

## **TERLIPRESSIN AND ALBUMIN VS MIDODRINE PLUS OCTREOTIDE AND ALBUMIN IN THE TREATMENT OF HEPATORENAL SYNDROME IN PATIENTS WITH CIRRHOSIS: RESULTS OF A CONTROLLED CLINICAL TRIAL BY THE ITALIAN ASSOCIATION FOR THE STUDY OF THE LIVER**

**Background** - Terlipressin plus albumin and midodrine plus octreotide and albumin are the two therapeutic options which are most commonly used in the treatment of HRS in patients with cirrhosis. Up to now their efficacy has never been compared in a randomized clinical trial.

**Aim** – Thus, the aim of this Italian multicenter randomized clinical trial (NCT00742339), was to compare terlipressin and albumin vs midodrine plus octreotide and albumin in the treatment of the HRS in patients with cirrhosis.

**Methods** - Forty-seven consecutive patients with cirrhosis and HRS were randomized to receive either terlipressin plus albumin (group A) or midodrine plus octreotide and albumin (group B). Patients of group A received terlipressin by continuous intravenous infusion at the initial dose of 3 mg/24 hr. In case of non response, the dose of terlipressin was progressively increased up to 12 mg/24 hr. Patients of group B received midodrine orally at the initial dose 7.5 *tid* together with octreotide at the initial dose of 100 µg subcutaneously *tid*. In case of no response the dose of midodrine and octreotide were increased to 12.5 mg *tid* and 200 µg *tid*, respectively. Patients in both groups received 20% human albumin solution at the dosage of 1 g/Kg of body weight, on first day, and then, to the dosage of 20-40 g/day. Full response to treatment was defined by a decrease in serum creatinine to a value < 1.5 mg/dl. Partial response was defined by a decrease in pretreatment peak serum creatinine > 50 % to a final value ≥ 1.5 mg/dl.

**Results** - Both groups were similar with respect to the baseline clinical and laboratory characteristics. Improvement of renal function was significantly more frequent in patients of Group A (76%) than in patients of Group B (27.3%),  $p < 0.01$ . In particular, a full response to treatment was observed in 14 of 25 (56 %) patients of Group A and in 2 of 22 patients (9%) of Group B,  $p < 0.01$ .

**Conclusions** - Terlipressin plus albumin is more effective in the treatment of HRS in patients with cirrhosis.

According to these results we have decided to stop the trial.