Median follow-up results from the ALTITUDE study

27 August 2012

Preliminary results from the Aliskiren Trial in Type 2 Diabetes Using Cardio-Renal Endpoints (ALTITUDE) do not support administration of aliskiren on top of standard therapy with renin-angiotensin-aldosterone system (RAAS) blockade in type 2 diabetics at high risk of cardiovascular and renal events, according to Professor Hans-Henrik Parving from Rigshospitalet, University of Copenhagen, Denmark. Presenting results from the study today, he said the treatment "may even be harmful".

The ALTITUDE trial was stopped prematurely in December 2011 on recommendation of the data monitoring committee after it found an increased occurrence of side effects and continuation of the study was deemed "futile". The study had been investigator initiated to determine whether use of the direct renin inhibitor aliskiren would improve prognosis by reducing fatal and non-fatal cardiovascular and renal events in type 2 diabetics at high risk of these complications. Macro- and microvascular complications of type 2 diabetes are augmented in those with concomitant kidney and/or cardiovascular disease.

ALTITUDE was an international double-blind study in 8561 subjects randomised to aliskiren 300 mg once daily or placebo on top of single RAAS blockade. The primary outcome measure was time to first event for the composite endpoint of cardiovascular death, resuscitated death, myocardial infarction, stroke, unplanned hospitalisation for heart failure, onset of end-stage renal disease or doubling of baseline creatinine.

At a median follow-up of 32 months the primary composite endpoint had occurred in 767 patients (17.9%) assigned to aliskiren and 721 (16.8%) assigned to placebo, HR for aliskiren vs. placebo 1.08 (95% CI 0.98-1.20, p=0.14). Stroke occurred in 146 (3.4%) of the aliskiren and 118 (2.7%) in placebo, HR 1.25 (95% CI 0.98-1.60, p=0.070).

Doubling of serum creatinine or end-stage renal disease was similar in the two groups and the mean reduction in albuminuria was 14% (95% CI 11-17) lower in aliskiren treated patients.

Patients in the aliskiren group experienced significantly increased serum potassium ?6 mmol/L (8.8% vs. 5.6%), and reported hypotension (12.1% vs. 8.0%).

Provided by European Society of Cardiology