

Effect of Pulsatile Mechanical Circulatory Support on Cardiac Mechanics (PULSE trial)

Marcelo B. Bastos, MD¹; Hannah McConkey², MD; Oren Malkin, Msc³; Corstiaan den Uil, MD, PhD^{1,4}; Joost Daemen, MD, PhD¹; Tiffany Patterson, MD, PhD²; Quinten Wolff, Bsc¹; Isabella Kardys, MD, PhD¹; Jan Schreuder MD, PhD¹; Mattie Lenzen, PhD¹; Felix Zijlstra, MD, PhD¹; Simon Redwood, MD, PhD²; Nicolas M Van Mieghem, MD, PhD¹



How was it executed?

This prospective single-arm two-center study included 29 patients who underwent high-risk PCI with iVAC2L MCS using simultaneous invasive pulmonary pressure monitoring and left ventricular pressure-volume analysis. Hemodynamic recordings were performed during steady state conditions with MCS off and on before and after PCI. Pressure-volume variations were analyzed to denote responders and non-responders.

Why this study?

Mechanical circulatory support (MCS) is increasingly used in the context of high-risk percutaneous coronary intervention (PCI). The effect of the pulsatile iVAC2L MCS on left ventricular loading conditions and myocardial oxygen consumption (MVO2) is unknown.

What were the essential results?

The mean age was 74 (IQR: 70-81) years and the mean SYNTAX score was 31 ± 8.3. Left ventricular unloading and reduced MVO2 with pulsatile MCS were demonstrated in 82% and 78% respectively. Pulsatile MCS activation reduced MAP (-4%), SBP (-9%), ESP (-11%), ESV (-15%) and EDV (-4%) among responders but not among non-responders. Responders experienced significant reductions in afterload (Ea: -19%) with increases in stroke volume (+11%) and cardiac output (+11%). Patients with moderate or severe mitral regurgitation or presenting with acute coronary syndrome (ACS) had higher filling pressures and volumes and were most responsive to iVAC2L unloading (9/10 patients with moderate or severe MR and 11/11 patients with ACS).

Conclusions: Pulsatile iVAC2LMCS in patients with advanced coronary artery disease at high to prohibitive operative risk resulted in LV unloading and reduced myocardial oxygen consumption particularly in patients with ACS or significant MR with higher filling pressures at baseline.

Disclosure: B. Bastos M. works for PulseCath B.V. and is Affiliated Researcher at the Erasmus MC. J.J. Schreuder works for CD Leycom and is Affiliated Researcher at the Erasmus MC. N.M. Van Mieghem is Clinical Advisor for PulseCath B.V. The other authors have nothing to disclose

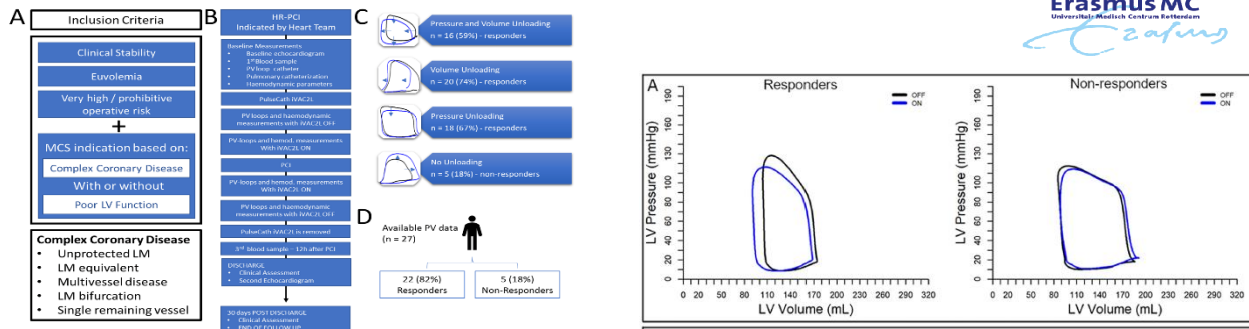


Figure 1. (A) Inclusion criteria. Patients were defined as high-risk based on the presence of complex coronary disease (bottom) with or without significant left ventricular dysfunction. (B) Study Flowchart. (C and D) Adjudication of Left ventricular unloading based on the occurrence of net negative variations in pressure, volume or both altogether, resulting in an 82% rate of responders

Percent changes among responders (n = 22)	OFF		ON		% variation
	Mean	SD	Mean	SD	
GENERAL LV FUNCTION					
HR _{10min}	76 ± 18		76 ± 14		+1 (-1; +5)
CO _{10min} (L/min)	4.56 ± 0.85		5.12 ± 0.89		+11 (+3; +18) [§]
CFI _{10min}	0.80 ± 0.20		0.96 ± 0.25		+21 ± 20 [§]
LV PRESSURES AND VOLUMES					
SBP _{10min} (mmHg)	115 ± 24		128 ± 25		+13 ± 21 [†]
DBP _{10min} (mmHg)	52 ± 14		60 ± 12		+22 ± 37 [†]
MAP _{10min} (mmHg)	74 ± 17		82 ± 15		+13 ± 26 [†]
ESP _{10min} (mmHg)	119 ± 24		106 ± 23		-11 ± 9 [†]
ESV _{10min} (mL)	90 (67; 140)		72 (56; 117)		-15 ± 10 [†]
EDP _{10min} (mmHg)	19 ± 7		22 (13; 27)		+13 ± 28 [†]
EDV _{10min} (mL)	155 (142; 213)		149 (139; 189)		-4 (-11; +0.01) [†]
SV _{10min} (mL)	62 ± 16		69 ± 15		+11 (+3; +16) [†]
PULMONARY CIRCULATION					
mPVCW _{10min} (mmHg)	19 ± 9		21 (14; 24)		+12 ± 34
mPAP _{10min} (mmHg)	24 ± 9		26 ± 9		+4 (-3; +12)
TPR _{10min} (mmHg/mL)	434 ± 143		437 (325; 562)		+7 ± 20
LV CONTRACTILITY					
E _{LV} (mmHg)	38 ± 13		45 ± 14		+13 (+8; +24) [§]
E _{ES} (mmHg/mL)	1.42 ± 0.67		1.27 ± 0.47		-4 ± 24
V _{10min} (mL)	59 (50; 125)		57 (50; 117)		-4 ± 8 [†]
+dP/dt _{max} (mmHg/s)	943 ± 281		900 ± 257		-4 ± 8 [†]
LV ENERGETICS					
SW _{10min} (mmHg/mL)	6371 ± 2245		6518 ± 2051		+6 ± 17
PV _{10min} (mmHg)	12,063 ± 3187		11,500 ± 3053		-8 (-15; -0.3) [†]
SW/PVA	0.52 ± 0.11		0.57 ± 0.11		+9 (+7; +13) [†]
LV AFTERLOAD					
E _a (mmHg/mL)	1.79 (1.66; 2.32)		1.47 (1.31; 1.85)		-19 (-24; -14) [†]
E _a E _{ES}	0.71 ± 0.25		0.82 ± 0.32		+19 ± 21 [†]
TSR _{10min} (mmHg)	1278 (1203; 1653)		1189 (1048; 1619)		-5 ± 18

^{*} p < 0.1 versus baseline.

[†] p < 0.05 versus baseline.

[‡] p < 0.01 versus baseline.

[§] p < 0.001 versus baseline.

