

Comparison of effect of raloxifene and herbal drug on BMD in postmenopausal CKD patients

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Introduction: Chronic kidney disease (CKD) is an international public health problem which is affecting 5-10% of world population. Chronic kidney disease affects males and females equally. The sex ratio of rural India is 944/1000 males and 922/1000 males in urban parts of India. Female population is 49.76% of total population; thus, females constitute nearly half of the CRF patients. Chronic kidney disease produces several metabolic alterations which can affect bones and mineral homeostasis.

Aim: In this study, we evaluated the effect of raloxifene and herbal drug on bone mineral density (BMD) in postmenopausal CKD patients.

Materials & Methods: Total of 78 cases of postmenopausal chronic kidney disease patients was included in the study. Patients, after inclusion in the study, were randomly assigned into three groups, namely group A, B and C by random number table group A: 28 postmenopausal CKD patients who received raloxifene 60 mg per day. Group B: 26 patients of postmenopausal chronic kidney disease who received herbal drug M2020 one cap. 500 mg BD. Group C: 24 patients of postmenopausal chronic kidney disease who received calcium and calcitriol. All 78 patients received calcium carbonate 500 mg thrice a day and low dose vitamin D3 0.25 micrograms per day according to Kidney Disease: Improving Global Outcomes (KDGO) Guidelines. Detailed history, examination investigations were performed at baseline. Patients were followed at six month intervals. Routine bio-chemical investigations along with iPTH and BMD by DEXA at vertebra and distal end of tibia were done at 0, 6 and 12 months. GFR was calculated by Cockcroft-Gault formula. Body mass index was calculated by Broca's formula. Corrected calcium was calculated by serum calcium and serum albumin level. iPTH was measured by IMMULITE 1000 kit by solid phase, two site chemiluminescent enzyme-labeled immunometric assay. BMD was measured by Lunar-DPX machine made by GE medical system Madison WI USA at lumbar vertebra and at lower end of tibia. Nutritional advice was provided to each patient by trained nutritionist according to BMI and other parameters. Statistical analysis was done using SPSS Software (version 16.0). Repeated ANOVA test were used to compare groups. P-value<0.05 was considered as statistically significant.

Discussion: In present study, we evaluated the effect of raloxifene and herbal drug M2020 in comparison to control group in reference to various parameters of CKD-MBD. Because of uncertainty of effective treatment in postmenopausal osteoporosis treatment, we have also evaluated effect of herbal drug M2020 which is made by four herbs namely *Dioscorea bulbifera*, *Terminalia arjuna*, *Bambusa arundinacea* and *Withania somnifera*. Although, we are not aware of any which has evaluated these ingredients alone or in any combination on BMD in postmenopausal CKD patients but they are being used to combat postmenopausal syndrome for a long time in India and most of them are containing phytoestrogens.

Conclusion: Both the drugs produced significant improvement in osteoporosis at lumbar vertebra as compared to control group at 12 months and M2020 causes numerically superior improvement as compared to raloxifene. Both the drugs produced significant improvement in T-score at peripheral bones also and effect was superior in M2020 group. In conclusion, raloxifene and M2020 both improve hypocalcaemia, hyperphosphatemia, controls secondary hyperparathyroidism and increases BMD at lumbar vertebra and peripheral bones and M2020 is numerically superior in every aspect.

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