INPLASY

Systematic Review and Meta-Analysis of the Incidence and Risk Factors of Delirium in ICU Patients with Sepsis

INPLASY2025110093

doi: 10.37766/inplasy2025.11.0093

Received: 28 November 2025

Published: 28 November 2025

Tang, J; Fu, X; Jiang, JX; Zong, XJ; Zou, JY.

Corresponding author:
Tang Jing

540710196@qq.com

Author Affiliation:
Huashan Hospital Affiliated to Fudan University.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2025110093

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 November 2025 and was last updated on 28 November 2025.

INTRODUCTION

Review question / Objective Among ICU adults with sepsis (P), what are the pooled incidence and multivariable-adjusted risk factors (I/O) for delirium diagnosed by validated tools (C).

Condition being studied Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. It is one of the leading causes of death among critically ill patients, and is characterized by high incidence, high mortality, multiple complications, and poor prognosis. According to the 2020 Global Burden of Disease Study, there were approximately 48.9 million cases of sepsis and about 11 million sepsis-related deaths worldwide, accounting for 19.7% of total global deaths. A study by Andrews et al. confirmed that 47.9% of delirium patients were admitted to the intensive care unit (ICU) due to sepsis. Sepsis-associated delirium is a common cerebral manifestation in patients with sepsis and represents a serious central nervous system complication. Its onset accelerates systemic immune dysregulation in sepsis patients, significantly prolongs hospital stay, increases mortality, and consumes more medical resources. Early studies have found that approximately 20%–50% of sepsis patients in the ICU develop delirium or altered consciousness. Although many studies have investigated the incidence and risk factors of delirium in sepsis patients, the results vary widely, limiting the generalizability of the conclusions. Therefore, this study aims to determine the incidence and influencing factors of delirium in ICU sepsis patients through meta-analysis, in order to provide evidence for healthcare professionals to identify high-risk populations early and develop targeted prevention and treatment strategies.

METHODS

Participant or population ICU patients who fulfil established diagnostic criteria for sepsis.

Intervention Not applicable.

Comparator Not applicable.

Study designs to be included Cohort, case-control and cross-sectional studies.

Eligibility criteria ICU adults (≥18 y) with confirmed sepsis.
Exclusion: studies that did not perform delirium assessment or in which delirium status could not be ascertained.

Information sources Electronic databases: PubMed, Embase, Cochrane Library, Web of Science, CINAHL, CNKI, WanFang, VIP from inception to 25 November 2025.
Grey literature: ProQuest dissertations, conference abstracts (ESICM, SCCM, ATS 2018-2025), Google Scholar.

Main outcome(s) Pooled incidence of delirium in ICU sepsis patients (proportion within ICU stay, measured by CAM-ICU, ICDSC).
Multivariable-adjusted risk factors: odds ratio (OR) with 95 % CI for each determinant reported, adjusted for at least age and severity of illness; timing of delirium assessment and effect measure clearly extracted from each study.

Quality assessment / Risk of bias analysis Two reviewers will independently rate methodological quality using the Newcastle–Ottawa Scale (NOS) for cohort, case–control and cross-sectional studies; disagreements resolved by consensus or third reviewer. Studies achieving ≥7 stars will be classed as low risk of bias, 5–6 stars moderate and <5 stars high. Summary tables will detail selection, comparability and outcome domains. Risk-of-bias across studies will inform sensitivity analyses and GRADE certainty ratings for both incidence and risk-factor estimates.

Strategy of data synthesis Analyses will be conducted with RevMan 5.4 and Stata 18.0.
- Risk factors: extract and pool dichotomous ORs or RRs as effect measures.
- Incidence: combine proportions with the direct (approximate normal) method.
- Sensitivity: omit one study at a time and re-estimate to assess result stability.
- Heterogeneity: if $P \geq 0.10$ and $I^2 \leq 50$ %, use a fixed-effect model; if $P < 0.10$ and $I^2 > 50$ %, explore sources. After investigation, persistent substantial heterogeneity will prompt either random-effects pooling or descriptive synthesis.
- Publication bias: funnel plot plus Egger's test.

Subgroup analysis Subgroup analyses (≤ 150 words)

We will stratify analyses by:
Sepsis definition (Sepsis-3 vs others).
Delirium instrument (CAM-ICU, ICDSC, other).
Study design (prospective cohort, retrospective cohort, cross-sectional).
Geographic income level (high vs middle/low).
Bas illness severity (APACHE II ≥ 20 vs < 20).
Each subgroup will be meta-analysed separately; meta-regression will test between-group differences.

Sensitivity analysis We will examine robustness by:
Excluding high risk-of-bias studies (NOS < 6).
Omitting one study at a time and re-pooling.
Restricting to prospective cohorts.
Using alternative effect measures (RR vs OR) where applicable.
Changes in pooled estimates will be quantified; conclusions will be downgraded if direction or significance shifts.

Language restriction Chinese or English.

Country(ies) involved China.

Keywords sepsis associated delirium; risk factors; incidence.

Contributions of each author
Author 1 - Tang Jing.
Email: 17721065252@163.com
Author 2 - Fu Xue.
Author 3 - Jiang Jinxia.
Author 4 - Zong Xiaojia.
Author 5 - Zou Jingyi.
Author 6 - Zheng Jiani.
Author 7 - Gong Lilin.