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Predictors of Discontinuation of Cinacalcet

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Introduction: Predictors of cinacalcet discontinuation and levels of parathyroid hormone (PTH) and calcium (Ca) prior to discontinuation have not been previously reported. We examined predictors of cinacalcet discontinuation and biochemical levels prior to discontinuation in a large population of patients receiving chronic hemodialysis.

Methods: Using data from the United States Renal Data System merged with clinical data from a large dialysis provider, we identified new users of cinacalcet from 2007 through 2010 using Part D prescription claims. Patients received in-center hemodialysis and were ≥ 18 years old with continuous Medicare coverage during the study period. New users were identified as patients with at least one 30-day cinacalcet prescription fill and no cinacalcet use 6 months prior to the initial fill. Covariates were assessed in 30-day intervals following cinacalcet initiation. Movement between quintiles of laboratory distributions was examined to determine changes in biochemical levels prior to discontinuation. We calculated hazard ratios (HR) and 95% confidence intervals (CI) for the risk of cinacalcet discontinuation.

Results: We identified 17,791 eligible cinacalcet initiators who contributed 101,147 30-day follow-up intervals. Over half of all patients discontinued cinacalcet by month 4. Proximal PTH levels <150 pg/mL were associated with discontinuation: HR = 1.23 (95% CI: 1.11-1.36), whereas low Ca (<7.5 mg/dL) was suggestive of an association, HR = 1.10 (95% CI 0.92-1.32). Entering the Medicare Part D gap period increased discontinuation risk: HR = 1.19 (95% CI: 1.00-1.42), and low-income subsidy status decreased the risk of discontinuation: HR = 0.77 (95% CI 0.69-0.86). Increasing PTH, HR = 1.15 (95% CI: 1.08-1.23), and Ca levels, HR = 1.23 (95% CI: 1.15-1.31), may be early markers of discontinuation.

Conclusions: Early discontinuation following cinacalcet initiation is common, and occurs frequently for clinical or economic reasons. It also appears that an unanticipated increase in biochemical levels may be an early marker of patient discontinuation.

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