients at start of study			
	GROUP A	**GROUP B**	**P VALUE**
Age (in years)	69.52±8.16	67.95±10.44	0.531
Gender			
Males	9	6	0.742
Females	11	14	
Fracture classification			
AO TYPE 31-A1	12	11	
AO TYPE 31-A2	5	5	
AO TYPE 31-A3	3	4	0.963
Serum Profile			
S. Calcium	9.14 ± 0.63	9.23 ± 0.56	0.506
S. Phosphate	3.76 ± 0.23	3.76 ± 0.23	1.000
S. Alkaline Phosphate	65.51± 5.31	69.23 ± 4.59	0.093
P1NP	44.93 ±6.31	44.04 ± 5.93	0.659
B-CTX	0.453 ±0.056	0.433 ± 0.056	0.541
BMD Hip (g/cm^2)			
Opposite Normal Hip	0.671 ±0.087	0.651 ± 0.087	0.689
T Score Hip			
Opposite Normal Hip	-3.04 ± 0.43	-3.17 ± 0.73	0.682

TABLE II: Comparison of Serum markers, BMD (opposite hip), T score (opposite hip) at the end of study			
VARIABLES	**GROUP A**	**GROUP B**	**P VALUE**
Serum Profile			
S. Calcium	9.61 ± 0.43	9.23 ± 0.56	0.04
S. Phosphate	3.94 ± 0.31	3.72 ± 0.24	0.03
S. Alkaline Phosphate	84.49 ± 4.31	68.48 ± 3.93	0.007
P1NP	132.93 ± 9.54	44.14 ± 5.61	0.001
B-CTX	0.824 ± 0.061	0.426 ±0.056	0.005
BMD (g/cm^2)			
Opposite Normal Hip	0.705 ± 0.066	0.656 ±0.087	0.073
T Score			
Opposite Normal Hip	-2.83 ± 0.43	-3.15 ± 0.73	0.06

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TABLE III: RUSH Score comparison at 6, 12, 24 weeks in both groups			
PARAMETER	**GROUP A**	**GROUP B**	**P VALUE**
RUSH Score			
6 weeks	22.52 ± 2.31	22.1 ± 2.87	0.192
12 weeks	28.62 ± 1.64	27.65 ± 1.47	0.039
24 weeks	29.95 ± 0.22	29.88 ± 0.33	0.045

DISCUSSION

Intertrochanteric femur fractures are among the most common injuries in the elderly population, placing a significant burden on patients, their families, and healthcare systems worldwide [13,14]. Although surgical fixation is the standard treatment for these fractures, the success of such interventions is highly dependent on fracture patterns and critical factors such as intraoperative reduction, stability, and bone quality [15]. Compromised bone quality often jeopardizes the stability of the fixation, even when optimal techniques are employed [16].

Teriparatide therapy has demonstrated significant improvements in bone mineral density (BMD), T-scores, functional outcomes, and overall bone health, while also reducing the incidence of new and subsequent osteoporotic fractures [17–19]. A noteworthy increase in BMD at the femoral neck following teriparatide treatment has been consistently reported, aligning with the findings of Lee S. Y. et al. (2022) [16] and Rana A. et al. (2021) [20]. This improvement in BMD has been accompanied by a corresponding decrease in T-scores, as seen in our study and corroborated by the research of Mishra S. et al. (2022) [21] and Singh A. et al. (2023) [22].

Teriparatide's osteoanabolic properties have been shown to expedite radiological fracture union in several studies. Our study evaluated the efficacy of teriparatide in promoting fracture healing in osteoporotic intertrochanteric femur fractures and found that it significantly accelerated the healing process. In the study by Huang T. W. et al. (2016) [23], the mean union time in the teriparatide group was 12.3 ± 1.3 weeks, compared to 13.6 ± 1.5 weeks in the control group. Singhal S. K. et al. (2018) [24] reported a mean union time of 8–12 weeks in the teriparatide group and 12–16 weeks in the control group. Similar findings were observed in studies by Mishra S. et al. (2022) [21], Singh A. et al. (2023) [22], Aspenberg et al. [25], Peichl et al. [26], and Moon et al. [27].

In addition to the significant improvement in BMD observed in our study, the Radiographic Union Score for Hip (RUSH) was notably higher in the teriparatide group at 12+6 weeks compared to the control group. Teriparatide markedly reduced the time to fracture union and improved radiological outcomes at the six-month follow-up, as opposed to the control group, which only received calcium supplements. The acceleration of fracture healing is especially crucial for elderly patients with unstable pertrochanteric fractures, as it allows for an earlier return to daily activities and a reduction in associated morbidity and mortality. These outcomes are consistent with the findings of Mishra S. et al. (2022) [21], Radhakrishna et al. (2023) [28], and Lou et al. [29].

Our study also confirmed that daily administration of 20 μg of subcutaneous teriparatide led to a significant increase in biochemical markers of bone formation after six months. A strong positive correlation was observed between procollagen type I N-terminal propeptide (P1NP) levels and changes in BMD at the femoral neck and lumbosacral spine. These findings mirror the results of Cohen A. et al. (2020) [30], who reported a three-fold increase in serum P1NP levels in the teriparatide group after six months, with no significant change in the control group ($P < 0.001$). Furthermore, a two-fold increase in serum β-CTx levels was observed in the teriparatide group at the six-month follow-up, further supporting the osteoanabolic effect of teriparatide.

Despite the promising results, this study has several limitations. First, as a pilot study with a relatively small sample size and short follow-up period, it is difficult to draw definitive conclusions regarding secondary outcomes. Additionally, ethical considerations prevented us from implementing a blinded study design, which may have introduced bias despite the objective criteria used for outcome assessment. Finally, due to the radiographic assessments being conducted at four-week intervals, it was not possible to precisely determine the exact time of fracture union.

CONCLUSION

In conclusion, teriparatide therapy demonstrates considerable potential in improving fracture healing and enhancing bone quality in patients with osteoporotic

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intertrochanteric femur fractures. However, larger, long-term studies are necessary to confirm these findings and establish teriparatide as a standard adjunctive treatment in this patient population.

LIST OF ABBREVIATIONS

BMD: Bone mineral density
BTM: bone turnover marker
RUSH: Radiographic Union Score for Hip PTH: Parathyroid hormone
TPTD: Teriperatide
PTHrP: Parathyroid hormone-related protein
P1NP: procollagen type I N-propeptide
CTx: C-telopeptide cross-linked type I collagen
NTx: N-telopeptide cross-linked type I collagen
DEXA: Dual Energy X-ray Absorptiometry
SD: Standard deviation
POD: Postoperative day
Rx: Treatment
IT: Intertrochanteric
S. Ca^{+2}: Serum Calcium
S. Po $^{-3}$: Serum Phosphate Alk. Po_4^{-3}: Alkaline Phosphatase

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