ICU
MANAGEMENT & PRACTICE

LIVES2018: Clinical effects of proton-pump inhibitor prophylaxis in ICU

Critically ill patients are at risk for stress-related gastrointestinal bleeding, which is associated with adverse outcomes. The Stress Ulcer Prophylaxis in the Intensive Care Unit (SUP-ICU) trial addressed the value of using the proton-pump inhibitor pantoprazole as prophylaxis for gastrointestinal bleeding in the ICU. The results were presented at the European Society of intensive Care Medicine congress, LIVES2018, in Paris.

In this trial involving adult patients who were admitted to the ICU for an acute condition and were at risk for gastrointestinal bleeding, researchers found no significant differences between pantoprazole and placebo with regard to either 90-day mortality or the number of clinically important events. The findings are published online in The New England Journal of Medicine.

Proton-pump inhibitors (PPIs) have not been approved by the U.S. Food and Drug Administration as prophylaxis for stress ulcers. Concerns have been raised about adverse effects associated with this class of drugs, including the risk of Clostridium difficile infection, pneumonia, and myocardial ischaemia, which may counterbalance their potential benefits.

SUP-ICU was multicentre, parallel-group, blinded trial that included a total of 3,298 patients, who were randomly assigned to receive 40 mg of intravenous pantoprazole (n = 1,645) and placebo (n = 1,653) daily during the ICU stay. The patient population was at high risk for clinically important gastrointestinal bleeding because of a history of liver disease, coagulopathy, shock, treatment with anticoagulant agents, renal replacement therapy, or mechanical ventilation that was expected to last for more than 24 hours.

Mette Krag, MD, PhD and co-researchers found no significant difference between the pantoprazole group and the placebo group in the rate of the primary outcome of death by 90 days after randomisation (31.1% and 30.4%, respectively). Similarly, no difference was found with regard to the secondary, unvalidated composite outcome of clinically important gastrointestinal bleeding, new-onset pneumonia, C. difficile infection, or acute myocardial ischaemia (21.9% in the pantoprazole group and 22.6% in the placebo group). The number of patients with infections or serious adverse reactions and the percentage of days alive without life support within 90 days were similar in the two groups.

"The results of this trial apply only to patients who meet the entry criteria used in the trial, including a high risk of gastrointestinal bleeding," Dr. Krag and co-authors note.

In a linked commentary, Alan Barkun, MD, CM (Divisions of Gastroenterology and Clinical Epidemiology, McGill University Health Centre, Montreal General Hospital) and Marc Bardou, MD, PhD (Centre d'Investigation Clinique 1432 and Division of Gastroenterology, Centre Hospitalier Universitaire Dijon–Bourgogne, France) write:

"In our view, the take-home message from this trial is that, given the low incidence of clinically important upper gastrointestinal bleeding in the ICU, prophylaxis with a PPI, if initiated, should be reserved for seriously ill patients who are at high risk for this complication."

Drs. Barkun and Bardou emphasise the need for additional data to: 1) determine the clinical effects of prophylaxis for gastrointestinal bleeding in the ICU, especially in groups of patients who are at very high risk for this complication; and 2) to quantify any protective or harmful effects attributable to the co-administration of enteral nutrition.

Source: The New England Journal of Medicine
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