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Outcomes of high-risk PCI assisted by VA-ECMO with local anaesthesia

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High-risk percutaneous coronary intervention (PCI) is increasingly performed because of an ageing population with a high incidence of comorbidities and high surgical risk scores[1]. Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) is an effective method to prevent haemodynamic deterioration during high-risk PCI. VA-ECMO is mainly surgically deployed under general anaesthesia. New developments have facilitated a completely percutaneous insertion of VA-ECMO with local anaesthesia, reducing operating team sizes and enabling early mobilisation after PCI without the need for intensive care unit (ICU) admission.

This study is a single-centre registry that included all patients undergoing high-risk PCI with VA-ECMO support between January 2020 and March 2024 at the Radboud University Medical Center in Nijmegen, the Netherlands. The study design has been previously described in detail[2]. Preprocedural angiographic computed tomography (CT) scans were performed in all cases to assess peripheral access. The procedural set-up for VA-ECMO (de)cannulation was similar for all cases **(Supplementary Figure 1, Moving image 1)**.

Procedural success was defined as successful revascularisation (final residual stenosis <50% with a Thrombolysis in Myocardial Infarction flow grade 3, achieved in at least one target vessel) without the occurrence of periprocedural myocardial infarction (MI) or death. Major adverse cardiac events (MACE) were defined as a composite endpoint of all-cause death, MI, target vessel revascularisation or clinical coronary bleeding requiring covered stent deployment or surgical treatment. The study endpoints were in-hospital MACE and MACE at 90 days, assessed after discharge. VA-ECMO-related access or access site complications were assessed using the Valve Academic Research Consortium (VARC)-2 consensus document, classifying major and minor complications.

Elective percutaneous VA-ECMO-assisted high-risk PCI, indicated according to expert consensus on the use of mechanical circulatory support (MCS) devices for high-risk PCI[3], was performed in 35 patients. The mean age of the population was 71.4±8.7 years, and 28 (80.0%) patients were male. Previous PCI and coronary artery bypass graft (CABG) had been performed in 8 (22.9%) and 3 (8.6%) patients, respectively. Peripheral artery vessel disease was present in 34.3% of the population. Three-vessel coronary artery disease and left main stenosis were present in 23 (65.7%) and 22 (62.9%) patients, respectively. The mean left ventricular ejection fraction was 28.5±10.9%, and complexity indices were high, including the Society of Thoracic Surgeons mortality score: 3.6 (interquartile range [IQR] 1.8-5.8), SYNTAX score I: 31.8±9.3, SYNTAX score II (PCI): 54.6±10.7 and SYNTAX score II (CABG): 41.8±11.4. Two (5.7%) patients were admitted to the ICU before the PCI procedure. Baseline and procedural characteristics are described in **Supplementary Table 1** and **Supplementary Table 2**.

VA-ECMO cannulation was performed in the femoral artery in 30 (85.7%) patients. Local anaesthesia with preprocedural oral benzodiazepine was the preferred choice of anaesthesia (85.7%). Closure was predominantly performed with a percutaneous closure device (97.1%), mostly a suture-based closure device (Perclose ProGlide System [Abbott]), which was generally sufficient after using two Proglides (77.4%). VA-ECMO-related access or access site complications

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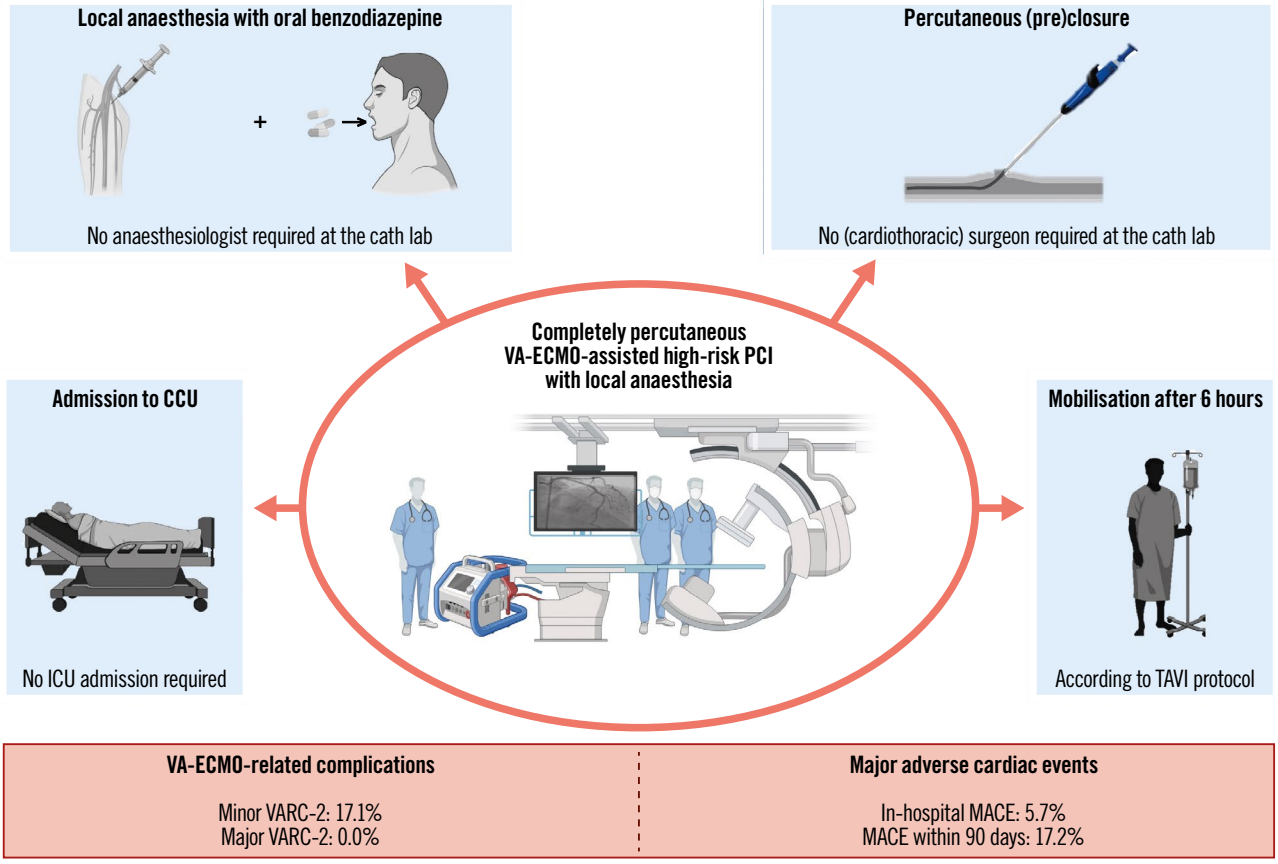
occurred in 6 (17.1%) patients. All were minor VARC-2 complications that occurred after using suture-based closure devices **(Supplementary Table 3)**.

Procedural success was achieved in all patients. Four (11.4%) patients were admitted to the ICU after PCI. The median time until discharge was 1 (IQR 1-3) day. In-hospital MACE occurred in 2 (5.7%) patients. MACE occurred in 5 patients (17.2%) within 90 days after discharge **(Central illustration)**.

Our study investigated whether VA-ECMO-assisted high-risk PCI procedures could be performed completely percutaneously and with local anaesthesia, and, as a result, with a small care team, admitting patients to the cardiac care unit for recovery afterwards and mobilising them within 6 hours after PCI. To date, this concept has not been thoroughly evaluated. The present study results are excellent and comparable to other studies[4]. Almost 90% of the procedures were performed with only local anaesthesia, without the presence of an anaesthesiologist. Procedures were predominantly performed with percutaneous deployment of VA-ECMO and closure with the Perclose ProGlide System. No cardiothoracic surgeon was present in the catheterisation laboratory. Outcomes of percutaneous closure using the ProGlide in this study were comparable to percutaneous closure as well as surgical closure in a previous study[5]. Almost all patients were admitted to the cardiac care unit afterwards and discharged to their referring hospital or home shortly after the PCI procedure. This study – investigating the largest population using completely percutaneous VA-ECMO with local anaesthesia – demonstrates the safety and feasibility of this simplified use of VA-ECMO during high-risk PCI. It provides new options for hospitals regarding the use of VA-ECMO. Future research should focus on studies

EuroIntervention — Central **Illustration**

Key features of completely percutaneous VA-ECMO-assisted high-risk PCI with local anaesthesia along with adverse outcomes.



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The key features are illustrated in the blue boxes, and adverse outcomes are detailed in the red boxes. CCU: cardiac care unit; ICU: intensive care unit; MACE: major adverse cardiac events; PCI: percutaneous coronary intervention; TAVI: transcatheter aortic valve implantation; VA-ECMO: veno-arterial extracorporeal membrane oxygenation; VARC: Valve Academic Research Consortium

comparing this concept with surgical techniques with respect to clinical outcomes.

Due to the retrospective and observational design of this study, some procedural and ECMO-related data are missing. This was also a highly selected population, increasing the risk of selection bias. Furthermore, no control group was included in the study. It is, therefore, not possible to make definite conclusions about a preferable treatment.

Completely percutaneous VA-ECMO-assisted high-risk PCI with local anaesthesia is a novel concept. Our results are excellent with respect to successful revascularisation and adverse events, subsequently, providing a suitable alternative to the standard surgical use of VA-ECMO with general anaesthesia.

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Conflict of interest statement

P. Damman reported grants, speaker fees and consultancy fees from Philips; grants and speaker fees from Abbott; and grants from AstraZeneca. N. van Royen reported grants and speaker fees from Abbott; and grants from Medtronic, Biotronik, and Philips. R.J.M. van Geuns reported grants and personal fees from Boston Scientific, Abbott, AstraZeneca, and Amgen; and grants from InfraRedx. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Table 1. Baseline and angiographic characteristics.

Supplementary Table 2. Procedural characteristics.

Supplementary Table 3. VA-ECMO characteristics.

Supplementary Figure 1. Example of a patient undergoing completely percutaneous VA-ECMO-assisted high-risk PCI with local anaesthesia, with an LVEF of 12%.

Moving image 1. Procedural set-up for VA-ECMO (de) cannulation.

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Supplementary data

Supplementary Table 1. Baseline and angiographic characteristics.

Baseline and angiographic characteristics	
	PCI with ECMO support (n = 35)
Age, years (± SD)	71.4 (±8.7)
Male, n (%)	28 (80.0)
Body mass index, kg/m^2 (IQR)	24.41 (21.96-30.19)
Hypertension , n (%)	18 (51.4)
Diabetes mellitus, n (%)	15 (42.9)
Dyslipidaemia, n (%)	12 (34.3)
Congestive heart failure, n (%)	20 (57.1)
Prior MI, n (%)	17 (48.6)
Prior PCI, n (%)	8 (22.9)
Prior CABG, n (%)	3 (8.6)
Peripheral artery vessel disease, n (%)	12 (34.3)
Lung disease, n (%)	3 (8.6)
Chronic kidney disease (GFR <30 ml/min), n (%)	4 (11.4)
Dialysis, n (%)	2 (5.7)
Three-vessel coronary artery disease, n (%)	23 (65.7)
Left main stenosis, n (%)	22 (62.9)
Generic bifurcation lesion, n (%)	17 (48.6)
CTO, n (%)	19 (54.3)
LVEF, % (± SD)	28.5 (±10.9)
STS mortality risk score (IQR)	3.6 (1.8-5.8)
SYNTAX Score I (± SD)	31.8 (±9.3)
SYNTAX Score II (PCI) (± SD)	54.6 (±10.7)
SYNTAX Score II (CABG) (± SD)	41.8 (±11.4)
Pre-procedural admission at ICU, n (%)	2 (5.7)

CABG: Coronary Artery Bypass Graft, CTO: Chronic Total Occlusion, ECMO: Extracorporeal Membrane Oxygenation, GFR: Glomerular Filtration Rate, ICU: Intensive Care Unit, IQR: Interquartile Ranges, MI: Myocardial infarction, PCI: Percutaneous Coronary Intervention, SD: Standard Deviation

Supplementary Table 2. Procedural characteristics.

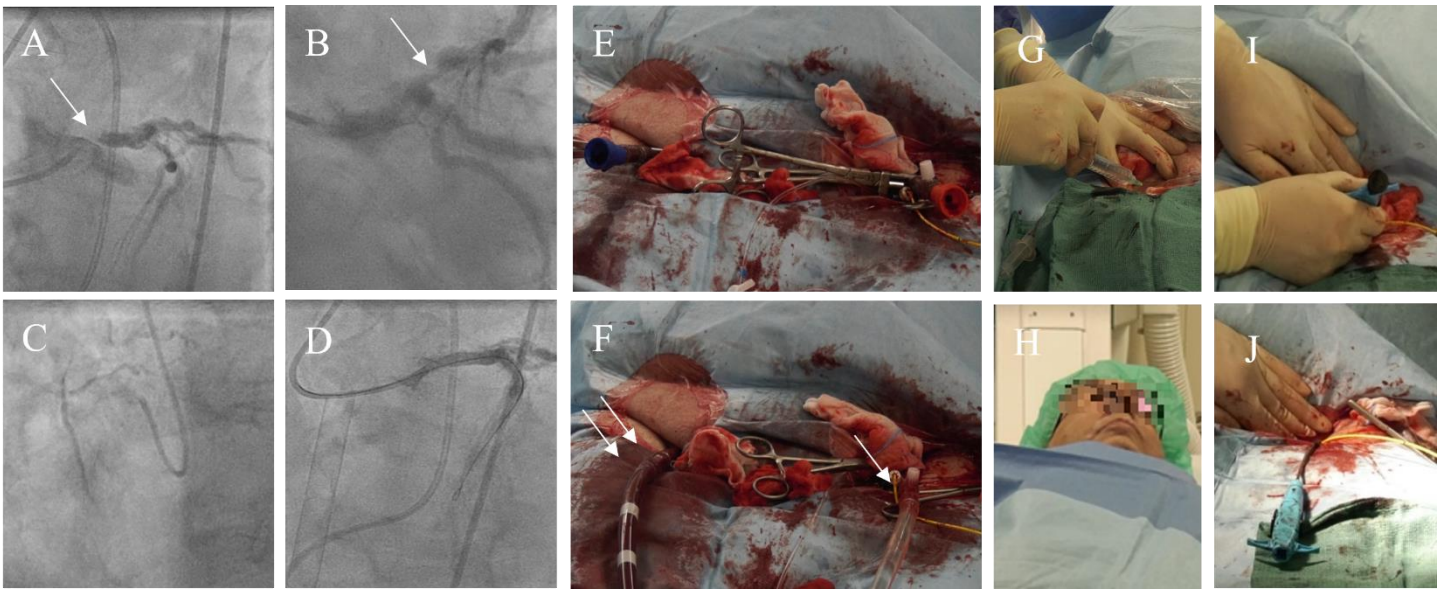
Procedural characteristics	
	PCI with ECMO support (n = 35)
Vessels planned for treatment, n (%)	
- LM	22 (62.9)
- LAD	29 (82.9)
- LCx	28 (80.0)
- RCA	15 (42.9)
Number of vessels planned for treatment (± SD)	2.7 (±0.7)
CTO planned for treatment, n (%)	8 (22.9)
Vessels definitely treated, n (%)	
- LM	22 (62.9)
- LAD	29 (82.9)
- LCx	27 (77.1)
- RCA	15 (42.9)
Number of vessel treated (± SD)	2.7 (±0.7)
CTO treated, n (%)	8 (22.9)
Complete revascularization, n (%)	34 (97.1)
Access site for PCI, n (%)	
Radial	12 (34.3)
Femoral	23 (65.7)
Additional access site for PCI, n (%)	
Radial	4 (11.4)
Femoral	1 (2.9)
Number of stents (± SD)	4.3 (±1.7)
Procedural time, min. (± SD)	171 (±49)
Contrast used, ml (± SD)	230 (±79)

CTO: Chronic Total Occlusion, ECMO: Extracorporeal Membrane Oxygenation, LAD: Left Anterior Descending, LCx: Left Circumflex, LM: Left Main, PCI: Percutaneous Coronary Intervention, RCA: Right Coronary Artery, SD: Standard Deviation

Supplementary Table 3. VA-ECMO characteristics.

ECMO characteristics	
	PCI with ECMO support (n = 35)
ECMO cannulation, n (%)	
- Femoral artery	30 (85.7)
- Femoral cannula	1 (2.9)
- Subclavian artery	5 (14.3)
Arterial cannula size, French (IQR)	17 (17-17)
- 15 French, n (%)	6 (18.8)
- 17 French, n (%)	19 (59.4)
- 19 French, n (%)	6 (18.8)
- 21 French, n (%)	1 (3.1)
Arterial cannula size per access site, n (%)	
Femoral artery	
15 French	3 (11.1)
17 French	17 (63.0)
19 French	6 (22.2)
21 French	1 (3.7)
Subclavian artery	
15 French	3 (60.0)
17 French	2 (40.0)
19 French	0 (0.0)
21 French	0 (0.0)
Anaesthesia, n (%)	
- Local anaesthesia with preprocedural medication sedation	30 (85.7)
- Procedural sedation and analgesia	2 (5.7)
- General anaesthesia	3 (8.6)
Duration of ECMO support, min. (± SD)	120 (±40)
Prolonged ECMO support, n (%)	1 (2.9)
ECMO flow, l/min. (± SD)	1.9 (±0.6)
Closure technique, n (%)	
- Surgical	1 (2.9)
- Collagen-plug based (Manta)	2 (5.7)
- Suture-based (Proglide)	32 (91.4)
o 1 Proglide	2 (6.5)
▪ Additional angioseal	0 (0.0)
o 2 Proglide	24 (77.4)
▪ Additional angioseal	1 (4.2)
o 3 Proglide	5 (16.1)
▪ Additional angioseal	2 (40.0)
Closure technique used per access site, n (%)	
Femoral artery	
Surgical	1 (3.3)
Collagen-plug (Manta)	2 (6.7)
Suture-based (Proglide)	27 (90.0)
Subclavian artery	
Surgical	0 (0.0)
Collagen-plug (Manta)	0 (0.0)
Suture-based (Proglide)	5 (15.6)
Contralateral final angiogram, n (%)	25 (71.4)
ECMO-related complications, n (%)	
- Vascular access site or access-related	6 (17.1)
- Minor vascular complication	6 (17.1)
- Major vascular complication	0 (0.0)

ECMO: Extracorporeal Membrane Oxygenation, IQR: Interquartile Ranges, PCI: Percutaneous Coronary Intervention, SD: Standard Deviation



Supplementary Figure 1. Example of a patient undergoing completely percutaneous VA-ECMO-assisted high-risk PCI with local anaesthesia, with an LVEF of 12%.

A) *Severe ostial left main stenosis (white arrow). B) Proximal LAD severely calcified up to 80% stenosis (white arrow). C) Ostial CTO of the RCA. D) Final angiogram after angioplasty and stent implantation. E/F) Arterial cannula (red cap and white arrow) and venous cannula (blue cap and double white arrows) during PCI procedure. G/H) Procedure performed with local anaethesia and oral benzodiazepine, without the use of general anaesthesia. I/J) Percutaneous (pre)closure performed with a percutaneous closure device.*

CTO: Chronic Total Occlusion, ECMO: Extracorporeal Membrane Oxygenation, LAD: Left Anterior Descending, LVEF: Left Ventricular Ejection Fraction, PCI: Percutaneous Coronary Intervention, RCA: Right Coronary Artery