Copenhagen, May 25, 2018

The effect of plasma exchange and the effect of reduced-dose oral glucocorticoids during remission induction in severe ANCA-associated vasculitis

Embargo until: May, 25; 13:15!

Background: Whether plasma exchange reduces the risk of end-stage renal disease or death in anti-neutrophil cytoplasm antibodies (ANCA)-associated vasculitis is uncertain. Also uncertain is whether lower doses of oral glucocorticoids reduce the risk of infection without increasing the risk of end-stage renal disease or death.

Methods: We performed a, 2-by-2 factorial randomized controlled trial to separately evaluate plasma exchange and two different regimens of oral glucocorticoids in patients with severe ANCA-associated vasculitis. Participants were randomly assigned to 7 treatments of plasma exchange or no plasma exchange. Participants were also randomly assigned to either a reduced-dose regimen that <60% of the cumulative oral glucocorticoid dose or a standard regimen by 6 months or the standard regimen. All patients received immunosuppression. Patients were followed for up to 7 years for the primary composite outcome of death from any cause or end-stage renal disease.

Results: Amongst 702 participants, the primary outcome occurred in 28% of patients allocated to plasma exchange compared to 31% in the no plasma exchange group (hazard ratio 0.86, 95% confidence interval [CI] 0.65 to 1.13; p=0.27). The primary outcome occurred in 28% of patients in the reduced glucocorticoid group and 26% in the standard glucocorticoid group (absolute risk difference 2.3%, 90% CI -3.4% to 8.0%; met non-inferiority hypothesis). Serious infections in the first year occurred less often in the reduced glucocorticoid group compared to the standard group (incidence rate ratio 0.70, 95% CI 0.52 to 0.94; p=0.02).

Conclusions: Plasma exchange did not reduce the risk of end-stage renal disease or death. Compared to a standard dose, reduced glucocorticoids did not substantially increase the risk of death or end-stage renal disease and resulted in fewer serious infections.
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