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Bisphosphonates as Treatment and Prevention of Risk of Fractures in Postmenopausal Osteoporosis

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ABSTRACT:Background: Incidence of osteoporosis-related fractures increases with age, so aim of pharmacological therapy in postmenopausal osteoporosis is to reduce the frequency of fractures.**Materials and Methods:** Study of 100 female patients divided into two groups. Group A – Alendronate once weekly plus Calcium amd Vitamin D daily and Group B – Calcium and Vitamin D daily. Followed at 3, 6 and 12 months to assess BMD scores and radiological assessment of vertebral and non-vertebral fractures.**Results:** Patients receiving bisphosphonates showed excellent BMD scores at the end of 12 months as compared to group B. More than three fourth of group A patient had improvement in BMD score. Group A patients showed significant decrease in number of vertebral and non-vertebral fractures as compared to group B.**Conclusion:**Bisphosphonate therapy can be used to increase bone mineral density and decrease the risk of future fractures.

Keywords: BMD, bisphosphonates, fracture

I. INTRODUCTION

Although osteoporosis is one of the most serious conditions in older women, it often is not taken seriously enough by menopausal women. With proper therapy, osteopenia is a largely preventable sequelae of menopause. Osteoporosis is defined as a bone mineral density (BMD) equal to or greater than 2.5 standard deviations (SDs) below the peak bone mass, or T score. Osteopenia is defined as a BMD that is 1.0-2.49 SDs below the T score [1].

Osteoporosis is characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased susceptibility to fractures. Bone loss is the result of an imbalance in bone turnover, with bone resorption occurring at a faster rate than new bone formation. The resulting reduction in bone mass and accompanying damage to bone microarchitecture increases the risk of fracture. The spine (vertebral fractures), hips, and wrists (nonvertebral fractures) are the most common sites of osteoporosis-related bone fractures (i.e., fractures that are out of proportion to the level of external trauma), although osteoporosis-related fractures can occur at almost any skeletal bone site [2].Fractures of the hip and spine are the most common that occur asa result of osteoporosis and they can lead to reduced quality of life, dependent living situations,and increased risk of death, in addition to psychological problems such as lowered self-esteem [3].

The incidence of osteoporosis-related fractures increases with age, so as the population ages, the number of osteoporosis-related fractures is projected to increase dramatically [4].Overall, 40% of women with postmenopausal osteoporosis will suffer one or more fragility fractures during their remaining lifetime [5].

The aim of pharmacological intervention in postmenopausal osteoporosis is to reduce the frequency of fractures and, consequently, reduce the related burden on patients and healthcare services and improve patients' quality of life. The leading treatments for postmenopausal osteoporosis are the nitrogen-containing bisphosphonates. These antiresorptive agents reduce postmenopausal bone loss by inhibiting osteoclast activity and reducing the rate of bone resorption. This shifts the balance in favor of bone formation, so that bone mass is increased [6].

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II. MATERIAL AND METHOD

Study was conducted on patients coming to outdoor in the department of Orthopaedics and Gynaecology during the period of December 2018 to December 2019. Total of 200female patients were selected with age group of 55 to 70 years with BMD T-score of -2.5 standard deviation (SD) or less at femoral neck, with or without evidence of existing vertebral fracture. Patients with existing fracture in the lower limb and past history of use of corticosteroids, parathyroid hormone, or any form of hormone replacement therapy taken were not included in this study.

Selected patients in this study were mainly divided in two groups who were followed up at regular intervals of 3, 6and 12 months. A complete history of all the patients was obtained along with routine blood investigations, X-rays (lumbar spine and hip) and BMD scores.

Group A: Alendronate (Oral – tablet 70mg) to be taken once every week plus Calcium + Vitamin D (oral – 1250 mg +250 IU) daily

Group B: Calcium + Vitamin D (oral – 1250 mg +250 IU) daily

Patients were instructed to take Alendronate in the morning, after an overnight fast, in an upright position and with a full glass of plain water. Patients were to remain fasting and in an upright position for at least 30 minutes after taking Alendronate. No special instructions were given for Calcium + Vitamin D tablet but to be taken on daily basis.

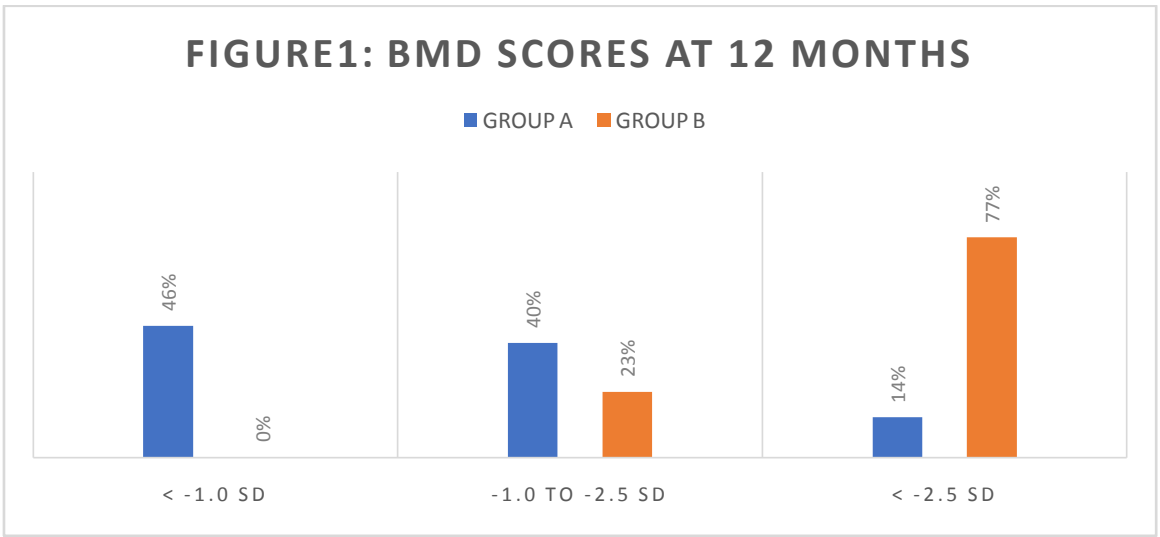
During follow up, patients were questioned about any symptoms. Bone mineral density and radiographic assessmentwere measured at base line and then at 6 and 12 months.Anteroposteriorand lateralradiographs of the lumbar spine wereobtained to detect any vertebral fractures and extentof vertebral deformity. Laboratory analyses, includinghematologic tests and tests of renal and liver functionand otherbiochemical markers, at base line were obtained.

The bone mineral density of the lumbar spine, hip, and total body was measured by dual-energy X-ray absorptiometry in the anteroposterior view. The diagnoses of osteopenia and osteoporosis were made in accordance with the WHO criteria for postmenopausal women based on bone mineral density (BMD) T-scores. Osteopenia was diagnosed if the T-score was -1.0 to -2.5 SDs and osteoporosis if the T score was lowers than –2.5 SDs.

III. RESULTS

All 200 female patients selected for this study completed the course of 12 months follow up program. Group A and B containing each 100 patients were given tablets over the period of 12 months. There were no significant intergroup differences at base line in the bone mineral density. Mean age of Group A and B are 62.17 years and 62 years respectively showing no significant difference between the two groups.

Group A patients showed excellent BMD scores at the end of 12 months as compared to group B. 86% of group A patients showed significant improvement in T-scores whereas group B with only 23% (Figure 1).



Lumbar spine X-rays were thoroughly assessed for further collapse of the already collapsed lumbar vertebrae or newly developed lumbar vertebral fractures which occurred during

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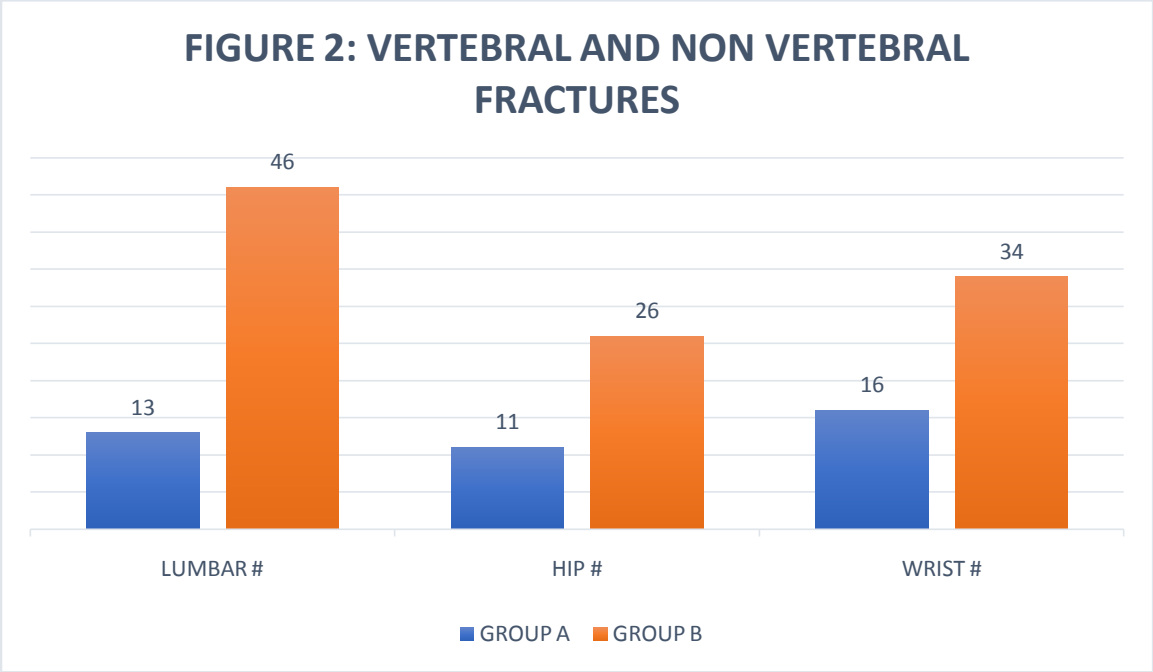
the course of the treatment. 46% of group B patients developed lumbar vertebrae fracture whereas in group A patients 13%(Figure 2).

The non-vertebral fractures related to osteoporosis were: 37% hip fractures (11% in group A and 26% six in group B) and50% wrist fractures (16% in groups A and 34% in group B) (Figure 2).



More than half of the group A patients complained about gastrointestinal upset after taking the tablet whereas none of the group B patients had such complains.

IV. DISCUSSION

Bisphosphonates are the most commonly prescribed anti resorptive medications for themanagement of osteoporosis [7,8].Bisphosphonates adhere to calcium bone hydroxyapatite, thus reducing bone resorption by affecting the osteoclasts' function and survivability.

Bisphosphonates are successfully used for the management of several bone diseases owingto its ability to suppress bone remodeling, as Paget's disease, myositis ossificans,progressive osteoporosis, drug-induced bone loss, heterotopic ossification, primaryhyperparathyroidism, fibrous dysplasia & multiple myeloma [9].

In our study, the effect of bisphosphonates on bone mineral density (BMD) showed significant improvement and more than three fourth patients showed decreased number of vertebral fractures who received bisphosphonates which was comparable to similar study [10]. This study also showed the inverse relation between increase in BMD T-scores after taking Bisphosphonates to the decrease in vertebral fractures.

Four ofthe five studies indicated unequivocally and at a statistically significant level thatpostmenopausal osteoporotic women who are given bisphosphonate treatment are less likely tohave a future fracture than women who do not take the bisphosphonate treatment [11].

Patients taking Alendronate were instructed to take on empty stomach as it is poorly absorbed and food further decreases its absorption and to sit upright after taking it [12,13].

Use of bisphosphonates in postmenopausal osteoporosis with BMD T-score -2.5 SD or less studied over a period of 12 months resulted in significant improvement in T-scores as well as reduction in number of vertebral and non-vertebral fractures.

V. CONCLUSION

Our study showed after administration of bisphosphonates in postmenopausal osteoporosis showed significant improvement in bone mineral density and decrease the risk of fracture. Alendronate is also cost effective and is considered safe with its benefits in use as treatment for postmenopausal osteoporosis.

Bisphosphonate therapy can be used to increase bone mineral density and decrease the risk of future fractures.

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