PRODUCT UPDATE

March 2020

Impella®
The World's Smallest Heart Pump

Use of Extracorporeal Membrane Oxygenation (ECMO) with Impella Patients in Cardiogenic Shock

What's New

Abiomed recently received FDA approval (P140003/S066) to update the Instructions for Use (IFU) of the Impella 2.5®, Impella CP®, Impella 5.0®, and Impella 5.5® systems to include a new caution along with additional instructions regarding continuing Impella therapy in cardiogenic shock (CS) patients where Extracorporeal Membrane Oxygenation (ECMO) is to be initiated. These labeling changes are discussed in this Impella update.

Background:
Abiomed became aware of important safety issues related to cardiogenic shock patients on Impella support who were escalated to ECMO therapy. In some cases, ECMO was added and the Impella pump support was immediately discontinued which, in some instances, resulted in poor outcomes likely due to continued LV loading with resultant LV distention and pulmonary edema.

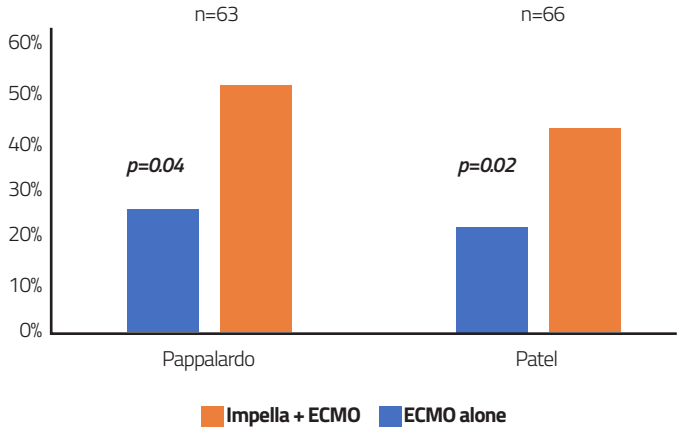
The Impella 2.5, Impella CP, Impella 5.0, and Impella 5.5 systems are approved by the FDA to treat cardiogenic shock in patients by unloading the ventricle (to reduce its work) and providing circulatory support to allow heart recovery (footnote, P140003/S004, S018, S050). These Impella devices are the only devices approved by the FDA to be safe and effective in the treatment of cardiogenic shock.

New Caution:
If Extracorporeal Membrane Oxygenation (ECMO) is to be initiated in a CS patient currently being treated with Impella, the benefits and risks of continuing Impella therapy for left ventricle unloading during ECMO support should be considered.

The intent of this caution is to ensure that the appropriate medical considerations are made when a decision is being considered for adding ECMO to a CS patient already on Impella support.

New Labeling:
Use of ECMO in CS patients has been shown to result in additional loading of the left ventricle (LV), which the Impella catheter alleviates, based on its favorable unloading properties, and use of Impella in these patients has been shown to improve outcomes (versus ECMO alone).[1,2]

AMI Cardiogenic Shock Survival
Impella+ECMO vs ECMO Alone[1,2]



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Delaying LV unloading therapy until LV distention may result in denied therapy since exposing the LV to this loading phenomenon may be very damaging if not immediately remedied. There is a growing consensus that unloading should be accomplished as soon as a peripheral ECMO circuit is started.[3] IABP is not an unloading strategy in ECMO patients as demonstrated by a >1500 patient meta-analysis demonstrating numerically worse outcomes in ECMO patients treated with IABP vs ECMO alone, although there was no difference statistically.[4]

New Instructions:
For CS patients treated with both ECMO and Impella unloading, the flow from the Impella device should be monitored and may need to be reduced to minimize the occurrence of an LV inflow limited condition (suction). If this condition occurs, the Automatic Impella Controller™ will alarm to notify the user. If a clinical decision is made to wean a CS patient treated with both ECMO and Impella unloading to allow assessment of residual myocardial function, support should be decreased by gradually lowering the ECMO flow, while increasing the Impella Catheter flow. If a patient tolerates the reduction in the ECMO flow, they can be transitioned to Impella support alone for continued LV recovery.

Abiomed suggests the following with respect to Impella use in patients supported with ECMO in order to achieve optimal outcomes.

1. Impella patients escalated to ECMO support should continue LV unloading with Impella, usually possible at low to moderate P-levels while on full ECMO support thus avoiding damaging LV distention.

2. Physicians treating acute cardiogenic shock patients with ECMO therapy should consider addition of unloading therapy to avoid LV distention and the attendant morbidity and mortality.

3. Weaning trials in such patients will usually involve reductions in ECMO flow while increasing Impella flow during ramp trials. This has allowed appropriate patients to undergo early weaning from ECMO to Impella support alone.

4. Right heart catheter use in cardiogenic shock patients has been associated with improved outcomes and is an important asset in management of patients receiving MCS.

1. *Pappalardo, F., Schulte, C., Pieri, M., et al. (2016). Concomitant implantation of Impella® on top of veno-arterial extracorporeal membrane oxygenation may improve survival of patients with cardiogenic shock. European Journal of Heart Failure, 19(3), 404–412.*
2. *Patel, S. M., Lipinski, J., Al-Kindi, S. G., et al. (2019). Simultaneous Venoarterial Extracorporeal Membrane Oxygenation and Percutaneous Left Ventricular Decompression Therapy with Impella Is Associated with Improved Outcomes in Refractory Cardiogenic Shock. ASAIO Journal, 65(1), 21–28.*
3. *Russo, J. J., Aleksova, N., Pitcher, I., et al. (2019). Left Ventricular Unloading During Extracorporeal Membrane Oxygenation in Patients With Cardiogenic Shock. Journal of the American College of Cardiology, 73(6), 654–662.*
4. *Cheng, R., Hachamovitch, R., Makkar, R., Ramzy, D., Moriguchi, J.D., Arabia, F.A., Esmailian, F., Azarbal, B. (2015). Lack of Survival Benefit Found With Use of Intraaortic Balloon Pump in Extracorporeal Membrane Oxygenation: A Pooled Experience of 1517 Patients. J Invasive Cardiol., 27(10), 453–458.*

Footnote, P140003/S004, S018, S050