INPLASY PROTOCOL

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Conflicts of interest: None declared. Early prediction models for prognosis of diabetic ketoacidosis in the Emergency Department. A protocol for systematic review and meta-analysis

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Review question / Objective: P:Adult; I:Patients with diabetic ketoacidosis who have bad prognosis; C:Patients with diabetic ketoacidosis who have good prognosis; O:Risk of disease due to the diabetic ketoacidosis; S:Prospective/ retrospective cohort study, RCT, etc.

Condition being studied: Diabetic ketoacidosis is one of the most serious complications after diabetes poor control, which seriously threatens human life, health and safety. Diabetic ketoacidosis can rapidly develop within hours or days leading to death. Early evaluation of the prognosis of diabetic ketoacidosis patients and timely and effective intervention are very important to improve the prognosis of patients. The combination of several variables or characteristics is used to predict the poor prognosis of diabetic ketoacidosis, which can allocate resources reasonably, which is beneficial to the early classification intervention and clinical treatment of the patients.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 May 2021 and was last updated on 06 May 2021 (registration number INPLASY202150023).

INTRODUCTION

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METHODS

Participant or population: We will collect all cross-sectional studies that predict or analyzed the admission and death of patients with diabetic ketoacidosis. The study includes adolescent participants, but children or pregnant women doesn't meet the inclusion criteria. No restrictions will be placed on sex or gender, race, comorbidities, or other characteristics.

Intervention: Patients with diabetic ketoacidosis who have bad prognosis.

Comparator: Patients with diabetic ketoacidosis who have good prognosis.

Study designs to be included: Prospective/ retrospective cohort study, RCT, etc.

Eligibility criteria: We will collect all crosssectional studies that predict or analyzed the admission and death of patients with diabetic ketoacidosis. The study includes adolescent participants, but children or pregnant women doesn't meet the inclusion criteria. No restrictions will be placed on sex or gender, race, comorbidities, or other characteristics. Animal studies, cadaver studies, case reports, comments, letters, protocols, guidelines, unpublished articles, and review papers will be excluded. Thissearch will be limited to reports in English, and for which full-text access is available. Participants who are included in the articles we selected should be diagnosed with diabetic ketoacidosis.

Information sources: At first, the collection of bibliographic data will be made in the electronic databases: PubMed, Web of science, EMBASE, Cochrane Library, Google scholar, CNKI, Wanfang and VIP. We use the available publications of the diabetic ketoacidosis living systematic review for a list of keywords. The words are considered: diabetic ketoacidosis, diagnostic, prognostic, prediction, prediction model, regression, score, artificial intelligence, algorithm, deep learning, machine learning. We make the search terms by combining the words above: #1 diabetic ketoacidosis #2 diagnostic OR imaging OR prognostic OR prognosis OR prediction OR prediction model OR mortality OR regression OR score OR artificial intelligence OR algorithm OR deep learning OR machine learning #3 APACH II OR PSI ORSOFA OR qSOFA OR SAPS #4 english NOT animal NOT meternal #1 AND #2 AND #3 AND #4.

Main outcome(s): The preliminary documents are obtained by looking through the titles and abstract, removing the duplications. For the further screening, the 2 reviewers will read the full text of the articles which are selected carefully, removing the unsatisfied articles and sending an email to ask author for the full text or the details. Any disagreements will be arbitrated by a third reviewer. The whole process of study selection is presented in the flow chart following the a PRISMA principle . Outcomes(needing for mechanical ventilation, needing for ICU care, or dead).

Data management: Two of three reviewers will extract the data from eligible studies, putting them into the pre-specified form that we make in advance: author information, study area, study time, study type, study design, setting of study, sample size, participant characteristics, primary and secondary outcomes(needing for mechanical ventilation, needing for ICU care, or dead), AUC(Area Under Curve). Another researcher will solve the divergence between the first two reviewers.

Quality assessment / Risk of bias analysis:

For qualified articles, we would like to combine the collected data according to characteristics of eligible trials. The Grading of Recommendations, Assessment, **Development and Evaluation (GRADE)** assessment tool will be used for conducting an appraisal of the studies' methodological quality. Every selected study will be evaluated by 2 reviewers independently, a third one as a consulter. The GRADE evaluation system included bias risk; heterogeneity; indirectness; imprecision; publication bias. And each level of evidence is divided into "very low", "low", "moderate", or "high" judgment.

Strategy of data synthesis: In line with the Cochrane guideline, we will express risk ratio with 95% confidence intervals(95%Cl) using fixed effect model. Besides the random effect model will be used for continuous outcomes because of clinical heterogeneity. Statistical heterogeneity will be investigated using χ^2 test and I2 statistic (50%, strong heterogeneity). We will assess possible publication bias using the Egger funnel plot. All data will be performed by using Review Manager (RevMan version 5.4.0) software and P value <.05 will be considered statistically significant.

Subgroup analysis: None.

Sensitivity analysis: In line with the Cochrane guideline, we will express risk ratio with 95% confidence intervals(95%CI) using fixed effect model. Besides the random effect model will be used for continuous outcomes because of clinical heterogeneity. Statistical heterogeneity will be investigated using χ^2 test and I2 statistic (50%, strong heterogeneity). We will assess possible publication bias using the Egger funnel plot. All data will be performed by using Review Manager (RevMan version 5.4.0) software and P value <.05 will be considered statistically significant.

Country(ies) involved: China.

Keywords: Prediction models, prognosis, Diabetic ketoacidosis protocol, systematic review, meta-analysis, Emergency, early.

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