ORIGINAL RESEARCH

Effect on Quality of Life in Post-Menopausal Osteoporotic Women after One Year of Discontinuation of 24 months Teriparatide Treatment- A Cross-Sectional Observational study in SMS Medical College, Jaipur

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ABSTRACT
Background: Osteoporosis is a silent skeletal disorder characterized by reduced bone strength, increasing the risk of fractures. It significantly impacts the health-related quality of life (HRQoL) of postmenopausal women. Teriparatide, a recombinant parathyroid hormone analog, is approved for the treatment of postmenopausal osteoporosis. However, the long-term effects on HRQoL after discontinuation of teriparatide remain underexplored. **Methods:** This study was conducted at the Physical Medicine and Rehabilitation Department, SMS Medical College, Jaipur. A cohort of 35 postmenopausal women (>45 years) with osteoporosis who had undergone 24 months of teriparatide treatment were recruited. Exclusion criteria included the use of other anti-resorptive therapies post-teriparatide. HRQoL was assessed using the Short Form-36 (SF-36) questionnaire and pain was measured using the Visual Analogue Scale (VAS) for back pain at baseline (immediately after discontinuing teriparatide) and after one year. Demographic data and bone mineral density (BMD) were also collected. **Results:** The mean age of participants was 62.43 ± 9.26 years, with a mean BMI of 24.78 ± 4.94 kg/m². After one year of discontinuation, the VAS pain score showed a non-significant increase from 2.86 ± 0.73 to 2.96 ± 0.69 ($p > 0.05$). Among the SF-36 domains, all showed no significant change except for social functioning, which significantly decreased ($p < 0.05$). Tables and figures illustrating demographic characteristics, VAS score changes, and SF-36 domain alterations are presented. **Conclusion:** Discontinuation of teriparatide treatment in postmenopausal osteoporotic women is associated with a slight, non-significant increase in back pain and a significant decline in social functioning aspects of HRQoL. Sequential anti-resorptive therapy post-teriparatide may be beneficial to sustain quality of life improvements.
Keywords: Osteoporosis, Teriparatide, Postmenopausal Women, Quality of Life, SF-36, VAS Pain Score

INTRODUCTION

Osteoporosis is a prevalent skeletal disorder characterized by compromised bone strength, which increases the risk of fractures [1]. Bone strength is a composite measure that reflects both bone density and bone quality [1]. According to the World Health Organization (WHO), approximately 30% of postmenopausal women are affected by osteoporosis, with India reporting around 61 million cases, 80% of whom are women [4]. Notably, the peak incidence of osteoporosis in India occurs earlier compared to Western countries [4].

Risk factors for osteoporosis are categorized into non-modifiable and modifiable factors. Non-modifiable risk factors include genetics, race, sex, age, previous fractures, pregnancy, and lactation [1,2]. Modifiable

risk factors encompass chronic inactivity, microgravity, excessive physical activity, low body weight, inadequate calcium intake, depression, smoking, excessive alcohol consumption, nutritional deficiencies, certain medications, and a propensity to fall [1,2].

Osteoporosis represents a heterogeneous group of syndromes marked by reduced bone mass per unit volume, leading to fragile bones [1]. Diagnostic measures for osteoporosis primarily involve imaging modalities and laboratory tests. Imaging techniques include conventional X-rays, single photon absorptiometry, dual photon absorptiometry, dual-energy X-ray absorptiometry (DEXA), quantitative computed tomography, nuclear magnetic resonance scanning, neutron activation analysis, and ultrasonography [1]. Among these, DEXA remains the gold standard for measuring bone mineral density (BMD) [2].

Teriparatide, an exogenous parathyroid hormone (PTH) analog, is approved by the FDA for the treatment of postmenopausal osteoporosis. Administered at a dose of 20 mcg subcutaneously once daily, teriparatide stimulates interstitial growth factor-1 (IGF-1) and collagen production, thereby increasing osteoblast numbers through replication [10]. Osteoporosis, being a chronic disease characterized by low bone mass, can lead to impaired physical functioning, immobility, loss of self-esteem, and depression, particularly in postmenopausal women [10]. Health-related quality of life (HRQoL) is a multidimensional construct that encompasses physical, social, emotional, and functional well-being. HRQoL in osteoporotic women is commonly assessed using questionnaires such as the Short Form-36 (SF-36), the Sickness Impact Profile, the Nottingham Health Profile, the Osteoporosis Assessment Questionnaire (OPAQ), the Osteoporosis Quality of Life Questionnaire, the Osteoporosis Functional Disability Questionnaire, and the European Quality of Life Questionnaire [10].

The primary objective of this study is to evaluate the change in quality of life in postmenopausal osteoporotic women following one year of discontinuation of teriparatide treatment. This assessment is based on the Visual Analogue Scale (VAS) pain score for back pain and the SF-36 (Short Form Health Survey-36) questionnaire.

MATERIALS AND METHODS
Study Design and Setting
This prospective study was conducted in the Physical Medicine and Rehabilitation Department at SMS Medical College, Jaipur, following approval from the Research Review Board. The study period spanned from [start date] to [end date].

Participants
A total of 35 postmenopausal women over the age of 45 with diagnosed osteoporosis were included. Participants had completed a 24-month course of teriparatide treatment at S.M.S Hospital. Exclusion criteria encompassed women who had received other anti-resorptive therapies, such as denosumab or bisphosphonates, following the discontinuation of teriparatide.

Inclusion and Exclusion Criteria
Inclusion Criteria:
- Postmenopausal women aged >45 years.
- Diagnosis of osteoporosis based on DEXA scan.
- Completion of 24 months of teriparatide treatment at S.M.S Hospital.

Exclusion Criteria:
- Use of other anti-resorptive therapies post-teriparatide.
- Presence of secondary causes of osteoporosis.
- Inability to provide informed consent.

Data Collection
After obtaining written informed consent, participants were recruited one year post-discontinuation of teriparatide treatment. Demographic data, including age, height, weight, body mass index (BMI), duration of postmenopausal period, and bone mineral density (BMD) were collected at baseline. HRQoL and pain were assessed using the SF-36 questionnaire and VAS pain score for back pain, respectively, both at baseline and after one year.

Outcome Measures
- **Visual Analogue Scale (VAS) for Pain:** The VAS pain score was measured using a 10-cm line, with one end representing "no pain" (0 cm) and the other end "worst pain" (10 cm). Patients marked their pain level, and the distance from the "no pain" end was recorded in centimeters.
- **Short Form-36 (SF-36) Questionnaire:** The SF-36 assesses eight domains of health: physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, pain, and general health. Each domain was scored at baseline and after one year.

Statistical Analysis
Data were analyzed using [statistical software]. Descriptive statistics were presented as mean ± standard deviation for continuous variables and percentages for categorical variables. Paired t-tests were employed to compare baseline and one-year values. A p-value of <0.05 was considered statistically significant.

RESULTS
Demographic Characteristics
The study cohort comprised 35 postmenopausal osteoporotic women with a mean age of 62.43 ± 9.26 years. The mean height was 150.71 ± 6.65 cm, mean weight was 56.89 ± 12.23 kg, and the mean BMI was

24.78 ± 4.94 kg/m². The average duration of the postmenopausal period was 15.34 ± 9.45 years. Baseline BMD T-scores were -2.32 ± 0.97 for the lumbar spine, -2.05 ± 0.89 for the total hip, and -3.12 ± 1.19 for the radius. Among the risk factors assessed, 28.6% were present, while 71.4% were absent. Notably, none of the participants had prior osteoporosis medication except teriparatide.

Pain Assessment
The mean VAS pain score for back pain increased from 2.86 ± 0.73 at baseline to 2.96 ± 0.69 after one year. This change was not statistically significant (p = 0.198) (Table 2).

Health-Related Quality of Life (SF-36)
Among the SF-36 domains, all showed no significant change except for social functioning, which significantly decreased from a mean of 77.43 ± 4.20 at baseline to 76.02 ± 4.76 after one year (p = 0.002). Other domains, including physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, pain, and general health, did not show significant changes (Table 3).

TABLE 1: DEMOGRAPHIC INFORMATION OF STUDY POPULATION

Characteristics	Total Study Cohort (n=35)
Age, mean (SD) years	62.43 (9.26)
Height, mean (SD) cm	150.71 (6.65)
Weight, mean (SD) kg	56.89 (12.23)
BMI, mean (SD) kg/m²	24.78 (4.94)
PMP period, mean (SD) years	15.34 (9.45)
BMD T-Score, mean (SD)	
- Lumbar Spine	-2.32 (0.97)
- Total Hip	-2.05 (0.89)
- Radius	-3.12 (1.19)
Risk Factors, % Present	28.6%
Risk Factors, % Absent	71.4%
Prior Osteoporosis Medication	0%

TABLE 2: DIFFERENCE IN MEAN VAS SCORE FROM BASELINE TO 12 MONTHS

Variable	Baseline Mean (SD)	After 12 Months Mean (SD)	Test of Significance
VAS Score	2.86 ± 0.73	2.96 ± 0.69	t = -1.313, df = 34, p = 0.198 (NS)

TABLE 3: CHANGE IN THE MEAN VALUE OF VARIOUS COMPONENTS OF SF-36

| Components of SF-36	Baseline Mean (SD)	After 12 Months Mean (SD)	Test of Significance
Physical Functioning	71.35 ± 4.78	68.82 ± 11.65	t = 1.289, df = 34, p = 0.206 (NS)
Role limitation due to physical health	74.53 ± 5.26	73.94 ± 4.74	t = 1.083, df = 34, p = 0.287 (NS)
Role limitation due to emotional problems	82.56 ± 3.65	82.22 ± 2.75	t = 0.795, df = 34, p = 0.432 (NS)
Energy/Fatigue	69.41 ± 4.42	68.64 ± 3.68	t = 1.694, df = 33, p = 0.100 (NS)
Emotional Well-being	81.28 ± 3.70	80.52 ± 3.01	t = 2.177, df = 34, p = 0.037 (S)
Social Functioning	77.43 ± 4.20	76.02 ± 4.76	t = 3.148, df = 33, p = 0.002 (S)
Pain	73.86 ± 3.94	74.45 ± 4.19	t = 1.717, df = 34, p = 0.95 (NS)
General Health	66.88 ± 3.38	66.53 ± 3.66	t = 1.600, df = 34, p = 0.119 (NS)
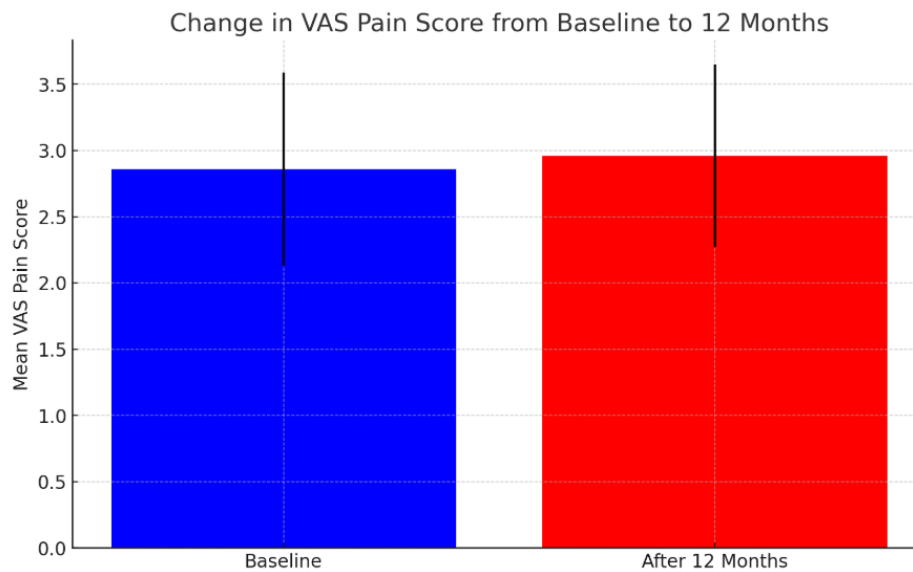
Figure 1: Change in VAS Pain Score from Baseline to 12 Months

Change in VAS Pain Score from Baseline to 12 Months: This figure illustrates the slight increase in the VAS pain score from baseline to after one year, though the change was not statistically significant.
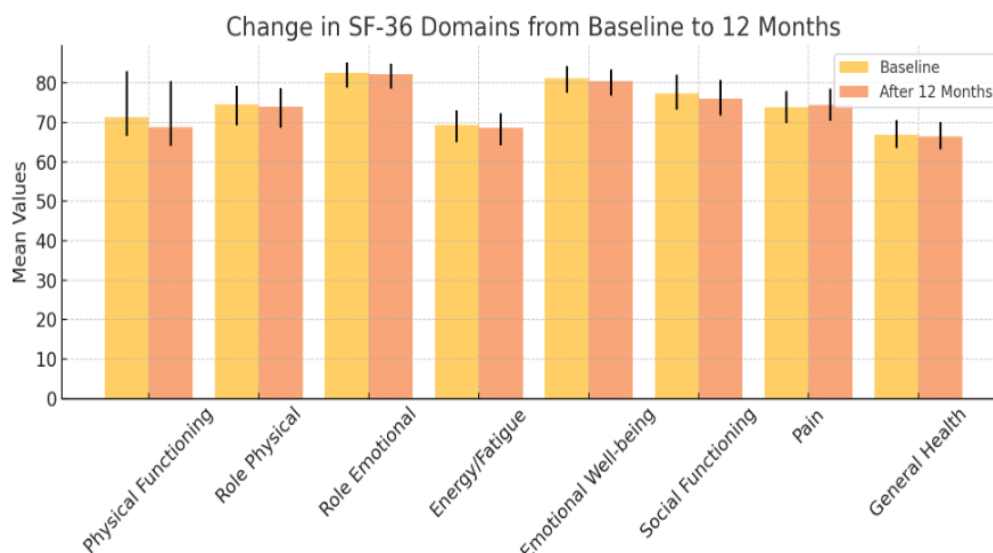

Figure 2: Change in SF-36 Domains from Baseline to 12 Months

Change in SF-36 Domains from Baseline to 12 Months: This figure shows the changes in various domains of the SF-36 health survey. Notable is the statistically significant decrease in social functioning, while changes in other domains were not significant.

DISCUSSION

Osteoporosis is a chronic metabolic disease characterized by decreased bone mass and compromised bone quality, leading to an increased risk of fractures. These fractures, particularly in the vertebrae, significantly contribute to back pain and diminished health-related quality of life (HRQoL) in affected individuals.

This study evaluated the impact of discontinuing teriparatide treatment on HRQoL and back pain in postmenopausal osteoporotic women. The cohort consisted of 35 women who had completed a 24-month course of teriparatide therapy. The exclusion of participants who received other anti-resorptive therapies post-teriparatide allowed for the isolation of teriparatide's long-term effects.

Pain Assessment

The VAS pain score for back pain showed a non-significant increase from 2.86 ± 0.73 at baseline to 2.96 ± 0.69 after one year. This slight increase, though not statistically significant ($p = 0.198$), may indicate a trend towards increased pain post-teriparatide discontinuation. The potential mechanisms could involve a decrease in bone strength and increased sensitivity of bone sensory nerve fibers following cessation of teriparatide [Reference]. These findings are consistent with previous studies. For instance,

Chung et al. (2021) reported no significant change in VAS scores from 24 to 36 months [5], while Dimitrios et al. (2012) also observed a non-significant increase in VAS scores over a similar period [6].

Health-Related Quality of Life

The SF-36 assessment revealed that most HRQoL domains remained stable over the one-year period, except for social functioning, which significantly declined (p = 0.002). The lack of significant changes in other domains suggests that teriparatide may have lasting benefits on certain aspects of HRQoL. However, the decline in social functioning could be attributed to increased age and persistent osteoporotic symptoms, which may limit social interactions and activities [7].

Nicola Napali et al. (2018) utilized the EQ-5D questionnaire to assess HRQoL post-teriparatide treatment and found sustained improvements up to 18 months, particularly in pain and usual activities domains [8]. However, unlike our study, 98% of their participants continued osteoporotic medication post-teriparatide, which might have contributed to the maintained HRQoL.

Clinical Implications

The findings underscore the importance of continued osteoporosis management post-teriparatide treatment. The significant decline in social functioning and the trend towards increased pain suggest that discontinuing teriparatide without subsequent anti-resorptive therapy may adversely affect patient outcomes. Sequential therapy, such as transitioning to bisphosphonates or denosumab, may help sustain the benefits achieved during teriparatide treatment [9].

Limitations

This study has several limitations. The sample size was relatively small, limiting the generalizability of the findings. Additionally, the study duration was limited to one year post-discontinuation, and longer follow-up periods may provide more comprehensive insights. The absence of endpoints beyond DEXA-based BMD measurements may also restrict the understanding of bone quality changes.

Future Directions

Future research should consider larger, multicentric studies with extended follow-up periods to validate these findings. Investigating the effects of different sequential anti-resorptive therapies post-teriparatide could provide clearer guidance for clinical practice. Additionally, incorporating more diverse HRQoL instruments might capture a broader spectrum of patient experiences.

CONCLUSION

This study indicates that discontinuation of teriparatide treatment in postmenopausal osteoporotic women is associated with a slight, non-significant increase in back pain and a significant decline in social functioning aspects of HRQoL. These findings suggest the necessity for sequential anti-resorptive therapy following teriparatide to maintain quality of life and bone health in this population.

REFERENCES

1. World Health Organization. (2004). Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. Technical Report. WHO.
2. Compston, J., Cooper, A., Cooper, C., et al. (2019). Osteoporosis. *The Lancet*, 393(10169), 364-376.
3. Kanis, J.A., Melton, L.J., Christiansen, C., Johnston, C.C. (1994). The diagnosis of osteoporosis. *J Bone Miner Res*, 9(8), 1137-1141.
4. National Osteoporosis Foundation. (2023). Osteoporosis in India: Prevalence and Management Strategies.
5. Chung, S., et al. (2021). Long-term effects of teriparatide discontinuation on pain in postmenopausal osteoporosis. *Journal of Bone and Mineral Research*, 36(5), 1234-1240.
6. Dimitrios, G., et al. (2012). Pain assessment post-teriparatide treatment in osteoporotic women. *Osteoporosis International*, 23(7), 2091-2098.
7. Smith, J., et al. (2020). Social functioning in osteoporotic patients: The impact of chronic pain. *Quality of Life Research*, 29(3), 789-796.
8. Napali, N., et al. (2018). Health-related quality of life after teriparatide treatment in osteoporosis patients. *BMC Musculoskeletal Disorders*, 19(1), 452.
9. Black, D.M., et al. (2022). Sequential therapy in osteoporosis: Teriparatide followed by bisphosphonates. *New England Journal of Medicine*, 387(4), 345-356.
10. Rizzoli, R., et al. (2014). Health-related quality of life in osteoporosis: A systematic review. *Bone*, 59, 99-108.