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Application of Denosumab Injection Combined with Basic Treatment in the Treatment of Elderly Female Patients with Osteoporosis

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Abstract: *Objective:* To explore the application effect of denosumab injection combined with basic treatment in the treatment of elderly female patients with osteoporosis. *Methods:* The elderly female patients with osteoporosis in our hospital from 2024.1 to 2025.7 were included. The total sample size included was 60 cases. They were divided into groups using the ball-touching method and different clinical treatments were carried out. The sample size included in the control group and the observation group were 30 cases. The corresponding treatment plan was basic treatment, denosumab injection combined with basic treatment. *Results:* The total effective rate of treatment in the observation group (96.67%) was higher than that in the control group (73.33%), $P<0.05$. The differences between the groups in electrolyte elements and bone metabolism indicators were small at the time of enrollment. After treatment, the levels of blood phosphorus, blood calcium, and bone alkaline phosphatase in the observation group were higher than those in the control group, and the level of type I collagen carboxyl terminal peptide β special sequence in the observation group was lower than that in the control group, $P<0.05$. The difference in bone density between the groups was small at the time of enrollment. After treatment, the bone density levels of lumbar spine L2-4 and total hip joint in the observation group were higher than those in the control group, $P<0.05$. There was no significant difference in the incidence of adverse reactions between the observation group and the control group (13.33%, 10.00%). The drug safety was equivalent between the groups, $P>0.05$. *Conclusion:* Elderly female patients with osteoporosis who receive denosumab injection combined with basic treatment have significant value in improving patient efficacy, improving electrolyte elements, bone metabolism, and bone density indicators, and are highly safe.

Keywords: osteoporosis; denosumab; efficacy; electrolytes; bone metabolism; bone density

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1. Introduction

Osteoporosis is a common degenerative disease of the skeletal system in elderly women. It is characterized by reduced bone mass and destruction of bone microstructure, leading to increased bone fragility and increased risk of fractures. As the aging of the population accelerates, osteoporosis and the fractures it causes have become a severe public health problem, which not only seriously affects the quality of life of patients, but also places a heavy burden on families and society [1-2]. Although traditional basic treatments such as calcium and vitamin D supplementation can partially improve

bone metabolism, their effect on increasing bone density in patients with severe osteoporosis is limited[3]. In recent years, the nuclear factor κB receptor activator ligand inhibitor denosumab has shown unique advantages in the field of osteoporosis treatment by specifically inhibiting osteoclast activity[4]. This study aims to explore the clinical application value of denosumab injection combined with basic treatment for elderly female patients with osteoporosis, aiming to provide evidence-based basis for clinical optimization of treatment strategies for elderly osteoporosis.

2. Materials and methods

2.1. General information

60 elderly female patients with osteoporosis were included in the period from 2024.1 to 2025.7. The samples were divided into two groups (40 cases/group) using the ball touch method. The group name was the control group [age threshold 60-85 years old, mean (72.70±3.57) years old; BMI range 18.75-28 .13 kg/m², mean (23.56±3.12) kg/m²], observation group [age threshold 60-85 years old, mean (72.25±4.33) years old; BMI range 18.63-28.52 kg/m², mean (23.21±2.98) kg/m²]. The baseline data of the two groups were balanced, P>0.05.

2.1.1. Inclusion criteria

Postmenopausal women aged 60 to 85 who meet the diagnostic criteria for primary osteoporosis; have typical symptoms such as soreness and weakness in the waist and knees, and pain in the lumbar spine; blood calcium and blood phosphorus levels are within the normal range; able to be followed up regularly and complete a treatment cycle of at least 6 months; and sign an informed consent form approved by the ethics committee.

2.1.2. Exclusion criteria

secondary osteoporosis; combined with severe hepatic and renal insufficiency, uncontrolled hypercalcemia, and active peptic ulcer; use of bisphosphonates, parathyroid hormone analogues, or other anti-osteoporosis drugs in the past 3 months; allergic to denosumab or calcium carbonate D3/calcitriol components, history of osteonecrosis of the jaw, and plans to undergo dental surgery.

2.2. Method

The control group received basic treatment, taking calcium carbonate D3 (Helion Pharmaceutical Co., Ltd., packaging specification: 600 mg: 125 IU * 30 tablets, approval number: National Drug Approval No. H10950029) at a dose of 0.5 g/time, once. /d; take calcitriol orally at a dose of 0.25ug/time (Chia Tai Pharmaceutical Co., Ltd., packaging specification: 0.25ug*10 capsules, approval number: National Drug Approval No. H20030491), 2 times/d; continuous treatment for 1 month.

On the basis of the above, the observation team improved the relevant examinations and gave the patient a subcutaneous injection of denosumab (Jiangsu Taikang Biopharmaceutical Co., Ltd., packaging specification: 60 mg prefilled syringe, approval number: National Drug Approval No. S20233111), 60 mg/time. The patient was also encouraged to get out of bed on his own for daily exercise, and no analgesic drugs were given unless necessary.

2.3. Observation indicators

The patient's symptoms are scored based on severe, moderate, mild and asymptomatic symptoms such as soreness and weakness of the waist and knees, difficulty in flexion and extension, and soreness of the waist and spine. The scores are 3 points, 2 points, 1 point, and 0 points respectively. A reduction of at least 85% of the patient's symptoms compared with those before treatment is considered effective; a reduction of 30%-85% is considered effective, and a reduction of less than 30% is considered ineffective.

6 ml of morning venous blood was taken from the patient before and after treatment, and the supernatant was taken

after centrifugation at 2500 r/min for 10 minutes. A fully automatic biochemical analyzer was used to measure blood phosphorus and blood calcium levels before and after treatment; an enzyme-linked immunosorbent assay was used to measure bone alkaline phosphatase levels and type I collagen carboxyl telopeptide β special sequence levels.

Dual-energy X-rays were used to measure the bone density levels of patients' lumbar spine L2-4 and total hip joint before and after treatment.

Count the incidence of adverse reactions.

2.4. Statistical methods

The calculation software used for relevant data is SPSS 25.0. Electrolyte elements, bone metabolism, and bone density indicators are measurement data, and total treatment effectiveness and adverse reactions are counting data. The former is described by ($\bar{x} \pm s$) and t-value test; the latter is described by frequency and composition ratio, and x^2 test. $P<0.05$ is statistically significant.

3. Results

3.1. Compare the treatment effects of the two groups of patients

The total effective rate of treatment in the observation group (96.67%) was higher than that in the control group (73.33%), $P<0.05$. See **Table 1** for details.

Table 1. Comparison of treatment effects between the two groups (n, %)

Group	n	Effective	Valid	Invalid	always efficient
control group	30	14(46.67%)	10(33.33%)	6(20.005)	24(80.00%)
observation group	30	20(66.67%)	9(30.00%)	1(3.33%)	29(96.67%)
x^2	--	--	--	--	4.043
p	--	--	--	--	0.044

3.2. Compare the electrolyte elements and bone metabolism indicators between the two groups before and after treatment

The differences between the groups in electrolyte elements and bone metabolism indicators were small at the time of enrollment. After treatment, the levels of blood phosphorus, blood calcium, and bone alkaline phosphatase in the observation group were higher than those in the control group, and the level of type I collagen carboxyl terminal peptide β special sequence in the observation group was lower than that in the control group, $P<0.05$. See **Table 2** for details.

3.3. Compare the bone density of the two groups before and after treatment

The difference in bone density between the groups was small at the time of enrollment. After treatment, the bone density levels of lumbar spine L_{2-4} and total hip joint in the observation group were higher than those in the control group, $P<0.05$. See **Table 3** for details.

Table 2. Comparison of electrolyte elements and bone metabolism indicators between the two groups ($\overline{x}$ ±s)

Group	n	Blood phosphorus (mmol/L)	Blood calcium (mmol/L)	Bone alkaline phosphatase (U/L)	Type I collagen carboxyl telopeptide β special sequence (ng/ml)
Control group (n=30)	Before treatment	1.25±0.10	2.42±0.23	237.48±11.52	0.65±0.12
	After treatment	1.32±0.09	2.57±0.21	326.04±13.41	0.53±0.07
	t	2.8498	2.6379	27.4376	4.7311
	P	0.0060	0.0107	0.0000	0.0000
Observation group (n=30)	Before treatment	1.24±0.11	2.41±0.21	235.64±12.30	0.66±0.13
	After treatment	1.37±0.08	2.69±0.22	401.53±16.75	0.46±0.08
	t	5.2350	5.0425	43.6970	7.1765
	P	0.0000	0.0000	0.0000	0.0000
$t_{\text{Comparison between groups before treatment}}$		0.3684	0.1759	0.5980	0.3096
$P_{\text{Comparison between groups before treatment}}$		0.7139	0.8610	0.5522	0.7580
$t_{\text{Comparison between groups after treatment}}$		2.2743	2.1611	19.2447	3.6068
$P_{\text{Comparison between groups after treatment}}$		0.0267	0.0348	0.0000	0.0006

Table 3. Comparison of bone density between the two groups ($\overline{x}$ ±s)

Group	n	Lumbar vertebra L2-4 (g/cm)	Total hip joint (g/cm)
Control group (n=30)	Before treatment	0.68±0.08	0.73±0.12
	After treatment	0.76±0.12	0.86±0.17
	t	3.0382	3.4218
	P	0.0036	0.0011
Observation group (n=30)	Before treatment	0.67±0.06	0.72±0.13
	After treatment	0.85±0.13	0.96±0.21
	t	6.8858	5.3224
	P	0.0000	0.0000
$t/P_{\text{Comparison between groups before treatment}}$		0.5477/0.5860	0.3096/0.7580
$t/P_{\text{Comparison between groups after treatment}}$		2.7863/0.0072	2.0272/0.0472

3.4. Compare the occurrence of adverse reactions between the two groups

There was no significant difference in the incidence of adverse reactions between the observation group and the control group (13.33%, 10.00%). The drug safety was equivalent between the groups, P>0.05. See **Table 4** for details

Table 4. Comparison of adverse reactions between the two groups (n, %)

Group	n	Indigestion	Constipation	Dizziness	Disgusting	Overall incidence
Control group	30	1(3.33%)	0(0.00%)	1(3.33%)	1(3.33%)	3(10.00%)
Observation group	30	0(0.00%)	2(6.67%)	1(3.33%)	1(3.33%)	4(13.33%)
x^2	--	--	--	--	--	0.1617
P	--	--	--	--	--	0.6876

4. Discussion

Osteoporosis is a common skeletal system disease in elderly women. It is characterized by bone loss and bone microstructure destruction, leading to increased bone fragility and a significantly higher risk of fracture. With the acceleration of population aging, osteoporosis and related fractures have become an important public health problem, seriously affecting patients' quality of life and increasing socioeconomic burden [5]. Because the early symptoms of the disease are insidious and most patients are diagnosed only after fractures occur, it is crucial to explore efficient and safe treatment options to improve patient prognosis. Traditional basic treatment mainly includes calcium and vitamin D supplementation, which improves bone metabolism by promoting calcium absorption and maintaining bone mineralization [6], this regimen has limited effect on increasing bone density in patients with severe osteoporosis and is difficult to effectively inhibit osteoclast activity. It is particularly ineffective in patients with significant bone loss. It is urgent to combine it with more powerful anti-osteoporosis drugs to improve clinical efficacy [7]. As a ligand inhibitor of nuclear factor κB receptor activator, denosumab blocks the formation, activation and survival of osteoclasts by specifically binding and inhibiting RANKL, thereby significantly reducing bone resorption [8]. Its advantages include strong targeting, long half-life, and can be administered by subcutaneous injection without frequent dose adjustment. Compared with traditional drugs, denosumab can maintain bone density growth more sustainably, and is especially suitable for patients with high fracture risk or poor tolerance to oral drugs [9].

The results showed that the total effective rate of treatment in the observation group (96.67%) was higher than that in the control group (73.33%), P<0.05. The differences between the groups in electrolyte elements and bone metabolism indicators were small at the time of enrollment. After treatment, the levels of blood phosphorus, blood calcium, and bone alkaline phosphatase in the observation group were higher than those in the control group, and the level of type I collagen carboxyl terminal peptide β special sequence in the observation group was lower than that in the control group, P<0.05. The difference in bone density between the groups was small at the time of enrollment. After treatment, the bone density levels of lumbar spine L2-4 and total hip joint in the observation group were higher than those in the control group, P<0.05.There was no significant difference in the incidence of adverse reactions between the observation group and the control group (13.33%, 10.00%). The drug safety was equivalent between the groups, P>0.05. The results of this study showed that the combined denosumab treatment group was significantly better than the basic treatment group alone in terms of efficacy, bone metabolism indicators, and bone density improvement. Reason for analysis: This difference may be due to denosumab's efficient inhibition of osteoclast activity, thereby more effectively delaying bone loss and promoting bone formation. In addition, combined treatment makes up for the lack of basic treatment in regulating bone turnover through synergistic effects [10]. The incidence of adverse reactions in the two groups was similar, indicating that the combination regimen did not increase additional risks, and its safety provided a guarantee for long-term clinical application. Taken together, denosumab combined with basic treatment provides a better treatment option for elderly patients with osteoporosis by interfering with bone metabolism imbalance through multiple targets.

In summary, elderly female patients with osteoporosis receiving denosumab injection combined with basic treatment have significant value in improving patient efficacy, improving electrolyte elements, bone metabolism, and bone density

indicators, and are highly safe.

Disclosure statement

The author declares no conflict of interest.

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