DENOSUMAB IN NINE CHRONIC KIDNEY DISEASE STAGE 5D PATIENTS WITH LOW BONE MINERAL DENSITY. A SINGLE CENTER PILOT STUDY.

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OBJECTIVES

Introduction: Osteoporosis is common among Chronic Kidney Disease (CKD) stage 5D patients[1]. Its association with bone fractures in this group of patients is still debatable[2]. Recent data suggest that discriminatory ability of bone mineral density (BMD) at total hip region for prevalent spine fracture was as effective as that for primary osteoporosis[3]. Denosumab (DMAb) is an antiresoptive agent, currently used for the treatment of osteoporosis in postmenopausal women. Few data exist on DMab's efficacy in HD patients with osteopenia or osteoporosis.

Purpose: To evaluate the effectiveness of DMAb in increasing the BMD of HD patients with osteopenia or osteoporosis. Also, to test how DMAb affects biochemical indices of bone metabolism in this group of patients.

METHODS

Nine (9) CKD stage 5D patients with osteopenia or osteoporosis received two doses of 60mg DMAb sc at days 0 and 180. The patients were followed until day 360. BMD was measured at the total hip region by Dual Energy X-ray Absorbsiometry (DEXA) twice(at entry and at day 360). Inclusion criteria were intact PTH (iPTH)>200 pg/ml, serum calcium (Ca)>8,4mg/dl and serum phosphorus (P)>3,5mg/dl. Also no intake of vitamin D analoges or calcium supplements. PTH, Ca and P were measured weekly for the first 15 days after each dose and then monthly until day 360. BMD change was correlated with demographic and biochemical data

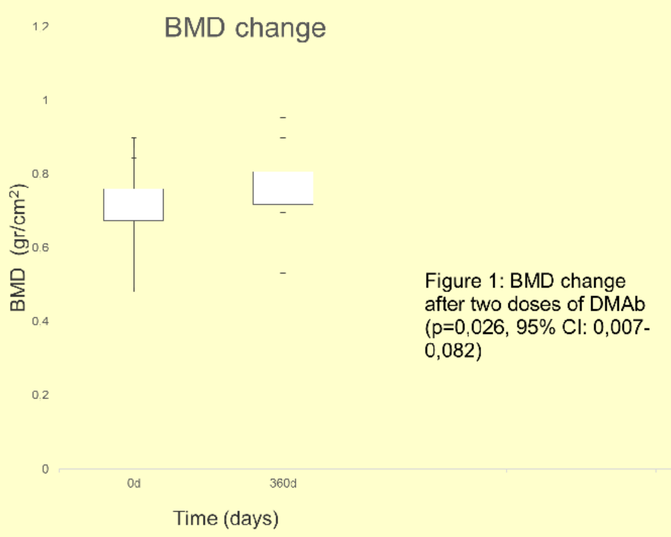

Figure 1: BMD change after two doses of DMAb (p=0,026, 95% CI: 0,007-0,082)

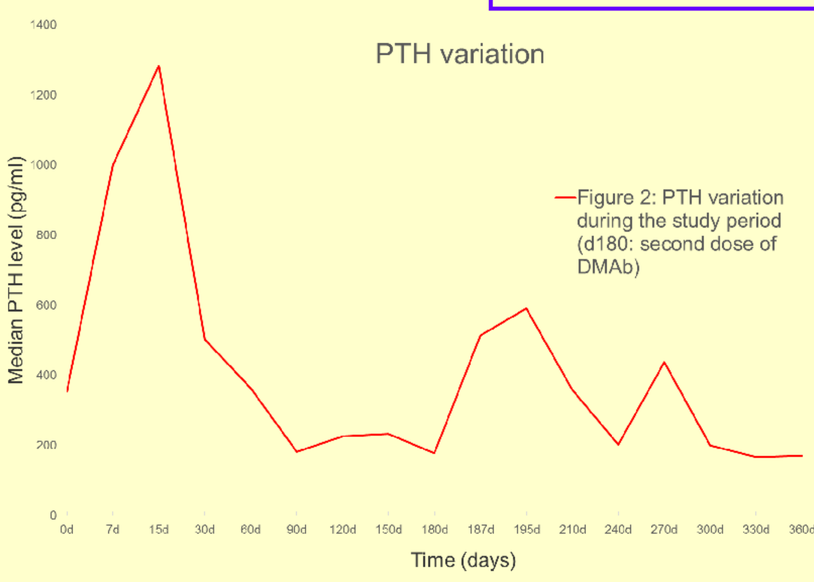

Figure 2: PTH variation during the study period (d180: second dose of DMAb)

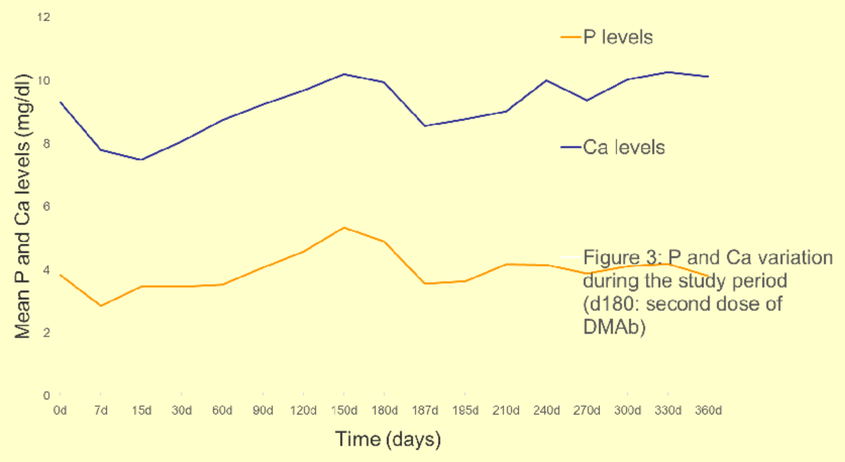

Figure 3: P and Ca variation during the study period (d180: second dose of DMAb)

RESULTS

All results were expressed as mean (± standard error) or median (interquartile range) value. One patient was lost at follow up. BMD increase in seven of the remaining eight patients. Mean BMD at entry was 0,717gr/cm^2 (± 0,043) and after the treatment period it raised to 0,762gr/cm (± 0,045). Mean BMD increase was 0,044gr/cm^2 (± 0,015) (p=0,026) (fig.1) The percentage change was +6,47% (± 2,36). A great increase i iPTH levels was observed after the first dose of DMAb together with a big decrease in serum Ca and a proportionate decrease in serum P Major iPTH levels and minor Ca levels were observed at day 15 (1085pg/ml and 7,6mg/dl respectively) (fig.2 and 3). There was a need fo addition of vitamin D analoges and calcium supplements in patients' regimen after the first dose. PTH and Ca levels returned to initial values b day 120. Study protocol had to change before the second dose of DMAb (all patients were administered vitamin D analoges and calciu supplements in low doses). Modest changes in iPTH and Ca levels were observed after the second dose (fig.2 and 3). The magnitude o increase in BMD was correlated significantly with major iPTH increase after the first dose (p=0,049, R=0,709). Age, gender, time on dialysis an initial iPTH didn't seem to affect the response.

CONCLUSIONS

Administration of DMAb in HD patients with osteopenia or osteoporosis resulted in significant increase of BMD. Decline in serum Ca and increase in iPTH levels were observed. Vitamin D analoges and calcium supplements addition before DMAb dose seemed to preserve Ca and iPTH levels.

References

1. Ott SM. Review article: Bone density in patients with chronic kidney disease stages 4-5. Nephrology (Carlton). 2009 Jun;14(4):395-403

2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2009; 113: S1–S130

3. Iimori S, Mori Y, Akita W et al. Diagnostic usefulness of bone mineral density and biochemical markers of bone

52 ERA 642--SP

J5) Chronic Kidney Disease. Bone disease.

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DOI: 10.3252/pso.eu.52era.2015

ePosters supported by F. Hoffmann- La Roche Ltd.

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