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Outcomes and complications of peripartum cardiomyopathy: protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Peripartum cardiomyopathy (PPCM) remains a major contributor to maternal morbidity and mortality worldwide. The disease is associated with various complications, which occur predominantly during the early stages of the disease. Adverse outcomes include decompensated heart failure, thromboembolic complications, arrhythmias and death. We present a protocol for a systematic review and meta-analysis to summarise the available data on the complications and outcomes of women with PPCM.

Methods and analysis A comprehensive search of all articles published between 2000 (the year in which the first universal definition of PPCM was used) and 1 June 2021 will be performed on PubMed/MEDLINE, Web of Science, Scopus and EBSCO Host, including Academic Search Premier, Africa-Wide Information, Cumulative Index to Nursing and Allied Health Literature. All cohort and cross-sectional studies, as well as control arms of randomised control trials (RCTs) reporting on the complications and outcomes of PPCM will be included in the review. Methodological quality assessment of included studies will be done by assessing the risk of bias. Heterogeneity of the data will be tested by visual inspection of the forest plot and I^2 and χ^2 tests. This study will report the burden of complications occurring around the time of diagnosis as well as the 6-month or 12-month outcomes of women with PPCM. A summarised description in form of a pooled analysis of across multiple centres, regions and continents would help us to better understand the estimates of complications and outcomes of women with PPCM.

Ethics and dissemination As this research is a systematic review of published literature, ethical approval is not required. The results will be reported according to the latest guidelines for Preferred Reporting Items for Systematic Reviews and Meta-Analyses 2020 statement, and will be submitted to a peer-reviewed journal.

PROSPERO registration number CRD42021255654.

Strengths and limitations of this study

- The planned systematic review will systematically report on the burden of complications occurring around the time of diagnosis, as well as 6-month or 12-month outcomes of women with peripartum cardiomyopathy (PPCM).
- This protocol describes a comprehensive search strategy and eligibility criteria, which have no geographical restriction.
- The systematic review might be limited by the presence of selection and/or attrition bias inherent in some of the selected studies.
- A meta-analysis will allow for pooled prevalence estimates of reported complications and outcomes in PPCM.
- As with many meta-analyses, the results may yield significant heterogeneity among the included studies.

INTRODUCTION

Peripartum cardiomyopathy (PPCM) is a life-threatening condition, in which women present with left ventricular (LV) systolic dysfunction that develops toward the end of their pregnancy or up to five months post partum.[1] The clinical presentation of PPCM ranges from severe acute heart failure with cardiogenic shock (often complicated by high morbidity and mortality)[2] to a more subtle presentation that results from impaired LV function.[3] Overall, PPCM contributes significantly to maternal morbidity and mortality.[4] Indeed, PPCM is a global disease, affecting approximately 1:1000 pregnancies worldwide.[4] However, incidence differs widely between different ethnic groups, countries and regions.

The outcome of PPCM remains markedly heterogeneous and seems to differ significantly between countries and ethnicities. Adverse outcomes associated with PPCM include decompensated heart failure, thromboembolic complications, arrhythmias and death. Depending on the severity of the disease, women with PPCM may require inotropic or mechanical circulatory support, pacing or cardioverter-defbrillator devices

or even cardiac transplantation.[5 6] Recent data from the European Observational Research Programme led by the European Society of Cardiology (ESC) on 739 women with PPCM from 49 countries showed that 46% of patients recovered their LV function after 6 months, whereas 28% remained with a persistently reduced LV ejection fraction (LVEF). All-cause mortality after 6 months was 6%, of which 42% were related to heart failure and 30% due to sudden cardiac death. Overall, 10% of women had readmissions to hospital after 6 months, of which more than half was related to heart failure.[4] Thromboembolic events occurred in 7% of women after 6 months. In the Investigators of Pregnancy Associated Cardiomyopathy cohort from North America, 13% of women with PPCM experienced a major event (ie, death, cardiac transplantation, or required an LV assist device) or remained with persistently severely reduced LV systolic function (LVEF <35%). Overall, 72% recovered their LV function after 1 year.[7]

Due to the low prevalence of the disease, studies reporting on the predictors of outcome in PPCM are mostly limited to single-centre studies with small sample sizes. These studies have described the initial degree of LV systolic dysfunction[7–9] and LV dilatation,[7 10 11] presence of LV thrombus,[10] right ventricular dysfunction,[12 13] obesity and African-American ethnicity[7 10 14 15] as factors associated with adverse outcomes.

Rationale

The current knowledge of short-term and long-term outcomes in PPCM is based on literature reporting on patients with different ethnic backgrounds and from various regions in the world.

Objectives

The objectives for this systematic review and meta-analyis are:

1. To determine the in-hospital complications of women with PPCM.
2. To describe the long-term outcome (ie, as reported at 6 and/or 12 months after index diagnosis) of women with PPCM.
3. To identify possible prognostic factors of outcome in PPCM.

METHODS AND ANALYSIS

In accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Protocols guidelines.[16]

Table 1 Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Population	Women with an index diagnosis of PPCM according to the ESC position statement.	Women presenting with heart failure earlier than the last month of pregnancy or women who were more than 6 months post partum. Women with PPCM and a subsequent pregnancy. Women with pre-existing heart disease. Studies in which the study population is not solely PPCM and their data cannot be differentiated from other patients with heart failure of other aetiologies. Animal studies.
Outcome	Reported in-hospital complications and outcomes at a 6-month and/or 12-month follow-up visit, such as, but not limited to: ► Death. ► LV non-recovery. ► Arrhythmias. ► Stroke. ► Thromboembolism.	No objective outcomes or complications reported for 6 months and/or 12 months.
Study design	Cohort studies Cross-sectional studies Retrospective studies Control arms of RCTs	Letters Commentaries Editorials Narrative reviews Case series (<10 patients) Case reports Congress abstracts Non-placebo control arms of RCTs Intervention arms of RCTs
Language		No English abstract available.
Year of publication	1 January 2000–1 June 2021.	Before the year 2000.

ESC, European Society of Cardiology; LV, left ventricular; PPCM, peripartum cardiomyopathy; RCTs, randomised controlled trials.

Table 2 Search strategies

A. Search strategy PubMed/MEDLINE		
Condition		
1	Title/abstract	"peripartum cardiomyopathy" OR "peri-partum cardiomyopathy" OR "postpartum cardiomyopathy" OR "post-partum cardiomyopathy" OR PPCM
Complications/outcomes		
2	Title/abstract	outcome OR complication OR "major adverse cardiac event" OR MACE OR death OR mortality OR morbidity OR hospitalisation OR hospitalisation OR rehospitalisation OR rehospitalisation OR admission OR readmission OR "ventricular recovery" OR "ventricular impairment" OR "ventricular dysfunction" OR "left ventricular assist device" OR LVAD OR transplant OR arrhythmia OR pacemaker OR "cardioverter-defibrillator" OR ICD OR WCD OR stroke OR "cerebrovascular accident" OR embolism OR thromboembolism OR "acute kidney injury" OR AKI OR "renal failure" OR "renal impairment" OR dialysis OR "renal replacement therapy" OR ECMO OR "extracorporeal membrane oxygenation"
3	MeSH terms	mortality [MeSH] OR death [MeSH] OR maternal death [MeSH] OR heart arrest [MeSH] OR hospitalisation [MeSH] OR ventricular dysfunction, left [MeSH] OR Heart-Assist Devices [MeSH] OR Transplants [MeSH] OR arrhythmias, cardiac [MeSH] OR pacemaker, artificial [MeSH] OR defibrillators, implantable [MeSH] OR stroke [MeSH] OR embolism and thrombosis [MeSH] OR renal replacement therapy [MeSH] OR renal insufficiency [MeSH] OR extracorporeal membrane oxygenation [MeSH] OR respiration, artificial [MeSH]
4	2 OR 3	
5	1 AND 4	
6		Timespan 2000 – to present
B: Search strategy Scopus		
Condition		
1	Title/abstract/keywords	"peripartum AND cardiomyopathy" OR "peri-partum cardiomyopathy" OR "postpartum AND cardiomyopathy" OR "post-partum AND cardiomyopathy" OR ppcm
Complications/outcomes		
2	Title/abstract/keywords	outcome OR complication OR "major AND adverse AND cardiac AND event" OR mace OR death OR mortality OR morbidity OR hospitalisation OR hospitalisation OR rehospitalisation OR rehospitalisation OR admission OR readmission OR "ventricular AND recovery" OR "ventricular AND impairment" OR "ventricular AND dysfunction" OR "left AND ventricular AND assist AND device" OR lvad OR transplant OR arrhythmia OR pacemaker OR "cardioverter-defibrillator" OR icd OR wcd OR stroke OR "cerebrovascular AND accident" OR embolism OR thromboembolism OR "acute AND kidney AND injury" OR aki OR "renal AND failure" OR "renal AND impairment" OR dialysis OR "renal AND replacement AND therapy" OR ecmo OR "extracorporeal AND membrane AND oxygenation"
3	1 AND 2	
4		Timespan 2000 – to present
C: Search strategy Web of science		
Condition		
1	Topic	"peripartum AND cardiomyopathy" OR "peri-partum cardiomyopathy" OR "postpartum AND cardiomyopathy" OR "post-partum AND cardiomyopathy" OR ppcm
Complications/outcomes		
2	Topic	outcome OR complication OR "major AND adverse AND cardiac AND event" OR mace OR death OR mortality OR morbidity OR hospitalisation OR hospitalisation OR rehospitalisation OR rehospitalisation OR admission OR readmission OR "ventricular AND recovery" OR "ventricular AND impairment" OR "ventricular AND dysfunction" OR "left AND ventricular AND assist AND device" OR lvad OR transplant OR arrhythmia OR pacemaker OR "cardioverter-defibrillator" OR icd OR wcd OR stroke OR "cerebrovascular AND accident" OR embolism OR thromboembolism OR "acute AND kidney AND injury" OR aki OR "renal AND failure" OR "renal AND impairment" OR dialysis OR "renal AND replacement AND therapy" OR ecmo OR "extracorporeal AND membrane AND oxygenation"
3	1 AND 2	
4		Timespan 2000 – to present

Continued

Table 2 Continued

D: Search strategy EBSCO Host		
Condition		
1	Abstract	"peripartum cardiomyopathy" OR "peri-partum cardiomyopathy" OR "postpartum cardiomyopathy" OR "post-partum cardiomyopathy" OR PPCM
Complications/outcomes		
2	Abstract	outcome OR complication OR "major adverse cardiac event" OR MACE OR death OR mortality OR morbidity OR hospitalisation OR hospitalisation OR rehospitalisation OR rehospitalisation OR admission OR readmission OR "ventricular recovery" OR "ventricular impairment" OR "ventricular dysfunction" OR "left ventricular assist device" OR LVAD OR transplant OR arrhythmia OR pacemaker OR "cardioverter-defibrillator" OR ICD OR WCD OR stroke OR "cerebrovascular accident" OR embolism OR thromboembolism OR "acute kidney injury" OR AKI OR "renal failure" OR "renal impairment" OR dialysis OR "renal replacement therapy" OR ECMO OR "extracorporeal membrane oxygenation"
3	1 AND 2	
4		Timespan 2000 – to present

Patient and public involvement

There will be no patient or public involvement in this systematic review and meta-analysis.

Eligibility criteria

Type of participants

As elaborated in table 1, women with a confirmed diagnosis of PPCM according to the latest ESC position statement, that is, heart failure secondary to LV systolic dysfunction with an LVEF <45%, which occurred towards the end of pregnancy or in the months following delivery in the absence of any other identifiable cause of heart failure.[1] We will not include studies on women with a prior diagnosis of PPCM and subsequent pregnancies, those where PPCM was not the only condition studied, or studies on women with pre-existing heart disease. Animal studies will not be considered for this systematic review.

Type of outcome measures

We will include all studies that report on in-hospital complications and 6-month and/or 12-month outcomes after the diagnosis of PPCM.

Type of studies

We will include cohort studies that reported the natural progression of the disease and cross-sectional studies describing complications and outcomes. We will also include the control arm of RCT that provided follow-up data, describing outcomes. Letters, commentaries, editorials, narrative reviews, case series (ie, less than 10 patients), case reports, congress abstracts will be excluded. In case of RCTs, we will only include the placebo control arm and exclude non-placebo control or intervention arms.

Language and years of publication

The year 2000 was the year that the first unified definition of PPCM was used by National Heart, Lung and Blood Institute and Office of Rare Diseases.[17] Therefore, articles published since 2000 will be considered for this systematic review and meta-analysis. To ensure the validity of the data, only studies for which an English abstract is available and which reported sufficient data will be included in the analysis.

Information sources

Electronic searches

We will search PubMed/MEDLINE, Web of Science, Scopus and EBSCO Host, including Academic Search Premier, Africa-Wide Information, Cumulative Index to Nursing and Allied Health Literature.

Searching other resources

We will review citation indexes and reference lists of all articles found through the database search to identify articles that the database search did not retrieve. In addition, we will conduct a grey literature search.

Search strategy

The lead reviewer (JH) and an expert librarian from the University of Cape Town's Faculty of Health Sciences will

conduct an extensive search for peer-reviewed articles. We will use a combination of free text terms and Medical Subject Heading terms (for PubMed) to search for articles. Table 2 shows the main search strategies that will be applied for the mentioned databases.

Data collection

The screening process and study selection will be done according to the guidelines of the *Cochrane Handbook for Systematic Reviews of Interventions*.[18]

Selection of studies

Two reviewers (JH and EM) will independently, and in duplicate, screen all articles identified by the search. We will use Rayyan QCRI to assist with the screening of articles.[19] In the case of an article being excluded, the reason will be documented. We will remove duplicate publications of articles. When we find duplicate publications with the same reported data, we will select the more recent publication with a more complete dataset.

The screening process will occur in two phases:

Phase 1: screening of titles and abstracts

All titles and abstracts of articles identified in the search will be screened for eligibility. If it is not apparent from the title or abstract whether an article meets eligibility criteria, or if both reviewers (JH and EM) do not exclude the article, the full text of the article will be reviewed.

Phase 2: screening of full-text studies

JH and EM will review the full texts of all potentially eligible articles. In the case of discrepancies between the reviewers, these will be discussed with a third reviewer (CAV), who will act as an adjudicator. We will document the reasons for excluding articles and present in an excluded studies table (figure 1).

Data extraction and management

References will be managed using EndNote V.20 software (Clarivate Analytics).

Data collection process

Two reviewers (JH and EM) will independently, and in duplicate, extract data from all articles meeting eligibility criteria. The reviewers will use a standardised electronic data collection form on Research Electronic Data Capture,[20] a secure online database manager hosted at the University of Cape Town.

Data items

For each study, the following information, but not limited to, will be collected (figure 2):

- Study characteristics such as authors, title and year of publication, journal, study design, setting and location, sample size and length of follow-up.
- Patient characteristics such as age, ethnicity, obstetric history, comorbidities, clinical presentation,

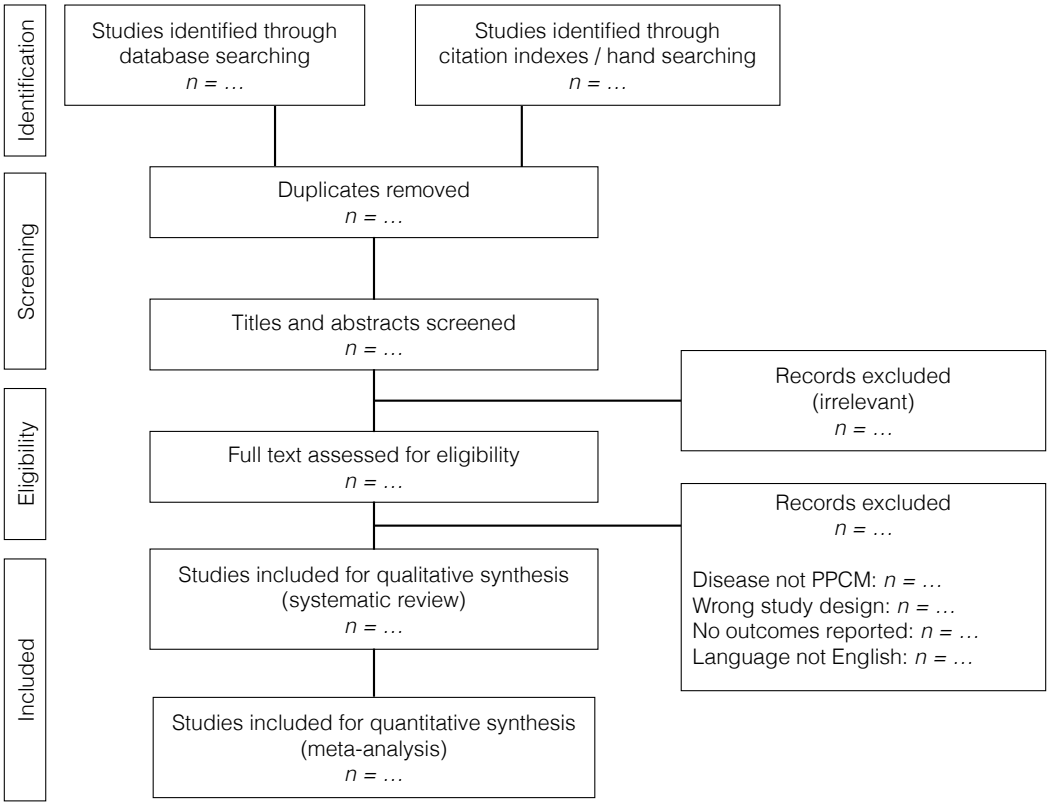

Figure 1 Study flow. PPCM, peripartum cardiomyopathy.

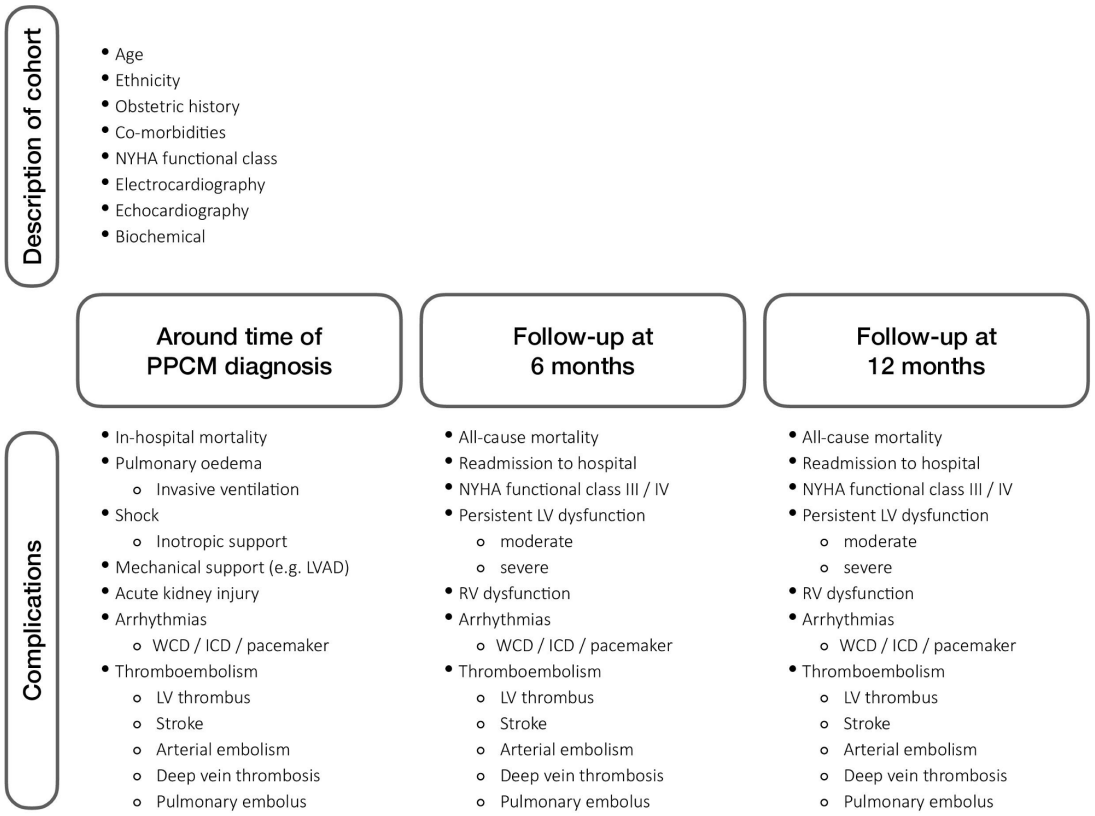

Figure 2 Data collection items at prespecified intervals. ICD, implantable cardioverter-defibrillator; LV, left ventricular; LVAD, left ventricular assist device; NYHA, New York Heart Association; PPCM, peripartum cardiomyopathy; RV, right ventricular; WCD, wearable cardioverter-defibrillator.

electrocardiography, echocardiography, biomarkers and treatment.

- In-hospital complications and outcomes prior to 6 months and/or 12 months follow-up, such as death, readmission to hospital, LV non-recovery (persistent LV dilatation and/or LVEF <50%), arrhythmias (eg, atrial fibrillation, ventricular tachycardia) or thromboembolism (eg, deep vein thrombosis, pulmonary embolism, LV thrombus, stroke, arterial embolism).

Assessment of methodological quality

Methodological quality assessment of non-randomised studies will be done independently, and in duplicate, by two reviewers (JH and EM) using the latest version of the recommended tool for assessing the risk of bias in prevalence studies by Hoy *et al*.[21]

Statistical analysis and data synthesis

Systematic review

We will provide a descriptive analysis of the study and patient characteristics, as well as the in-hospital complications and the outcomes reported at 6 months and/or 12 months for each included study (table 3).

Meta-analysis

Data synthesis will comprise two steps. The first step will involve identifying the data sources and the documentation of the numerators and denominators that will be used for calculating prevalence. Thereafter, we will determine the pooled estimates by using the Metaprop package in Stata (V.17). The pooled rates will be estimated using the Freeman-Tukey double arcsine transformation method to

Table 3 Results will be summarised in table format

Study characteristics	Patients' characteristics	In-hospital complications	Six-month outcome	Twelve-month outcome
Lead author, title and year of publication, journal, study design, setting and location, sample size and length of follow-up.	Age, ethnicity, obstetric history, comorbidities, clinical presentation, electrocardiography, echocardiography, biomarkers and treatment.	Death, arrhythmias (eg, AF, VT) or thromboembolism (eg, DVT, PE, LV thrombus, stroke, arterial embolism), LV assist device, pacemaker, invasive ventilation, acute kidney injury.	Death, readmission to hospital, LV non-recovery (persistent LV dilatation and/or LVEF <50%), arrhythmias (eg, AF, VT) or thromboembolism (eg, DVT, PE, LV thrombus, stroke, arterial embolism).	Death, readmission to hospital, LV non-recovery (persistent LV dilatation and/or LVEF <50%), arrhythmias (eg, AF, VT) or thromboembolism (eg, DVT, PE, LV thrombus, stroke, arterial embolism).

AF, atrial fibrillation; DVT, deep vein thrombosis; LV, left ventricular; LVEF, LV ejection fraction; PE, pulmonary embolism; VT, ventricular tachycardia.

stabilise the variance of proportion within each study.[22] The stabilisation of variance will help minimise the influence of studies with outliers before the data is pooled together. Stratification of the data will be conducted by study design and by samples sizes. We will assess heterogeneity by inspecting forest plots as well as I^2 and χ^2 tests. We will use a fixed-effects model only if studies are judged to be homogeneous. Should heterogeneity be present, we will use the random-effects model. Where found, the possible reasons for any heterogeneity will be explored, and if unexplainable, findings will be reported in a narrative review.

Analyses will be conducted if possible, taking into account previously reported prognostic factors such as LVEF <35% at first presentation, ethnicity, advanced maternal age, high parity, twin pregnancy. The relative risk and/or the OR will be used to determine the strength of effects among dichotomous variables, and weighted mean difference will be calculated for continuous variables. The statistical significance will be evaluated through inspection of the 95% CIs.

Sensitivity analyses

We intend to do sensitivity analyses to determine the potential sources of heterogeneity, and we will determine the impact of including only high-quality studies on the result. In the absence of data amenable to meta-analysis, a narrative description will be provided.

DISCUSSION

Expected significance of the study

PPCM, a global disease occurring across all continents and in patients of all ethnicities, remains a major risk factor for maternal morbidity and mortality. Published data on complications and outcome are mainly limited to national, single centre studies with limited sample size. Moreover, the reported outcomes after six or twelve months differ considerably across various regions. Prior systematic reviews reporting on outcome in PPCM included patients with variable follow-up (with large ranges) and did not report on complications other than all-cause mortality and LV recovery.[23 24] To the best of our knowledge, no prior systematic review has systematically reported on the burden of complications occurring around the time of diagnosis as well as 6-month and/or 12-month outcomes of women with PPCM. Furthermore, no prior systematic review has specifically compared these outcomes among different regions. A summarised description in form of a pooled analysis of across multiple centres, regions and continents would help us to better understand the estimates of complications and outcomes of women with PPCM. It may also help to identify new possible risk factors, which influence outcome.

Ethics and dissemination

As this research is a systematic review of published literature, ethical approval is not required. The results will be reported according to the latest guidelines for PRISMA 2020 statement,[25] and will be submitted to a peer-reviewed journal. The protocol and the systematic review will be included in a PhD dissertation.

Amendments to protocol

To ensure transparency, any change from this protocol will be amended on the PROSPERO database.

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Contributors JH, CAV, KS and MEE designed the study. JH registered the protocol with the PROSPERO database. JH and CAV drafted the manuscript, which was critically revised by AH, EM, KS, MB and MEE. All authors agreed on the final manuscript for submission.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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