Abstract: TH-PO1199

A Phase 3 Randomized Controlled Trial on the Effect of Losartan vs. Add-On Aliskiren in CKD

Session Information

- Late-Breaking Clinical Trials Posters
  November 07, 2019 | Location: Exhibit Hall, Walter E. Washington Convention Center
  Abstract Time: 10:00 AM - 12:00 PM

Category: CKD (Non-Dialysis)

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Background

The potential long-term safety and efficacy of aliskiren in non-diabetic CKD is unknown.

Methods

Non-diabetic CKD stages 3-4 patients were randomized to receive aliskiren added on to losartan (maximal tolerated dose) or losartan alone. The primary outcome was the slope of eGFR at 3 years, along with other secondary endpoints. Composite renal outcomes of doubling of baseline serum creatinine (sCr) or a 40% reduction in eGFR or incident end-stage renal disease (ESRD) or death was analysed as post-hoc analysis.

Results

After follow-up of 144 weeks in 76 subjects (Table 1), there was no difference in the slope of eGFR (Fig 1). 6 patients receiving aliskiren and 7 control patients reached the renal composite endpoint (16.2% *vs.* 17.9%, P=0.84). Cardiovascular events rate was 10.8% *vs.* 2.6%, P=0.217. Hyperkalemia rate was 18.9% *vs.* 5.1% (Fig 2).

Conclusion

Compared to losartan alone, add-on aliskiren conferred no further renoprotective benefit but increased hyperkalemia risks in non-diabetic CKD patients.

Baseline demographics

	Aliskiren Group (N=37)	Control Group (N=39)
Age, y	55.1(11.1)	55.0(9.4)
UP, g/24h	1.14(1.54)	0.77(0.81)
eGFR, ml/min/1.73 m2 BSA	31.9(9.0)	27.7(9.0)

Fig 1. Slope of eGFR. Adjusted mean of eGFR (95 CI) by mixed model adjusted for baseline, treatment, trial visit, interaction between trial visit and baseline. P (χ^2 test)=0.52 for intergroup difference.

Fig 2. Cumulative incidence of hyperkalemia with 95% CI. Adjusted HR=7.71