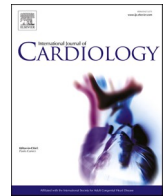




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## Comparison of a pulsatile and a continuous flow left ventricular assist device in high-risk PCI<sup>☆</sup>

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## ABSTRACT

**Background:** Mechanical circulatory support devices are able to generate additional cardiac output or maintain sufficient circulation during high-risk PCI. We prospectively compared the hemodynamic and clinical performance of the new iVAC2L® device with the Impella 2.5® device during high-risk PCI.

**Materials and methods:** In 40 patients [10 female, age 75 ± 8 years, left ventricular ejection fraction (LVEF) 44 ± 11%] high-risk PCIs were performed under iVAC (n = 20) or Impella (n = 20) support. Hemodynamic parameters were collected before and after device placement as well as immediately after PCI. Blood parameters of hemolysis were analyzed before and after support.

**Results:** Correct device placement was achieved in 17 patients (85%) under iVAC use and in 19 patients (95%) under Impella use. PCI success was 98%. Under iVAC2L® support, systolic, diastolic and mean aortic blood pressure increased significantly with increasing support time. In contrast, aortic pressure increased directly under Impella support, but the increase was comparable between both devices. Impella support generated a significantly higher additional blood flow, as compared to iVAC support (2.07 ± 0.09 l/min vs. 1.25 ± 0.05 l/min, p < 0.001). Five patients (iVAC n = 3) suffered from critical events during high-risk PCI, but both devices were able to maintain stable hemodynamic conditions. After PCI, one severe bleeding occurred in each group. After Impella support, haptoglobin was significantly decreased, indicating potential hemolysis.

**Conclusions:** High-risk PCIs under support by both devices are feasible and safe and ensure stable hemodynamic conditions also if complications occur. Aortic pressure increases significantly with both devices, but later under iVAC use. Potential hemolysis occurs more frequent under Impella support.

### 1. Introduction

Percutaneous coronary interventions (PCI) became a relevant technique in treating patients with acute and chronic coronary syndrome [1–3]. Current guidelines suggest PCI even as an alternative therapeutic option to coronary artery bypass grafting (CABG) in appropriate patients with three-vessel or left main coronary artery disease (CAD) [1]. A growing number of patients with severe CAD and distinct comorbidity, which are unsuitable for CABG, can be treated by PCI due to rapid development of interventional techniques and devices [4]. These PCIs are termed “high-risk PCIs” and may be accompanied by hemodynamic instability of the patient which might impede complete revascularization or even lead to cardiopulmonary resuscitation during the procedure [4]. Under these circumstances, percutaneous mechanical circulatory

support (MCS) systems can be used to maintain hemodynamic stability during or after high-risk PCIs [1–4].

The intra-aortic balloon pump (IABP) generates a small increase in cardiac output of up to 0.5 l/min [5] and was widely used in patients with cardiogenic shock and acute myocardial infarction until the IABP-SHOCK II trial showed no reduction of mortality in these patients [6–8]. Notable, application of elective IABP in contrast to rescue IABP in patients undergoing high-risk PCI seems to reduce mortality [9–11].

The continuous flow devices Impella 2.5, CP and 5 (ABIOMED, Danvers, MA, USA) provide cardiac outputs of up to 2.5 l/min, 4.0 l/min and 5.0 l/min, respectively [1,12]. The Impella device shows a widespread application in high-risk PCIs. The PROTECT I Trial [13] demonstrated secure implantation and sufficient hemodynamic support of the 2.5 device during high-risk PCIs [13]. The PROTECT II Trial

<sup>☆</sup> All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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compared the use of IABP and Impella 2.5® in patients undergoing high-risk PCI and demonstrated superior hemodynamic support by the Impella device [14]. The 30-day incidence of major adverse events was not different for both devices but there was evidence for improved outcome at 90-days for the Impella 2.5® device [14].

The iVAC2L® (PulseCath BV; Amsterdam; The Netherlands) is a new developed pulsatile left ventricular assist device, which is driven by a commercial-available IABP console. It is able to create an additional cardiac output up to 2 l/min [15]. Initial case reports and studies demonstrated sufficient hemodynamic support by iVAC2L® in patients undergoing high-risk PCIs [16–18].

Studies directly comparing hemodynamic support of different MCS systems in high-risk PCIs are lacking. Therefore, we performed a prospective trial and compared the hemodynamic and clinical performance of the new pulsatile assist device iVAC2L® with the mostly used continuous flow assist device Impella 2.5® in high-risk PCI patients.

## 2. Materials and methods

### 2.1. Study patients

This study was performed according to the Declarations of Helsinki and approved by the Ethics Committee of the Aertztekammer Westfalen-Lippe (reference number 2018–427).

Forty patients (10 female, age  $75 \pm 8$  years, left ventricular ejection fraction (LVEF)  $44 \pm 11\%$ ) with indication for high-risk PCI were prospectively enrolled in our study. Clinical characteristics are shown in Table 1. No power analysis was performed to calculate an adequate size of patient cohort, thus the results are only of descriptive character. After giving their written informed consent, the first 20 patients were consecutively treated by high-risk PCI under support of iVAC2L® ( $n = 20$ ), the next 20 patients were consecutively treated under support of Impella 2.5® ( $n = 20$ ). We defined high-risk PCI as a PCI of the last remaining vessel, a PCI of a complex left main stenosis with at least one bifurcation with a two stent treatment strategy in patients with left-dominant coronary circulation and a PCI of at least one proximal bifurcation stenosis with a two stent treatment strategy in patients with severe three-vessel disease and a left ventricular ejection fraction (LVEF) lower than 30%. Twenty-eight patients underwent PCI of complex left main lesions, five patients underwent PCI of the last remaining vessel, and seven patients underwent complex PCI in severe three-vessel disease with reduced LVEF. Inclusion criteria were age above 18 years, written informed consent and an expected support duration under 24 h.

**Table 1**

Patient characteristic and differences between the two support groups. LVEF = left ventricular ejection fraction, f = female, m = male, GFR = glomerular filtration rate, RV = right ventricle, 3VD = three-vessel disease, LM = left main stenosis, LRV = last remaining vessel, PCI = percutaneous coronary intervention, device benefit = occurrence of critical PCI-related complication or situations which would have led to hemodynamical instability without mechanical circulatory support.

	iVAC2L ( $n = 20$ )	Impella 2.5 ( $n = 20$ )	p
age (years)	$71.9 \pm 9.4$	$78.8 \pm 4.2$	0.006
LVEF (%)	$44 \pm 12$	$45 \pm 10$	0.878
sex (f/m)	3/17 (15%/85%)	7/13 (35%/65%)	0.273
hemoglobin (g/l)	$136.8 \pm 15.9$	$126.2 \pm 20.7$	0.08
creatinine (mg/dl)	$1.30 \pm 0.56$	$1.36 \pm 0.67$	0.79
GFR (ml/min)	$60.7 \pm 22.2$	$53.6 \pm 20.0$	0.30
pulmonary hypertension (n)	3 (15%)	7 (35%)	0.273
diastolic dysfunction (n)	15 (75%)	11 (55%)	0.320
RV dysfunction (n)	2 (10%)	4 (20%)	0.661
disease (3VD/LM/LRV) (n)	7/11/2 (35%/55%/10%)	0/17/3 (0%/85%/15%)	0.009
contrast agent (ml)	$264.8 \pm 77.0$	$321.2 \pm 67.2$	0.02
support duration (min)	$122.4 \pm 31.9$	$94.3 \pm 40.4$	0.012
PCI success (n)	20 (100%)	19 (95%)	0.5
device benefit (n)	3 (15%)	2 (10%)	0.5

Exclusion criteria were aortic disease, aortic valve disease or mechanical valve replacement, severe peripheral artery disease, left ventricle thrombus, ventricular septum defects and coagulation disorders. In all patients high risk-PCI was performed in a second procedure after an initial diagnostic coronary angiography. During the initial diagnostic coronary angiography procedure, a pigtail catheter was placed in the descending aorta to perform angiography of the distal aorta and femoral artery to enable angiographic-guided access to the femoral artery, to evaluate the femoral-iliac area and to exclude severe peripheral artery disease.

### 2.2. Implantation of the iVAC2L® system

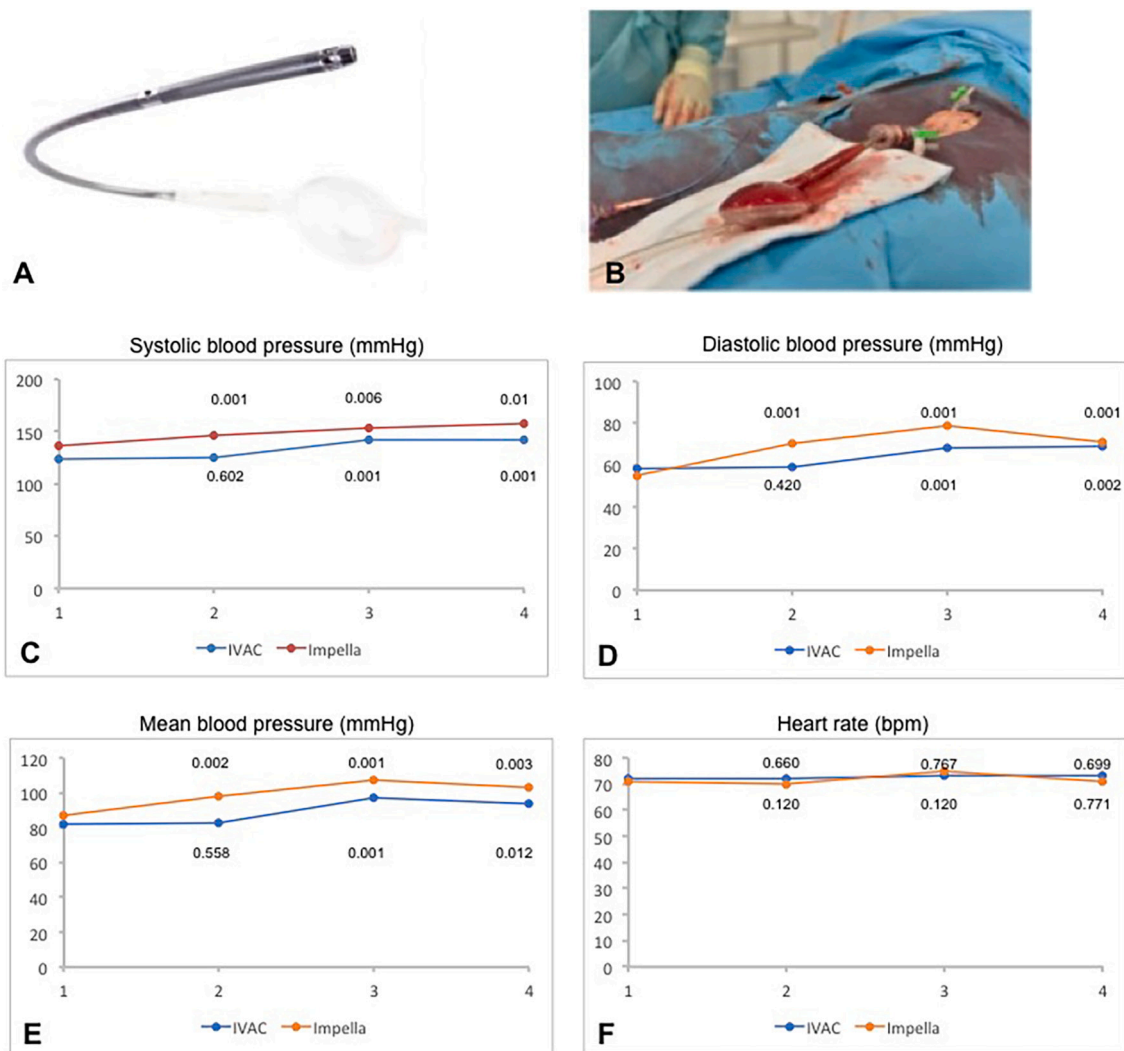
The implantation procedure of the iVAC2L® device was reported recently [18]. In brief, femoral artery access was achieved and two ProGlide® (Abbott, Abbott Park, Illinois, USA) vascular closure devices were inserted. Activated clotting time (ACT) was measured and implantation procedure was continued if ACT was above 250 s. A SoloPath® re-collapsible 13.5F access system was placed and inflated to 19F. Under support of a 5F pigtail catheter we placed an extra-stiff wire (Amplatz Extra Stiff Wire Guide; Cook Medical, Bloomington, IN, USA) in the left ventricle and the iVAC catheter (Fig. 1A) was placed in the left outflow tract with the catheter tip in the left ventricle and the bidirectional valve in the ascending aorta. In the next step, iVAC2L® device was connected to a conventional IABP console and ECG-triggered pulsatile cardiac output (CO) support was started (Fig. 1B). Before support, as well as five minutes after placement under stable support by the device and immediately after PCI (full ECG-triggered support, beat-to-beat; 1:1), aortic pressure and flow data were collected. If necessary, application of atropine i.v. was performed to keep heart rate  $\geq 70$  bpm. We performed flow measurements under use of a SonoTT™ Ultrasonic Flow Meter (em-tec GmbH, Finning, Germany). The CO generated by the device was measured with the incorporated measurement module of the iVAC2L device. Finally, five minutes after end of support additional pressure data were collected. Thereafter, the iVAC2L® device was retrieved and the SoloPath® femoral access was decollapsed and removed. Femoral artery access was closed with the earlier inserted ProGlide® devices.

### 2.3. Implantation of the Impella 2.5® system

Implantation of Impella 2.5® was performed in accordance with the standardized procedure for the placement of this device: We inserted two ProGlide® (Abbott, Abbott Park, Illinois, USA) vascular closure devices and placed the 13F Impella peel-away sheath. After documentation of an ACT of more than 250 s the dilatator was removed and a 5F pigtail diagnostic catheter was placed in the left ventricle using a conventional J-wire. Then, the Impella guiding wire was placed in the left ventricle and pigtail catheter was removed. After standardized preparation and connection of the Impella pump catheter to the device console, it was placed in the left ventricle and the wire was removed. Support was started and Impella position was stabilized using the x-ray marker for aortic valve position. Collection of pressure data were performed similar to the iVAC group before support, five minutes after placement, immediately after PCI, and five minutes after end of support. CO was documented using actually CO-data displayed at the ABIOMED console screen. Thereafter, the Impella device was retrieved, the 13F sheath removed and femoral artery access was closed with the ProGlide® devices.

### 2.4. Follow up

Clinical data were collected by phone contact as well as from reports of outpatient controls or hospital treatment of the patients.



**Fig. 1.** iVAC2L® 17F Nitinol single lumen catheter (A) and the transfemoral access area with connected membrane pump chamber (B). Comparison of hemodynamic systolic (C), diastolic (D) and mean (E) aortic pressure parameters and heart rate (F) between iVAC2L® and Impella 2.5®. Measurement times: 1 = pre PCI no mechanical circulatory support (MCS), 2 = pre PCI full MCS, 3 = post PCI full MCS, 4 = post PCI no MCS. *P*-values are listed for differences of measurement times against pre PCI no support.

### 2.5. Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics (version 25 for Mac, IBM Corporation, Somers, NY, USA). Categorical variables are presented as absolute numbers and percentages. Continuous variables are shown as mean  $\pm$  standard deviation. Changes over time of metric variables were assessed with one-way repeated analysis of variance (ANOVA), Wilcoxon signed rank test or Friedman test.

### 3. Results

Correct device placement was achieved in 17 (85%) patients in the iVAC2L® group and in 19 (95%) patients in the Impella 2.5® group ( $p = ns$ ). Placement failures due to severe kinking of iliac and femoral arteries occurred in two patients in the iVAC2L® group and in one patient in the Impella group. In the remaining patient in the iVAC2L® group, the length of the pump catheter was inadequate for placement in the left ventricle. Therefore, PCI was performed without hemodynamic support in two patients of the iVAC2L® group and in one patient of the Impella 2.5® group and with hemodynamic support in ascending aorta in one case in the iVAC2L® group. Except for contrast agent, no fluids were infused. Mean support time was significantly shorter under Impella use

( $122 \pm 32$  min vs.  $94 \pm 40$  min,  $p = 0.012$ ). PCI success was 98% ( $n = 20$  iVAC2L®,  $n = 19$  Impella 2.5®). In one patient in the Impella group despite a correct running assist device, PCI failed due to impossibility of placing the guide wire through a massively calcified subtotal ostial lesion of the left circumflex artery.

#### 3.1. Hemodynamic changes under device support

There was no early increase in systolic ( $123 \pm 29$  vs.  $125 \pm 21$  mmHg,  $p = 0.602$ ), diastolic ( $58 \pm 16$  vs.  $59 \pm 14$  mmHg,  $p = 0.420$ ) and mean aortic blood pressure ( $82 \pm 16$  vs.  $83 \pm 16$  mmHg,  $p = 0.558$ ) under full iVAC2L® support, but with prolonged support time of at least 45 min the systolic ( $123 \pm 29$  vs.  $142 \pm 28$  mmHg,  $p = 0.001$ ), diastolic ( $58 \pm 16$  vs.  $68 \pm 18$  mmHg,  $p < 0.001$ ) and mean aortic blood pressure ( $82 \pm 16$  vs.  $97 \pm 21$  mmHg,  $p < 0.001$ ) increased significantly and kept their higher level (Table 2, Fig. 1C-E). In contrast, systolic ( $136 \pm 23$  vs.  $146 \pm 29$  mmHg,  $p < 0.001$ ), diastolic ( $55 \pm 13$  vs.  $70 \pm 18$  mmHg,  $p < 0.001$ ) and mean aortic pressure ( $87 \pm 15$  vs.  $98 \pm 19$  mmHg,  $p = 0.002$ ) increased significantly immediately after starting Impella support (Table 2, Fig. 1C-E), but with ongoing support the increase in these hemodynamic parameters was comparable between the two groups after PCI (Table 2). After removal of the support device systolic, diastolic and

**Table 2**

Comparison of hemodynamic parameters under iVAC2L® vs. Impella 2.5® support. MCS = mechanical circulatory support, PCI = percutaneous coronary intervention, bp = blood pressure, SD = standard deviation.

		pre PCI (no MCS)	pre PCI (full MCS)	post PCI (full MCS)	post PCI (no MCS)	p pre PCI no MCS vs. pre PCI full MCS	p pre PCI no MCS vs. post PCI full MCS	p pre PCI no MCS vs. post PCI no MCS	p pre PCI full MCS vs. post PCI full MCS	p pre PCI full MCS vs. post PCI no MCS
Systolic bp (mmHg, mean ± SD)	iVAC2L	123 ± 29	125 ± 21	142 ± 28	142 ± 31	0.602	0.001	0.001	0.004	0.009
	Impella 2.5	136 ± 23	146 ± 29	154 ± 22	156 ± 21	0.001	0.006	0.01	0.235	0.271
P (iVAC2L vs. Impella 2.5)		0.152	0.023	0.173	0.155					
Diastolic bp (mmHg, mean ± SD)	iVAC2L	58 ± 16	59 ± 14	68 ± 18	69 ± 18	0.420	0.001	0.002	0.044	0.083
	Impella 2.5	55 ± 13	70 ± 18	79 ± 16	71 ± 17	0.001	0.001	0.001	0.005	0.986
P (iVAC2L vs. Impella 2.5)		0.584	0.064	0.080	0.748					
Mean bp (mmHg, mean ± SD)	iVAC2L	82 ± 16	83 ± 16	97 ± 21	94 ± 27	0.558	0.001	0.012	0.011	0.109
	Impella 2.5	87 ± 15	98 ± 19	107 ± 15	103 ± 16	0.002	0.001	0.003	0.031	0.355
P (iVAC2L vs. Impella 2.5)		0.298	0.018	0.103	0.256					

mean aortic blood pressure were stable or decreased slightly in both groups as compared to the same parameters post PCI under device support (Table 2, Fig. 1C-E). Significant differences in heart rate between the two groups or before, during or after MCS were not observed (Fig. 1F). In the iVAC group no drop in aortic pressure was noted in patients without complications during PCI, whereas systolic aortic pressure dropped from above 110 mmHg to below 80 mmHg in all three mentioned patients with severe complications during PCI, but the iVAC2L system managed to maintain a mean aortic pressure above 60 mmHg in these three patients. In the Impella group we also could not observe a drop in aortic pressure in patients without complications. The two patients with complications also showed a slightly drop of aortic pressure with systolic pressure above 100 mmHg and with mean aortic pressure above 70 mmHg.

Mean continuous flow generated by the Impella device during the whole procedure was significantly higher, as compared to the mean pulsatile flow generated by the iVAC device ( $2.07 \pm 0.09$  l/min vs.  $1.25 \pm 0.05$  l/min,  $p < 0.001$ ).

Despite of a significant shorter mean support time under Impella use ( $122 \pm 32$  min vs.  $94 \pm 49$  min,  $p = 0.03$ ), Haptoglobin was significantly decreased after Impella use. There was also a trend in haptoglobin decrease in the iVAC group without statistical significance. In both groups, hemoglobin showed a significant reduction after PCI. This effect is mainly not related to hemolysis but rather due to blood loss during the procedure and MCS removal and fluid substitution after PCI to eliminate contrast agent. No other parameters of hemolysis or renal function showed significant differences between the two device groups (Table 3). We found no clinically relevance of the observed hemolysis in the

**Table 3**

Parameters of hemolysis and renal function before and after hemodynamic support.

		Pre MCS	post MCS	p
haptoglobin (mg/l, mean ± SD)	iVAC2L	1485 ± 689	1261 ± 648	0.072
	Impella 2.5	1720 ± 734	1156 ± 591	0.001
LDH (U/l, mean ± SD)	iVAC2L	240 ± 90	241 ± 68	0.963
	Impella 2.5	227 ± 80	256 ± 91	0.053
hemoglobin (g/l)	iVAC2L	136.8 ± 15.9	118.3 ± 23.5	0.001
	Impella 2.5	124.1 ± 19.2	106.2 ± 21.8	0.001
creatinine (mg/dl)	iVAC2L	1.32 ± 0.57	1.38 ± 0.89	0.278
	Impella 2.5	1.37 ± 0.69	1.44 ± 0.85	0.555
GFR (ml/min)	iVAC2L	59.9 ± 22.5	62.5 ± 25.5	0.242
	Impella 2.5	54.0 ± 20.5	53.1 ± 23.1	0.733

Impella group.

### 3.2. Clinical outcome

High-risk PCI was successful in 98% ( $n = 20$  iVAC2L®,  $n = 19$  Impella 2.5®). The complexity of the lesions and the treatment strategies are listed in table 4 (supplementary data). In five patients (12.5%) (iVAC  $n = 3$  (15%), Impella  $n = 2$  (10%), (Table 5, supplementary data) not device-related critical events occurred during PCI. In the iVAC group one patient developed massive vasospasm, the second patient a coronary perforation after balloon dilatation and the third patient showed no coronary flow after wire placement into the left main coronary artery. In the Impella group a second-degree AV-block with hemodynamical significance occurred and in the second case a pericardial tamponade due to guide wire perforation occurred with the need for pericardiocentesis. In our study, no death or myocardial infarction did occur. In all patients, mechanical support helped to remain stable circulatory conditions with no need for cardiopulmonary resuscitation, fluid infusion or application of vasoactive agents and thus, the critical events were adequately handled during the procedure and the PCI was successfully finished. The support device helped to maintain stable hemodynamic conditions in these patients.

After PCI one severe bleeding occurred in each group (5% in each group), both due to an aneurysm of the femoral artery and one transitory ischemic attack (TIA) ( $\leq 24$  h) occurred in the iVAC2L® group (5%) (Table 5, supplementary data). Both patients with femoral artery aneurysms were successfully treated by vascular surgery. The patient with TIA showed no stroke delineation in serial cerebral imaging and was discharged from our stroke unit with no remaining disabilities 48 h hours after PCI.

All patients could routinely be discharged from hospital. After a follow up of  $6 \pm 4.7$  months no patient died. In the iVAC2L® group, a stent thrombosis occurred 89 days after PCI. Dual antiplatelet therapy was interrupted in this patient four weeks after PCI because of high bleeding risk. A second PCI under use of a drug-eluting balloon was performed in this patient establishing TIMI III flow in the vessel. The patient with the unsuccessfully PCI in the Impella group due to a massively calcified ostial lesion of the left circumflex artery underwent coronary artery bypass surgery with complete revascularization of coronary arteries and good clinical outcome.

## 4. Discussion

To our knowledge our single-centre study is the first, comparing head to head hemodynamic and clinical performance of the new pulsatile assist device iVAC2L® with the most used continuous flow assist device Impella 2.5® in a prospective high-risk PCI setting.

We could demonstrate a high rate of correct device placement in the iVAC2L® group and in the Impella 2.5® group. Severe kinking of iliac and femoral arteries was the main reason that impeded device placement in both groups. In one patient in the iVAC group, the device was too short to be placed in the left ventricle but circulatory support was given in ascending aorta during PCI. Another study using iVAC2L® in high-risk PCI reported a comparable successful implantation rate in 13 of 14 (93%) patients [19]. In this study, vascular anatomy also impeded iVAC2L® placement in one patient [19]. In addition, the Protect I Trail reported 100% successful Impella 2.5® implantations in 20 patients, which is comparable to our study results [13]. Based on these reports, implantation of percutaneous MCS systems seems to be feasible with high success rates. Failure of placement is mainly due to tortuosity of the iliac and femoral arteries. New technologies which are under development with smaller catheter diameter could probably overcome this problem.

We could demonstrate that the PCI revascularization was successful in 39 patients (98%,  $n = 20$  iVAC2L®,  $n = 19$  Impella 2.5®). The study by den Uil reported a similar high-risk PCI success rate with 100% (13 patients) under iVAC2L® support [19]. The PROTECT I Trail showed a high-risk PCI success rate of 100% (20 patients) by use of Impella 2.5® [13]. In summary, the reported various types of MCS systems altogether maintained stable hemodynamic conditions during high-risk PCIs which may have contributed to the high PCI success rate of over 90%.

In our study, five patients (12.5%) suffered from not device related critical events and complications during high-risk PCI (three patients iVAC2L® group (15%), two patients Impella 2.5® group (10%)). Despite these critical episodes, both MCS systems generated sufficient CO with no need for cardiopulmonary resuscitation or additional fluid infusions. We had one severe bleeding in each group due to aneurysm of the femoral artery (5% in each group) after PCI. In addition, one stroke (5%) within 24 h after PCI was found in the iVAC2L® group. In summary, use of iVAC2L® and Impella 2.5® seem to be accompanied by a relative low rate of vascular and neurologic complications. Severe complications such as death or myocardial infarction did not occur in our study. The study by den Uil with iVAC2L® support found a device related procedural complication rate of 8% (1 patient with intractable pain in the iVAC2L® accessed leg) during PCI [19]. Further, this study found no vascular access site complications or neurologic complications during or after the use of iVAC2L® [19]. The PROTECT I trail with Impella 2.5® support reported two periprocedural myocardial infarctions (10%) and had no cases of vascular injury or neurologic dysfunction [13]. In the PROTECT II trail, stroke occurred in 0.8% of patients under IABP® support and in none of the patients under Impella 2.5® support [14]. Altogether, these studies indicate that vascular and neurologic complication rates of percutaneous MCS systems seem to be acceptable. In contrast, death and periprocedural myocardial infarction may also occur in some patients with high-risk PCIs despite use of MCS systems.

In our study, mean support time was significant shorter under Impella 2.5® use compared to the iVAC2L®-system. Another study, using iVAC2L® reported a mean support time of 67 min [19]. In contrast to our study, 38% of patients under iVAC2L® support in the this study required additional fluid administration for circulatory support [19] which may explain the difference in support time. The PROTECT I trail reported a mean duration of circulatory support by the Impella 2.5® device of 102 min, which is comparable to our result [13]. The PROTECT II trail found also a significant shorter mean support time with the Impella 2.5® device (114 min) compared to the IABP® device (504 min) [14]. In this study, 36.7% of patients were on IABP® support and 5.9% of patients were on Impella 2.5® support when discharged from the cath lab, which might explain especially the prolonged support time in the IABP® group [14]. In our study, all patients were discharged from the catheter lab without need for further mechanical hemodynamic support. Due to the reported short support durations, the Impella 2.5® device seems to be more favourable compared to the other MCS systems.

In our iVAC2L® group there was no early increase of systolic,

diastolic and mean aortic pressure, but with prolonged circulatory support these parameters increased significantly. In contrast, in the Impella 2.5® group, these hemodynamic parameters significantly increased directly after start of the Impella 2.5® support. After PCI with and without circulatory support, aortic pressure values were comparable between both groups and significantly higher compared to pre-PCI values in both groups. This increase in aortic pressures after complete PCI may be due to successful revascularization and improvement of myocardial perfusion resulting in an increased cardiac output. Another iVAC2L® study also demonstrated a significant increase in mean arterial pressure during iVAC2L® support and after PCI compared to baseline [19]. Therefore, both devices seem to increase aortic pressures significantly. However, based on our data the Impella 2.5® device enhances aortic pressures immediately after start of mechanical circulatory support and thus may be more practicable in emergency PCI-settings where hemodynamic support is immediately needed.

In our study, the mean generated flow by the Impella 2.5® device was significantly higher as compared to the iVAC2L® system. The CO generated by the devices were measured with the incorporated measurement modules of the devices using different methods of acquisition, thus the CO data and its differences should be interpreted with caution. The iVAC2L® study by den Uil found an increase of CO by 1.0 l/min during iVAC2L support [19], which is comparable to our result. In accordance, the PROTECT I trail demonstrated a mean flow of 2.2 l/min by the Impella 2.5® device, which is also similar to our study. Although the Impella 2.5® device generates a twofold higher additional CO compared to the iVAC2L® system, both circulatory support systems seem to generate enough additional CO for compensation of CO decrease during intraprocedural complications and thus enable both complete revascularization in high-risk PCI procedures.

Despite a significantly shorter mean support time with the Impella 2.5® device, haptoglobin was significantly reduced in the Impella 2.5® group compared to the iVAC2L® group which may be a sign of potential hemolysis due to Impella support. However, no clinically relevant hemolysis was detected. In contrast, the iVAC2L® study by den Uil showed not only a significant decrease of hemoglobin but also of haptoglobin without signs of clinically relevant hemolysis under iVAC use [19]. The PROTECT I trail found mild hemolysis in 10% of the patients without clinical relevance under Impella 2.5® support [13]. Both devices seem to cause low rates of hemolysis without clinical relevance, which may change during longer MCS periods.

## 5. Conclusions

High-risk PCIs under mechanical circulatory support by the pulsatile iVAC2L® or the continuous flow Impella 2.5® device are feasible and safe. Both devices led to a significant increase in aortic pressure, which is achieved almost instantly by the Impella 2.5® device and over an extended period by the iVAC2L® device. Both devices ensured stable hemodynamic conditions for performing successful high-risk PCI. Complication rates by use of both devices seem acceptable. Although mean duration of circulatory support by the Impella 2.5® device was significantly shorter, signs of potential hemolysis were only present under Impella 2.5® support without clinical relevance.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcard.2022.05.038>.

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