Background and Aims

- Patients with severe alcohol-associated hepatitis (AAH) often have liver cirrhosis and, consequently, may develop acute kidney injury (AKI)\(^1\).
- Hepatorenal syndrome (HRS) is a potentially reversible form of AKI\(^1\).
- Terlipressin is the first and only treatment for patients with HRS-AKI approved by the United States Food and Drug Administration and is more likely to be of clinical benefit for those patients with acute-on-chronic liver failure (ACLF) grade 0–2\(^2\).
- In this study, we determined the effect of terlipressin on renal function among patients with AAH and HRS-AKI who had ACLF grades 0–2.

Methods

- Data were pooled from a subpopulation from 3 Phase III studies (OT-0401\(^1\), REVERSE\(^2\), and CONFIRM\(^3\)) of patients with AAH, HRS-AKI, and ACLF grades 0–2 who received terlipressin or placebo (Figure 1).

Results

- The study population with AAH, HRS-AKI, and ACLF grades 0–2 included 84 patients in the terlipressin arm and 60 patients in the placebo arm.
- The incidence of HRS reversal was significantly higher in the terlipressin arm versus the placebo arm (44.1% vs 11.7%, p < 0.001 respectively, Figure 2).
- Change in renal function from baseline to the end of treatment
  - For the 141 patients evaluated, SCR decreased from baseline to the EOT in both treatment arms (Figure 3).
  - The decrease in SCR from baseline to EOT was significantly larger in the terlipressin vs placebo arms in the analyses with and without interaction between treatment and day.
  - The difference in LS mean change in SCR between terlipressin and placebo was -0.64 mg/dL without interaction and -0.76 mg/dL with interaction (both p < 0.001).

Conclusions

- Terlipressin significantly improved renal function and increased HRS reversal among patients with AAH and HRS-AKI who had ACLF grades 0–2, compared with placebo, and was associated with fewer deaths by Day 60.
- Although SCR levels decreased significantly more in the terlipressin arm (versus placebo) from baseline to the EOT, the incidence of RRT in this population was similar in both treatment arms.
- HRS reversal and improvement in renal function provide patients with AAH time to recover, receive other treatment, or achieve eligibility for liver transplantation\(^7\).

References

3. OT-0401-CONFIRM. Terlipressin. A full prescribing information.

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