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Effect of three months course of daily teriparatide injection on osteoporosis in a rural population: a one year follow up study using pDEXA

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Abstract

Osteoporosis continues to represent a significant public-health problem, especially in the rural setting, where access to the availability of sophisticated diagnosis and treatment options limited. Awareness, knowledge and long term consequences, and the importance of calcium supplementation are often inadequate among rural population. Additionally, inadequate finances are also a significant barrier towards patient compliance, which increases disease burden and the risk of fractures. The present study aim is to test the intervention on the effects of a three-month trial of daily intramuscular teriparatide (20µg) administered subcutaneously on the patients with osteoporosis in a rural community. Then treatment outcomes assessed using peripheral dual-energy X-ray absorptiometry (pDEXA; EXA 3000). The study patients with osteoporotic cracks in the spine were included people who experienced spinal fractures. Inj teriparatide intervention was administered three months daily as SC injections. Patients were followed by regular follow-up up to 3 months and pDEXA measurements at a year time. The findings of the study helped to improve the knowledge of teriparatide effectiveness for the treatment of osteoporosis in the rural population and provided evidence to support therapeutic interventions to develop feasible and effective osteoporosis management strategies.

KEYWORDS: Teriparatide; Osteoporosis; Bone Mineral Density; pDEXA.

Introduction

Osteoporosis is a systemic bone disorder, characterized by the decreased bone mass and bone micro-architecture deterioration; it leads to individuals vulnerable to bone fragility, and heightened risk of fractures [1]. Despite osteoporosis affects individual across a wide range of demographic traits, rural populations are often encountered with some unique barriers that may limit access to adequate healthcare and therapeutic services [2]. The occurrence, prevalence rate of osteoporosis is a serious public-health particularly among the geriatric population [3]. Factors such as age, gender, genetic predisposition, lifestyle and nutritional status contribute variations between the incidence and prevalence rates in specific demographic cohorts and geographical locations [4]. As a result, osteoporosis represents a critical issue at the level of the general population globally, owing to morbidity and mortality associated with fragility fractures [5, 6].

The condition is expected to affect approximately 40% of women and 13 – 22% of men who are above the age of 50 years [7]. In Europe, the prevalence predicted was 27.6 million patients in 2010 [8]. In Japan reported between 3.4 to 26.5 % among patients age 40 years and older, with

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estimated prevalence between 6.4- 12.8 million affected between the year 2012 and 2014 [9, 10]. Furthermore, Japanese aged 65 years or older was 23% in 2010, which is estimated to increase to 32% in the year 2030 and 40% in 2050. These demographic trends emphasize the growing burden of osteoporosis in aging societies [11].

The effectiveness of daily teriparatide over three month's administration has been assessed in several clinical studies. Teriparatide therapy resulted a substantial increase in the bone mineral density (BMD) at a multiple skeletal locations- such as lumbar spine, hip, and femoral neck and has also led to the fact that reduction fracture risk. The therapeutic effect of teriparatide is mediated by the stimulation of osteoplastic activity, increase bone formation and countering the balance between bone formation and resorption [12].

Positron emission tomography dual-energy X-ray absorptiometry (pDEXA) allows a non-invasive and reliable method for BMD allowing assessing. Studies using pDEXA have demonstrated significant increase in BMD after a three-month regimen of teriparatide and suggesting the drug has the possibility of being applied as a short-term intervention in osteoporosis [13].

Osteoporotic fracture, such as hip, vertebral and wrist fracture are serve as important indicators of disease burden and are linked with high levels of morbidity, mortality, and eventually, high medical costs. The high prevalence rates of osteoporotic fractures are expected to rise with the ageing of the population and the longer life expectancy, thus necessitating effective preventive and curative strategies [14].

Epidemiological estimates of Osteoporosis prevalence are help in the comprehension of disease burden and planning for appropriate health care modification. Recombinant parathyroid hormone and Teriparatide has merged as a sought-after promising drug in the treatment of osteoporosis. It promotes BMD and reduces the risk of fracture by stimulating the activities of osteoblasts. However, despite of its known effectiveness in several of clinical settings, limited information is present on rural population [15]. Therefore, the research aims to appraise the alterations of a three-month intervention of daily injection of teriparatide on patients with osteoporosis living in a rural environment through the use of BMD changes assessed through the use of pDEXA in the end of one year follow-up period.

Materials and Methods

This prospective cohort study was conducted at Orthopaedics department in the Pravara Institute of Medical Sciences, Loni. Osteoporosis was diagnosed based on reduced bone mineral density (BMD) measured using peripheral dual-energy X-ray absorptiometry (pDEXA). A total 55 Patients diagnosed with osteoporosis spinal fracture of both gender were initially enrolled in current study after the following exclusion criteria i.e, secondary osteoporosis, other metabolic bone disorders, malignancy or chronic renal disease, and prior anabolic osteoporosis therapy. All participants were received standard treatment for acute treatment for fracture, which included analgesics therapy and immobilization with Taylor's brace.

At baseline, demographic data, clinical history, and fracture details were recorded. Base line assessment included parameters of BMD (Forearm & Calcaneus bones) by using pDEXA [16] with EXA 3000 system; biochemical parameters such as serum calcium, phosphorus, and alkaline phosphate and vitamin D3 levels were estimated. Those patients with deficiencies of above mentioned biochemical parameters are received appropriate corrective supplements along with intervention therapy. Especially serum calcium less than 8.5 mg/dl were received calcium supplements, Vit D3 along with Teriparatide therapy. Participants received daily injections teriparatide 20 µg subcutaneously for three months under medical supervision [17].

The primary outcome measure was the changes in BMD, T Score, and Z score of the forearm and calcaneus bones were assessed by pDEXA at baseline and following. Follow-up evaluations were scheduled at three months and one year post initiation of therapy. Of the 55 enrolled patients, 23 patients successfully completed the one year follow up and were included in the final analysis.

Descriptive statistics were used to summarize demographic and clinical characteristics of study population. Continuous variables were expressed as mean ± standard deviation (SD). Comparison of BMD parameters across baseline, three months, and one year was performed using repeated measures analysis / paired t-test where applicable. A p-value <0.05 was considered statistically significant.

Results

Of the 55 enrolled patients, 23 patients successfully completed the one year follow up and were included in the final analysis. Mean age group of patients was 66 ±8.8 years, minimum age was 51 and maximum age was 90 years. Gender wise distribution was 21 females and 2 male patients. The pre and post BMD parameters were mentioned in table 1 & 2 for forearm and Calcaneus bone.

Table 1. Comparison of Forearm BMD Parameters at Baseline, 3 Months, and 1 Year

Parameter (n=23)	Baseline	3 Months	1 Year	P value*
Bone Mineral Density (g/cm²)	0.23 ± 0.05	0.25 ± 0.06	0.26 ± 0.07	0.002
T-score	-4.2 ± 0.67	-3.9 ± 0.74	-3.7 ± 0.88	0.001
Z-score	-3.1 ± 0.77	-2.8 ± 0.80	-2.6 ± 0.83	0.001

A progressive improvement in forearm BMD parameters was observed from baseline to three months and sustained at one year. Mean BMD increased significantly from baseline to three months and further improved at one year. T-score showed significant improvement from baseline to one year ($p < 0.01$), Z-score also demonstrated statistically significant improvement over time ($p < 0.01$). These findings indicate a sustained anabolic effect of teriparatide on cortical bone.

Table 2. Comparison of Calcaneal BMD Parameters at Baseline, 3 Months, and 1 Year

Parameter (n=23)	Baseline	3 Months	1 Year	P value
Bone Mineral Density (g/cm²)	0.23 ± 0.08	0.24 ± 0.08	0.24 ± 0.08	0.15
T-score	-3.5 ± 0.98	-3.4 ± 1.01	-3.3 ± 1.02	0.06
Z-score	-2.7 ± 0.91	-2.5 ± 0.89	-2.4 ± 0.88	0.05

Calcaneal BMD showed modest improvement across follow-up periods. A slight increase in BMD was observed at three months, which was maintained at one year. Improvement in T-score and Z-score was noted; however, these changes did not reach strong statistical significance

When compared across baseline, three months, and one year, teriparatide therapy resulted in: Early improvement in BMD parameterst three months, sustained and greater improvement at one year, particularly at the forearm, and better response at cortical bone sites compared to trabecular bone sites.

Table 3. Comparison of Biochemical Parameters at Baseline, 3 Months, and 1 Year

Parameter (n=23)	Baseline	3 Months	1 Year	P value
Serum Calcium (mg/dL)	8.1 ± 0.6	8.8 ± 0.5	9.1 ± 0.4	0.001
Serum Phosphorus (mg/dL)	3.2 ± 0.5	3.5 ± 0.4	3.6 ± 0.4	0.01
Alkaline Phosphatase (IU/L)	142 ± 32	156 ± 35	148 ± 30	0.04
Vitamin D_3 (ng/mL)	17.4 ± 6.2	26.8 ± 7.1	31.2 ± 6.5	0.001

Discussion

The current study evaluated the effects of a three-month regimen of daily teriparatide injections on bone mineral density (BMD) in patients with osteoporotic spinal fractures residing in a rural population, with outcome measured using peripheral dual-energy X-ray absorptiometry (pDEXA). The findings indicate that short term anabolic treatment with teriparatide causes significant changes in the of bone health parameters, particularly at cortical bone sites, thereby supporting its use in the treatment of osteoporosis even in resource limited rural settings.

Effect of Teriparatide on Forearm BMD: In the present cohort study, a statistical significant increase in forearm BMD was observed followed administration of teriparatide. The mean T -score was improved from -4.19 at baseline to -3.73 at 1-year follow-up ($p=0.66$) , reflecting a marked significant anabolic response. The improvement of cortical bone quality suggestive of an improved bone formation process. Intermittent exposure to parathyroid hormone stimulates osteoblastic proliferation and activity, leading to new bone formation and increased skeletal strength [18].

The findings are consistent with the earlier published studies that have shown the beneficial effects of teriparatide on cortical bone sites such as the radius and forearm. According to Neer et al., postmenopausal women who experienced osteoporosis made significant improvements in BMD and experienced vertebral and non-vertebral fracture reduction after receiving teriparatide therapy [19]. Similarly, Miyauchi et al. showed improvement in peripheral skeletal sites following teriparatide therapy, but not the axial skeleton, as noticed [20]. The specified changes in T -scores and Z -scores observed in the current study suggest a clinically significant decrease in fracture risk among the responders, which is especially advantageous in terms of rural communities where access to surgical and rehabilitative services is limited [21].

Calcaneal BMD Findings: Conversely, the alterations in the calcaneal BMD were modest and did not achieve the standard statistical significance. Although a slight increase BMD results, but the corresponding p -value (0.15) indicates that this change was not significant enough to prove the statistically significant effect within the constraints of the duration and sample size. Similarly, T score and Z score had observed decreases with p-values of 0.06 and 0.05 respectively, merely missed by a very low margin for statically significance.

These results may be justified by variations in bone composition and remodelling dynamics.

Calcaneus comprises a higher proportion of trabecular bone, which may respond variably to short-term anabolic therapy, when measured with peripheral devices. Previous studies suggested that improvements in rich skeletal sites may require longer durations of teriparatide therapy for statistical significance [22] Also, pDEXA measurement values at the calcaneus may be subject to grater technical variability compared to central DXA assessment values.

However, clinically perspective, even modest changes or stabilization in BMD at weight-bearing bones like the calcaneus may be converted to functional gain, especially in elderly patients at high risk of falls and fracture. Therefore, perceived change should not be completely disregarded solely on the basis of statistical cut-offs, especially within real real-life rural clinical scenario.

Overall, results of this study are in line with existing literature support the anabolic nature of teriparatide therapy. Multiple randomized controlled trials and observational studies have established that teriparatide is effective in increasing the BMD and in lowering the risk of fractures at the vertebral and non-vertebral areas 4/5. [23, 24] Furthermore, early increases of BMD during treatment may continue, provided adequate calcium and Vit D3 supplementation.

Nevertheless, the majority of published studies have been conducted in urban or tertiary-care settings and efficacy of teriparatide among rural communities are also scarce. The current study contribute effective evidence by proving that teriparatide is still effective in a rural context, despite challenges such as delayed diagnosis, malnutrition, and restricted access to healthcare. These findings support the feasibility to implement anabolic osteoporosis therapy with in rural health care systems, provided appropriate biochemical correction and structured medical follow-up are implemented.

Conclusion

These results support the use of short-course teriparatide in patients residing in rural areas, there by addressing existing evidence gaps in population characterized by deficiency of vitamin D and insufficient calcium consumption. Sequential antiresorptive therapy post-teriparatide could sustain gains, as one-year follow-up shows promise. pDEXA proves accessible for tracking in low-resource clinics. The peripheral dual-energy X-ray absorptiometry (pDEXA) turns out to be a feasible device to be used to track bone density in low-resource clinics especially in rural areas.

Limitations: The relatively short duration of the three-month dosing phase limits direct comparison with more prolonged studies (6-24 months). The results, observed, may be biased by rural levels of adherence and nutritional confounders. The limited number of samples, together with the low accuracy of peripheral DEXA compared to central DEXA, should be taken into consideration when interpreting the findings

Conflict of interest: None

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