Original Research Article

A Compare Study of Effectiveness of oral Bisphosphonates and Vitamin D in Osteoporosis; Gandhi medical college & Hospital, Secunderabad

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Abstract

Background: Osteoporosis is a common skeletal disease characterized by a reduction in bone strength and an increased risk of fractures. Treatments for osteoporosis have been shown to increase bone strength and reduce fracture risk. The drugs most commonly used to treat osteoporosis are bisphosphonates and Calcium & Vitamin D supplements. Clinical challenges in using bisphosphonates, Calcium & Vitamin D supplements to treat osteoporosis.**Methods:** Oral Bisphosphonates, Calcium & Vitamin D supplements to treat osteoporosis include an appropriate selection of patients for initiating therapy. Comparisons between two drugs were done by using paired and unpaired T-test, calculations between before treatment & after treatment. The patient's bone density has been increased following T-score values obtained from DXA (quantitative ultrasound). **Results:** 120 patients were included. The majority of the adult were aged 38-59 years. Of the 120 students, 69 (57.50%) were males and 51 (42.50%) were females. The proportion of males and females was 1.35:1. In a study amongst 120 Patients, 50 % of Patients are given Ibandronic acid & the other 50 % of Patients s given calcium& Vitamin D. 60 Patients were assessed osteoporotic after DXA-I was treated with Ibandronic acid. After the treatment T-Score was -2.3. 60 Patients were assessed osteoporotic after DXA-II was treated with calcium & Vitamin D. After the treatment T-Score was -2.5. Ibandronic acid shows more effectiveness than calcium & Vitamin D in increasing the BMD in osteoporotic patients. **Conclusions:** The study summarizes that Patients who are exposed to ibandronic acids show greater results (BMD) rather than subjects who are exposed to calcium & Vitamin D. The study summarizes that oral bisphosphonates show more effectiveness on BMD than calcium supplements for osteoporosis.

Keywords; Osteoporosis, Osteopenia, Calcium, Vitamin D, Ibandronic acid.

Introduction

Osteoporosis is a common systemic skeletal disease with serious clinical consequences due to fractures. It is characterized by low bone mineral density (BMD) and poor bone quality that reduces bone strength and increases fracture risk [1]. It has been estimated that more than 200 million people worldwide have osteoporosis [2] Osteoporotic fractures of the spine and hip are associated with increased morbidity and mortality [3, 4]. Osteoporosis can be easily diagnosed before a fracture occurs by measuring BMD with dual-energy X-ray absorptiometry(DXA) using the diagnostic classification system of the World Health Organization (WHO) [5] with standards for quality control and clinical application established by the International Society for Clinical Densitometry (ISCD) [6]. Clinical practice guidelines based on cost-utility modeling have identified levels of fracture risk at which it is likely to be cost-effective to treat with a pharmacological agent to reduce fracture risk, using numerous country-specific socio-economic assumptions and mortality data [7, 8]. Pharmacological agents that have been proven to reduce fracture risk with favorable benefit-risk ratios are now widely available [9]. The drugs most often used in the treatment of osteoporosis are in the class of bisphosphonates. These are analogs of naturally occurring inorganic pyrophosphate, an endogenous inhibitor of bone mineralization that has been found in body fluids that include plasma, urine, and synovial fluid [10]. Pyrophosphate is the simplest form of polyphosphates, substances that inhibit the crystallization of calcium salts.

Clinical studies of the effects of Bisphosphonate and calcium supplements on bone mass in Osteoporosis patients, discuss the factors that may influence the effectiveness of calcium supplements in preventing bone loss and report the safety of Bisphosphonates and calcium supplements. A thorough understanding of their pharmacological properties, efficacy, and safety is likely to enhance clinical outcomes in treating patients with osteoporosis

Materials and Methods

A prospective observational study was carried out in the department of orthopedics of Gandhi medical college & Hospital, Secunderabad for eight months (June 2019 to February 2020), after obtaining the institutional ethical permission. The calculated sample size was not less than 100 patients for the current study. The prospective data were obtained from the orthopedic outpatient department after obtaining permission from the concerned. An appropriate data collection form was developed for recording all the relevant details,

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including the socio-demographics, obtained from the patient treatment chart and laboratory datasheets with the informed consent of the patient. Data, including the name of the drug, dosage form, frequency, and route of administration, were also collected in the data collection form. The collected information was summarized in an excel sheet and analyzed by using descriptive statistics such as frequency and percentage. Quantitative ultrasound (T-score values), medication prescribed to patient-based T score. BMD (Bone densitometer) was calculated.

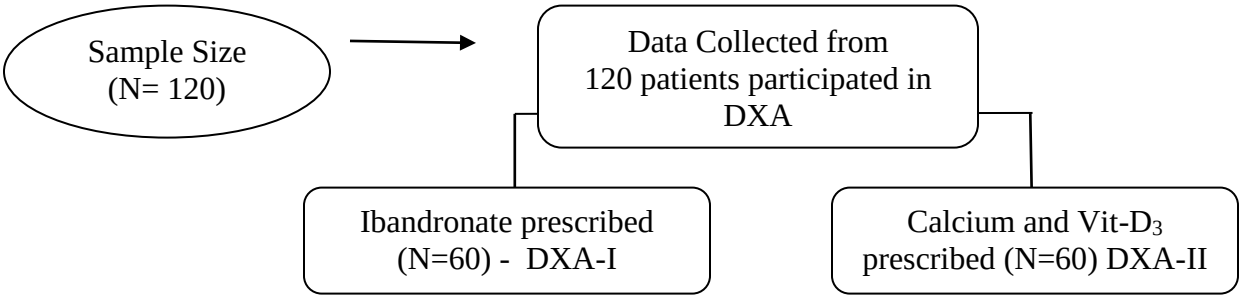
Sample Size:

Study Design
A hospital-based study.

Study Setting
Gandhi medical college & Hospital, Secunderabad

Study Period
June 2019 to February 2020.

Data Collection
By using a pre-designed, pretested questionnaire.



BMD was calculated for subjects before treatment & after 12 weeks (3months) (i.e., the follow-up has been done) BMD was checked which is considered after treatment changes in T-score are checked.

Treatment with bisphosphonates
Oral ibandronate in doses of either 2.5 mg daily or 20 mg every other day for 12 doses every 3 months led to a significant reduction in vertebral fracture risk.

Calcium and Vitamin D
Dietary calcium intake should be 1200-1500 mg, consistent with the National Institutes of Health and Food and Nutrition Board recommendations for optimal calcium intake [19]. Vitamin D intake must also be adequate and individuals should receive 400–600 IU/day.

Statically Analysis
Study statistical values were shown as Frequency, percentage, mean & SD. Comparisons between two drugs were done by using paired and unpaired t-test, calculations between before treatment & after treatment. All statistical analysis was performed using SPSS statistical software, version 22

Results

120 patients were included. The majority of the adult were aged 38-59 years. Of the 120 patients, 69 (57.50%) were males and 51 (42.50%) were females. The proportion of males and females was 1.35:1.

In a study amongst 120 Patients, 50 % of Patients are given Ibandronic acid & the other 50 % of Patients s given calcium& Vitamin D.

120 patients, before the treatment of DXA-I (T- Score -2.97) and DXA-II (T- Score -3.00) were involved in BMD studies. T-score values of both Ibandronic acid and calcium & Vitamin D receiving subjects are categorized into osteoporotic conditions initially (Fig-1).

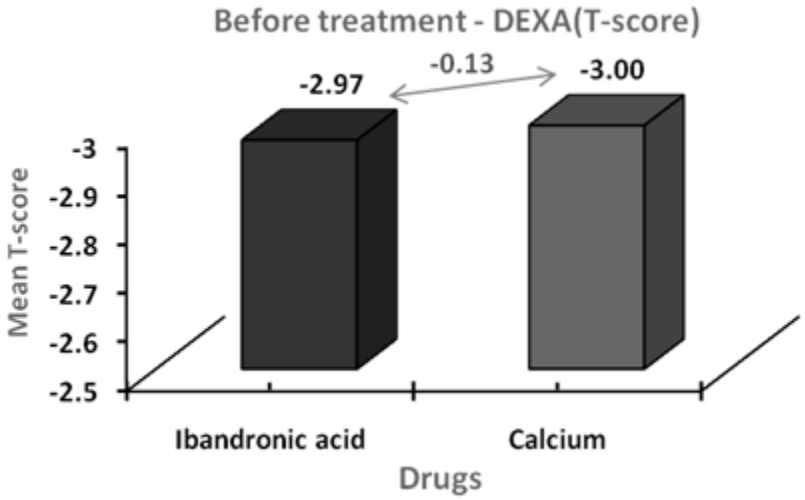


Fig-1: Before treatment of Ibandronic acid and calcium

60 Patients were assessed osteoporotic after DXA-I was treated with Ibandronic acid. After the treatment T-Score was -2.3. 46 (76.68%) Patients were osteopenia, and the remaining 14 (23.32) were osteoporotic (Fig-2).

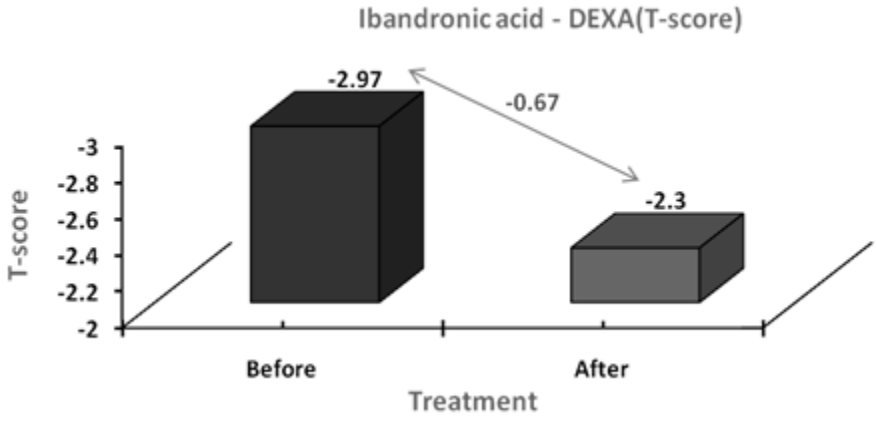


Fig-2: Before and after treatment of Ibandronic acid

60 Patients were assessed osteoporotic after DXA-II was treated with calcium & Vitamin D. After the treatment T-Score was -2.5. 39 (65%) Patients were osteopenia, and the remaining 21 (35%) were osteoporotic (Fig-3)

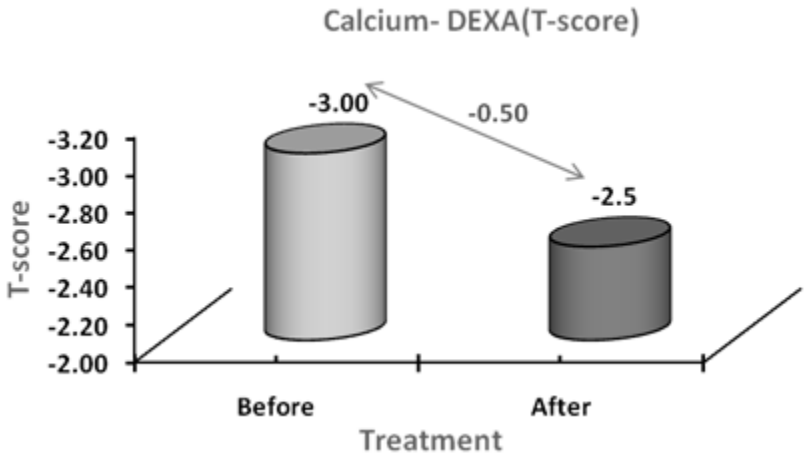


Fig-3: Before and after treatment of calcium &Vitamin D

Ibandronic acid shows more effectiveness than calcium & Vitamin D in increasing the BMD in osteoporotic patients.

Discussion

Osteoporosis is a common medical problem, although the majority of these fractures occur in postmenopausal women, the social and economic burden of osteoporosis-related fracture in men is considerable, with 25%–30% of all hip fractures occurring in males [11]. Despite this, there is a lack of understanding of the etiology and epidemiology of male osteoporosis. In many cases, a secondary cause is evident, such as alcohol abuse, glucocorticoid excess (either therapy with glucocorticoids or endogenous Cushing's syndrome), hypogonadism, or hyperparathyroidism. In a large number, however, no cause can be identified (so-called idiopathic osteoporosis) [12]. Even though uncertainties remain about whether to use absolute or relative risk in diagnosing male osteoporosis, the International Society for Clinical Densitometry recommends that we use the male database and the T-score of less than-2.5 to diagnose osteoporosis in men. By applying these standards, according to the World Health Organization, it is estimated that 1-2 million men in the United States have osteoporosis (T score-2.5) and another 8–13 million have osteopenia (T-score between-1.0 and-2.5). The respective age-adjusted prevalence figures are impressive: 6% for osteoporosis and 47% for osteopenia. On the other hand, if one applies the female reference standard to men (BMD-2.5 SD below peak bone mass for women), the numbers become much smaller, namely, 0.3–1 million men with osteoporosis (age-adjusted prevalence, 4%) and 4-9 million with osteopenia (age-adjusted prevalence, 33%). These latter figures are not consistent with epidemiological data. The National Osteoporosis Foundation (NOF) [13] recommends pharmacologic treatment for patients with non-vertebral or vertebral (clinical or asymptomatic) fractures. Therapy should also be initiated for those with T-scores below -2.5 at the femoral neck, total hip, or lumbar

spine by DXA, as this is consistent with a diagnosis of osteoporosis. Pharmacologic treatment is also recommended for postmenopausal women and men age 50 and older who meet the criteria for osteopenia as evidence by BMD T-score between -1.0 and -2.5 at the femoral neck, total hip, or lumbar spine by DXA. A patient with a 10-year hip fracture probability > 3 percent (based on the WHO FRAX) or a 10-year major osteoporosis-related fracture probability > 20 percent (based on the WHO FRAX) should also have pharmacologic treatment NOF [13]. Bisphosphonates are the most prescribed drugs for the treatment of osteoporosis [14]. Although controversy exists over what database to use, it is clear that men, like women, are at substantial risk for developing osteoporosis throughout the world.

Patients having osteoporosis were on average about 7-year-older than those having osteopenia, possibly giving a glimpse into the natural history of the disease. Aging in men, like aging in women, is associated with dramatic increases in fracture risk. The exponential increase in risk occurs approximately one decade later than in women. It has been estimated that the lifetime risk of a man suffering an osteoporotic fracture is greater than his likelihood of developing prostate cancer [15]. Age >70 years was a strong risk factor for osteoporosis in our study. The causes of bone loss in men are thought to be related to genetics, environmental, hormonal, and disease-specific factors. As in females, osteoporosis in males can be attributable to specific, underlying etiologies requiring careful clinical evaluation. Approximately, 50% of men with osteoporosis are diagnosed with an underlying "secondary" cause. This leaves a large percentage of men whose osteoporosis is not explained, so-called "primary" or "idiopathic" osteoporosis. Most of the men in this category are <65–70 years of age. Of course, there are men over 70 with osteoporosis for which the cause is not known. The older the patient, however, the more we are likely to relate the osteoporosis to age and not to a specific or unknown cause. Clearly, the younger the patient, the more likely it is that other explanations are needed to account for the condition. The three major causes of secondary osteoporosis in men are alcohol abuse, glucocorticoid excess (either endogenous Cushing's syndrome or, more commonly, chronic glucocorticoid therapy), and hypogonadism [16, 17]. We had excluded men with alcohol abuse. Hypogonadism was a strong risk factor for osteoporosis in our study accounting for about 70% of cases. Several studies conducted in the second half of the 20th century found an association between osteopenia or osteoporosis and Vitamin D deficiency, which was common in older individuals [18]. The response of the parathyroid glands to a given degree of Vitamin D deficiency increases with age [19]. There is widespread agreement that serum 25-OH-D levels should be kept above 80 nmol/L (32 ng/ml) although several studies fail to support this high target level [20]. Dietary calcium intake should be 1200-1500 mg, consistent with the National Institutes of Health and Food and Nutrition Board recommendations for optimal calcium intake [21]. Vitamin D intake must also be adequate and individuals should receive 400–600 IU/day. In men over 70 years of age, many experts make a general recommendation of 600-800 IU/day. Adequate exercise should also be strongly advised. However, drug therapy is almost always indicated in men at high risk for fracture. Bisphosphonate therapy is becoming a mainstay in the treatment of male osteoporosis [22]. A meta-analysis of placebo-controlled trials of testosterone treatment in men with any degree of androgen deficiency (most of them showing low normal or normal testosterone levels at baseline) suggested a beneficial effect on lumbar spine BMD, but equivocal findings at the femoral neck [22]. The limitation of our study was about 20% dropouts in the follow-up. In our study, we were unable to find out the association of bone markers with BMD as has been reported from various studies. This could be attributed to standardization issues.

Conclusion

Oral bisphosphonates, Calcium & Vitamin D supplements in osteoporosis. The effectiveness of these agents in clinical practice is limited by poor compliance and persistence with therapy. Oral bisphosphonates show that more potent compared with calcium & Vitamin D, before treatments & after treatments T-scores. The study summarizes that oral bisphosphonates show more effectiveness on BMD than calcium supplements for osteoporosis.

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