

## *Analysis of the Clinical Effect of Teriparatide and Zoledronic Acid in Postmenopausal Osteoporosis*

Panxiang Li<sup>1</sup>, Lan Yang<sup>1,\*</sup>, Shike Wu<sup>1</sup>, Xiaoming Wu<sup>1</sup>, Yilei Liu<sup>1</sup>, Meng Cao<sup>2</sup>

<sup>1</sup>Bone Three Families, Affiliated Hospital of Hebei University, Baoding, Hebei, 071000, China

<sup>2</sup>Science and Education, Baoding No.1 Central Hospital, Baoding, Hebei, 071000, China

\*Corresponding author

**Keywords:** Teriparatide; zoledronic acid; postmenopausal osteoporosis; bone mineral density; adverse reactions

**Abstract:** This paper mainly analyzes the clinical effect of teriparatide and zoledronic acid treatment in postmenopausal patients with osteoporosis. 56 postmenopausal osteoporosis patients admitted to our hospital were divided into two groups according to the lottery method. 28 patients treated with teriparatide were included in the observation group, and patients treated with zoledronic acid were included in the control group. The study was conducted from January 2021 to September 2022, and the efficacy of the two groups was analyzed and compared. result display, There was no difference between lumbar spine 1-4 and femoral neck BMD, PINP, ALP,  $\beta$ -CTX level, VAS score, BMD level of femoral neck and the probability of adverse drug reactions ( $P > 0.05$ ); Both groups differ significantly between lumbar 1-4 BMD, femoral neck BMD, PINP, ALP,  $\beta$ -CTX levels, and VAS scores before and after treatment, PINP, ALP,  $\beta$ -CTX levels were higher than before treatment, The control group was lower than before the treatment ( $P < 0.05$ ); The 1-4 BMD levels, PINP, ALP, and  $\beta$ -CTX levels in the treatment observation group were higher than those in the control group ( $P < 0.05$ ); VAS scores at 3 months, 6 months and 1 year compared with the control group ( $P < 0.05$ ). Thus, it is known that teriparatide and zoledronic acid have good therapeutic effects on postmenopausal osteoporosis, which can improve the bone density level of patients, adjust the bone turnover index level, and the medication is relatively safe, but teriparatide is more effective in improving lumbar bone density and reducing pain.

Osteoporosis (OP) belongs to metabolic bone disease, which is mainly reduced bone mass, destruction of bone tissue microstructure, improved bone fragility, and increased risk of bone fracture. Generally, the elderly over 60 years old are a high prevalence group, and it is an important risk factor affecting the health of the middle-aged and elderly[1]. Postmenopausal osteoporosis is a primary disease in women with 5 to 10 years[2]. There are generally no obvious symptoms in the initial stage of the disease. With the aggravation of the disease, symptoms such as fatigue, bone pain and spinal deformation gradually appear, and fracture is easy to occur. Although there is no direct life danger, the disability rate is high, which has a great negative impact on the life of patients[3]. At present, the clinical treatment of this disease mainly adopts drug treatment, with

calcium and vitamin D as the basic treatment, at the same time, drugs to inhibit osteoclast, drugs to inhibit bone absorption, sex hormone supplements can be selected. The specific how to choose should comprehensively consider the patient's condition, the acceptance of treatment and economic status and other factors[4]. In this study, teriparatide and zoledronic acid were treated in the two groups, respectively, and the clinical efficacy of the two groups were analyzed and compared, as follows.

## 1. Data and Methods

### 1.1 General Information

Fifty-six postmenopausal osteoporosis patients admitted to our hospital were divided into two groups and 28 patients / groups according to the lottery method. Among them, patients treated with teriparatide were included in the observation group, and patients treated with zoledronic acid were included in the control group. The study was conducted in the period from January 2021 to September 2022. Differences between the two data groups, ( $P > 0.05$ ). See Table 1.

Table 1: Compares the two groups of general data [n (%)] ( $\pm S$ ) $\bar{x}$

divide into groups	Example number	Age (year)	Menopause duration (years)	BMI(kg/m <sup>2</sup> )
observation group	28	64.18 $\pm$ 2.68	15.39 $\pm$ 2.52	21.29 $\pm$ 2.15
control group	28	65.03 $\pm$ 2.54	15.27 $\pm$ 2.61	21.32 $\pm$ 2.26
$\chi^2/t$		1.218	0.175	0.050
$p$		0.228	0.861	0.959

Inclusion criteria: (1) confirm the clinical diagnosis of osteoporosis in the guidelines for the diagnosis and treatment of primary osteoporosis; (2) natural postmenopausal women; (3) having basic cognitive ability to cooperate with the study investigation; (4) no allergy history and contraindications for study drugs such as teriparatide and zoledronic acid; (5) voluntarily joining the study.

Exclusion criteria: (1) severe disease of the reproductive system; (2) malignancy; (3) severe endocrine and immune system diseases; (4) history of other serious orthopedic diseases; (5) recent use of anti-osteoporosis drugs; and (6) incomplete clinical data.

### 1.2 Methods

Patients in both groups received alfacalcidol and calcium carbonate D3, based on which the drugs were given in groups.

The patients in the control group were treated with zoledronic acid (Sichuan Hairong Pharmaceutical Co., Ltd., Yangtze River Pharmaceutical Group, H20123153, 5ml: 4mg), dissolved 4mg of zoledronic acid into 100ml glucose injection (0.5%), intravenous injection for no less than 15min, and the tube was flushed with 100ml normal saline, and the patients were told to drink more water once per year.

Patients in the observation group were treated with teriparatide (Lilly France, approval number S20110021, 20 mcg: 80ml) by subcutaneous injection in the thigh or abdomen, 20 mcg / d.

Both groups were treated for 1 year.

### 1.3 Observed Indicators

(1) Compare the changes of bone mineral density level between the two groups, and test the bone

mineral density level by double-energy X-ray bone mineral density absorption method.

(2) To compare the changes of bone turnover index level between the two groups, fasting venous blood was collected before and after treatment, and serum isolation was used to detect the levels of PINP (type I amino terminal propeptide), ALP (alkaline phosphatase) and  $\beta$ -CTX ( $\beta$ -linked degradation products) by electrochemiluminescence immunoassay.

(3) Compare the two groups and score according to the VAS pain scale.

(4) Compare the occurrence of adverse drug reactions between the two groups.

## 1.4 Statistical Approach

Apply SPSS.21 The software calculates, including measurement data by ( $\pm S$ ), t-test, and count data by (%) and X2Test, the difference was statistically significant, ( $P < 0.05$ ).

## 2. Results

### 2.1 Comparing the Two Groups, the Changes in Bone Mineral Density Level

The BMD levels of lumbar 1-4 and femoral neck were significantly different before treatment ( $P < 0.05$ ); the difference in BMD was 1-4 before treatment ( $P > 0.05$ ); the BMD 1-4 in the post-treatment group was higher than in the control group ( $P < 0.05$ ). See Table 2.

Table 2: Compares the BMD level changes in the two groups [ $g / cm^2 \bar{x} (\pm S)$ ]

metric	time	Observation group (n=28)	Control group (n=28)	<i>t</i>	<i>p</i>
Lumbar spine 1-4 BMD	pretherapy	0.731 $\pm$ 0.041	0.729 $\pm$ 0.039	0.187	0.852
	post-treatment	0.805 $\pm$ 0.021*	0.764 $\pm$ 0.019*	7.660	0.000
collum femoris BMD	pretherapy	0.652 $\pm$ 0.028	0.658 $\pm$ 0.031	0.760	0.450
	post-treatment	0.689 $\pm$ 0.016*	0.684 $\pm$ 0.013*	1.283	0.204

Note: \*  $P < 0.05$  compared to before treatment.

### 2.2 Comparing the Changes of Bone Turnover Indicators between the Two Groups

PINP, ALP, and  $\beta$ -CTX levels varied significantly before and after treatment, and the observation group was higher after treatment than before treatment; the control group was lower ( $P < 0.05$ ); PINP, ALP, and  $\beta$ -CTX levels were not different ( $P > 0.05$ ); PINP, ALP, and  $\beta$ -CTX levels were higher than the control group. See Table 3.

Table 3: Compared the changes of bone turnover index level between the two groups ( $\pm S$ ) $\bar{x}$

metric	time	Observation group (n=28)	Control group (n=28)	<i>t</i>	<i>p</i>
PINP(ng/L)	pretherapy	29.60 $\pm$ 5.25	28.94 $\pm$ 5.64	0.453	0.652
	post-treatment	151.21 $\pm$ 15.58*	18.72 $\pm$ 6.52*	41.509	0.000
ALP(U/L)	pretherapy	70.67 $\pm$ 6.85	70.24 $\pm$ 6.51	0.240	0.810
	post-treatment	73.58 $\pm$ 5.36*	64.52 $\pm$ 6.10*	5.903	0.000
$\beta$ -CTX (ng/L)	pretherapy	0.25 $\pm$ 0.04	0.24 $\pm$ 0.05	0.826	0.412
	post-treatment	0.68 $\pm$ 0.07*	0.13 $\pm$ 0.05*	33.831	0.000

Note: \*  $P < 0.05$  compared to before treatment.

### 2.3 Comparing the Two Groups of Pain Scores

Pretreatment VAS scores were not significant ( $P > 0.05$ ); 3 months, 6 months and 1 year were lower than before treatment, and the observation group had lower VAS scores at 3 months, 6 months and 1 year than the control group ( $P < 0.05$ ). See Table 4.

Table 4: Compares the pain scores between the two groups [points ( $\pm S$ )] $\bar{x}$

divide into groups	Example number	pretherapy	Treatment was performed for 3 months	Treatment was performed for 6 months	Treatment for 1 year
observation group	28	6.27 $\pm$ 0.65	3.31 $\pm$ 0.46*	2.35 $\pm$ 0.31*	1.42 $\pm$ 0.33*
control group	28	6.21 $\pm$ 0.63	4.13 $\pm$ 0.52*	2.71 $\pm$ 0.47*	2.03 $\pm$ 0.54*
<i>t</i>		0.350	6.249	3.383	5.100
<i>p</i>		0.727	0.000	0.001	0.000

Note: \*  $P < 0.05$  compared to before treatment.

### 2.4 Comparison of Adverse Drug Reactions between the Two Groups

The probability of adverse drug reactions in the two groups was not significant ( $P > 0.05$ ). See Table 5.

Table 5: Compares the occurrence of adverse drug reactions in the two groups [n (%)]

divide into groups	Example number	N and V	Limb / joint pain	give out heat	circumgyration	Total occurrence
observation group	28	2(7.14)	2(7.14)	0(0.00)	1(3.57)	5(17.86)
control group	28	2(7.14)	3(10.71)	3(10.71)	2(7.14)	10(35.71)
$X^2$		-	-	-	-	2.276
<i>p</i>		-	-	-	-	0.131

## 3. Discussion

Postmenopausal osteoporosis is one of the primary osteoporosis. Due to the reduction of estrogen secretion in women's body after menopause, the ability to inhibit osteoclasts decreases, which increases the activity of osteoclasts, accelerates the loss of bone mass, increases the space in the bone, and eventually develops osteoporosis[5-6]. According to the survey, postmenopausal women lose about 1~2% of the bone mass every year, the fastest in the second to three years after menopause, compared with women of the same age, the earlier the menopause, the more likely to appear osteoporosis[7]. The most serious complication of the disease is osteoporotic fracture, which is also an important factor in disability or death and a risk factor threatening the health of postmenopausal women[8]. For this disease, prevention is greater than treatment. At the age of 40, attention is paid to bone density examination, and early detection and early treatment can improve the prognosis[9]. In the present study, Patients in the observation group were treated with teriparatide, Whereas the control group was treated with zoledronic acid, The results of the two groups found that there was no difference between lumbar spine 1-4 and femoral neck BMD, PINP, ALP,  $\beta$ -CTX levels, VAS score, femoral neck BMD level and the probability of adverse drug reactions before treatment ( $P > 0.05$ ); Significant differences between lumbar 1-4 BMD, femoral neck BMD, PINP, ALP, and  $\beta$ -CTX levels, PINP, ALP,  $\beta$ -CTX levels were higher than before

treatment, The control group was lower than before the treatment ( $P < 0.05$ ); The 1-4 BMD levels, PINP, ALP, and  $\beta$ -CTX levels in the treatment observation group were higher than those in the control group ( $P < 0.05$ ); VAS scores were lower at 3 months, 6 months and 1 year than before treatment, And the observation group was lower than the control group ( $P < 0.05$ ). As can be seen from the data, the treatment effect of the two groups was comparable, but teriparatide was more effective in lumbar bone mineral density and pain reduction. The reason is that zoledronic acid is the third generation of bisphosphonate drugs, its main effect is to inhibit osteoclast drugs, accelerate the dissipation of osteoclasts, and then inhibit bone absorption. Its diazimidazole heterocyclic structure can work on the bone surface, reduce the activity of osteoclasts, and finally play the effect of anti-osteoporosis[10]. Teriparatide is a synthetic polypeptide hormone, a 1 – 34 amino acid segment of human PTH PTH that stimulates bone formation and bone resorption and reduces the occurrence of fractures in postmenopausal women[11]. In this study, teriparatide showed a better effect on lumbar BMD and pain reduction, which suggested that the drug may promote bone formation and inhibit bone resorption; pain may be related to the mechanism of action. In addition, the difference between the two groups was small, and no serious adverse reactions occurred, indicating high drug safety.

To sum up, teripeptide andazole leedronic acid for postmenopausal osteoporosis have good treatment effect, can improve the level of bone mineral density, reduce the probability of fracture, and use relatively safe, but teripeptide improve lumbar bone density and reduce pain curative effect is more significant, because of the two drug mechanism is different, specific drugs should be combined with the actual situation of patients.

## References

- [1] Huguang, Liu Zihan, Li Can, et al. Reticular Meta-analysis of the effectiveness and safety of anti-osteoporosis drugs for the prevention of postmenopausal osteoporotic fractures [J]. *Chinese Journal of Osteoporosis*, 2020,26 (11): 1646-1654,1699.
- [2] Ji Yichao, Zhang Linlin, Yang Huilin. Comparative study of the efficacy of teriparatide and zoledronic acid in the treatment of postmenopausal osteoporotic vertebral fractures [J]. *Chinese Journal of Bone and Joint Surgery*, 2021,14 (12): 1011-1015.
- [3] Gao Qian, Chen Yunxia, Dai Jia, et al. The improvement effect of teriparatide plus raloxifene on abnormal bone metabolism in postmenopausal osteoporosis [J]. *Journal of Difficult Diseases*, 2020,19 (3): 257-260,265.
- [4] Yang Tongbao. Clinical studies of bone healing capsules combined with zoledronic acid in the treatment of postmenopausal osteoporosis [J]. *Modern Medicine and Clinical*, 2021, (6): 1236-1240.
- [5] Liu Yanxia. Clinical efficacy and safety of salmonid calcitonin alendronate combined with estrogen tablets in the treatment of postmenopausal osteoporosis [J]. *Shanxi Medical Journal*, 2020,49 (4): 442-444.
- [6] Chen Qingxian, Liu Lixia, Chen Qingqing, et al. Exploring the effect of tonifying kidney, invigorating spleen and strengthening bone combined with zoledronic acid on bone metabolism and prognosis in postmenopausal osteoporosis [J]. *China Journal of Traditional Chinese Medicine*, 2022,40 (2): 112-114.
- [7] Ma Junteng, Qu Sing, Fu Wenbo. Effect of zoledronic acid combined with fairy bone bao capsule on bone metabolic indexes and carotid intimal thickness in elderly postmenopausal patients with osteoporosis [J]. *Medical Theory and Practice*, 2021, 34 (24): 4292-4293.
- [8] Liu Yuzhang, Li Yaohua, Duan Yonggang, et al. Effect of teriparatide combined with alendronate on bone mineral density, bone metabolism, and quality of life in postmenopausal osteoporosis [J]. *Clinical misdiagnosis and mistreatment*, 2021, 34 (9): 35-39.
- [9] Sun Yuefei, Wang Feifei, Zhang Chen, et al. Effect of alendronate and zoledronic acid on bone mineral density and serum bone metabolic markers in postmenopausal osteoporosis [J]. *Maternal and Child Health in China*, 2021,36 (24): 5652-5654.
- [10] Cheng Maoyang, Zeng Huadong, Lu Guohua, et al. Comparative analysis of the effects of zoledronic acid and teriparatide on lumbar interbody fusion in patients with osteoporosis [J]. *Chinese Journal of Bone and Joint Surgery*, 2022, 15 (3): 176-182.
- [11] Li Haiming, Dong Bingzi, Yang Nailong, et al. Clinical comparative study of teriparatide and zoledronic acid in the treatment of postmenopausal low transformation type osteoporosis [J]. *Advances in Clinical Medicine*, 2021,11 (6): 2670-2677.