

Efficacy and Safety of Dif1stat® for the Treatment of Secondary Dyslipidemia in Chronic Kidney Disease

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Abstract: 1104 patients with Secondary Dyslipidemia and CKD (Chronic Kidney Disease) (females: 387; males: 717; aged: 70 ± 11 years) were given Dif1stat® with diet to evaluate efficacy and safety. The study lasted two years. Patients were assigned to three groups (A, B, C) based upon basal renal function. Group A consisted of 180 patients with GFR (glomerular filtration rate) of 67 ± 16 mL/min/m². TC (Total Cholesterol) (-31%), LDLC (LDL-Cholesterol) (-42%), TG (triglycerides) (-36.8%) levels, and non-HDLC (non HDLC cholesterol) (-41%) and TC/HDLC ratio (-40%) were significantly reduced ($P < 0.001$). GFR (+2.5%) increased significantly. No significant changes were observed in HDLC (+13%). Group B was of 744 patients, 69% (males: 514), 31% (females: 230) (median age: 70 ± 13 years), and moderate stage III CKD (GFR: 38 ± 12 mL/min/1.73m²). After 24 months the change of HDLC (+3.5%) was not significant, while TC (-27%), TG (-32%), LDLC (-33%), non-HDLC (33.4%), TC/HDLC (-30%), and GFR (+2.1%) were statistically significant ($P < 0.001$). Group C consisted of 180 patients, 51.6% (males: 93), 48.3% (females: 87) (median age: 72 ± 11 years), with severe stage IV CKD (GFR: 19 mL/min/1.73m²). HDLC (+13%) was not significant, while TC (-32%), TG (-38%), LDLC (-35%), non-HDLC (-38.5%), TC/HDLC (-40%), and GFR (+2.1%) were statistically significant ($P < 0.001$). An effective but safe lipid-lowering therapy in patients with CKD, may be crucial to prevent cardiovascular events. The treatment with Dif1stat® combined with diet is to be started as soon as possible in patients with CKD in order of improving lipid and lipoprotein profile, and reducing the progression of renal damage.