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

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INTRODUCTION

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 these situations circulatory support devices maybe helpful to generate additional cardiac output or maintain sufficient circulation.

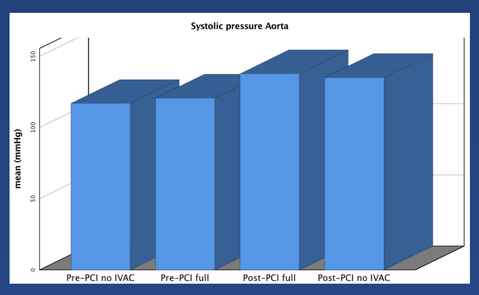
PATIENTS AND METHODS:

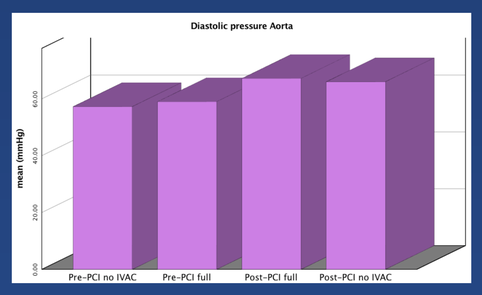
In 17 patients (3 female, age 73±9 years, left ventricular ejection fraction (LVEF) 45±12%) high-risk PCI (complex left main PCI n=8, PCI of last remaining vessel n=1, complex PCI in severe three vessel disease and reduced LVEF n=8) was performed under use of the iVAC2L system, a new trans-femoral pulsatile assist device with up to 2l additional cardiac output. Before and after device placement as well as immediately after PCI aortic and intracoronary pressure data were collected.

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

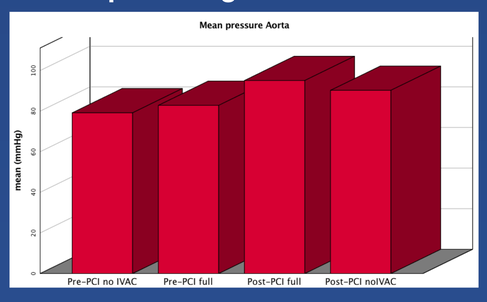
RESULTS:

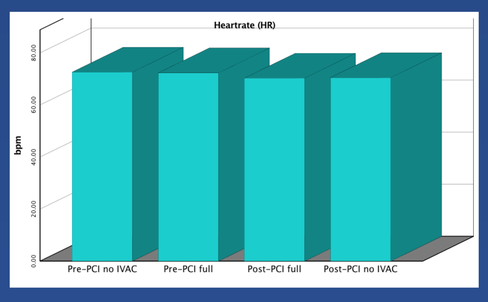
Correct device placement was achieved in 14 (82%) patients; in two patients device placement failed due to severe tortuosity of iliac and femoral artery, whereas in the remaining patient the device was too short for placement in the left ventricle





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





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.

THE iVAC2L DEVICE

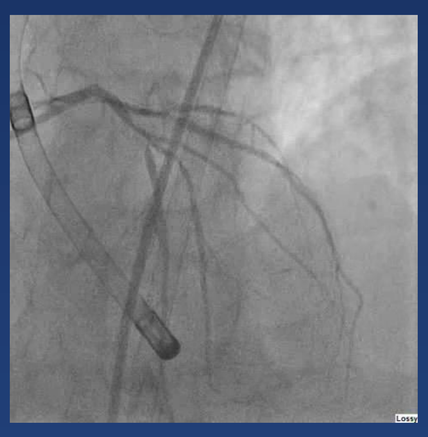
-pVAD = percutaneous (left-) ventricular cardiac assist device
-Application: up to 24 hours
-Support performance: up to 2 liter/min.
-Pump concept: pulsatile – aspiration from LV during systole, ejection into ascending aorta during diastole
-Driven by any commercial-available IABP console

17F nitinol pump catheter with tip and bidirectional valve

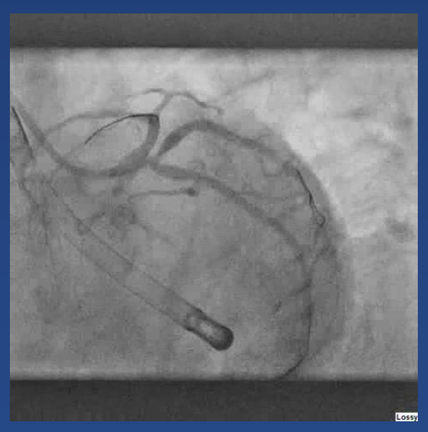
Membrane pump connected to IABP console inserted via SoloPath sheet

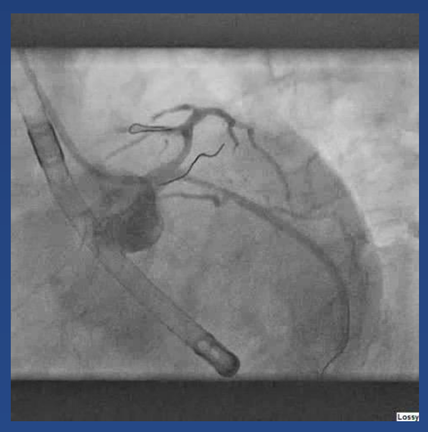
CLINICAL OUTCOME

-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:

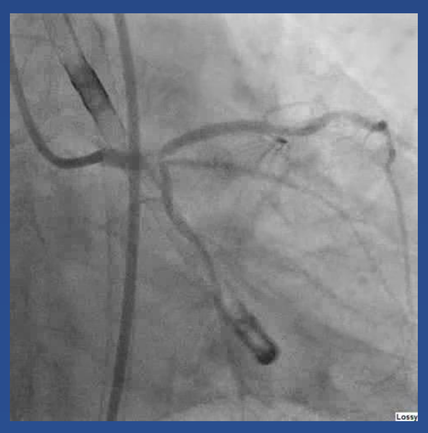


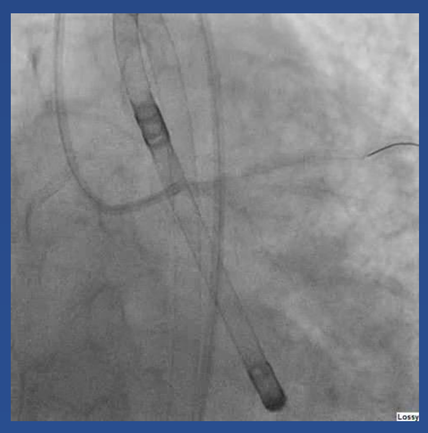
Coronary perforation





Massive vasospasm





No flow 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

CONCLUSIONS

- **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**

No conflict of interests

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