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## Lactate Clearance vs Central Venous Oxygen Saturation as Goals of Early Sepsis Therapy: A Randomized Clinical Trial

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### Abstract:

Context Goal-directed resuscitation for severe sepsis and septic shock has been reported to reduce mortality when applied in the emergency department. Objective To test the hypothesis of noninferiority between lactate clearance and central venous oxygen saturation (ScvO<sub>2</sub>) as goals of early sepsis resuscitation. Design, Setting, and Patients Multicenter randomized, noninferiority trial involving patients with severe sepsis and evidence of hypoperfusion or septic shock who were admitted to the emergency department from January 2007 to January 2009 at 1 of 3 participating US urban hospitals. Interventions We randomly assigned patients to 1 of 2 resuscitation protocols. The ScvO<sub>2</sub> group was resuscitated to normalize central venous pressure, mean arterial pressure, and ScvO<sub>2</sub> of at least 70%; and the lactate clearance group was resuscitated to normalize central venous pressure, mean arterial pressure, and lactate clearance of at least 10%. The study protocol was continued until all goals were achieved or for up to 6 hours. Clinicians who subsequently assumed the care of the patients were blinded to the treatment assignment. Main Outcome Measure The primary outcome was absolute in-hospital mortality rate; the noninferiority threshold was set at  $\Delta$  equal to  $-10\%$ . Results Of the 300 patients enrolled, 150 were assigned to each group and patients were well matched by demographic, comorbidities, and physiological features.

There were no differences in treatments administered during the initial 72 hours of hospitalization. Thirty-four patients (23%) in the ScvO2 group died while in the hospital (95% confidence interval [CI], 17%-30%) compared with 25 (17%; 95% CI, 11%-24%) in the lactate clearance group. This observed difference between mortality rates did not reach the predefined –10% threshold (intent-to-treat analysis: 95% CI for the 6% difference, –3% to 15%). There were no differences in treatment-related adverse events between the groups. Conclusion Among patients with septic shock who were treated to normalize central venous and mean arterial pressure, additional management to normalize lactate clearance compared with management to normalize ScvO2 did not result in significantly different in-hospital mortality.

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