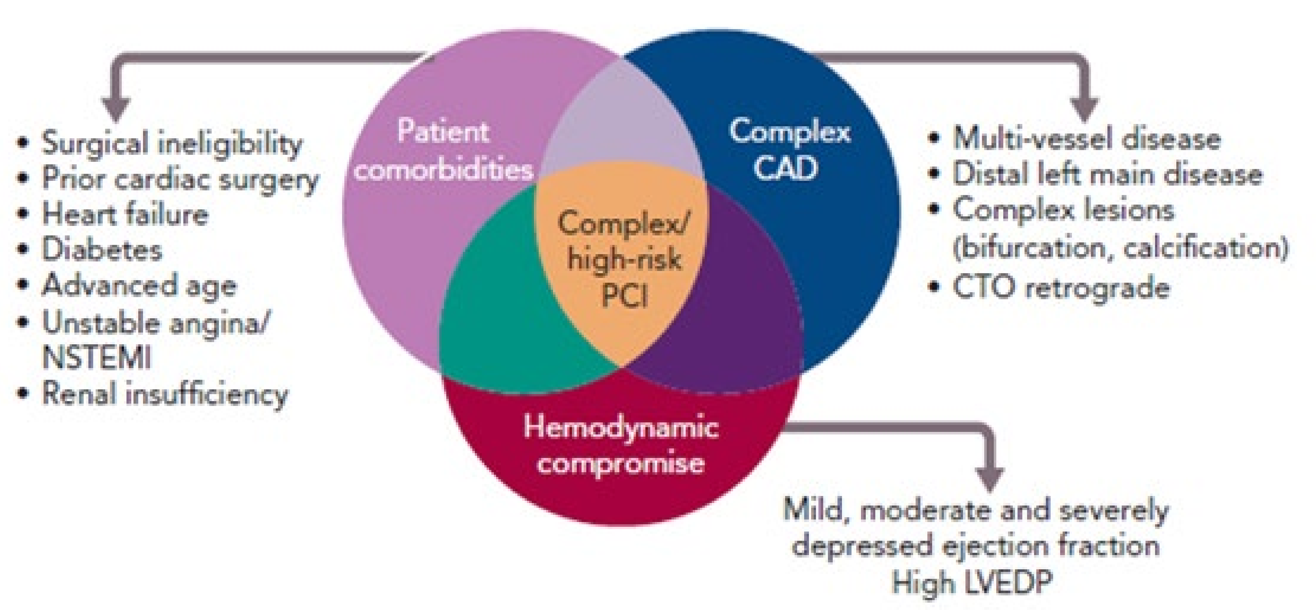
Mechanical Circulatory Support &
High-Risk Percutaneous Coronary Intervention

Purpose of protected High-Risk PCI with pVAD

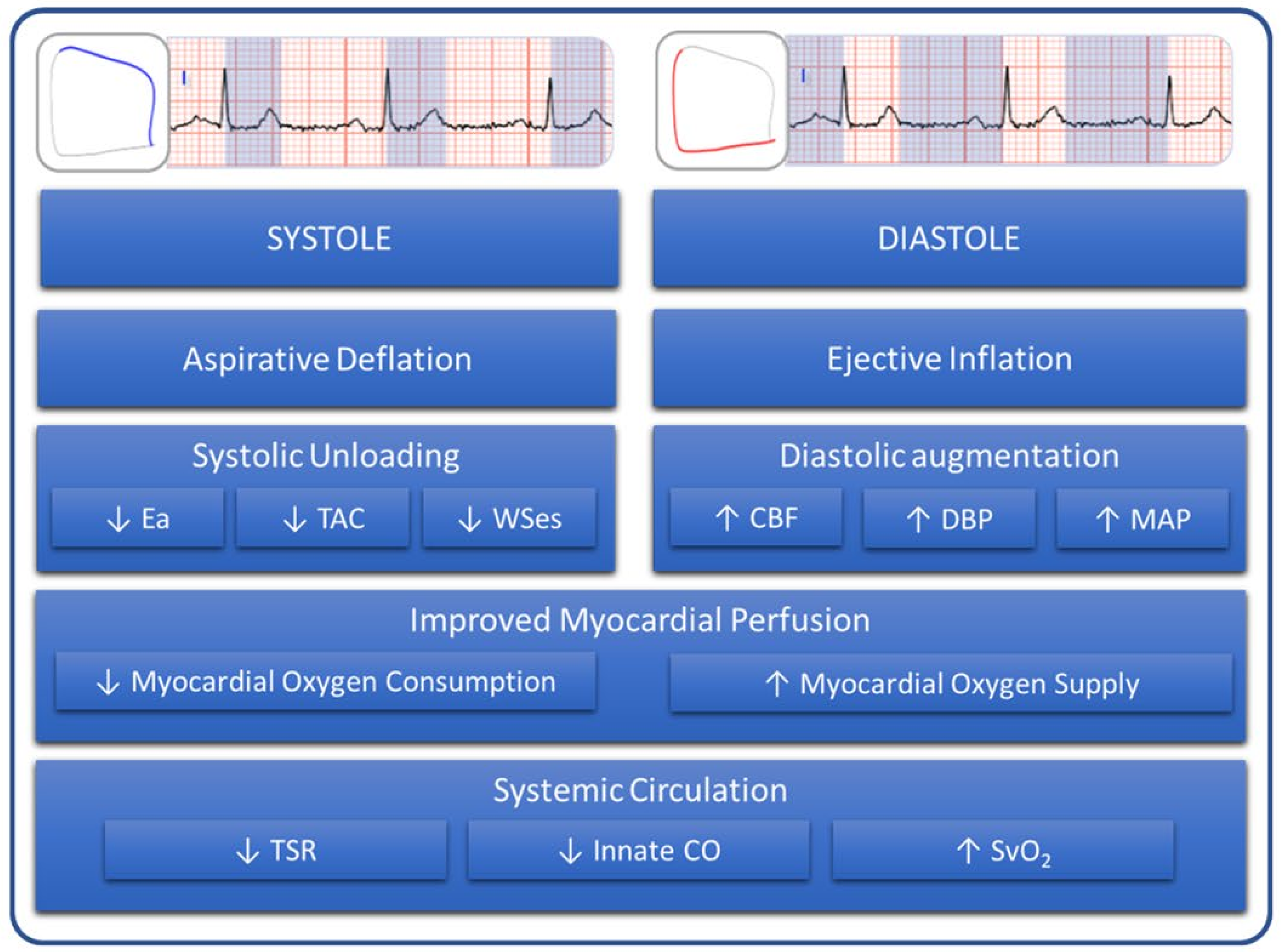
In-hospital mortality rate of high-risk PCI patients is higher than usual, and may reach 28% after 30 days. The aims of prophylactic Mechanical Circulatory Support (MCS) in the setting of high-risk PCI are to assure hemodynamical from the first minutes of the intervention. This may reduce the risk of profound hypotension or deterioration to cardiogenic shock during coronary manipulation, and allow sufficient time to achieve optimal and complete revascularization[1, 2].

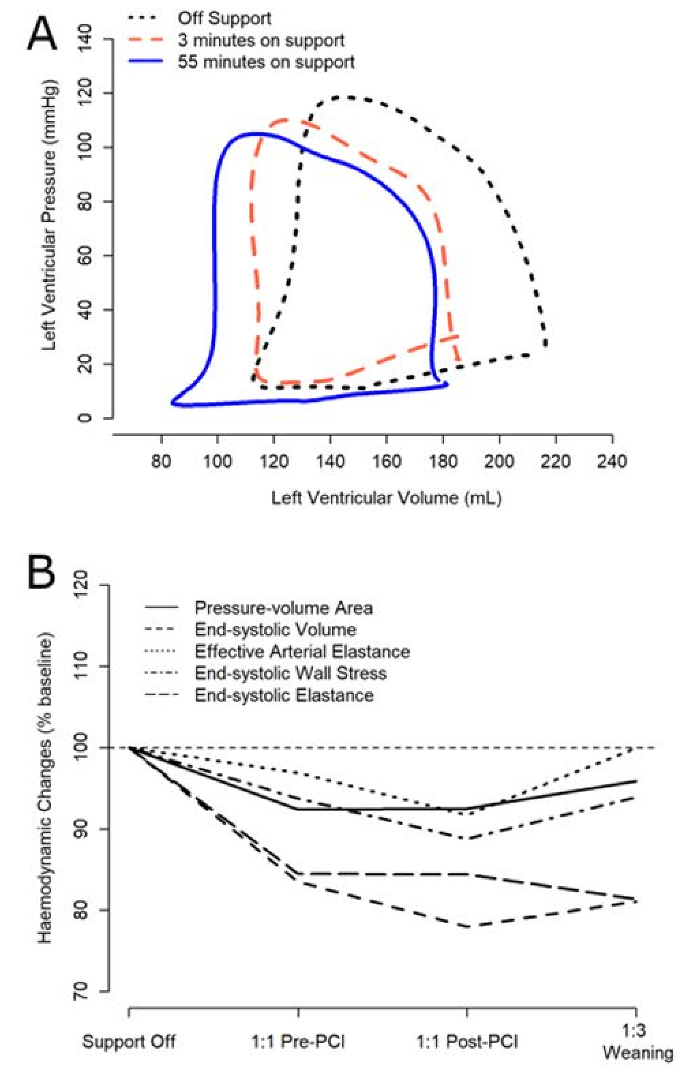
Growing population of complex High-Risk PCI who could benefit from hemodynamic support[3]



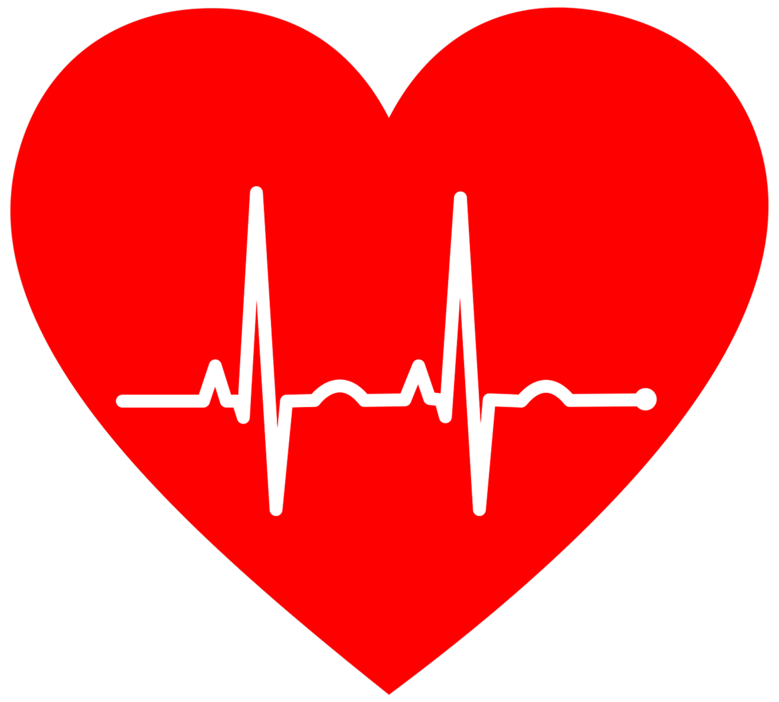
CAD = coronary artery disease; CTO = chronic total occlusion; LVEDP = left ventricular end-diastolic pressure; NSTEMI = non-ST elevation MI; PCI = percutaneous coronary intervention. Adapted with permission from Abiomed 'Protected PCI' Clinical Dossier 2020.

Summary of hemodynamic effects of pulsatile MCS with iVAC 2L[4]



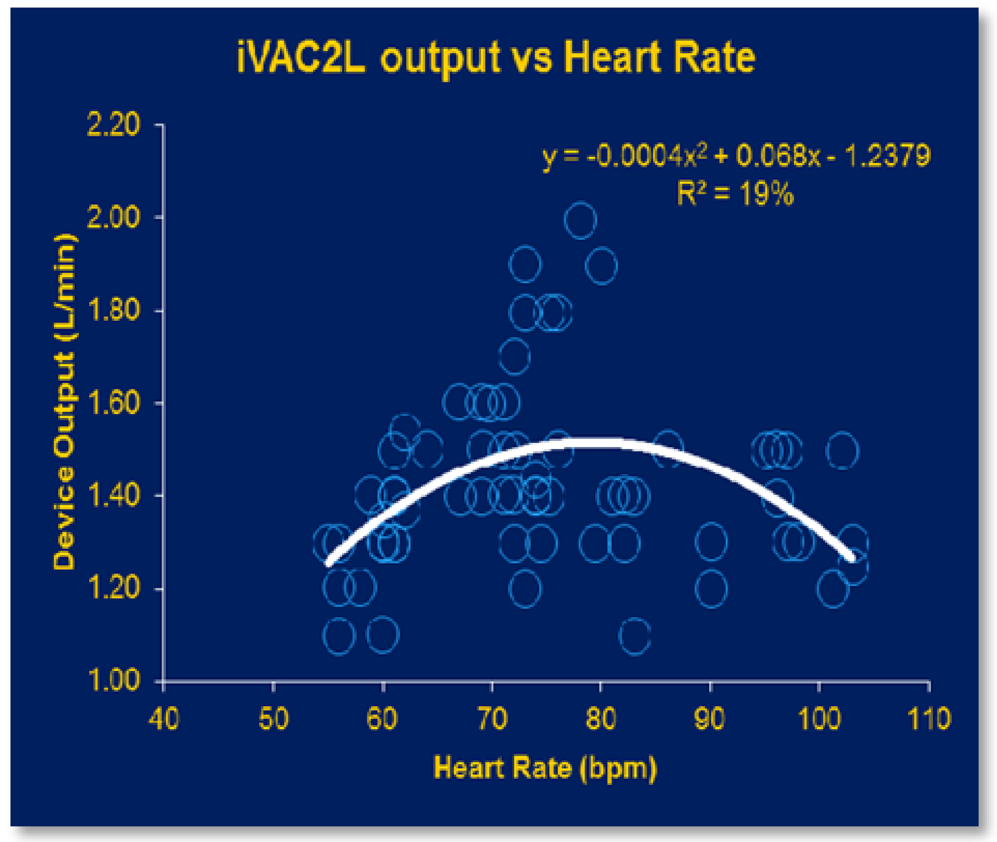


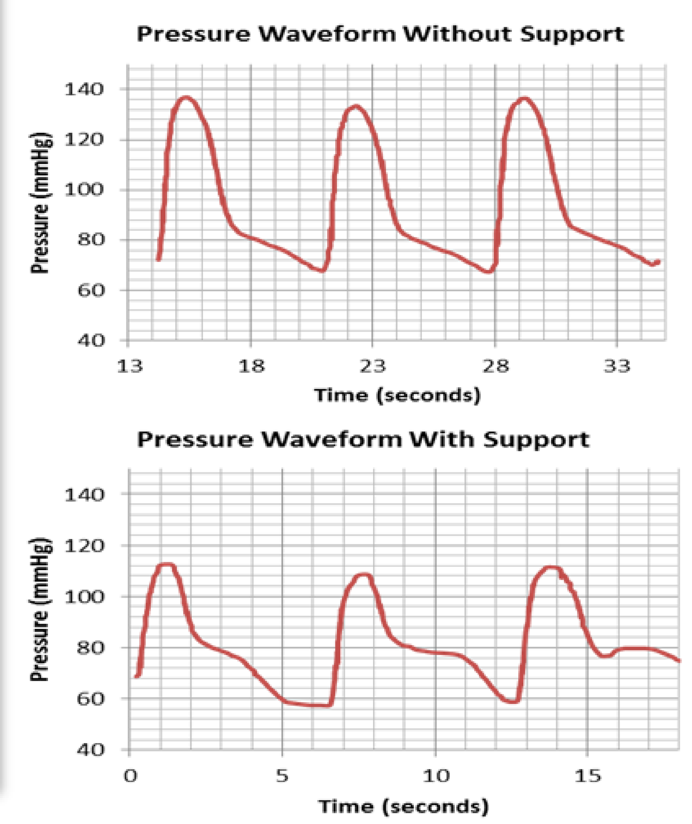
(Left panel) In systole, aspirative deflation is most commonly set to occur between the QRS complex and the end of the T wave of the electrocardiogram. Left ventricular blood is aspirated and systolic unloading reduces Ea, TAC and end-systolic WSes. Myocardial oxygen consumption decreases as a consequence of reduced afterload. In diastole, iVAC2L ejects the volume of blood stored in the extracorporeal dual chamber back into the aorta (ejective inflation) increasing the aortic DBP and the MAP. CBF increases in diastole and improves myocardial oxygen supply. The cardiac output of the native heart (innate CO) decreases as iVAC2L assumes part of the systolic workload. The optimized hemodynamic setting induces improvements in TSR and in the SvO2. CBF: Coronary blood flow; CO: Cardiac output; DBP: Diastolic blood pressure; Ea: Effective arterial elastance; MAP: Mean arterial pressure; SvO2: Mixed venous oxygen saturation; TAC: Total arterial compliance; TSR: Total systemic resistance; WSes: Wall stress



iVAC 2L overview[4, 5]

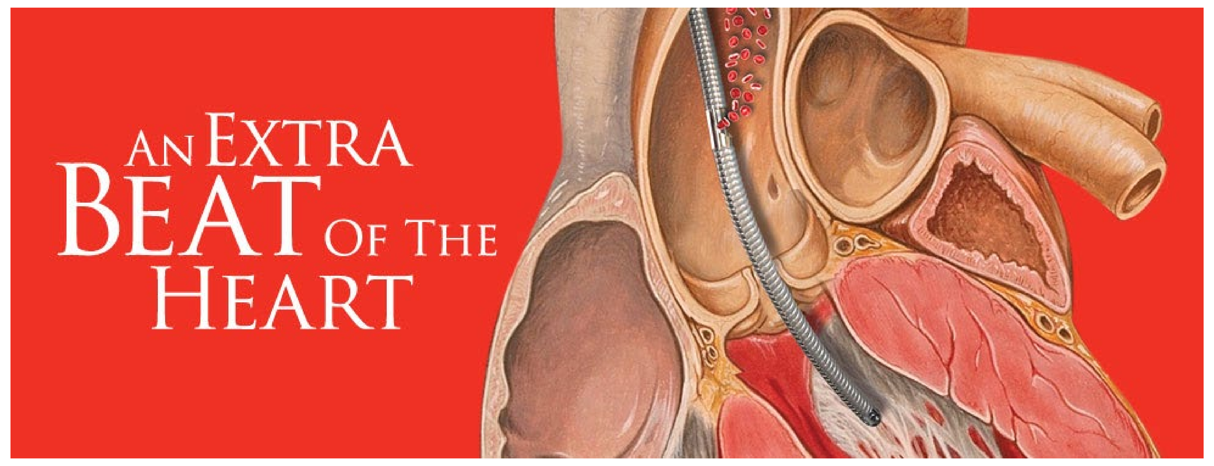
- Bi-directional flow
- Entirely percutaneous
- LV-to-aorta support
- 21mL added to the innate SV
- Counter-pulsation
- Driven by an IABP console





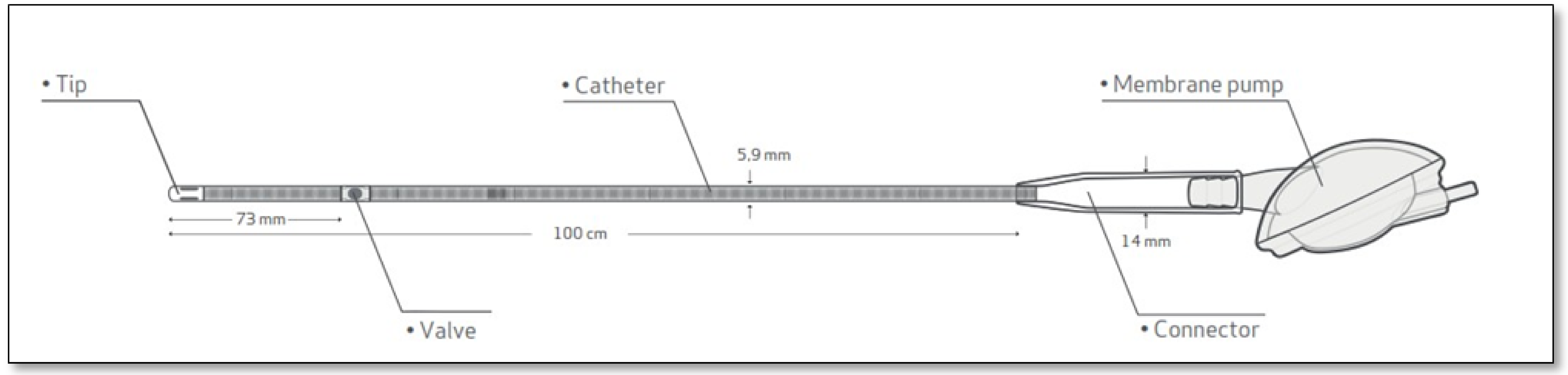
Continous vs pulsatile flow[4]

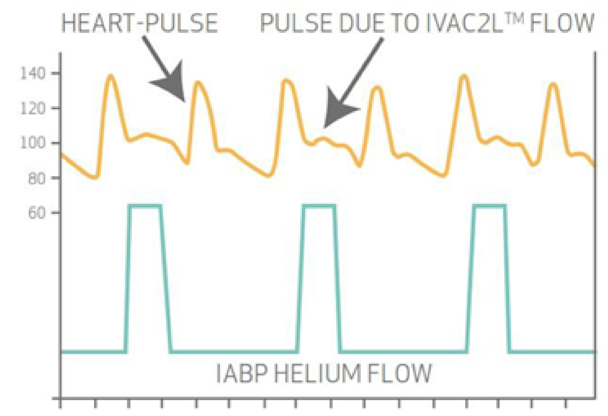
There is a difference between pulsatile vs continuous flow. Continuous flow reduces the motility of the aortic valve and may increase the aortic impedance. Furthermore, it has been related to worse end-organ perfusion. In contrast, synchronized pulsatile flow as found in the iVAC 2L system creates additional pulsatility in the systemic vasculature, potentially improving peripheral perfusion. In addition, it may potentialize coronary blood flow in diastole thus increasing oxygen delivery to the heart while sparing the native myocardium from the additional burden of pumping blood against increased aortic impedance[4].



Criteria for High-Risk PCI[3, 4]

- ✓ Poor LV function: EF < 35-40%
- ✓ Three-vessel disease
- ✓ Last patent conduit
- ✓ Unprotected LM Stem Disease
- ✓ STEMI or NSTEMI with hemodynamical instability
- ✓ Emergent PCI with borderline hemodynamical state
- ✓ Treatment of procedural complications e.g. coronary perforation, tamponade, etc.
- ✓ PCI in the presence of severe valve disease
- ✓ Frailty / multiple co-morbidities





References

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4. Bastos, Marcelo B et al. "PulseCath iVAC2L: next-generation pulsatile mechanical circulatory support." Future cardiology vol. 16,2 (2020): 103-112. & Effect of next generation pulsatile mechanical circulatory support on cardiac mechanics - The PULSE trial. *Cardiovascular Revascularization Medicine,* March 2022
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