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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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Interessenskonflikt

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Im Rahmen dieses Vortrages bestehen folgende Interessenkonflikte:

Referentenhonorar: nein

Forschungsförderung: TERUMO

Beratervertrag: nein

Background

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- Due to efforts in percutaneous coronary intervention (PCI) the interventional treatment of complex stenosis has become an alternative to coronary bypass surgery

- During PCI critical situations or complication may occur leading to unstable hemodynamic conditions with the need for sudden additional circulatory support

- In those situations circulatory support devices maybe helpful to generate additional cardiac output or maintain sufficient circulation

Objectives

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- We investigated the safety and efficacy, hemodynamic effects and potential hemolysis of the IVAC2L system, a new trans-femoral pulsatile assist device with up to 2l additional cardiac output, driven by a common IABP console in patients receiving high-risk-PCI

Methods

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- In 17 patients (3 female, age 73±9 years, LVEF 45±12% high-risk PCI (complex left main PCI n=8, PCI of last remaining vessel n=1, complex PCI in severe three vessel disease and reduced LVEF n=8) was performed under use of the IVAC2L system, a new trans-femoral pulsatile assist device with up to 2l additional cardiac output

- After device placement and immediately after PCI aortic and intracoronary pressure data were collected and flow measurements were performed, if necessary application of atropine i.v. was performed to keep heart rate ≥ 70bpm

- Before and after PCI blood samples were collected to investigate hemolytic effects of the device

Methods

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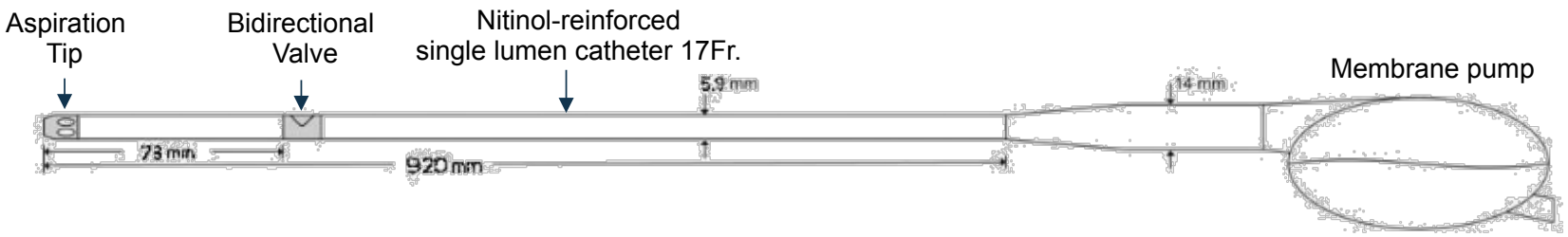
Inclusion criteria	Exclusion criteria
Indicated high-risk PCI	Aortic disease
Expected support duration <24h	Aortic valvular disease
Age > 18	Aortic mechanical valve prothesis
Written informed consent	Thrombus in left ventricle
	Ventricular septum defect
	Severe peripheral vasculare disease
	Coagulation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

What is iVAC2L™?

- pVAD = percutaneous (left-) ventricular cardiac asist 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 Konsole

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iVAC2L components

Membrane pump for connection with IABP console

Bidirectional Valve

Femoral access

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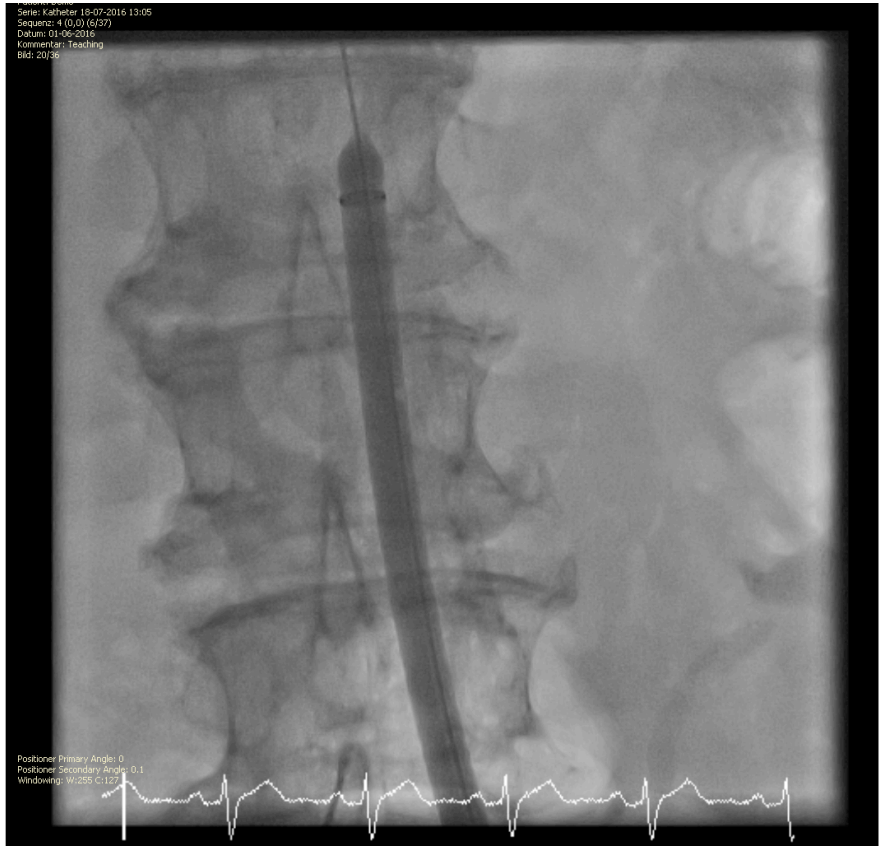
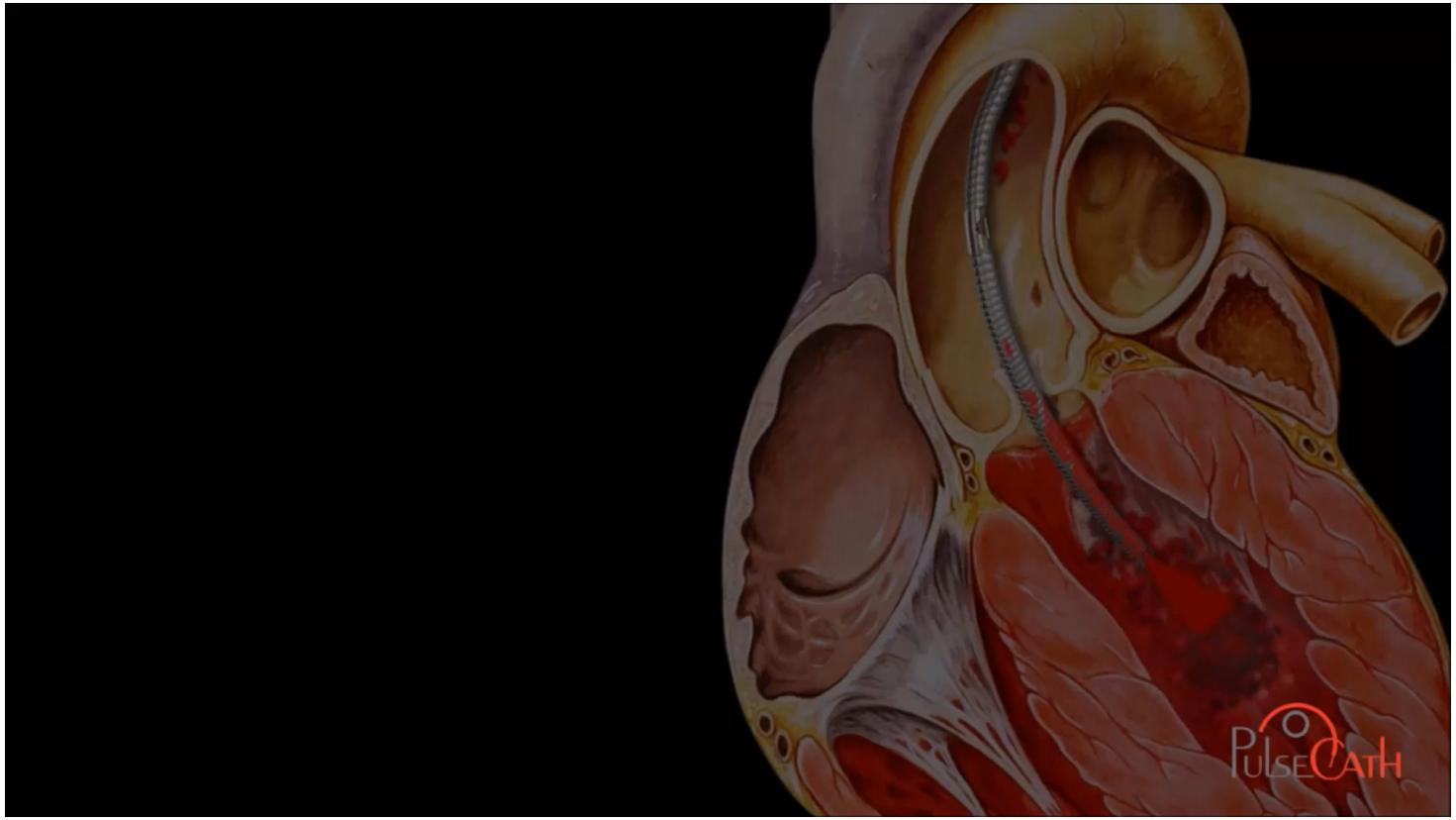


1. Insertion of vascular closure devices (z. B. ProGlide)
2. Solopath Balloon-expanding 19Fr sheet

Short Animation of the iVAC2L catheter

- Trigger/ Synchronization: ECG/ arterial pressure, driven by IABP-console
- Ejection into ascending aorta during diastole
  - ➔ The bi-directional valve in the catheter is opened
- Aspiration out of the left ventricle during systole
  - ➔ The bi-directional valve in the catheter is closed



Results

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- Correct device placement was achieved in 14 (82%) patients; in two patients device placement failed due to severe tortuosity of iliac and femoral artery, whereas in the remaining patient the device was too short for placement in the left ventricle

- Except for contrast agent (275±67ml), no fluids were infused. PCI success was 100%. Mean support time was 130±26min

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

- After PCI one severe bleeding due to an aneurysm of the femoral artery and one ischemic stroke ≤24h occurred

Results

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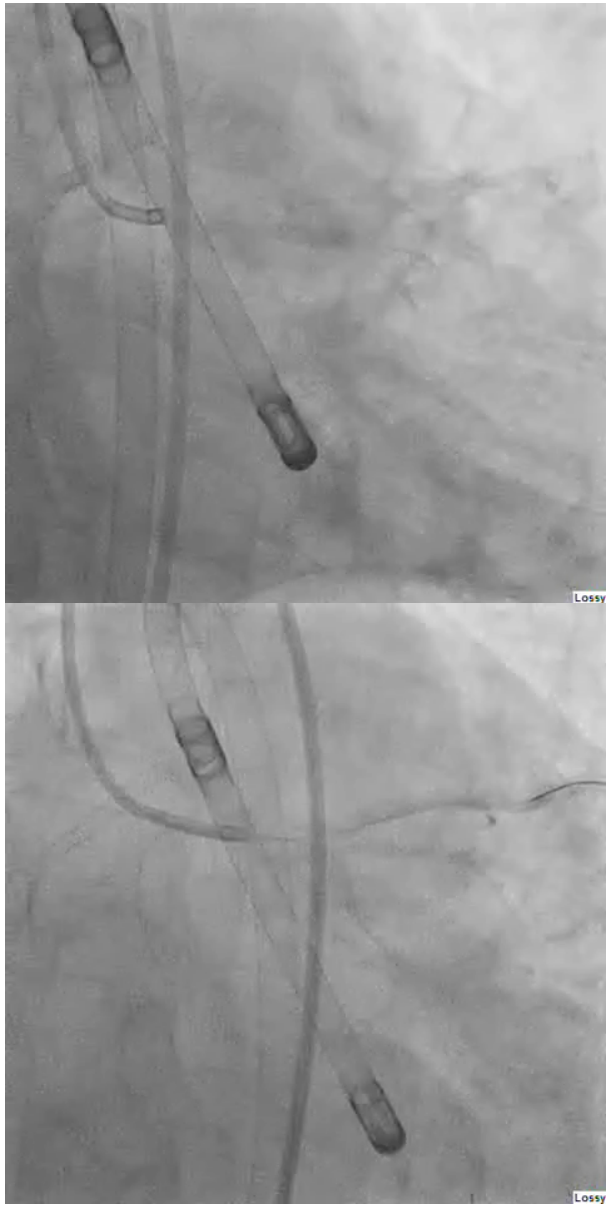

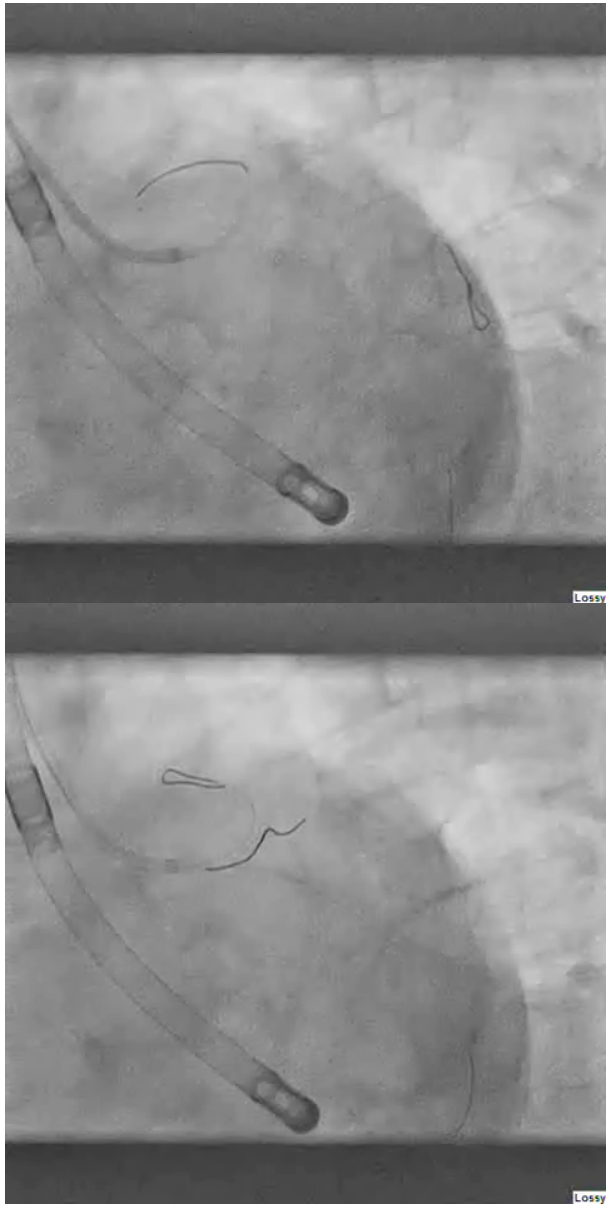

Results

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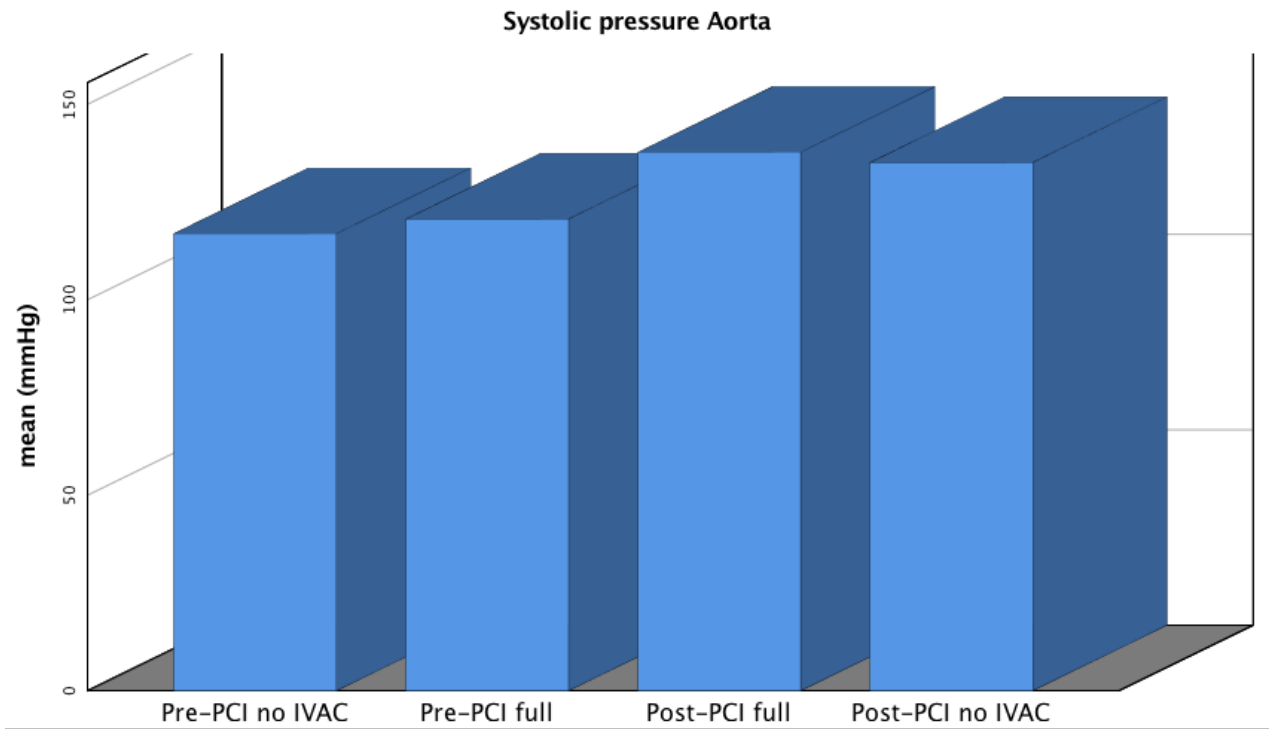

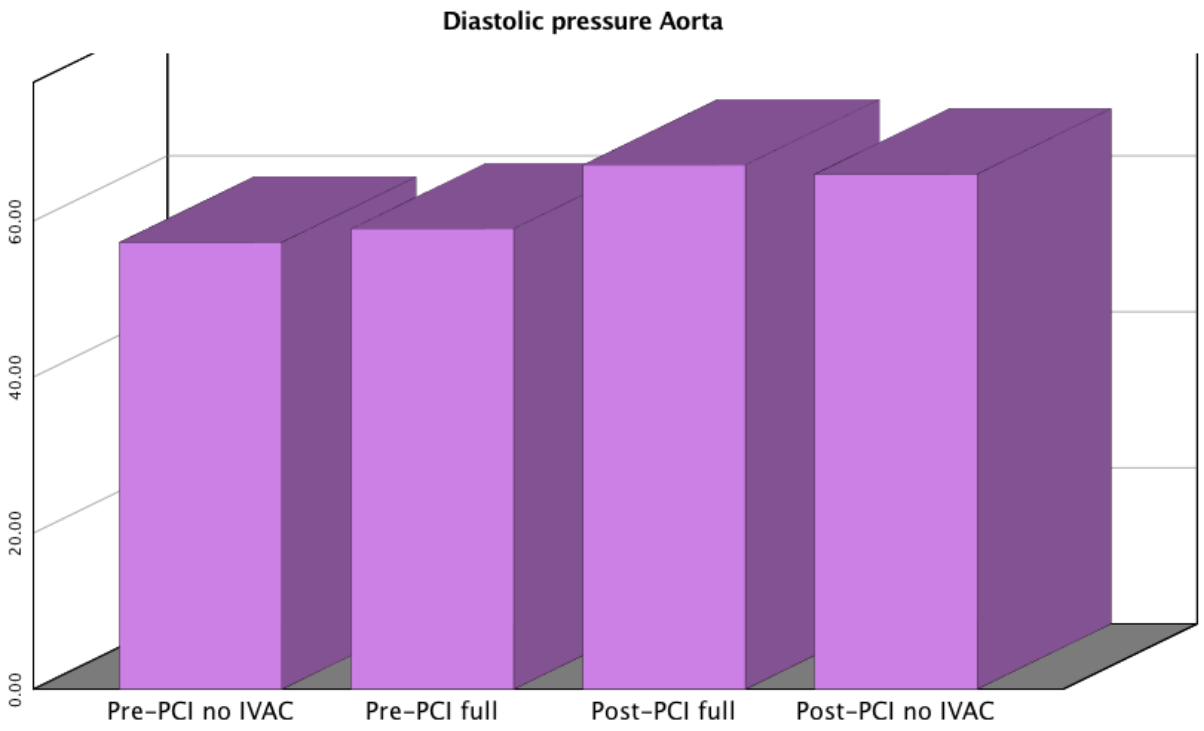

There was no early increase in systolic (119±27 vs. 122±19mmHg) or diastolic (56±17 vs. 59±15mmHg) under full iVAC2L-support, but with prolonged support time systolic (117±28 vs. 138±25mmHg, p=0.006), diastolic (58±18 vs. 68±20mmHg, p<0.001) increased significantly and kept the higher level.

Results

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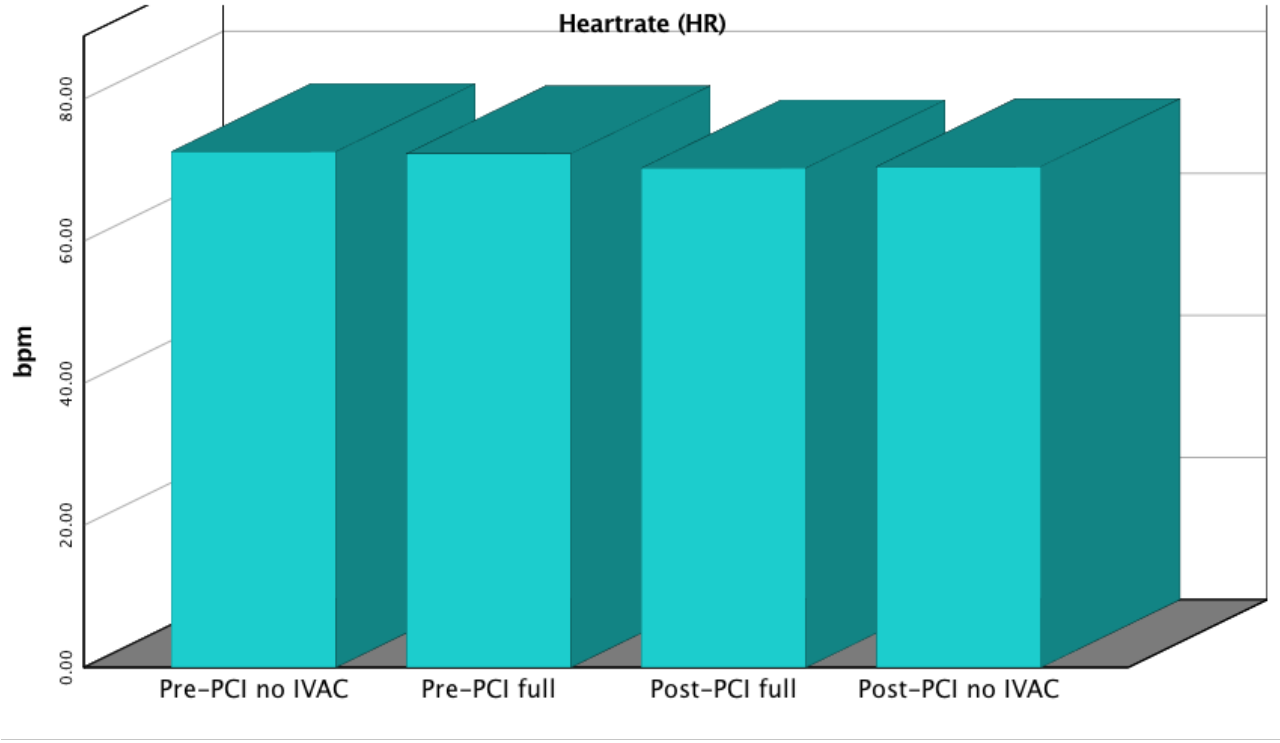

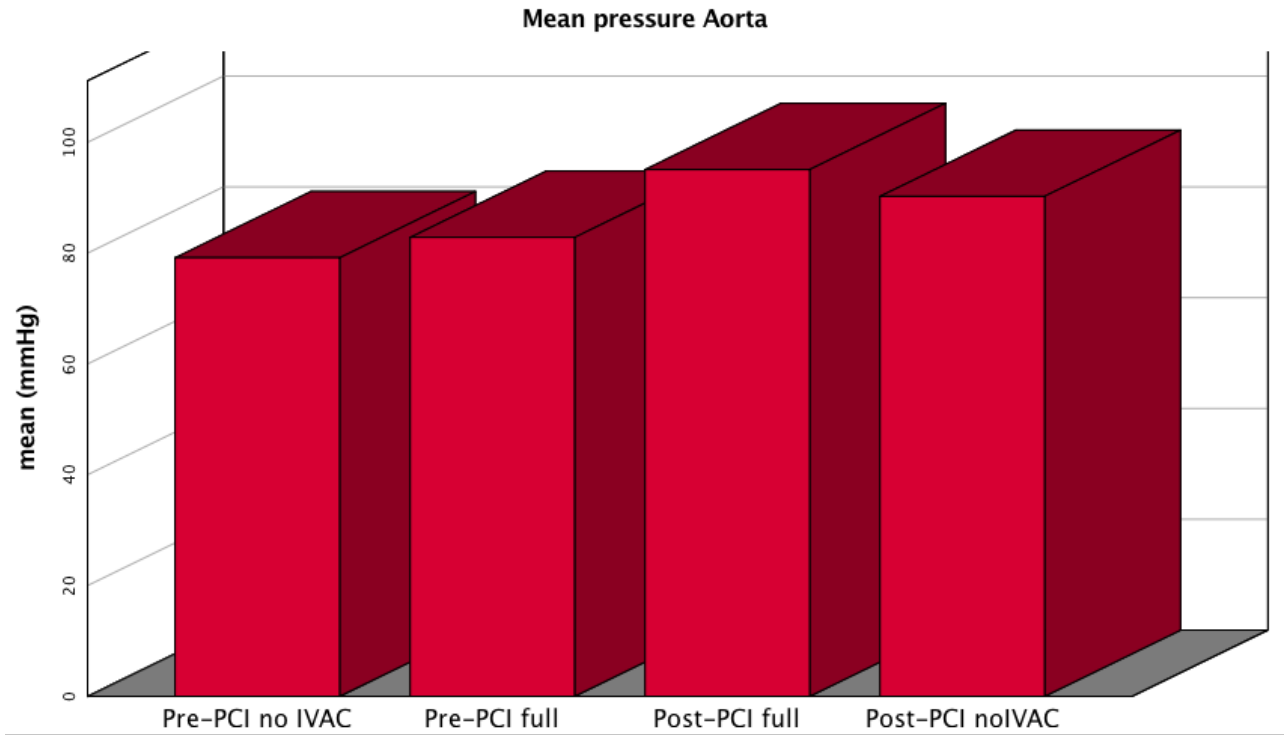

There was also no early increase in mean aortic blood pressure (80±17 vs. 83±18mmHg) under full iVAC2L-support, but with prolonged support time mean aortic pressure (80±17 vs. 95±21mmHg, p=0.001) increased significantly and kept the higher level.

Results

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Flow measurements

	Pre-PCI	Post-PCI	Heartrate (bpm)
1:1 support (l/min)	1.21±0.12	1.25±0.06	72±10
1:2 Support (l/min)	0.95±0.18	0.76±0.18	72±09
1:3 Support (l/min)	0.58±0.16	0.54±0.22	72±10

Flow measurements were performed in four patients

Results

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Parameters of hemolysis

	Pre-PCI	Post-PCI	p
LDH	195±36	215±53	0.321
Bilirubin	0.42±0.34	0.42±0.29	1.0
Haptoglobin	1814±490	1540±572	0.134
Free Hb	10.1±6.6	6.2±3.5	0.053

During mean support time of 130±26min no evidence for hemolysis was observed in 7 patients

Conclusion

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- High-risk PCI under hemodynamic support by the iVAC2L device is feasible and safe, aortic pressure seems to increase with continuous support

- The device seems to stabilize hemodynamic situation sufficiently, if complication during high-risk PCI occur

- Multi-center studies are required to further evaluate our observed iVAC2L effect on hemodynamic conditions and patients' outcome

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Thank you very much for your attention

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