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Do we need to administer fludrocortisone in addition to hydrocortisone for adult patients with septic shock? A Bayesian network meta-analysis of randomized controlled trials and observational study with target trial emulation

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 June 2023 and was last updated on 30 July 2023.

INTRODUCTION

Review question / Objective P: adults withseptic shcok; I: low dose hydrocortisone plus fludrocortisone, or hydrocortisone alone; C: placebo; O: short-term mortality and major adverse events.

Condition being studied Critical-illness-related corticosteroid and mineralocorticoid insufficiency is becoming increasingly concerning among intensivists. The International Guideline of Surviving Sepsis Campaign weakly recommended the use of hydrocortisone at a dose of 200 mg/day in adults with septic shock who require vasopressor therapy. The Japanese Clinical Practice Guidelines issued a similar announcement with the additional suggestion of the concomitant administration of hydrocortisone and fludrocortisone to such patients.1 This weak recommendation was based on a meta-analysis of two randomized controlled trials (RCTs). Further examination is needed to evaluate the use of fludrocortisone in adults with septic shock.

METHODS

Participant or population Adults with septic shcok.

Intervention Low dose hydrocortisone plus fludrocortisone, or hydrocortisone alone.

Comparator Placebo.

Study designs to be included RCTs and observational studies using target trial emulation (TTE).

Eligibility criteria Inclusion criteria: only adults with septic shock treated with low dose of hydrocortisone plus fludrocortisone or hydrocortisone alone.

Information sources PubMed, Embase, Cochrane liberary, clinicaltrials.gov, Google Scholar, references in rpevious published systematic reviews.

Main outcome(s) We prioritized short-term mortality outcomes by extracting data on 28- or 30-day mortality as the primary measure, followed by in-hospital mortality or ICU mortality.

Additional outcome(s) Major adverse events, including gastroduodenal bleeding, superinfection, and hyderglycemia.

Quality assessment / Risk of bias analysis RoB 2.o for RCTs; ROBINS-I for non-RCTs.

Strategy of data synthesis We employed a Bayesian approach, deemed more suitable for formulating guidelines, utilizing Microsoft-Excel-based NetMetaXL V.1.6.1 to perform WinBUGS 1.4.3 with 10000 simulations and applied a random-effects model with informative priors.

Subgroup analysis Focusing on RCTs using a specific dose of 200 mg/day of intravenous hydrocortisone.

Sensitivity analysis Bayesian random-effects model using vague priors was applied as sensitivity analysis.

Other relevant information The certainty of the evidence in primary outcome was evaluated according to the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) Working Group guidelines for network meta-analysis.

Country(ies) involved Taiwan.

Keywords Septic shock, hydrocortisone, fludrocortisone.

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