Chapter 7

Extracorporeal Membrane Oxygenation Support for Complex Percutaneous Coronary Interventions in Patients without Cardiogenic Shock

Vladimir I. Ganyukov, Roman S. Tarasov and Dmitry L. Shukevich

Additional information is available at the end of the chapter

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Abstract

It has been shown that extracorporeal membrane oxygenation (ECMO) may provide cardiopulmonary support during percutaneous coronary interventions (PCI) in patients with refractory cardiogenic shock. Current guidelines consider ECMO and implantable left ventricular assist devices in selected non-ST-segment elevation acute coronary syndrome (NSTE-ACS) patients. High-risk PCI remains a viable revascularization strategy for those patients who are not suitable for surgery or those refusing it. However, such a subset of patients is considered to be at an extremely high risk of PCI complications as there is a risk of hemodynamic collapse during balloon inflations or complex procedures, particularly, if coronary dissection with vessel closure or no reflow occurs. This chapter is devoted to the use of ECMO support for high-risk complex PCI in NSTE-ACS patients without cardiogenic shock based on the theoretical rationale, observational retrospective single-center studies and clinical case examples.

Keywords: ECMO, high-risk PCI, multivessel disease, non-ST-elevation acute coronary syndrome, stable hemodynamics patients

1. Introduction

In this chapter, we will try to justify the use of extracorporeal membrane oxygenation (ECMO) support for high-risk complex percutaneous coronary interventions (PCI) in non-ST-segment elevation acute coronary syndrome (NSTE-ACS) patients without cardiogenic shock

based on the theoretical rationale, observational retrospective single-center studies and clinical case examples.

Cardiogenic shock complicates up to 8% of ST-segment-elevation (MI) and up to 3% of non-ST-segment-elevation myocardial infarctions. For cardiogenic shock patients, who fail pharmacological treatment, mechanical circulatory support devices can be introduced to augment myocardial performance and systemic perfusion. It has been shown that ECMO may provide cardiopulmonary support during PCI in patients with refractory cardiogenic shock [1–6]. Nichol et al. reviewed 84 studies of 1494 patients with cardiogenic shock, cardiac arrest or both, who were treated with PCI supported by ECMO, and showed an overall survival of 50% [3]. A similar more recent analysis found 49% survival rate either in the setting of mechanical circulatory support devices or ECMO and concluded that, in the current era, roughly half of the patients, who need a mechanical circulatory support device for refractory cardiogenic shock, survive, and roughly half of these survivors require an implantable ventricular assist device [4]. As there are no large randomized controlled trials with the use of ECMO for cardiogenic shock patients, the opinion of European experts on revascularizing this patient setting with ECMO support is not clear: "In younger patients with no contraindication for cardiac transplantation, left ventricular assist device therapy can be implemented as a bridge to transplantation. In patients not eligible for transplant, left ventricular assist devices may be inserted as a bridge to recovery or with the goal of destination therapy" [2]. At the same time, there is not enough evidence regarding safety and efficacy of ECMO during PCI in high-risk patients with NSTE-ACS without cardiogenic shock. Therefore, current guidelines consider ECMO and implantable left ventricular assist devices in selected NSTE-ACS patients [7].

Based on the United States registry data, there were ~0.4 million NSTE-ACS discharges in 2010 [8], which makes approximately1250 discharges per 1 million of the population per year. Additionally, it is well known that NSTE-ACS prognosis is unfavorable. Despite the fact that hospital mortality rate in NSTE-ACS is lower than in ST-segment-elevation myocardial infarctions, mortality at 6 months is comparable and, furthermore, mortality at 4 years is two-fold higher [9–11]. Based on our experience, we have had the evidence of an extremely poor prognosis in NSTE-ACS patients with multivessel disease that often undergo high-risk PCI [12]. Thus, this is a significant medical and social issue.

What do we know about NSTE-ACS with multivessel disease? First of all, this patient settings make up to 50% of all NSTE-ACS patients [13]. Secondly, no contemporary randomized clinical trials comparing PCI with coronary artery bypass surgery (CABG) in patients with NSTE-ACS and multivessel disease are available. Therefore, the selection of the optimal revascularization modality continues to be controversial. What is the right way to revascularize patients with NSTE-ACS and multivessel disease? Should we use CABG or PCI? Should we perform a complete or target vessel procedure? Should we choose stand-alone revascularization or a staged approach? When is it suitable to perform the procedure in relation to perioperative antithrombotic therapy and very high-risk NSTE-ACS? What is the place of staged (PCI-CABG) strategy? Currently, all these questions do not have answers apart from the point of view on complete revascularization: a complete revascularization strategy for significant

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lesions should be pursued in NSTE-ACS with multivessel disease patients [7]. This statement is based on the results of several trials which demonstrated, on the one hand, the benefit of an early complete revascularization approach irrespective of the possibility to identify the culprit lesion and; on the other hand, data show a poor 1-year outcome in NSTE-ACS patients with multivessel disease, who had a residual SYNTAX Score >8 [14–17].

There are limitations for CABG and PCI revascularization. Surgeons refuse CABG for high STS score or EuroScore II patients [18–21]. Factors associated with surgical mortality after CABG surgery include acute coronary syndrome, low left ventricular ejection fraction (EF), obesity, prior CABG and significant comorbidity (diabetes mellitus, cerebrovascular disease, peripheral artery disease, chronic obstructive pulmonary disease and renal failure) [22]. The rejection could be also based on the difficulties in balancing ischemic and bleeding risks (P2Y12 inhibitors loading) [23, 24].

The reason for PCI refusal is a high risk of death or major complications during or after PCI. At present, variables that contribute to a higher risk during PCI have been well defined by 2015 SCAI/ACC/HFSA/STS clinical expert consensus statement [1] and can be categorized into three major groups: (1) patient specific, (2) lesion specific and (3) clinical presentation specific. The statement demonstrates patient-specific (age, left ventricular function, symptoms of heart failure, diabetes mellitus, chronic kidney disease, prior myocardial infarction, peripheral vascular disease) and lesion-specific data (multivessel or left main disease, saphenous vein grafts) for high-risk PCI. There is no doubt that the clinical setting (acute coronary syndrome, cardiogenic shock) can increase a risk of PCI-related adverse events. A PCI is more high risk if we deal with a combination of factors, i.e., a large amount of myocardium at risk, complex PCI, low global left ventricular function, comorbidities and, finally, if we deal with acute coronary syndrome. For instance, if we are treating a complex coronary stenosis that affects a large amount of the left ventricle (Jeopardy score ≥ 8/12 [25] or the last patent coronary vessel) in patient with ejection fraction less than 40%, it can result in a quick hypotension or cardiovascular collapse. All of these factors may lead to a high incidence of death and major complications during and after PCI and require a personalized approach to treatment. One of the right ways to exclude a risk of hemodynamic compromise during and after a complex high-risk procedure is to use percutaneous mechanical circulatory support devices as an adjunct to PCI. Unfortunately, there are no risk calculators to assess the immediate need for mechanical circulatory support devices during PCI and this requires further investigation.

There are a lot of hemodynamically stable NSTE-ACS patients with multivessel disease in a real clinical practice. A surgical revascularization is not always feasible due to the criticality of the patient status (which is associated with a high mortality risk). Because of high surgical risk, CABG intervention could be refused either by the heart team or by a patient. Therefore, high-risk PCI remains a viable revascularization strategy for those patients who are not suitable for surgery or those refusing it. However, such a subset of patients is considered to be at an extremely high risk of PCI complications as there is a risk of hemodynamic collapse during balloon inflations or complex procedures, particularly, if coronary dissection with vessel closure or no reflow occurs. Nowadays, the development of cardiac support devices has allowed a safer approach for high-risk patients.

The next part of this chapter will discuss the number of NSTE-ACS patients with multivessel disease and the results of their treatment based on the single-center registry data reflecting real clinical practice.

2. Single-center experience in the management of NSTE-ACS patients with multivessel disease

We have observed NSTE-ACS patients consecutively admitted to our hospital in 2012. All patients had multivessel coronary disease (stenoses of two or more significant epicardial arteries and /or large branches (≥2.5 mm) ≥70% and / or stenosis of the left main coronary artery (LMCA) ≥50%). In general, NSTE-ACS patients (n = 150) had a high risk of adverse cardiovascular outcomes (mean GRACE Score 135±47.6, 40% patients had GRACE ≥140) and a significant surgical risk: mean EuroScore II was 5.7±6.4. Significant LMCA stenosis was diagnosed in 16% of patients and mean SYNTAX Score was 21.3 ± 9.9. Diabetes mellitus was presented in every fourth patient, 45% had a history of myocardial infarction, and peripheral artery disease was observed in 42% of patients of the study population (**Table 1**).

NSTE-ACS patients	***n* =150**
Mean age	61.6 ± 9.8 (35–82)
Male	89 (58.9%)
Mean left ventricular ejection fraction	55.9 ± 11.2 (21–73)
Mean GRACE Score	135 ± 47.6 (63–328)
GRACE ≥140	60 (40%)
LMCA stenosis ≥50%	24 (16%)
Chronic kidney disease	14 (9.3%)
Diabetes mellitus	36 (24%)
Prior myocardial infarction	68 (45.3%)
Arterial hypertension	134 (89.3%)
Peripheral artery disease	64 (42.6%)
Prior stroke	9 (6%)
EuroScore II	5.7 ± 6.4
SYNTAX Score	21.3 ± 9.9

Table 1. Baseline characteristics of the study population.

After coronary angiography all the cases were discussed by the multidisciplinary team and were divided into three groups depending on the treatment strategy: (1) PCI (n = 91, 60.6%); (2) CABG (n = 40, 26.6%) and (3) pharmacological treatment (n = 9, 6%). In addition, 10 patients

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(6.6%) required PCI followed by CABG. The mean hospital stay was 15.3±4.2 days (from 10 to 32 days). There was a conversion of treatment strategies for some patients. As a result, the treatment groups were made as follows: PCI/CABG/pharmacological treatment: 107 (71.3%)/25 (16.6%)/18 (12%), respectively. The comparison of clinical and demographic characteristics of the patient groups is presented in **Table 2**.

Variables	**PCI* (*n* = 107)**	**CABG (*n* = 25)**	**Pharmacological treatment (*n* = 18)**	***p* ≤ 0.05 (PCI vs. CABG)**	***P* ≤ 0.05 (PCI vs. pharmaco)**	***P* ≤ 0.05 (CABG vs. pharmaco)**
Mean age	60.5 ± 9.9	62.1 ± 7.9	67.4 ± 10.2		0.05	
Male	66 (61.7%)	17 (68%)	6 (33%)		0.04	0.05
Mean left ventricular ejection fraction	56.4 ± 10.8	56.3 ± 10.8	51.9 ± 14.1			
Mean GRACE Score	130.4 ± 41.7	133.7 ± 49.3	180.5 ± 72.9		0.004	0.02
LMCA ≥ 50%	9 (8.4%)	9 (36%)	6 (33%)	0.0005	0.009	
Chronic kidney disease	10 (9.3%)	2 (8%)	2 (11.1%)			
Diabetes mellitus	25 (23.4%)	5 (20%)	6 (33%)			
Prior myocardial infarction	44 (41.1%)	12 (48%)	12 (67%)			
Arterial hypertension	94 (87.9%)	23 (92%)	17 (94.4%)			
Peripheral artery disease	40 (37.4%)	15 (60%)	9 (50%)	0.06		
Prior stroke	4 (3.7%)	2 (8%)	3 (16.6%)			
EuroScore II	5.2 ± 6.0	5.0 ± 5.4	9.8 ± 8.4		0.03	0.03
SYNTAX Score	18.7 ± 8.8	26 ± 10.8	29.5 ± 7.6	0.001	0.001	

Table 2. Baseline characteristics of the groups.

The largest number of conversion strategy cases (n = 15) have been reported among patients who were initially selected for CABG. Seven patients were moved to the PCI group and eight patients to the pharmacological treatment group. The main reason for the strategy conversion was an extremely high risk of surgery associated with older age, female sex, severe concomitant diseases, obesity, reduced global contractility of the left ventricle, valvular pathology and a poor condition of the distal parts of the coronary arteries. It is important that hospital mortality in patients initially planned for CABG, but finally having received only pharmacological treatment was extremely high (20%). If any strategy of revascularization (PCI or CABG) was substituted with a pharmacological treatment, every third of such cases was associated with in-hospital mortality.

There were significant differences between the CABG and PCI groups in the incidence of LMCA stenosis (36% vs. 8.4%, respectively, p = 0.009) and peripheral artery disease (60% vs. 37%, respectively, p = 0.06). Patients receiving pharmacological treatment compared with the

PCI and CABG groups had older age (67.4 ± 10.2 years), higher number of females (67%) and a high risk of adverse cardiac outcomes (mean GRACE Score 180.5±72.9), significantly greater SYNTAX Score (29.5±7.6) and EuroScore II (9.8±8.4), which reflected the greatest risk of surgical and endovascular treatment.

During the first day after admission to hospital, 62.6% (n = 94), patients underwent revascularization (93 PCI and 1 CABG). Thus, in the first day of hospitalization PCI was performed for 86.9% of patients of the PCI group (93 of 107), whereas only 4% of CABG-group patients underwent CABG in this period (1 of 25). The absolute majority of the patients remaining free of revascularization in the first day received PCI within 7 days, whereas CABG was performed during 2–3 weeks after hospital admission.

Variables	PCI* (n = 107)	CABG (n = 25)	Pharmacological treatment (n = 18)	NSTE-ACS (n = 150)	$p \leq 0.05$ (PCI vs. CABG)	$p \leq 0.05$ (PCI vs. pharmaco)	$p \leq 0.05$ (CABG vs. pharmaco)
Death	10 (9.3%)	2 (8%)	6 (33.3%)	18 (12%)	–	0.015	–
Myocardial infarction	16 (15%)	1 (4%)	5 (27.7%)	22 (14.7%)	–	–	–
Stroke	3 (2.8%)	0	1 (5.5%)	4 (2.7%)	–	–	
Revascularization (all)	35 (32.7%)	1 (4%)	6 (33.3%)	42 (28%)	0.008	–	–
Revascularization (elective)	27 (25.2%)	1 (4%)	5 (27.8%)	33 (22%)	0.04	–	–
Combined endpoint (death + non-fatal MI)	18 (16.8%)	2 (8%)	6 (33.3%)	26 (17.3%)	–	–	–

Table 3. Long-term out comes of various treatment strategies.

The study endpoints included significant adverse events such as death, myocardial infarction, stroke and unplanned revascularization, which occurred during the follow-up period (15.3 ± 4.2 days and 27.6 ± 3.5 months). A comparative analysis of the hospital outcomes showed the worst results in the pharmacological treatment group. Hospital mortality among patients, who did not receive revascularization, was 27.7% (n = 5), compared with 5.6% and 8% in the PCI and CABG groups, respectively.

Long-term outcomes (27.6 ± 3.5 months) of the study are presented in **Table 3**. Twelve percent mortality was observed in the long-term follow-up in the overall patient population. The

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pharmacological treatment group kept leadership in the number of deaths. Mortality and the incidence of the combined endpoint (death + non-fatal MI) in patients who did not receive revascularization in the hospital period significantly exceeded mortality in the PCI and CABG groups. It is important to note that 33% of patients in the pharmacological treatment group received revascularization in the long-term follow-up period. This might have prevented a dramatic mortality increase in this group.

Myocardial infarction in the long-term follow-up period was predominantly due to the complicated hospital period in the pharmacological treatment group and a significant number of post-PCI myocardial infarctions. In the long-term follow-up period, the general incidence of repeat revascularizations was 28%. The majority of these cases (78.6%) were elective as part of the staged procedure in patients with multivessel coronary artery disease.

It is important that hospital mortality (15.3 ± 4.2 days) in the pharmacological treatment group was 27.7% and 30% among the patients converted to pharmacological treatment. The outcomes in the pharmacological therapy group could have been improved by increasing the availability of early revascularization. There are the two most important treatment strategies for these patients: early CABG or PCI with left ventricular assist device, which can be used for severe patients, representing a very high risk for CABG.

In summary, the results of the presented study showed that the majority of NSTE-ACS patients with multivessel disease required PCI. Nevertheless, for a significant number of patients, CABG is an optimal revascularization strategy. An essential proportion of patients, who require CABG, do not receive it in the early hospital period due to a high surgical risk, and this leads to poorer hospital outcomes among acute coronary syndrome patients. Patients of the pharmacological treatment group have the highest rate of hospital mortality. This fact suggests a need to increase the availability of early CABG or PCI with left ventricular assist device in high-risk PCI patients. A rationale for the choice of ECMO as support for a high-risk PCI in NSTE-ACS patients will be presented in the next section of this chapter.

3. Why did we choose ECMO to support a high-risk PCI in patients without cardiogenic shock?

To rule out the risk of hemodynamic compromise during and after the high-risk PCI, we can use percutaneous mechanical circulatory support devices. There has been a significant increase in the utilization of mechanical circulatory support devices from 1.3% of all PCIs in 2004 to 3.4% in 2012 (p trend < 0.001) in patients undergoing PCI in the United States [26]. Historically, the intra-aortic balloon pump (IABP) has long been used as a percutaneous hemodynamic support [27, 28]. Nowadays, a number of new devices have become available and have entered clinical practice. These include left ventricle to aorta assist devices, such as Impella (microaxial flow pumps); left atrial to the iliofemoral arterial system bypass pumps, specifically the TandemHeart; and extracorporeal membrane oxygenation [1].

The IABP provides modest ventricular unloading and enhances cardiac output, but does increase mean arterial pressure and coronary blood flow. A trigger from electrocardiographic

rhythm or arterial pressure ensures balloon inflation and deflation. Based on the BSIC-I randomized trial, Perera et al. [29] concluded that routine elective use of IABP did not reduce the incidence of major adverse cardiac and cardiovascular events following high-risk PCI. There was no difference between the two groups in the 6-month mortality rate (IABP 4.6% vs. no IABP 7.4%; $p = 0.32$). These results do not support a strategy of routine IABP placement before PCI in all patients with severe left ventricular dysfunction and extensive coronary disease.

The Impella moves blood from the left ventricle to the aorta, thereby unloading the left chambers of the heart and increasing the cardiac output. A sufficient right ventricular performance or additional right ventricular assist devices are necessary to maintain left ventricular preload and hemodynamic support during Impella pumping [1]. Only 14-F (CP device) or 21-F cannula (5.0 and LD devices) can provide an output of 5 L/min. The biggest experience to date has been gained with the Impella 2.5 device which can provide the flow rate only up to 2.5 L/min. CE mark approves the use of Impella up to 6 days. The PROTECT II study represents the largest prospective, randomized trial comparing hemodynamic support with Impella 2.5 ($n = 226$) versus IABP ($n = 226$), initiated prior to planned high-risk PCI in symptomatic patients with complex three-vessel disease or unprotected LMCA coronary artery disease, and severe ventricular dysfunction [30]. Although Impella provided better hemodynamic support with a maximum decrease in the cardiac power output from the baseline (0.04±0.24 W for Impella 2.5 in comparison with 0.14±0.27 W for IABP ($p = 0.001$)) and was required for a shorter duration, no significant difference in 30-day major adverse event rate was observed between the two groups (35.1% for Impella vs. 40.1% for IABP; $p = 0.227$). However, at 90 days, a strong trend toward lower major adverse event rate was observed in Impella 2.5L supported patients in comparison with IABP (40.6% vs. 49.3%; $p = 0.066$). Cohen et al. have published the article [31], analyzing the use of percutaneous left ventricular assist device to support high-risk PCI. The authors performed retrospective observational analysis of 339 patients included in the USpella registry, who were supported for high-risk PCI with a micro-axial rotational pump (Impella 2.5). There were patients who have met the eligibility criteria for the Impella arm of the PROTECT II trial [2]. In-hospital outcomes of the USpella registry patients were compared with the results of 216 patients treated in the Impella arm of the PROTECT II randomized trial. The authors concluded that despite a higher risk in the registry patients, clinical outcomes appeared to be favorable and consistent compared with the randomized trial.

The TandemHeart pumps blood from the left atrium to the iliofemoral arterial system through a transseptally placed cannula, thereby bypassing the left ventricle. The device reduces left ventricular preload, left ventricular workload, filling pressures and myocardial oxygen demand [1]. The TandemHeart provides an option of including an oxygenating membrane within its circuit. CE mark approves the use of the TandemHeart up to 30 days. No contemporary comparable large-scale randomized clinical trials of high-risk PCI with the TandemHeart device are available. Several observational studies have reported centers' experience of elective implantation of the TandemHeart device prior to high-risk PCI [32–34]. Although these latter small studies confirmed that the TandemHeart is technically feasible and may provide excellent hemodynamic support, the device use continues to be associated with significant

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complications such as stroke, limb ischemia and bleeding around the cannulation site. More recently, in 54 patients with extensive CAD (mean SYNTAX Score 33), undergoing high-risk PCI with the TandemHeart device for support, Alli et al. [35] reported 97% of success and 13% of major vascular complications, with survival rates at 30 days and at 6 months, as high as 90% and 87%, respectively. Finally, a small study compared the Impella 2.5 versus the TandemHeart to support high-risk PCI [36]. The 30-day major adverse cardiac event rate (death, myocardial infarction and target lesion revascularization) was 5.8% and was similar between the two groups with 99% of the PCI success rate in the both groups.

ECMO uses a centrifugal pump to drive blood from a patient through an oxygenator system before returning to the patient's arterial system. Cannulation sites include the femoral artery and the femoral vein (venoarterial ECMO) or the internal jugular vein/right atrium and the common femoral vein (venovenous ECMO). In addition to blood oxygenation, venoarterial ECMO can provide systemic circulatory support, augment cardiac output and unload both the right and left ventricles. The advantages of ECMO include the possibility of cannulation at the bedside. Currently, we have very few data on the use of ECMO to support high-risk PCI without cardiogenic shock as adjunct modality. The data are limited to single report. Galassi et al. [37] reported the successful use of ECMO for a high-risk NSTE-ACS patient with low ejection fraction (<20%) who underwent three-vessel total occlusive antegrade revascularization by PCI. Tomasello et al. [38] demonstrated a single-center experience of ECMO support for complex high-risk elective PCIs. Twelve patients underwent elective high-risk PCI with ECMO support. All PCI procedures were successful and no in-hospital major adverse cardiac or cardiovascular events were observed. At 6 months, neither death nor MI was observed. Two patients (17%) required further revascularization, and one patient required chronic hemodialysis. The authors concluded that elective high-risk PCI supported by ECMO is a viable therapeutic alternative for patients with severe coronary artery disease and left ventricular dysfunction, who are at a very high risk for CABG and able to ensure good immediate and mid-term outcome.

Our single-center registry data showed extremely poor prognosis if the revascularization for high-risk multivessel NSTE-ACS was refused [10]. As shown in the previous part of this chapter, hospital mortality rate is 28% if we choose a pharmacological strategy versus 5.5% for PCI and 8% for CABG. The pharmacological strategy group patients were refused any kind of revascularization and, of course, there were predictors of high-risk PCI (the mean SYNTAX Score 32, the mean GRACE Score 180 and unprotected left main stenosis in 33% of patients, all patients had signs of high-risk NSTE-ACS). At that moment we asked ourselves: What can we do with such multivessel high-risk NSTE-ACS patients? Could we help such patients with PCI supported by ECMO?

Why did we choose ECMO support for high-risk PCI in patients without cardiogenic shock? As compared with other devices, IABP provides a relatively modest augmentation of cardiac output (0.3–0.5 L/min). Conversely, the TandemHeart and ECMO may provide up to 3.5 and 5 L/min of cardiac support, respectively, whereas the Impella catheter can increase the cardiac output up to 2.5, 3.8 or 5 L/min, according to the selected size. Notably ECMO, TandemHeart and Impella 5L devices, often required a surgical cut-down, whereas IABP, Impella 2.5L and

3.8L could be exclusively managed percutaneously. In comparison with other ventricular assist devices, ECMO has the advantage to provide a more comprehensive circulatory support as it is responsible for both cardiac pump function and pulmonary gas exchange. For example, with ECMO, even if we deal with a cardiac arrest, a patient is still alive, and we can continue the high-risk PCI procedure. Importantly, the TandemHeart provides an option of including an oxygenating membrane within its circuit, thus, creating an ECMO-type circuit. However, despite their encouraging results, the expensive cost of both TandemHeart and Impella devices represents a major problem to extend their use.

It is believed that ECMO is limited by its complexity and the need for perfusion expertise and is rarely used in the cath-labs. These restrictions are not significant for Russian cath-lab teams as there is a widespread use of Prostar XL devices and 24/7 on-duty anesthesiologist (a member of the cath-lab team) who can provide ECMO perfusion. On the other hand, usually, these NSTE-ACS patients without cardiogenic shock do not need immediate revascularization, which means that a calm perfusion preparation and performing PCI on an elective basis is possible. Additionally, one of the main limitations of ECMO is that the left ventricle is not decompressed and this leads to a higher left ventricular wall stress. Theoretically, this has negative consequences on myocardial protection that can be decreased by a combination of ECMO and Impella (IABP) support [1, 39].

Thus, based on our single-center real-life registry data, there are up to 12% of the hemodynamically stable multivessel disease NSTE-ACS patients who were refused any kind of revascularization and had extremely poor prognosis with pharmacological approach [10]. PCIs for this setting have an extremely high risk of hemodynamic collapse so they need to be performed with hemodynamic support. A number of devices have been used for this purpose but we consider ECMO to be the best device. ECMO is able to provide the cheapest complete circulatory support (both oxygenation and circulatory support). However, randomized trials are necessary to establish effectiveness of percutaneous mechanical circulatory support devices in adjunction with high-risk PCI. Since 2012, we have begun to perform PCI with ECMO support for extremely high-risk multivessel NSTE-ACS patients who have been refused any form of revascularization. To evaluate the results, we decided to compare them with the outcomes of CABG for multivessel NSTE-ACS patients. The next part of this chapter will show the analysis of our single-center retrospective observation.

4. Extracorporeal membrane oxygenation support for complex high-risk percutaneous coronary interventions in patients without cardiogenic shock: a single-center experience

PCI with ECMO support and high-risk CABG for NSTE-ACS patients with multivessel disease will be presented in this section. It was a single-center registry, which compared 30-day outcomes of PCI with ECMO support and CABG in high-risk NSTE-ACS patients.

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Variables	PCI + ECMO (*n* = 22)	CABG (*n* = 53)	*p*
Demographic			
Age	64.2 ± 9.7	63.5 ± 7.5	0.4
Male	68.2% (15)	66% (35)	0.4
Body mass index	31.9 ± 6	27.1 ± 4.7	0.0002
Clinical			
Diabetes	31.8% (7)	15% (8)	0.05
Arterial hypertension	100% (22)	90.5% (48)	0.07
Hypercholesterolemia	81.8% (18)	39.6% (21)	0.0007
Prior MI	40.9% (9)	50.9% (27)	0.2
Prior stroke	9.1% (2)	7.5% (4)	0.4
Prior CABG	0	1.9% (1)	0.3
Chronic obstructive pulmonary disease	9.1% (2)	1.9% (1)	0.08
Peripheral artery disease	63.6% (14)	30.2% (16)	0.004
Glomerular filtration rate	91.5 ± 31.7	75.2 ± 28.4	0.05
Left ventricular ejection fraction, %	38.8 ± 12.7	53.6 ± 10	0.0001
GRACE	148 ± 22.9	95.6 ± 16.4	0.0001
EuroScore II, %	4.7 ± 3.7	3.61 ± 1.9	0.05
Angio			
Multivessel disease	100% (22)	100% (53)	0.5
Unprotected LMCA	81.8% (18)	39.6% (21)	0.0007
Mean LMCA stenosis %	78.1 ± 21.5	69.7 ± 18.1	0.1
Right dominance	68.2% (15)	92.4% (49)	0.02
SYNTAX Score	34±9.7	30±8.2	0.04
Jeopardy Score	11.2±1.7	8.4±1.9	0.0001

*Cockroft–Gault formula.

Table 4. Baseline characteristics and angiographic data.

High-risk CABG was based on a high-risk logistic EuroSCORE II (>5) and included one of the following: obesity (body mass index (BMI) > 30); severe concomitant disease (diabetes, cerebrovascular disease, peripheral vascular disease, chronic obstructive pulmonary disease and renal dysfunction); and dual antiplatelet therapy within the past 24 h.

High-risk PCI was defined as (1) the presence of impaired left ventricular function (ejection fraction < 30% on echocardiography); (2) a large amount of myocardium affected by stenosed vessels (Jeopardy Score ≥ 8), characterized by LMCA stenosis or by a target vessel that provided collateral supply to the occluded second vessel that, in turn, supplied > 40% of the myocardium; and, additionally, technical difficulties with the PCI procedure; and (3) intervention for bifurcation and/or left main and/or chronic total occlusion.

The study included 75 patients (PCI + ECMO, n = 22; and CABG, n = 53). All patients had multivessel disease with Syntax Score >25. PCI + ECMO group had more patients with obesity, hypercholesterolemia, diabetes, low ejection fraction, unprotected LMCA and peripheral artery disease, compared with the CABG group. In addition, the PCI group had a higher risk of the deterioration in the following scores: GRACE, EuroScore II, SYNTAX Score and Jeopardy Score. Thus, PCI + ECMO group had a potentially poorer prognosis (**Table 4**).

For PCI + ECMO, 21–23 Fr venous cannula was inserted in the right common femoral vein to the right atrium using a surgical technique. The 17–18 Fr arterial cannula was placed in the iliac artery. The mean cardiopulmonary support flow was 2.2–2.7 L/min/m^2. The mean bypass duration was 95.4 ± 25.2 min. The medications during PCI included unfractionated heparin and acetylsalicylic acid. The loading dose of clopidogrel before PCI received 42% of patients. The remaining 58% of patients had a loading dose of clopidogrel immediately after the surgical cannulation wound closure.

ECMO began immediately prior to PCI. We used the "RotaFlow System," developed by the MAQUET Getinge Groupe, Hirrlingen, Germany. The study endpoints were the success of the intervention, death, myocardial infarction, stroke, repeated revascularization and bleeding, as well as the combined endpoint of death, myocardial infarction, stroke and revascularization.

The mean revascularization waiting time was about 2 weeks in the both groups. In all the cases, the revascularization was successful in the both groups. Most of the CABG patients (94.3%) had a complete revascularization compared with 54.5% in the PCI + ECMO group (p = 0.0001). The mean length and diameter of implanted stents were 49 ± 16.7 mm and 3.5 ± 0.5 mm, respectively.

There were two fatal cases (9.1%) in the PCI + ECMO group and four patients died (7.5%) in the CABG group at 30-day follow-up (p = 0.2). Two patients (3.8%) of the CABG group had myocardial infarction as a complication of the postoperative period. One of these cases led to death. A major bleeding was observed in seven patients (13.2%) in the CABG group versus two patients (9.1%) in the PCI + ECMO group (p = 0.3). There were no significant differences in the incidence of endpoints at 30-day follow-up (**Table 5**).

Variables	**PCI + ECMO (n = 22)**	**CABG (n = 53)**	p
Successful revascularization	100% (22)	100% (53)	0.5
MACE	9.1% (2)	9.4% (5)	0.15
Death	9.1% (2)	7.5% (4)	0.2
Myocardial infarction	0	3.8% (2)	0.2
Repeated revascularization	0	0	0.5
Stroke	0	0	0.5
Major bleeding (TIMI)	9.1% (2)	13.2% (7)	0.3

Table 5. Thirty-day outcomes of revascularization.

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The present study included patients with high risk of adverse outcomes for any kind of revascularization (CABG and PCI). The main hypothesis of the study was that PCI + ECMO may be an alternative strategy of revascularization for NSTE-ACS patients at a high risk for CABG.

All the patients had an extremely severe diffuse coronary artery disease with LMCA stenoses, bifurcation lesions and chronic total occlusions (CTO) and underwent challenging PCI with ECMO support, which allowed to carry out a successful revascularization in stable hemodynamic conditions.

Despite the fact that CABG is a preferred method of revascularization for complex multivessel coronary disease patients, PCI with ECMO as a hemodynamic support can be successfully performed in a high-risk cohort of NSTE-ACS patients. Therefore, PCI with ECMO support may increase revascularization availability for this severe group of patients with a very high risk of in-hospital fatal outcomes, reaching 27% in the absence of the procedure.

The present study had several limitations. First of all, it was not randomized and the groups were not comparable. Nevertheless, the PCI +ECMO patients group had a more severe clinical and angiographic status, which made it possible to test PCI with ECMO as a method of revascularization in extremely high-risk cohort of NSTE-ACS patients. Second of all, a small number of patients included in the study did not allow to make definitive conclusions. Thus, in order to answer the question on the role of ECMO for high-risk PCI NSTE-ACS patients, randomized trials are required.

5. Clinical case examples of high-risk PCI supported by ECMO in NSTE-ACS patients

5.1. Clinical case example 1

The first case is presenting a successful antegrade recanalization of a 67-year-old male who survived cardiopulmonary resuscitation after non-ST-segment-elevation myocardial infarction. The patient experienced a cardiac arrest due to ventricular fibrillation after admission to hospital and he was stabilized after 25 min of cardiopulmonary resuscitation. After the resuscitation no neurological symptoms were detected. Coronary angiography revealed CTO in three vessels with severe coronary calcifications (**Figure 1A–C**); the patient was not considered to be a surgical candidate due to his poor clinical condition (very low EF <20% and ACS at presentation) and to his angiographic characteristics (very small coronary arteries without visualization of distal coronary segments). ECMO (ECMO for the circulatory failing heart system in real clinical patient setting after epidural anesthesia and surgical cannulation of the femoral vein and artery; the pump maintained a minimum flow of 2.0 L/min/m^2) and PCI, with the use of new composite dual coil guidewire Fielder XTR (Asahi Intecc Co., Japan) 48h after acute MI, were used to fully recanalize the left anterior descending artery (LAD), circumflex artery (CX) and right coronary artery (RCA). Excellent angiographic results were

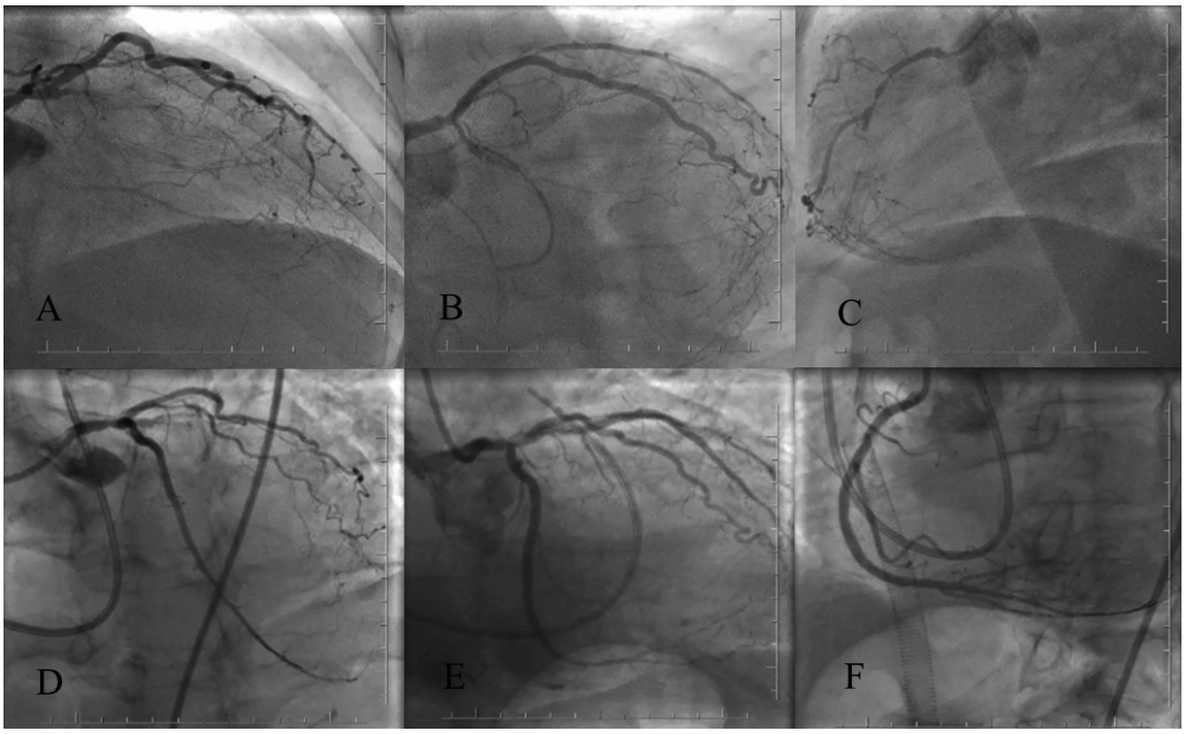

Figure 1. A successful antegrade recanalization of three CTOs in the NSTE-ACS patient supported by ECMO.

obtained by the use of three, two and four drug eluting stents (DES) in the LAD, CX, and RCA, respectively (**Figure 1D–F**), and ECMO was terminated at the end of the procedure.

In the search of technical solutions to improve the results of PCI in CTO, intracoronary guide wires represent, probably, the most advanced class of devices. The recent setup of the so-called "composite core, dual coil" guidewires can be considered an absolute turning point, especially when the complexity of CTO, patient clinical conditions and the use of an antegrade technique might limit procedural success.

To the best of our knowledge, this is the first case presentation of a three-CTO PCI executed in a single procedure and supported by ECMO in a patient in critical clinical condition. Percutaneous coronary intervention was considered the last remaining option to improve the outcome, and ECMO was used to guarantee circulatory assistance during the procedure. Indeed, CTO lesions and a critical hemodynamic patient condition due to ACS are considered the worst revascularization scenario taking into account that these patients are not suitable for cardiac surgery. Nevertheless, based on the excellent results of CTO revascularization already demonstrated in less complex clinical conditions, we believe that, by minimizing the risk of intra-procedural adverse events with the use of ECMO, revascularization of CTOs is possible even in the case of severe clinical conditions, by offering a patient an opportunity of revascularization therapy, the survival could be improved. Notably, the patient did not have any periprocedural adverse events, the EF improved up to 32% at 1-week follow-up, and he was discharged 9 days after the procedure.

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5.2. Clinical case example 2

The second case is presenting a successful high-risk multivessel PCI of a 58-year-old NSTE-ACS patient with a hemodynamic support by ECMO. The patient was presented with high-risk ACS (GRACE = 173). Coronary angiography revealed a three-vessel disease with significant severe thrombotic LMCA stenosis (85%) and RCA stenosis (75% of prox. part and 90% of mid. part) (SYNTAX Score = 23) (**Figure 2A** and **B**). The patient was obese with a body mass index of 35 kg/m^2. According to the echocardiography assessment, left ventricular ejection fraction was 50%. Before the admission to hospital, the patient received a loading dose of clopidogrel (300 mg) and acetylsalicylic acid (250 mg). At the time of angiography, the patient had severe chest pain associated with hemodynamic instability (hypotension, bradycardia), requiring analgesia and cardiotonic infusion. There was a very high risk for emergency CABG (hemodynamic instability, dual antiplatelet therapy, obesity), and the multidisciplinary team decided to carry out multivessel PCI supported by ECMO. Using artificial lung ventilation and multicomponent anesthesia, the puncture of the common femoral artery and the common femoral vein with closure device placement of ("Pro-Star" system) was performed (**Figure 3**). A venous cannula was positioned in the right atrium and an arterial cannula in the infrarenal part of the aorta. The pump maintaining a flow of 2.4–2.7 L/min was used. The middle and proximal RCA stenting was performed in ECMO conditions. Two DES were implanted with a diameter of 4 mm and a length of 22 mm (**Figure 2C** and **D**). As the next step kissing-predilation of LMCA-LAD and LMCA-IMA was performed. DES with a diameter of 4 mm and a length of 23 mm was implanted to LMCA-LAD. At the end of PCI T-provisional technique with kissing-dilatation of LMCA-LAD (balloon catheter 4.5–20 mm) and LMCA-IMA (balloon catheter 3.5–20 mm) was used (**Figure 2E** and **F**). ECMO was terminated at the end of the procedure. The arterial and vein cannulas were removed. The vascular access was successfully closed with the "Pro-Star" system. The patient was transferred to the intensive care unit. The patient was extubated when awake. The hemodynamics remained stable and

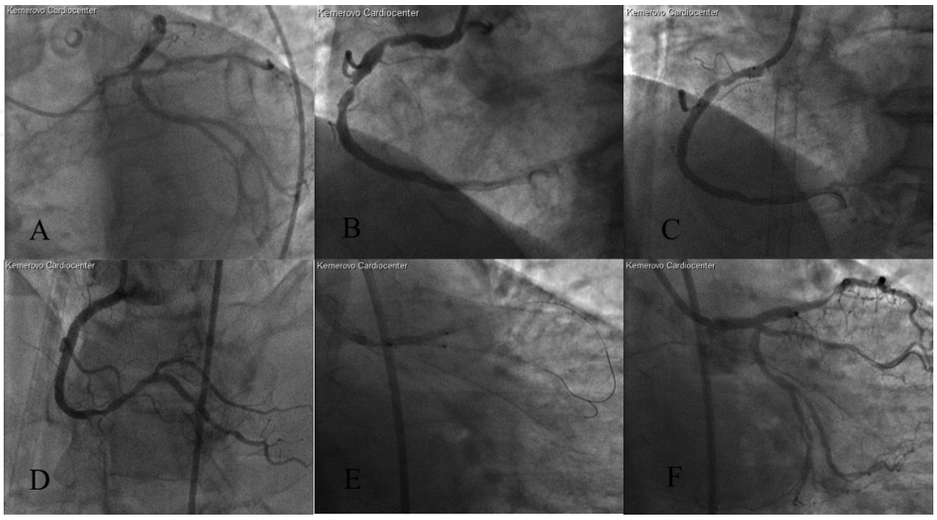

Figure 2. High-risk multivessel PCI with hemodynamic support by ECMO in the NSTE-ACS patient.

ischemia did not recurred. After 10 days, the patient was discharged from the clinic. Therefore, the use of ECMO allowed to perform a high-risk multivessel PCI in the NSTE-ACS patient in stable hemodynamic conditions.

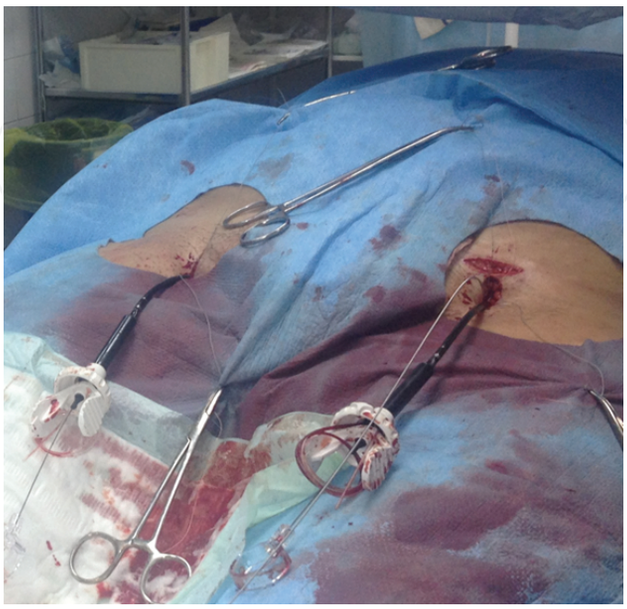

Figure 3. Using the "Pro-Star" system for arterial and venous vascular access closure.

Thus, these clinical cases showed efficacy and safety of high-risk PCI with ECMO support in the treatment of NSTE-ACS patients, unsuitable for CABG and having extremely poor prognosis in the absence of revascularization. It is possible to use ECMO cannulas with a surgical or a puncture method and the Pro-Star system as a vascular access closure device. A local anesthesia in combination with an epidural block or total intravenous anesthesia can be used.

6. Conclusions

The current status of ischemic heart disease patients is characterized by an increase in the prevalence of advanced coronary disease, poor distal targets, severe comorbidities, reoperation, advanced age or impaired left ventricular function, which make surgical revascularization unattractive. PCI may be an alternative for these so-called high-risk PCI patients. Given aging population, increasing morbidity, technical advantages of percutaneous revascularization and improved quality of medical care, the number of such patients will grow.

Multivessel NSTE-ACS patients are one of the high-risk PCI groups based on such predictors as advanced complex coronary disease, a large amount of myocardium at risk, low global left ventricular function, comorbidities and high GRACE Score. The prevalence of multivessel NSTE-ACS (up to 50% of all NSTE-ACS patients [13]) and extremely poor prognosis with a pharmacological approach (hospital mortality rate of 28% [12]) make the issue of these patients

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treatment very important. PCI supported by ECMO is an unexplored strategy for this patient setting. Current recommendations suggest performing PCI with ECMO support for cardiogenic shock or cardiac arrest patients [1, 2]. There are limited data on the use of ECMO for high-risk PCI as well as for complex PCI in NSTE-ACS patients without cardiogenic shock [37, 38]. However, elective application of the device has a theoretical rationale, showed encouraging results based on the results of our single-center retrospective observation and was demonstrated by the presented clinical case examples.

There are two main unresolved issues related to the use of percutaneous mechanical circulatory support devices for high-risk elective PCI that will represent a challenge for the future progress. When should we use them? Which device is the best? The expert consensus statement suggested a schema for the support device use in high-risk PCI, which provides a clear solution only in the case of a combination of two risk factors: severe left ventricular dysfunction and an anticipated technically challenging PCI [1]. One of these makes it necessary to use the approach with IABP/Impella as a backup, which creates issues in case there is a need for emergency complete circulatory support. Clearly, the main disadvantage of this scheme is that it does not take into account an important adverse prognostic factor such as acute coronary syndrome. Thus, there is a necessity to further investigate the risk calculators to assess the online need for mechanical circulatory support devices during high-risk PCI. Finally, device selection is a matter of a personalized approach and the results of subsequent large randomized comparative studies.

Thus, in the current chapter, we attempted to provide the rationale for the hypothesis that a very high-risk complex PCI facilitated by ECMO can provide successful myocardial revascularization in patients ineligible for CABG. PCI with ECMO support is a feasible approach for high-risk interventions in hemodynamically stable NSTE-ACS patients with multivessel disease who were refused any kind of revascularization. Further research is needed to define precise indications for the use of ECMO and its priority role in high-risk PCI patients.

Author details

Vladimir I. Ganyukov[1*], Roman S. Tarasov[2] and Dmitry L. Shukevich[3]

*Address all correspondence to: ganyukov@mail.ru

1 Laboratory of Interventional Cardiology, State Research Institute for Complex Issue of Cardiovascular Diseases, Kemerovo, Russia

2 Laboratory of Reconstructive Surgery, State Research Institute for Complex Issue of Cardiovascular Diseases, Kemerovo, Russia

3 Laboratory of Critical Conditions, State Research Institute for Complex Issue of Cardiovascular Diseases, Kemerovo, Russia

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Appendices

Appendix A.

The GRACE (2.0) Acute Coronary Syndrome Risk Calculator

The GRACE (Global Registry of Acute Coronary Events) 2.0 Acute Coronary Syndrome (ACS) Risk Calculator is a tool to help clinicians assess the future risk of death or myocardial infarction (MI), as a guide to treatment options, in a patient with ACS. It includes clinical findings at admission that have been shown to have predictive power for adverse events. These factors include age, pulse rate, systolic blood pressure, renal function, congestive heart failure, ST-segment deviation, cardiac arrest and elevated biomarkers, which together provide more than 90% of the accuracy of the complete multivariable prediction model. Outputs are given in terms of probability of dying (as a percentage) while in hospital, and at 6 months and 1 and 3 years after admission. The combined risk of death or MI at 1 year is also given. The GRACE Score at 6 months is also provided as guidelines have categorized patients into low (≤108 GRACE Score), medium (109–140 GRACE Score) and high risk (>140 GRACE Score) [7].

The updated calculator is derived from the original GRACE Score. The work on the updated calculator was supported by the British Heart Foundation, the Chief Scientist in Scotland and an educational grant from AstraZeneca to the University of Edinburgh. Professors Frederick

A. Anderson, Jr. and Gordon FitzGerald of the Center for Outcomes Research, University of Massachusetts Medical School, analyzed the GRACE population risk factors and created the algorithms. The algorithms were implemented, and the app and website were created by AS&K Communications.

GRACE is an international observational program of outcomes for patients who were hospitalized with ACS in a period of 10 years from 1999. GRACE includes nearly 250 hospitals in 30 countries, and enrolled a total of 102,341 patients. Participating physicians receive confidential quarterly reports showing their outcomes side by side with the aggregate outcomes of all participating hospitals. The GRACE Risk Score has been extensively validated prospectively and externally.

The GRACE 2.0 ACS Risk Calculator is available online on the Internet (http://www.gracescore.org). To calculate the GRACE risk for any patient with documented or suspected ACS, enter the patient data by selecting from the ranges given or by using the yes/no toggle switches. Press "Calculate" to obtain risk of event probabilities or "Reset" to clear all entered data. On the results screen, use "Edit input" to change individual parameters for the same patient or "New calculation" to reset the calculator and start over. The results are given first as a probability (expressed as a percentage) of either death alone, or death/MI, occurring up to given time points after admission. The original GRACE Score is also provided for 6-month results (**Figure A1**).

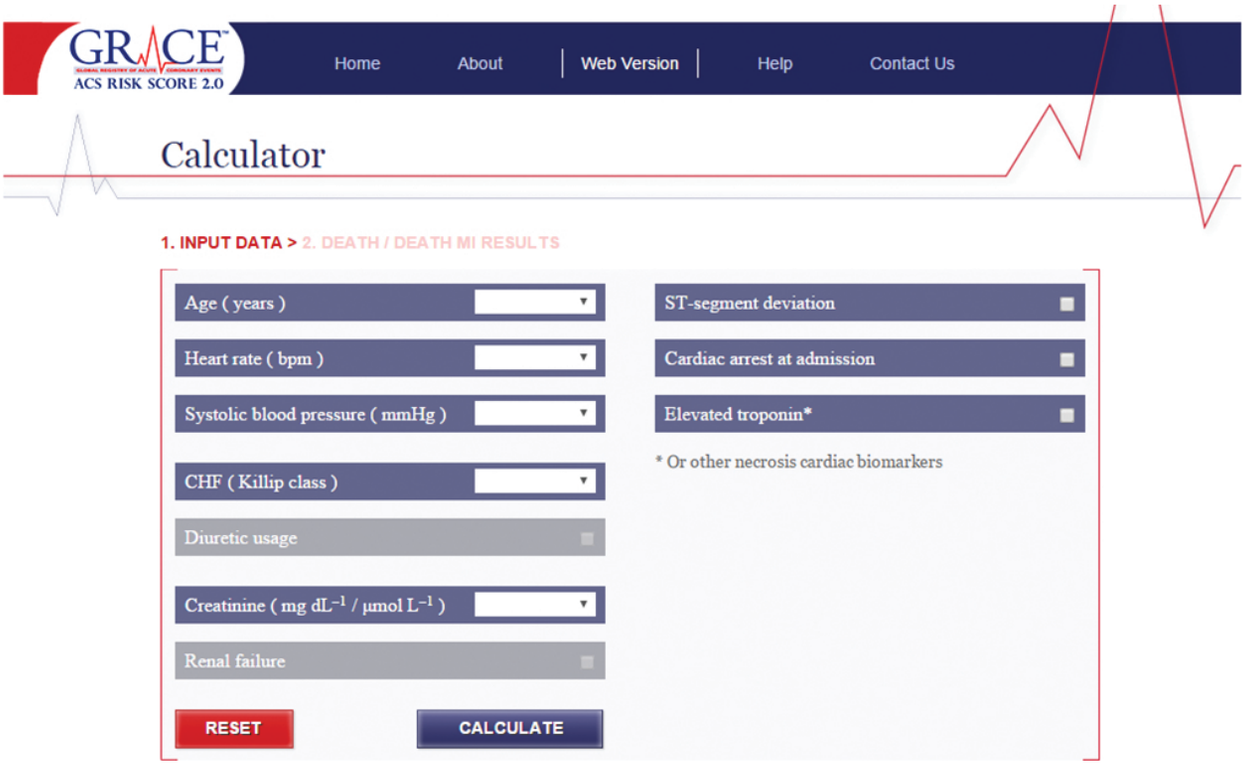

Figure A1. The Global Registry of Acute Coronary Events 2.0 Acute Coronary Syndrome Risk Calculator (http://www.gracescore.org).

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Appendix B.

The SYNTAX Score calculator

The SYNTAX Score is an angiographic tool used to characterize the coronary vasculature and predict outcomes of coronary intervention based on anatomical complexity. The SYNTAX Score was developed in connection with the SYNTAX (The SYNergy between percutaneous coronary intervention with TAXus and cardiac surgery) trial, which compared percutaneous coronary intervention (PCI) using Taxus Express paclitaxel-eluting stents (Boston Scientific Corporation, Natick, MA) to cardiac surgery in complex, high-risk patients with left main and/or three-vessel disease. A heart team (cardiac surgeon and interventional cardiologist) assessed each patient for suitability for both revascularization modalities, and consequently calculated the patient's SYNTAX Score based on coronary lesion complexity prior to the revascularization procedure. The Syntax Score and related materials were developed under the direction of the SYNTAX Steering Committee, and it was made possible by the support from Boston Scientific Corporation and Cardialysis BV.

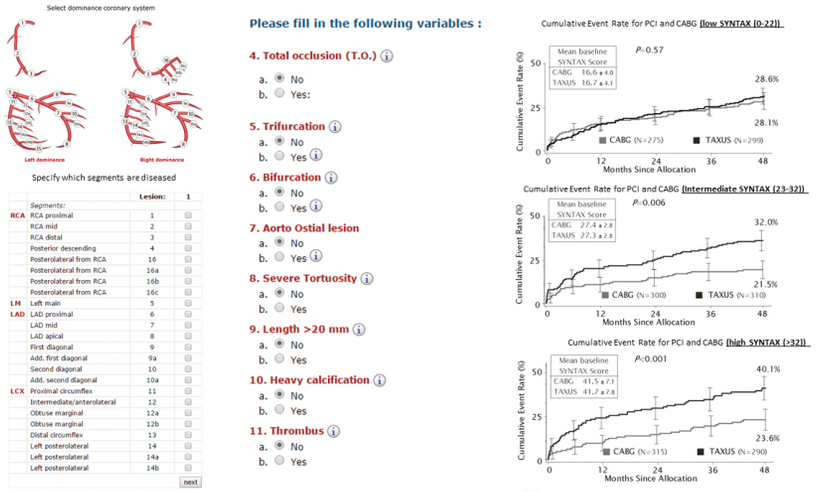

Figure B1. The SYNTAX Score Calculator (http://www.syntaxscore.com).

A computer program calculates the SYNTAX Score after answering a set of interactive, self-guided questions. The online SYNTAX Score calculator consists of 11 questions. Two questions determine the coronary artery dominance and diffuse disease/small vessels and will be asked only once per patient. The remaining questions refer to detailed adverse lesion characteristics and will be repeated for each lesion separately. The SYNTAX Score calculates a point value for each lesion, which will be summed to generate the patient's overall SYNTAX score. For patients with three-vessel disease and/or left main disease (SYNTAX trial population), the cumulative MACCE outcomes by SYNTAX score will be illustrated on a Kaplan–Meier curve. The patient's name, ID number and date of birth can be added, and the SYNTAX score document can be saved or printed for the patient's file. The SYNTAX Score Calculator is available online on the Internet (http://www.syntaxscore.com) (**Figure B1**).

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