*Health Science Reports*

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METHODS AND PROTOCOLS OPEN ACCESS

# Clinical and Preclinical Evidence on a Novel Percutaneous Pulsatile Ventricular Assist Device (PulseCath): Protocol for a Scoping Review

Viviana Teresa Agosta | Alice Bottussi | Jacopo D'Andria Ursoleo | Letizia Perinati | Fabrizio Monaco

Department of Anesthesia and Intensive Care, IRCCS San Raffaele Scientific Institute, Milan, Italy

**Correspondence:** Fabrizio Monaco (monaco.fabrizio@hsr.it)

**Received:** 10 December 2024 | **Revised:** 3 March 2025 | **Accepted:** 15 March 2025

**Funding:** The authors received no specific funding for this work.

**Keywords:** cardiogenic shock | hemodynamic instability | Impella | intra-aortic balloon pump | iVAC2L | iVAC3L | pulsatile ventricular assist device | PulseCath | temporary mechanical circulatory support

## ABSTRACT

**Background and Aims:** Temporary mechanical circulatory support (tMCS) devices play a crucial role in improving survival for patients with hemodynamic instability by providing cardiac assistance, and may serve as either a bridge to recovery or destination therapy. Recently, the PulseCath (iVAC2L and iVAC3L) has been introduced into the broader tMCS landscape. Due to its ease of implantation and low cost, it appears to enhance and complement the spectrum of tMCS devices. This planned scoping review aims to summarize the potential applications and reported side effects of PulseCath, while elucidating its underlying pathophysiological principles and hemodynamic effects, incorporating both preclinical in vivo and clinical published data.

**Methods:** We will perform a scoping review in accordance to the JBI methodology and the extension for Scoping Reviews of the PRISMA checklist. We will conduct a comprehensive search of PubMed/MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Web of Science, Scopus, and Google Scholar (from their inception until February 28, 2025) to identify and retrieve preclinical in vivo and clinical investigations on the implantation of the PulseCath. EndNote X9 and Rayyan softwares will be used to aid article selection. Standardized forms will be employed for subsequent data charting and extraction. The ROBINS-I and RoB2 tools will be employed to perform a formal assessment of the risk of bias of included studies.

**Results:** Included studies will be categorized into two groups: preclinical in vivo and clinical. The clinical studies will be further classified according to implantation strategy, either pre-emptive or bail-out. The main findings from the selected studies will be presented through a narrative synthesis. If sufficient homogeneity exists among the studies, the presentation of quantitative data will be conducted. Tables and figures will be used to aid in the illustration of the findings.

**Conclusion:** The planned scoping review will systematically examine the existing evidence on the hemodynamic effects, pathophysiology, and potential complications of PulseCath, ultimately seeking to delineate optimal clinical settings for its use. The findings could highlight research gaps in tMCS support and expand the clinical application of PulseCath, thus improving patient outcomes and enhancing clinicians' understanding of this novel device.

## 1 | Introduction

### 1.1 | Background

Over the last decade, temporary mechanical circulatory support (tMCS) has been increasingly employed to provide cardiac assistance in patients experiencing hemodynamic instability, thus serving as either a bridge to recovery of native heart function or destination therapy (i.e., heart transplantation [HTx], long-term MCS) [1]. In patients presenting with cardiogenic shock or severe hemodynamic instability, tMCS temporarily enhances end-organ perfusion and oxygen delivery and should be considered, on a case-by-case basis, in patients with refractory shock who are unresponsive to high-dose conventional medical therapy (i.e., vasopressors and/or inotropes) [2]. The timely implantation of tMCS has showed benefits regarding patient outcomes in several clinical scenarios, including high-risk percutaneous coronary intervention (PCI), acute heart failure (AHF), and cardiogenic shock [1–4] as demonstrated by the observed significant reduction in patient morbidity and mortality [5].

A wide range of tMCS devices is currently available, which exhibit substantial differences in terms of hemodynamic effects, level of support, preferred access site, implantation approach (i.e., percutaneous or surgical), sheath size, and configuration. The intra-aortic balloon pump (IABP) has been the first widely used tMCS device in the setting of severe cardiogenic shock and is still largely employed nowadays [6]. Although it provides only a limited degree of circulatory support (i.e., maximum flow of 0.5–1 L/min), it is associated with the occurrence of fewer potential complications and lower costs compared to other tMCS devices [1, 7]. The TandemHeart (TandemHeart, Cardiac Assist, Pittsburgh, PA, USA) provides selective support for either the left (LV) or right ventricle (RV) and can be upgraded with the addition of an oxygenator to support gas exchanges when hemodynamic instability is associated with hypoxia [1]. The Impella (Abiomed Europe, Aachen, Germany) heart pump encompasses a family of percutaneous, intravascular transvalvular microaxial blood pumps, which are deployed across the aortic valve and provide left ventricular unloading by pumping blood from the LV into the ascending aorta. Impella can achieve a flow of up to 5.5 L/min. However, it is associated with severe complications spanning vascular injuries, bleeding events, and hemolysis, the latter of which can potentially result in the occurrence or precipitation of acute kidney injury (AKI) [7]. Venoarterial extracorporeal membrane oxygenation (V-A ECMO) provides both respiratory and hemodynamic support and can be implanted with either peripheral or central configurations [1]. Compared to IABP, the two latter tMCS devices are more expensive, require specific equipment and are associated with a broader range of complications, the incidence of which increases proportionally with the device's level of invasiveness [8].

The PulseCath (iVAC2L and iVAC3L, BV, Arnhem, The Netherlands) is a novel percutaneous LV assist device which was first conceived as an evolution of IABP and constitutes a promising addition to the tMCS array. This device consists of a 17 or 21 Fr-valved catheter allowing for a bidirectional flow, coupled with a novel extracorporeal membrane pump. The catheter can be positioned either in the LV or RV via a percutaneous or surgical approach [9–11]. Additionally, the compatibility of PulseCath with traditional IABP drivers provides a significant advantage by eliminating the need for additional equipment, thereby reducing associated costs [9]. PulseCath offers a sustained flow of 2–3 L/min, higher than that of the IABP (0.5–1 L/min) but lower than that of the Impella (2.5–5.5 L/min) pump [12–14]. Additionally, the device is relatively easy and safe to deploy, although access-site complications, bleeding, and potential aortic valve injury still persist as inherent safety concerns [11].

In the wide array of available tMCS, PulseCath appears to fill the gap between IABP and Impella by providing intermediate circulatory support with the advantage of lower treatment costs and simpler logistics. Moreover, although major vascular complications (e.g., access-site hematoma, leg ischemia requiring urgent intervention, false aneurysm or femoral artery occlusion) remain a potential concern, the reported incidence of the aforementioned complications in the published literature appears to be lower for PulseCath compared to both Impella and IABP [11]. While its pre-emptive use in high-risk PCI has been previously reported in the available literature, further evidence supporting its broader clinical application is limited and—to date—requires further investigation [15–17]. Still, the quest for an optimal tMCS device extends beyond hemodynamic optimization, provided that these devices should demonstrate a favorable risk-benefit profile, prioritizing patient safety and efficacy, while also ensuring cost-effectiveness and easy accessibility. Moreover, ease of insertion and compatibility with existing healthcare infrastructure will be critical to their widespread adoption. With its innovative design and favorable compatibility profile, PulseCath could represent a step forward in addressing current gaps in tMCS options. Consequently, performing a scoping review is essential in this context as it seeks to systematically map the existing body of evidence, while identifying knowledge gaps, and delineating research priorities, thereby providing a foundational framework to guide future primary studies (i.e., original research).

### 1.2 | Study Objectives

We will conduct a systematically structured scoping review of the available literature aiming to provide the first comprehensive summary of the published evidence regarding the clinical and preclinical in vivo applications of PulseCath, with the results of our report being planned for submission to a peer-reviewed and indexed journal by March 31, 2025.

The primary goal will be to elucidate both on the pathophysiological foundations of the PulseCath and the relationship between patients' underlying pathological condition and the hemodynamic variations induced by this device. This will be considered in the context of both its “pre-emptive” use (i.e., enabling otherwise unfeasible interventions such as high-risk PCI, transcatheter ablations of arrhythmias, etc.) and “bail-out” use (i.e., in patients with hemodynamic instability who experience acute cardiac failure) [9, 10, 16, 17].

This scoping review is expected to enhance knowledge dissemination within the scientific community, thus facilitating broader insights into the potential application of the PulseCath

in clinical practice. Furthermore, it will highlight ongoing research and future directions, with a focus on advancements aimed at improving patient outcomes, while also expanding upon the clinical indications of PulseCath implantation.

## 2 | Materials and Methods

To formulate the present research protocol we employed the JBI (formerly known as "Joanna Briggs Institute"—an international research organization partnering with universities and hospitals to foster the integration of evidence-based healthcare within a broader theoretical model, with the aim of improving global health outcomes and service delivery), alongside the Preferred Reporting Items for Systematic Review and Meta-Analyses Protocols (PRISMA-P) guidelines [18, 19]. The subsequent review process will adhere to the approach outlined in the PRISMA-P extension for Scoping Reviews (PRISMA-ScR) [20].

### 2.1 | Protocol Development and Approval

In accordance with the PRISMA-ScR guidelines, this scoping review protocol was drafted and approved by all authors before the commencement of the study.

### 2.2 | Eligibility Criteria

To outline the potential applications and advantages of the PulseCath in both the perioperative and non-perioperative settings—while also elucidating on both the hemodynamic and pathophysiological foundations which support its use—we will conduct a systematically structured scoping review of the published literature.

The clinical focus will then shift toward assessing its efficacy and safety profile, including its potential to facilitate surgical procedures, improve patient outcomes, and manage the occurrence of acute cardiac events. Moreover, its benefits will be assessed beyond the surgical setting, in combination with other tMCS devices as well. Study selection will be conducted in adherence to the specific inclusion and exclusion criteria detailed in the following sections.

#### 2.2.1 | Inclusion Criteria

- Study designs: All types of study designs will be considered.
- Population: Both preclinical in vivo studies and clinical studies involving adult patients that detail the effectiveness of PulseCath will be retrieved.
- Interventions: Inclusion will be limited to studies evaluating the perioperative implantation of PulseCath for elective or emergent procedures (both preemptively to reduce inherent surgical risk and as part of a bail-out strategy in the event of unexpected acute heart failure), or its implantation independently of surgical intervention in the context of acute cardiac failure, either alone or in combination with other tMCS devices.
- Language: No language restrictions will be applied to the search process. Papers in languages other than English will be retrieved only if clear, adequate, and unambiguous translations can be provided using free online translation tools (e.g., Google Translate, DeepL Translator).
- Territories: No geographical restrictions will be applied during the studies selection process.

#### 2.2.2 | Exclusion Criteria

Studies including pediatric patients (aged $< 18$ years old), pregnant women, and preclinical non-in vivo data, as well as studies that do not present original data (i.e., systematic or narrative reviews, meta-analyses, commentaries, conference abstracts that remained unpublished, and editorials) and overlapping populations will be excluded from our scoping review. No other restrictions on study design will be imposed.

### 2.3 | Data Sources

A systematic search of the following databases will be conducted: PubMed/MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Web of Science, Scopus, and Google Scholar, from their inception until February 28, 2025. No additional time restrictions will be imposed.

#### 2.3.1 | Search Strategy and Selection Process

The core concepts guiding this scoping review, which will also be integrated into the search strategy, are as follows:

i PulseCath (PulseCath B.V., Amsterdam, The Netherlands);

ii iVAC2L;

iii iVAC3L;

iv adult patients;

v preclinical in vivo data;

vi clinical data in the aforementioned population (i.e., adults).

Given the variability in how some concepts are addressed in the published literature, synonym counterparts for each of the key concept (i)–(vi) will be included in the search string to ensure a comprehensive examination of the published literature. Boolean operators 'OR', 'AND', and 'NOT' will be used to refine search results, thus increasing search precision.

The search terms may need to be updated during the review process so as to guarantee a comprehensive analysis. Any variations made will be clearly documented and motivated in the final paper, along with a comprehensive assessment of their impact on the search results.

The literature search will be carried out by two experienced investigators (V.T.A. and A.B.) to identify studies pertinent to the research question and satisfying the abovementioned search parameters (i)–(vi).

An additional final search will be performed by a third investigator (J.D.U.) before submitting the final draft of the scoping review manuscript for consideration of publication to ensure that all pertinent studies have been included.

Backward and forward snowballing techniques will be applied to further scrutinize the references of retrieved studies, so as to identify additional relevant studies.

#### 2.3.2 | Study Selection Process

Following the study retrieval process, removal of duplicate studies will be performed using EndNote X9 (Clarivate Analytics). The remaining citations will then be uploaded to Rayyan for further evaluation [21].

The intuitive interface provided by Rayyan will streamline the identification, inclusion, and exclusion of articles according to pre-specified criteria. The Rayyan tool optimizes the task of shifting through and identifying studies for systematic reviews, particularly when handling large data sets of scientific publications, while fostering collaboration and minimizing bias in study selection.

Every retrieved reference will undergo independent assessment by two experienced investigators (V.T.A. and A.B.), at both title and abstract levels.

In case of disagreement, a third investigator (J.D.U.) will be consulted who will ultimately review and discuss each retrieved article in its full-text version.

The PRISMA flow diagram will be used to visually represent, record, and summarize the study selection process. Moreover, the number of studies identified, screened, excluded, and ultimately included into the final analysis will be recorded (Figure 1).

### 2.4 | Data Extraction

A standardized approach to data charting and extraction will be adopted aided by Tables 1–3. Additional evaluations and refinements to the data chart forms may be conducted during the review process, with any modifications being subsequently detailed in the final draft of the scoping review.

Data from the retrieved studies will be manually extracted by two independent investigators (V.T.A. and A.B.), and will then be subject to further review and assessment by a third investigator (J.D.U.). A fourth, senior investigator (F.M.) will be consulted in instances of discordance and resolution will be achieved through mutual discussion.

Should any data from the retrieved studies be missing, the corresponding author will be consulted.

To avoid the duplication of multiple reports on a single study, we will adhere to the criteria for comparing reports as recommended by Lefebvre et al. in the Cochrane Handbook for Systematic Reviews of Interventions [22].

### 2.5 | Assessment of the Risk of Bias

Our scoping review will aim to systematically identify and describe the key findings of the retrieved studies, thus providing a narrative synthesis of the current evidence regarding the use of PulseCath across several clinical and preclinical settings. As a result, a formal assessment of the risk of bias (RoB) for each of the included studies is not mandatory.

However, to further characterize the quality of the retrieved evidence and provide a solid evaluation of the potential clinical application of PulseCath, a formal assessment of the risk of bias will be conducted, utilizing the Risk Of Bias In Non-Randomized Studies – of Interventions (ROBINS-I) tool for observational studies available online at: https://www.riskofbias.info [23].

Moreover, a thorough qualitative assessment of the collective evidence will be incorporated within the Section 3 of our review.

### 2.6 | Data Synthesis

Data extracted from the selected studies will be summarized in a narrative fashion to characterize its relevance with respect to the research question.

Retrieved studies will be initially sorted into two main groups according to the setting (i.e., preclinical in vivo and clinical) in which they were performed. More specifically:

- Preclinical studies: the focus of this analysis will be on presenting and summarizing in vivo data.
- Clinical studies: this analysis will present and summarize data on the use of PulseCath in adult hospitalized patients. Furthermore, clinical studies will be further categorized based on the timing and rationale underlying the PulseCath implantation as follows:
  - o "Pre-emptive PulseCath implantation": this refers to the pre-planned implantation of the PulseCath device in patients before the actual beginning of the surgical procedure, with the aim of either minimizing the surgical risk or to enable the procedure in patients who would otherwise be deemed ineligible for upfront surgery.
  - o "Bail-out PulseCath implantation": this refers to the implantation of the PulseCath in patients as a rescue therapy for refractory cardiac failure occurring either periprocedurally or unexpectedly in any nonsurgical setting.

### 2.7 | Statistical Analysis

We will present results for each individual study, encompassing predictive performances for predefined outcomes. The characteristics of the patient population will encompass categorical variables in terms of frequency and percentages, and continuous variables as either means with standard deviation (SD) or medians with interquartile ranges (IQR), as appropriate. The data presentation will include descriptive statistics and illustration through tables and figures, when indicated. If the

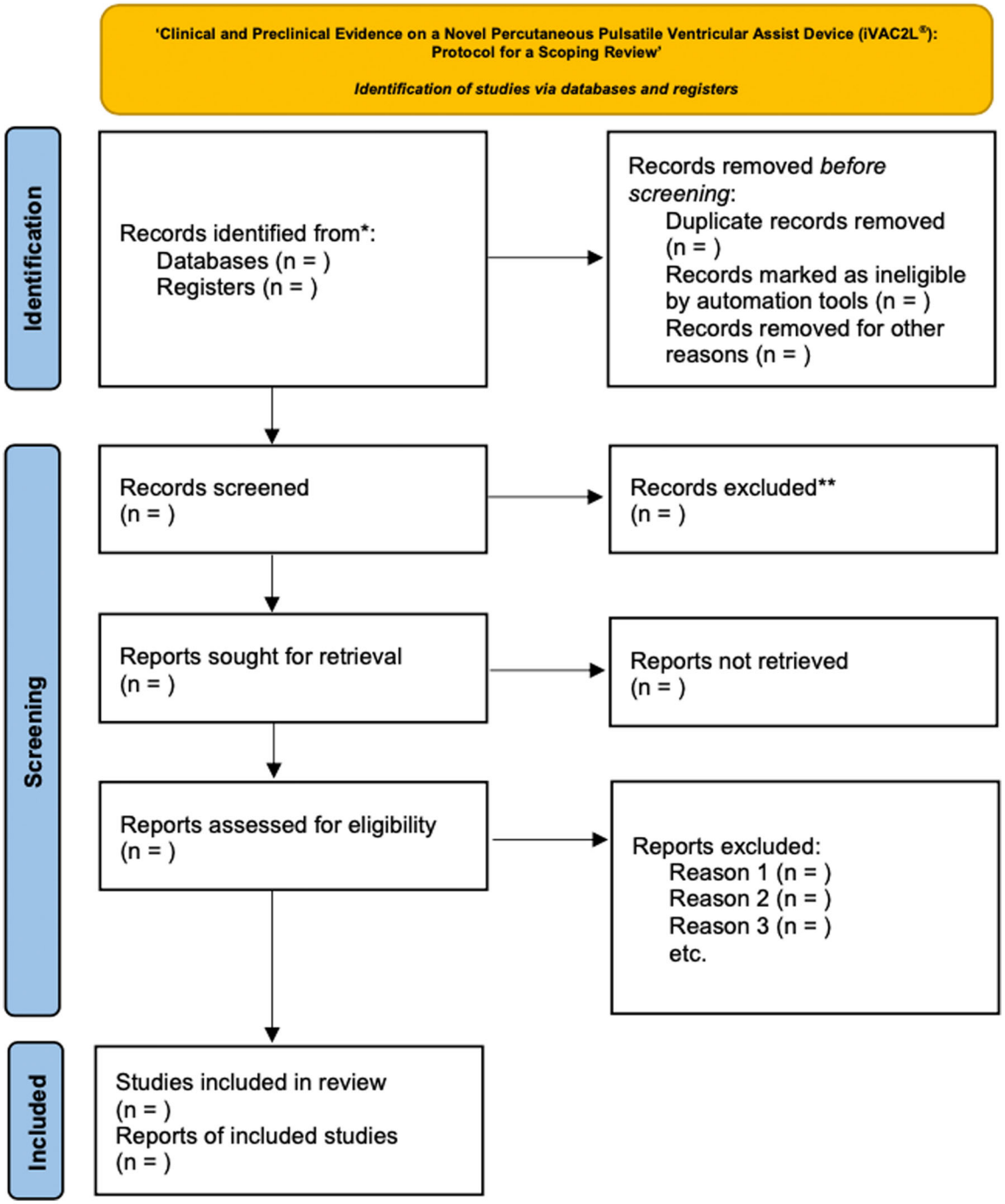


**FIGURE 1** | Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) 2020 flow diagram for new reviews which included systematic searches of databases and registers only.

retrieved studies exhibit substantial heterogeneity, formal data synthesis or statistical analyses will not be conducted.

## 2.8 | Data Dissemination

The study data will be made accessible upon reasonable request to F.M.

We plan to submit the result of this scoping review for consideration and publication to a relevant indexed, peer-reviewed journal for publication within March 31, 2025.

## 2.9 | Ethical Issues

As this study poses no ethical risks, a formal approval or publication consent will not be required.

## 3 | Discussion

This scoping review will be the first systematically structured research effort to comprehensively evaluate the existing literature on the PulseCath, aiming to elucidate its potential clinical applications while identifying key knowledge gaps requiring

**TABLE 1** | Preclinical in vivo applications of PulseCath—data extraction.

| |
|---|
| Characteristics of the included studies |
| First author,[reference] |
| Publication year |
| Number and disease of animal models involved |
| Characteristics of PulseCath utilization |
| Ventricular assistance |
| Flow |
| Type of implantation, lumen catheter |
| Heparin, ACT |
| Duration of PulseCath support |
| PulseCath: OFF |
| Hemodynamic parameters |
| PulseCath: ON |
| Hemodynamic parameters |
| Outcomes |
| PulseCath complications |

Abbreviation: ACT, Activated clotting time.

**TABLE 2** | Clinical applications of PulseCath—included studies and perioperative data extraction.

| |
|---|
| Characteristics of the included studies |
| First author,[reference] |
| Publication year |
| Study design |
| Characteristics of patients included |
| Number of patients |
| Concomitant cardiac disease |
| Surgical procedure performed |
| Characteristics of PulseCath utilization |
| Reason for implantation |
| Pre-emptive or bail-out implantation |
| Site of implantation, lumen catheter |
| Heparin infusion, ACT target |
| Duration of PulseCath support |
| Outcomes |
| PulseCath complications |
| ICU stay |
| In-hospital stay |
| Patient status at the latest available follow-up |

Abbreviation: ACT, activated clotting time.

further investigation. Therefore, its primary objectives are: (i) to explore its potential clinical uses; (ii) to define patient populations most likely to benefit from PulseCath device implantation; and (iii) to assess the safety and hemodynamic performance of the PulseCath device.

**TABLE 3** | Clinical applications of PulseCath—hemodynamic and echocardiography data extraction.

| |
|---|
| Characteristics of the included studies |
| First author,[reference] |
| Publication year |
| Number of patients involved |
| Characteristics of PulseCath utilization |
| Pre-emptive or bail-out implantation |
| Ventricular assistance |
| Flow |
| Concomitant tMCS |
| PulseCath: OFF |
| Hemodynamic parameters |
| Echocardiography parameters |
| Inotropes and vasopressors administration (type and dose, if available) |
| Vasoactive-inotropic score (VIS) |
| PulseCath: ON |
| Hemodynamic parameters |
| Echocardiography parameters |
| Inotropes and vasopressors administration (type and dose, if available) |
| Vasoactive-inotropic score (VIS) |

Abbreviation: tMCS, temporary mechanical circulatory support.

We will employ an interdisciplinary approach to conduct a comprehensive evaluation of the PulseCath, combining clinical evidence with preclinical in vivo data. Specifically, preclinical studies will delve into the device's underlying pathophysiological mechanisms and how these affect hemodynamics. Clinical studies will instead enable us to identify optimal clinical scenarios, implantation rationales, and patient-specific hemodynamic responses in the context of both pre-emptive and rescue (i.e., bail-out) strategies [10, 16]. A thorough safety assessment, encompassing device-related adverse events, will also be conducted to weigh the benefits of the PulseCath against its potential inherent risks.

In the broad landscape of tMCS devices available, a rigorous systematic review is necessary to comprehensively assess the advantages of PulseCath compared to existing devices (i.e., IABP, Impella and V-A ECMO). Notably, PulseCath may address the existing gap between IABP and Impella in terms of both invasiveness and the level of hemodynamic support provided. Furthermore, its ease of implantation positions it as a potentially valuable option in emergent and urgent clinical scenarios as well [11]. By integrating the available clinical and preclinical data on the PulseCath, this scoping review aims be to explore and characterize its hemodynamic effects. Building upon the established evidence demonstrating improved survival in patients with hemodynamic instability managed with tMCS [24, 25], this comprehensive review will provide a framework for the potential applications of this innovative

device, both as a stand-alone therapy and in combination with other tMCS modalities [10].

### 3.1 | Strengths and Limitations

The methodological strengths of the proposed scoping review include: (i) a clear and pre-defined research objective; (ii) a rigorous methodology guided by a pre-specified research protocol; (iii) adherence to both JBI and PRISMA-ScR guidelines to ensure methodological accuracy; (iv) a systematic search of multiple online databases to identify all significant literature [18–20]; and lastly, (v) standardized data extraction forms to guide data extraction from the retrieved literature.

Notwithstanding the aforementioned methodological strengths, it is relevant to consider the potential limitations exhibited by our search strategy, such as the potential lack of formal risk of bias assessment coupled with the heterogeneity of the data which may ultimately jeopardize the possibility of performing statistical data synthesis or analysis. Nonetheless, as a scoping review, this study can still provide physicians with an exhaustive comprehensive overview of the existing evidence.

## 4 | Conclusion

The PulseCath represents a promising venue for patients experiencing hemodynamic instability. Its key advantages (e.g., a flow rate of 2–3 L/min coupled with ease-of-implantation compared to other tMCS devices) allow for a potentially broader application across several settings, both in the context of a "pre-emptive" use (e.g., during high-risk PCI), and as a rescue therapy in overt refractory cardiogenic shock.

Building on a comprehensive review of the available evidence, the planned scoping review aims to outline the potential clinical applications of this novel device. This will with an exploration of its underlying pathophysiology and the hemodynamic changes it elicits, with the ultimate goal of improving patient outcomes.

#### Author Contributions

**Viviana Teresa Agosta:** conceptualization, investigation and writing – original draft. **Alice Bottussi:** investigation, writing – original draft and writing – review and editing. **Jacopo D'Andria Ursoleo:** conceptualization, supervision, investigation, writing – original draft and writing – review and editing. **Letizia Perinati:** investigation and writing – review and editing. **Fabrizio Monaco:** conceptualization, supervision and writing – review and editing. All authors of the present work adhere to the authorship guidelines delineated by the International Committee of Medical Journal Editors. All authors have read and approved the final version of the manuscript. Fabrizio Monaco had full access to all of the data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

#### Acknowledgments

The authors have nothing to report.

#### Ethics Statement

The authors have nothing to report.

#### Consent

The authors have nothing to report.

#### Conflicts of Interest

The authors declare no conflicts of interest.

#### Data Availability Statement

The authors have nothing to report.

#### Transparency Statement

The lead author Fabrizio Monaco, affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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