IMPELLA PERCUTANEOUS TEMPORARY VAD

Abbreviated Points for Quick Reference

**BACKGROUND**

The use of mechanical circulatory support in children is restricted to a few devices, many of which have been adapted from the adult experience. The Impella, is one such example that offers temporary mechanical circulatory support in children. Due to limited pediatric experience with this device, it is essential to have a structured approach to patient selection, device deployment, post-implant monitoring and guided therapy de-escalation.

**ACTION REVISED DATE:** 08/03/2022

**OBJECTIVES**

This document provides an abbreviated bedside overview of the Impella® percutaneous heart pumps. Please reference “IMPELLA PERCUTANEOUS TEMPORARY VAD Bedside Pearls for the Pediatric Patient” for more details.

**PROTOCOL**

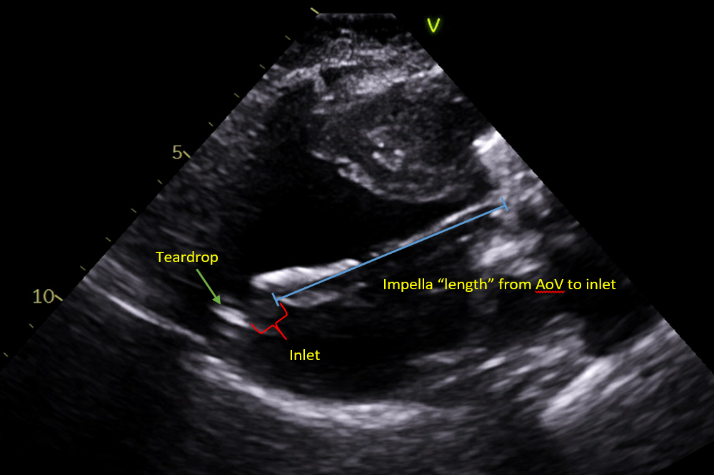
## **ICU MANAGEMENT**

## **ANTICOAGULATION**

* Obtain baseline coagulation labs
* Start anticoagulation via the purge fluid as soon as patient is in ICU, if not already started in the OR
* Purge flow rate is automatically adjusted by the controller
* If anticoagulation goals are not met with purge fluid alone (heparin 25 IU/mL in D5W typically), add systemic heparin infusion
* If patient is supra-therapeutic on purge heparin alone, decrease heparin concentration by half to 12.5 IU/mL, if still supra-therapeutic, go down to 6.25 IU/mL
* If HITT is suspected, call Abiomed representative for recommendations (e.g. sodium bicarbonate in D5W)
* Antiplatelet agents are not typically used for Impella pumps

**Monitoring of Anticoagulation**

* Impella only (Anti-Xa or PTT per institutional preference)
  + Low risk of thrombosis, short term use or surgical bleeding – Anti-Xa 0.15-0.25 or PTT 50-60 sec
  + High risk of thrombosis or longer term use – Anti-Xa 0.2-0.3, PTT 60-70 sec  
    \* high PTT ranges with adequate or sub-therapeutic Xa goals, please consult with your local hematology or transfusion medicine team
* Impella + ECMO: Use ECMO anticoagulation goals (ACT, Anti-Xa, PTT per institutional protocol)



## **IMAGING TO MONITOR DEVICE POSITION**

When to image:

* CXR daily x2-3 days, then space as able
* ECHO daily post placement x48 hours, measuring distance in ventricle - measure from the aortic valve to the inlet (lucent area prior to teardrop) in parasternal long-axis view
  + **Impella 5.5**: Distance 4.5cm below aortic valve
  + **Impella 2.5, CP, 5.0**: 3.5cm below aortic valve
* Repeat ECHO as needed if:
  + Having device alarms
  + >20% change in flows
  + Acute onset of hematuria or evidence of hemolysis
  + Suspected device movement
  + New or increasing ectopy or arrhythmia burden

# **DEVICE ALARMS**

**Malposition:**

* Assess positioning of the Impella device with ECHO +/- CXR. If repositioning is required, notify interventional cardiology or surgical team and:
  + If deep in LV, pull back with ECHO guidance
  + If pulled out in aorta, should only be repositioned under fluoroscopic guidance

**Low flow on Impella:**

* Flow is lower than expected for set performance level. Either due to suction, inadequate preload, RV dysfunction, or due to high afterload. Assess position & function with echo, volume status and blood pressure.

**No flow or Impella stops/acute device stoppage:**

* Clinically support the patient. If CPR is needed, drop Impella P-level to 2 and perform CPR. See ‘Emergency Procedures’ section for proper procedure post ROSC.
* Check electric outlet and ensure that the Impella is plugged in. If off, attempt to restart.
* STAT ECHO and CXR. If device has power, decrease P-level by 1-3 lower than what was set (not below 2), and monitor for improvement of flow and function along with patient hemodynamics.
  + If flow resumes at a lower P-level, evaluate the patient's intravascular volume status as well as RV function and positioning. Under these circumstances, catheter function is not reliable and the Impella may stop again.
  + If flow does not resume at lower P-level, assess & clinically support the patient, call Abiomed, and STAT call to cath/surgery team for potential device explant or exchange.

**Suction alarms:**

* Intermittent alarm: alerts ‘suction alarm,’ and the controller will reduce the motor speed to resolve the suction, then resume flow and will resolve itself. Assess position with echo, assess preload, and evaluate RV function.
* Continuous alarm: an event does not resolve and continues to alarm, you will see lower flows and systolic pressures. Drop the P-level and assess positioning of the catheter, RV function and preload.

# **MANAGING COMPLICATIONS AND ADVERSE EVENTS**

Potential adverse events include: hemolysis, bleeding, arrhythmias, thrombocytopenia, aortic valve or mitral apparatus injury, vascular injury, limb ischemia, device malfunction, site infections, cerebral vascular accident/stroke, or death.

## **HEMOLYSIS**

* + Can be due to the expected RBC shearing from the device, from higher P-level settings, suction events, or mal-positioning of the Impella device, especially in first 24-48 hours of support.
  + Check fluid status, LDH, plasma free Hb, evaluate for suction events, and consider adjusting P-level setting, ECHO to assess positioning.
    - May need fluid administration vs drop in P-level settings vs device repositioning.

## **BLEEDING**

* + At access site or surgical sites – assess if coagulopathy vs surgical site issue:
    - Workup: Anticoagulation studies, platelet count/function, TEG
    - Evaluation of procedural sites by cath/surgical teams, consider hematology consult
    - Consider compression devices (safeguard or dressing for <6 hours), monitor extremity perfusion
  + Anticoagulation goals may need to be adjusted if ongoing bleeding/oozing and the pump is otherwise working well. May need to hold heparin for up to 6-12 hours for clinically concerning bleeding.
    - Manufacturer recommendations: Max duration without heparin is no longer than 24 hours.
  + If bleeding continues, consider platelet dysfunction, low fibrinogen, HITT, recheck labs, hematology consult.
  + Surgical intervention should be considered if bleeding is difficult to control with medical therapies.

## **DEVICE CLOT**

* + If suboptimal anticoagulation or concerns for systemic inflammation, thrombus can form in the pump.
  + May see a rise in purge pressure, drop in purge flow, rise in motor current, or drop in device flow overall.
  + Consider tPA administration per Abiomed or your institution’s protocol.
  + Consider bivalirudin as thrombolytic therapy, if heparin is contraindicated or unable to achieve therapeutic levels (Abiomed does not recommend bivalirudin for routine use)
  + If the device stops, provide clinical support and STAT call the cath/surgical team for replacement or explant.

## **DEVICE FAILURE**

* + Can be seen with prolonged use when device reaches end-of-life
  + If the motor current trend is increasing and nearing its upper threshold, or there is an acute rise, the ICU team, and proceduralist should be notified, as this may be an early sign of the motor reaching end of life. Each type of Impella device, at each P setting, will have a different motor current upper limit. Discussion may be had with your Abiomed representative regarding recommended thresholds and potential device exchange.

## **INFECTION**

* Prophylactic antibiotics not recommended but may consider cefazolin for 24 hours peri-operatively.
* If an infection occurs related to the device, antibiotic regimen to be based on your institution.

## **SUCTION**

* + Suction is manifested by material (myocardium, biofilm) being entrained into the inflow.
  + Etiologies include inadequate LV filling or preload, incorrect Impella position, or RV failure.
  + Suction results in a decrease in Impella flow, arterial pressure and cardiac output.
  + It can damage blood cells, leading to hemolysis.
  + If suction occurs, Impella automatically reduces motor speed to lower the flow rate to resolve the suction and displays the “Impella Flow Reduced” advisory alarm. If cleared, the controller returns the flow rate to the desired setting. If suction is still detected at the lowest motor speed, the controller displays the “Suction” alarm.
  + If suction continues, reduce the P-level by 1 or 2 levels, and assess the volume status, hemodynamics, RV function, evaluate catheter position using the placement signal, motor current, and imaging. Reposition Impella if necessary. When the suction alarm is resolved, resume pre-alarm flow rate.

## **ARRHYTHMIAS**

* + If ectopy or arrhythmia occurs, as long as there is sufficient preload to the LV, the patient should be adequately supported with the Impella providing continuous flow and perfusion pressure.
  + Recurrent refractory ventricular arrhythmias warrant assessment of device parameters and alarms for suction events as well as device position, LV filling and RV function by echo.
  + May lose pulsatility during an arrhythmia, though should be able to measure a mean arterial pressure (MAP). If the MAP range is appropriate during the periods of arrhythmia, the patient is well supported.
  + If the patient doesn’t have adequate MAPs during periods of arrhythmia, clinically support patient appropriately while assessing RV function, volume status, antiarrhythmic agent and consider adjusting P-level if appropriate to better support the patient clinically while the arrhythmia is being medically managed.

## **EMERGENCY PROCEDURES**

**CARDIOPULMONARY ARREST**  
If the patient arrests and loses blood pressure and perfusion pressure, and CPR is required:

* Notify interventional cardiologist and/or surgeon ASAP
* Decrease Impella to P-2 and continue chest compression as usual
  + During CPR, P-2 is utilized to minimize potential damage due to dislodgement of the device during resuscitation.
  + Once ROSC is achieved and hemodynamics have been restored, an echo should be done to re-confirm placement.
  + Increase P-level by two levels at a time, every 5-15 minutes depending on patient stability, until desired P-level is achieved.

**DEFIBRILLATION/CARDIOVERSION**

If defibrillation and/or cardioversion is required:

* P-level does not need to be adjusted
* Defibrillate/cardiovert as usual
* Image after to confirm accurate device position

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