

Patients with septic shock benefit from a combination of hydrocortisone-fludrocortisone therapy

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Sepsis occurs in approximately 1.7 million hospitalizations in the U.S. with in more than a third of hospitalizations resulting in death. Patients



with septic shock benefit from steroid medications (corticosteroids) to reduce shock duration and potentially decrease the chance of dying. However, it is unclear if one of the two main frequently used steroid regimens (hydrocortisone alone versus hydrocortisone and fludrocortisone together) is better than the other regimen.

A new study in *JAMA Internal Medicine* by researchers from Boston University Chobanian & Avedisian School of Medicine shows that <u>patients</u> receiving a combination of hydrocortisone and fludrocortisone had lower death rates and discharge to hospice compared to those who only received hydrocortisone.

"Our results provide robust evidence that one steroid regimen is superior to the other regimen and, in absence of further clinical trials, directly inform the choice of steroids in patients with <u>septic shock</u>," said corresponding author Nicholas Bosch MD, MSc, assistant professor of medicine at the School.

To compare the effectiveness of both treatment regimens, the researchers used a large multicenter database made up of approximately 25% of U.S. hospitalizations and an observational study design that was intended to mimic a randomized clinical trial to compare the outcome of death or discharge to hospice between patients who received the regimen of hydrocortisone and fludrocortisone to those who received hydrocortisone alone.

They found that the regimen of hydrocortisone and fludrocortisone together was superior to hydrocortisone alone; on average, patients who received hydrocortisone and fludrocortisone died or were discharged to hospice approximately four percent less of the time compared to patients who received hydrocortisone alone.

According to the researchers, these findings may change <u>clinical practice</u>



. "It is possible that guideline recommendations, which currently suggest to start hydrocortisone alone, will change as a result of this study," said Bosch, who also is a pulmonologist at Boston Medical Center.

The researchers believe this study has additional implications due to its use of target trial emulation, a modern approach to comparative effectiveness studies using observational data ("big" electronic health record data) that is designed to mimic a prospective randomized controlled trial. "These target trial emulations are likely to be seen with increasing frequency going forward as "big data" becomes more and more available and have the potential to answer complex clinical questions in situations where a <u>randomized clinical trial</u> may not be feasible," Bosch said.

More information: Nicholas A. Bosch et al, Comparative Effectiveness of Fludrocortisone and Hydrocortisone vs Hydrocortisone Alone Among Patients With Septic Shock, *JAMA Internal Medicine* (2023). DOI: 10.1001/jamainternmed.2023.0258

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