

INPLASY PROTOCOL

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**Review Stage at time of this
submission:** Preliminary
searches.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: What is the incidence rate of thrombosis and bleeding events among patients undergoing Extracorporeal Membrane Oxygenation (ECMO) therapy? Additionally, what are the mortality rates associated with this treatment? **P:** patients receiving ECMO

The incidence of bleeding and thrombosis among patients receiving extracorporeal membrane oxygenation (ECMO): a systematic review and meta-analysis

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Review question / Objective: What is the incidence rate of thrombosis and bleeding events among patients undergoing Extracorporeal Membrane Oxygenation (ECMO) therapy? Additionally, what are the mortality rates associated with this treatment? **P:** patients receiving ECMO therapy. **I:** ECMO therapy. **C:** not applicable. **O:** primary: thrombosis and bleeding events; secondary: mortality. **S:** both prospective and retrospective studies are eligible.

Study designs to be included: Both prospective and retrospective studies are eligible. Reviews, meta-analysis, case reports, editorials, letters, and preclinical studies will be excluded.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 May 2023 and was last updated on 11 May 2023 (registration number INPLASY202350039).

therapy. **I:** ECMO therapy. **C:** not applicable. **O:** primary: thrombosis and bleeding events; secondary: mortality. **S:** both prospective and retrospective studies are eligible.

Condition being studied: Patients receiving ECMO therapy.

METHODS

Participant or population: Patients receiving ECMO therapy.

Intervention: ECMO therapy.

Comparator: Not applicable.

Study designs to be included: Both prospective and retrospective studies are eligible. Reviews, meta-analysis, case reports, editorials, letters, and preclinical studies will be excluded.

Eligibility criteria: Inclusion criteria is studies with at least one arm of patients who received any configuration of ECMO, and the incidence of thrombosis and/or bleeding based on all included population or a specific subgroup population was reported. Studies analyzing the Extracorporeal Life Support Organization (ELSO) register or National Inpatient Sample (NIS) database will be excluded due to concerns regarding overlapping patient populations with other studies. Additionally, studies based on other databases will also be excluded if we cannot exclude overlapping patient populations with studies from original submitting centers. If multiple studies have overlapped patient populations, studies reporting on larger or more recent patient populations, or those with more detailed reports on complications related to bleeding and thrombosis will be included. To reduce the impact of publication bias, an initial threshold of at least 300 cases of ECMO therapy per study is set arbitrarily.

Information sources: Three international databases (Cochrane Library, PubMed and EMBASE) and two Chinese databased (China National Knowledge Infrastructure-CNKI and Wanfang).

Main outcome(s): Thrombosis and bleeding among patients receiving ECMO.

Additional outcome(s): Mortality among patients receiving ECMO.

Quality assessment / Risk of bias analysis: Quality assessment will be performed by two authors independently who are blinded to each other's decisions. Dissent will be solved by discussion or consultation form a third author. The Newcastle-Ottawa scale (NOS) or Joanna Briggs Institute (JBI) quality assessment tool was used to evaluate the quality of the studies.

Strategy of data synthesis: The pooled rates and 95% confidence intervals (CI) of thrombosis, bleeding and mortality will be calculated. Proportions with 95% confidence intervals (CIs) of outcome variables will be presented. The random-effects model will be applied to calculate the pooled proportions and their 95% CIs. Heterogeneity among studies is assessed by Cochran Q statistic and I² test.

Subgroup analysis: Subgroup analyses will be performed to identify the incidence of thrombosis, bleeding and mortality in any subpopulations (if data allow), such as subpopulations based on the configuration of ECMO (venovenous ECMO and venoarterial ECMO).

Sensitivity analysis: Not determined.

Language restriction: English and Chinese.

Country(ies) involved: China.

Keywords: ECMO, thrombosis, bleeding, complication, mortality, meta-analysis.

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