

## STUDY ON THE EFFECT OF CALCIUM, VIT D & IBANDRONIC ACID ON BONE MINERAL DENSITY



### Medicine

**KEYWORDS:** Bone Mineral Density ,Calcium

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### ABSTRACT

**BACKGROUND:** Osteoporosis can be measured by Bone Mineral Density (BMD). Supplementing, Calcium Vitamin D & Ibandronic acid can improve bone mass to an extent **OBJECTIVE:** To assess the effect of change of bone mineral density with calcium, Vitamin D & Ibandronic acid in patients with osteoporosis and to document the overall pain score by the Visual Analogue Scale (VAS) **METHODS:** Prospective study, over 6 months, where 201 patients were screened, and detected were treated and followed up by the BMD score. **RESULTS :** among the patients screened, 100 patients had osteoporosis and 29 had osteopenia, and were treated with Calcium, Vit D3 & Ibandronic acid. Statistically significant improvement in mean T score of BMD documented, with overall pain reduction **CONCLUSION :** Appropriate timely supplementation of Calcium, Vit D & Ibandronic acid can improve the BMD and to an extent reduce overall pain.

### INTRODUCTION

Osteoporosis is described as a systemic skeletal disease characterized by low bone mass and micro architectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture[1], based on available data and clinical experience, an estimated 50 million Indians may be affected, as reported by Malhotra et al[2]. The description focuses on measurements of BMD as well as on bone quality, but at present, only BMD can be readily measured in the clinic. And osteoporosis is based solely on Bone Mineral Density BMD measurement[1]

Inadequate intake of calcium and vitamin D leads to reduced calcium absorption, increased serum parathyroid hormone concentrations, and bone loss. Low bone mass is a strong predictor of fracture [3] evaluation of BMD. DEXA (dual energy X-ray absorptiometry) is the gold standard to assess BMD.[4], calcaneal quantitative ultrasound (QUS) ultrasound devices can also be used to used examine the BMD and the T-score threshold that would be appropriate to identify people at risk of osteoporosis using QUS[5] Supplemental calcium reduces bone loss in middle-aged, postmenopausal women[6] and lowers rates of vertebral fracture in women with previous vertebral fractures.[7] Supplementation with vitamin D alone reduced bone loss from the femoral neck in postmenopausal women[8] Elderly people are at a high risk of osteoporosis, hence Vitamin D and Calcium supplements are recommended for fracture prevention [9] This can be administered either alone or together. There is supportive evidence on ibandronic acid on Osteoporosis[10].

WHO has defined osteoporosis[8] as Bone Mineral Density 2.5 SD (standard deviation) below the mean bone mass of young normal adults. Normal BMD is T-score  $\geq -1$ ; Osteopenia - T-score between -1 and -2.5 Osteoporosis - T-score  $< -2.5$ ; Severe osteoporosis - T-score  $< -2.5$  with fractures. [5] Pain associated with osteoporosis can be charted with a Visual Analogue scale.(VAS) [11] VAS pain score is a 0-10 Numeric pain rating scale in which the patients pain intensity is measured in linear pattern. '0' is taken as 'No pain' and '10' is taken the 'worst possible pain' '1 to 3' is taken as 'mild pain', '4 to 6' is taken as 'moderate pain' and '7 to 9' is taken as 'severe pain'. In the article by Peter et al, pain is associated with the musculoskeletal disease [12] and the burden of musculoskeletal problems is a broad one.

### MATERIALS & METHODS

**DESIGN** A prospective study of 201 pts above age of 50 were screened for osteoporosis and osteopenia. In a tertiary level Rehabilitation outpatient centre.

**Period of study:** 6 months

**CRITERIA** included patients above 50 yrs of age, of both gender. (t score as measured by the calcaneal QUS) were included. Patients

who were already taking Steroids and Calcium, and reported liver, renal, thyroid and autoimmune disorders were excluded.

### METHODOLOGY

After selection of the patients with BMD measurements with calcaneal QUS, nature of disease and treatment were explained, consent obtained.. The Initial Bone Mineral Density and the T-score was recorded and the patients identified with Osteoporosis & osteopenia, their VAS score were recorded. Analgesics and anti inflammatory medications were given to all patients during acute episodes of pain (Diclofenac - 50mg twice daily, tab paracetamol 500mg twice daily). Patients with osteoporosis and osteopenia were given tab Ibandronic acid 150 mg once monthly, Calcium 1000mg+Vit D3 400 IU daily. Patients with t-score  $< -1$  were followed up at regular intervals of 2 months for a period of 6 months. T-score and VAS score on subsequent follow up were recorded. Patients with normal BMD were not followed up subsequently. No adverse effects were reported.

### OUTCOME MEASURES

BMD assessments were done by subsequent t-scores using Calcaneal QUS. Relief of pain was assessed by VAS scale. Patients were asked to mark the point which represented the intensity of pain. Change of t-score and pain were assessed by statistical methods.

### STATISTICAL ANALYSIS

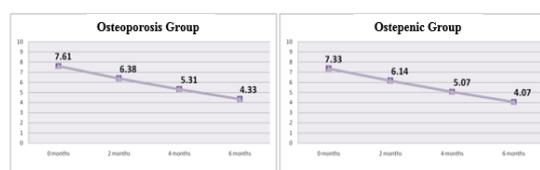
Results were analysed using SPSS 16 version. Paired t- test, Wilcoxon signed rank test, chi-square tests were used to analyse the data.

### RESULTS

Total of 201 patients were studied. , Out of 201 patients studied, 166 were females (83%) and 35 were males (17%) 100 patients had (t-score  $\leq -2.5$ ) Osteoporosis, and 72 patients had (t score between -1 and -2.5) Osteopenia, 29 patients had normal (t score  $\geq -1$ ). Out of 166 females, 88 female (53%) were osteoporotic and 54 female (33%) were osteopenic and 24 females (14%) were normal . Out of 35 males 12 males (34%) Osteoporotic and 18 males (52%) were Osteopenic and 5 males (14%) were normal.

### VAS Score in Osteoporosis Group (100 Patients)

There was significant decrease in the VAS pain score in the osteoporosis group at 2 months, 4 months & 6 months follow up. This was statistically significant.

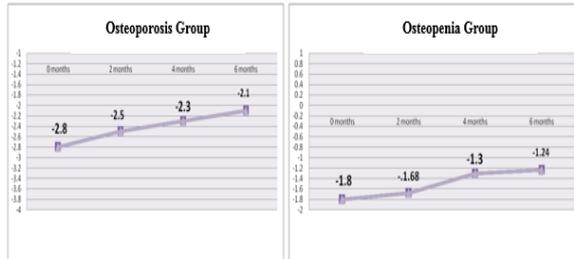


**Figure-1 Mean VAS in Osteoporosis Group and Osteopenic Group**

There was statistically significant decrease in mean VAS score in the osteoporosis group from 7.61 (high pain level) to 4.33 (moderate pain level) at the end of 6 months.

**VAS Score in Osteopenia Group (72 Patients)**

There was significant decrease in VAS pain score at the end of 6 months. This was statistically significant. The mean VAS in Osteopenia Group, showed statistically significant improvement in mean VAS score from 7.33 to 4.07 at the end of 6 months.



**Figure -2 MeanT Score in Osteoporosis Group and Osteopenia Group**

**MeanT Score in Osteoporosis Group**

There was statistically significant improvement in mean t score from -2.8 at first visit (Osteoporosis) to -2.1 at the end of 6 months.

**Mean T Score in Osteopenia Group**

This group also showed statistically significant increase in t score from -1.8 at first visit to -1.24 at the end of 6 months.

**CONCLUSIONS**

The Bone Mineral Density(BMD) is an important marker to detect early osteoporosis and osteopenia It was found that Calcaneal QUS can be used as a baseline screening tool to assess BMD.

Supplementation with Ibandronic acid & Calcium and Vitamin D in osteoporotic and osteopenic patients show significant improvement in level of t score. There was better control of pain in these patients also.

Limitations of the Study This was a small sample size and the follow up was short, which spanned over 6 months only.

**REFERENCES**

- [1] O Sahota et al; Vitamin D insufficiency increases bone turnover markers and enhances bone loss at the hip in patients with established vertebral osteoporosis; Clinical Endocrinology Volume 51, Issue 2 August 1999 Pages 217–221
- [2] N.Malhotra, A. Mithal, Osteoporosis in Indians ; Indian J . Med. Res 127 , March 2008, pp263-268
- [3] Bess Dawson, Hughes M D, susan S Harris et al ; Effect of Calcium and Vitamin D Supplementation on Bone Density in Men and Women 65 Years of Age or Older; N Engl J Med 1997; 337:670-67 Sept 4
- [4] Aggarwal N, Raveendran A, Khandelwal N, Sen RK, Thakur J S, Dhaliwal LK, Singla V, Manoharan SR. Prevalence and related risk factors of osteoporosis in peri- and postmenopausal Indian women. J Mid-life Health 2011;2:81-5
- [5] M L Frost, G L Blake, I. Fogelman ; Can the WHO criteria for diagnosing osteoporosis be applied to calcaneal quantitative ultrasound ? ; Osteoporosis international ; May 2000, Vol 11, issue 4, pp321-330
- [6] Prince R, Devine A, Dick I, et al. The effects of calcium supplementation (milk powder or tablets) and exercise on bone density in postmenopausal women. J Bone Miner Res 1995;10:1068-1075
- [7] Recker RR, Hinders S, Davies KM, et al. Correcting calcium nutritional deficiency prevents spine fractures in elderly women. J Bone Miner Res 1996;11:1961-1966
- [8] Dawson-Hughes B, Harris SS, Krall EA, Dallal GE, Falconer G, Green CL. Rates of bone loss in postmenopausal women randomly assigned to one of two dosages of vitamin D. Am J Clin Nutr 1995;61:1140-1145
- [9] Philip Sambrook, the Record trial group. Oral vitamin D3 and calcium for secondary prevention of low trauma fractures in elderly people ( Randomised Evaluation of Calcium or Vitamin D, RECORD): a randomized placebo – controlled trial. The Lancet , vol 365, issue 9471, 7-13 May 2005 1621-1628
- [10] Maurizio Rossini, Giovani Orsolini, Silvano Adami et al; Osteoporosis treatment: why ibandronic acid? Expert Opinion on Pharmacology; vol 14, 2013- issue 10
- [11] Sally L Collins, R Andrew Moore et al ; The visual analogue scale, what is moderate pain in millimeters?; PAIN:vol72, issue 1-2, August 1997, pp95-97
- [12] P M Brooks, The burden of musculoskeletal disease- a global perspective; Clin Rheumatology ; novem 2006, vol25, issue 6 pp778-781