Chapter 3

Long-Term Outcome of High-Risk Percutaneous Coronary Interventions with Extracorporeal Membrane Oxygenation Support for Patients Without Cardiogenic Shock

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Abstract

Percutaneous coronary intervention (PCI) has evolved into the high-risk category in the past 2 decades. Endovascular patients are on average sicker than in the past due to increased age, complex anatomy, reduced global left ventricular systolic function and a greater frequency of surgical refusal. Extracorporeal membrane oxygenation (ECMO) can be taken into account for the management of extremely high-risk PCI without any hemodynamic instability. The rationale for the use of ECMO includes a lower risk of hemodynamic collapse which leads to low perfusion episodes minimization. In the evidence based on ECMO-assisted high-risk PCI, there are no randomized clinical trials but only observational studies and case reports. In this paper, we describe one-year long-term results of ECMO support for PCI in patients without hemodynamic disturbances.

Keywords: elective high-risk PCI, ECMO, stable angina, acute coronary syndrome

1. Introduction

At present, a clear-cut definition of what is a high-risk percutaneous coronary intervention (PCI) is not completely determined. In general, high-risk PCI is an intervention which is likely to cause adverse events that will worsen ischemia and reduced cardiac output culminating into cardiogenic shock. According to the clinical expert consensus statement [1], variables that

contribute to an increased risk of PCI can be classified into three groups: (1) lesion specific (Jeopardy Score ≥ 8 [2], calcification, bifurcation, tortuosity, occlusion), (2) clinical presentation specific (cardiogenic shock, acute coronary syndrome (ACS)), and (3) patient specific (age, a history of diabetes mellitus and/or prior myocardial infarction, chronic kidney disease, ejection fraction <35% on the echocardiography assessment). A different combination of these variables can provoke cardiogenic shock in high-risk PCI, whereas the most unfavorable option is a combination of severe left ventricular dysfunction (ejection fraction of the left ventricle (EF) <35% or recent decompensated heart failure) and a technically complicated PCI (left main, last remaining conduit, severe multivessel disease) [1].

In observational studies, extracorporeal membrane oxygenation (ECMO) has an encouraging result for PCI in patients with hemodynamic disturbances [3–6]. A meta-analysis or randomized clinical trials data are not available for ECMO. That is why current European guidelines can only be based on the expert consensus [7–9]: "Short-term mechanical support may be considered in patients with refractory shock" (Class of recommendations IIb, level of evidence C.)" There is no evidence of the ECMO benefits for PCI in patients with stable angina and non–ST-segment elevation acute coronary syndrome (NSTE-ACS) based on long-term results data. We are dealing only with single studies presenting hospital outcomes in small series of patients and case reports [10–13]. Today, only selected NSTE-ACS patients with cardiogenic shock are considered for left ventricular assist devices [7]. Approaches implying the use of circulatory support devices for patients without hemodynamic disturbances who require high-risk PCI are not discussed in the guidelines.

Nowadays, an evolution of PCI to the high-risk category could be observed. Endovascular patients are, on average, sicker than in the past due to increased age, complex anatomy, severity and extent of coronary artery disease, low left ventricular ejection fraction, co-morbidities (renal failure, cerebrovascular disease, peripheral artery disease, diabetes mellitus and chronic obstructive pulmonary disease) and a personal choice of PCI to improve their symptoms [1, 14, 15]. Cardiac surgeons are the biggest providers of patients with high-risk PCI. Because of an elevated surgical risk (high STS score or EuroScore II) as well as elevated ischemic and bleeding risks (in NSTE-ACS patients after P2Y12 inhibitors loading), surgeons could refuse coronary artery bypass graft (CABG) interventions [16–19]. Thus, high-risk PCI is an appropriate revascularization strategy for patients who are not suitable for surgery or have refused CABG.

A patient with co-morbidities and severe stable coronary artery disease (CAD) or NSTE-ACS can have a significantly weakened cardiovascular reserve and be more receptive to low myocardial perfusion stunning. At the same time, an aggressive endovascular approach with technically complex high-risk PCI can be complicated by coronary dissection with vessel closure or no reflow or can require longer and balloon inflations with higher pressure. As a result, a sequence of adverse events can occur, leading to reduced ejection fraction and increased hypoperfusion, resulting in the progression of myocardial ischemia and the development of cardiogenic shock and/or multiple organ failures. The rationale for the use of ECMO includes a decreased risk of hemodynamic collapse which leads to fewer low perfusion episodes. Additionally, a lower risk of hypotensive events could provide an interventional cardiologist

with more time to achieve optimal results and complete revascularization. The problem is that it is very difficult to take into account all the unfavorable factors, to correctly assess the complexity of a particular clinical case and to determine the indications for mechanical circulatory support. Having two seemingly comparable patients, we can perform a high-risk PCI procedure without adverse outcomes in one case, and with severe hemodynamic disorders in the other. To resolve the issue we need to conduct a randomized study in the ECMO support PCI versus PCI only but, at the moment, it is not possible due to ethical problems issues and a small number of observations.

Currently, a large number of percutaneous mechanical circulatory support devices is available and has entered clinical practice. These include TandemHeart, intra-aortic balloon pump (IABP), ECMO, Impella [1, 14, 15].

ECMO uses a centrifugal pump for artificial circulation of blood. For the purposes of PCI, veno-arterial ECMO cannulation approach is selected. There are very little data on the use of ECMO in the elective pre-procedural setting: data are limited to reports [12, 13] which demonstrated a single-center experience of high-risk PCI with ECMO support as an adjunct modality. The conclusion of these reports was that elective pre-PCI ECMO is a viable therapeutic alternative capable of ensuring good immediate and mid-term outcomes in high-risk CABG patients.

The reason for choosing ECMO support versus other devices for elective high-risk PCI in patients without cardiogenic shock is given in our earlier publications [20].

Thus, taking into account a high incidence of chronic CAD and ACS [21] as well as an evolution of PCI to the high-risk category there is a strong medical and social need to treat these patients safely. A number of high-risk PCI patients are considered to be at extremely high risk of PCI complications during these complex procedures. Nowadays, the development of cardiac support devices such as ECMO has allowed to introduce a safer approach for the extremely high-risk patient subset. The extracorporeal membrane oxygenation has some advantages over the other types of mechanical circulatory support devices. There is limited evidence data on the safety and efficacy of ECMO-assisted high-risk PCI in patients with stable CAD and NSTE-ACS. The next parts of this chapter are devoted to analyzing immediate and long-term outcomes of ECMO support for high-risk PCI without cardiogenic shock as an adjunct modality in the elective pre-procedural setting.

2. Immediate and long-term outcomes of ECMO support for complex high-risk PCI in stable angina patients: A single-center experience

Elective high-risk PCI with ECMO support in **stable angina** patients with the multivessel disease will be presented in this section. These data are based on the in-hospital and 12-month outcomes of a single-center retrospective observational study in the small series of 16 patients. The purpose of the study was to evaluate the incidence of MACCE (a composite of all-cause death, myocardial infarction (MI), stroke and target vessel revascularization) at 30 days

and 12 months. Additionally, bleeding and complete revascularization rates were evaluated. Complete revascularization was defined as the PCI procedure, as a result of which the residual SYNTAX score was ≤2. For the classification of bleeding, the definition of Bleeding Academic Research Consortium (BARC) was used [22]. Hemorrhagic complications of type 3 and higher were taken into account.

High-risk PCI was defined as having two of the three parameters [20]: (1) ejection fraction <35%; (2) Jeopardy Score ≥ 8 [2]; (3) intervention for bifurcation and/or left main and/or chronic total occlusion. An indication for high-risk PCI with ECMO support was based on the heart team decision for those patients, who were not suitable for some types of revascularization (CABG or PCI) and who had two of the three parameters of high-risk PCI.

We started ECMO prior to PCI and used the "RotaFlow System" (by MAQUET). The ECMO cannula was inserted using a surgical technique (9 (56.2%)) and endovascular approach (ProStar XL, 7 (45.8%)). The mean ECMO time was 2.4–3.2 L/min/m^2 (70–100% from the estimated).

The medications during PCI included unfractionated heparin and acetylsalicylic acid. All of the patients received the loading dose of clopidogrel before PCI. Aspirin was prescribed before revascularization (75 mg once daily) for all the study patients and it was continued indefinitely. Unfractionated heparin was used (IV bolus of 100 IU per kilogram of body weight followed by an adjustment according to the target activated clotting time of 250–300 seconds). Antiplatelet regimen routinely included clopidogrel (a loading dose of 300 mg at the time of PCI unless used in advance; then 75 mg daily, the recommended duration of treatment was 12 months).

Baseline clinical and angiographic characteristics of the study patients are shown in **Table 1**. Of note, the mean age was 62.8 ± 6.5 years, and the majority of patients were males (81.2%). Diabetes mellitus was present in 18.7, 75% had a history of myocardial infarction, peripheral artery disease was observed in 50% of patients. Left ventricular ejection fraction (LVEF) was poor: 37.9 ± 17.5%. Our patients had stenotic lesions of two or more significant epicardial arteries and/or large branches (≥2.5 mm) ≥70% and/or stenosis of LMCA ≥50%. The target vessel for PCI was determined taking into account the data on the viability of the myocardium on cardiac magnetic resonance imaging. Fifteen (93.7%) patients had 3 or more affected vessels, significant LMCA stenosis was diagnosed in 7 (43.7%) patients and mean SYNTAX score was 31.4 ± 9.8. In general, stable CAD patients (n = 16) were characterized by a high incidence of a prior MI, very low ejection fraction and severe multivessel disease involving LMCA.

We successfully performed all PCI + ECMO interventions. Procedural characteristics and in-hospital outcomes of the study patients are shown in **Table 2**. The mean bypass/PCI duration was 115.6 ± 43.7/98.6 ± 31.1 minutes. All of the patients were weaned from the system immediately after PCI directly in the cath-lab. Only six (37.5%) patients had a complete revascularization while the mean number/length of implanted stents was 3.6 ± 1.2 and 75.8 ± 23.4 mm, respectively. Only second-generation drug-eluting stents (DES) were implanted. There was one stroke case (6.2%) 5 days after PCI + ECMO which led to the death

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Variables	Stable CAD patients PCI+ ECMO (n = 16)
Mean age	62.8 ± 6.5 (51–75)
Male	13 (81.2%)
Mean left ventricular ejection fraction	37.9 ± 17.5
Left ventricular ejection fraction <35	11 (68.7%)
EuroScore II	3.2 ± 2.4
CCS II	6 (37.5%)
CCS III-IV	10 (62.5%)
Chronic kidney disease	4 (25%)
COPD	2 (12.5%)
Diabetes mellitus	3 (18.7%)
Prior myocardial infarction	12 (75%)
Arterial hypertension	134 (89.3%)
Peripheral artery disease	8 (50%)
Prior stroke	1 (6.2%)
SYNTAX Score	31.4 ± 9.8
Jeopardy score [2]	11.3 ± 0.9
Affected vessels: 1, 2	1 (6.2%)
Affected vessels: ≥3	15 (93.7%)
LMCA stenosis ≥50%	7 (43.7%)

BARC: Bleeding Academic Research Consortium, COPD: chronic obstructive pulmonary disease, CCS: Canadian Cardiovascular Society grading of angina pectoris.

Table 1. Baseline characteristics of the study population.

of the patient with carotid artery disease. A BARC bleeding of type 3 or more was observed in 6 (37.5%) patients. The mean hospital stay was 12.6 ± 4.8 days. A significant decrease in hemoglobin levels required blood transfusion in six cases. The blood use averaged 4.2 units of red blood cells.

Long-term outcomes of the study are presented in **Table 2**. About 25% mortality rate was observed at 12 months. The combined endpoint (all-cause death, myocardial infarction (MI), stroke and target vessel revascularization) was observed in 4 (25%) patients. Three (18.7%) deaths occurred in the post-hospitalization period as a result of acute myocardial infarction. Two were due to acute stent thrombosis and one as a consequence of stent restenosis. Myocardial infarctions in the long-term follow-up period (3 (18.7%)) were predominantly new cases after the hospital discharge and led to TVR in two patients. There were no additional stroke cases in the follow-up period.

Variables	Stable CAD patients PCI+ ECMO (n = 16)
In-hospital outcomes	
MACCE	1 (6.2%)
• Death	1 (6.2%)
• Stroke	1 (6.2%)
• MI	0
• TVR	0
Mean bypass duration (min)	115.6 ± 43.7
Mean total time of PCI (min)	98.6 ± 31.1
Mean № of stents	3.6 ± 1.2
Mean diameter of stents	3.25 ± 0.5
Mean length of stents (mm)	75.8 ± 23.4
Bleeding (BARC≥3)	6 (37.5%)
Complete revascularization	6 (37.5%)
Residual SYNTAX score	8.5 ± 10.8
Hospital stay (days)	12.6 ± 4.8
12-month outcomes	
MACCE	4 (25%)
• Death	4 (25%)
• Stroke	1 (6.2%)
• MI	3 (18.7%)
• TVR	2 (12.5%)

BARC: Bleeding Academic Research Consortium, MI: myocardial infarction, TVR: target vessel revascularization.

Table 2. Procedural characteristics and study end points.

This study had patients at high risk of adverse events for any type of revascularization (CABG and PCI). This is the largest series of consecutive high CABG risk chronic CAD patients who underwent ECMO in the elective pre-procedural manner. The main hypothesis of the study was that PCI + ECMO may be a feasible strategy of revascularization for **stable angina** patients at a high risk for CABG or PCI only.

All the patients had severe multivessel disease involving LMCA, poor left ventricular fraction as a result of a prior MI and underwent challenging PCI with ECMO support as an adjunct modality in the elective pre-procedural setting, which allowed to complete a successful revascularization without hemodynamic disturbances and to wean from ECMO immediately after PCI. The hospital results looked satisfactory. There were no serious cardiac adverse outcomes. Hemorrhagic complications were not fatal, although it is necessary to note a high incidence of

bleeding and blood transfusions. At the 12-month follow-up, the results became less encouraging. A high number of myocardial infarctions in combination with an in-hospital stroke led to an increased number of cumulative adverse outcomes of 25%. The attention should be drawn to the unsatisfactory effect of implantation of second-generation DES (myocardial infarction and death from myocardial infarction in 18.7% of patients). Nevertheless, our data do not go beyond the results presented in the literature. The long-term all-cause mortality in ischemic cardiomyopathy patients with reduced ejection fraction increased up to 58.9 and 66.1% in the CABG and guideline-directed medical therapy groups, respectively [23, 24]. The main limitation of our analysis is a small number of patients. Therefore, in order to answer the question on the role of ECMO for high-risk PCI in chronic CAD patients, larger trials are required.

In conclusion, our study was designed to report the unique single-center experience in using ECMO to manage high-risk **stable angina** patients in the catheterization laboratory. In-hospital results suggest that PCI with ECMO can be successfully performed and may be a feasible strategy of revascularization in a high-risk cohort of chronic CAD patients with adverse outcomes after any type of revascularization (CABG and PCI). Bleeding control is a critical aspect of care during the PCI + ECMO procedure. The long-term results of PCI with the support of artificial circulation require additional evaluation in larger or/and randomized studies. Particular attention should be paid to factors that increase the risk of stent thrombosis (the number of stents, the quality of stents, the procedure for stent implantation, antiplatelet therapy).

3. PCI + ECMO vs. CABG for NSTE-ACS patients with multivessel disease

We followed NSTE-ACS multivessel coronary artery disease (MVCAD) patients consecutively admitted to our hospital from 2012 to 2015 and undergone revascularization with high-risk PCI + ECMO support or CABG. The study included 53 patients (PCI + ECMO, n = 23, and CABG, n = 30). It was a single-center registry, which compared 12-month outcomes. Inclusion criteria were significant multivessel coronary disease and/or stenosis of the left main coronary artery (LMCA) ≥50%. The PCI + ECMO group of NSTE-ACS patients had an intermediate risk of adverse cardiovascular outcomes (mean GRACE score 117.3 ± 19.4, mean EuroScore II 4.3 ± 3.9%), and a high SYNTAX Score: 33.3 ± 8.3. Significant LMCA stenosis was diagnosed in 60.7% of patients. Every third patient had diabetes mellitus, a prior myocardial infarction was observed in 56.4% cases, peripheral artery disease was diagnosed in 60.7% of patients of the study population. High-risk PCI was defined as having two of the three parameters: (1) left ventricular ejection fraction less than 35%; (2) a large amount of myocardium at risk (Jeopardy Score 8 and more [2]) and (3) complex PCI. An indication for high-risk PCI with ECMO support was based on the heart team decision for those patients, who were not suitable for some types of revascularization (CABG or PCI) and who had two of the three parameters of high-risk PCI.

The CABG group patients also had a moderate risk of adverse cardiovascular outcomes (mean GRACE score 97.5 ± 15.0, mean EuroScore II 2.7 ± 2.1%), and an intermediate-high SYNTAX Score: 29.7 ± 8.3. Significant LMCA stenosis was diagnosed in 36.6% of patients. Diabetes mellitus was present in 16.6% of patients, 60% of patients had a prior myocardial infarction and in every third patient of the study population, peripheral artery disease was diagnosed. Thus, there were no statistically significant differences between the groups in terms of the baseline clinical characteristics, but the PCI + ECMO group had a potentially slightly poorer prognosis compared with the CABG group (**Table 3**).

In order to perform PCI + ECMO, we used 21–23 Fr venous cannula for the right common femoral vein with a surgical technique. For the iliac artery—17-18 Fr arterial cannula was used. The mean ECMO flow was about 2.5 L/min/m2 with a duration of 95.4 ± 25.2 min. During PCI all patients received unfractionated heparin, and acetylsalicylic acid before PCI. About 42%of patients received the loading dose of clopidogrel before PCI. After the surgical cannulation wound closure, the remaining patients received the loading dose of clopidogrel. We connected ECMO ("RotaFlow System" developed by the MAQUET Getinge Groupe, Hirrlingen, Germany) before the start of PCI.

The patients in both groups were waiting for revascularization for about 2 weeks. About 89.9% of the CABG patients had complete revascularization. There were significantly fewer patients having had complete revascularization in the PCI + ECMO group: 30.3% (p = 0.0001).

Variables	PCI + ECMO (n = 23)	CABG (n = 30)	P
Mean age	67.5 ± 8.5 (48–82)	64.4 ± 7 (45–75)	0.125
Male	15 (65.2%)	19 (63.3%)	0.9
Mean left ventricular ejection fraction	47.5 ± 12.8%	54.4 ± 10.0%	0.069
Left ventricular ejection fraction ≤40%	9 (39%)	1 (3.3%)	0.001
Mean GRACE SCORE	117.3 ± 19.4	97.5 ± 15.0	0.205
LMCA stenosis ≥50%	14 (60.7%)	11 (36.6%)	0.08
Diabetes mellitus	8 (34.7%)	5 (16.6%)	0.13
Prior myocardial infarction	13 (56.4%)	18 (60%)	0.8
Arterial hypertension	22 (95.4%)	27 (89.9%)	0.5
Peripheral artery disease	14 (60.7%)	11 (33.3%)	0.049
Prior stroke	2 (8.6%)	2 (6.6%)	0.8
EuroScore II	4.3 ± 3.9%	2.7 ± 2.1	0.01
SYNTAX Score	33.3 ± 8.3	29.7 ± 8.3	0.062
Jeopardy score	10.6 ± 1.8	10.6 ± 1.7	0.876

Table 3. Baseline characteristics of the study groups.

Implanted stents mean length and diameter were 54.6 ± 25.3 mm and 3.28 ± 0.4 mm, respectively. During the PCI procedure, 2.8 ± 1.1 DES were implanted. The average number of grafts in the CABG group was 2.8 ± 0.6.

The study endpoints included death, myocardial infarction, stroke, repeated unplanned revascularization and the combined endpoint of death, myocardial infarction, stroke, and revascularization.

It is important to note, that the in-hospital mortality in the PCI + ECMO group was 4.3% and the combined endpoint of adverse events (MACE) (death, MI, stroke, repeated revascularization) was 8.7%. We observed a high rate of significant hemorrhagic complications (BARC 3) caused by the use of the ECMO cannula: up to 47.8%. Despite this, after 12 months of follow-up, mortality and MACE increased only to 8.7 and 17.4%, respectively. Repeated revascularization was required only in 1 (4.3%) case. These results make it clear that the revascularization approach is justified when PCI is performed on severe stenotic lesions in the large proximal parts of the coronary arteries that supply significant areas of the viable myocardium.

The in-hospital results in the CABG group were characterized by a high mortality level (9.99%). MACE in the hospital period reached 13.3%. Significant hemorrhagic complications (BARC 3–4) occurred in 26.6% of cases, which was the expected outcome in the group of open surgical treatment. Mortality and MACE in the CABG group increased to 13.3 and 23.3%, respectively, after 12 months of follow-up. The analysis of the results shows a high proportion of in-hospital and long-term adverse events, which is caused by a high risk of the open surgery in NSTE-ACS MVCAD patients with a high SYNTAX score. These results should not be considered as unfavorable because according to the data of our Registry [25], the prognosis in this group of patients was extremely poor in the absence of revascularization (mortality rate reached 28%).

The comparison of the PCI + ECMO and CABG results of in NSTE-ACS MVCAD patients showed no significant differences in the study endpoints at 12-month follow-up (**Table 4**) despite a potentially poorer prognosis in the PCI + ECMO group compare to the CABG group based on baseline clinical characteristics.

Thus, PCI + ECMO may be an alternative to the CABG revascularization strategy for NSTE-ACS MVCAD patients with a high surgical risk. Although CABG remains the conventional

Variables	PCI + ECMO (n = 23)	CABG (n = 30)	P
Death	2 (8.7%)	4 (13.3%)	0.27
Myocardial infarction	2 (8.7%)	2 (6.6%)	0.77
Stroke	1 (4.3%)	0	0.26
Revascularization (unplanned)	1 (4.3%)	2 (6.6%)	0.7
MACE (death, MI, stroke, repeated revascularization)	4 (17.4)	7 (23.3%)	0.6

Table 4. Twelve-month outcomes of various treatment strategies.

method of revascularization for patients with complex coronary disease including multivessel and LMCA disease, PCI + ECMO is a technique that improves the access to revascularization for high-risk patients who are often refused a CABG surgery.

In our study, we included patients with a high risk of adverse outcomes for any type of revascularization (CABG and PCI). We assume that PCI + ECMO is a possible strategy of revascularization for high-risk NSTE-ACS patients. These patients usually have diffuse coronary artery disease involving LMCA. PCI with ECMO support makes it possible to perform a successful revascularization with no hemodynamic instability.

The present study had several limitations. First of all, it was not randomized. A very critical clinical and angiographic status of the PCI patient group gave us the opportunity to test ECMO as a method of PCI support in a high-risk cohort of NSTE-ACS patients. It is necessary to conduct randomized trials to answer the question on the role of ECMO support for high-risk PCI in NSTE-ACS patients.

4. Conclusions

Currently, the guidelines approve the use of ECMO support in cardiogenic shock or cardiac arrest patients. There are limited data on the use of ECMO support for PCI in stable angina and NSTE-ACS patients without hemodynamic disturbances. However, the use of ECMO for PCI support has a theoretical and practical rationale and showed encouraging results in our single-center observation. Our single-center experience demonstrated that PCI supported by ECMO may be an alternative for high-risk revascularization (CABG and PCI) for both stable angina and NSTE-ACS patients. The extremely poor prognosis in high-risk patients treated with a pharmacological approach who are often refused a CABG surgery or standard PCI makes PCI + ECMO method very promising as it improves the access to revascularization.

Our experience in this study allowed us to come to the following conclusions. A detailed assessment of the viable myocardium in a group of patients with stable coronary artery disease can improve the 12-month results as a more accurate selection of patients for PCI + ECMO support will be done. A particular attention should be paid to factors that increase the probability of stent thrombosis. The role of this revascularization method for NSTE-ACS patients is more obvious. PCI + ECMO is a life-saving technique that significantly improves hospital and 12-month survival of patients who were refused a CABG surgery or standard PCI. Unfortunately, we do not know the exact indications for ECMO in the elective pre-procedural setting, therefore, we need to develop a methodology (calculator) to immediately assess the need for mechanical circulatory support devices during high-risk PCI. In the end, selection of mechanical circulatory support devices is a matter of a personalized approach and should be based on the results of upcoming large randomized comparative studies.

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