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ORIGINAL ARTICLE

Observational Study

Long-term outcomes of high-risk percutaneous coronary interventions under extracorporeal membrane oxygenation support: An observational study

Yi-Xiong Huang, Zheng-Ming Xu, Li Zhao, Yi Cao, Yu Chen, Yi-Gang Qiu, Ying-Ming Liu, Peng-Yu Zhang, Jiang-Chun He, Tian-Chang Li

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Abstract

BACKGROUND

Venoarterial extracorporeal membrane oxygenation (VA-ECMO) offers hemodynamic support for patients undergoing high-risk percutaneous coronary interventions (PCIs). However, long-term outcomes associated with VA-ECMO have not previously been studied.

AIM

To explore long-term outcomes in high-risk cases undergoing PCI supported by VA-ECMO.

METHODS

In the present observational cohort study, 61 patients who received VA-ECMO-supported high-risk PCI between April 2012 and January 2020 at the Sixth Medical Center of Chinese People's Liberation Army General Hospital were enrolled. The endpoint characteristics such as all-cause mortality, repeated cardiovascular diseases, and cardiac death were examined.

RESULTS

Among 61 patients, three failed stent implantation due to chronic total occlusions with severely calcified lesions. One patient showed VA-ECMO intolerance because of high left ventricular afterload. PCI was successfully performed in 57 patients (93.4%). The in-hospital mortality was 23.0%, and the overall survival was 45.9%, with a median follow-up period of 38.6 (8.6-62.1) mo.

CONCLUSION
VA-ECMO can be used as a support in patients undergoing high-risk PCI as it is associated with favorable long-term patient survival.

Key Words: High-risk percutaneous coronary intervention; Venoarterial extracorporeal membrane oxygenation; Overall survival; Long-term survival

Core Tip: High-risk percutaneous coronary intervention (PCI) can result in hemodynamic instability during the perioperative period and is associated with poor outcomes. Venoarterial extracorporeal membrane oxygenation (VA-ECMO) can provide hemodynamic support for patients who undergo high-risk PCI. The main role of VA-ECMO in high-risk PCI is to prevent profound hypotension or low cardiac output episodes and allow sufficient time to achieve optimal and complete revascularization. We present a single-center, observational cohort study of all patients undergoing high-risk PCI supported by VA-ECMO. PCI was successfully performed in 57 patients (93.4%). The in-hospital mortality was 23.0%. The overall survival was 45.9% with a median follow-up time of 38.6 (8.6-62.1) mo. VA-ECMO can be successfully used in patients undergoing high-risk PCI with good long-term survival.

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INTRODUCTION

The use of percutaneous coronary intervention (PCI) has shown an increasing trend worldwide due to the anatomic and clinical complexity of cases experiencing coronary artery disease[1,2]. Coronary artery bypass graft (CABG) represents the first revascularization strategy recommended for patients with an acceptable surgical risk and multivessel disease in line with myocardial revascularization guidelines[3]. However, due to severe clinical and anatomic conditions, CABG is not possible in some patients. In such cases, PCI is the only available revascularization strategy. High-risk PCI can cause hemodynamic instability *via* procedure-induced cardiac ischemia, especially in the case of coronary dissection with no-reflow or vascular closure. Therefore, temporary circulatory support is required in the perioperative period if high-risk PCI is planned. Impella CP and Impella 2.5 have been reported to be safe, feasible, and potentially beneficial support devices for high-risk PCI[4-6]. However, the cost of Impella is higher than that of extracorporeal membrane oxygenation (ECMO) and is not covered in public medical insurance in most regions of China, thereby restricting the use of this device. Some studies have reported the feasibility of ECMO application in high-risk PCI, and showed good short-term outcomes in patients[7-11]. However, the long-term outcomes among cases undergoing high-risk PCI supported by ECMO have not been studied. Therefore, this work focused on the long-term outcomes of patients who underwent high-risk PCI supported by venoarterial ECMO (VA-ECMO).

MATERIALS AND METHODS

Study population

In the present unicentric, retrospective, and observational cohort study, 61 patients who received VA-ECMO-supported high-risk PCI at the Sixth Medical Center of Chinese People's Liberation Army General Hospital between April 2012 and January 2020 were enrolled. High-risk PCI was defined according to the patient's hemodynamic status (shock or dysfunction of the left ventricle), clinical features, and underlying diseases such as heart failure, diabetes mellitus (DM), peripheral vascular disease, advanced chronic kidney disease (CKD), prior history of cardiac surgery, chronic obstructive pulmonary disease (COPD), or coronary anatomy/lesion complexities such as saphenous vein graft degeneration, unprotected three-vessel or left main vessel disease, last patent conduit, severe calcified lesions, and chronic total occlusions (CTO) among multivessel disease patients[12].

Procedure for venoarterial extracorporeal membrane oxygenation

The VA-ECMO support (Bio-Medicus, Medtronic Inc., Minneapolis, MN, United States) comprises a circuit constituted by arterial and venous cannulas, a membrane oxygenator used for gas exchange and a centrifugal pump used for blood propulsion. VA-ECMO cannulation was performed by cardiothoracic surgeons in the catheterization laboratory using Seldinger's technique. The tips of venous and arterial cannulas were placed in the inferior vena cava and descending aorta, respectively. The patients were administered heparin to achieve and maintain an activated clotting time of > 300 s after ECMO cannulation. The ECMO flow in the arterial line was maintained at 1.5-2 L/min during the PCI procedure. If the patient had severe hypotension, a higher flow of ECMO was considered. The concomitant use of an intra-aortic balloon pump (IABP) was determined by the operator.

Procedure for percutaneous coronary intervention

The revascularization strategy was developed by a multidisciplinary heart team consisting of cardiologists, cardiothoracic surgeons, anesthesiologists, perfusionists, critical care physicians, as well as specialized nurses. All the patients were considered unsuitable for surgery according to the heart team and were approved to undergo high-risk PCI under VA-ECMO hemodynamic support. Dual-antiplatelet treatment (loading doses: Aspirin: 300 mg; ticagrelor: 180 mg; or $P2Y_{12}$ receptor inhibitor clopidogrel (300/600 mg) was initiated prior to coronary angiography. Guidewires, balloons, and stents were selected by the operator.

Study definitions and endpoint determination

Intraoperative hypotension was diagnosed according to the threshold of systolic blood pressure (SBP) below 90 mmHg or a reduction in the baseline SBP of more than 40 mmHg, without any other cause of hypotension. PCI success was defined as the residual diameter of stenosis < 30% (according to visual estimation) with translesional pressure gradient with hemodynamic significance or flow-limiting dissection. Patients with cardiac shock after receiving PCI under VA-ECMO support were defined as rescue VA-ECMO use.

We determined SYNTAX score by adopting the SYNTAX online score calculator (http://www.syntaxscore.com/calculator/start.htm)[13]. EuroSCORE was prospectively evaluated to assess perioperative risk of mortality (http://www.euroscore.org/calc.html). We also determined the GRACE score by adopting the GRACE online score calculator (https://www.merckmanuals.com/medical-calculators/GRACEScore.htm). Baseline characteristics, procedural and vascular access complications were recorded. Patient follow-up consisted of phone calls, hospital record reviews, or outpatient visits.

The present work was performed according to the Helsinki declaration. Informed consent was obtained from each patient who participated in the study.

Statistical analysis

Results were analyzed using SPSS 26.0 for Windows (SPSS Inc., Chicago, IL, United States). Categorical variables are presented as percentages and counts. Continuous variables with normal distribution are expressed as mean ± SD, whereas abnormally distributed variables are shown as medians (interquartile range). Fisher's exact test or Pearson's χ^2 test was performed to compare categorical variable frequencies. Each test was two-sided. P value < 0.05 was considered statistically significant.

RESULTS

Baseline features

Table 1 shows baseline clinical features of the patients who underwent high-risk PCI supported by VA-ECMO. The age of the patients ranged from 64 to 79 years (median: 74 years), and most patients (73.8%) were male. The average body mass index (BMI) and median left ventricular ejection fraction (LVEF) were 25.0 ± 3.4 kg/m^2 and 42% (32%-49%), respectively. The LVEF was 42% (32%-49%), and 32.8% (n = 20) of patients had a LVEF ≤ 35%. Approximately 29.5% of patients (n = 18) were admitted for ST-elevation myocardial infarction. Twenty cases (32.8%) had a myocardial infarction history. Eleven patients (18.0%) had previously received CABG. The mean SYNTAX score was 42.5 ± 10.0 in patients who had never undergone CABG (n = 50). The majority of patients had a high risk for cardiac surgery with a median EuroSCORE of 12 (10-15). Most patients had a poor prognosis with a median GRACE score of 163 (145-195).

Procedural characteristics

Femoral-femoral VA-ECMO cannulation was performed in all patients. Fifty-two patients (85.2%) received prophylactic VA-ECMO before PCI, whereas nine patients (14.8%) received rescue VA-ECMO support. Twenty-five patients (41.9%) underwent IABP insertion. The stent was not implanted in three patients (4.9%) due to CTO with severely calcified lesions. One patient (1.6%) was intolerant to ECMO because of increased left ventricular afterload. PCI was successfully performed in 93.4% (n = 57) of

Table 1 Baseline clinical features

Features	Cases (*n* = 61)
Age (yr)	74 (64-79)
Male, *n* (%)	45 (73.8)
BMI (kg/m^2)	25.0 ± 3.4
Diabetes mellitus, *n* (%)	30 (49.2)
Hypertension, *n* (%)	40 (65.6)
Dyslipidemia, *n* (%)	8 (13.1)
Current smoking, *n* (%)	20 (32.8)
Previous MI, *n* (%)	20 (32.8)
Previous PCI, *n* (%)	9 (14.8)
Previous CABG, *n* (%)	11 (18.0)
Previous stroke, *n* (%)	16 (26.2)
COPD, *n* (%)	3 (4.9)
CRF, *n* (%)	30 (49.2)
Peripheral vascular disease, *n* (%)	3 (4.9)
LVEF	42 (32-49)
LVEF ≤ 35%, *n* (%)	20 (32.8)
Clinical presentation STEMI, *n* (%)	18 (29.5)
NSTEMI, *n* (%)	11 (18.0)
UA, *n* (%)	32 (52.5)
[1]SYNTAX score	43.2 ± 10.0
EuroSCORE	12 (10-15)
GRACE score	163 (145-195)

[1]SYNTAX score was only calculated in patients without prior CABG, *n* = 50.

BMI: Body mass index; MI: Myocardial infarction; PCI: Percutaneous coronary intervention; CABG: Coronary artery bypass graft; COPD: Chronic obstructive pulmonary disease; CRF: Chronic renal failure; LVEF: Left ventricular ejection fraction; STEMI: ST-elevation myocardial infarction; NSTEMI: Non-ST-elevation myocardial infarction; UA: Unstable angina.

patients, and the median number of stents implanted per patient was two (1-3). The median amount of contrast was 120 (95-161) mL. The median ECMO run was 1.6 (1.2-2.4) h. The mean residual SYNTAX score after PCI under VA-ECMO support was 18.9 ± 13.1 in patients without CABG (Table 2).

Fifteen patients (24.6%) experienced intraoperative hypotension, and surgery was performed safely by increasing the ECMO flow. One patient (1.6%) received antegrade perfusion of the leg due to lower extremity ischemia. Hemorrhagic complications occurred in eight patients (13.1%), and six of these patients required blood transfusion (9.8%). The median length of stay was 20 (13-29) d, and the median cardiac care unit stay was 7 (3-18) d. The median hospitalization costs were ¥153000 (¥118000-¥216000) (approximately $24000).

Clinical outcomes

The total in-hospital mortality was 23% (*n* = 14). Of which, ten patients died due to cardiac shock, three due to septic shock, and one patient succumbed to early stent thrombosis. Post-operative cerebral infarction occurred in four patients (6.6%) because of hypoperfusion caused by cardiac or septic shock. The overall mortality was 31.1% at one-year follow-up. Prophylactic VA-ECMO support (*n* = 52) resulted in lower in-hospital mortality (13.5% *vs* 77.8%, *P* = 0.000) and 1-year mortality (21.2% *vs* 77.8%, *P* = 0.002) compared with patients who received rescue VA-ECMO support.

The long-term survival rate was 45.9%, and the median follow-up period was 38.6 (8.6-62.1) mo. Two patients (3.3%) required further revascularization owing to unstable angina at one-year follow-up. One patient was re-admitted due to symptomatic heart failure (Table 3).

Table 2 Procedural characteristics

Characteristics	Patients (*n* = 61)
IABP, *n* (%)	25 (41.0)
Successful PCI, *n* (%)	57 (93.4)
Number of DESs	2 (1-3)
Duration of VA-ECMO (h)	1.6 (1.2-2.4)
Dosage of contrast (mL)	120 (95-161)
Residual SYNTAX score	18.9 ± 13.1
Intraoperative hypotension, *n* (%)	15 (24.6)

IABP: Intra-aortic balloon pump; PCI: Percutaneous coronary intervention; DESs: Drug-eluting stents; VA-ECMO: Venoarterial extracorporeal membrane oxygenation.

Table 3 Clinical outcomes, *n* (%)

Characteristics	Patients (*n* = 61)
In-hospital mortality	14 (23.0)
Cardiac shock	10 (16.4)
Septic shock	3 (4.9)
Early stent thrombosis	1 (1.6)
Postoperative cerebral infarction	4 (6.6)
One-year mortality	19 (31.1)
Overall mortality	33 (54.1)
Cardiac death	18 (29.5)
Sepsis	7 (11.5)
Hemorrhage	1 (1.6)
Malignant tumor	3 (4.9)
Fracture	2 (3.4)
End-stage renal disease	1 (1.6)
Aplastic anemia	1 (1.6)

DISCUSSION

Based on our results, high-risk PCI can be considered safe under VA-ECMO support with a promising long-term survival. VA-ECMO can provide hemodynamic support during high-risk PCI, and allows sufficient time to complete the PCI procedure when profound hypotension occurs.

With the rapid development in PCI technology, more and more high-risk cases are being treated worldwide[1,14]. High-risk PCI is usually defined by three aspects: Patient characteristics, lesion characteristics, and clinical presentation[15-17]. These characteristics pose a great challenge to cardiologists not only because of the risk of peri-procedural complications but also because of poor outcomes. In our study, most patients were elderly with several comorbidities, including DM, hypertension, prior myocardial infarction, CKD, serious peripheral arterial disorders, and left ventricular dysfunction. The anatomical complexity of the coronary artery and high SYNTAX score made surgical intervention difficult. Moreover, all the patients had acute coronary syndrome, and the GRACE score was high, which indicated poor outcomes in these patients[18].

Coronary revascularization minimizes unfavorable clinical events in high-risk cases and improves life quality[19-21]. Selecting revascularization strategies (PCI or CABG) should be performed by a heart team considering both risks and benefits[22]. As suggested by the existing myocardial revascularization guidelines[23], when CAD is anatomically complex (namely, unprotected three-vessel or left main vessel disease), CABG can be considered the first choice for treating patients with a SYNTAX score of more than 32. However, CABG is not recommended in patients with frailty, severe underlying diseases,

and a prior history of cardiac surgery due to the risk of high postoperative mortality. PCI under temporary mechanical circulatory support (MCS) could be considered another option for high-risk cases.

At present, the percutaneous MCS instruments are Impella, TandemHeart, and VA-ECMO. Hemodynamic support should have four major objectives, including ventricular unloading, circulatory support, end-organ perfusion, and coronary perfusion[24]. The Impella device is an axial-flow pump that provides 2.5-5 L cardiac output with rapidly decreasing left ventricular preload. In March 2015, the United States Food and Drug Administration approved the Impella 2.5 as a transitory ventricular support device for patients undergoing high-risk PCI. As reported in the PROTECT series of studies, Impella 2.5 can offer favorable hemodynamic support during high-risk PCI and better outcomes than those with IABP support[25,26]. Some studies performed with a large-sample size reported that Impella is related to a higher incidence of side effects and massive bleeding among patients receiving PCI under MCS[27,28]. Furthermore, the application of Impella is associated with higher hospital costs[27,29]. Currently, the cost of the Impella device is $37000 (approximately ¥240000) in China, which is a tremendous burden in high-risk patients, especially in developing countries. Therefore, VA-ECMO should be considered an alternative to the MCS device in high-risk PCI.

VA-ECMO is an extracorporeal life support, which can provide partial respiratory and circulatory support. F. S. van den Brink and colleagues reported on a few cases who had stable coronary artery disease who received prophylactic VA-ECMO-supported PCI and showed good short-term outcomes [7]. Salvatore and coworkers[9] reported 12 patients who underwent elective ECMO-supported high-risk PCI, and were at high risk for CABG who achieved favorable and immediate mid-term outcomes. However, long-term survival in ECMO-supported PCI has not yet been reported. As demonstrated in this work, high-risk PCI may be feasible with VA-ECMO support and can lead to good long-term outcomes. Cardiac death occurred in 29.5% (n = 18) of cases with a median follow-up time of 38.6 (8.6-62.1) mo, and most events occurred within a year.

High-risk PCI can result in hemodynamic instability during the perioperative period, especially when managing complex coronary anatomy (*i.e.*, degenerated saphenous vein grafts, unprotected left main vessel disease, last patent conduit, severely calcified lesions with a need for rotational atherectomy, and CTO with multivessel disease). In the present study, 15 patients (24.6%) experienced intraoperative hypotension after a guidewire was placed through the lesion or balloon dilation. Fortunately, VA-ECMO offered cardio-cerebral perfusion and arterial oxygenation during hypotension. Therefore, hemodynamic support was crucial in these patients during high-risk PCI procedures.

At present, large-scale randomized trials are not available to compare the application of prophylactic ECMO with the standby strategies, and no consensus has been reached regarding the optimal timing of ECMO cannulation. Elvis *et al*[30] reported the application of prophylactic ECMO in high-risk patients who received coronary combined with structural percutaneous interventions. The procedure was reported to be safe and successful, considering favorable in-hospital as well as mid-term outcomes. In a study on high-risk coronary angioplasty, Teirstein *et al*[31] reported that standby cardiopulmonary support is preferable to prophylactic cardiopulmonary support due to fewer complications with standby cardiopulmonary support. Moreover, those with compromised left ventricular function can gain benefits from prophylactic cardiopulmonary support. Our study found that prophylactic VA-ECMO resulted in low in-hospital and one-year mortality compared with rescue VA-ECMO support. Although the prophylactic group had a lower rate of cardiac shock, early intervention with MCS may prevent progression to cardiac shock in high-risk patients.

VA-ECMO provides retrograde aortic flow for maintaining vital organ perfusion. Such a strategy is significantly limited by its increased left ventricular afterload, resulting in increased left ventricular end-diastolic pressure, aortic and mitral regurgitation, and pulmonary edema[32]. Blood stasis occurred in one patient in our study after VA-ECMO cannulation due to impaired left ejection fraction. VA-ECMO was immediately removed, and IABP was inserted in the contralateral femoral. The strategies to reduce left ventricular afterload include decreased pump flow, inotropes, concomitant use of IABP or Impella, and left ventricular venting[33]. As suggested by a meta-analysis, left ventricular unloading is related to reduced mortality among adult cases who have cardiogenic shock and receive VA-ECMO treatment [34]. Therefore, left ventricular unloading is probably adopted in some patients who have severe impaired left ejection fraction.

CONCLUSION

VA-ECMO can be used as a support in patients undergoing high-risk PCI as it confers good long-term survival.

ARTICLE HIGHLIGHTS

Research background

Venoarterial extracorporeal membrane oxygenation (VA-ECMO) offers hemodynamic support for patients who undergo high-risk percutaneous coronary intervention (PCI). However, long-term outcomes associated with VA-ECMO have not previously been studied.

Research motivation

High-risk PCI can result in hemodynamic instability during the perioperative period and is associated with poor outcomes. Hemodynamic support is crucial in patients undergoing high-risk PCI.

Research objectives

To investigate long-term outcomes in high-risk cases receiving PCI supported by VA-ECMO.

Research methods

Patients who received VA-ECMO-supported high-risk PCI were assessed. High-risk PCI was defined according to the patient's hemodynamic status, clinical features, underlying diseases, and coronary anatomy/lesion complexities. The long-term outcomes comprising all-cause mortality, repeated cardiovascular diseases, and cardiac death were recorded.

Research results

Of 61 enrolled patients, 57 patients (93.4%) were successfully treated by VA-ECMO-supported PCI. The in-hospital mortality was 23.0%, and the overall survival was 45.9% with a median follow-up period of 38.6 (8.6-62.1) mo.

Research conclusions

VA-ECMO can be used as a support for patients undergoing high-risk PCI as it is related to favorable long-term patient survival.

Research perspectives

A large multicenter prospective trial is required to confirm the benefit and safety of VA-ECMO-supported high-risk PCI.

FOOTNOTES

Author contributions: Huang YX, Chen Y, and Li TC designed the study; Huang YX drafted the manuscript; Cao Y, Qiu YG, Liu YM, and He JC revised it critically for important intellectual content; Xu ZM, Zhao L, and Zhang PY contributed to the analysis and interpretation of data; Li TC, the corresponding author of this manuscript, gave final approval of the manuscript submitted.

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