

### 31. Biological Survey in Patients Treated with the Combination Spironolactone and Angiotensin Converting Enzyme Inhibitor: a Population-Based Analysis

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**Background:** Since the Randomized Aldactone Evaluation Study (RALES) has demonstrated improved outcomes in patients with severe heart failure treated with low dosage of spironolactone (SPIR), angiotensin converting enzyme inhibitor (ACEI), and loop diuretic, the use of this drug combination has considerably increased. The main risks of this association consist of hyperkalaemia and decreased renal function and justify a periodic control of both kalaemia and creatininaemia to minimise the seriousness of these effects. In accordance with RALES study and recommendations of the summaries of product characteristics, this control must be at least six-monthly in patients treated for one year or more.

**Objective:** It was to evaluate the rate of patients who get a minimal biological survey among patients chronically treated with SPIR-ACEI. The association with others drugs which could worsen the risk of hyperkalaemia were also analysed in the same population.

**Methodology:** The study was a population-based analysis using computerised healthcare records of the general and agricultural health insurance system of the French Region Pays de la Loire which covered about 3 millions people. The records contain all dispensed drugs, all biological analysis and all hospitalisations which give rise to reimbursement. The study population consisted of patients older than 15 years, insured in the same office since at least one year, and chronically treated with SPIR-ACEI. A simultaneous deliverance of both drugs from one prescription, at two different times separated by a six-month period, in a same patient, defined a chronic treatment. For each patient included, kalaemia and creatininaemia determinations were searched for the six months preceding the index date (date of the last deliverance). The prescription at the index date was used to analyse others associated drugs.

**Results:** The study population consisted of 3,620 patients (M/F: 0.95, mean age: 71 ± 11 years [21-100]). In the six months preceding the index date, 1,846 patients (51%) had at least one determination of both kalaemia and creatininaemia, of whom 763 (21%) were hospitalised. Fifteen percent of patients had either kalaemia- or creatininaemia determination but not both and 34% had no biochemical control. Various drugs were co-prescribed: digitalics in 14% of patients, potassium salts in 10%, non steroidal anti-inflammatory drugs in 7% and loop diuretics in 31%.

**Conclusion:** The use conditions of drugs in general practice greatly differ from those defined in clinical trials and pose the difficult problem of the evaluation of risk/benefit ratio in general population.