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Risk predictors of severe adverse maternal outcomes in pre-eclampsia: a systematic review and meta-analysis protocol

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ABSTRACT

Introduction Pre-eclampsia (PE) remains a major contributor to maternal morbidity and mortality globally. Early identification of risk factors and evaluation of prognostic models for severe adverse maternal outcomes are essential for improving management and reducing complications. While numerous studies have explored potential risk markers, there is still no consensus on the most reliable factors and models to use in clinical practice. This systematic review aims to consolidate research on both individual predictors and prognostic models of severe adverse maternal outcomes in PE, providing a comprehensive overview to support better clinical decision-making and patient care.

Methods and analysis This review follows the Meta-analyses Of Observational Studies in Epidemiology (MOOSE) guidelines and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocol 2015 checklist. A systematic search will be performed using a detailed strategy across Medline, Embase, Cochrane, ProQuest dissertations, and grey literature from inception to 2 April 2024. Eligible studies will include those investigating clinical, laboratory-based, and sociodemographic predictors of severe adverse maternal outcomes in PE. Two reviewers will independently assess titles, abstracts, full texts, and extract data and assess study quality using the Quality In Prognostic Studies (QUIPS) tool for studies on risk predictors and the Prediction model Risk of Bias Assessment Tool (PROBAST) for prognostic models. The inclusion criteria will encompass cohort, case-control, and cross-sectional studies published in English and French involving women diagnosed with PE and reporting on the risk prediction for adverse maternal outcomes. The main outcomes of interest will include severe maternal morbidity and mortality during pregnancy, delivery, or within the postpartum period. Analyses will include both narrative synthesis and, where appropriate, meta-analysis using random-effects models. Pooled estimates will be calculated, with publication bias assessed through funnel plots and statistical tests (eg, Begg's and Egger's). Heterogeneity will be primarily assessed through visual inspection of forest plots, supported by statistical measures, such as the I^2 test, with further exploration through sensitivity, subgroup, and meta-regression analyses.

Ethics and dissemination This systematic review will be based on published data and will not require ethics approval. Results will be disseminated through peer-reviewed publications and presentations at academic conferences.

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STRENGTHS AND LIMITATIONS OF THE STUDY

⇒ First systematic review to evaluate both individual predictors and prognostic models for severe adverse maternal outcomes, including in the postpartum period among individuals with pre-eclampsia (PE).
⇒ Quality assessment using Quality In Prognostic Studies (QUIPS) tool and Prediction model Risk of Bias Assessment Tool (PROBAST) will ensure reliable results and actionable recommendations.
⇒ Findings have the potential to shape future research and clinical guidelines, providing a basis for targeted interventions and improved maternal care in PE.
⇒ Potential heterogeneity and publication bias could affect the results.

INTRODUCTION

Pre-eclampsia (PE) is defined by the new onset of hypertension after 20 weeks of pregnancy, associated with maternal organ dysfunction with or without proteinuria.[1] It affects 2%–5% of pregnancies, and despite advances in obstetrical care in the last decades, it remains a leading cause of maternal morbidity and mortality worldwide.[2] The incidence of PE has been increasing globally, partly due to the rising prevalence of risk factors such as increasing maternal age and pre-existing cardiometabolic conditions, including obesity, type 2 diabetes, and chronic hypertension, as

well as the growing use of assisted reproduction and multiple pregnancies.[3–6] Moreover, individuals with PE have an increased risk of developing long-term adverse outcomes, such as myocardial infarction, stroke, coronary heart disease, cardiomyopathy, and cerebrovascular diseases.[7–9]

The pathophysiology of PE is complex and involves various genetic, angiogenic and metabolic pathways, resulting in abnormal placental development, endothelial dysfunction and systemic inflammatory responses, manifesting clinically with hypertension and multiorgan insults.[10] PE evolves along a continuum of severe adverse maternal outcomes including eclampsia, haemolysis, elevated liver enzymes and low platelet (HELLP) syndrome, stroke, renal failure and, in some cases, maternal death.[11 12] Notably, 44% of patients with PE at term will develop severe features, with progression occurring in 27% before delivery, 47% during delivery, and 26% post partum.[13]

Predictors of PE can include a broad range of demographic, clinical and biochemical factors such as maternal age, body mass index, parity, prior history of PE, pre-pregnancy blood pressure levels, and biomarkers such as placental growth factor and soluble Fms-like tyrosine kinase-1.[10] Identifying prognostic markers of severe adverse maternal outcomes among women with established PE is crucial to promptly identify and eventually reduce the associated burden of severe maternal morbidity and mortality. As such, early identification allows for closer monitoring, timely interventions, and informed decision-making regarding the timing and mode of delivery.[14] Additionally, a validated approach could help triage individuals at low risk, enabling their care to be managed in community settings, thus allowing for appropriate resource allocation.

While several studies have investigated potential predictors of adverse outcomes in PE, the findings have often been inconsistent, and the relative importance of different predictors still needs to be clarified.[15] Furthermore, existing predictive models vary widely in their methodology, population, and outcome measures, leading to challenging generalisability and clinical application. Recent studies have applied machine learning techniques to predict adverse maternal outcomes among individuals diagnosed with PE. These models incorporate clinical and biochemical variables to estimate short-term risk and have been developed and validated across different populations and healthcare settings.[16–18] Such approaches reflect an emerging effort to improve prognostic accuracy through data-driven modelling of complex clinical interactions.[16]

This systematic review aims to synthesise the existing evidence on both individual predictors and prognostic models of severe adverse maternal outcomes among women with PE. By comprehensively evaluating the available data, we aim to identify the most robust and clinically useful predictors, assess the quality and certainty of the evidence, and highlight knowledge gaps to direct future research. The findings from this review will inform clinical practice guidelines and future research priorities.

Objectives

Primary objective

The primary objective of this review is to identify and evaluate individual predictors associated with severe adverse maternal outcomes in women diagnosed with PE, focusing on severe maternal morbidity and mortality in the postpartum period, as defined by existing literature.

Secondary objective

The secondary objective is to assess and compare the accuracy and predictive performance of various prognostic models in forecasting severe adverse maternal outcomes and, where applicable, to evaluate the relative contribution of individual predictors within these models.

This review is structured using the PICOTS (Population, Index predictors, Comparator, Outcomes, Timing and Setting) framework, which is more appropriate for prognostic reviews than the PICO (Population, Intervention, Comparator, Outcome) framework typically used in intervention studies.

- Population (P): pregnant or postpartum individuals diagnosed with PE.
- Index predictors (I): clinical, biochemical, and sociodemographic predictors or multivariable prognostic models.
- Comparator (C): not applicable for most studies; however, where available, alternative predictors or usual care groups may be included.
- Outcomes (O): severe adverse maternal outcomes, including morbidity and mortality occurring during pregnancy, delivery, or within 3 months post partum.
- Timing (T): from the time of PE diagnosis through the pregnancy and up to 3 months post partum.
- Setting (S): any healthcare or clinical setting, including hospital-based and community-based environments.

METHODS

We will conduct a systematic review and meta-analysis, adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) checklist to ensure a rigorous and transparent approach.[19] This protocol was written in adherence with the 'Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols' (PRISMA) guidelines (online supplemental appendix 1).[20]

Eligibility criteria

Study design

This review will include observational studies such as cohort, case-control and cross-sectional designs, considering publications up until 2 April 2024, to ensure the inclusion of the most recent and relevant data. Additionally, publications in both English and French will be considered.

Population

Individuals diagnosed with PE according to accepted diagnostic criteria, including new-onset hypertension after 20 weeks of gestation combined with proteinuria or other end-organ dysfunction.

Outcomes

The main outcome of interest is severe adverse maternal outcomes within 3 months post partum, including severe maternal morbidity and all-cause mortality. Severe maternal morbidity encompasses conditions such as eclampsia, HELLP syndrome, acute kidney injury, pulmonary oedema and other serious complications arising in the context of PE.

Exclusion criteria

Studies that do not clearly define PE according to established criteria, non-human studies, and in vitro studies will be excluded. Additionally, we will not consider case reports, case series, cost-benefit analyses or qualitative research. Reviews, newspapers, books, conference abstracts, theses, commentaries, letters, editorials and unpublished data will also be excluded. Furthermore, studies reporting only simple associations (eg, ORs, risk ratios (RRs) or HRs) without accompanying predictive performance metrics (eg, accuracy or calibration) will be excluded.

Handling of studies with unclear definitions of pre-eclampsia

To address variations in the definition of PE, studies that do not strictly adhere to established diagnostic criteria will not be excluded outright. Instead, these studies, including those where PE cannot be clearly subsetted, will be analysed separately through subgroup analysis. This will allow us to explore how varying definitions and classifications may affect the review's outcomes. This approach ensures comprehensive coverage of the literature and aids in understanding the impact of diagnostic criteria variations on reported outcomes.

Information sources

Our search covered a range of databases to ensure comprehensive data collection, including Medline (via PubMed), Embase Classic+Embase (via Ovid), and Cochrane (via Wiley); additionally, grey literature sources such as unpublished theses and dissertations were accessed via ProQuest and Google Scholar. Reference lists of included studies, existing systematic reviews (eg, Cochrane reviews) and PE guidelines will also be reviewed to identify additional studies.

Search strategy

A systematic search was conducted across the above-mentioned databases to identify literature published from inception until 2 April 2024. The search strategy was developed in collaboration with a medical librarian. Although initially framed using the PICO framework to ensure a broad capture of studies, we recognise that PICOTS is more appropriate for prognostic research. Therefore, eligibility criteria and data extraction were structured using the PICOTS framework, as recommended in the Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies (CHARMS) checklist, a widely accepted tool developed to guide the conduct of systematic reviews of prognostic and diagnostic prediction models.[21–23]

This strategy adhered to the Peer Review Electronic Search Strategies (PRESS) guidelines to enhance the accuracy and reliability of the literature search.[24] Controlled vocabulary terms and text words related to PE and severe adverse maternal outcomes were used. Specifically, Medical Subject Headings (MeSH) were applied for Medline searches, while Emtree terms were used for Embase searches. The terms included were "pre-eclampsia," "predictive models," "maternal outcomes," "risk factors," "severe maternal morbidity" and "maternal mortality." A detailed search strategy for each database, highlighting these specific terminologies, is provided in online supplemental appendix 2.

Study selection

Title and abstract screening will be performed using Covidence, a web-based systematic review tool. A third reviewer will resolve disagreements during the screening process. Following the title and abstract screening, a full-text screening will be conducted, with disagreements again resolved by a third reviewer. Reasons for the studies' exclusion will be documented during the full-text screening phase.

Data extraction and quality assessment

Two reviewers will extract data independently using a pilot-tested standardised form. Extracted data will include the following:

- Study characteristics: information such as the author, year of publication, country, study design, sample size and population characteristics.
- Predictors: details of individual predictors or models, including their definition, measurement methods, timing in relation to PE diagnosis and validation status (eg, cut-off values for predictors or internal/external validation for models).
- Outcomes: definitions and measurements of severe adverse maternal outcomes in the postpartum period.
- Results: For individual predictors, we will extract measures of predictive accuracy such as the area under the receiver operating characteristic (ROC) curve (AUC) and other discrimination metrics. For prognostic models, we will record discrimination metrics (eg, AUC and C-index), calibration measures (eg, calibration plots and slopes) and overall performance (eg, brier score and decision curve analysis).

Discrepancies between reviewers will be resolved through discussion, with a third reviewer consulted if necessary. The data extraction template is provided in online supplemental appendix 3.

The methodological quality of included studies will be assessed using tools tailored to the study designs and objectives of this review. For studies evaluating individual predictors of severe adverse maternal outcomes, we will use the Quality in Prognostic Studies (QUIPS) tool to assess the risk of bias.[23 25 26] We will use the Prediction model Risk of Bias Assessment Tool (PROBAST) for studies developing, validating or updating prognostic models.[27 28] This dual approach ensures that the methodological quality of both prognostic factor and model studies is rigorously assessed, allowing for a comprehensive and reliable synthesis of the evidence.

Handling of missing data

If data are missing or unclear, we will attempt to contact the study authors for clarification. Where key data are not available and authors cannot be reached, the study will be included in the qualitative synthesis but excluded from the quantitative meta-analysis. We will document all instances of missing data and report them in the results.

Data synthesis and statistical analysis

We will categorise results by study setting (eg, hospital and community) and use a narrative synthesis approach to summarise study characteristics and findings. Results will be stratified based on the focus of the included studies, distinguishing between those evaluating individual predictors (eg, uric acid, N-terminal pro B-type natriuretic peptide (NT-proBNP) and blood pressure levels) and those deriving, validating, or evaluating prognostic models. To address variations in the definition of PE, studies not strictly adhering to established diagnostic criteria will be included but analysed separately through subgroup analyses.

Statistical analyses will evaluate predictive performance across discrimination, calibration and overall performance metrics. For discrimination, the AUC will be reported for both individual predictors and prognostic models, with an AUC of ≥0.70 considered indicative of good discriminatory ability. The C-index will be extracted for time-to-event data where available. Calibration will be assessed using calibration plots, slopes and calibration-in-the-large, with the Hosmer-Lemeshow Goodness-of-Fit Test included if reported (p values>0.05 indicative of adequate calibration). Observed-to-expected ratios will provide additional calibration insights, with values >1.0 indicating underestimation and <1.0 overestimation of risk. If calibration metrics are missing, qualitative descriptions (eg, 'well-calibrated') will be documented. For overall performance, metrics such as the Brier score and R^2 statistics (explained variance) will be reported. The net reclassification index will be included if available to assess improvements in classification over baseline models.

The primary analysis will focus on the associations between predictors and outcomes, reporting ORs, RRs and HRs with 95% CIs. Continuous predictors will be analysed using HRs or regression coefficients to quantify their contributions to the risk of severe adverse maternal outcomes. These analyses will complement predictive accuracy metrics by elucidating the independent contributions of each predictor.

To ensure robustness, critical prognostic factors will be considered when evaluating study adjustments. These include maternal age, gestational age at PE diagnosis, baseline comorbidities (eg, chronic hypertension, diabetes, obesity and renal disease), ethnicity or race, parity, socioeconomic status and history of hypertensive disorders in previous pregnancies. Studies that do not account for these key factors will be flagged during risk of bias assessment using the QUIPS tool for individual predictors and the PROBAST tool for prognostic models. Clustering effects, such as observations from the same geographic locations or institutions, will be accounted for using intracluster correlation estimates and average cluster sizes.

Meta-analysis will use random-effects models to account for variability across studies when predictors or models are sufficiently comparable. Between-study heterogeneity will be assessed through visual inspection of forest plots, focusing on consistency of effect estimates and overlap of confidence intervals. Statistical measures such as the I^2 statistic and χ^2 test will be calculated, interpreted cautiously and supplemented with sensitivity and subgroup analyses to explore heterogeneity. Funnel plots and Begg's and Egger's tests will evaluate publication bias where feasible, with significance set at $p<0.05$.

The feasibility of these analyses will depend on the availability of relevant metrics in the included studies. If certain metrics (eg, Brier score and calibration slopes) are inconsistently reported, analyses will focus on the most commonly available metrics (eg, AUC and C-index). Any gaps in available metrics will be noted and discussed as limitations.

Protocol amendments

Any amendments to this protocol will be documented on PROSPERO with a description of the change, the rationale and the date of the amendment to ensure transparency throughout the review process. This approach aligns with our commitment to maintaining the highest standards of research integrity and ethical rigour.

Confidence in cumulative evidence

Two reviewers will assess the confidence in effect estimates for each reported outcome using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, with a third reviewer resolving disagreements.[29–32]

Patient and public involvement

None.

DISCUSSION

This systematic review aims to elucidate the predictors associated with severe adverse maternal outcomes in PE,

spanning sociodemographic factors, clinical indicators such as blood pressure and gestational age, and biochemical markers, including placental biomarkers, platelet count, serum creatinine, and liver enzymes.[14 33] By synthesising and clarifying the predictive value of these diverse factors, our findings are expected to inform clinical decision-making and advance research aimed at closing gaps in the management of PE. This enhanced understanding could drive better outcomes for women affected by this condition.

Strengths and limitations

Our comprehensive search strategy and rigorous quality assessment protocols are key strengths of this review, ensuring the inclusion of diverse studies and reliable synthesis of evidence. The use of the GRADE framework adds significant value by enabling an assessment of the certainty of evidence, an aspect often overlooked in systematic reviews. However, the generalisability of findings may be influenced by the characteristics of populations included in the original studies. Challenges such as heterogeneity in study designs and definitions, as well as potential publication bias, particularly the underrepresentation of studies with negative or non-significant results, must also be considered. These limitations highlight the need for cautious interpretation, particularly when applying findings to varied geographical and clinical contexts.

Implications for practice

The identification of key predictors of morbidity and mortality has the potential to transform clinical practice by enabling early recognition of high-risk women with PE. Tailored interventions, such as enhanced monitoring and proactive management strategies, can reduce adverse outcomes while optimising healthcare resource allocation. This review will provide critical insights into how predictive factors can be integrated into clinical protocols to improve maternal care.

Implications for research

Our findings will underline key areas for future research to address gaps in the literature. Promising avenues include the evaluation of novel biomarkers for risk prediction, which could enhance the early identification of high-risk cases. While many studies emphasise standardised outcomes such as those in the fullPIERS (Preeclampsia Integrated Estimate of RiSk) model,[14] future research should investigate a broader range of adverse maternal outcomes, including acute cardiovascular events. Expanding the scope of research in these areas will deepen understanding and shape priorities for future studies.

ETHICS AND DISSEMINATION

This systematic review is based on the secondary analysis of publicly available and published data and, as such, does not require ethics approval. However, we are committed to maintaining the highest standards of research integrity and transparency in our analysis to ensure that all findings are reported responsibly and accurately. The findings of this systematic review will be disseminated widely to maximise its impact on clinical practice and future research regarding adverse maternal outcomes in women with PE. We intend to publish our findings in high-impact, open-access, peer-reviewed journals to guarantee academic rigour and extensive dissemination across the scientific community. We will also present our results at international conferences focused on obstetrics, obstetric medicine, hypertensive disorders of pregnancy and public health, facilitating engagement with clinicians and researchers. Additionally, our outreach will extend to social media platforms and direct interactions with healthcare knowledge users, aiming to enhance access to our research and its practical application in clinical settings. These efforts are directed towards improving the understanding and management of PE, which will help shape future clinical interventions and health policies.

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Contributors IM and HD conceived the study, developed the protocol and will oversee the systematic review process, with input from SB, RD'S, FF, SSD, SG, AK and KN. LH contributed to the development of the search strategy with assistance from HD. BD-C, HD and MH will perform title and abstract screening, screening of the full text of articles and data extraction of finalised articles. BD-C and MH will perform a risk of bias assessment with input from HD. HD will perform data synthesis and data analysis. FF will perform the GRADE assessment. RD'S, SSD, AK, IM and KN provided clinical and methodological expertise and will contribute to the interpretation of findings. All authors reviewed and approved the final manuscript. IM is the guarantor of this protocol and accepts full responsibility for the planning, conduct and reporting of the proposed systematic review, including access to the data and the decision to submit it for publication.

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