# Effects of Pulsatile Left Ventricular Support on Mechanical Efficiency in Ischemic

Cardiomyopathy

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PULSE trial



## Purpose

Mechanical Dyssynchrony increases in ischemic cardiomyopathy (ICM) and reduces contractility. Counterpulsation reduces afterload and attenuates this phenomenon. We measured effects of the new pulsatile iVAC2L<sup>TM</sup> (PulseCath B.V., Amsterdam, The Netherlands) support on MDS in ICM.

#### Methods

Invasive Left Ventricular (LV) PV loops obtained using conductance catheters and dedicated software (CDLeycom, Hengelo, The Netherlands) from 11 patients undergoing high-risk PCI were compared. Regional and Global Cycle Efficiency (CE) were compared using paired analysis with student t test or Wilcoxon signed-rank test as appropriate, before and after activating iVAC2L. Mean variations are reported and tested with one sample parametric and non-parametric tests as appropriate.

#### Results

1:1 iVAC2L support increased apical CE ( $75.2\pm15.6$  vs  $81.0\pm13.9\%$ , p=0.01) and global CE ( $73.6\pm17.7$  vs  $77.9\pm15.3\%$ , p=0.08), but not basal ( $74.2\pm23.5$  vs  $77.3\pm17.8\%$ , p=0.5). SV ( $64.9\pm18.7$  vs  $70.2\pm20.1$ mL, p=0.03), EF ( $47.4\pm13.9$  vs  $51.6\pm14.4\%$ , p=0.01) and PRSW ( $38.2\pm19.0$  vs  $42.2\pm18.4$ mmHg, p<0.01) increased. +dP/dtmax ( $852\pm344$  vs  $888\pm363$ mmHg/s, p=0.14) and Tau ( $45.2\pm11$  vs  $42.6\pm7.1$ ms, p=0.19) did not change significantly. ESV (-4.13%) and ESP (-0.32%) decreased, while EDV (+0.69%) and EDP (+4.46%) increased.

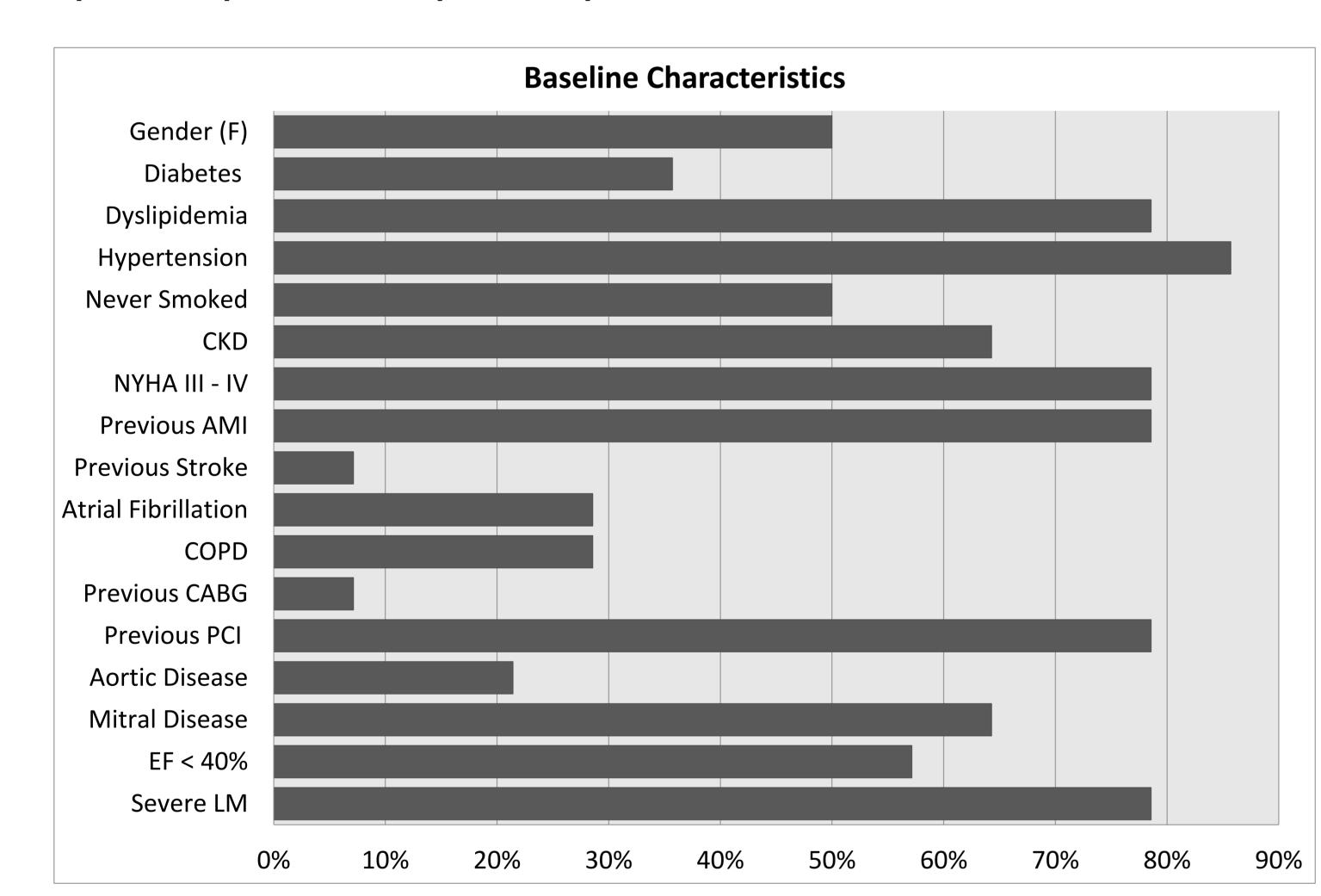


Figure 1. Baseline characteristics presented as frequencies.

	Mean % variation (SD) post-activation	95% Confidence Interval
HR	+2.35 (5.41)	(0.09 to 4.61)
EDP	+4.46 (12.98)	(-3.21 to 12.13)
EDV	+0.69 (6.09)	(-2.91 to 4.29)
ESP	-0.32 (9.01)	(-5.64 to 5)
ESV	-4.13 (9.19)	(-9.69 to 1.43)
+dP/dt <sub>max</sub>	+5.66 (13.50)	(-2.32 to 13.64)
PRSW	+15.55 (18.08)	(4.87 to 26.23)
Ea	-7.70 (10.10)	(-13.67 to -1.73)
Tau	-3.99 (10.40)	(-10.14 to 2.16)
-dP/dt <sub>max</sub>	+3.19 (10.96)	(-3.28 to 9.66)
EF	+9.71 (10.81)	(3.32 to 16.1)
CO	+14.21 (12.81)	(3.32 to 16.1)
SV	+8.72 (11.09)	(2.17 to 15.27)
Dys. (mid-systole)	+0.34 (33.97)	(-19.74 to 20.42)
Dys (early diastole)	-0.58 (17.55)	(-10.95 to 9.79)
GCE	+7.35 (12.42)	(0.01 to 14.69)
RCE <sub>base</sub>	+7.68 (18.56)	(-3.4 to 18.76)
RCE <sub>apex</sub>	+8.67 (9.54)	(3.03 to 14.31)

Table 1. quantitative analysis of beat-to-beat haemodynamics before PCI.

### Results

#### Effects of iVAC2L on Global Cycle Efficiency

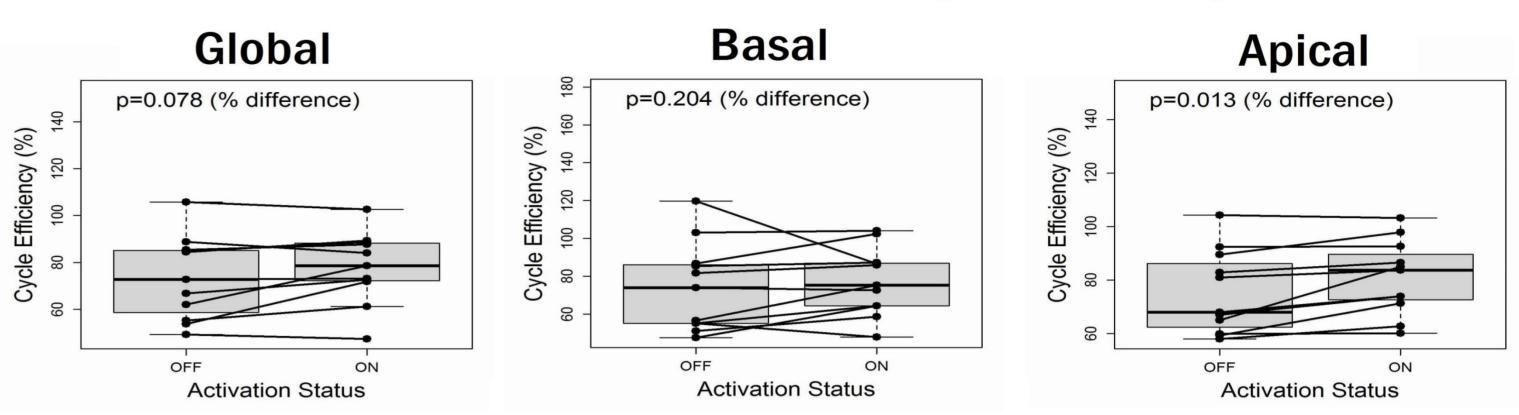


Figure 2: Comparison of Global CE before and after activating iVAC2L. Global CE was measured in the basal segments and in the apical segments. Basal and apical CE are also shown.

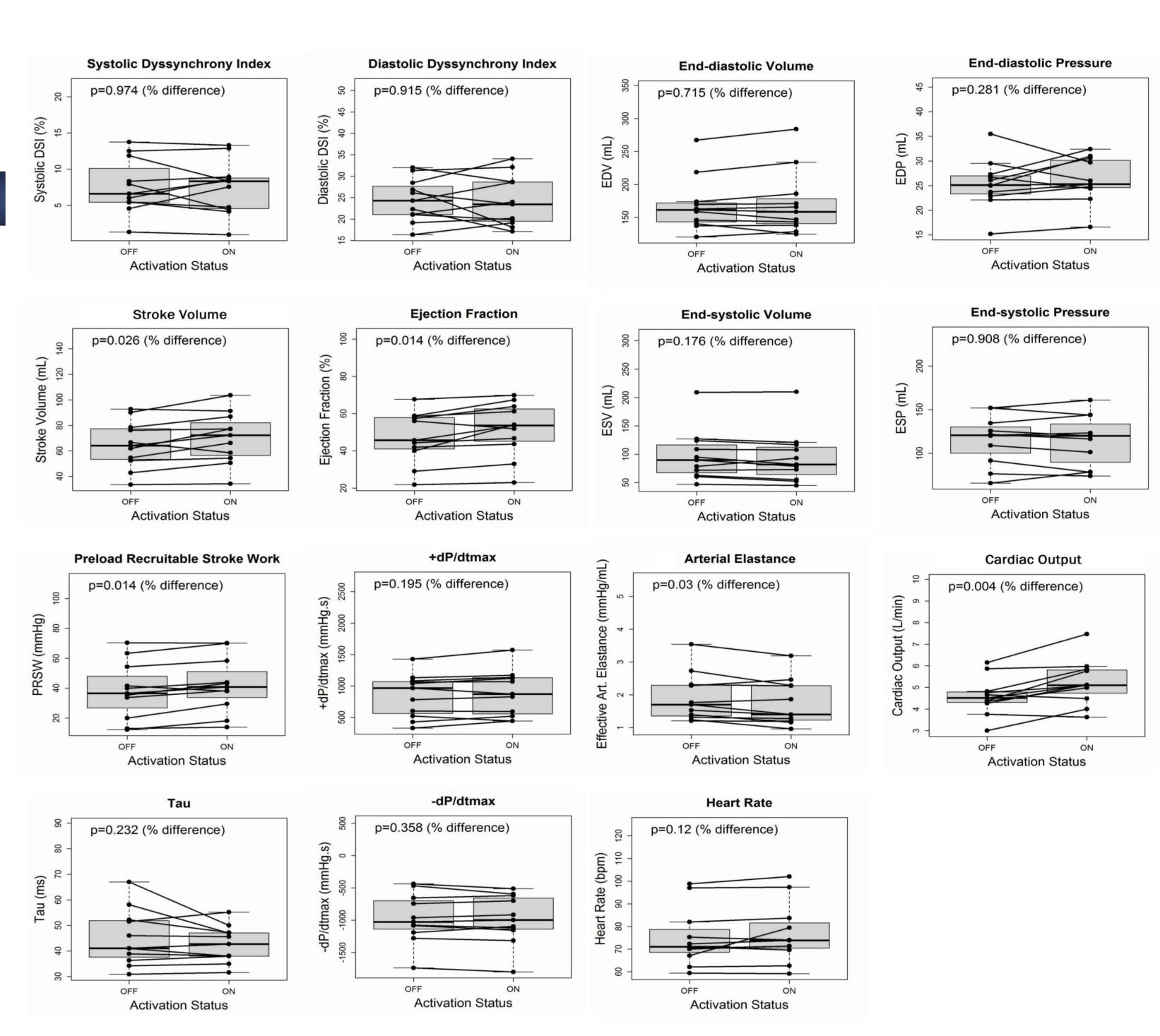
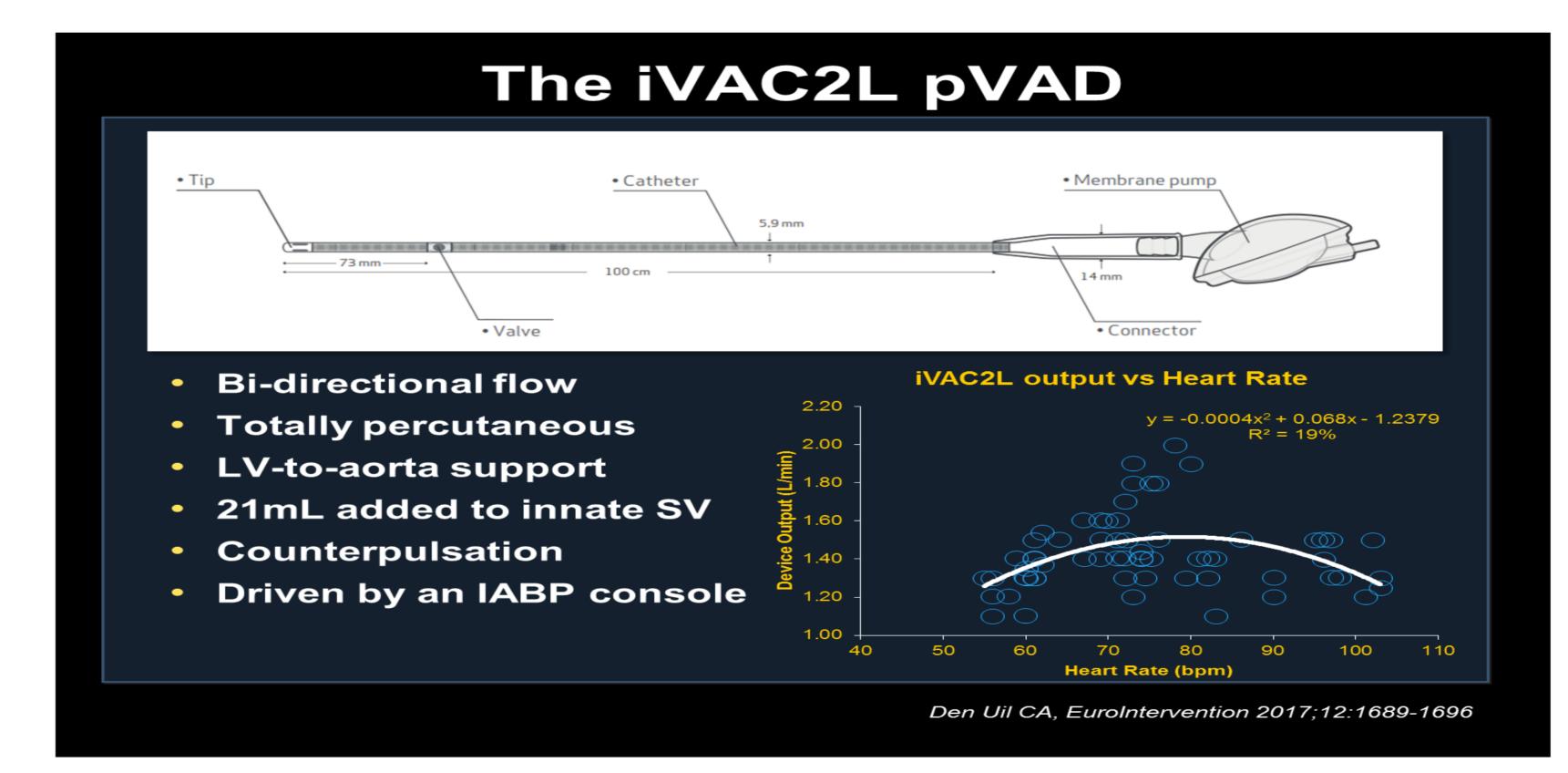


Figure 3. Paired analysis of different hemodynamical parameters before and after activating iVAC2L. Stroke Volume, Cardiac Output, and contractility, the last one represented by PRSW (Preload Recruitable Stroke Work), increased. Non-significant changes in Tau and –dP/dt<sub>max</sub> suggest improvements on active relaxation. P-values for percent differences are reported.



#### Conclusion

LV support improved mechanical dyssynchrony, increasing SV, EF and PRSW, optimizing baseline conditions to undergo critical PCI. Consistency of these findings will be further assessed in the upcoming PULSE trial (Clinicaltrials.gov NCT03200990).