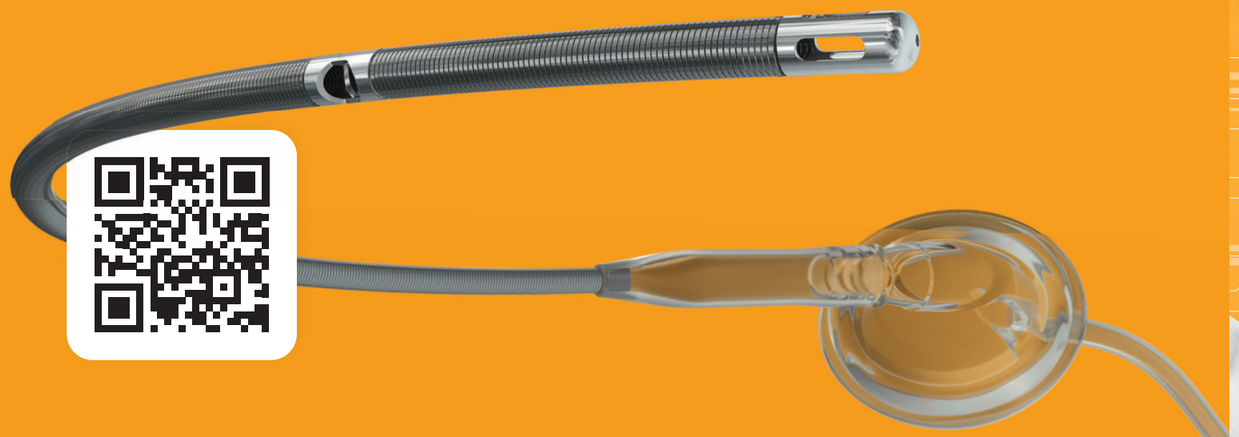
In addition, PulseCath iVAC 2L pumps using Pulsatile flow

There is a difference between pulsatile and 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 flow as found in the iVAC 2L system creates additional pulsatility in the systemic vasculature, potentially improving peripheral perfusion.
iVAC 2L may also optimize coronary blood flow thus increasing oxygen delivery to the myocardium while sparing it from the additional burden of pumping blood against increased aortic impedance.

3. Comparison of continuous-flow and pulsatile-flow left ventricular assist devices: is there an advantage to pulsatility? Allen Cheng et al. Ann Cardiothorac Surg. 2014 Nov.



distribuito in Italia da:

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PulseCath BV -Nieuwe Stationsstraat 20,
6811 KS Arnhem, The Netherlands

iVAC 2L pVAD

Percutaneous Ventricular Assist Device

NATURAL PULSATILE SUPPORT FOR PROTECTED PCI

EUKON
Future Healthcare Now

PulseCath

PRODUCT FEATURES:

- Transfermoral ultra-flexible pVAD system
- 17 Fr single lumen, bi-directional flow catheter
- Exclusive pulsatile support
- ECG- or AP-triggered counterpulsation
- Driven and compatible with standard IABP consoles

CLINICAL INDICATION:

The iVAC2L is intended for use in patients with impaired left ventricular function, which require left ventricular mechanical circulatory support for up to 24h.
The iVAC2L is found to be effective in high-risk PCI procedures. (1,2)

PRODUCT ADVANTAGES:

- Swift percutaneous approach, also in emergency situations (1 , 2)
- Provides up to 2.0L/min additional diastolic flow
- Improves coronary artery and end-organ perfusion (1, 2)
- Non-significant hemolysis, fHb <10 µmol/L (1,2)
- No additional cost for a console; compatible with a standard IABP console
- Easy to operate, time-efficient

MECHANISM OF ACTION:

The operating mechanism of the iVAC2L is a patented 2-way valve integrated in a 17 Fr single lumen and bi-directional, 1000 mm long catheter.
This catheter is connected to an extracorporeal 40cc membrane pump.
The system is compatible with a standard IABP console and does not require dedicated hardware.

When the heart is in the systolic phase, blood is aspirated from the ventricle through the tip of the catheter and transported via the lumen Into the membrane pump.

During the diastolic phase, the membrane pump (with the IABP console as a driver) directs the blood back through the catheter to the ascending aorta by opening the 2-way valve.

The pulsatile synchronization between closing of the aortic valve and the opening of the catheter valve ensures that the aortic valve function is not impaired, but supported.

1. Application of a Pulsatile Catheter Pump in Left Ventricle Cardiac Assistance for up to 24 hours in high-risk PCI Patients; An interim Clinical investigation Report; PulseCath October 2014
2. Evaluation of the PulseCath iVAC2L, a Pulsatile Catheter Pump, in high-risk PCI Patients who need cardiac assist – first 14 cases PulseCath, March 2014.

Clinical benefits

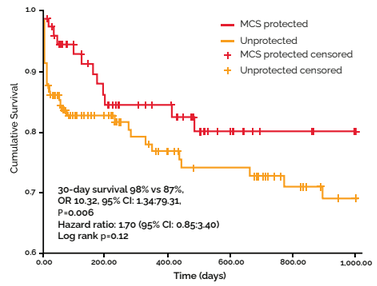

Figure 1. *Kaplan-Meyer survival curves showing that mechanically-assisted HR-PCI may have better survival compared to HR-PCI with no mechanical support. Adapted from Ameloot et Al, 2018.*

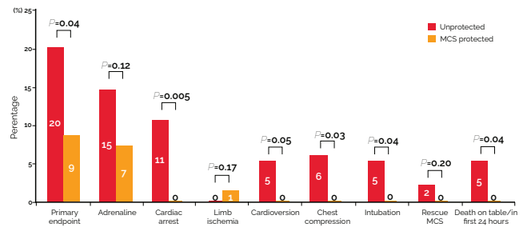

Figure 2. *Severe procedural adverse events related with the use of mechanical support during HR-PCI. The primary endpoint of the study (composite of cardiac arrest requiring resuscitation, hypotension with need for vasopressor support, need for rescue MCS, limb ischaemia with need for surgery and need for endotracheal intubation) occurred in 20% of the unprotected patients and in 9% of the MCS protected patients (OR: 0.38, 95%CI: 0.15-0.97, p = 0.04). Adapted from Ameloot et al, 2018.*

Ventricle unloading

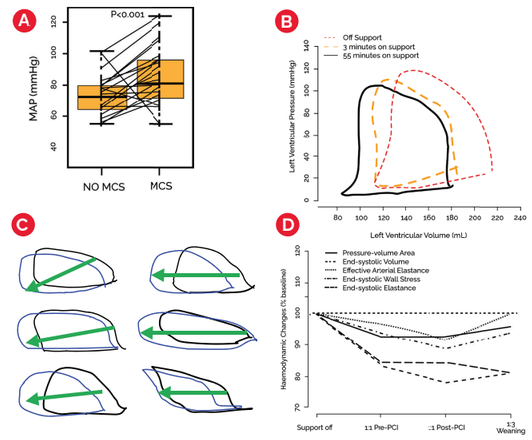

Figure 3. *(A) MCS with iVAC 2L significantly increased the mean arterial pressure (MAP) when activated. (B) Pressure-volume loops show progressive unloading of the left ventricle during the period iVAC 2L is active. (C) Pressure-volume loops from separate individuals showing left ventricular unloading with iVAC 2L activated (blue loops) as opposed to baseline (black loops) with iVAC 2L in stand-by. (D) Progression of hemodynamic markers during use of iVAC 2L show a gradual reduction in the Pressure-volume Area (MVO_2), Effective arterial elastance (afterload), wall stress and in chamber volumes. Additionally, a partial return to baseline levels can be observed at weaning.*

PULSE Trial

- Design: prospective single-arm two center prospective cohort.
- Study population: patients undergoing HR-PCI with MCS.
- Objective: to understand the hemodynamic changes produced by iVAC 2L.
- Primary endpoint: change in pressure-volume area (PVA).
- Secondary endpoints: clinical endpoints at 30 days.

Investigators: Prof Nicolas Van Mieghem MD PhD (PI)[1], Dr M. B. Bastos MD MHSc[1], Dr J. Daemen MD PhD[1], Dr J. Schreuder MD PhD[1] and Dr S. Redwood, MD, PhD[2].

(1) Erasmus University Medical Center, Rotterdam, The Netherlands
(2) St. Thomas Hospital, London, United Kingdom

Main results

- LV unloading with reduction in pressures and volumes in the LV chamber.
- Significant reduction in MVO_2 as demonstrated by a fall in PVA.
- Reduction in LV afterload.
- Decrease in mechanical dyssynchrony.
- Increase in MAP.

Conclusion

The efficacy of iVAC 2L is demonstrated by the following features:

- Unloaded the LV
- Increased the Mean Arterial Pressure by 17%
- Reduced the Afterload also by 17%
- Increased the Cardiac Power Output by 23%
- Reduced MVO_2 by 7 to 8%
- 30-day mortality (6.9%) comparable to PROTECT II (6.9%)
- Low rates of intraprocedural hemodynamical instability
- Low rates of major bleeding if operated by qualified hands

Webinar: The Benefits of iVAC2L