SAFETY PROFILE OF STATIN-TREATED PATIENTS WITH LDL-C < 30MG/DL

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Background: While combinations of pharmacologic agents capable of reducing LDL-C well below recommended treatment guidelines are rapidly becoming available, safety and adverse event data in this setting is scarce.

Methods and Results: Of participants in the JUPITER trial with baseline LDL-C <130 mg/dL allocated to rosuvastatin 20 mg, 767 achieved at least one on-treatment LDL-C <30 mg/dL during a median follow-up of 2 years, whereas 7,387 did not. Compared with participants with LDL ≥30 mg/dL on rosuvastatin, rates of any adverse event, myalgia, nervous system disorders, creatinine kinase elevations, liver function test abnormalities, or cancer were not significantly different among participants achieving LDL-C <30 mg/dL (all P values >0.05). In exploratory analyses evaluating a broad spectrum of potential adverse effects, an increase in total renal or urinary disorders was observed (adjusted relative risk (RR) 1.49, 95% CI 1.19-1.86) which appeared to primarily reflect an increase in hematuria (RR 2.20, 95% CI 1.47-3.28). Other hypothesis generating findings of uncertain pathobiology include possible increases in psychiatric (RR 1.43, 95% CI 1.09-1.88) and hepatobiliary disorders (RR 1.68, 95% CI 1.09-2.60).

Conclusions: In this post-hoc analysis of the JUPITER trial, achieving LDL-C levels <30 mg/dL appeared safe for the major side effects known to be associated with statin therapy. However, potential adverse effects on less well described pathways were suggested, indicating that close monitoring in future trials of very low LDL-C reduction is warranted.