Surviving Sepsis Campaign Responds to ProCESS Trial
Updated 19 May 2014

The Surviving Sepsis Campaign (SSC) has received many inquiries regarding the recent publication of the Protocol-Based Care for Early Septic Shock (ProCESS) trial's effect on the continuing activities of the Campaign. (1)

(1) The ProCESS trial reflects the consensus that early diagnosis of septic shock is essential. Notably, all groups in the study received on average more than 2 liters of fluid prior to randomization and more than 75% received antibiotics prior to randomization--both elements of the 3-hour Surviving Sepsis Campaign bundle. (2) The editorial accompanying the ProCESS study highlights these points. (3)
(2) The 18% mortality rate in the "usual care" arm of ProCESS illustrates a dramatic change in the management and outcomes of patients with septic shock. (1) In comparison, septic shock mortality was 46.5% in the 2001 early goal-directed therapy trial by Rivers. (4)
(3) Given the remarkably low mortality rate in the control arm of ProCESS, and the pending results of 2 large ongoing trials (the Australian Resuscitation In Sepsis Evaluation Randomised Controlled Trial [ARISE] and The Protocolised Management in Sepsis Trial [ProMISe]), the SSC will determine any appropriate revisions to the bundle elements when these study results are available.
(4) ProCESS does not address the protocolized management of patients with severe sepsis without septic shock, a group of patients for whom early detection and treatment remain critical. The aggressive protocolized management of these patients who do not yet have shock has likely lowered severe sepsis and septic shock mortality since the inception of the SSC. The recently formed Society of Critical Care Medicine/Society of Hospital Medicine (SCCM/SHM) Early Diagnosis and Treatment of Severe Sepsis on the Hospital Floors Collaboratives will focus in large part on this population. Further, the ProCESS results have no impact on the 3-hour bundle, which is the primary focus for the Collaboratives.
(5) Regarding the SSC 6-hour bundle (2):
    a. A companion paper appears to support a mean initial arterial pressure (MAP) target of 65 mm Hg, which is one of the indicators in this bundle. (5)
    b. The ProCESS paper does not address repeating lactate measures in patients with elevated lactate while literature supports doing so. (6,7)
    c. When measured, the first $ScvO_2$ was 71 ± 13%, which is another of the indication of the bundle.
    d. The majority of the patients in the usual care (56.5%) and protocol-based standard care arms (57.9%) of ProCESS had central lines inserted as part of clinical care. (1) The 6-hour bundle currently asks only that central venous pressure (CVP) be measured and that a venous blood gas be sent from that line to obtain the central venous oxygen saturation ($ScvO_2$). SSC recognizes that alternate means of obtaining results exist and will address specific ways of including those data in future iterations of the quality improvement database.

The Surviving Sepsis Campaign looks forward to additional evidence regarding the optimal resuscitation of patients with severe sepsis and septic shock.

References:

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