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Risk factors associated with adverse outcomes in pregnant individuals with valvular heart disease: A Scoping Review Protocol

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ADMINISTRATIVE INFORMATION

Support - Heart and stroke Foundation.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 December 2025 and was last updated on 17 December 2025.

INTRODUCTION

Review question / Objective The aim of this systematic review is to determine what risk factors predict the occurrence of adverse cardiac and pregnancy outcomes in patients with valvular heart disease.

Background Pregnant individuals with valvular heart disease (VHD) are at increased risk for adverse maternal cardiac and obstetric outcomes such as heart failure, arrhythmias, and thromboembolic events, severe hemorrhage and mortality as well as perinatal complications like preterm birth, fetal growth restriction and perinatal mortality[1]. However, the degree of risk varies based on the primary valvular lesion and other patient characteristics. Accurate risk stratification is essential for targeted care and efficient triaging, which in turn could reduce patient anxiety, improve outcomes and optimize healthcare resource utilization.

Current risk stratification tools—such as CARPREG, CARPREG-II, and ZAHARA—were primarily developed and validated in populations with congenital heart disease (CHD), with limited inclusion of VHD patients[2]. Although CHD is the leading cause of VHD in high-income countries, most cases of heart disease in in low- and middle-income countries (LMICs) stem from rheumatic VHD[3]. The absence of rheumatic VHD from these risk models highlights a significant gap, particularly given RHD's prevalence and the distinct risks it poses to maternal health in resource-limited settings.

Rationale A VHD-specific tool (DEVI score) has been developed in a LMIC and validated in a few settings [4,5]. However, although this tool

demonstrates slightly improved predictive performance, over other existing tools,[5] it still has two major limitations. First, the DEVI score relies on clinical variables alone and not on echocardiographic variables and other biomarkers, which are increasingly being used in risk stratification [6] and to assess prognosis in patients with heart disease [7]. Second, the DEVI score does not consider sociodemographic factors, and healthcare access, which have been shown to influence pregnancy outcomes [3]. Including these elements is essential for more accurate risk stratification where data on these variables are available.

This scoping review aims to synthesize the existing literature to identify all clinical risk factors as well as blood-based, echocardiographic and other biomarkers that are associated with adverse cardiac and pregnancy outcomes in individuals with VHD, laying the groundwork for the development of more inclusive and accurate risk stratification tool.

METHODS

Strategy of data synthesis We used a search strategy developed for a systematic review aimed at identifying all outcomes reported in studies on pregnancy and heart disease[8]. For this study, we had, with the help of a medical information specialist, conducted a comprehensive search in Medline, Embase, Web of Science and Cochrane Central databases from 1980 to 2018 to identify all experimental and observational studies on pregnancy and heart disease published in English and describing 5 patients or more. We updated the search on 17 June 2024. Additionally, we also examined the reference lists from review articles found to locate any additional observational studies that may have been missed in the initial search.

Eligibility criteria Inclusion criteria:

1. Original research papers published in English that include pregnant individuals with native VHD
2. Availability of full texts to ensure access to complete data for thorough analysis.

Exclusion criteria

1. Studies that include patients with valve replacements, or non-VHD populations, wherein these populations comprise >5% of the entire sample.
2. Studies published prior to 1980 which may not be reflective of contemporary care for pregnant individuals with heart disease.

Source of evidence screening and selection Two reviewers will independently screen titles/abstracts of retrieved studies on DistillerSR to identify studies that potentially meet the inclusion criteria outlined above. Full texts of potentially eligible studies will be retrieved and independently assessed for eligibility in duplicate. Any disagreement over the eligibility of particular studies will be resolved through discussion or adjudication by a third reviewer.

Data management Two reviewers will extract data independently and discrepancies will be resolved through discussion and adjudication by a third reviewer where necessary. Extracted information will include: year of publication; title; author names; journal and impact factor; countries studied; study setting; study objective; population sampled; sample size; study period; study design; type of VHD (CHD or RHD); details on valve lesions (for e.g. location, number of valves affected); baseline characteristics and demographics of participants; cardiac, obstetric, and perinatal outcomes analyzed; risk factors analyzed and the degrees of their association with adverse outcomes (based on univariate or multivariate analysis).

Reporting results / Analysis of the evidence Study reporting and presentation will be done in accordance to the PRISMA-ScR guidelines[9].The data will be mainly synthesized using a narrative approach. Where data are available, we will aim to conduct a meta-analysis of point estimates for each risk factor, for each outcome group. In the case that there are differences in outcome reporting among the studies, this will be stated as a limitation. Subgroup analyses are planned for the separation of VHD into congenital/rheumatic, tricuspid/pulmonary/mitral/aortic, and stenosis/regurgitation/prolapse, if data are available. No sensitivity analysis is planned.

Presentation of the results Tables will be used to provide a descriptive summary of the key characteristics of the included studies, such as the country, VHD type, sample size, study design, study period, baseline characteristics of participants, as well as key associations found with values. These tables may be organized by outcome group (i.e. cardiac, obstetric, perinatal), study setting, VHD type, and/or specific valve lesion, depending on the findings. Figures will be used to present risk factors and outcomes that were commonly analyzed among the studies, as well as to present the strongest associations between them.

Language restriction Studies published in English language only will be considered for inclusion.

Country(ies) involved Canada and India.

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Keywords Pregnancy; Valvular Heart Disease (VHD); Congenital Heart Disease (CHD); Rheumatic Heart Disease (RHD); Adverse pregnancy outcomes; Adverse cardiac outcomes.

Dissemination plans The findings will be published in a peer-reviewed journal specializing in cardiology, obstetrics, or maternal-fetal health, ensuring the work is accessible to healthcare professionals and researchers.

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