1,25(OH)$_2$D$_3$ administration in moderate renal failure: A prospective double-blind trial.


Summary/Abstract.

This study represents the first randomized prospective, double-blind, placebo-controlled trial of the efficacy of 1,25(OH)$_2$D$_3$ on bone histology and serum biochemistry in patients with mild to moderate renal failure. Sixteen patients with chronic renal impairment (creatinine clearance 20 to 59 ml per min) received either 1,25(OH)$_2$D$_3$ at a dose of 0.25 to 0.5 µg daily (eight patients), or placebo. Transilliac crest bone biopsies were performed before entrance into the study and after 12 months of experimental observation. None of the patients were symptomatic or had radiological evidence of bone disease. Of the thirteen patients who completed the study, initial serum 1,25(OH)$_2$D$_3$ levels were low in seven patients and parathyroid hormone levels were elevated in seven patients. Bone histology was abnormal in all patients. 1,25(OH)$_2$D$_3$ treatment was associated with a significant fall in serum phosphorus and alkaline phosphatase concentrations as well as with histological evidence of an amelioration of hyperparathyroid changes. In contrast to previous reports, no deterioration of renal function attributable to the treatment occurred, perhaps because a modest dose of 1,25(OH)$_2$D$_3$ was employed combined with meticulous monitoring. Further investigation is required to determine whether alternative therapeutic strategies (smaller doses or intermittent therapy) may avoid the potential for suppressing bone turnover to abnormally low levels in the long term.