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High-risk PCI under support of a pulsatile left ventricular assist device – First German experience with the iVAC2L system☆

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ABSTRACT

Background: During high-risk percutaneous coronary intervention (PCI) complications may occur, leading to unstable hemodynamic conditions. Circulatory support devices might help to intercept these conditions by supporting cardiac output. We investigated in a prospective trial the performance of the pulsatile iVAC2L system in the setting of high-risk PCI.

Methods: Circulatory support by the iVAC2L device was attempted in 20 consecutive patients (three females, mean age 72 ± 9 years, LVEF 44 ± 12%) undergoing high-risk PCI. Aortic pressure data were collected after device placement and immediately after PCI.

Results: Successful device placement was achieved in 17 (85%) patients; kinking of iliac artery and device length limited correct device placement in the remaining three patients. PCI success was 100%. With ongoing support (overall support time 122 ± 32min) systolic, diastolic and mean blood pressure increased significantly and kept the higher level until device removal.

Critical events occurred in three patients (massive vasospasm, coronary perforation, no-flow in LCA after wire placement), but the iVAC2L device helped to maintain stable hemodynamic conditions with no need for cardiopulmonary resuscitation.

Serial controls of hemolysis related parameters in a subgroup of ten patients revealed no significant device related hemolysis after the performance of the iVAC2l system.

Conclusions: High-risk PCI under hemodynamic support by the iVAC2L device is feasible and safe. Aortic pressure increases with ongoing support. The device helps to stabilize hemodynamic situations if complications occur.

1. Introduction

Percutaneous coronary intervention (PCI) has become an alternative therapeutic strategy to coronary artery bypass grafting (CABG) in appropriate patients with coronary artery disease and complex stenoses [1]. Significant progress in interventional techniques and stent technology made possible the increasing implementation of PCI in older patients suffering from an increasing amount of comorbidities according to their higher age [1]. Current guidelines recommend PCI with a high level of evidence in appropriate patients with complex coronary stenosis, such as left main stenosis [2]. During high-risk PCI unstable hemodynamic situations or complications may necessitate immediate partial or full extracorporal circulation support. To protect patients' circulation and especially coronary perfusion during or after high-risk PCI procedures, several devices were implemented and evaluated recently.

Intra-aortic balloon pump (IABP) is a technically easy to handle assist device for interventional cardiologists. Due to the disappointing results in a large randomized multi-centre trial, its use is no more recommended in the setting of cardiogenic shock by the current guidelines [3]. On the other hand, several smaller studies assume a potential benefit of IABP use in patients undergoing high-risk PCI [4–6].

The use of full circulatory assist devices during PCI, such as the extra-corporeal membrane oxygenation (ECMO), guarantees an adequate circulation at the expense of a more complex setting (including specially-trained technicians, which are often only available in tertiary care centres) and shows higher rates of adverse

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events, as compared to IABP [7,8].

The implantation of a Tandem Heart device (Cardiac Assist, Pittsburgh, PA, USA) shows more bleeding and ischemic complications as compared to IABP (due to larger insertion cannulae; one positioned in the left atrium). Furthermore, for the implantation of the Tandem Heart device the interventional cardiologist should be familiar and experienced with the transseptal puncture technique [7,9].

The most used supporting device during high-risk PCI is the Impella 2.5 (ABIOMED, Danvers, MA, USA), a continuous flow device, which supports the cardiac output (CO) by up to 2.5 L per minute. Impella 2.5 is inserted via transfemoral access through a 13F sheath [10]. For more circulatory support the Impella CP and Impella 5 devices are available providing additional CO support by up to 4.0 and 5.0 L per minute, respectively.

The iVAC2L device (PulseCath BV; Amsterdam; The Netherlands), a new pulsatile ventricular assist device, is able to support CO by up to 2 l/min [11]. The iVAC3L system (PulseCath BV; Amsterdam; The Netherlands), a recently developed pulsatile device, is able to support CO by up to 3 l/min, but the insertion via the right subclavian artery is complex and requires surgical assistance [12].

We investigated in a prospective trial the performance of the iVAC2L system in patients undergoing high-risk PCI as well as the impact of continuous circulatory support by this system on important hemodynamic parameters.

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 Aerztekammer Westfalen-Lippe (reference number 2018-427).

Twenty patients with indication for high-risk PCI were consecutively enrolled in our study after giving their written informed consent. Eleven patients underwent PCI of complex left main stenosis, one patient underwent PCI of the last remaining vessel and the remaining eight patients underwent complex PCI in severe three vessel disease with reduced left ventricular ejection fraction (LVEF). Inclusion and exclusion criteria are shown in Table 1.

2.2. Implantation of the iVAC2L system

A 6F sheath was placed into the femoral artery and used for insertion of two ProGlide® (Abbott, Abbott Park, Illinois, USA) vascular closure devices. After heparine administration with a target activated clotting time (ACT) of more than 250s, a SoloPath re-collapsable 13.5F access system was placed and inflated to 19F. An extra-stiff wire (Amplatz Extra Stiff Wire Guide; Cook Medical, Bloomington, IN, USA) was placed in the left ventricle using a pigtail diagnostic catheter and the 100 cm-long 17F single lumen bidirectional flow catheter was placed in the left outflow tract with the catheter tip in the left ventricle and the bidirectional valve in the ascending aorta (Fig. 1A–C). Thereafter, the device was connected to a conventional IABP console and ECG-triggered pulsatile CO support was started. Pressure curves in aortic position showed the typical notches in diastolic phase assuming correct device function (Fig. 1D). Five minutes after placement and stable support by the device as well as immediately after` PCI, aortic pressure and flow data were collected during full (beat-to-beat; 1:1) and intermittent [every second beat (1:2) and every third beat (1:3)] device support. Flow measurements were performed using a SonoTT™ Ultrasonic Flow Meter (em-tec GmbH, Finning, Germany); a clamp-on flow probe was placed on the iVAC2L catheter near the membrane pump on that purpose. After PCI and 5 min after support was stopped final aortic pressure data were collected. Thereafter, the iVAC2L device was retrieved and the SoloPath femoral access was decollapsed and removed. The artery access was closed with the Proglide devices.

Table 1
Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Indicated high-risk PCI	Aortic disease
Expected support duration <24 h	Aortic valvular disease
Age >18	Aortic mechanical valve prothesis
Written informed consent	Thrombus in left ventricle
	Ventricular septum defect
	Severe peripheral vascular disease
	Coagulation disorders

2.3. Follow up

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

2.4. Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics (version 24 for Mac, IBM Corporation, Somers, NY, USA). Categorial variables are presented as absolute numbers and percentages. Continuous variables are shown as mean ± 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

Clinical characteristics are shown in Table 2. Correct device placement was achieved in 17 (85%) patients. In two patients the iVAC2L device could not be introduced into the ascending aorta because of severe kinking of iliac and femoral arteries and PCI was therefore performed without hemodynamic support. In another patient the device was too short to be placed in the left ventricle and pulsatile hemodynamic support was performed in the aortic arch. Except for contrast agent, no fluids were administered. Mean hemodynamic support time was 122 ± 32 min.

3.1. Hemodynamic changes under iVAC2L support

There was no immediate increase in systolic (123 ± 29 vs. 125 ± 21 mmHg, p = n.s.) or diastolic (57 ± 16 vs. 59 ± 14 mmHg, p = n.s.) blood pressure 5 min after initiation of full iVAC2L support as compared to spontaneous circulation, but at PCI completion systolic and diastolic blood pressure had increased significantly (122 ± 30 vs. 142 ± 28 mmHg, p = 0.001 and 59 ± 17 vs. 68 ± 18 mmHg, p < 0.001, respectively). Systolic and diastolic blood pressure decreased slightly after removal of the iVAC2l device as compared to the same parameters post PCI under full iVAC2l support, see Fig. 2 for details. Similarly, there was no early increase in mean aortic blood pressure (81 ± 17 vs. 83 ± 16 mmHg, p = n.s.) under full iVAC2L-support, as compared to no support, but at PCI completion mean aortic pressure had increased significantly as well (82 ± 17 vs. 97 ± 21 mmHg, p < 0.001). Similar to systolic and diastolic pressure, mean aortic pressure decreased slightly after iVAC2l removal as compared to the same parameter at PCI completion, but it remained higher compared to the baseline or early support values (Fig. 2; baseline = no iVAC2l support; early support = 5 min after

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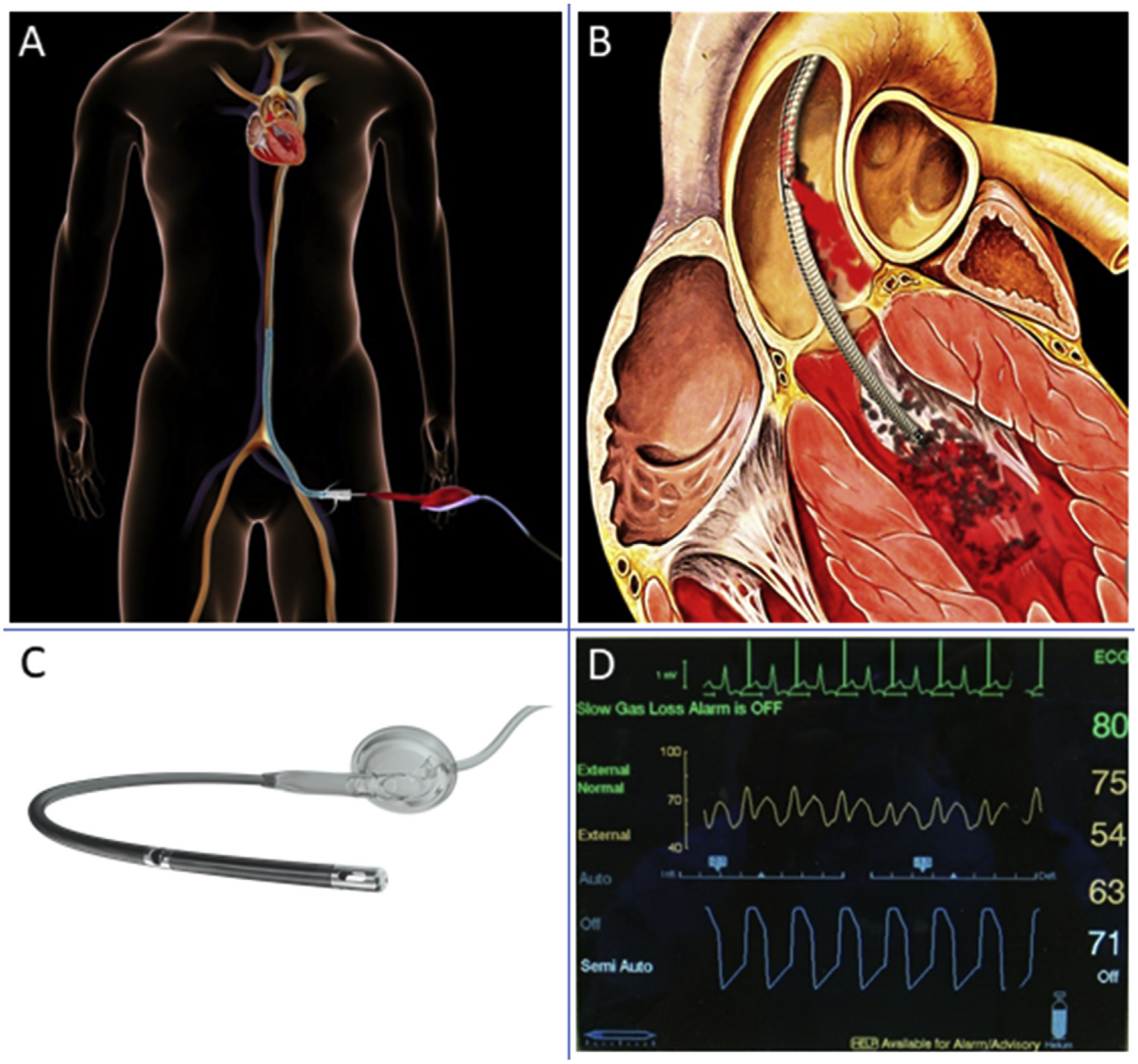

Fig. 1. A: Picture showing the 17F, single lumen, 100 cm-long iVAC2l catheter inserted from the femoral artery to the left ventricle via the re-collapsable sheath and the connected extra-corporeal membrane pump, which is driven by the IABP console (the latter provides ECG-triggered negative pressure in the helium chamber of the membrane pump during systole and positive pressure during diastole, allowing blood flow from the left ventricle to the blood chamber of the membrane pump in the systole and from here to the ascending aorta in the diastole); B: cartoon of the correctly placed iVAC2l device, with the inlet in the left ventricular outflow tract and outlet in the ascending aorta; C: picture of the iVAC2l-System showing the extracorporeal membrane pump connected to the single-lumen catheter, with the inlet at the distal end and the outlet containing the bidirectional valve more proximally; D: Example-tracing from the IABP console during 1:1 beat circulatory support by iVAC2l; green trace showing the ECG of the patient; orange trace showing the blood pressure in the ascending aorta; blue trace showing helium gas pressure in the membrane pump chamber. *Parts of* Fig. 1 *are courtesy of PulseCath BV, Amsterdam, The Netherlands.* (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

initiation of full iVAC2l support).

Additional flow measurements under full (1:1) and intermittent (1:2 and 1:3) hemodynamic support were performed in a subgroup of seven patients by using a Sono TT™ Ultrasonic Flow Meter (emtec GmbH, Finning, Germany). In these patients the flow over the assist device under full support (1:1) at a mean heart rate of 72 ± 9 bpm was 1.23 ± 0.09 l/min and 1.25 ± 0.05 l/min before and after PCI, respectively. At an identical heart rate, the flow over the device decreased significantly with intermittent support: 0.89 ± 0.16 and 0.77 ± 0.14 l/min before and after PCI under support of every second heartbeat and 0.53 ± 0.13 and 0.51 ± 0.18 l/min before and after PCI under support of every third heartbeat.

In a subgroup of ten patients blood samples were collected before and the morning after PCI. There was no change in hemolysis related parameters leading to the assumption of no (or non-significant) device related hemolysis after the performance of the iVAC2L system, see Table 3 for details.

3.2. Clinical outcome

High-risk PCI was successful in all patients. Critical events were observed in three patients; 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 all three patients the critical events could be adequately treated and PCI successfully accomplished. The support device helped to maintain stable hemodynamic conditions with no need for cardiopulmonary resuscitation, fluid infusion or application of vasoactive agents in these patients. Whereas no significant drop in aortic pressure was noted in patients with no complications during PCI, systolic pressure in the ascending aorta 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 all three patients.

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Table 2
Patient baseline characteristics (* = patient with pulsatile hemodynamic support in the aortic arch; S3VD = severe three-vessel disease; cLM = complex left main; LRV = last remaining vessel; SYNTAX = SYNTAX I score).

Pat.-Nr.	Sex (m/f)	Age (years)	Size (m)	Weight (kg)	BSA (m^2)	disease	EF (%)	Syntax
1	m	75	1.74	75	1.90	S3VD	31	33
2	m	68	1.72	100	2.12	cLM	45	31
3	m	81	1.79	75	1.93	cLM	55	33
4	m	72	1.78	82	2.00	S3VD	25	30.5
5	f	79	1.58	54	1.54	cLM	40	30
6	m	53	1.83	86	2.08	cLM	46	32
7	m	64	1.76	72	1.88	S3VD	29	33
8	m	86	1.60	70	1.73	S3VD	21	35
9	m	80	1.75	80	1.96	cLM	63	23
10	m	74	1.80	80	2.00	S3VD	38	26
11	m	70	1.72	82	1.95	S3VD	36	34
12	f	81	1.68	118	2.24	cLM	55	27
13	m	63	1.81	90	2.11	cLM	50	30
14	m	71	1.83	91	2.13	cLM	55	32
15	m	53	1.70	85	1.97	cLM	40	23
16*	m	76	1.71	100	2.11	LRV	46	34
17	m	73	1.63	74	1.80	cLM	39	36
18	m	59	1.73	60	1.72	S3VD	63	22
19	m	82	1.78	82	2.00	cLM	46	32
20	f	77	1.68	67	1.76	cLM	52	27.5

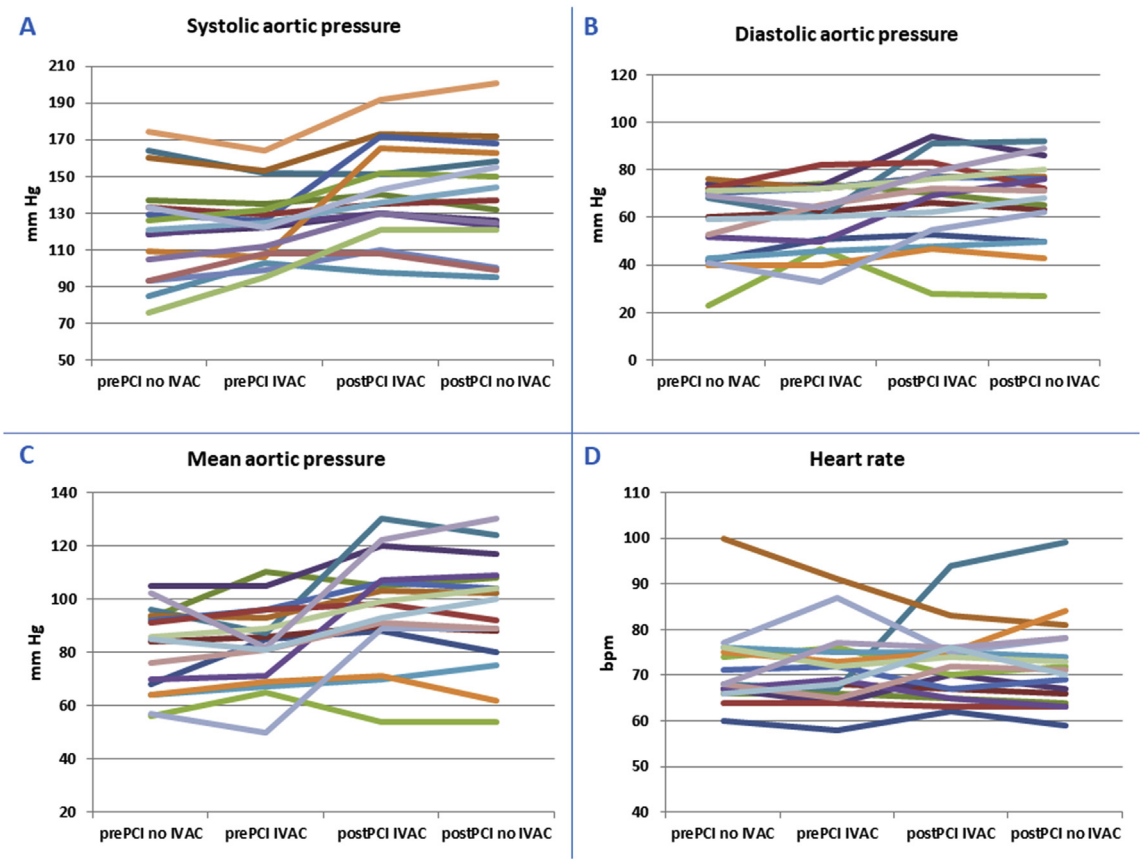

Fig. 2. Changes in systolic (A), diastolic (B) and mean (C) aortic pressure at no support (prePCI no iVAC), early support before PCI (5 min after iVAC2l start = prePCI iVAC), late support (immediately after PCI completion = postPCI iVAC) and no support after PCI (postPCI no iVAC) for the individual patients. D: Individual heart rates at the mentioned measure time points.

After PCI one severe bleeding with aneurysm of the femoral artery and one transitory ischemic attack (TIA) (≤24 h) occurred. The patient with the false aneurysm was successfully treated by vascular surgery. The patient with TIA was monitored in our stroke unit for 48 h; serial cerebral imaging revealed no stroke delineation.

All patients could be normally discharged from the hospital. After a follow up of 7 ± 4.2 months no patient died. One patient suffered a stent thrombosis 89 days after PCI; in this patient dual antiplatelet therapy was interrupted four weeks after PCI because of high bleeding risk. PCI with a drug eluting balloon was performed establishing TIMI III flow in the vessel.

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Table 3
Parameters of hemolysis before and after iVAC2L support.

	Pre-PCI	Post-PCI	p
LDH (U/l)	240 ± 90	241 ± 68	0.963
Bilirubin (mg/dl)	0.43 ± 0.15	0.38 ± 0.13	0.08
Haptoglobin (mg/l)	1485 ± 689	1261 ± 648	0.07

4. Discussion

To our best knowledge we report the results of the largest prospective single-centre study of high-risk coronary intervention under circulatory support with the iVAC2L device. Furthermore, we report for the first time, to our best knowledge, the potential clinical benefit of this device in the management of critical conditions during high-risk PCI. The pulsatile circulatory support provided by the iVAC2L device helped to maintain stable hemodynamic conditions with no need for cardiopulmonary resuscitation or application of vasoactive agents in three patients with critical situations during high-risk PCI. During the pulsatile circulatory support, the aortic pressure increased continuously and was significantly higher at PCI completion as compared to the baseline and early support values.

Den Uil and colleagues investigated previously the feasibility and safety of the iVAC2L support as well as changes in hemodynamic parameters in 14 patients undergoing high-risk PCI [13]. They reported an increase in mean arterial pressure and cardiac output during a mean support time of 67 min, but their patients received fluid substitution (besides contrast agent infusion) during the procedures [13]. In contrast, our patients did not receive additional fluids (except for contrast agent) and the mean support time was twice as long. Our results confirm similar pulsatile blood flow levels provided by the iVAC2L device and an increase in the aortic pressure during circulatory support, ruling out the potential influence of large fluid amounts infusion on these parameters.

Most surgical myocardial revascularisation procedures are supported by extracorporal circulation to guarantee sufficient hemodynamic stability for cerebral or systemic perfusion. Similar to CABG, sufficient CO and coronary perfusion is mandatory during high-risk PCI, where a sudden drop in CO may occur, due to unpredictable critical events or complications. Several circulatory supporting devices have been developed to help in managing these situations [14]. The IABP, mainly used in patients with cardiogenic shock, was assumed to increase coronary perfusion and increase CO by up to 0.5 L/min, but the device failed to show a lower mortality rate or circulatory benefits in the IABP-SHOCK II trial [3]. In contrast, some smaller trials suggest a potential benefit of IABP use in patients undergoing high-risk PCI [4–6]. Data on alternative left ventricular assist devices or extra-corporal membrane oxygenation (ECMO) support during high-risk PCI are limited. The implantation of these devices is complex and specialized technical staff is often required [14]. In a previously published single centre study ECMO support in elective high-risk PCI patients showed no periprocedural major adverse cardiac and cerebrovascular events (MACCE) or death during a follow up of six months [15]. However, there is still lack of evidence for mortality benefit and its general use in high-risk PCI is therefore not recommended.

In the last years the use of Impella 2.5 (ABIOMED, Danvers, MA, USA) device has progressively increased in patients undergoing elective high-risk PCI. This device generates a continuous flow supporting the cardiac output by up to 2.5 l/min. The use of Impella 2.5 failed to show a reduction in major adverse events during the first 30 days as compared to IABP in patients undergoing high-risk PCI in the PROTECT II Trial [10]. However, a trend to a better outcome after 90 days was noticed in the intention to treat analysis in the same trial. In a recently published retrospective cross-sectional analysis Ameloot et al. compared the clinical outcome in 69 patients undergoing high-risk PCI under mechanical circulatory support (MCS) by new generation assist devices (including iVAC2L, Impella CP and Heartmate PHP) and 129 control high-risk PCI patients without MCS [16]. They reported a significant lower combined end point of death, cardiac arrest, need for vasopressors, rescue MCS, endotracheal intubation and limb ischemia with need for surgery as well as a significant higher 30-days survival in MCS protected high-risk PCI patients as compared to the control group. The clinical data in our study with 100% survival after a follow up of 7 ± 4.2 months are similar to those from the analysis by Ameloot and colleagues and confirm the safety of the iVAC2l use in high-risk PCI patients.

The iVAC2L device, which was investigated in our study, has a larger diameter and is inserted via a larger SoloPath sheath with a maximum diameter of 19F when compared to the Impella 2.5 device and the 13F peel away sheath used for its implantation. The need for placement of a larger introduction sheath might limit implantation success of iVAC2L (as in two patients of our study) when compared to Impella 2.5. Furthermore, a prolonged support duration by iVAC2L may lead to a higher rate of limb ischemia, comparable to the one caused by other extra-corporal membrane oxygenation systems. However, the rate of access site complications was low in our study. The routinely use of pre-procedural non-invasive imaging modalities (computed tomography or magnetic resonance imaging) for angiographic evaluation should improve the selection of patients with adequate conditions at access site.

In a subgroup of seven patients blood samples before and after iVAC2L support revealed no significant changes in haemolytic parameters. That might be a potential advantage of the IVAC2L over the Impella 2.5 usage, especially in patients, in whom longer support duration is needed. However, randomized comparisons are warranted to investigate potential advantages of pulsatile over continuous flow devices regarding survival, hemodynamic improvement or hemolytic issues.

5. Conclusion

Circulation support by the iVAC2L device in patients undergoing high-risk PCI is feasible and safe. Aortic pressure increases with continuous support. The relatively low (as compared to other assist devices) but ECG-triggered pulsatile flow provided by the iVAC2L device, helps to stabilize hemodynamic conditions during coronary intervention, especially if severe complications or critical events occur.

Potential advantages of pulsatile over continuous flow assist devices regarding performance, survival or hemodynamic issues need to be investigated in larger multi-centre randomized trials.

Conflicts of interest

The authors have no conflicts of interest to declare.

References

[1] S. Kar, Percutaneous mechanical circulatory support devices for high-risk percutaneous coronary intervention, Curr. Cardiol. Rep. 20 (2018) 2.
[2] Authors/Task Force m, S. Windecker, P. Kolh, F. Alfonso, J.P. Collet, J. Cremer, et al., ESC/EACTS guidelines on myocardial revascularization: the task force on myocardial revascularization of the european society of cardiology (ESC) and the european association for cardio-thoracic surgery (EACTS)developed with the special contribution of the european association of percutaneous cardiovascular interventions (EAPCI), Eur. Heart J. 35 (2014) (2014) 2541–2619.
[3] H. Thiele, U. Zeymer, F.J. Neumann, M. Ferenc, H.G. Olbrich, J. Hausleiter, et al.,

Please cite this article as: A. Samol et al., High-risk PCI under support of a pulsatile left ventricular assist device – First German experience with the iVAC2L system, International Journal of Cardiology, https://doi.org/10.1016/j.ijcard.2019.10.020

Intra-aortic balloon counterpulsation in acute myocardial infarction complicated by cardiogenic shock (IABP-SHOCK II): final 12 month results of a randomised, open-label trial, Lancet 382 (2013) 1638–1645.
[4] D. Perera, R. Stables, T. Clayton, K. De Silva, M. Lumley, L. Clack, et al., Long-term mortality data from the balloon pump-assisted coronary intervention study (BCIS-1): a randomized, controlled trial of elective balloon counterpulsation during high-risk percutaneous coronary intervention, Circulation 127 (2013) 207–212.
[5] S. Mishra, W.W. Chu, R. Torguson, R. Wolfram, R. Deible, W.O. Suddath, et al., Role of prophylactic intra-aortic balloon pump in high-risk patients undergoing percutaneous coronary intervention, Am. J. Cardiol. 98 (2006) 608–612.
[6] C. Briguori, C. Sarais, P. Pagnotta, F. Airoldi, F. Liistro, F. Sgura, et al., Elective versus provisional intra-aortic balloon pumping in high-risk percutaneous transluminal coronary angioplasty, Am. Heart J. 145 (2003) 700–707.
[7] H. Thiele, P. Sick, E. Boudriot, K.W. Diederich, R. Hambrecht, J. Niebauer, et al., Randomized comparison of intra-aortic balloon support with a percutaneous left ventricular assist device in patients with revascularized acute myocardial infarction complicated by cardiogenic shock, Eur. Heart J. 26 (2005) 1276–1283.
[8] M. Seyfarth, D. Sibbing, I. Bauer, G. Frohlich, L. Bott-Flugel, R. Byrne, et al., A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction, J. Am. Coll. Cardiol. 52 (2008) 1584–1588.
[9] K. Ergle, P. Parto, S.R. Krim, Percutaneous ventricular assist devices: a novel approach in the management of patients with acute cardiogenic shock, Ochsner J. 16 (2016) 243–249.
[10] W.W. O'Neill, N.S. Kleiman, J. Moses, J.P. Henriques, S. Dixon, J. Massaro, et al., A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study, Circulation 126 (2012) 1717–1727.
[11] N.M. Van Mieghem, J. Daemen, M.J. Lenzen, R. Zandstra, O. Malkin, R.J. van Geuns, The PulseCath iVAC 2L left ventricular assist device: conversion to a percutaneous transfemoral approach, EuroIntervention 11 (2015) 835–839.
[12] A. Amico, M.S. Brigiani, A. Vallabini, B. Ferrante, A. Marzovillo, D. Loizzi, et al., PulseCath, a new short-term ventricular assist device: our experience in off-pump coronary artery bypass graft surgery, J. Cardiovasc. Med. 9 (2008) 423–426.
[13] C.A. den Uil, J. Daemen, M.J. Lenzen, A.M. Maugenest, L. Joziasse, R.J. van Geuns, et al., Pulsatile iVAC 2L circulatory support in high-risk percutaneous coronary intervention, EuroIntervention 12 (2017) 1689–1696.
[14] H.A. Jones, D.R. Kalisetti, M. Gaba, D.J. McCormick, S. Goldberg, Left ventricular assist for high-risk percutaneous coronary intervention, J. Invasive Cardiol. 24 (2012) 544–550.
[15] S.D. Tomasello, M. Boukhris, V. Ganyukov, A.R. Galassi, D. Shukevich, B. Haes, et al., Outcome of extracorporeal membrane oxygenation support for complex high-risk elective percutaneous coronary interventions: a single-center experience, Heart Lung 44 (2015) 309–313.
[16] K. Ameloot, M.B.B., J. Daemen, J. Schreuder, E. Boersma, F. Zijlstra, et al., New Generation mechanical circulatory support during high-risk PCI: a cross sectional analysis, EuroIntervention 15 (2019) 427–433.

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