Head to head comparison of a pulsatile and a continuous flow left ventricular assist device in high-risk PCI setting – iVAC2L vs. Impella 2.5

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INTRODUCTION

Due to significant progress in interventional techniques, percutaneous coronary intervention (PCI) has become an alternative therapy to coronary bypass surgery in complex stenosis. Several circulatory support devices have been developed to support cardiac output or maintain sufficient circulation in critical situations or complications during PCI. We compared in a prospective trial the hemodynamic and clinical performance of a new trans-femoral pulsatile assist device (iVAC2L) with the most used continuous flow assist device (Impella 2.5) in high-risk PCI patients.

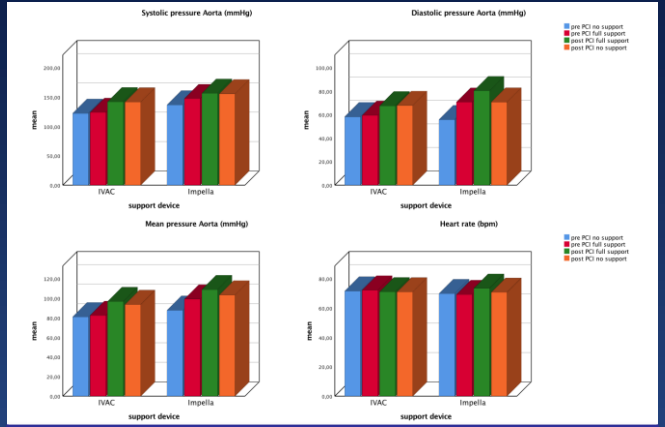
PATIENTS AND METHODS:

In 40 patients [10 female, age 75±8 years, left ventricular ejection fraction (LVEF) 44±11%] high-risk PCI (complex left main n=28, last remaining vessel n=5, severe three vessel disease and reduced LVEF n=7) was performed under circulatory support with the Impella 2.5 (n=20) or IVAC2L system (n=20). Aortic pressure data and flow measurements were collected before and after device placement as well as immediately after PCI. Blood parameters of hemolysis were collected before and after support.

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

THE iVAC2L DEVICE

- pVAD = percutaneous (left-) ventricular cardiac assist device
- Application: up to 24 hours
- Support performance: up to 2 liter/min.
- Pump concept: pulsatile – aspiration from LV during systole, ejection into ascending aorta during diastole
- Driven by any commercial-available IABP console



		prePCI (no)	prePCI (full)	postPCI (no)	postPCI (full)
iVAC2L	RRsyst Ao (mmHg, mean±SD)	123±28	125±21%	142±28*	142±31#,$,+
Impella 2.5	RRsyst Ao (mmHg, mean±SD)	136±23	146±29%,&	154±22*	156±21#
iVAC2L	RRdiast Ao (mmHg, mean±SD)	58±16	59±14	68±18*	69±18#,$
Impella 2.5	RRdiast Ao (mmHg, mean±SD)	55±13	70±18&	79±16*	71±17#,§
iVAC2L	RRmean Ao (mmHg, mean±SD)	82±16	83±16%	97±21*	94±27#,$
Impella 2.5	RRmean Ao (mmHg, mean±SD)	87±15	98±19%,&	107±15*	103±16#,§
iVAC2L	Haptoglobin (mg/l, mean±SD)	1607±741			1261±648
Impella 2.5	Haptoglobin (mg/l, mean±SD)	1651±762			1211±626#
iVAC2L	LDH (U/l, mean±SD)	240±90			241±68
Impella 2.5	LDH (U/l, mean±SD)	227±80			256±91

Table 1 (Ao = Aorta, * = p < 0.05 prePCI (no support) vs. postPCI (full support); # = p < 0.05 prePCI (no support) vs. postPCI (no support) , § = p < 0.05 prePCI (full support) vs. postPCI (full support); & = p < 0.05 prePCI (no support) vs. prePCI (full support); % = p < 0.05 iVAC vs. Impella.

RESULTS:

Patients in the Impella group were significantly older. Correct device placement was achieved in 17 (85%) patients in the iVAC2L-group and in 19 (95%) patients in the Impella-group (p=n.s.).
There was no early increase in systolic, diastolic and mean aortic blood pressure under full iVAC2L-support, but with prolonged support time these parameters increased significantly and kept their higher level (Table 1). In contrast, systolic, diastolic and mean aortic pressure increased significantly immediately after starting Impella-support, but with increasing support the increase in these hemodynamic parameters was comparable between the two groups after PCI. Continuous flow generated by the Impella device was significantly higher before and after PCI, as compared to the pulsatile flow generated by the iVAC2L device (2.07±0.09l/min vs. 1.25±0.05l/min, p<0.001).

CLINICAL OUTCOME

- Except for contrast agent (295±77ml), no fluids were infused.
- PCI success was 97%
- Mean support time was significantly shorter under Impella use (122±32min vs. 94±40min, p=0.03)
- In five patients (three under iVAC2L-support) critical events during PCI occurred (massive vasospasm, coronary perforation, no flow in LCA, II° -AV-block with hemodynamic significance, pericardial tamponade), but both devices helped to maintain stable hemodynamic conditions with no need for cardiopulmonary resuscitation.
- After PCI, one severe bleeding in each group (both due to aneurysm of the femoral artery) and one stroke ≤24h in iVAC2L-group occurred
- No signs of potential hemolysis were observed in both groups

CONCLUSIONS

- High-risk PCI under circulatory support with either the pulsatile iVAC2L or the continuous flow Impella 2.5 device is feasible and safe
- Aortic pressure increases under circulatory support with both devices, but seems to increase earlier under Impella support
- Potential differences between the two supporting systems with respect to patients' outcome or hemodynamic parameters need to be evaluated in large multi-center studies

no conflict of interest
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