

Abstract Submission No.: A-0863**Efficacy of Denosumab for Osteoporosis in Hemodialysis Patients**

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Objectives : Chronic kidney disease (CKD) is a well-known risk factor for osteoporosis and fractures, but treatment options are very limited in these patients. Although Denosumab is a bone anti-resorptive drug that can be considered in dialysis patients, small RCTs (randomized controlled trial) and observational studies have shown some benefits, data on efficacy is still lacking. Therefore, this study aims to evaluate the safety and efficacy of denosumab in hemodialysis (HD) patients with osteoporosis.

Methods : We retrospectively analyzed 91 HD patients with osteoporosis received denosumab more than twice every 6 months between August 2018 and March 2023. Before each administration, biochemical markers including calcium, phosphate, parathyroid hormone and bone turnover markers are confirmed. Blood samples are taken every 3-5 days for two weeks after administration to monitor the occurrence of hypocalcemia, and changes in PTH over two months are measured.

Results : The average age was 73.3 ± 10.4 years, with 25 males (27.5%) and 51 diabetic patients (56.0%). Baseline BMDs at the lumbar spine and femur neck were -2.2 ± 1.1 and -2.7 ± 0.7 , respectively. One year after denosumab administration, there was a significant increase in BMD at lumbar spine (-2.2 ± 1.1 and -1.9 ± 1.0 , $p < 0.001$), but not in femur neck BMD (-2.73 ± 0.73 and 2.66 ± 0.82 , $P = 0.08$). Increases in BMD at the lumbar spine and femur neck from baseline were observed in 79.4% and 62.7 % of patients, respectively. Although serum level of calcium significantly decreased after administration of denosumab, none of the patients experienced severe hypocalcemia or jaw osteonecrosis.

Conclusions : Our results suggests that denosumab can significantly increase BMD in HD patients without serious side effects. However, since this study did not evaluate effectiveness for fracture prevention or conduct long-term follow-up observations, further research is necessary.

Table 1.png

Table 1. Baseline characteristics and demographics of study population

	Total (n = 91)
Age (years)	73.3 ± 10.4
Male sex, n (%)	25 (27.5)
Body mass index (Kg/m²)	21.7 ± 3.2
Vintage of dialysis (years)	5.15 ± 5.75
Cause of ESRD, n (%)	
Diabetes	42 (46.2)
Hypertension	27 (29.7)
GN	9 (9.9)
ADPKD	4 (4.4)
Others	9 (4.4)
Diabetes mellitus, n (%)	51 (56.0)
Hypertension, n (%)	79 (86.8)
CVD, n (%)	13.5(22.0)
CVA, n (%)	14 (15.4)
PAOD, n (%)	7 (7.7)
Protein (mg/dL)	6.6 ± 0.5
Albumin (mg/dL)	3.7 ± 0.3
Corrected Calcium (mg/dL)	9.7 ± 0.7
Phosphorus (mg/dL)	3.8 ± 1.3
Intact PTH (pg/mL)	191.7 ± 175.0
Bone specific ALP (µg/L)	21.1 ± 10.3
C-terminal telopeptide (ng/mL)	1.42 ± 0.69
25-Hydroxy Vitamin D (ng/mL)	14.3 ± 9.3
P1NP (ng/mL)	242.7 ± 172.3
BMD, T score	
L1-L2	-2.1 ± 1.4
L1-L3	-2.0 ± 1.4
L1-L4	-1.9 ± 1.4
L2-L3	-2.0 ± 1.4
L2-L4	-1.9 ± 1.5
L3-L4	-1.8 ± 1.6
Femur, Neck	-2.8 ± 0.7
Femur, Wards	-3.2 ± 0.6
Femur, Troch	-2.4 ± 0.7
Femur, Total	-2.8 ± 0.8
CaCO₃ supplement (mg/day)	954 ± 1264
Vitamin D2 Supplement (IU/day)	27 ± 69
Vitamin D3 Supplement (IU/day)	160 ± 416
PO Calcitriol supplement (mcg/week)	0.7 ± 1.1
IV Calcitriol supplement (mcg/week)	0.1 ± 0.5
Total calcitriol supplement (mcg/week)	0.8 ± 1.1
IV Paricalcitol supplement (mcg/week)	0.6 ± 2.1

All data are expressed as mean ± SD. Abbreviations: ESRD, end-stage renal disease; GN, glomerulonephritis; ADPKD, autosomal dominant polycystic kidney disease; CVD, cardiovascular disease; CVA, cerebrovascular accident; PAOD, peripheral artery occlusive disease; PTH, parathyroid hormone; ALP, alkaline phosphatase; P1NP, procollagen type 1 N propeptide; BMD, bone mineral density; PO, Per os; IV, intravenous.

Table 1.png

Table 2. Numerical Comparison Between BMD of Baseline and 1 year after denosumab injection

	BMD, baseline	BMD, 1 year after denosumab injection	P value
BMD			
L1-L2	-2.2 ± 1.4	-1.8 ± 1.4	<0.001
L1-L3	-2.1 ± 1.3	-1.7 ± 1.4	<0.001
L1-L4	-1.9 ± 1.4	-1.6 ± 1.4	<0.001
L2-L3	-2.1 ± 1.4	-1.8 ± 1.5	<0.001
L2-L4	-1.9 ± 1.4	-1.6 ± 1.5	<0.001
L3-L4	-1.7 ± 1.5	-1.4 ± 1.6	<0.001
Femur, Neck	-2.7 ± 0.7	-2.7 ± 0.8	0.080
Femur, Wards	-3.1 ± 0.6	-3.1 ± 0.6	0.885
Femur, Troch	-2.3 ± 0.7	-2.2 ± 0.8	<0.001
Femur, Total	-2.7 ± 0.8	-2.7 ± 0.8	0.004
Biochemicals			
Corrected Calcium (mg/dL)	9.9 ± 0.7	9.6 ± 0.7	0.016
Phosphorus (mg/dL)	4.0 ± 1.3	4.5 ± 1.3	0.008
Intact PTH (pg/mL)	196.1 ± 193.4	187.2 ± 148.3	0.710
Bone specific ALP (µg/L)	21.4 ± 11.1	13.9 ± 7.5	<0.001
C-terminal telopeptide (ng/mL)	1.34 ± 0.64	1.08 ± 0.80	0.025
25-OH Vitamin D (ng/mL)	14.3 ± 10.4	16.5 ± 12.8	0.103
Protein (mg/dL)	6.7 ± 0.5	6.5 ± 0.5	0.012
Albumin (mg/dL)	3.7 ± 0.3	3.8 ± 0.4	0.099

Increases in BMD at the lumbar spine and femur neck from baseline were observed in 79.4% and 62.7 % of patients, respectively. Abbreviations: BMD, bone mineral density; PTH, parathyroid hormone; ALP, alkaline phosphatase.