

# INPLASY

## Diagnostic and prognostic value of CC16 for ARDS: a systematic review and meta-analysis

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### ADMINISTRATIVE INFORMATION

**Support** - None.

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

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202390076

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 September 2023 and was last updated on 22 September 2023.

### INTRODUCTION

**Review question / Objective** The PICO items: P: patients with ALI/ARDS; I: CC16 expression; C: Patients without ALI/ARDS as controls; O: Defined ALI/ARDS diagnosis, and in-hospital prognosis.

**Rationale** This is the first study to assess the diagnostic and prognostic value of CC16 for ARDS, by summarising diagnostic studies (the main difference from other reviews) with a comprehensive search for relevant literature published by scholars worldwide.

**Condition being studied** No systematic review and meta-analysis with a comprehensive synthesis of available evidence has assessed the reliability and practicality of CC16 as a non-invasive circulating biomarker for ARDS diagnosis and prognosis with satisfactory precision. It is

necessary to evaluate the diagnostic and prognostic value of CC16 in patients with ARDS.

### METHODS

**Search strategy** A comprehensive search was conducted for relevant literature published by scholars worldwide on diagnostic and prognostic value of CC16 for ARDS. The databases searched were the Wanfang Data Knowledge Service Platform, the China National Knowledge Infrastructure (CNKI), the SinoMed, PubMed, Embase, the Cochrane Library, and Web of Science. The retrieval time was set from initial, to Sep 10, 2023. The search terms were "CC16" and "ARDS". The results were limited to articles in English and Chinese.

The two researchers independently screened the literature to exclude the literature that did not meet the inclusion criteria. Differences were resolved through group discussion. Data were extracted

independently according to the predesigned form, and the extracted data were cross-checked.

The quality of the included literature was evaluated by two independent researchers in strict accordance with the Newcastle-Ottawa Scale (NOS) and QUADAS-2. The selectivity, comparability and exposure of each article were assessed.

**Participant or population** 1. The patients studied in the literature were clearly diagnosed with Acute respiratory distress syndrome (ARDS), and the control group comprised patients without ARDS.

**Intervention** CC16 data of ARDS patients or controls were provided in the comparison study.

**Comparator** Diagnostic accuracy or Prognostic accuracy.

**Study designs to be included** Observational studies (including cohort, case-control studies, cross-sectional studies).

**Eligibility criteria** Inclusion criteria: Published as a complete inhuman article studying issues including the expression of CC16 and ARDS diagnosis or prognosis ; (2) Objects of study: patients suspected of having ARDS. (3) Gold standard: ARDS was diagnosed according to authoritative and comprehensive clinical guidelines; (4) True positive (TP), false positive (FP), false negative (FN), and true negative (TN) results could be obtained either from the original article or calculated based on the reported sensitivity and specificity.

**Information sources** The databases searched were the Wanfang Data Knowledge Service Platform , the China National Knowledge Infrastructure (CNKI), the SinoMed, PubMed, Embase, the Cochrane Library, and Web of Science.

We also searched other related literature such as trial registers, or grey literature.

**Main outcome(s)** CC16 has potential diagnostic and prognostic value for ARDS.

**Additional outcome(s)** Detecting time-specified diagnostic or prognostic accuracy by subgroup analysis.

**Data management** We will use a structured Excel sheet to ingest, store, and analyze the data.

**Quality assessment / Risk of bias analysis** The quality of the included literature was evaluated by two independent researchers in strict accordance

with the Newcastle-Ottawa Scale (NOS) and QUADAS-2.

The two researchers independently screened the literature to exclude the literature that did not meet the inclusion criteria. Differences were resolved through group discussion.

**Strategy of data synthesis** In the meta-analysis, the bivariate model was used to plot the summary receiver operator characteristic (SROC) curve, circulate the area under the curve (AUC), pooled sensitivity (pSEN), specificity (pSPE), pooled positive likelihood ratio (pPLR), pooled negative likelihood ratio (pNLR), diagnostic orders ratio (DOR). Spearman correlation coefficient was used to analyze threshold effect related heterogeneity, Cochran's-Q, and I<sup>2</sup> tests were used to analyze non-threshold effect related heterogeneity. Influence analysis and meta-regression were conducted to identify potential sources of study heterogeneity . A Fagan nomogram based on Bayesian approach was plotted assess the clinical utility. Data analysis was executed using STATA 13.1 (Stata Corporation, College Station, TX, USA) and MetaDisc 1.4.

**Subgroup analysis** If the necessary data are available, subgroup analyses will be done by: (publication history (within or without 3 years), sample size (>100 or ≤ 100), and specimen (serum or plasma)).

**Sensitivity analysis** Influence analysis and meta-regression were conducted to identify potential sources of study heterogeneity.

**Language restriction** English and Chinese.

**Country(ies) involved** China.

**Keywords** CC16; diagnosis; mortality; acute respiratory distress syndrome (ARDS); meta-analysis.

**Dissemination plans** This research contains no sensitive or protected data, we will publish this research in an academic journal and will share research data with other academic researchers under reasonable request.

**Contributions of each author**

Author 1 - Qianglin Zeng - The author designed this study, developed of the selection criteria, and the risk of bias assessment strategy, data collection, and provided statistical expertise.

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