Impella® Anticoagulation Management

Purpose: This document describes anticoagulation management for the Abiomed Impella devices. Impella is a percutaneous ventricular assist device (pVAD) used for short-term mechanical circulatory support. Because Impella requires use of anticoagulation, standardized approaches are essential for optimized efficacy and safety.

General Information:
- Indications for an Impella pVAD
  - High-risk percutaneous coronary intervention (PCI)
  - Cardiogenic shock
  - Acute decompensated heart failure
- Most patients with Impella devices will have unfractionated heparin (UFH) from two sources:
  - Heparinized purge solution that runs counter-current to blood flow via the Impella catheter
  - Systemic heparinization
- Purge solution:
  - The standard purge solution at UNMH is UFH 25 units/mL in D5W.
  - The purge solution should be continuously running to prevent blood from entering the Impella motor and protect against device thrombosis.
  - Flow rates on the purge solution are automatically determined by the device to maintain the appropriate purge pressure.
  - Flow rates are usually between 2-30 mL/hr and average around 7-20 mL/hr.
  - Non-standard purge solutions
    - Bicarbonate-based purge solution (BBPS) may be considered for patients with:
      - Bleeding or persistently supratherapeutic anti-Xa levels in the absence of systemic IV UFH.
      - Heparin-induced thrombocytopenia (HIT) along with systemic bivalirudin (see UNMH HIT protocol).
    - D5W only purge solution should only be used if BBPS is not available.
- Systemic heparinization
  - Should be initiated if heparin levels from purge solution alone are below target range.
  - UNMH has an Impella-specific heparin protocol that uses a lower initial heparin rate to account for heparin exposure via the purge solution.
    - The recommended starting IV UFH rate is 7 units/kg/hr.
    - Future systemic heparin adjustments are based on anti-Xa irrespective of changes in the purge solution.

Systemic Heparinization Protocol:

Impella Anti-Xa Monitoring (Standard)
- Standard monitoring for most patients.
- Draw anti-Xa as a baseline upon arrival to the ICU and again 4 hours after initiation of purge solution.
- Initiate systemic heparin infusion once anti-Xa < 0.3 units/mL.
  Starting rate = 7 units/kg/hr (Pharmacy will adjust to a maximum initial rate of 750 units/hour).

Anti-Xa (units/mL)	Titration
<0.1	Bolus 25 units/kg; increase infusion by 3 units/kg/hr
0.1-0.19	Increase infusion by 2 units/kg/hour
0.2-0.29	Increase infusion by 1 units/kg/hour
0.3-0.5	NO CHANGE (goal)
0.51-0.6	Decrease by 1 units/kg/hr
0.61-0.75	STOP INFUSION for 1 hr, then decrease by 2 units/kg/hr
>=0.76	STOP INFUSION for 1 hr, then decrease by 3 units/kg/hr and notify provider

- Monitor anti-Xa every 6 hours x 24 hours initially and after each dose change; thereafter, once a therapeutic anti-Xa is achieved x 2 consecutive measurements, anti-Xa monitoring may be decreased to every 12 hours and/or after each dose change.

Impella ACT Monitoring
- In the rare cases where elevated bilirubin levels preclude the use of anti-Xa monitoring (e.g. bilirubin levels greater than 40 mg/dL), monitoring should be transitioned to ACT.
  - Careset for Impella ACT monitoring is located in Cerner MedManager.
- Initiate systemic heparin infusion once the ACT is less than 200.
  Starting rate = 7 unit/kg/hr (Pharmacy will adjust to a maximum initial rate of 750 units/hour).

ACT Value	Titration
<140	Bolus with 10 unit/kg, then increase infusion by 2 unit/kg/hr
140-159	Increase infusion by 1 unit/kg/hr
160-180	GOAL = NO CHANGE
181-200	Decrease infusion by 1 unit/kg/hr
>200	HOLD infusion for 1 hour, decrease infusion by 1 unit/kg/hr

  Check ACT every hour until within goal x 4 hours, then every 4 hours thereafter.

Ongoing Monitoring
- CBC at least every other day and more frequently if deemed necessary.
- Monitor for signs and symptoms of HIT.
  - If suspected, refer to UNMH HIT guideline which includes information for HIT with Impella

References:
1. Allender JE, et al. Pharmacologic Considerations in the Management of Patients Receiving Left Ventricular Percutaneous Mechanical Circulatory Support. Pharmacotherapy 2017. https://doi.org/10.1002/phar.1995
2. Amin AP, et al. The evolving landscape of Impella use in the United States among patients undergoing percutaneous coronary intervention with mechanical circulatory support. Circulation 2020. https://doi.org/10.1161/CIRCULATIONAHA.119.044007
3. Beavers CJ, et al. Optimizing Anticoagulation for Patients Receiving Impella Support. Pharmacotherapy 2021. https://doi.org/10.1002/phar.2629
4. Moretz J, et al. Bicarbonate purge solution to support Impella devices for patients with clinically suspected or confirmed heparin-induced thrombocytopenia. ASAIO J 2021;67.
5. Moretz J, et al. Bicarbonate-based purge solution as a bleeding reduction strategy in patients on Impella support. ASAIO J 2021;67:116.
6. Vandenbriele C, et al. Optimal antithrombotic regimen in patients with cardiogenic shock on ImpellaTM mechanical support: less might be more. EHJ 2020. https://doi.org/10.1093/ehjci/ehaa946.1843

Please contact Pharmacy ED/ICU supervisor or Antithrombosis Stewardship via TigerConnect for any questions or concerns pertaining to this clinical guidance.

Reviewed and approved by: UNMH Antithrombosis Subcommittee
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