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Benefits of prophylactic veno-arterial extracorporeal membrane oxygenation for high-risk cardiac interventions

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Abstract

Background Complex high-risk percutaneous coronary intervention (PCI) and transcatheter aortic valve implantation (TAVI) are challenging and frequently associated with life-threatening complications. We evaluated the benefits of prophylactic extracorporeal membrane oxygenation (ECMO)-supported interventions and the risks of this approach.

Methods From March 2020 to September 2021, 11 patients underwent TAVI, and 15 patients underwent PCI supported with prophylactic ECMO. Clinical characteristics and outcomes in terms of the requirement of ECMO were evaluated.

Results Cannulation was femoro-femoral in all patients. TAVI was performed via transfemoral access. In the TAVI group, mean patient age was 72 ± 7.84 years and 63.64% were male. During valve implantation, supportive ECMO flow was maintained at 3.24 ± 0.19 L/min. The additional median time in the ICU was 2 (1–4) days. Patients were discharged from the hospital after 16 (15–27) days. All of them were successfully weaned off V-AECMO. Only 1 patient died of respiratory and cardiac arrest 10 days after the operation. During PCI, ECMO flow was maintained at 3.35 ± 0.22 L/min. The average age of the patients in this group was 59 ± 10.80 years, and the ejection fraction was 42.59 ± 16.34%. Fourteen patients were successfully weaned off veno-arterial ECMO and survived to hospital discharge. No ECMO-related, peripheral cannulation-related or life-threatening bleeding complications were observed in the two groups. The median follow-up was 6 months, and there was 1 late death.

Conclusion Based on this experience, we consider ECMO support to be a viable alternative and effective approach for complex high-risk cardiac interventions.

Keywords Extracorporeal membrane oxygenation, Transcatheter aortic valve implantation, Percutaneous coronary intervention, High-risk

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Introduction

Extracorporeal membrane oxygenation (ECMO) applications have expanded rapidly over the past few decades and were originally developed by Dr. Bartlett in the early 1970s as an improvement to cardiopulmonary bypass (CPB) [1]. ECMO has become an essential tool for critically ill patients in whom conventional treatment has failed. Especially after the COVID-19 pandemic, the role of ECMO has been increasing recognized, and it has been used to provide rescue therapy in patients with severe pulmonary and/or cardiac dysfunction [2]. Moreover, ECMO can be used emergently in very high-risk or unstable patients undergoing transcatheter aortic valve replacement (TAVR) or high-risk percutaneous coronary intervention (PCI) [3], and it can be used as prophylactic support for complex tracheo-bronchial reconstruction, lung resections, or lung transplantation in unstable patients [4, 5]. More importantly, evidence suggests that ECMO support is a feasible and safe emergency approach for very high-risk or unstable surgery.

With the aging of the population and the prevalence of diseases such as heart failure, the prevalence of complex high-risk types of heart disease has increased significantly. Nonetheless, a considerable group of patients are not suitable for surgical coronary artery bypass grafting or valve replacement because of the high risk of surgical morbidity and mortality or because they refuse to undergo surgery [6, 7]. Minimally invasive techniques allow patients who cannot tolerate conventional thoracotomy for valve replacement to receive complete care and achieve rapid postoperative recovery [8, 9]. Nevertheless, high-risk cardiac interventions is often accompanied by hemodynamic instability. This can cause hypoperfusion and lead to an adverse outcome of intervention treatment.

Recently, numerous centers have published their experiences with the emergency use of ECMO or CPB in complicated cardiac interventions, with high short-term mortality [10, 11]. Moreover, when a patient's hemodynamics are unstable or there are life-threatening complications, the emergency establishment of ECMO or CPB usually takes a certain amount of time due to intubation and tube prefilling. During this period, all organs throughout the body suffer from hypoperfusion, low oxygen delivery and subsequent ischemia. The benefit of ECMO is that it provides hemodynamic support and concurrently reduces myocardial oxygen demand while maintaining systemic and coronary perfusion. Therefore, in this study, we describe the clinical outcomes of patients undergoing prophylactic ECMO for complex high-risk cardiac interventions, including PCI and TAVI, in our center.

Materials and methods

Patients and definitions

The present study was approved by the Fujian Medical University Union Hospital Ethics Committee, and patients or their legal representatives provided informed consent before the operation. High-risk cardiac interventions includes PCI and TAVI with prophylactic veno-arterial ECMO (V-AECMO) support.

The definition of high-risk PCI was as follows [12–14]: impaired left ventricular function (left ventricular ejection fraction (LVEF) ≤ 35% on echocardiography); LVEF > 35% in combination with lesion-specific variables including left main stenosis, disease at the bifurcation or ostium, vein grafts or heavily calcified lesions, or chronic total occlusions; and a large amount of myocardium subtended by the stenosed vessels.

The decision to use prophylactic ECMO for TAVI surgery was made by the cardiac team consisting of interventional cardiologists and cardiac surgeons as previously described [15, 16]. In patients with moderately or severely impaired left ventricular function, mean pulmonary artery pressure > 60 mmHg, and cardiac index < 2.0 with no improvement on inotropes, we considered prophylactic ECMO use during the procedure.

Operative method

All of the procedures were performed in our institution's catheterization laboratory by a multidisciplinary cardiac team. After general anesthesia, percutaneous cannulation for femoro-femoral V-AECMO was carried out using Seldinger's technique. In brief, V-AECMO access was performed using percutaneous femoral cannulation in all patients. If cannulas were inserted, they were connected to the ECMO system. The ECMO perfusion system consists of a centrifugal pump (Medtronic), a coated membrane oxygenator (Medtronic), 15 ~ 17 F-coated femoral artery intubation (Medtronic or Maquet) and 19 ~ 21 F-coated femoral vein intubation (Medtronic or Maquet). A single dose of Na–heparin (between 3000 and 5000 IU) was administered i.v. immediately before cannulation. The initial pump flow rates were 3.0 ~ 4.0 L/min. During ECMO, the flow and gas supply rates were adjusted using blood gas examinations to meet the patient's demand.

TAVI was performed via the transfemoral route in all patients. A temporary pacemaker was implanted through the right internal jugular vein. The vascular sheath was inserted into the right radial artery, and the pigtail catheter was inserted to the right or noncoronary sinus floor under the guidance of a super slippery loach guide wire for angiography. The sheath was inserted through the right femoral artery for TAVI access. All patients underwent PCI and coronary angiography through radial artery puncture and percutaneous coronary stent implantation.

Table 1 Preoperative TAVR patient characteristics ($n=11$)

Parameter	All patients ($n=11$)
Age (year)	72 ± 7.84
Male (n, %)	7 (63.64)
Euroscore II (%)	13.1 ± 8.9
Ejection fraction (%)	33.1 ± 7.85
Body mass index (kg/m^2)	26.55 ± 3.51
NYHA functional class > 2 (n,%)	11 (100%)
Chronic obstructive pulmonary disease (n,%)	6 (54.55%)
Diabetes mellitus (n,%)	2 (18.18%)
Hypertension (n,%)	6 (54.55%)
Peripheral arterial disease (n,%)	2 (18.18%)
Previous cerebrovascular accident (n,%)	1 (9.1%)
Previous Coronary artery disease (n,%)	3 (27.27%)
Previous myocardial infarction (n,%)	1 (9.1%)
History of malignancy (n,%)	1 (9.1%)
Previous PCI (n,%)	1 (9.1%)
Pulmonary artery pressure>60 mm Hg (n,%)	4 (36.36%)
Mean aortic gradient (mm Hg)	53 ± 12
Aortic valve area (cm ^{2})	0.76 ± 0.15

TAVR: transcatheter aortic valve implantation; NYHA: New York Heart Association; PCI: percutaneous coronary intervention

Table 2 Preoperative PCI patient characteristics ($n=15$)

Parameter	All patients ($n=15$)
Age (y)	59 ± 10.80
Male (n, %)	11 (73.33)
Body mass index (kg/m^2)	25.78 ± 3.46
Smoking (n, %)	12 (80.00%)
Previous myocardial infarction (n, %)	8 (53.33%)
Previous revascularization (n, %)	3 (20.00%)
Previous stroke (n, %)	0 (0%)
Chronic obstructive pulmonary disease (n, %)	1 (6.67%)
Hypertension (n, %)	9 (60.00%)
Diabetes mellitus (n, %)	8 (53.33%)
Ejection fraction (%)	42.59 ± 16.34
Euroscore II	6.2 ± 1.7
Number of target vessels	3 (2.75,3.25)
Left main coronary artery (n, %)	9 (60%)
Left anterior descending artery (n, %)	7 (46.67%)
Left circumflexus (n, %)	6 (40.00%)
Right coronary artery (n, %)	7 (46.67%)
Chronic total occlusion (n, %)	11 (73.33%)
SYNTAX Score	35.3 ± 9.0

PCI: percutaneous coronary intervention

During the operation, the type and number of stents were selected according to the actual lesions of the patients.

Data collection and outcomes

This is a retrospective analysis. All data, including preoperative B-ultrasound and CTA examination results, intraoperative and postoperative ECMO bypass-related data, operation mode, ICU stay time, hospitalization time, and so on, were prospectively collected. All patients underwent echocardiography to evaluate the improvement in perivalvular leakage and reflux, ventricular morphology, cardiac function, perioperative mortality and complications. Patients were followed-up for 6 months.

Table 3 Intra- and postprocedural data and outcome of the TAVR patient population

Parameter	All patients ($n=11$)
Transfemoral (n,%)	11 (100%)
ECMO flow (L/min)	3.24 ± 0.19
Duration of ECMO (min)	104.2 ± 30.63
Open conversion (n,%)	1 (9.1%)
PCI at time of TAVR (n,%)	2 (18.18%)
Perivalvular leakage (n,%)	1 (9.1%)
Valve migration (n,%)	0 (0%)
Coronary artery obstruction (n,%)	0 (0%)
Bleeding from left ventricular apex (n,%)	1 (18.18%)
Atrio-ventricular block (n,%)	0 (0%)
Access route rupture or dissection (n,%)	0 (0%)
Major stroke (n,%)	0 (0%)
Hemodialysis post-TAVR (n,%)	0 (0%)
ICU stay time (d)	2[1–4]
Ventilation support time (h)	22[15–36]
Length of hospital stay (d)	16[15–27]
Hospital death (n,%)	1 (9.1%)

ECMO: extracorporeal membrane oxygenation; PCI: percutaneous coronary intervention; TAVI: transcatheter aortic valve implantation; ICU: intensive care unit

Statistical analysis

Continuous variables are presented as the means, standard deviations and ranges. Categorical variables are presented as frequencies and percentages. The independent-samples t test with unequal variances assumption was used for comparison of continuous variables, and the Pearson chi-square test was used for comparison of categorical variables. Two-sided tests were used, and a "p" value of less than 0.05 was considered significant. IBM SPSS Statistics v22 package was used.

Results

From March 2020 to September 2021, 26 patients underwent high-risk cardiac interventions with prophylactic V-AECMO support. Percutaneous interventions included TAVI ($n=11$) and PCI ($n=15$). The baseline and clinical characteristics of these patients are shown in Tables 1 and 2. Intra- and postprocedural data and outcomes of the patient population are presented in Tables 3 and 4.

TAVI was performed in 11 patients via transfemoral access. The mean age was 72 ± 7.84 years, and 63.64% were male. The patients had a mean Euroscore II was 13.1 ± 8.9% and were all highly symptomatic in New York Heart > 2. The mean left ventricular ejection fraction was 33.1 ± 7.85%, and the mean aortic valve gradient

Table 4 Intra- and postprocedural data and outcome of the PCI patient ($n=15$)

Parameter	All patients ($n=15$)
Preoperative ECPR (n, %)	2 (13.33%)
ECMO flow (L/min)	3.35 ± 0.22
Duration of ECMO (h)	6.5 (5,12)
Post-procedural admission to ICU (n, %)	8 (53.33%)
Ventilation support time (h)	10 (0.5,31)
Hemodialysis post-PCI (n, %)	1 (6.67%)
Combined with IABP (n, %)	4 (26.67%)
Length of hospital stay (d)	11.8 ± 6.5
Hospital death (n, %)	2 (13.33%)

PCI: percutaneous coronary intervention; ECPR: extracorporeal cardiopulmonary resuscitation; ECMO: extracorporeal membrane oxygenation; ICU: intensive care unit; IABP: Intra-aortic balloon pump

Table 5 Laboratory parameters at baseline and after TAVR or PCI with ECMO

Parameter	Baseline	24 h after ECMO
WBC($\times10^9$/L)	9.26 ± 2.38	10.32 ± 2.68
Hb (g/l)	126.5 ± 17.85	109.9 ± 15.65
PLT ($\times10^3$/ml)	268 ± 97.19	228 ± 87.25
Creatinine (μmol/L)	83.95 ± 11.19	93.2 ± 12.15
AST(IU/L)	35.13 ± 17.22	55.25 ± 19.32
Albumin (g/l)	37.04 ± 2.04	35.17 ± 1.99
RBC transfusion (U)	0	1 (0,2)

WBC: white blood cell; Hb: hemoglobin; PLT: bloodplatelet; ALT: glutamate aminotransferase; RBC: red blood cell

was 53 ± 12 mmHg. The average V-AECMO flow during valve deployment was 3.24 ± 0.19 L/min. The median time in the ICU was 2 (1–4) days. The patients were discharged from the hospital after 16 (15–27) days. Among these cases, only one patient required conversion to open surgery to control bleeding secondary to left ventricular apical hemorrhage. This complication was caused by guidewire-induced perforation of the left ventricular wall. Ten patients had improved left ventricular ejection fraction, were successfully weaned off V-AECMO and survived to hospital discharge. Another patient died due to sudden respiratory and cardiac arrest after the operation.

The majority of the 15 patients undergoing V-AECMO-supported PCI were male (73.33%), with a median age of 59 ± 10.80 years. 60% of patients had a previous history of hypertension, and 53.33% had diabetes mellitus. Most patients had multivessel coronary artery disease. No patient had a previous history of stroke at the time of this study. The average Euroscore II was 6.2 ± 1.7, and the ejection fraction was 42.59 ± 16.34%. The average V-AECMO flow during the PCI was 3.35 ± 0.22 L/min. Additional IABP counterpulsation was used in 26.67% of patients. Fourteen patients were successfully weaned off V-AECMO and survived to hospital discharge. One patient underwent cardiopulmonary resuscitation before the operation, remained unconscious after the operation and was automatically discharged the next day. After follow-up, the patient died the same day after discharge.

Patients had no peripheral cannulation-related complications. Additionally, there were no major vascular complications or life-threatening bleeding. None of our patients experienced heparin-induced thrombocytopenia during ECMO support. The hemoglobin level and platelet count of all patients did not decrease significantly, and liver function was preserved in all patients after ECMO. Table 5 shows the changes in laboratory parameters after operation with ECMO support. The median follow-up was 6 months, and there was 1 death after hospital discharge who died of cardiac arrest.

Discussion

This experience demonstrates that prophylactic use of ECMO is a technically feasible, safe, and effective strategy to provide circulatory support for complex high-risk cardiac interventions. Mortality and complications were low, and despite the highly complex and mostly extensive coronary artery disease or severely impaired left ventricular function of these patients, TAVI or PCI was successful in all cases. For patients who underwent complex and high-risk cardiac interventions, selective high-risk PCI or TAVI supported by V-AECMO can be used as an alternative support strategy. These results are consistent with those of other single-center studies [11, 12, 16].

TAVI is a new technology that has developed rapidly over the last decade. It is a good choice for patients with a high risk of surgical thoracic aortic valve replacement because it is associated with limited trauma, no thoracotomy and no cardiopulmonary bypass cardiac arrest. However, for patients with cardiac insufficiency, long history and extremely poor cardiac function, even TAVI operation still has a great risk. Moreover, with the continuous maturity of PCI, its diagnosis and treatment scope has been expanded to include high-risk patients with poor left ventricular function, multivessel disease, acute myocardial infarction, old age and many comorbidities [17]. Unfortunately, these patients are extremely prone to severe hemodynamic disorders and high vasopressor requirements during surgery. In addition, the stability of hemodynamics during surgery is closely related to the survival of patients [18]. Therefore, extracorporeal circulation support technology can provide relatively stable hemodynamics and improve the outcome [3].

Conventional short-term circulatory supplementary means, including cardiopulmonary bypass, ECMO, the Impella system and intra-aortic balloon counterpulsation (IABP), can theoretically be used as circulatory support in cardiac interventions [19–21]. In one study [22], among 2,108,715 consecutive patients with stable coronary artery disease undergoing elective PCI, 6905

(0.3%) patients underwent elective PCI with prophylactic mechanical circulatory support (MCS). The published experience with the IABP-SHOCK II trial suggested that IABP, an older circulatory assist device, was ineffective in patients with circulatory failure [23]. However, in clinical application, IABP will affect the operation process of intra-aortic surgery because the counterpulsation balloon is placed in the descending aorta. Compared with other ventricular assist devices, cardiopulmonary bypass and ECMO have the advantage that they can simultaneously replace the functions of cardiac blood pumping and lung gas exchange, so they can provide more comprehensive circulatory support [10, 12]. In theory, while traditional cardiopulmonary circuits can provide an ideal operative environment, ECMO is a relatively miniaturized circuit that has lower priming volumes. In other words, they are more compact, have fewer anticoagulant requirements, are associated with less coagulopathy, and attenuate the systemic inflammatory response [24, 25]. Notably, ECMO has been demonstrated to replace CPB as prophylaxis in very high-risk patients undergoing TAVR or PCI for hemodynamic support. While there are currently only limited data on the systemic application of ECMO as preventive support, this strategy might potentially minimize the effects of procedural complications in these high-risk patients. A study demonstrated that a low ECMO average annual case volume was associated with significantly higher mortality, and a minimum volume of 22 cases per year was associated with improved mortality [26]. Obviously, we can maintain the level of experience because the number of critical patients treated with ECMO in our center every year exceeds 22.

There was more experience with the use of ECMO as a rescue approach during the operation. An ECMO circuit will be present in the catheterization laboratory, ready for use when needed. This might lead to fewer ECMO-related complications and reduce costs. Unfortunately, life-threatening complications during TAVI can be managed using emergency V-AECMO, but mortality remains high [11]. Moreover, Trenkwalder et al. demonstrated that in-hospital mortality and 30-day mortality were 46% (15/33) [27]. Therefore, many experts have proposed the preventive use of ECMO during surgery for high-risk patients. Husser et al. [11] reported that the use of prophylactic V-AECMO in very high-risk patients is safe and may be advocated in selected cases. A meta-analysis revealed the same findings across studies [28]. Other clinical evidence suggests that V-AECMO mechanical circulation support during high-risk PCI is a safe and feasible strategy for achieving revascularization in complex and high-risk coronary artery lesions [12]. Additionally, it has been suggested that V-AECMO in high-risk PCI is feasible with a good outcome [14, 29]. However, published experience with ECMO prophylactic support during complex high-risk cardiac interventional procedures is also limited. Early coronary revascularization can significantly improve the survival rate of patients, but the stability of hemodynamics before revascularization is closely related to the survival of patients. Therefore, it is necessary to use ECMO, which can provide relatively stable hemodynamics, to improve the rescue success rate of cardiac arrest. The main purpose of this study was to describe the clinical outcomes of patients undergoing prophylactic ECMO to support complex high-risk cardiac interventions at our center. Our findings highlight the importance of the early identification of patients with very poor cardiac and functional reserve who should be stabilized before TAVR or PCI and who could potentially benefit from the early use of ECMO. There is growing evidence that ECMO is increasingly used in TAVR or PCI and has a significantly lower impact on immunomodulatory systems, such as the release of inflammatory cytokines, than CPB. Our results showed that patients had no peripheral cannulation-related complications. Furthermore, there were no major vascular complications or life-threatening bleeding. None of our patients experienced heparin-induced thrombocytopenia during ECMO support.

Limitations

Our study reporting a single-center registry with the early use of V-AECMO implantation is limited by the small sample size of patients undergoing PCI and TAVI. Therefore, we need to increase the number of patients in the future, such as by conducting a multicenter study. Furthermore, this study was a retrospective analysis and included carefully selected patients; thus, selection bias cannot be excluded. This study only analyzed cases of prophylactic ECMO support and did not compare it with other MCS and emergency ECMO-supported percutaneous interventions. In addition, the absence of a control group in this study limits causal inference. Future observational comparisons may help address this gap.

Conclusion

Based on this experience, instituting prophylactic V-AECMO in selected complex high-risk cardiac interventional surgeries, including PCI or TAVI, is a feasible elective strategy to avoid intraprocedural complications.

Author contributions

L.X.C. and W.L. wrote the main manuscript text, D.Y. and H.Y.T. prepared table, C.L.W. revising it critically for important intellectual content. All authors reviewed the manuscript.

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Data availability
All data supporting the findings of this study are available within the paper.

Declarations

Ethical approval and consent to participate
This study complied with the requirements of the Ethics Committee of Fujian Medical University Union Hospital and adhered to the Declaration of Helsinki. The need for written informed consent was waived due to retrospective nature of the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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