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1-h Bundle and Mortality in Patients With Suspected Sepsis

Sepsis and septic shock, caused by a dysregulated response to infection, affect nearly 50 million people globally, resulting in approximately 11 million deaths. Early identification and management, including source control, antimicrobial therapy, and fluid resuscitation, are associated with reduced mortality. The Surviving Sepsis Campaign (SSC) recommends a sepsis bundle that includes early lactate measurement, microbiological culture, antibiotic treatment, and fluid resuscitation for patients with hypotension or lactate levels ≥ 4 mmol/L. Early antibiotic administration within the first hour has improved outcomes, but early fluid resuscitation has not.

The 2018 SSC guidelines recommend initiating the sepsis bundle within 1 hour of triage. However, this 1-h bundle faces challenges in routine emergency department practice due to the difficulty of confirming a sepsis diagnosis quickly. The 2021 SSC guidelines recommended against using the quick sequential organ failure assessment (qSOFA) alone for sepsis screening, but a qSOFA score ≥ 2 can be a criterion for initiating the sepsis bundle.

Due to ongoing debate and insufficient evidence for the 1-hour bundle, the 2021 SSC recommended using a 3-hour bundle. The 1BED trial is a multicentre trial designed to evaluate whether the 1-hour bundle, compared to usual care, reduces 28-day in-hospital mortality for patients with suspected sepsis in the emergency department. This bundle includes lactate measurement, blood culture, administration of broad-spectrum antibiotics, and administration of 30 mL/kg crystalloid fluid for hypotension or lactate levels ≥ 4 mmol/L.

The trial was conducted in 23 emergency departments in France and Spain. Adult patients with Sepsis-3 criteria, a quick SOFA score ≥ 2, or lactate > 2 mmol/L were eligible. The intervention involved implementing the 1-hour sepsis bundle. The primary outcome measured was in-hospital mortality truncated at 28 days. Secondary outcomes included fluid resuscitation volume at 24 hours, acute heart failure at 24 hours, SOFA score at 72 hours, ICU length of stay, days on mechanical ventilation or renal replacement therapy, vasopressor-free days, unnecessary antibiotic administration, and mortality at 28 days.

The study included 872 patients - 387 (44.4%) in the intervention group and 485 (55.6%) in the control group. The median SOFA score was 3. The median time to antibiotic administration was 40 minutes in the intervention group versus 113 minutes in the control group (difference –73 minutes. The intervention group had a higher rate, volume, and shorter time to fluid resuscitation within 3 hours. In-hospital deaths were 47 (12.1%) in the intervention group compared to 61 (12.6%) in the control group. There were no significant differences between the groups for other secondary endpoints.

Overall, these findings show that implementing the 1-hour sepsis bundle did not significantly improve in-hospital mortality among patients with suspected sepsis in the emergency department. However, the trial may not have had enough statistical power to detect a clinically significant difference.

Source: Intensive Care Medicine

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