TCT-321

Head-to-Head Comparison of a Pulsatile and a Continuous Flow Left Ventricular Assist Device in High-Risk PCI Setting: iVAC2L Versus Impella 2.5

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BACKGROUND To compare the hemodynamic and clinical performance of a new transfemoral pulsatile assist device (iVAC2L) with the Impella 2.5 device in high-risk percutaneous coronary intervention (PCI) patients.

METHODS In 40 patients (10 female, age 75 ± 8 years, left ventricular ejection fraction 44 ± 11%) high-risk PCI was performed under support with Impella 2.5 (n = 20) or iVAC2L system (n = 20). Aortic pressure data and flow measurements were collected before and after device placement and immediately after PCI. Blood parameters of hemolysis were collected before and after support.

RESULTS Correct device placement was achieved in 17 patients in the iVAC2L group and in 19 patients in the Impella group (p = NS). PCI was successful in 39 patients. Except for contrast agent (295 ± 77 ml), no fluids were infused. Mean support time was significantly shorter under Impella use (122 ± 32 min vs. 94 ± 14 min; p = 0.03). There was no early increase in aortic blood pressure under iVAC2L support, but with prolonged support time, these parameters increased significantly and kept their higher level (Table 1). In contrast, aortic pressure increased significantly immediately after starting Impella support, but with increasing support, the increase was comparable between the 2 groups after PCI. Continuous Impella flow was significantly higher as compared to the pulsatile iVAC2L flow (2.07 ± 0.09 l/min vs. 1.25 ± 0.05 l/min; p < 0.001). Five critical events during PCI (iVAC2L n = 3) occurred (massive vasospasm, coronary perforation, no flow in left coronary artery, hemodynamic significant II°-atrioventricular block, pericardial tamponade), but both devices were able to stabilize hemodynamic conditions with no need for cardiopulmonary resuscitation. After PCI, 1 severe bleeding in each group and 1 stroke <24 h in the iVAC2L group occurred. Significant haptoglobin decrease after Impella was a sign of potential hemolysis (Table).

		Pre-PCI (No Support)	Pre-PCI (Full Support)	Post-PCI (Full Support)	Post-PCI (No Support)
iVAC2L	RRsyst Ao, mm Hg,	123 ± 29	125 ± 21*	142 ± 28†‡	142 ± 31§‖
Impella 2.5	RRsyst Ao, mm Hg	136 ± 23	146 ± 29*¶	154 ± 22†	156 ± 21§
iVAC2L	RRdiast Ao, mm Hg	58 ± 16	59 ± 14	68 ± 18†‡	69 ± 18§
Impella 2.5	RRdiast Ao, mm Hg	55 ± 13	70 ± 18¶	79 ± 16†‡	71 ± 17§‖
iVAC2L	RRmean Ao, mm Hg	82 ± 16	83 ± 16*	97 ± 21†‡	94 ± 27§
Impella 2.5	RRmean Ao, mm Hg	87 ± 15	98 ± 19*¶	107 ± 15†‡	103 ± 16§‖
iVAC2L	Haptoglobin, mg/l	1,607 ± 741			1,261 ± 648
Impella 2.5	Haptoglobin, mg/l	1,651 ± 762			1,211 ± 626§

Values are mean ± SD. *p < 0.05 iVAC vs. Impella; †p < 0.05 pre-PCI (no support) vs. post-PCI (full support); ‡p < 0.05 pre-PCI (full support) vs. post-PCI (full support); §p < 0.05 pre-PCI (no support) vs. post-PCI (no support); ‖p < 0.05 pre-PCI (full support) vs. post-PCI (no support); ¶p < 0.05 pre-PCI (no support) vs. pre-PCI (full support).
Ao = aorta; diast = diastolic; RR = respiratory rate; syst = systolic.

CONCLUSION High-risk PCI under support with both devices is feasible and safe. Aortic pressure increases under support with both devices, but earlier under Impella support. Differences between the 2 systems in patients' outcomes or hemodynamic parameters need to be evaluated in large multicenter studies.

CATEGORIES CORONARY: Complex and Higher-Risk Procedures for Indicated Patients (CHIP)