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Hydrocortisone for the Treatment of Acute Respiratory Distress Syndrom: A Systematic Review and Meta-Analysis

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Astract
Acute respiratory distress syndrome (ARDS) remains associated with substantial morbidity and mortality, while the efficacy and safety of hydrocortisone in its treatment remain uncertain. This study aimed to evaluate the efficacy and safety of hydrocortisone in patients with ARDS through a systematic review and meta-analysis of randomized controlled trials (RCTs). PubMed, the Cochrane Library, and the China National Knowledge Infrastructure (CNKI) database were searched for eligible studies published during the 20-year period preceding June 1, 2024. The review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, and the methodological quality of the included studies was assessed using the Cochrane risk-of-bias tool. Statistical analyses were performed using Review Manager (RevMan) version 5.3, with treatment effects expressed as odds ratios (ORs) and corresponding 95% confidence intervals (CIs). Four RCTs involving 566 participants were included in the meta-analysis. Hydrocortisone treatment was associated with significantly lower overall mortality (OR = 0.60; 95% CI: 0.42–0.87). However, the reduction in 28-day mortality was not statistically significant (OR = 0.70; 95% CI: 0.45–1.08). No statistically significant differences were observed between treatment groups in the incidence of nosocomial infections or gastrointestinal bleeding. These findings suggested a potential survival benefit associated with hydrocortisone treatment in patients with ARDS. Nevertheless, variations in follow-up duration, clinical heterogeneity, and the limited number of included trials and participants restricted the strength and generalizability of the evidence. Hydrocortisone may have a beneficial role as an adjunctive treatment for ARDS; however, the available findings did not demonstrate a consistent improvement in short-term survival or establish definitive safety. Larger, adequately powered multicenter RCTs using standardized treatment regimens, consistent outcome definitions, and comprehensive adverse-event monitoring are warranted to clarify the efficacy and safety of hydrocortisone in ARDS management.

INTRODUCTION

Acute respiratory distress syndrome (ARDS) is a severe clinical syndrome characterized by acute hypoxemic respiratory failure, bilateral pulmonary opacities, and inflammatory lung injury, often involving diffuse alveolar damage, and is associated with substantial morbidity and mortality (Bellani et al., 2016; Matthay et al., 2024; Meyer et al., 2021; Ranieri et al., 2012). Despite advances in intensive care management, mortality remains high, with reported rates varying according to disease severity, patient characteristics, and clinical setting (Bellani et al., 2016; Kurahashi, 2022; Meyer et al., 2021).

No single pharmacological intervention has been universally established as an effective treatment for all patients with ARDS (Chaudhuri et al., 2024; European Medicines Agency, 2025; Grasselli et al., 2023; Papazian et al., 2019). Consequently, ARDS management continues to rely on evidence-based supportive care and the evaluation of adjunctive therapies that may improve clinical outcomes (Meyer et al., 2021). Corticosteroids have been extensively investigated because of their anti-inflammatory and immunomodulatory properties, including the suppression of proinflammatory cytokine production and modulation of nuclear factor kappa B (NF-κB) signaling pathways (Chaudhuri et al., 2024; Kuperminc et al., 2023). Among these agents, hydrocortisone has attracted attention because of its glucocorticoid and mineralocorticoid activities and its established clinical use in selected critically ill populations. Nevertheless, its efficacy and safety specifically in patients with ARDS require further evaluation (Chang et al., 2022; Ichikado et al., 2023; Qadir et al., 2024).

Several randomized controlled trials (RCTs) have investigated the potential benefits of hydrocortisone for pulmonary function and clinical outcomes, particularly among patients with sepsis-associated ARDS (Annane et al., 2006; Confalonieri et al., 2005; Dequin et al., 2020; Tongyoo et al., 2016). However, the findings have been inconsistent, and uncertainty remains regarding its effects on survival and treatment-related complications (Chang et al., 2022; Li et al., 2024; Wu et al., 2024). Therefore, a systematic evaluation of the available randomized evidence is necessary to clarify the efficacy and safety of hydrocortisone in patients with ARDS.

The international burden of ARDS was demonstrated by the LUNG SAFE study conducted by Bellani et al. (2016), which involved 459 intensive care units across 50 countries. Hospital mortality was 34.9% among patients with mild ARDS, 40.3% among those with moderate ARDS, and 46.1% among those with severe ARDS. These findings highlighted the substantial mortality associated with ARDS and the relationship between disease severity and clinical outcomes. Although these estimates reflected a specific historical cohort rather than current global mortality rates, they provided important multinational evidence supporting the need for continued improvements in ARDS management.

Within this clinical context, corticosteroid therapy has received increasing attention as a potential adjunctive treatment. The 2024 American Thoracic Society clinical practice guideline (Qadir et al., 2024) conditionally recommended systemic corticosteroids for patients with ARDS based on moderate-certainty evidence. However, the guideline also acknowledged substantial variation in corticosteroid selection, treatment initiation, dosage, and duration across clinical trials. Accordingly, uncertainty remains not only regarding the benefits of corticosteroid therapy but also concerning the specific treatment regimens that may provide the most favorable balance between efficacy and safety across heterogeneous ARDS populations.

Hydrocortisone warrants particular consideration because it has been investigated in patients with early sepsis-associated ARDS, in whom pulmonary injury frequently occurs alongside systemic inflammation and circulatory dysfunction. In this setting, improvements in oxygenation, pulmonary function, or organ support requirements may indicate potentially beneficial physiological responses. Nevertheless, such improvements do not necessarily translate into increased survival. Therefore, evaluating hydrocortisone requires careful consideration of patient-centered outcomes, particularly mortality, alongside treatment-

associated adverse events. This distinction is essential when interpreting clinical trials that report improvements in physiological parameters without demonstrating statistically significant reductions in mortality.

Direct randomized evidence illustrates this uncertainty. Tongyoo et al. (2016) randomized 197 patients with early sepsis-associated ARDS to receive hydrocortisone or placebo. Hydrocortisone treatment improved oxygenation and lung injury scores; however, the trial did not demonstrate a statistically significant survival benefit. The investigators also reported no statistically significant difference in the time to discontinuation of vital organ support. These findings suggested that hydrocortisone might improve certain physiological indicators of pulmonary recovery without necessarily improving major clinical outcomes. This discrepancy provided a rationale for synthesizing randomized evidence to assess whether the observed physiological benefits were accompanied by clinically meaningful survival advantages.

Broader evidence has supported the potential benefits of corticosteroid therapy while emphasizing the need to distinguish class-level findings from agent-specific effects. Chaudhuri et al. (2021) included 18 randomized controlled trials involving 2,826 patients in a systematic review and meta-analysis of corticosteroid treatment for COVID-19-related and non-COVID-19 ARDS. Their mortality analysis, which included 16 trials and 2,740 patients, indicated a probable reduction in mortality, with a risk ratio (RR) of 0.82 and a 95% confidence interval (CI) of 0.72–0.95. Although subgroup analyses suggested broadly consistent findings across corticosteroid types, this pooled estimate did not independently establish the magnitude or certainty of the treatment effect attributable specifically to hydrocortisone. Consequently, hydrocortisone-specific evidence must be examined separately before drawing conclusions regarding its clinical effectiveness.

The principal research gap concerns the precision, consistency, and clinical applicability of evidence specifically addressing hydrocortisone in patients with ARDS. Available trials differ in patient populations, treatment protocols, clinical severity, and outcome assessment periods, potentially contributing to variations in reported treatment effects. Reflecting these uncertainties, the 2024 Society of Critical Care Medicine focused guideline update (Chaudhuri et al., 2024) did not recommend a specific corticosteroid agent, dosage, or treatment duration for ARDS. These limitations highlighted the need for a focused synthesis that distinguished evidence supporting systemic corticosteroids as a therapeutic class from evidence directly evaluating hydrocortisone in patients with established ARDS.

Addressing this research gap is clinically important because therapeutic decisions must consider both the substantial mortality associated with ARDS and the uncertainties surrounding optimal corticosteroid treatment. Potential survival benefits should be evaluated alongside adverse events, including nosocomial infections and gastrointestinal bleeding, to provide a balanced assessment of treatment efficacy and safety. Furthermore, mortality outcomes measured at different follow-up periods should be analyzed separately because they may reflect different phases of critical illness and recovery. A comprehensive evaluation of these outcomes could improve the interpretation of hydrocortisone's potential clinical benefits and limitations.

Against this background, the present systematic review and meta-analysis aimed to evaluate the efficacy and safety of hydrocortisone compared with placebo or standard care in

patients with ARDS. The specific objectives were to estimate its association with all-cause mortality at the reported follow-up periods, assess 28-day mortality separately, and evaluate the reported incidence of nosocomial infections and gastrointestinal bleeding. The study's principal contribution was its specific focus on hydrocortisone rather than combining different corticosteroid agents into a single treatment category. Accordingly, the synthesis focused on randomized controlled trials involving patients with confirmed ARDS or trials from which ARDS-specific subgroup data could be extracted separately.

By synthesizing findings from eligible randomized controlled trials, this study sought to clarify the magnitude, consistency, and limitations of the available evidence concerning hydrocortisone treatment in ARDS. Its scientific contribution was to refine the interpretation of broader corticosteroid evidence by examining the outcomes associated with a specific therapeutic agent. From a clinical perspective, the findings were expected to provide a clearer basis for evaluating potential survival benefits against reported adverse events, while acknowledging limitations related to trial heterogeneity and statistical precision. The review also aimed to identify priorities for future research, particularly adequately powered multicenter trials employing standardized treatment protocols, consistent mortality endpoints, and comprehensive adverse-event monitoring. Ultimately, the study sought to support evidence-based clinical decision-making and inform further investigations into the role of hydrocortisone in ARDS management.

METHOD

This systematic review and meta-analysis used secondary data from published clinical studies; therefore, institutional ethics committee approval was not required. The review was registered in the International Prospective Register of Systematic Reviews (PROSPERO; registration number CRD42024576362) and conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. A systematic literature search was performed in PubMed, the Cochrane Library, and the China National Knowledge Infrastructure (CNKI) database to identify studies published during the 20-year period ending June 1, 2024. The search incorporated the terms "hydrocortisone" and "acute respiratory distress syndrome" or "ARDS," with Boolean operators adapted to the requirements of each database. No language restrictions were applied, and the search was limited to studies involving human participants.

Eligible studies were identified according to the Population, Intervention, Comparator, Outcomes, and Study Design (PICOS) framework. The population comprised patients diagnosed with acute respiratory distress syndrome (ARDS), the intervention was hydrocortisone treatment, and the comparator was placebo or standard supportive care, as defined in the individual trials. The outcomes of interest included mortality and treatment-related adverse events. Only randomized controlled trials (RCTs) were eligible for inclusion. Nonrandomized studies, trials with insufficient outcome data, and publications for which the full text was unavailable were excluded. Two reviewers (GAS and AP) independently screened titles and abstracts and subsequently assessed potentially eligible full-text articles. Disagreements regarding study eligibility were resolved through consultation with a third reviewer. Data were extracted using a standardized form that recorded study characteristics,

publication year, sample size, participant age, hydrocortisone dosage, treatment duration, follow-up period, and reported outcomes.

Two reviewers independently assessed the risk of bias in the included studies using the Cochrane risk-of-bias assessment tool, with disagreements resolved through consultation with a third reviewer. Statistical analyses were performed using Review Manager (RevMan) version 5.3. Statistical heterogeneity was assessed using Cochran's chi-square (χ^2) test and the I^2 statistic, with a χ^2 test p-value below 0.10 and an I^2 value of at least 50% considered indicators of potentially important heterogeneity. A fixed-effect meta-analysis model was used when heterogeneity was considered low, based on an I^2 value below 50% and a χ^2 test p-value greater than 0.10. When these indicators produced conflicting results, model selection was guided primarily by the χ^2 test, although its limited statistical power in meta-analyses involving few studies was acknowledged. Dichotomous outcomes were pooled using the Mantel–Haenszel method, and treatment effects were expressed as odds ratios (ORs) with corresponding 95% confidence intervals (CIs).

RESULTS AND DISCUSSION

Results of the research

We conducted a comprehensive search of the PubMed, Cochrane Library, and CNKI databases for a period of 20 years until June 1, 2024, and eliminated any duplicate entries. After this process, we reviewed a total of 368 articles and identified 293 papers with probable relevance. We eliminated 226 papers during the screening process by considering the titles and full-text publications for their relevance. In addition, 46 papers were excluded based on the specified criteria for inclusion and exclusion, and 17 articles were excluded for valid reasons. This meta-analysis comprised a quantitative combination of four randomized controlled trial (RCT) research publications published between 2004 and 2024. Figure 1 illustrates the flowchart depicting the procedure of selecting participants for this study.

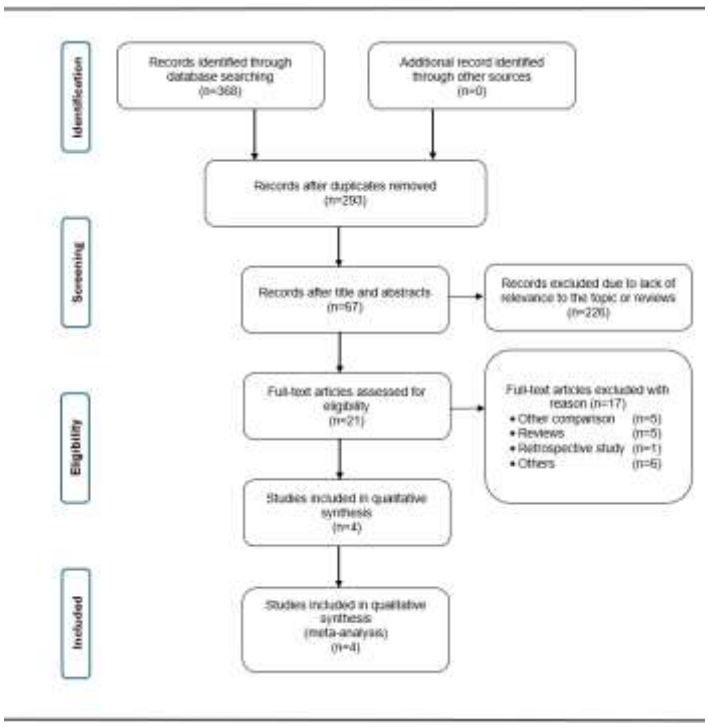


Figure 1. Flowchart of the selection process

Description of the study's attributes

Four randomized clinical trials (RCTs) examined a combined total of 566 participants. The sample sizes varied from 46 to 197, and the follow-up periods ranged from 21 to 60 days. Table 1 provides an overview of the key features of the 4 RCTs that were included in this investigation.

Tabel 1. Baseline characteristics of studies.

		Sample		Age					Follow up (days)
Study (year)	**Country**	**I**	**C**	**I**	**C**	**Intervention**	**Control**	**Hydrocortisone dose**	
Dequin et al. (2020)	France	76	73	63.1±9,7	66.3±9,6	Hydrocortison	Standard care	200mg/d	21
Tongyoo et al. (2016)	Thailand	98	99	64.5±17.3	64.3±16.0	Hydrocortison	Stancard care	200 mg/d	60
Annane et al. (2006)	France	85	92	61±16	59 ±18	Hydrocortison	Standard care	200mg/d	28
Confalonieri et al. (2005)	Italy	23		60.4±17.3	66.6±14.7		Standard	200-mg bolus +	

	23	Hydrocortison	care	240 mg/d	60

Evaluating the risk of bias

Figure 2 displays the outcomes of the risk of bias evaluation for the 4 randomized controlled trials (RCTs). All four investigations provided sufficient information on random sequence creation, selective reporting details, and other biases (Annane et al., 2006; Confalonieri et al., 2005; Dequin et al., 2020; Tongyoo et al., 2016). Four research provided specific information regarding allocation concealment (Annane et al., 2006; Confalonieri et al., 2005; Dequin et al., 2020; Tongyoo et al., 2016). Outcome concealment information were not reported in one study (Annane et al., 2006). Only one study presented sufficient data on blinding for participants, investigators, and outcome assessors (Tongyoo et al., 2016).

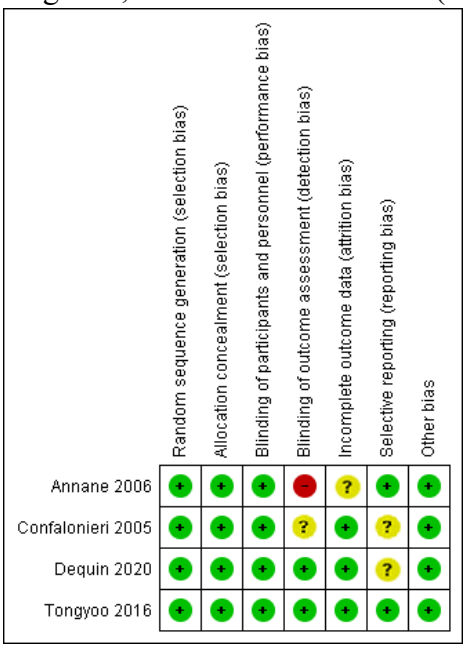


Figure 2. Risk of bias assessment

Efficacy and safety of hydrocortisone for ARDS

Four studies, with a total of 566 participants, examined mortality rates as an outcome measure. These investigations found a significant difference between the use of hydrocortisone and a placebo, with an OR of 0.60 and a 95% CL ranging from 0.42 to 0.87. The heterogeneity between the studies was measured at 40% (Figure 3). Three studies (N=417) pooled to examine mortality at day 28. The results showed that there was no significant difference between the use of hydrocortisone and placebo (OR=0.70; 95% CI: 0.45–1.08; I2= 0%) (Fig. 4). Three trials, with a total of 422 patients, examined the occurrence of adverse events. The meta-analysis results indicated that there was no statistically significant difference in nosocomial infections (OR = 0.84; 95% CI: 0.49–1.42; I2 = 20%) (Figure 5) and gastrointestinal bleeding (OR = 0.1.36; 95% CI: 0.5–3.71; I2 = 0%) (Figure 6).

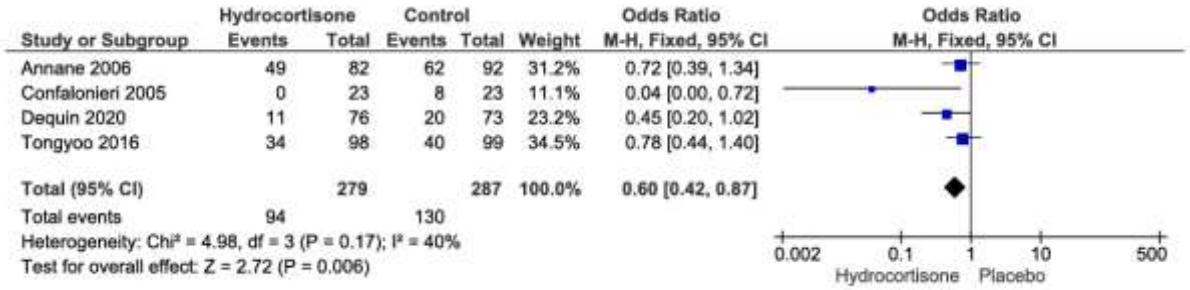


Figure 3. Meta-analysis of all causes of death

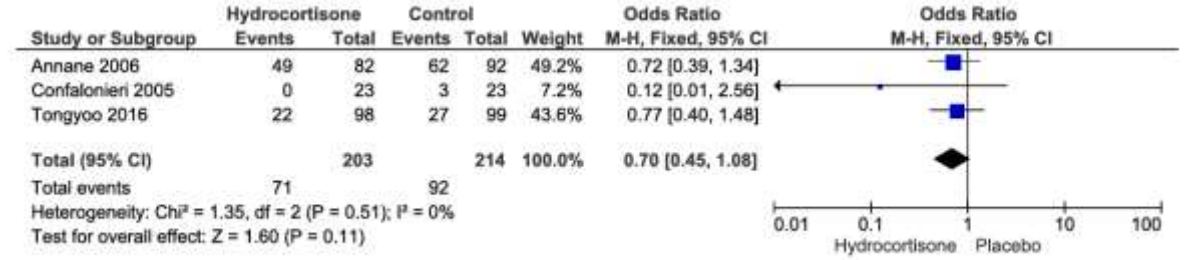


Figure 4. Meta-analysis of mortality at day 28

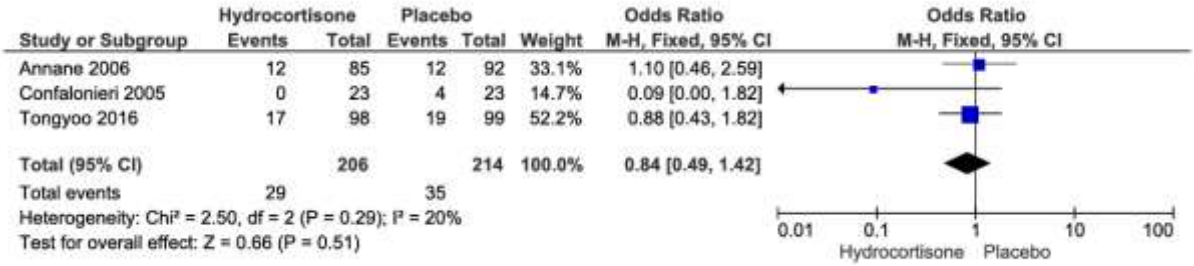


Figure 5. Meta-analysis of the adverse effects of nosocomial infections

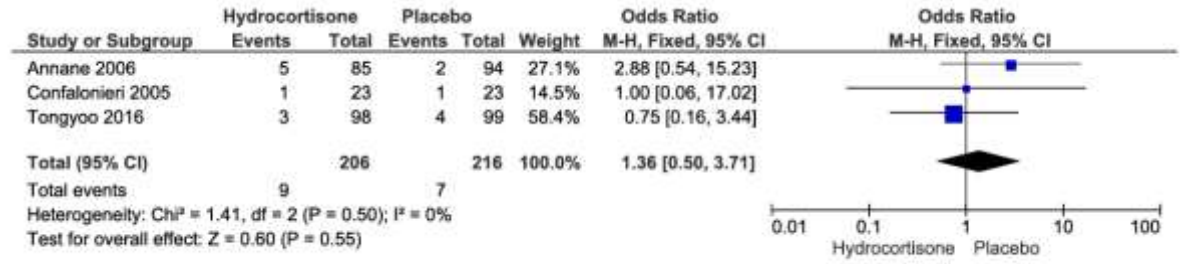


Figure 6. Meta-analysis of adverse effects of gastrointestinal bleeding

Acute respiratory distress syndrome (ARDS) is a critical inflammatory lung disorder resulting from acute injury to the pulmonary system and systemic insults, contributing to high rates of morbidity and mortality (Bellani et al., 2016; Meyer et al., 2021; Ranieri et al., 2012). The risk of death increases in parallel with disease severity, reaching approximately 27% in mild cases, 32% in moderate cases, and up to 45% in severe forms (Ranieri et al., 2012). At present, no pharmacological therapy has consistently demonstrated a definitive benefit in improving clinical outcomes among patients with ARDS (Kuperminc et al., 2023; Papazian et

al., 2019). Consequently, management primarily relies on supportive care, particularly the application of evidence-based mechanical ventilation strategies (Fan et al., 2018; Papazian et al., 2019).

The underlying pathophysiology of ARDS involves an excessive inflammatory response following injury to alveolar epithelial and endothelial structures, resulting in increased vascular permeability, interstitial and alveolar fluid accumulation, airway compromise, and alveolar collapse. Corticosteroids have been proposed as a therapeutic option due to their ability to modulate inflammatory pathways. Early administration of corticosteroid may reduce systemic inflammation and promote recovery of lung function, largely through glucocorticoid-mediated suppression of pro-inflammatory cytokines and regulation of immune cell activity, including T lymphocytes and macrophages (Chang et al., 2022).

Nevertheless, findings regarding the efficacy of corticosteroids in ARDS remain variable and inconclusive across studies. Hydrocortisone, in particular, has been investigated as an adjunctive treatment given its anti-inflammatory effects; however, its overall clinical benefit and safety profile remain uncertain. Evidence from systematic reviews and meta-analyses has yet to establish definitive conclusions regarding its effectiveness (Chang et al., 2022; Fan et al., 2018; Papazian et al., 2019). Therefore, further well-designed studies are required to clarify its role in ARDS management.

This meta-analysis included four randomized controlled trials comprising 566 patients. The results demonstrated that hydrocortisone was associated may reduce overall mortality , although no significant impact was observed on 28-day mortality. Additionally, its use did not lead to an increased risk of adverse events, including nosocomial infections and gastrointestinal bleeding (Annane et al., 2006; Confalonieri et al., 2005; Dequin et al., 2020; Tongyoo et al., 2016). These findings indicate a potential clinical benefit of hydrocortisone in ARDS. However, several limitations should be considered, including small sample sizes, heterogeneity among studies, and limited long-term outcome data. Moreover, the predominance of single-center trials may affect the external validity of the findings.

CONCLUSION

This systematic review and meta-analysis of four randomized controlled trials involving 566 participants suggested that hydrocortisone treatment might reduce overall mortality in patients with acute respiratory distress syndrome (ARDS). However, the separate analysis of 28-day mortality did not demonstrate a statistically significant reduction, indicating that the observed survival benefit should be interpreted cautiously, particularly given differences in follow-up periods. No statistically significant differences were identified in the incidence of nosocomial infections or gastrointestinal bleeding between treatment groups, although these findings did not establish the absence of treatment-related adverse effects. The limited number of included trials, relatively small sample sizes, clinical heterogeneity, and methodological limitations reduced the certainty and generalizability of the evidence. Overall, hydrocortisone showed potential as an adjunctive treatment for ARDS, but the available evidence was insufficient to establish a consistent survival benefit or definitive safety profile. Further high-quality research is therefore required to clarify its therapeutic role in ARDS management.

Future research should prioritize adequately powered, multicenter randomized controlled trials involving patients with clearly defined ARDS and standardized hydrocortisone treatment protocols. These investigations should determine the optimal dosage, timing of treatment initiation, and duration of therapy while distinguishing the effects of hydrocortisone monotherapy from those of regimens involving additional corticosteroids. Standardized mortality endpoints, extended follow-up periods, and comprehensive adverse-event monitoring are essential for establishing a more reliable assessment of treatment benefits and risks. Future studies should also evaluate clinically meaningful secondary outcomes, including ventilator-free days, long-term functional recovery, and health-related quality of life. Furthermore, prespecified subgroup analyses should investigate whether treatment responses differ according to ARDS severity, underlying etiology, and the presence of concomitant septic shock. Such investigations could strengthen the evidence base and support more precise clinical recommendations regarding hydrocortisone use in patients with ARDS.

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