Prednisolone with vs without pentoxifylline and survival of patients with severe alcoholic hepatitis: A randomized clinical trial

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Résumé en anglais	Importance Prednisolone or pentoxifylline is recommended for severe alcoholic hepatitis, a life-threatening disease. The benefit of their combination is unknown.Objective To determine whether the addition of pentoxifylline to prednisolone is more effective than prednisolone alone.Design, Setting, and Participants Multicenter, randomized, double-blind clinical trial conducted between December 2007 and March 2010 in 1 Belgian and 23 French hospitals of 270 patients aged 18 to 70 years who were heavy drinkers with severe biopsy-proven alcoholic hepatitis, as indicated by recent onset of jaundice in the prior 3 months and a Maddrey score of at least 32. Duration of follow-up was 6 months. The last included patient completed the study in October 2010. None of the patients were lost to follow-up for the main outcome.Intervention Patients were randomly assigned to receive either a combination of 40 mg of prednisolone once a day and 400 mg of pentoxifylline 3 times a day (n=133) for 28 days, or 40 mg of prednisolone and matching placebo (n=137) for 28 days.Main Outcomes and Measures Six-month survival, with secondary end points of development of hepatorenal syndrome and response to therapy based on the Lille model, which defines treatment nonresponders after 7 days of initiation of treatment.Results In intention-to-treat analysis, 6-month survival was not different in the pentoxifylline-prednisolone and placebo-prednisolone groups (69.9% [95% CI, 62.1%-77.7%] vs 69.2% [95% CI; 61.4%-76.9%], P = .91), corresponding to 40 vs 42 deaths, respectively. In multivariable analysis, only the Lille model and the Model for End-Stage Liver Disease score were independently associated with 6-month survival. At 7 days, response to therapy assessed by the Lille model was not significantly different between the 2 groups (Lille model score, 0.41 [95% CI, 0.36-0.46] vs 0.40 [95% CI, 0.35-0.45], P = .80). The probability of being a responder was not different in both groups (62.6% [95% CI, 53.9%-71.3%] vs 61.9% [95% CI, 53.7%-70.3%], P = .91). The cumulative incidence of hepatorenal syndrome at 6 months was not significantly different in the pentoxifylline-prednisolone and the placebo-prednisolone groups (8.4% [95% CI, 4.8%-14.8%] vs 15.3% [95% CI, 10.3%-22.7%], P = .07).Conclusion and Relevance In patients with alcoholic hepatitis, 4-week treatment with pentoxifylline and prednisolone, compared with prednisolone alone, did not result in improved 6-month survival. The study may have been underpowered to detect a significant difference in incidence of hepatorenal syndrome, which was less frequent in the group receiving pentoxifylline.
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