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RESEARCH ARTICLE
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CLINICAL EFFICACY OF ZOLEDRONIC ACID IN THE TREATMENT OF SENILE OSTEOPOROSIS

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Abstract

Background: Patients with osteoporosis are given medication treatments in clinics to boost their bone mineral density and lower their risk of fracture. In the past, senile osteoporosis was often treated with oral calcium D supplementation, which can have therapeutic effects. However, in practical application, the overall effective rate is generally poor

Objective: this study was carried out to explore the Clinical efficacy of Zoledronic Acid in the treatment of Senile Osteoporosis

Materials and methods: This study was conducted at the Orthopaedic department MTI mardan medical complex from May 2022 December 2023. A total of 165 participants diagnosed with osteoporosis were enrolled. All patients diagnosed with osteoporosis and had the ability to endure the testing medication were included in this study and those had fracture other than osteoporosis and had organ failure like liver digestive system disorders thyroid abnormalities or tumors were excluded. Conventional therapy was administered to the control group, and zoledronic acid was added to the treatment regimen for the observation group. The two groups' bone mineral density, level of discomfort, treatment outcome, and adverse events were compared. All the data was analyzed by using SPSS version 23.

Results: The observation group's overall effective rate was 96.67%, which was greater than the control group's 80.00% ($P<0.05$). After six months of therapy, the bone density of the two groups reach to satisfaction in the lumbar vertebrae, femoral neck, and Ward' region, with the observation group showing a greater rise than the control group ($P<0.05$). After six months of therapy, the observation group's pain level was lower than the control groups, and the difference was statistically significant ($P<0.05$). Between the two groups, there was not a significant difference in the incidence of adverse responses ($P>0.05$).

Conclusion: In addition to being highly safe while treating senile osteoporosis, zoledronic acid is beneficial in reducing the severity of bone pain, promoting the growth of bone mass, and relieving clinical symptoms**.**

Key words: Clinical efficacy; Zoledronic Acid; Treatment; Senile Osteoporosis

Introduction

A third of women and a fifth of men over 50 may experience an osteoporotic fracture at some point in their lives, according to the IDF information sheet from 2012.(1) In the Middle East, where the eastern Mediterranean population has been found to have lesser bone density when compared to the western population, osteoporosis constitutes one of the primary causes of diseases and impaired standard of life.[2] "Increase fracture risk as a consequence of reduced bone mass, collagen, and the mineral makeup of the bone" is how the World Health Organization defines osteoporosis.[3] One strength is ascertained using many exact and non-invasive techniques. Bone mineral density (BMD), expressed as grams of mineral per unit projected area of the bone, or bones densitometry, Dual-energy x-ray absorptiometry (DXA), which evaluates the total bone mineral content (BMC) of an expressed region as grams of bone mineral.[4] Apart from the biomarker of bone turnover, beta-car boxy-terminal collagen crosslinks (B-CTX), there is another blood test that has a strong correlation with bone turnover.[5] Despite the significance of this health issue, little research has been done in the Middle East to evaluate the effectiveness of anti-osteoporotic drugs, particularly zoledronic acid. Osteoporosis has a variety of etiologies, such as hormone loss from androgen deprivation and the postmenopausal period, medication usage related to glucocorticoids or other substances, inactivity, and hereditary susceptibility. [6]

Materials and methods

This study was conducted at the Orthopaedic department MTI mardan medical complex from May 2022 December 2023. A total of 165 participants diagnosed with osteoporosis were enrolled. All patients diagnosed with osteoporosis and had the ability to endure the testing medication were included in this study and those had fracture other than osteoporosis and had organ failure like liver digestive system disorders thyroid abnormalities or tumors were excluded .They were distributed into observational group and control group 55 cases in each group. In the observational group the number of males were 29 and female were 26. The age in this group ranged from 64 to 80 (70.46±3.52) years and course of disease was 2-18 ((10.02±6.21) years. Various fractures in observational group were, vertebral 18, carpel 12, femoral 23 and dorsal pedal had 3 fractures. **(Fig 1)** In control group males were 28 and females were 27 whose age was from 65 to 82((71.02±3.91) years and course of disease was 3 to 19 (10.11±6.32) years and the frequency of fracture were, vertebral ,16, carpel 12, femoral 22 and dorsal pedal were 5 cases**. (Fig 2**)The overall data, including gender, age, illness course, and fracture type, did not show a significant difference between both of these groups (P>0.05), indicating that the outcomes were equivalent. Following the ethics committee's clearance, all patients completed the informed consent form and accepted being included in the study.

Treatment methodology

The two groups underwent standard treatment, which consisted of 600 mg of calcium D (Wyeth Pharmaceuticals Company Limited.; the Food and Drug Administration approval number: H10950029) provided once daily. Using Novartis Parma Schwarz AG (SFDA approval number: H201220204), the observation group received intravenous drip treatment once daily using a mixture of 5 mg of zoledronic acid and 100 mL of saline. After taking medicine consistently for six months, the two groups were assessed. The following nursing interventions were made during the course of the therapy. Providing pain treatment is the first nursing measure**.** Patients with osteoporosis frequently have systemic migratory bone pain, varied in intensity. Patients' pain location, intensity, kind, and contributing variables were assessed in order to assist them with removing incentives. When the agony got really bad, they were told to go to bed and calm. When the patient was properly laying down, physical therapy treatments such ultra-short wave or infrared radiation were applied to the painful location. Patients used analgesics as directed by their doctor if the sensation was severe and intolerable, and the medications' healing benefits were noted. The psychological nursing measure was the second one. The condition osteoporosis is long-lasting. The quality of life is impacted by the

pain. Negative feelings including tension, worry, and anxiety are common among patients. As a result, medical personnel tended to the patients in order to establish a line of communication, inform individuals and their loved ones about the professional knowledge about both the prevention and the treatment of osteoporosis, and assist them in comprehending the risk factors associated with osteoporosis and osteoporotic fracture. The drug safety nursing is the third measure. Drug compatibility, physicochemical characteristics, and pharmacological action are all quite intricate. Clinicians and nurses are unable to fully take into account medication stability, compatibility taboos, repeated administration, dose, and dilution concentration due to the effect of several objective elements. Pharmaceutical specialists and technicians thoroughly inspected medical orders before medications were sent out from our hospital via a static dispensing Centre. Patients should get in touch with physicians as soon as any of the aforementioned issues surfaced in order for better drug safety and address issues in a timely manner.

Observation index

Bone mineral density (BMD): measured by an X-ray bone density detector at the lower back, femoral neck, and Wards' region both prior to and six months after therapy. Pain severity (measured using the visual analogue scale (VAS) technique prior to and six months following therapy; 0 represents painless and 10 represents severe pain), the impact of the treatment, and the two groups' adverse effects were noted**.**

Evaluation criteria for efficacy

Clinical signs including discomfort and a noticeable rise in BMD disappeared, indicating that the therapy was notable efficacy. The onset of basic clinical signs and the rise in BMD demonstrated the efficacy of the therapy. Failure to meet the aforementioned criteria or worsening of the illness state suggested that the therapy was not working. Whole effective rate is equal to (number of effective cases plus number of very effective cases) divided by the whole number of cases (i.e., 100%).

Statistical analysis

For this study, SPSS 23.0 was used to analyze all of the data. The outcomes of the measurement were presented as Mean SD, and the inter-group analysis was performed using the t test. Counting data were reported as a percentage, and intergroup comparison was performed using the X 2 test. A significance level of $P<0.05$ meant that the difference was statistically significant.

Results

Following six months of therapy, the observation group's overall effective rate was 92.67%, which was more than the control group's 74.00%; the difference was significant statistically ($P<0.05$).(table 1). Prior to treatment, the two groups' BMD in the lumbar vertebrae, femoral neck, and Wards' area weren't different significantly ($P>0.05$); however, six months later, the BMD in the group receiving treatment was higher than that of the control group in the lumbar vertebrae, femoral neck, and Wards' area, and the differences were statistically significant ($P<0.05$,) table no 2. The degree of pain in both groups was significantly reduced after six months of treatment than that experienced before ($P<0.05$); at six months of treatment, the study group's VAS score was lower than the control group's ($P<0.05$), and the difference was statistically significant ($P<0.05$,) table 3. The observation group experienced a single case of muscular pain, two episodes of vomiting and nausea, and three instances of fever during the treatment period; the rate of adverse events was 11.3%.There were two incidents of fever, two instances of vomiting and nausea, and one case of discomfort in muscle tissue in the control group; the rate of adverse responses was 10.0%. The results of the two groups' comparison revealed that $X\ 2 = 0.125$, $P = 0.723>0.05$. Following symptomatic treatment, the two groups' modest adverse effects were resolved without withdrawal.

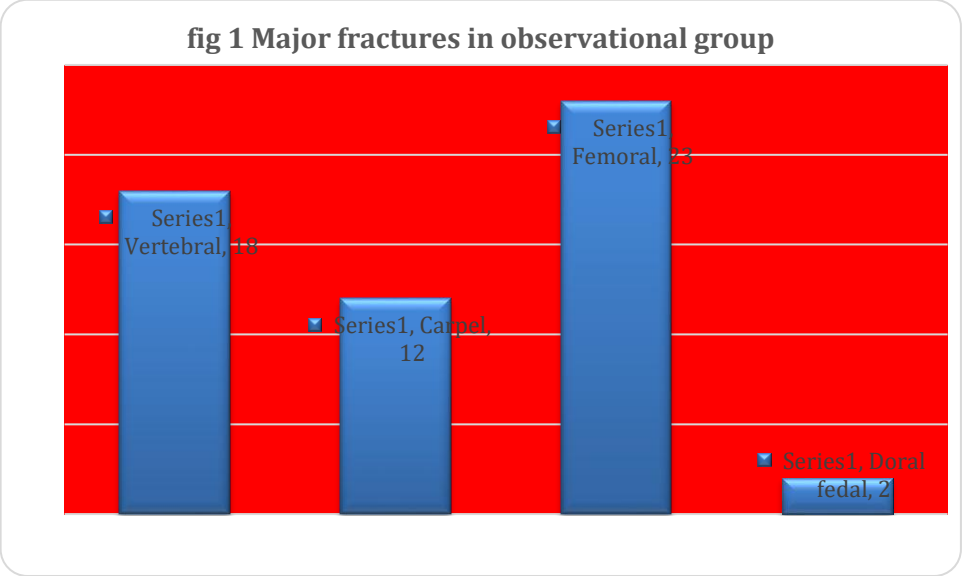

fig 2. fractures in Control group

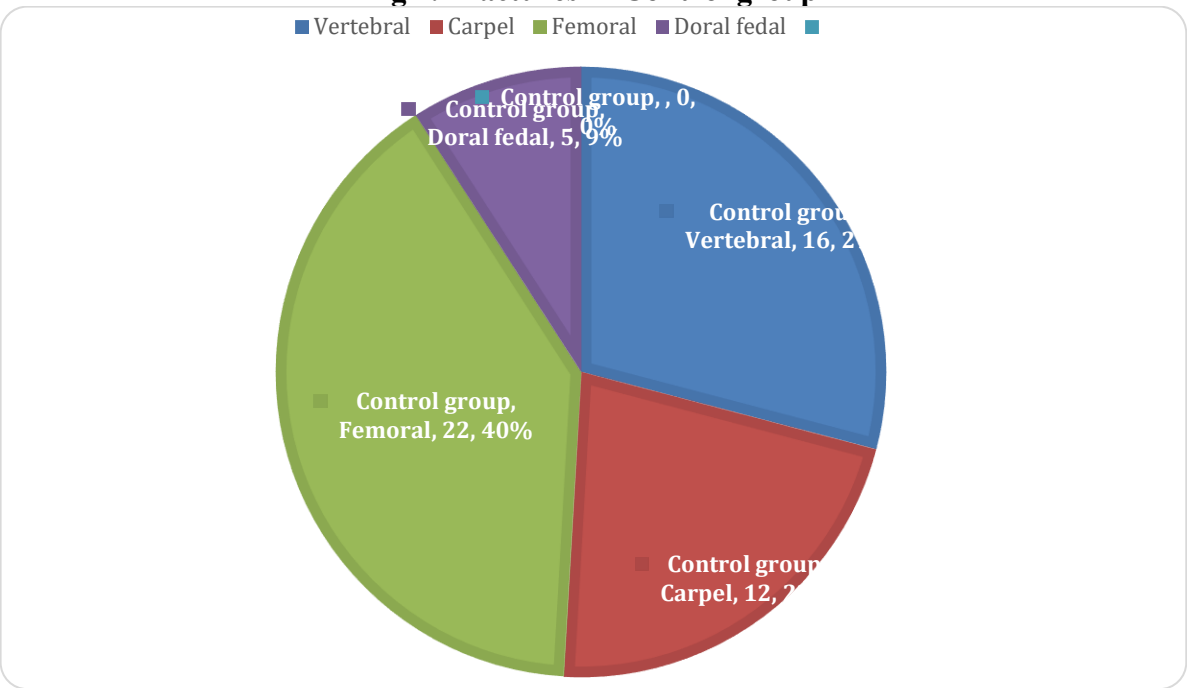

Table 1: Therapeutic effects comparison between two groups n (%)				
Groups	Considerably effective	Effective	None effective	Rate of total effectiveness
Observational	30(54.5%)	22(40%)	4(7.7%)	51(92%)
Control	20(36.36%	25(45.4%)	10(18.1%)	41(74%)
X^2	/	/	/	5.53
P	/	/	/	Less than 0.05

Table-2: BMD comparison of the two groups before and after the therapy (g/cm2)				
Group		Lumber vertebrae	Femoral	Wards' zone
Observational	Before treatment	0.82±0.14	0.61±0.06	0.38±0.08
	After treatment	0.99±0.08	0.69±0.05	0.52±0.04
Control	Before treatment	0.85±0.13	0.62±0.07	0.39±0.06
	After treatment	0.88±0.12	0.64±0.06	0.46±0.07

Table-3: Comparison of pain degree before and after therapy between two groups		
Group	Before therapy	After therapy
Experimental	6.86±1.26	2.10±0.47
Control	6.73±1.23	3.28±0.64
t	0.476	9.562
P	Greater than 0.05	Less than 0.05

Discussion

Patients with osteoporosis are given medication treatments in clinics to boost their bone mineral density and lower their risk of fracture. (11)In the past, senile osteoporosis was often treated with oral calcium D supplementation, which can have therapeutic effects. (12). However, in practical application, the overall effective rate is generally poor, the therapeutic impact is frequently restricted, and the patients' BMD does not considerably improve after therapy. As Guo et al. have noted, using some medications for osteoporosis concurrently is required to increase clinical effectiveness. Studying the curative effects of calcium drugs and particular medications on senile osteoporosis is therefore quite important. (13) Bisphosphates have a significant affinity for bone, absorb quickly, and have positive effects. They have high clinical acceptability and are able to sustain effective concentration in bone for an extended period of time. According to earlier research, bisphosphonates can successfully lower the risk of fracture and are useful in treating osteoporosis. (14, 15). One among the bisphosphonate medications used by the participants in the group that was observed in this study is zoledronic acid. This synthetic substance has the ability to precisely block osteoclast-mediated bone reabsorption, block osteoclast activation, and directly impact osteoclast production and activation to hasten the death of these cells and raise bone mineral density.(16, 17) Furthermore, the trial included intravenous delivery, which significantly reduced the risk of gastrointestinal tract adverse reactions from oral bisphosphonate therapy and increased patient compliance. The study's findings indicate that zoledronic acid may be able to improve bone calcium and osteolysis conditions within a certain range, better inhibit bone reabsorption, relieve pain from vertebral deformity caused by osteoporosis, and lower the risk of fracture in patients with these conditions when compared to conventional treatment. These findings are consistent with those of Sun et al. (18). The most frequent side effect of zoledronic acid is fever. Five cases of fever symptoms, of the study, were seen, and the maximum recorded temperature of the body was 39 o C, which was in line with reports from other nations. (19,, 20) After using antipyretic analgesics, the fever subsided. In addition, three days later, the tightness in two instances' muscles and the flu-like symptoms in one case subsided.

Conclusion

Zoledronic acid has a definite clinical effect in the treatment of senile osteoporosis. It can effectively alleviate pain and related clinical symptoms, and the incidence of adverse reactions is low. It is worthy of clinical application. However, due to the limited case number and time, the long-term efficacy of zoledronic acid in elderly patients with osteoporosis remains to be further explored

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