

### **Appropriateness and complications of the use of Aldospirone in patients treated in a Heart Failure clinic.**

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Background Aldospirone (ALDO) has been reported (RALES trial) to decrease morbidity and mortality in patients NYHA class III and IV heart failure (HF). With widespread use of ALDO in patients with HF side effects and complications were reported. To examine tolerability and safety of ALDO in clinical practice, we analyzed a cohort of patients treated by a dedicated HF team.

Methods and results Overall 157 patients with appropriate laboratory (1,3,6,12 months) and clinical follow-up (3-6 months and 1year) of at least for 1 year were included. Data of 100 patients who received ALDO were analyzed retrospectively. The incidence of the complications following ALDO use, were defined as development of the following: a) hyperkalemia with serum potassium  $\geq 5.2$  or serious hyperkalemia  $\geq 6.0$  mEq/l; b) serum creatinine  $\geq 2.0$  mg/dl; and c) hyponatremia with serum Na  $\leq 135$  mEq/l, d) hypotension and side effects including gynecomastia and abdominal pain. The baseline characteristics are presented in the table. At 1 year follow-up 6 patients developed hyperkalemia ( $K > 5.2$ , mean  $5.6 \pm 0.3$ , range 5.3-5.9 mEq/l), 4 of them had  $K > 5.5$ . Two patients developed hyponatremia ( $Na < 134$  mEq/l). Six patients stopped ALDO for: 1-gynecomastia, 2- worsening renal failure and hyperkalemia, 2- hyperkalemia (5.9 mEq/l), 1 patient due to bradycardia. There was increase in mean creatinine level at 1 year ( $1.12 \pm 0.35$  vs.  $1.21 \pm 0.38$  mg/dl,  $p = 0.02$ ), however, no significant changes were found in GFR ( $99.9 \pm 33.5$  vs.  $65.7 \pm 27.7$  mL  $\cdot$  min<sup>-1</sup>  $\cdot$  1.73 m<sup>-2</sup>,  $p = ns$ ) and potassium ( $4.5 \pm 0.4$  vs.  $4.6 \pm 0.5$  mEq/l). We found improvement of creatinine clearance by  $>10\%$  in 19 patients and worsening by  $>10\%$  in 38 patients. No significant changes in BP or HR were observed. No patient had been admitted or needed urgent treatment for ALDO side effect.

Conclusion Appropriate ALDO use and close follow-up by HF team is safe and can minimize the risk for adverse events and complications.