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Research Article

Procedure and Effectiveness of Extracorporeal Membrane Oxygenation in Percutaneous Coronary Intervention for High-risk Complex Coronary Disease

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ABSTRACT

Objective: It has been demonstrated that performing percutaneous coronary intervention (PCI) in the absence of mechanical circulation support (MCS) for patients with complex high-risk coronary artery disease bears a high risk. Alternatively, to figure out the procedure effectiveness and the mid-term prognosis of PCI for complex high-risk coronary artery disease, we accomplished the whole process by the assistance of extracorporeal membrane oxygenation (ECMO).

Methods: Between July 2016 and October 2017, 6 consecutive complex and high-risk coronary disease patients underwent routine ECMO-supported PCI.

Results: The average age of the patients was 70.5 ± 11.98 , and half of them (50%) were male. The mean creatinine (Cr) was $188.67 \pm 151.68 \mu\text{mol/L}$. The average scores for SYNTAX, SYNTAX II, and LVEF pre the procedure was 41.33 ± 12.14 , 47.87 ± 9.45 / 31.55 ± 8.82 , and $44.40 \pm 12.58\%$, respectively. The mean supporting duration of ECMO was 10.50 ± 7.79 h. Regarding the postoperative complication, one case observed lower limb venous thrombosis and another reported infection at the access site. Two patients (33.3%) died for refractory heart failure during the follow-up course of 17.00 ± 9.51 months, and the average net improvement index (NII) was $28.30 \pm 25.11\%$ for this period.

Conclusion: With the support of ECMO, the prognosis of complex high-risk coronary disease has shown to be improved by intervention in our study.

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Introduction

The percutaneous coronary intervention (PCI) has developed rapidly during the past four decades, which has increasingly become one of the mainstream treatments for coronary atherosclerotic heart disease (CHD) [1-3]. Previous studies have shown that revascularization therapy, both PCI and coronary artery bypass graft (CABG), could reduce all-cause mortality and cardiac death among patients with complex high-risk coronary disease in contrast to conventional medication treatments [4, 5]. Regarding the preference for the revascularization strategy, numerous studies recommend CABG to patients who are under such complex high-risk coronary conditions [6-9]. However, due to intricate

and asymmetrical characteristics shared among patients like advanced age, complicated multi-organ dysfunction, or previous thoracotomy, the PCI seems to be the only option for those who are unable to tolerate general anaesthesia or surgical procedure of CABG. Also, with the increasing amount of complexity and the risks associated become greater. To complete the revascularization of complicated coronary lesions effectively has increasingly rendered into an urgent focus for cardiologists than ever before [10, 11]. Fortunately, the venoarterial extracorporeal membrane oxygenation (VA-ECMO), as mechanical circulation support (MCS) devices, for such coronary disease during interventional procedures has been applied in the current study and the paralleled mid-term prognosis has been further figured out.

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Methods

I Study Population

Case data of this study were retrospectively collected from July 2016 to October 2017 in China-Japan Friendship Hospital. The inclusion criteria were defined as followings: (i) Coronary angiography showed severe coronary lesions (manifested as multivessel disease, unprotected left main (UPLM) disease, and severe coronary artery calcification); (ii) The patients experienced frequent attacks of angina pectoris; (iii) The patients were either unable to tolerate or refuse CABG due to advanced age, severe heart failure, or another organ dysfunction. The risk assessment was given based on the reference of combined clinical, anatomic, and hemodynamic factors and agreed upon all members of a cardiac clinical research team consisting of a primary cardiologist, an interventional cardiologist, and a cardiothoracic surgeon.

II Data Collection and End-Point Definition

This study collected clinical data draw from both in-hospital and follow-up cases, including general clinical information, intraoperative records, and in-hospital and follow-up major adverse cardiac and cerebrovascular events (MACCEs). MACCEs were defined as: (i) All-cause mortality; (ii) Acute myocardial infarction (AMI); (iii) Stroke; (iv) Further revascularization by either PCI or CABG. Additionally, we attempted to use the average of net improvement index (NII), which described as the net area above the curve during the whole period of follow-up time per month from the basic level of left ventricular ejection fraction (LVEF) pre the procedure, to assess the improvement in cardiac function throughout the follow-up period.

$$NII = (S_a - S_b) / t$$

S_a = The area above the basic line.

S_b = The area below the basic line.

t = Follow-up time (month).

III Establishment and Management of ECMO

The ECMO circuitry and instrumentation (Medtronic, Inc., St. Paul, MN, USA) involved a centrifugal machine (Medtronic-550), customized heparin coating integrated package pipeline (including pump and membrane oxygenator), heparin coating femoral venoarterial cannula, air-oxygen mixer, variable temperature water tank, and MAQUET hemoconcentrators. All the patients were received ECMO via femoral venoarterial catheterization (VA mode). The auxiliary flow rate was set to 40-50 ml/ (kg × min). The arterial puncture catheter was used to monitor the pressure, and the mean arterial pressure (MAP) was

maintained at the range of 50-70 mmHg. In the case of the unstable hemodynamic or malignant arrhythmia, the auxiliary flow was increased to 3 L/min to preserve tissue perfusion. An air-oxygen mixer can provide 50-60% concentration of oxygen with the simultaneous demand of ECMO support, with a ventilation-to-blood flow ratio stabilized at 0.6-1:1 and PCO_2 maintained at 35-45 mmHg. Activated clotting time (ACT) was maintained at the range of 150-180s and under the unintermittent detection every 2 hours during the operation.

IV Procedure and Protocol for PCI

All the patients received the antiplatelet therapy and unfractionated heparin (UFH) for 100 U/kg intra-arterial injection before starting the procedure. Severe coronary calcified lesions indicated the rotational atherectomy, and the drug-eluting stent (DES) was placed at the severe stenosis lesions. The successful revascularization of the target lesion was defined as the residual stenosis < 20% and with thrombolysis in myocardial infarction (TIMI) grade 3 flow.

V Weaning of ECMO

After the PCI, the ECMO auxiliary flow was reduced gradually until the machine shut down completely if the patient was stable in hemodynamically. Successful weaning is defined as hemodynamic stability for 72 hours after weaning with no needs for additional circulation supporting.

VI Statistical Methods

Descriptive data analyses were observed as mean±SD. Relationships of different types of variables were examined using the t-test and chi-square test in STATA (14.1 version, StataStata College Station, Texas). P-value < 0.05 was considered statistically significant.

Results

I Baseline Characteristics

According to the inclusion criteria, six patients, three males and three females, completed the complex high-risk coronary PCI supported by ECMO. The average age was 70.5±11.98 years old. Five patients (83.33%) reported a history of diabetes, and four of them (66.67%) stated a history of chronic kidney disease (CKD). The average Cr was 188.67±151.68 μmol/L, and the average LVEF was 46.50±13.58% pre the procedure (Table 1).

Table 1: Baseline information of preprocedural.

Case number	Gender	Age	Date of procedure	Hypertension	DM	Smoking	CABG	Cr (μmol /L)
1	M	67	2016.07.11	N	Y	Y	Y	350
2	F	54	2017.04.05	N	Y	N	N	121
3	M	78	2017.05.08	Y	Y	N	N	117
4	F	60	2017.05.11	Y	Y	N	N	411
5	M	83	2017.06.12	Y	Y	N	N	68
6	F	81	2017.10.23	N	N	N	N	65
Mean/Percentages %	M=50%	70.50±11.98		50.00%	83.33%	16.67%	16.67%	188.67±151.68

*DM: diabetes mellitus; CABG: coronary artery bypass grafting; Cr: creatinine; Y: Yes; N: No.

All the patients had triple vessel disease, and even among 4 of them had UPLM disease. The average SYNTAX score was 41.33 ± 12.14 , and the SYNTAX II score was $47.87 \pm 9.45 / 31.55 \pm 8.82$ (Table 2).

Table 2: Coronary lesion score and interventional treatment and follow-up.

Case number	1	2	3	4	5	6	Percentage / Mean±SD
Left main disease	Y	Y	N	N	Y	Y	66.70%
Triple vessel disease	Y	Y	Y	Y	Y	Y	100%
Bifurcation lesions	Y	Y	Y	N	N	Y	66.70%
Severe calcification	Y	N	Y	Y	Y	Y	83.33%
Gensini Score	312	126	64	189	96	155	157.00±87.62
SYNTAX Score	59	49	27	29	44	40	41.33±12.14
SYNTAX II Score	58.0/38.4	57.4/22.2	38.9/37.9	50.5/22.7	35.0/41.9	47.4/26.2	47.87±9.50 / 31.55±8.82
Coronary of athrectomy	LAD, LCX	N	LAD; LCX	LAD	LAD	LM-LAD, RCA	8 in total
Number of stents	3	2	3	2	2	3	2.50±0.55
CR	Y	Y	Y	Y	Y	Y	100%
Support time (h)	9	26	6	10	6	6	10.50±7.79
Arrhythmia	ST	N	N	N	N	N	16.67%
CRRT	N	Y	N	Y	N	N	33.33%
LVEF (%)	Basic	35	30	63	40	50	39
	Mean NII	0.00	45.32	2.20	46.88	16.95	58.43
Follow-up time (months)	N	25	25	4	10	21	20.25±7.09
Complication	N	infection	N	N	thrombus	N	33.33%
MACCEs	Died	Survival	Survival	Died	Survival	Survival	33.33%

*CR: complete revascularization, complete revascularization; ST: sinus bradycardia, sinus bradycardia; CRRT: continuous renal replacement; LAD: left anterior descending branch; LCX: left circumflex; RCA: right coronary artery; LM: left main therapy, continuous renal replacement therapy; LVEF: left ventricular ejection fraction; NII: net improvement index; MACCEs: major adverse cardiac and cerebrovascular events; Y: Yes; N: No.

II Result of the Procedures and Prognosis

All the patients completed PCI supported by ECMO successfully. The mean course of ECMO support time was 10.50 ± 7.79 hours, and the average number of DES placed for each patient was 2.5. Although no malignant arrhythmia or other serious complications such as haemorrhage including gastrointestinal and intracranial haemorrhage or acute renal dysfunction reported during the procedure, one case witnessed a catheter-punctured site infection after the procedure, and another case showed deep venous thrombosis in the catheter-punctured site.

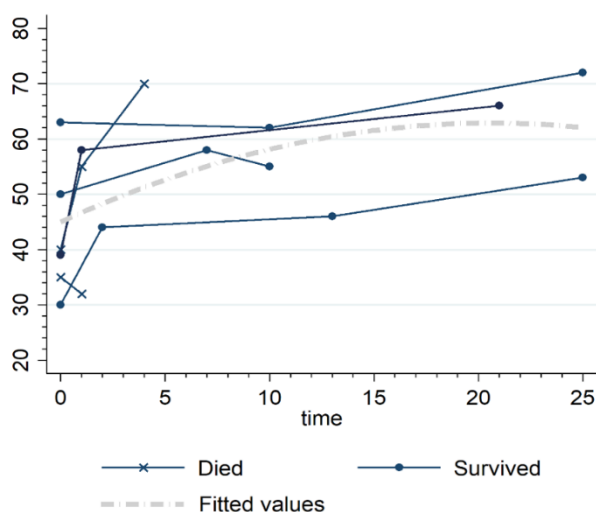


Figure 1: LVEF changes during follow-up and fitting curve.

All ECMO were weaned successfully, and no hospitalized deaths occurred. The survival rate throughout the follow-up period of 17.00 ± 9.51 months was 66.7% ($n=4$) with 2 patients died for refractory heart failure. The average NII was $28.30 \pm 25.11\%$ for the follow-up, and the max NII was 58.43% reported by one case (Table 2, Figure 1). The pre-procedure Gensini score and creatinine (Cr) level were higher in the survived group though this difference was not statistically significant ($P = 0.06$) (Table 3, Figure 2).

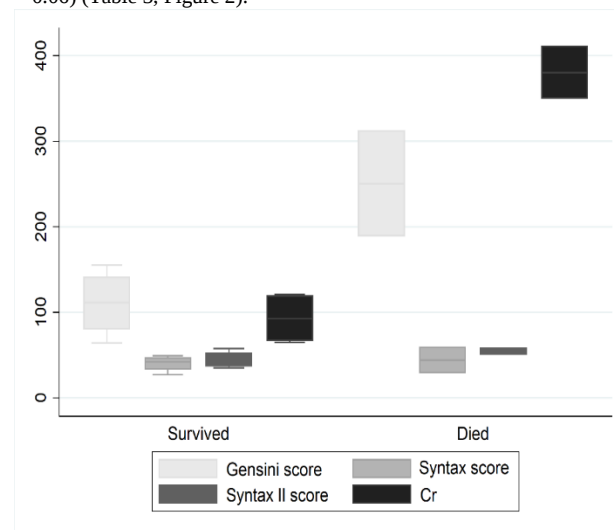


Figure 2: Different prognostic group lesion scores and creatinine comparison.

Table 3: Different prognostic group lesion scores and creatinine comparison.

Group	Gensini score	Syntax score	Syntax II score	Cr (μmol /L)
Survival group	110.38±39.19	40.00±9.42	44.58±9.90/32.05±9.35	92.75±30.38
Death group	250.50±86.97	44.00±21.21	54.25±5.30/30.55±11.10	380.50±43.13
<i>p</i> value	0.06	0.643	0.165	0.06

*Cr: creatinine.

Discussion

The strategy of revascularization for complex high-risk coronary disease had been no more limited to CABG owing to the rapid advancement of the interventional technique and equipment. However, when complicated with severe cardiac insufficiency or multi-organ dysfunction, the patients are prone to circulatory collapse during the interventional procedure. By undergoing the PCI in such a complex high-risk coronary lesion, the guidelines have recommended the MCS devices to keep the hemodynamics stable [12].

The idea of potential and contingent values from the intra-aortic balloon pump (IABP) in providing hemodynamic supports all along the interventional procedure of complex high-risk coronary disease seems plausible and convincing among the cardiologists during the past years [13]. An increasing number of new studies, however, have started to challenge the entrenched viewpoint and argue the opposite that IABP contributes little to the delineated situation [14, 15]. Moreover, other options, like percutaneous left ventricular assist devices (PVADs) such as Impella and TandemHeart, have been demonstrated to offer effective yet partial hemodynamic supports for complex coronary lesions [16, 17].

Nevertheless, Becher found that there was no significant difference in MACCEs between the groups that applied the PVADs and not in terms of circulatory assistance in PCIs among 61 cases which had triple vessel disease and severe heart failure [18]. Besides, implied by a meta-analysis designed for MCS in PCI for high-risk coronary disease, although the Impella could provide relatively stable circulatory supports, the mortality between the group using IABP and the another applied the Impella yields no significant difference, and the cost-benefit analysis even suggested a higher cost for Impella 2.5 [19]. Moreover, Kovacic *et al.* compared the supporting competency between Impella 2.5 and TandemHeart for 68 high-risk coronary disease patients who received the PCI [20]. They found that both MCS could provide stable circulatory assistance but without a major difference in the complication of insertion position or MACEs during 30 days of follow-up. Furthermore, a meta-analysis showed that there was no significant difference in the mortality between IABP and PVADs as the MCS during the PCI procedure for severe heart dysfunction patients, but the relative risk in the PVADs group was higher than that of IABP group [21].

Unlike the PVADs, the ECMO has been applied in maintaining organ perfusion by the artificial heart pump in the replacement of the patient self-heart pump efficiently in interventional procedures over the recent years [22, 13]. In the early 1990s, Teirstein *et al.* found the optimal time for ECMO insertion [23]. In their study, there were 389 patients in the prophylactic support group and 180 in the standby support group, and both groups achieved comparable success and major rates of complication. Patients with severe left ventricular dysfunction might benefit from the institution of prophylactic ECMO support. Therefore, in the current study, we adapted that strategy in the opportunity which is

the institution of prophylactic ECMO support in the interventional procedure.

However, previous discussions about complex high-risk PCI under the assistance of the MCS devices still bog on the nascent stage. To date, there have been few significant results reported on large-scale multi-center and long-term follow-up studies, in particular, focusing on the ECMO supported PCI for complex high-risk coronary disease. A study from Tomasello presented a single-center experience in ECMO supported complex high-risk PCI among 12 patients, with a mean age of 63.5±8.7 years and a mean SYNTAX score of 30.1±10.1. Whereas all patients included in that study survived during a period of a 6-month follow-up though two of them needed further revascularization [24]. As for the mid-term follow-up, Shaukat's study enrolled five male patients who successfully received the ECMO supported PCI. The mean age for patients was 66.8±8.6 years, and mean LVEF was 26.6±18.0%. The same study further illustrated that ECMO supported PCI were well-tailored for patients with lower LVEF, and there was no MACCE occurrence during the subsequent course of a one-year follow-up [25].

The patients included in our study were observed in a much more serious status, featuring higher age, more complex coronary lesions followed with higher SYNTAX score, UPLM or multivessel disease with heavy calcification, and more severe organ dysfunction such as depressed systolic function or CKD. This noticeable stack of characteristics has thus given a viable opportunity for the MCS assistance intervention procedure to step in. Between the group of the survived and the dead, no significant difference in the Gensini score and the CR level may indicate that the more complicated the situation, the worse the ending. The mean follow-up time in our study is much longer than any of previous ones, achieving 17±9.51 months, and the timespan for the most prolonged case even continued up to 25 months. Besides, we attempted to employ the NII to standardize the LVEF change during the period of follow-up, aiming at exploring the method to eliminate the bias caused by differences from follow-up time. The result showed that the PCIs were all successful, no hospitalized death occurred, and the incidence of MACCEs in the longer term of follow-up was satisfied. According to the previous study, the mortality of medication therapy group represented more than twice compared with that of revascularization group [26]. The same picture was captured in our study. Compared with conservative therapy, the interventional method significantly improved the prognosis of patients facing such complex high-risk situations. Also, based on our follow-up surveys, the LVEF increased post the procedure, strongly confirming the positive significance of revascularization therapy for myocardial perfusion.

Still, ECMO can provide full circulatory support on the one hand but can also introduce complications on the other. With the ECMO supporting time increasing, the number of reported incidences of complications such as haemorrhage, thrombosis, infection, liver or kidney dysfunction, and distal limb ischaemic necrosis climbs gradually [27, 28]. In this

study, one case observed catheter-inserted site infection postoperative and another case had venous thrombosis in the catheter-inserted site. For the rest of cases, no other severe complications were observed. Past studies had shown a connection between the mortality and ECMO supporting time, which may due to the increased complications after longer ECMO duration [29]. So, we suggest that ECMO should get weaned off as soon as the patient is hemodynamically stable.

Patients who seek ECMO support are often in a more severe situation, and their complication risk of interventional therapy is thus much higher than those of others. As a result, indications of ECMO supported PCI are advised to go through a stringent evaluation and to be overseen on the case-by-case bases. The current empirical study thus suggests that cardiologists take into account the characteristics of the lesion and related benefits as well as risks when deciding the type of treatment, say intervention or CABG, for individual cases.

This study still bears limitations although it has yielded a good clinical result. First, the sample size is too small to generalize to the rest of the population. Second, due to the absence of a control group, the benefit of ECMO implementation from this observational study needs further investigation.

Conclusion

Our study reveals that VA ECMO can provide effective circulatory support and ensure a great degree of safety during the intervention procedure for complex high-risk coronary disease. More importantly, we find that ECMO supported PCI provides a more viable strategy for treating the complex high-risk coronary disease.

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Conflicts of Interest

None.

Consent

All the patients signed informed consent before the initiation of the procedure.

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