#### Systematic Review

# Effect of Extracorporeal Membrane Oxygenation Support on Complex High-Risk Elective Percutaneous Coronary Intervention: A Clinical Research Review of Progress and Outcomes

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#### Abstract

Background: The landscape of percutaneous coronary intervention (PCI) has expanded to encompass complex highrisk elective cases, necessitating advanced support strategies to mitigate procedural challenges and ensure patient safety. In this review manuscript, the effect of extracorporeal membrane oxygenation (ECMO) support on complex high-risk elective PCI was critically evaluated through an analysis of relevant clinical studies. The objective is to elucidate the role of ECMO in optimizing procedural success, mitigating complications, and improving long-term patient outcomes in this high-stake domain of interventional cardiology. Methods: A comprehensive search strategy identified seven publications encompassing single-center prospective, retrospective, and case report designs, collectively involving 91 patients undergoing high-risk elective PCI with ECMO support. Results: The results from these studies demonstrated the potential of ECMO support to facilitate successful high-risk elective PCI with favorable procedural outcomes, highlighting the importance of careful patient selection and proactive management of potential complications to further optimize the use of ECMO in this clinical setting. The refinement of patient selection criteria, optimization of procedural techniques, and assessment of long-term clinical outcomes following ECMO-assisted high-risk PCI procedures represent crucial avenues for future research. Conclusions: Overall, the reviewed evidence supports the notion that ECMO represents a valuable tool for providing hemodynamic support during high-risk PCI procedures, particularly in patients deemed at very high risk for surgical revascularization.

## Keywords

percutaneous coronary intervention; extracorporeal membrane oxygenation; high-risk elective PCI; cardiopulmonary support; outcomes

## Introduction

Percutaneous coronary intervention (PCI) is a widely used procedure for the treatment of coronary artery disease (CAD), and it has evolved to encompass increasingly complex cases, including high-risk elective interventions [1,2]. While the majority of elective PCIs are performed without major complications, a subset of patients with complex, high-risk features presents a significant clinical challenge [3–5]. Historically, high-risk elective PCI cases have posed substantial challenges for interventional cardiologists, because they often involve patients with severe multi-vessel disease, left main artery stenosis, severely reduced left ventricular function, or a combination of these factors [5–7]. In such cases, the potential for hemodynamic compromise, myocardial infarction, and malignant arrhythmias during the procedure is increased, thus necessitating careful consideration of the optimal support strategies to ensure procedural success and patient safety [8,9].

In recent years, the use of extracorporeal membrane oxygenation (ECMO) to support patients during high-risk PCI has gained attention owing to its potential to mitigate the risk of hemodynamic instability and provide vital cardiopulmonary support [10–13]. The intersection of ECMO support and high-risk elective PCI represents a compelling area of clinical research, because it addresses the management of patients with complex CAD who are at increased risk of adverse cardiovascular events during PCI [14–16]. The emergence of ECMO as a viable adjunctive support modality in the context of high-risk elective PCI has prom-

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Author	Country	Type of study	Study population	Results/findings	Conclusion
Fomasello et al. [23]	Italy	single-center prospectical study	12	Following the PCI procedures, no in-hospital major adverse car- diac events (MACE) was observed, and at the 6-month follow-up, there were no instances of death or myocardial infarction (MI). Among the patients, 17% required additional revascularization, and one patient needed chronic hemodialysis.	Elective high-risk percutaneous coronary intervention (PCI) backed by extracorporeal membrane oxygenation (ECMO) presents a feasible option for patients with a high predisposi- tion for CABG.
Shaukat <i>et al</i> . [24]	USA	single-center retro- spective study	5	All PCIs were performed successfully, with only one patient needing surgical repair of the femoral artery. The average post-procedure hospital stay was $6.4 \pm 2.0$ days. ECMO removal was successful in all cases, and in four instances, ECMO was required for less than 24 h. During the hospital stay, no instances of inhospital complications occurred, and no major adverse cardiac and cerebrovascular events (MACCEs) were reported within 1 year.	
Ungureanu <i>et al</i> . [25]	Belgium	single-center retro- spective study	9	All patients underwent successful PCI to revascularize all target and additional lesions. Of the nine patients, eight survived for a minimum of 30 days post-procedure, and seven survived for 3 years. Complications included limb ischemia in two patients, which was managed with antegrade perfusion; femoral perforation requiring surgical repair in one patient; hematoma in six patients, significant hemoglobin drop necessitating blood transfusions in five patients; septicemia in two patients, and hemodialysis in two patients.	In elective patients, the prophylactic use of veno-arterial (VA)- ECMO is an acceptable strategy for revascularization during high-risk coronary percutaneous interventions, leading to good long-term outcomes for patients considered inoperable when a clear clinical benefit is anticipated. In the series, the candidate selection for VA-ECMO was based on a multiparameter analy- sis to assess the potential risk of complications associated with the system. The primary rationales for prophylactic VA-ECMO in the studies were recent history of heart failure and high like- lihood of prolonged impairment of the coronary flow through the major epicardial artery during the peri-procedural period.
Kmiec et al. [18]	Germany	single-center case re- port	1	The case illustrates the safe use of temporary prophylactic ECMO support with immediate vascular closure for elderly and frail patients undergoing TAVR and complex PCI in an elective setting, demonstrating the feasibility of this approach for such patients.	Elective prophylactic ECMO can be implemented in carefully chosen highly at-risk and frail patients undergoing transcatheter aortic valve replacement and PCI to prevent intraprocedural complications.

## Table 1. Publications related to the effect of ECMO support on complex high-risk elective PCI.

				Table 1. Continued.	
Author	Country	Type of study	Study population	Results/findings	Conclusion
Griffioen et al. [26]	Netherlands	single-center retro- spective study	13	In 13 out of 14 patients, femoral artery ECMO cannulation was carried out, and an additional antegrade femoral artery cannula was required in one patient due to periprocedural limb ischemia. The average duration of the ECMO run was 151 min, with one patient needing prolonged ECMO sup- port for 2 days before being weaned off. Revascularization was successfully achieved in 13 patients (92.8%), and the procedural success rate was 85.7%, with one unsuccessful revascularization and one procedural death. During the hospital stay, four patients (28.6%) experienced MACE, and within 60 days after discharge, two patients (16.7%) had MACE.	makes high-risk PCI a viable treatment choice when surgical revascularization is deemed to pose
Awar <i>et al</i> . [27]	USA	single-center retro- spective study	15	After PCI was performed on all patients, the procedure was found to be successful. In-hospital mortality was observed in three patients (20%), whereas seven patients (47%) required blood transfusion. Additionally, no major vascular complications were reported.	high-risk PCI is deemed satisfactory and could of-
Bai <i>et al</i> . [28]	China	single-center retro- spective study	36	ECMO was utilized in 44.4% of the patient cohort. Pre- and post- operatively, the SYNTAX scores averaged 34.6 $\pm$ 8.4 and 10.8 $\pm$ 8.8, re- spectively ( $p < 0.001$ ). Intraoperative complications encompassed pericar- dial tamponade (N = 2, 5.6%), acute left-sided heart failure (N = 1, 2.8%) and malignant arrhythmia necessitating electrocardioversion (N = 2, 5.6%), with no reported fatalities. The hemoglobin levels before PCI measured 145.4 $\pm$ 20.2 g/L, and 24 h after ECMO withdrawal, they averaged 105.7 $\pm$ 21.7 g/L ( $p < 0.001$ ). The hospitalization outcomes included mortality (N = 1, 2.8%), stroke (N = 1, 2.8%), lower limb ischemia (N = 2, 5.6%), lower limb deep venous thrombosis (N = 1, 2.8%), cannulation site hematoma (N = 2, 5.6%), acute kidney injury (N = 2, 5.6%), bacteremia (N = 2, 5.6%), bleeding re- quiring transfusion (N = 5, 13.9%), and no instances of recurrent myocardial infarctions. Within 1 year post-operation, hospitalizations for heart failure were recorded for two patients (5.6%).	support during high-risk PCI is a secure and vi- able method for accomplishing revascularization in intricate and high-risk coronary artery obstruc- tions, albeit necessitating special attention to VA-

PCI, percutaneous coronary intervention; ECMO, extracorporeal membrane oxygenation; MACCE, major adverse cardiac and cerebrovascular events; CAD, coronary artery disease; VA, veno-arterial; CABG, coronary artery bypass grafting; TAVR, transcatheter aortic valve replacement.

pted extensive exploration of its role in optimizing patient outcomes [17–19]. ECMO provides a means of maintaining systemic and pulmonary perfusion while allowing for temporary circulatory support, thereby enabling interventionalists to perform complex PCI procedures with enhanced hemodynamic stability [20]. Additionally, ECMO offers the potential for rapid response to unexpected cardiovascular decompensation, serving as a safety net for patients undergoing high-risk interventions [21,22].

As the landscape of cardiovascular medicine continues to evolve, the integration of ECMO support into the management of complex high-risk elective PCI represents a paradigm shift in the approach to challenging coronary interventions. By examining the latest clinical research and outcomes data, this review manuscript aimed to evaluate the effect of ECMO on procedural success, complications, and long-term patient outcomes in the context of high-risk elective PCI, providing valuable insights for clinicians, researchers, and healthcare stakeholders.

## **Materials and Methods**

#### Search Strategy

A comprehensive search strategy was employed to identify relevant clinical studies, trials, and case reports focusing on the use of ECMO support in the setting of complex high-risk elective PCI following PICOS principles: (Population) patients undergoing complex high-risk elective PCI; (Intervention) receiving ECMO support; (Comparison) as compared to conventional high-risk PCI without ECMO support; (Outcome) reporting of clinical outcomes, progress data, or pertinent findings related to the effect of ECMO support; and (Study design) clinic trials including prospective and retrospective studies. Electronic databases, including PubMed, MEDLINE, and Cochrane Library, were systematically queried using appropriate Medical Subject Headings (MeSH) terms and relevant keywords (Fig. 1). The search strategy aimed to capture articles published in English within the last decade, with no restrictions placed on geographic location. The retrieval formulas were "ECMO Support and Complex High-Risk Elective PCI", "ECMO Support and High-Risk Elective PCI", "ECMO Support and Complex Elective PCI", "ECMO Support and Complex PCI", "ECMO and Complex PCI", and "ECMO and High-Risk PCI". Each source was last searched on 20 December 2023.

#### Inclusion and Exclusion Criteria

Studies were included in the review if they met the following criteria: (1) evaluation of ECMO support during complex high-risk elective PCI procedures; (2) reporting of clinical outcomes, progress data, or pertinent findings related to the effect of ECMO support; (3) peer-reviewed ar-

ticles, clinical trials, and case reports. Preclinical studies, reviews, and non-peer-reviewed literature were excluded from consideration.

#### Data Extraction and Analysis

Once the relevant articles were identified, data extraction was carried out to capture key information, including study design, following the guideline of PRISMA (**Supplementary Material**), patient demographics, procedural details, ECMO support characteristics, and clinical outcomes. The extracted data were systematically organized and synthesized to facilitate comparative analysis across studies. An integrative approach was utilized to consolidate findings and progress data from diverse sources, enabling an in-depth assessment of the effects of ECMO support on complex high-risk elective PCI.

#### Results

This review of the effect of ECMO support on complex high-risk elective PCI identified seven publications (Table 1, Ref. [18,23–28]) from Italy, USA, Belgium, Germany, Netherlands, and China. These publications encompassed single-center prospective, retrospective, and case report designs, collectively involving 91 patients undergoing high-risk elective PCI with ECMO support. Here, the key findings and conclusions from each study were summarized.

Tomasello *et al.* [23] conducted a single-center prospective study in Italy involving 12 patients and reported that all PCI procedures were successful with no in-hospital major adverse cardiac and cerebrovascular events (MAC-CEs). The authors concluded that elective high-risk PCI supported by ECMO is a viable alternative for patients at very high risk for coronary artery bypass grafting (CABG).

Shaukat *et al.*'s [24] single-center retrospective study in the USA, involving five patients, indicated the successful use of ECMO for hemodynamic support during elective high-risk PCI. All PCIs were successful, and the duration of ECMO was less than 24 h in four cases, with no in-hospital nor 1-year MACCEs observed.

Ungureanu *et al.*'s [25] single-center retrospective study in Belgium, comprising nine patients, found that prophylactic use of veno-arterial (VA)-ECMO in elective highrisk PCI resulted in successful revascularization with good long-term outcomes for inoperable patients. The authors highlighted the importance of patient selection on the basis of a multiparameter analysis to mitigate the potential risk of complications associated with VA-ECMO.

Kmiec *et al.* [18] presented a single-center case report from Germany and demonstrated the feasibility of elective prophylactic ECMO implementation in very high-risk and frail patients undergoing transcatheter aortic valve replacement and PCI to avoid intraprocedural complications.

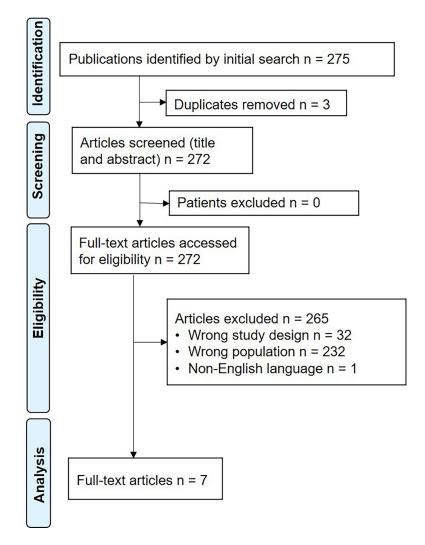


Fig. 1. PRISMA flowchart of literature review.

Griffioen *et al.*'s [26] single-center retrospective study in the Netherlands included 13 patients and showed that high-risk PCI with hemodynamic support using VA-ECMO is a feasible treatment option, particularly for patients for whom surgical revascularization is considered very high risk.

Awar *et al.*'s [27] single-center retrospective study in the USA, involving 15 patients, suggested that temporary use of ECMO for high-risk PCI is associated with acceptable short-term outcomes and may be a new option for patients with complex CAD and left ventricular dysfunction.

Finally, Bai *et al.*'s [28] single-center retrospective study in China, involving 36 patients, indicated that VA-ECMO mechanical circulation support during high-risk PCI is a safe and feasible strategy for achieving revascularization in complex and high-risk coronary artery lesions. However, the authors emphasized the need for special attention to VA-ECMO-related complications.

The reviewed studies collectively demonstrate the potential of ECMO support to facilitate successful high-risk elective PCI with favorable procedural outcomes. The findings highlight the importance of careful patient selection and proactive management of potential complications to further optimize the use of ECMO in this clinical setting.

## Discussion

## Background on High-Risk Elective PCI

PCI has become a cornerstone in the management of CAD, offering a less invasive alternative to CABG in selected patients [3-5]. However, the landscape of PCI extends beyond routine cases to encompass a subset of patients with complex and high-risk coronary anatomy, where the interventional approach presents unique challenges and considerations [6,7].

Complex high-risk elective PCI procedures often involve patients with multivessel disease, severely calcified lesions, chronic total occlusions, or left main disease, among other high-risk features [29–32]. These cases demand a higher degree of technical expertise and a nuanced understanding of lesion characteristics, hemodynamics, and patient comorbidities. The procedural intricacy is further compounded by the potential for hemodynamic instability, compromised left ventricular function, and the need for circulatory support in select cases [33].

Risk stratification in elective PCI extends beyond anatomical considerations to encompass the assessment of patient-related factors, procedural risk scores, and the availability of advanced technical resources [10,13]. The management of high-risk elective PCI cases necessitates a comprehensive approach that integrates clinical judgment, advanced imaging modalities, adjunctive devices, and strategic planning to optimize outcomes and mitigate potential complications.

The evolving landscape of advanced interventional cardiology has witnessed the emergence of novel techniques, adjunctive devices, and therapeutic strategies tailored to address the complexity and challenges associated with high-risk elective PCI. Despite these advancements, the optimal management of complex lesions and high-risk patients remains an area of ongoing refinement and exploration [10,11].

Understanding the unique characteristics, challenges, and risk profile of high-risk elective PCI is paramount for contextualizing the potential role of ECMO support in this clinical setting. This review provides a comprehensive backdrop for examining the effect of ECMO support on procedural outcomes and patient wellbeing in this high-stake domain of interventional cardiology by delineating the intricacies of high-risk elective PCI.

#### Role of ECMO in High-Risk PCI

The landscape of PCI has evolved to encompass increasingly complex cases, including high-risk elective interventions [19,33,34]. These cases demand a higher degree of technical expertise and a nuanced understanding of lesion characteristics, hemodynamics, and patient comorbidities [17]. Additionally, the potential for hemodynamic compromise, compromised left ventricular function, and the need for circulatory support in select cases further underscores the significance of tailored, multidisciplinary decision-making, and nuanced patient selection to optimize the risk–benefit profile [17,18].

The utilization of ECMO in the setting of high-risk PCI is predicated on its ability to provide robust circulatory support, mitigate the risks of hemodynamic compromise, and potentially expand the procedural window for complex interventions [19,35]. By maintaining adequate oxygenation and perfusion, ECMO can afford clinicians a degree of hemodynamic stability, allowing for meticulous procedural execution and the management of unforeseen complications [19].

The advent of percutaneous mechanical circulatory support devices, such as VA-ECMO, has further broad-

ened the spectrum of circulatory support options available to interventional cardiologists [30,32]. These devices offer adaptable hemodynamic support, potential left ventricular unloading, and the capacity to interface with the circulatory system, thereby enhancing the safety and feasibility of high-risk PCI procedures.

The role of ECMO in high-risk elective PCI extends beyond mere mechanical support, encompassing its potential to safeguard against procedural complications, facilitate the management of hemodynamic instability, and contribute to the overall safety and success of the intervention [32,36]. Furthermore, the integration of ECMO support in select high-risk cases underscores the need for tailored, multidisciplinary decision-making and nuanced patient selection to optimize the risk-benefit profile.

By elucidating the pivotal role of ECMO in the context of high-risk PCI, this review aimed to underscore the significance of integrated circulatory support in optimizing procedural outcomes, expanding the therapeutic window, and mitigating the inherent challenges of complex interventions in high-risk patients.

#### **Outcomes and Progress**

The evaluation of outcomes and progress in the context of ECMO support during high-risk PCI procedures is essential for discerning the effect of this integrated approach on patient wellbeing, procedural success, and clinical endpoints. The synthesis of clinical data and progress reports from relevant studies provides a comprehensive vantage point for appreciating the real-world implications of incorporating ECMO support into the realm of high-risk elective PCI.

Clinical outcomes, including metrics such as procedural success rates, hemodynamic stability, myocardial recovery, and major adverse cardiovascular events, offer meaningful insights into the immediate and longer-term ramifications of ECMO-assisted high-risk PCI [35,37]. The analysis of progress data pertaining to patient survival, hospital length of stay, complications, and functional recovery further enhances the understanding of the holistic effect of ECMO support on patient trajectories and post-procedural outcomes [35,37].

The data from the studies by Tomasello *et al.* [23], Shaukat *et al.* [24], and Awar *et al.* [27] collectively emphasize the successful implementation of ECMO for hemodynamic support during high-risk elective PCI procedures, with all PCIs reported as successful and acceptable shortterm outcomes. These findings suggest that ECMO could be safely used to facilitate complex PCIs in patients who are at increased risk for adverse events during the procedure.

Furthermore, the studies by Ungureanu *et al.* [25], Kmiec *et al.* [18], and Bai *et al.* [28] present compelling evidence in support of the prophylactic use of ECMO in selected very-high-risk patients undergoing elective PCI, highlighting successful revascularization, long-term outcomes, and the safety and feasibility of this strategy. Notably, these studies underscore the importance of careful patient selection and proactive management of ECMO-related complications to optimize the clinical benefits of ECMO in high-risk PCI scenarios.

The study by Griffioen *et al.* [26] contributes to the discussion by demonstrating the feasibility of high-risk PCI with hemodynamic support using ECMO, particularly for patients for whom surgical revascularization is considered very high risk. This feasibility adds to the body of evidence supporting the potential role of ECMO in addressing the challenges associated with complex PCI procedures in patients with significant comorbidities and high surgical risk.

As evidenced by the diverse patient populations and study designs, the findings collectively underscore the importance of tailored patient selection criteria, proactive complication management, and diligent monitoring to ensure the safe and effective use of ECMO in the context of high-risk elective PCI. Additionally, the identified studies present encouraging prospects for the application of ECMO in facilitating successful revascularization in patients with complex coronary artery lesions and left ventricular dysfunction.

Acknowledging the inherent limitations associated with the predominantly single-center retrospective studies and case reports is essential. Notably, the retrospective nature of these studies may have introduced selection bias and confounding factors that could have influenced the observed outcomes. Additionally, the reliance on data from single-center experiences may limit the generalizability of the findings to broader patient populations and varied clinical settings. Besides, the limited number of studies included in this review and the relatively small sample sizes within each eligible study pose inherent limitations that may have affected the statistical robustness and generalizability of the findings. The modest sample sizes, exemplified by the largest study encompassing 36 patients, may have restricted the precision and clinical significance of the reported outcomes. Moreover, the diversity in patient populations, procedural techniques, and clinical endpoints across the included studies could complicate direct comparisons and meta-analytical approaches. As such, the present review narrative conveys a comprehensive synthesis of the existing evidence but falls short of constituting a formal meta-analysis due to the heterogeneous nature of the included studies. Notably, the limited availability of comparative studies directly comparing outcomes with and without ECMO presents a challenge in delineating the distinct effect of ECMO on high-risk elective PCI procedures.

Overall, the reviewed evidence supports the notion that ECMO represents a valuable tool for providing hemodynamic support during high-risk PCI procedures, particularly in patients deemed at very high risk for surgical revascularization.

## Future Directions

Additional research efforts should be directed towards refining patient selection criteria, optimizing procedural techniques, and further delineating the long-term outcomes and potential complications associated with ECMOsupported high-risk elective PCI to continue advancing the field and enhancing patient care. Besides, the identification of optimal patient selection criteria, procedural decision algorithms, and risk stratification frameworks for ECMOsupported high-risk PCI warrants continued attention and refinement. The assessment of long-term clinical and functional outcomes following ECMO-assisted high-risk PCI procedures presents an opportunity for prospective investigations, offering an enhanced and comprehensive understanding of the durability and effect of this integrated approach.

The exploration of adjunctive technologies, such as percutaneous mechanical circulatory support devices, and the integration of advanced imaging modalities and procedural techniques hold promise for enhancing the safety, feasibility, and success rates of high-risk PCI in the era of ECMO support. The refinement of best practices, the evidence-based guidelines, and the delineation of prognostic determinants in the domain of ECMO-assisted high-risk PCI stands poised to shape the trajectory of interventional cardiology and patient care through rigorous clinical research and collaborative endeavors.

#### Conclusions

The reviewed evidence supports the notion that ECMO represents a valuable tool for providing hemodynamic support during high-risk PCI procedures, particularly in patients deemed at very high risk for surgical revascularization.

#### Availability of Data and Materials

Data to support the findings of this study are available on reasonable request from the corresponding author.

## **Author Contributions**

YiT, XK, and AL performed the research. YS and YaT provided help and advice on the experiments. YS also performed literature search and revised the manuscript. YaT and LJ contributed to the analysis and interpretation of the data. All authors contributed to editorial changes in the manuscript, read and approved the final manuscript, and participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

## **Ethics Approval and Consent to Participate**

Not applicable.

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## **Conflict of Interest**

The authors declare no conflict of interest.

## **Supplementary Material**

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10. 59958/hsf.7319.

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