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THE EFFICACY AND SAFETY OF TOLVAPTAN ON TREATING CONGESTIVE HEART FAILURE PATIENTS WITH HYPONATREMIA

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Objective To evaluate the efficacy and safety of Tolvaptan on treating congestive heart failure patients with hyponatremia.
Methods This randomised double-blind placebo–controlled trial enrolled 65 patients with congestive heart failure and hyponatremia (serum sodium concentration <130 mmol/l) in multicentre. Patients were randomised to receive either Tolvaptan 15–60 mg (n=35) daily or placebo (n=30) according to the change of serum sodium concentration. The primary end points were the change of average daily serum sodium concentration comparing the baseline with the day 4 and the day 7 respectively. Patients' weight, urine volume, sign of heart failure, heart function, blood pressure, heart rate, and all adverse events were observed to evaluate the efficacy and safety of Tolvaptan.
Results In Tolvaptan group the change in average daily serum sodium concentration from baseline to day 4 and the change from baseline to day 7 was 5.6±3.5 mmol/l and 5.9±3.5 mmol/l respectively, and in placebo group the change was 2.5±3.4 mmol/l and 2.8±3.3 mmol/l respectively. The daily serum sodium concentration increased more in Tolvaptan group than in placebo group, and the increment during the first 4 days was 3.06 mmol/l and during the first 7 days was 2.91 mmol/l. More increased daily urine volume and decreased weight in Tolvaptan group than in placebo group ($p<0.05$). The change of sign of heart failure, heart function, blood pressure and heart rate was similar between two groups ($p>0.05$). Drug related adverse events more frequently in Tolvaptan group were thirst

(11.4%) and hypernatremia (5.7%). There was 1 possible drug related serious adverse event. The patient was diagnosed as agranulocytosis during therapy period, and after treating with granulocyte colony-stimulating factor he was recovered.

Conclusion Tolvaptan could effectively increase serum sodium concentration, urine volume, and improve liquid balance in congestive heart failure patients with hyponatremia. Tolvaptan had low incidence of serious adverse event and an acceptable margin of tolerance.