Commentary: Preemptive Left Ventricular Unloading in High-Risk Cardiac Operations – Uncertain Risk/Benefit Relationships But Promising!

Victor A. Ferraris, M.D., Ph.D

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Commentary: Preemptive Left Ventricular Unloading in High-Risk Cardiac Operations – Uncertain Risk/Benefit Relationships But Promising!

Victor A. Ferraris, M.D., Ph.D.
Lexington VA Medical Center & University of Kentucky
Department of Surgery
Room B504
1101 Veterans Drive
Lexington, KY 40502-0284

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Correspondence:
Victor A. Ferraris, M.D., Ph.D.
Lexington VA Medical Center & University of Kentucky
Department of Surgery
Room B504
1101 Veterans Drive
Lexington, KY 40502-0284
Central Message: Preemptive left ventricular unloading with Impella device may have benefit in high-risk patients with left ventricular impairment during high risk cardiac operations.

Central Picture Legend: Preemptive left ventricular unloading in high-risk cardiac operations may prove beneficial.

The Authors present a preliminary report on the use of advance Abiomed Impella support device (version 5.5) for preemptive ventricular support in high-risk patients having operations in the setting of significant ventricular compromise. Postoperative mechanical support methods are often necessary in this high-risk cohort and have included aggressive intraoperative and postoperative device support (IABP, Impella device and LVAD). When pre-existing stunned, hibernating and/or acutely ischemic myocardium is subjected to the pathophysiology of the cardiopulmonary bypass circuit, to the ischemia mandated by cross clamping and possibly to suboptimal cardioprotection, the result is often a dangerous combination of vasoplegia and postoperative low cardiac output. Treatments for this set of circumstances has traditionally involved inotropes and IABP support. More invasive options often follow if these support options were ineffective, ranging from ECMO to more elaborate ventricular support interventions. Consensus suggests that ECMO support is not a perfect option in the setting of extreme post-bypass ventricular dysfunction. Similarly, more extreme forms of ventricular support are high-risk undertakings that often are used in the setting of patients who have failed other support methods. These concerns often lead to reluctance of undertaking an operative
intervention in this setting. Other rather extreme measures like LVAD support and transplantation are final steps in this decision algorithm and these are even less likely to provide a satisfactory outcome in the urgent setting of low cardiac output and severe LV dysfunction after operation. In response to these ‘nightmares’ of postcardiotomy shock (PCS) that every cardiothoracic surgeon has faced at one time or another during their career, the Authors present an intriguing option – the paradigm of preventive support with preemptive ventricular unloading.

The Authors start by suggesting that reliable information and prediction models for PCS development do not exist. They suggest, with emphasis on ‘suggest’, that preemptive ventricular unloading may limit ventricular dysfunction after CPB and provide support to allow reparative operative interventions to provide improved recovery and enhanced postoperative survival. Their choice for providing this ‘preemptive ventricular support’ is implantation of an Impella device (Abiomed Inc., Danvers, MA). Their hypothesis is that the preemptive ventricular unloading with this device, during high-risk cardiac operations, may limit intraoperative myocardial damage and allow improved surgical outcomes in high-risk patients.

To be fair, the current Impella device (version 5.5) has not been used, and is not approved, for this indication. The prophylactic use of the Impella device to limit LV dysfunction during and following high risk cardiac operations would be a new indication for use of this device. The Authors have skirted this issue a bit, perhaps for understandable reasons. The acknowledge that the use of the Impella device has not been used in a prophylactic manner. Further, the conduct of a randomized trial to test the effectiveness of the Impella device as a prophylactic intervention would be a ‘statistical design nightmare’. A trial to randomly use the Impella device in patients
who are at risk for postoperative ventricular dysfunction might be clouded with ethical issues and uncertain indications for use. The Authors are aware of these issues and acknowledge that the published experience with the Impella device is limited to two published reports that studied a cohort of slightly more than 200 patients, nearly all of whom did not have device insertion for prophylactic purposes.

To summarize, the use of the Impella device for prophylaxis in certain high-risk patients is novel. This use is very appealing and needs further exploration. The exact path forward is complicated, but it appears that traditional pathways for approval of a new device indication are likely to be too cumbersome and may not be necessary. Nonetheless, more evidence about the use of this device in the setting of prophylaxis in patients with LV dysfunction who need cardiac operations may only be obtained by experiential observations and anecdotal reports. This is a new pathway in the modern era but may be the best option.

References