Role of Proton Pump Inhibitor as Stress Ulcer Prophylaxis in Sick Children: A Randomized Controlled Trial

Original Article

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ABSTRACT

OBJECTIVES

To evaluate the efficacy of intravenous pantoprazole as a stress ulcer prophylaxis in sick children to prevent gastrointestinal (GI) bleeding.

METHODS

A randomized controlled trial included children aged one-month to 18 years requiring intensive care. Participants were randomly assigned to receive intravenous pantoprazole or a placebo (normal saline) daily. The primary outcome was the incidence of GI bleeding (clinically significant or overt). Secondary outcomes were the median time of onset of GI bleeding, incidence of ventilator-associated pneumonia (VAP), duration of hospitalization, organ dysfunction scores, and all-cause mortality.

RESULTS

A total of 151 and 150 children were allocated to group A (pantoprazole) and group B (placebo), respectively. No significant difference was observed in the incidence of GI bleeding between the groups (group A: 21/151 vs group B: 19/150 [RR (95% CI) 1.03 (0.18, 5.82), P = 0.985]. Comparable results were observed for clinically significant GI bleeding (1.3% vs 0.6%; RR (95% CI) 0.54 (0.21, 1.28); P = 0.653 and overt GI bleeding [12.6% vs 12%; RR (95% CI) 0.98 (0.39, 2.23); P value = 0.313]. On multivariate analysis, there was a reduced incidence of GI bleeding in children with coagulopathy in pantoprazole group (n = 29) as compared to placebo (n = 25) [RR (95%CI) 0.52 (0.32, 0.87); P = 0.022].

CONCLUSION

Among critically ill children, pantoprazole prophylaxis did not reduce the incidence of gastrointestinal bleeding, although, a notable decrease in gastrointestinal bleeding was observed in children with coagulopathy.

Keywords: Critically ill children · PPI · Stress ulcer prophylaxis · Pantoprazole · GI bleeding

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