# **Surgical Neurology International**

SNI: Spine, a supplement to Surgical Neurology International

OPEN ACCESS

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# Effects of teriparatide on lung function and pain relief in women with multiple osteoporotic vertebral compression fractures

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Received: 25 March 14 Accepted: 17 April 14 Published: 28 August 14

This article may be cited as:

Chen C, Lin P, Chen Y, Jin Y, Huang AP, Lin S, et al. Effects of teriparatide on lung function and pain relief in women with multiple osteoporotic vertebral compression fractures. Surg Neurol Int 2014;5:S339-42.

Available FREE in open access from: http://www.surgicalneurologyint.com/text.asp?2014/5/8/339/139653

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#### Abstract

**Background:** Osteoporosis is predominantly a condition of the elderly. In this study, we evaluated the effects of teriparatide on lung function and pain relief in elderly women with multiple osteoporotic vertebral compression fractures.

**Methods:** A total of 37 patients who received teriparatide treatment during the period January 2010 to December 2011 were enrolled. Dual-energy X-ray absorptiometry scans were used to measure bone mineral density (BMD) and lung function was measured using a MasterScreen Body Jaeger spirometer. Forced expiratory volume in 1 s (FEV<sub>1</sub>) and forced vital capacity (FVC) values were recorded. The Oswestry Disability Index (ODI) and the Visual Analog Scale (VAS) for pain were used to evaluate physical health and pain intensity, respectively, at baseline and after 6 months of teriparatide treatment.

**Results:** Mean BMD at the lumbar spine increased from 0.716 g/cm<sup>2</sup> at baseline to 0.829 g/cm<sup>2</sup> after 6 months of treatment. In addition, both mean FVC and FEV<sub>1</sub> values after 6 months of treatment were significantly higher than baseline values (99.01% and 100.06% vs. 87.62% and 90.62%, respectively). Teriparatide treatment also resulted in a significant reduction in self-reported pain intensity and a significant improvement in physical health as measured by VAS and ODI scores, respectively.

**Conclusions:** In addition to increasing BMD, teriparatide treatment improves the lung function and results in diminished pain intensity in women with multiple osteoporotic vertebral compression fractures.

Key Words: Lung function, osteoporosis, teriparatide



# INTRODUCTION

Osteoporosis is a debilitating disease characterized by low bone density and structural deterioration of bone tissue. Although it affects both men and women, the prevalence of osteoporosis is significantly higher in women and increases markedly for each decade after age 50 years.<sup>[10]</sup> Postmenopausal women are particularly at a high risk for developing osteoporosis because they are deficient in estrogen, a hormone that reduces bone resorption and increases bone formation.<sup>[12]</sup> Fragility fractures, a common consequence of osteoporosis, especially in women of advanced age, cause substantial pain and severe disability, often leading to reduced quality of life.<sup>[6]</sup>

Teriparatide, a recombinant form of human parathyroid hormone (1-34) that was approved by the US Food and Drug Administration (FDA) for the treatment of osteoporosis in postmenopausal women in 2002, preferentially stimulates the formation of trabecular and cortical bone, increases bone mineral density (BMD), and reduces the risk of incident vertebral fractures in patients with osteoporosis. <sup>[1,3,15]</sup> A recent observational study found that teriparatide treatment also improved health-related quality of life for women with severe postmenopausal osteoporosis.<sup>[9]</sup> The high prevalence of osteoporosis in patients with advanced chronic obstructive pulmonary disease (COPD) is well documented.<sup>[2,8,13,14]</sup> However, few studies have investigated the effectiveness of teriparatide treatment on lung function in elderly women with osteoporosis and even fewer studies have investigated the relationship between lung function and osteoporosis in patients without pulmonary disease. In this study, we evaluated whether teriparatide treatment improves the lung function and diminishes the intensity of back pain in elderly women with multiple osteoporotic vertebral compression fractures.

# **MATERIALS AND METHODS**

#### **Patients**

This prospective study was conducted at the Changhua Christian Hospital, a 1742-bed tertiary care facility in central Taiwan, between January 2010 and December 2011. During the study period, 63 women of advanced age with multiple osteoporotic vertebral compression fractures but without a specific pulmonary diagnosis were selected to receive a 6-month treatment regimen comprising a daily injection of teriparatide (20  $\mu$ g), calcium carbonate (600 mg), and a vitamin D supplement (800 IU). Osteoporosis was diagnosed based on the World Health Organization (WHO) criteria for osteoporosis. Of the 63 patients who received the treatment during the study period, 37 completed the 6-month regimen and were enrolled in the study. All patients provided written informed consent and the study protocol was approved by the hospital's institutional review board.

#### **Clinical features**

### Bone mass density and lung function assessment

Severity of osteoporosis was evaluated in all patients before commencement of treatment. BMD was measured on dual-energy X-ray absorptiometry scans (GE-Lunar Prodigy, Encore v11.2 software; GE-Lunar Corp, Madison, WI, USA) at the time of entry into the study and at the end of the 6-month treatment regimen. Lung function was measured using a MasterScreen Body Jaeger spirometer (CareFusion Ltd, Viasys Healthcare, Hoöchberg, Germany) to evaluate the patient's forced expiratory volume in 1 s (FEV<sub>1</sub>) and forced vital capacity (FVC) in a seated position with a nose clip at the beginning and end of the study.

#### Assessment of back pain intensity

In addition to physical examinations, all patients were required to complete two self-administered questionnaires, the Oswestry Disability index (ODI) and the Visual Analog Scale (VAS), at the beginning and end of the study to measure changes in functional status and pain intensity, respectively. The ODI is a well-validated and vigorous measure of condition-specific outcomes of spinal disorders.<sup>[4]</sup> The ODI questionnaire contains 10 topics and is considered as the gold standard for measuring degree of disability in a patient with low back pain. In this study, the ODI was used to measured patients' physical health. Regarding the measurement of the degree of back pain before and after treatment, we used VAS with a six-point face pain scale to measure the patient's pain intensity. The VAS is a measurement instrument for subjective attitudes and is a reliable and well-validated measure of self-reported pain intensity.

#### **Statistical analyses**

All data were recorded on a computer database. Patients were classified into one of two groups depending on whether they had vertebral compression fractures at either the thoracic or the lumbar spine (group 1) or compression fractures at both the thoracic and lumbar spine (group 2). The Mann-Whitney U-test was used to compare differences in continuous variables between the two groups and the Wilcoxon signed-rank test was used to examine differences in continuous variables before and after treatment. Continuous variables are presented as mean  $\pm$  standard deviation (SD). Categorical variables were compared using the Chi-square test or Fisher's exact test when appropriate. P values lower than 0.05 were considered to be statistically significant. All statistical analyses were performed using SPSS for Windows (Version 17.0; SPSS Inc., Chicago, IL, USA).

#### **RESULTS**

The clinical features of the patients are presented in Table 1. The mean age of the patients was 76.43 (SD = 8.37) years and the mean body mass index (BMI) was 24.01 (SD = 5.12) kg/m<sup>2</sup>. Mean BMD at the lumbar spine increased from 0.716 g/cm<sup>2</sup> at baseline to 0.829 g/cm<sup>2</sup> after 6 months of treatment. There was also an increase in the mean T scores at the end of treatment (from -3.119 to -2.159).

Table 2 lists the lung function and pain scores before and after teriparatide treatment. Both mean FVC and FEV<sub>1</sub> values after 6 months of treatment were significantly higher than baseline values (99.01% and 100.06% vs. 87.62% and 90.62%, respectively) in both groups, although the increase in values was slightly greater in patients with compression fractures at both the thoracic and lumbar spine than in patients with fractures at either the thoracic or the lumbar spine [Figure 1].

In addition, teriparatide treatment also resulted in a significant reduction in self-reported pain intensity and a significant improvement in physical health. For example, the mean VAS scores decreased significantly from 7.14 (SD = 1.65) at baseline to 1.77 (SD = 1.24) after 6 months of treatment and the mean ODI scores increased significantly from 28.89 (SD = 6.43) at baseline to 11.63 (SD = 5.65) at the end of the 6-month treatment regimen.

## DISCUSSION

The consequences of vertebral compression fractures include back pain, reduced pulmonary function, disability, and a diminished quality of life. Teriparatide has been shown to be effective in reducing back pain<sup>[5,11]</sup> and back pain-related functional limitations<sup>[7]</sup> and improving

Table	1:	Clinical	features	of	patients	(mean±SD)
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Variable	N=37
Age (years)	76.43 (8.365)
Height (cm)	148.35 (6.342)
BMI (kg/m²)	24.01 (5.12)
BMD (g/cm², baseline)	0.716 (0.158)
BMD (g/cm <sup>2</sup> , after 6 months of treatment)	0.829 (0.165)
T-score (baseline)	—3.119 (1.265)
T-score (after 6 months of treatment)	-2.159 (1.331)
SD: Standard deviation	

SD: Standard deviation

 Table 2: Lung function and pain scores before and after

 treatment with teriparatide for 6 months

Variable	Baseline	After 6 months of treatment	<i>P</i> value
FVC, % (best/predicted)	87.62 (24.63)	99.01 (24.36)	< 0.001
FEV <sub>1</sub> , % (best/predicted)	90.62 (27.80)	100.06 (29.49)	< 0.001
VAS for pain	7.14 (1.65)	1.77 (1.24)	< 0.001
ODI	28.89 (6.43)	11.63 (5.65)	< 0.001

FVC: Forced vital capacity, FEV1: Forced expiratory volume in 1,VAS:Visual analog scale, ODI: Oswestry disability index

health-related quality of life in postmenopausal women with osteoporotic compression fractures.<sup>[16]</sup> Similarly, our findings show that a 6-month regimen of teriparatide treatment markedly reduced the severity of pain and resulted in significant improvement in physical health.

To the best of our knowledge, this is the first study that evaluated the effectiveness of teriparatide on lung function in postmenopausal women with multiple osteoporotic vertebral compression fractures. We found that after 6 months of a daily injection of teriparatide (20 µg), calcium carbonate (600 mg), and a vitamin D supplement (800 IU), there was a significant positive change in baseline FEV, and FVC values, indicating that teriparatide treatment resulted in improved lung function. We also found that improvement in lung function was most prominent in patients who reported greater reduction in back pain after teriparatide treatment. The increase in muscular strength and reduction in severity of pain explain, at least in part, how teriparatide results in improved lung function. In this study, we took measurements only at two time points (at baseline and after 6 months of treatment). Thus, long-term follow-up is needed to measure changes in lung function after discontinuation of teriparatide.

# CONCLUSIONS

A 6-month regimen of teriparatide treatment improves the lung function and results in diminished pain intensity in women with multiple osteoporotic vertebral compression fractures.



Figure 1: Distribution of patients by bone fracture locations and effects of teriparatide treatment on lung function

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