



Outcome of extracorporeal membrane oxygenation support for complex high-risk elective percutaneous coronary interventions: A single-center experience



Salvatore Davide Tomasello, MD^a, Marouane Boukhris, MD^{a,b}, Vladimir Ganyukov, MD^{c,*}, Alfredo R. Galassi, MD, FACC, FESC, FSCAI^a, Dmitri Shukevich, MD^a, Boris Haes, MD^c, Nikita Kochergin, MD^c, Roman Tarasov, MD^c, Vadim Popov, MD^c, Leonid Barbarash, MD^c

^aDepartment of Medical Sciences and Pediatrics, Catheterization Laboratory and Cardiovascular Interventional Unit, Cannizzaro Hospital, University of Catania, Via Messina 829, 95126 Catania, Italy

^bFaculty of Medicine of Tunis, University Tunis El Manar, Tunisia

^cDepartment of Interventional Cardiology, State Research Institute for Complex Issues of Cardiovascular Diseases, Siberian Branch of the Russian Academy of Medical Sciences, 6 Sosnovy Boulevard, Kemerovo 650002, Russia

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ABSTRACT

Objective: We report our initial experience with extracorporeal membrane oxygenation (ECMO) use in elective high-risk complex percutaneous coronary intervention (PCI).

Background: ECMO has been employed as hemodynamic support in patients with cardiac arrest and hemodynamic shock.

Methods: We performed a single-center prospectual study, enrolling all patients at very high-risk for coronary artery bypass grafting (CABG). Major adverse cardiac and cerebrovascular events (MACCE) were defined as a composite of death, acute myocardial infarction (MI), stroke and further need for revascularization.

Results: Twelve patients underwent elective high-risk PCI with ECMO support (mean age = 63.5 ± 8.7 years). The mean SYNTAX score was 30.1 ± 10.1 . All PCI procedures were successful and no in-hospital MACCE was observed. At 6-months, neither death nor MI was noticed. Two patients (17%) required further revascularization, and one patient required chronic hemodialysis.

Conclusions: Elective high-risk PCI supported by ECMO is a viable alternative for patients who are at very high risk for CABG.

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Introduction

In the last decade, there has been a widespread of percutaneous coronary intervention (PCI) not only in acute coronary syndromes, but also in stable coronary artery disease (CAD). Indeed, it has been shown that in patients with single or multivessel non complex CAD, PCI outcome was similar to that of coronary artery bypass grafting (CABG). Differently, in patients affected by complex and diffuse CAD, CABG was associated with greater clinical benefit, as recommended by the European guidelines.^{1–3}

However, surgical revascularization is not always feasible due to critical patients' health status (which is associated with high risk of mortality), or extensive CAD with very small diseased arteries. Variables related to mortality after CABG included: recent myocardial infarction (MI), ventricular arrhythmia, congestive heart failure, associated valve disease, diabetes, cerebrovascular disease, peripheral vascular disease, chronic obstructive pulmonary disease, and chronic renal failure.¹ Because of high operative risk, CABG intervention could be rejected either by the heart team, or by the patient. Therefore, high risk PCI remains a viable revascularization strategy for patients non suitable for surgery or those refusing it.⁴ However, such a subset of patients is considered to be at very high risk for PCI complications, due to the danger of hemodynamic collapse during balloon inflations or complex procedures, particularly if coronary dissection with vessel closure or no reflow should occur.^{5–8}

Conflicts of interest: None.

* Corresponding author. Tel.: +79131273905 (mobile); fax: +73842642718.

E-mail address: ganyukov@mail.ru (V. Ganyukov).

Nowadays, the development of cardiac support devices has allowed a safer approach for high-risk patients. Through literature, extracorporeal membrane oxygenation (ECMO) has been employed as a hemodynamic support for PCI in patients with cardiac arrest and hemodynamic shock. We report our initial experience and the outcomes of elective high-risk complex PCI using ECMO.

Methods

Study population

We performed a single-center prospectical study, enrolling all patients at very high-risk for CABG, who refused surgical revascularization indicated by the heart team, and accepted to undergo elective high-risk PCI of native coronary arteries with ECMO hemodynamic support.

High-risk CABG was defined as a logistic EuroSCORE > 5,⁹ with at least one of the following characteristics: obesity [body mass index (BMI) > 30], diabetes, cerebrovascular disease, peripheral vascular disease, chronic obstructive pulmonary disease, and renal dysfunction.

High-risk PCI was defined as follows: (1) the presence of an impaired left ventricular function (ejection fraction < 40% on echocardiography); (2) a large amount of myocardium subtended by the stenosed vessels (Jeopardy Score ≥ 8)¹⁰; and additionally (3) technical difficulties during PCI procedure, defined as the presence of bifurcation lesions, left main (LM) stenosis and/or chronic total occlusions.

The study was carried out according to Helsinki declaration and all patients signed a consent form.

Definitions and study endpoints

PCI success was defined as a final residual stenosis less than 30%, with a final Thrombolysis In Myocardial Infarction (TIMI) flow grade 3 without in-hospital major adverse cardiac and cerebrovascular events (MACCE). MACCE were defined as a composite of death, acute myocardial infarction (MI), stroke and further need for revascularization by PCI or CABG. Peri-procedural MI was defined as an increase in troponin levels by > 3-fold of the upper limit of the reference range within 72 h after PCI. Beyond 72 h after PCI, universal definitions of MI were applied, based on elevation of cardiac troponin levels in association with typical symptoms or electrocardiographic changes.¹¹ Definite or probable stent thrombosis were classified according the Academic Research Consortium definition.¹² Bleeding was evaluated according to Bleeding Academic Research Consortium (BARC) Definition for Bleeding.¹³ The overall cost of hospitalization was reported in US dollars (USD). Patients were followed-up by clinical visits at 1, 3 and at 6 months.

Ventricular assistance procedure

Patients enrolled into the study, received ECMO insertion before the index PCI. The ECMO system comprised a centrifugal pump, membrane oxygenator heat exchanger, and bypass cannulas. The percutaneous cannulation for femoro-femoral v-a ECMO was carried out using Seldinger's technique. Depending on the patient's biometric data, either 21 or 23 Fr cannulas for venous outflow, and 15 or 17 Fr cannulas (with a length of 15 cm) for the arterial backflow were used (both from MAQUET AG, Hechingen, Germany). In patients who had been completely heparinized or received dual platelet inhibition, initial heparin-free ECMO was performed. The tip of the arterial cannula (patient inflow) was positioned in the common iliac artery or in the distal abdominal aorta; whereas, the tip of the venous cannula (patient outflow) was placed in the inferior vena

cava, close to the right atrium, to optimally decrease the preload on the right heart. Pump flow rates were initiated up to 4.0 l/min and the gas supplied to the oxygenator was adjusted to achieve an arterial oxygen partial pressure of 150 mm Hg and normocapnia upon lung-protective ventilation. On ECMO, the flow and gas supply rates were adjusted using blood gas examinations to meet the patient's demand. Patient monitoring included invasive blood pressure measurement, electrocardiography, capnography and pulse oximetry. One arterial line was placed in the right radial artery to gain blood gas measurements to detect if there was insufficient oxygenation to the supra aortic vessels. The patients were placed on cardiopulmonary support with an average flow of 2.8 l/min/m² using CARDIOHELP System (MAQUET AG, Hechingen, Germany).

PCI procedure

At the beginning of the procedure patients received intravenous unfractionated (UNF) heparin (80–100 IU/kg) to maintain activated clotting time (ACT) higher than 300 s and ACT time was monitored every 30 min throughout the procedure, to determine if an additional bolus of UNF heparin was necessary. All patients were on aspirin, and a 600-mg loading dose of clopidogrel before the procedure was administered in those not pre-treated. The PCI strategy and the use of Gp IIb/IIIa inhibitors were left to operators' discretion. Only second-generation drug-eluting stents (DES) were implanted.

Statistical analysis

Continuous variables were presented as mean \pm standard deviation. Categorical variables were presented as counts and percentages. All data were processed using the statistical package for social science, version 19 (SPSS, Chicago, Illinois).

Results

Baseline clinical and angiographic characteristics

From March 2013 to April 2014, 12 patients underwent elective high-risk PCI with ECMO support; patients were enrolled at a mean rate of 1 per month.

The mean age was 63.5 \pm 8.7 years (range, 51–77 years), and 8 patients (66.7%) were males. Nine patients (75%) were obese (BMI > 30), with a mean BMI of 32.9 \pm 5.9. Notably, no patient had undergone a prior myocardial revascularization. The mean left ventricular ejection fraction was 34 \pm 12.6%. The mean logistic Euroscore was 7.3 \pm 1.4.

All patients showed a three-vessel disease with a mean SYNTAX score of 30.1 \pm 10.1. LM stenosis was present in 10 patients (83.3%) involving the distal bifurcation in all cases; and a chronic total occlusion was found in 4 patients (33.3%). A maximal Jeopardy score of 12 was observed in 8 patients (66.7%). Baseline clinical and angiographic characteristics are summarized in [Tables 1 and 2](#), respectively.

Procedural characteristics and outcomes

The mean PCI and artificial circulation durations were 70.4 \pm 30.2 min and 95.4 \pm 25.2 min, respectively. All PCI procedures were successful and no in-hospital MACCE was observed. The mean number of DES implanted per patient was 3.7 \pm 1.5 stents, for a mean length of 49 \pm 16.7 mm; the mean load of contrast was 383.3 \pm 113.5 ml. All distal left main lesions were treated and a complete revascularization was achieved in 5 cases (41.6%), with a residual SYNTAX Score of 7.3 \pm 6.9.

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