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An Open, Multi-center, Single Arm Study to Determine the Efficacy and Safety of Cinacalcet in Korean Patients on Hemodialysis using Recommended Dosage

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The treatment of secondary hyperparathyroidism in end-stage renal disease (ESRD) has evolved based on new insights into the pathogenesis of this disorder. The calcimimetic cinacalcet HCl acts on the calcium-sensing receptor of parathyroid gland, increase its sensitivity to calcium, thereby regulate the release of parathyroid hormone (PTH). We conducted nationwide multicenter study to determine the efficacy and safety of cinacalcet in Korean hemodialysis patients. Clinically stable hemodialysis patients with secondary hyperparathyroidism that was resistant to conventional treatments were enrolled. Before the treatment with cinacalcet, baseline serum levels of iPTH was over 300 pg/ml for two consecutive times and the albumin-adjusted calcium was over than 9.0 mg/dl. A total of 51 patients received once-daily oral cinacalcet, increased from 25 mg to 100 mg during the first 8 weeks of dose-titration phase and thereafter, fixed dose was used for the following 16 weeks of maintenance phase. The primary endpoint was to achieve a target intact PTH (iPTH) level of < 300 pg/ml. Definite reduction of iPTH <300 were observed in 24 (70.6%) patients. Interestingly, median time required to the complete response was only 35.4 days (21.0-91.0). Although target level did not reached, 3 (8.8%) patients showed intermediate response, decrease of iPTH >30% from baseline, within an average of 63.5 days (49.3-70.2). However, 7 patients showed minimal response: among these patients, 4 patients could not undergo optimal dose increment due to significant hypocalcemia, while the other 3 patients showed completely no response even at full-dose cinacalcet. The maximal percentage changes of iPTH level was -69.8%, -54.4% and +0.1% in definite, intermediate and minimal response group, respectively. Cinacalcet also significantly reduced serum calcium, phosphorus, and Ca X P levels; the changes were independent to the response of iPTH. The decrease of iPTH levels >50% from baseline within 4 weeks after the treatment was a strong predictor for the achievement of primary endpoint [Odds ratio (OR) 899.7, 95% confidence interval 55.8-1226.3, p=0.022]. The most common adverse effect was upper gastrointestinal discomfort and they were more common with the higher dose of cinacalcet. The response to cinacalcet was also excellent in Korean hemodialysis patients. Earlier response of iPTH within 4 weeks could be an important prognostic marker for the prediction of clinical response to cinacalcet.

Key Words: 시나칼세트, 혈액투석
Cinacalcet, Hemodialysis