



The Effect of Subcutaneous Teriparatide Treatment on Mobility, Back Pain, and Patient Satisfaction in Patients with Vertebral Osteoporotic Fractures: A Cross-Sectional Study with 36-Month Follow-up

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Abstract

Aim: Although the effectiveness of teriparatide on bone mineral density (BMD), fracture risk, and back pain in severe osteoporosis is known, no comprehensive study has been conducted in the Turkish population regarding its impact on mobility and patient satisfaction. This study aimed to evaluate the effectiveness of teriparatide treatment on mobility, back pain, and patient satisfaction in patients with osteoporotic vertebral fractures, as well as its side effects in midterm follow-up.

Methods: The study was designed as a retrospective, cross-sectional study. Between February 2018 and April 2023, 50 consecutive patients (mean age 69.9±9.0 years; range, 53 to 94 years) who were diagnosed with vertebral fractures due to severe osteoporosis and had received 20 µg/day subcutaneous teriparatide (median, 18 months) were included in the study. The patients were evaluated using BMD measurements, blood tests, radiological imaging, a visual pain score (VAS-pain), mobility assessments [Functional Ambulation Classification (FAC)], and patient satisfaction levels at baseline, 6th, and 18th months.

Results: At 6 and 18 months, a significant decrease in VAS-pain and a significant increase in BMD and FAC were observed ($p<0.001$ for all values). The improvement observed at 6 months continued to increase until the 18th month. 96% of the patients reported being satisfied or very satisfied with the treatment. The treatment of three patients (6%) was discontinued because of side effects in the 15th month of treatment. After the completion of teriparatide treatment, two patients developed clinical vertebral fractures during follow-up. No life-threatening side effects or laboratory abnormalities were observed in any patient.

Conclusion: Teriparatide treatment in severe osteoporotic vertebral fractures with back pain has shown a dramatic reduction in pain and significant improvement in ambulation levels, providing high patient satisfaction with reasonable side effects.

Keywords: Fractures, osteoporosis, teriparatide, back pain, mobility, patient satisfaction

Introduction

Osteoporosis is a chronic, progressive, and most common metabolic bone disease characterized by an imbalance between bone formation and resorption, leading to low bone mass and deterioration of bone microarchitecture, resulting in an increased risk of bone fractures (1). The diagnosis of osteoporosis is based on dual-energy X-ray absorptiometry. The prevalence of osteoporosis increases with age. The rising life expectancy

worldwide has made osteoporosis a significant global health and economic problem (2). In Turkey, it is estimated that the prevalence of osteoporosis is over 20% among individuals aged 50 years. However, the diagnostic rate is reported to be approximately 25%, and it is stated that more than three-quarters of the patients are not receiving pharmacological treatment (3).

The most severe and dreaded consequences of osteoporosis are hip and vertebral fractures. Additionally,



height loss, spinal deformities, including kyphosis and scoliosis, and back pain may occur, leading to restricted mobility. The primary goal of osteoporosis treatment is to prevent new bone fractures by increasing or at least preserving bone mass and quality (1,3). While antiresorptive drugs known as bisphosphonates, which reduce osteoclastic activity, have been widely used for many years, the role of anabolic agents that promote bone formation has recently started to gain prominence in treatment (4). Teriparatide, a recombinant human parathyroid hormone [PTH (1-34)], is the first and only available anabolic agent used for treating postmenopausal osteoporosis, male osteoporosis, and steroid-induced osteoporosis in Turkey (3,5,6). Subcutaneously administered teriparatide, at a daily dose of 20 µg/day, is frequently used in clinical practice for osteoporotic vertebral fractures and is taken daily for 18-24 months (5,6).

In studies evaluating the clinical efficacy of teriparatide, it has been demonstrated that it increases bone density, reduces fracture risk, and improves and decrease back pain and improves quality of life, showing different mechanisms of action from bisphosphonates (6-8). However, the number of significant and comprehensive studies on its impact on mobility and patient satisfaction is limited (8,9). The use of teriparatide in Turkey is restricted because of its narrow indications compared with other antiresorptive agents, high treatment costs, and limited clinical experience related to the follow-up process. In this context, this study aimed to investigate the effects of teriparatide treatment on mobility, back pain, bone mineral density (BMD), and patient satisfaction levels in patients with severe osteoporosis-related painful vertebral fractures, as well as the side effects during midterm follow-up.

Methods

Compliance with Ethical Standards

This study was a cross-sectional study which is a type of observational studies conducted at a tertiary care hospital. Study approval was obtained from the KTO Karatay University Non-Pharmaceutical and Non-Medical Device Research Ethics Committee (date: April 4, 2023, and approval number: 2023/044). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and the principles of the Declaration of Helsinki.

Study Design and Data Collection

Between February 2018 and April 2023, 50 consecutive patients (mean age 69.9±9.0 years; range, 53 to 94 years) who were diagnosed with vertebral

fractures due to severe osteoporosis in the Physical Medicine and Rehabilitation outpatient clinics and had received 20 µg/day subcutaneous teriparatide (Forsteo®; Eli Lilly and Company, Indianapolis, IN, USA) treatment were retrospectively examined by reviewing hospital and physician records. During this period, teriparatide treatment was initiated in 51 patients diagnosed with vertebral fractures and severe osteoporosis. Only one patient discontinued follow-up for unknown reasons, resulting in the completion of the study with 50 patients (Figure 1).

The study included patients who presented with acute back pain and had osteoporotic compression fractures detected on thoracolumbar magnetic resonance imaging (MRI) and/or computed tomography (CT) imaging and had a BMD T-score of -1.50 or lower at the lumbar spine, femoral neck, or total hip. In accordance with the literature, patients with radiologically detected vertebral compression fractures corresponding to at least grade 1 according to the Genant classification and showing a minimum of 20% reduction in vertebral height were considered to have osteoporotic fractures (10). Patients with hypercalcemia, hyperparathyroidism, or Paget's disease of bone, those with hyperthyroidism, chronic kidney and liver failure, malabsorption, atypical femur fracture,

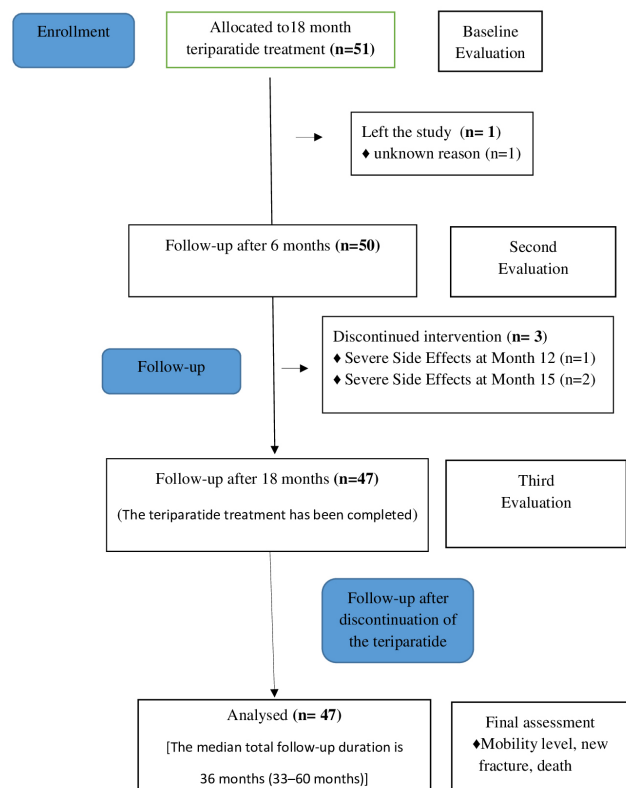


Figure 1. Flow chart of the study

jaw osteonecrosis, direct trauma history in the last 6 months, any other conditions explaining back pain besides osteoporosis, as well as those with unexplained elevation in alkaline phosphatase (ALP) levels, bone malignancies, or metastases, and those who have undergone radiation therapy to the bone, were excluded from the study (6). Additionally, patients who had received zoledronic acid infusion in the last 12 months, denosumab in the last 6 months, or ibandronate intravenous treatment in the last 3 months were also excluded from the study.

Patients' socio-demographic data, such as age, gender, marital status, body mass index, clinical history, medications used for osteoporosis, comorbidities, presence of polypharmacy (≥ 5 medications), and smoking and alcohol use, were recorded. All patients received daily subcutaneous treatment with 20 μg of teriparatide for a duration of 12 to 18 months. In addition, all patients were administered 1000 mg/day of calcium (Ca), and those with vitamin D deficiency (25-hydroxyvitamin D < 20 ng/mL) received additional oral cholecalciferol supplementation. Baseline and follow-up laboratory blood values (hemogram, creatinine, alanine aminotransferase, Ca, P, ALP, albumin, vitamin D, and PTH) and BMD (DXA: lumbar and femoral T-score) measurements taken at the 6th and 18th months were recorded. Fractures detected in radiological imaging (radiographs, MRI, and/or CT) were noted according to the Genant classification (Grade 0-3) (10). Patients' mobility assistive devices and mobility levels, ranging from 1 to 5, were assessed using the Functional Ambulation Classification (FAC) (Level 0, non-ambulation; Level 5, independent, all surfaces) (11). The severity of back pain was recorded using the visual analogue scale (VAS, 0-10) (9). At the end of the treatment, patients' satisfaction levels were determined using the Likert scale, ranging from 1 to 5 (12). Patients' satisfaction levels were assessed using a 5-point Likert scale as follows: 1, "no satisfaction at all"; 2, "low satisfaction"; 3, neutral (neither satisfied nor dissatisfied); 4, "satisfied"; and 5, "very satisfied". Throughout the follow-up period, DXA results, VAS pain scores, biochemical tests, medication-related side effects, patients who underwent vertebroplasty or kyphoplasty, and those with new fractures were recorded.

Statistical Analysis

Statistical analyses were performed using IBM® SPSS Statistics 22 software (Armonk, NY, USA). The frequency and percentage of categorical data are given as n (%); numerical data are given as the median and interquartile range or mean \pm standard deviation. The Shapiro-Wilk test was used to determine whether the data were normally distributed. In the dependent group with repeated measures, Friedman's test was applied. The Wilcoxon signed-rank test was used to calculate the

difference between two non-parametric measurements at different time points. Spearman's rho test was used for correlating non-parametric data that did not have a normal distribution. All statistical analyzes were performed in two directions, at the 5% significance limit and 95% confidence interval.

Results

The demographic and clinical characteristics of the patients are presented in Table 1. Mild symptoms such as

Table 1. Demographic and clinical characteristics of patients		
		N (%) or mean \pm SD
Age, y		69.9 \pm 9.0
Sex	Female Male	40 (80) 10 (20)
Age at menopause, y		39.3 \pm 8.1 40.3 \pm 5.1
BMI (kg/m ²)		28.7 \pm 4.9
Marital status	Married Single or widow	44 (88) 6 (12)
Comorbidity	Yes No	47 (94) 3 (6)
Polypharmacy	Yes No	37 (74) 13 (26)
Smoking	Yes No	7 (14) 43 (86)
Number of old vertebral fracture Number of new vertebral fracture		2.6 \pm 1.2 1.3 \pm 0.9
Genant classification	Grade 1 Grade 2 Grade 3	5 (10) 25 (50) 20 (40)
Use of mobility assistive devices	Wheelchair Walker Cane	5 (10) 14 (28) 31 (62)
FAC level	0 (non-ambulatory) 1 2 3 4 5 (independent, fully)	8 (16) 1 (2) 6 (12) 29 (58) 6 (12) 0
Previous oral bisphosphonate use* Previous denosumab use*		16 (32) 1 (2)
Teriparatide treatment duration, m Total follow-up duration, y Post-teriparatide treatment Denosumab Zoledronic acid Alendronate Ibandronate		17.8 \pm 1.0 3.6 \pm 1.3 49 (98) 38 (76) 7 (14) 3 (6) 1 (2)

*Duration of bisphosphonate use was one to eight years, while denosumab was used for two years.
SD: Standard deviation, BMI: Body mass index, FAC: Functional ambulation classification, m: Months, y: Years

nausea, headache, fatigue, arm-leg pain, and leg cramps were reported in 32% of the patients. Only 3 (6%) patients discontinued the treatment at the 15th month because of severe side effects, including hypotension, dizziness, palpitations, limb pain, and extreme fatigue. There were no deaths during the treatment period, but three patients experienced fatal outcomes after 6 months, 3 years, and 3.5 years following treatment because of cardiac and respiratory failure, which were pre-existing comorbidities. Eleven (22%) patients had undergone one- or two-level vertebroplasty surgery in the neurosurgical clinic within the past month because of acutely painful vertebral osteoporotic compression fractures and were referred to our clinic for postoperative osteoporosis treatment. In contrast, in nine (18%) patients who were newly referred to our Physical Medicine and Rehabilitation clinic and started teriparatide treatment, vertebroplasty surgery was performed because of their severe clinical condition and the intensity of compression and edema observed on MRI. Table 1 presents the demographic and clinical characteristics of the patients.

The mean baseline lumbar vertebral and femoral neck T-scores of the patients were -3.73 ± 0.72 and -2.98 ± 0.82 , respectively (Table 2). After treatment, a significant increase was observed in both T-scores at 6 and 18 months, according to DXA values ($p < 0.001$). Significant improvement in back pain and ambulation levels was detected in patients at 6 and 18 months after treatment ($p < 0.001$ for all values). The changes in clinical evaluation parameters and laboratory values of the patients during the 18-month follow-up are summarized in Table 2.

At the end of teriparatide treatment, patients' satisfaction levels were quite high (Figure 2). The two patients who were neutral in treatment satisfaction were among the three patients who experienced significant side

effects. No patient was dissatisfied with the treatment. Among the patients who completed teriparatide treatment, 38 (76%) switched to denosumab, 7 (14%) to zoledronic acid, 3 to alendronate, and 1 to ibandronate. One patient did not wish to receive maintenance antiresorptive medication.

During teriparatide treatment and after switching to antiresorptive treatment, no patient experienced life-threatening side effects or hypercalcemia. A mild increase in pain was observed in some patients in the months following the completion of teriparatide treatment.

However, two patients who switched to denosumab after completing 18 months of teriparatide treatment developed new clinically painful vertebral fractures. At the end of the follow-up period after teriparatide treatment, all patients were mobilized. No significant correlation was found between patients' pain or treatment satisfaction levels and the number of fractures or Genant stages.

Discussion

Osteoporotic fractures are a major concern that can lead to severe pain, disability, and even death, imposing significant economic burdens on healthcare systems. More than three-quarters of these fractures occur in women, with the highest prevalence observed in the thoracolumbar vertebrae (13). Unfortunately, there is currently no treatment for osteoporosis that exhibits strong efficacy and provides a permanent cure. Therefore, primary and secondary prevention are of great importance. Current evidence suggests that the most potent drugs for high-risk osteoporosis and osteoporotic fractures are teriparatide, denosumab, and romosozumab (14). However, the effectiveness of these drugs also diminishes shortly after discontinuation of treatment, which does not eliminate the need for continuous therapy (14,15).

Table 2. Changes in clinical and laboratory evaluation parameters over the course of treatment

Evaluation parameters	Baseline	At 6 months of treatment	At 18 months of treatment	p-value
VAS-pain (0-10)	8 (7-9)	2 (2-3)	1 (1-1)	<0.001 ^a
Lumbar T-score	-3.7 (-3.2 - -4.0)	-3.2 (-2.6 - -3.5)	-2.6 (-2.1 - -3.0)	<0.001 ^a
Femoral neck T-score	-2.9 (-2.5 - -3.5)	-2.6 (-2.1 - -3.1)	-2.5 (-1.9 - -2.8)	<0.001 ^a
DXA BMD (g/cm ²)				
Posterior-anterior spine	0.621 (0.565-0.666)	0.721 (0.626-0.757)	0.794 (0.736-0.865)	<0.001 ^a
Femoral neck	0.743 (0.673-0.796)	0.790 (0.747-0.829)	0.824 (0.747-0.880)	<0.001 ^a
Ca (mg/dL)	8.8 (8.4-9.2)	8.5 (8.2- 8.8)	8.3 (8.1-8.6)	<0.001 ^a
P (mg/dL)	3.05 (2.8-3.4)	3.1 (2.9-3.4)	3.2 (3.0-3.5)	<0.001 ^a
ALP	80.0 (62.3-103.5)	-	78.0 (65.3-89.0)	0.082 ^b
25-hydroxyvitamin D (ng/mL)	11.0 (4.2-15.0)	23.5 (8.5-33.0)	38.0 (30.0-45.8)	<0.001 ^a
PTH (mg/dL)	68.0 (56.0-85.8)	54.5 (45.0-70.8)	51.0 (39.0-62.0)	<0.001 ^a
FAC level	3 (2-3)	4 (3-4)	4 (4-4)	<0.001 ^a

^aFriedman test; ^bWilcoxon-Signed Ranks test; mean ± SD values for normal distribution and median (interquartile range) for non-normal distribution values were used. BMD: Bone mineral density, DXA: Dual-energy X-ray absorptiometry, SD: Standard deviation, VAS: Visual analogue scale (for back pain), FAC: Functional ambulation classification, Ca: Calcium, P: Phosphorus, ALP: Alkaline phosphatase

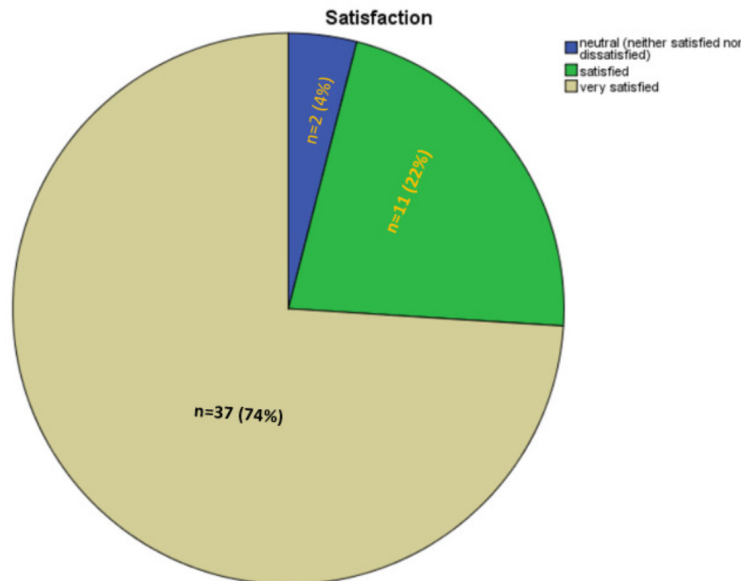


Figure 2. Patient satisfaction levels at the end of teriparatide treatment

Teriparatide exhibits dual effects on bone formation and bone resorption, which are time-dependent. The intermittent use of recombinant teriparatide in osteoporosis treatment directly enhances osteoblast activity and indirectly promotes bone resorption (16). Teriparatide, with its anabolic effect, can rapidly increase bone mass, and in clinical practice, it is more commonly used for post-fracture treatment than for fracture prevention (17). In Turkey, health insurance covers teriparatide treatment only for managing osteoporotic fractures. We investigated the effectiveness and safety of teriparatide in painful, severe osteoporotic vertebral fractures in accordance with the general terms of use. To the best of our knowledge, this study is highly valuable as it represents the most comprehensive reporting of teriparatide treatment results in a single center in Turkey.

Çevikol et al. (18) examined the effects of teriparatide treatment in 15 patients with severe osteoporosis who were unresponsive to bisphosphonate therapy. In their study, a 12-month treatment with teriparatide resulted in an increase in bone density and quality of life, as well as a significant reduction in back pain. In their study, due to financial constraints and side effects, only six of 15 patients could complete the treatment for up to 18 months. In two more recent single-center studies with a similar methodology, one including 13 severe osteoporosis cases and the other including 21 cases, the results of teriparatide were reported (19,20). Teriparatide was found to be effective on DXA, back pain, and quality of life, whereas it was reported to be ineffective on spinal deformity (20). One notable difference in our study compared with these studies is the much longer follow-up

period of patients and the absence of the high treatment discontinuation rate seen in those studies. Indeed, the fact that our study was conducted in a private hospital might have eliminated the financial reasons that could have led to the discontinuation of treatment.

Studies in the literature have reported high adherence to teriparatide treatment with a relatively low occurrence of side effects (21-23). The high cost of the treatment and daily subcutaneous injection administration appear to be the main factors that disrupt treatment adherence. After sequential treatment with teriparatide followed by denosumab or zoledronic acid, an increase in BMD and bone strength occurs (24,25). Additionally, denosumab, with its subcutaneous administration every 6 months, and zoledronic acid, with its annual intravenous usage, are high-compliance anti-resorptive agents (26,27). Therefore, in the present study, the majority of patients received denosumab or zoledronic acid after teriparatide treatment.

Teriparatide is effective in severe osteoporosis, increases both trabecular and cortical bone density, dramatically reduces low back pain, and does not adversely affect blood values (23,28). In this context, the results obtained in our study are compatible with the literature. Surprisingly, there are few and narrow studies in the literature on the effect of teriparatide on ambulation. However, the most significant cause of morbidity and mortality associated with osteoporotic fractures is immobility and related complications. Kim et al. (29), in a systematic review, reported the effect of teriparatide on fracture healing, functional recovery, and mobility. In the present study, the significant improvement in patients' FAC levels throughout the follow-up period demonstrated the concrete functional

contribution of the treatment. In patients receiving teriparatide treatment, the occurrence of approximately 5-10% new vertebral fractures can be expected (6). The absence of any clinical vertebral fractures in any of our patients during the 18-month treatment period in our study may be attributed to the relatively small sample size. The two new vertebral fractures observed in two patients during the follow-up period after the completion of teriparatide treatment agree with the overall risk and expectations.

In recent years, both in Turkey and globally, patient satisfaction has become a crucial aspect of evaluating treatment outcomes. The increasing patient expectations and the rise of patient-centered approaches have led to the recognition of patient satisfaction as a highly prioritized value in the healthcare domain (9,30). In osteoporosis treatment as well, patient satisfaction and preferences emerge as significant factors (31,32). In this context, our study examined patient satisfaction and observed that teriparatide provided a high level of satisfaction among patients. We believe that the effectiveness of relieving acute, severe pain played a critical role in achieving this high level of satisfaction. Additionally, economic considerations and care standards might have also influenced overall satisfaction.

Study Limitations

The most important limitation of our study was its retrospective and single-center design. In addition, the fact that some patients had undergone vertebroplasty may have influenced the results of teriparatide. However, the observation of similar outcomes in studies where vertebroplasty was not performed might support the insignificance of this effect. Despite these limitations, we believe that our study makes a valuable clinical contribution to the literature because of its presentation of long-term follow-up data exceeding the duration of teriparatide treatment and involving a significant number of patients that can be considered high for previous studies. Moreover, being the only study investigating both changes in patients' mobility levels and patient satisfaction adds to the strength and uniqueness of our research.

Conclusion

Teriparatide treatment in severe osteoporotic vertebral fractures with back pain has shown a dramatic reduction in pain and significant improvement in ambulation levels, providing a high level of patient satisfaction. Teriparatide treatment can be considered safe in terms of side effects; however, close clinical and laboratory monitoring of patients is essential. To further substantiate the existing findings, multicenter and prospective studies are required.

Ethics

Ethics Committee Approval: Study approval was obtained from the KTO Karatay University Non-Pharmaceutical and Non-Medical Device Research Ethics Committee (date: April 4, 2023, and approval number: 2023/044).

Informed Consent: Retrospective study.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Concept: R.Y., S.B., Design: R.Y., S.B., Data Collection and/or Processing: R.Y., S.B., Analysis and/or Interpretation: R.Y., S.B., Literature Research: R.Y., Writing: R.Y., S.B.

Conflict of Interest: No conflicts of interest were declared by the authors.

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