

## IMPACT OF CINACALCET THERAPY ON PATIENT-REPORTED SYMPTOMS IN PATIENTS WITH MODERATE TO SEVERE SECONDARY HYPERPARATHYROIDISM

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Patients (pts) with secondary hyperparathyroidism (sHPT) often experience symptoms affecting physical and cognitive function. We analyzed the change in symptoms and health-related quality of life (HRQOL) in an open-label study of cinacalcet and low dose vitamin D combination therapy (TARGET study (Block et al, *Nephrol Dial Transplant* (2008) 23: 231-2318)).

At study baseline, end of titration and end of treatment, study subjects completed a questionnaire including 14 selected items from the KDQOL instrument to measure the sHPT symptom frequency and bother, and the SF-36 scale to measure overall physical and mental well-being. Scores were standardized to a 0 to 100 scale, with improved symptom represented by a higher score. Paired t-tests were used to evaluate change from baseline in individual symptom score and SF-36 functional domain score.

Demographic and baseline clinical characteristics of the 294 pts completing all 3 assessments were similar to the overall clinical trial sample (n=444). Mean age was 55 years and 56% were men and 47% were black. Median baseline biPTH was 249 pg/mL (interquartile range 192, 327) and median dialysis vintage was 42 months (interquartile range 21, 75). We observed significant improvement by end of treatment in frequency of reported symptoms of muscle soreness, joint pain, stiffening of joints, ache in bones, dry skin, excessive thirst, fatigue, and trouble with memory during the study ( $p < 0.05$ ; range = 2.5 to 7.7). The extent of bother from joint pain, ache in bones, dry skin, excessive thirst, trouble concentrating, and trouble with memory during the study was also significantly improved by end of treatment ( $p < 0.05$ ; range = 2.7 to 5.7). The magnitude of improvement appeared to increase with treatment duration. No significant improvement in SF-36 physical or mental scales was noted.

Cinacalcet therapy may improve musculoskeletal, cognitive and other symptoms in dialysis-dependent patients with sHPT. Although no significant differences in the SF-36 scores were observed, additional analyses on the sensitivity of the questionnaire in this setting are on-going.