MANAGEMENT OF CARDIOGENIC SHOCK REQUIRING MECHANICAL CIRCULATORY SUPPORT (IMPELLA) IN THE ICU AT UF HEALTH FLAGLER HOSPITAL

As with any protocol, this protocol serves to provide evidence-based, comprehensive recommendations to guide our multidisciplinary team in patient care, with the expectation that expert practitioners will modify and customize as necessary the present protocol to meet individual patient needs. This Protocol is not intended to replace the physician's judgment; it is intended to provide guidance to the physician for the group of patients described in this Protocol.

Current literature was reviewed including the more recent scientific statement from the American Heart Association and the International Society for Heart and Lung Transplantation and Heart Failure Society of America guideline on acute mechanical circulatory support and cardiogenic shock (1-8).

OBJECTIVE:

To optimize the management of cardiogenic shock (CS) requiring mechanical circulatory support (MCS/Impella) in the ICU at UF Health Flagler Hospital.

Development of standardized protocols

- Reduces practice variations and facilitate the care of critically ill patients.
- Particularly in the case of CS, the AHA in its more recent scientific statement regarding management of CS suggested that each CS center develops a care pathway to deliver a comprehensive, collaborative, and multidisciplinary care to be managed in either an ICU or CICU (1-3).

BACKGROUND:

A primary cardiac insult can result in an abrupt onset of acute or acute-on-chronic ventricular dysfunction (either systolic or diastolic) and stimulates a cascade of pathologic and compensatory reactions including systemic vasoconstriction, systemic inflammatory response syndrome, fluid retention, and impaired tissue microcirculation which in turn can result in progressive tissue hypoperfusion, myocardial hypoperfusion, decreased contractility and increased afterload with resultant further decrease in CO, thus propagating the death spiral of CS.

Currently there are different available methods of MCS including the Impella that can deliver a wide range of cardiac output and unload the ventricles

- The Impella device (Abiomed) is an intravascular microaxial blood pump that provides temporary MCS, thereby reducing the workload of the heart and improving systemic circulation.
- There are different available versions of Impella that depending on the size can provide a wide range of cardiac output (see table below)

	Impella CP® with SmartAssist®	Impella 5.5® with SmartAssist®	Impella RP® with SmartAssist®	Impella RP Flex® with SmartAssist®
Catheter size	9Fr	9Fr	11Fr	11Fr
Flow rate	Peak flow up to 4.3 L/min	Peak flow up to 6 L/min	4.0+ L/min	Peak Flow up to 4.2 L/min
Motor Housing size	14Fr	19Fr	21Fr	21Fr
Introducer size	14Fr	23Fr	23Fr	23Fr
Insertion method	Percutaneous via introducer sheath	Axillary or direct, surgical insertion	Percutaneous via introducer sheath	Percutaneous via introducer sheath
Guidewire thickness	0.018"	0.018"	0.027"	0.027"

The Impella CP and RP with SmartAssist can be placed in a cath lab setting by cardiologists. The Impella 5.5 require surgical placement (axillary cutdown, or direct Aortic Insertion).

- The Impella 5.5 was designed to allow for longer support duration (more rigid, has a shorter motor, and lack of a pigtail). Produces more LV support, allows ambulation, and is associated with less complications such as limb ischemia, hemolysis and AKI.

Indications for MCS/Impella

Primary cardiac insults that may require MCS/Impella include

- Acute myocardial infarction (AMI)
- Acute decompensated heart failure (ADHF)
- Fulminant myocarditis
- Massive-high risk pulmonary embolism
- Postcardiotomy after cardiac surgery

Contraindications for MCS/Impella

- Moderate to severe aortic insufficiency
- Severe aortic stenosis
- Mechanical aortic valve
- Aortic dissection
- Myxomatous MV
- LV thrombus
- LVOT narrowing/obstruction
- Atrial or ventricular septal defect
- Significant RV failure
- Additional considerations include:
    - Coagulopathy
    - Blood stream infections
    - Medical futility

DIAGNOSIS OF CARDIOGENIC SHOCK

- CS will be clinically defined as:
    - Systolic blood pressure <90 mm Hg for 30 min or the need for vasopressors to maintain systolic blood pressure (SBP) ≥90 mm Hg along with evidence of end-organ hypoperfusion (altered mental status, cold/clammy skin, urine output <0.5 ml/Kg/h, or lactate >2.0 mmol/L).
    - Hemodynamic criteria will include CI of ≤2.2 L/min/m2 and PCWP >15 mmHg along with impaired end-organ perfusion as above.

- CS will be diagnosed based on the etiology of the primary cardiac insult state above

CLASSIFICATION OF CARDIOGENIC SHOCK

The Society for Cardiovascular Angiography and Intervention (SCAI) in 2019 developed a CS classification for risk stratification and predict mortality that was endorsed by the AHA, SCCM, ACC and STS. This classification consensus statement describes 5 stages of CS (5):

- Stage A (“at risk”)
    - Patients without CS who are hemodynamically stable but have acute MI or acute on chronic heart failure putting them at risk of developing C
- Stage B (“beginning”)
    - Patients without CS who display hemodynamic instability, including hypotension and/or tachycardia, but with normal perfusion
- Stage C (“classic”)

    - Patients with CS, manifested by hypoperfusion (hyperlactatemia, oliguria, cool/clammy skin, or altered mentation) that requires intervention (inotrope, vasopressor or MCS) to restore perfusion
- Stage D ("deteriorating)"
    - Patients with CS whose hemodynamic instability and/or hypoperfusion fails to respond to initial interventions
- Stage E ("extremis")
    - Patients with CS and overt or impending circulatory collapse including hypotension despite maximal support or cardiac arrest with ongoing resuscitation

MONITORING

Upon ICU admission and on daily basis, the severity of CS will be assessed in all patients using the SCAI classification.

- In patients with stages A and B, blood pressure and urinary output will be measured hourly along with ABGs with lactate and BMP every 12 hours and as needed.
- In patients with stages C, D and E consideration for placement of MCS, if not already in place, will be discussed among interventional cardiologists and intensivists and with cardiovascular surgeon if surgical etiology or need for surgical placement.

All patients admitted to the ICU with CS and MCS/Impella placed by the interventional cardiologist or cardiovascular surgeon will be included in the protocol. The etiology of CS will be established (AMI, ADHF, myocarditis, massive-high risk PE, or postcardiotomy).

- All patients with clinical diagnosis of CS and MCS/Impella in place must have a pulmonary artery catheter able to measure continuous cardiac output placed.
- Frequent clinical assessment and hourly urine output will be performed following ICU protocols.
- The intensivist team will communicate daily and as needed with the interventional cardiologist and with the cardiovascular surgeon if applicable.

Labs and Ancillary Tests

- The following tests will be done stat on admission to the ICU: ABGs with lactate, SvO_2 from distal PA catheter, CBC, CMP, serum magnesium, serum ionized calcium, INR, PTT, ACT, troponin, LDH, EKG and CXR.
- The following labs will be done every 6 hours x1 day, then every 12 hours x1 day and then daily while Impella/MCS is in place: CBC, CMP, INR, troponin, ABGs with lactate, SvO_2 from distal PA catheter, LDH and ACT and as needed.
- CXR will be done daily in AM and as needed while Impella is in place and patient intubated on mechanical ventilatory support.
- Monitor for hemolysis will be done daily and as needed including Hb, LDH, and bilirubin levels along with urine color visualization looking for hematuria.

IMPELLA/MCS MANAGEMENT

- On admission to the ICU the nurse will document the Impella device catheter length at insertion site, then every 1 hour and PRN.
- The head of the bed should not be higher that 30° for femorally-placed device.
- The ICU nurse should always maintain visibility of Impella catheter device and document flow control, performance level, console mode, placement signal, motor current, purge flow rate, **distal extremity pulses**, and location of Impella device in cm hourly.
- The ICU nurse must notify stat interventional cardiologist and intensivist team if distal tip (pigtail) of the Impella device becomes displaced or if any changes with doppler signals or palpable pulses of the affected lower extremity.

- The ICU nurse should notify the interventional cardiologist and Abiomed Clinical Support if high pressure alarms remain unresolved for more than 2 hours.
- The arterial pressure (placement signal) on the Impella console is reflected pressure of the aorta and will be used for catheter positioning only and not true arterial pressure. Clinical decision making for interventions must be based on blood pressure recorded by the arterial line.
- To maintain purge patency and ensuring pump motor reliability of the Impella cartridge, a purge solution will be initiated with Bicarbonate-Based Purge Solution (BBPS)
    - 12.5 meq of NaHCO3 will be diluted in 500 ml of D5W and the infusion into the purge cartridge will be started at 2 ml/h. In standard configuration, purge flow can range from 2-30 ml/hr.
    - The BBPS solution will be changed every 24 hours and the Impella cartridge every 96 hours
        - Complete change must occur in less than 2 minutes to prevent damage to Impella device.
    - Nurse will document hourly the purge flow rate on the Impella parameter found on the vital sign flowsheet.

Hemodynamic assessment

- Hemodynamic monitoring including continuous CO/CI, SvO_2 from distal PA catheter, BP, CVP, PA diastolic pressure, cardiac power output (CPO)/ cardiac power index (CPI) and pulmonary artery pulsatility index (PAPI) will be performed on admission and every 6 hours while the MCS/Impella is in place along with organ perfusion markers as above.
    - Cardiac power output (CPO) = MAP x CO divided by 451
    - Cardiac power index (CPI) = MAP x CI divided by 451
    - Pulmonary artery pulsatility index (PAPI) = sPAP – dPAP divided by CVP
- Regarding PCWP, when a pulmonary artery diastolic (PAD) pressure is not adequate for medical management of a patient's clinical situation and a pulmonary capillary wedge pressure (PCWP) is required, a MICU/SICU/OHR nurse with appropriate experience and comfort in performing PCWP may obtain a measurement and will have the ability to pull the PA catheter if ordered by a cardiologist or intensivist physician caring for the patient. This is not applicable for patients under the care of the cardiothoracic service.
    - To ensure competency, nurses working with such patients will be provided with the theoretical knowledge through CNO-approved educational resources available at Flagler Hospital and unit level education and training for safely obtaining a PCWP. Such training is required of all nurses in Open Heart Recovery, the SICU, and the MICU.
    - PCWP is to only be obtained using the manufacturers supplied balloon inflation syringe.
    - Do not inflate the balloon in order to obtain wedge pressure for greater than 20 seconds. The default status for PA catheters is the deflated position.
    - A physician's order is necessary to perform a PCWP and such orders may be requested on a PRN or scheduled per-shift basis but must be renewed every 48hrs. Such orders may prompt or guide medical management such as diuretic dosing or vasoactive medication titration based on results obtained.
    - Physicians are not required to be physically present for PCWP measurement by appropriately trained MICU/SICU nurses.
- A physician's order is required to have the patient sit in a chair at the bedside or ambulating when a pulmonary artery catheter (PAC) is in situ.
- A physician order is required for PA catheter removal if not outlined in an approved care pathway protocol or if radiologic imaging suggests a knotted PA catheter.
- Bedside echocardiograms will be performed daily and as needed to evaluate heart function and ventricular assist device positioning to confirm that the Impella is positioned correctly at 3 cm to 3.5 cm from the aortic valve. For patients in the open heart recovery unit the echo will be performed preferably early in AM by 7:30 so it can be repositioned prior to going to the operating room. For

patients with Impella 5.5 can be performed weekly and as needed. If the MCS/Impella needs to be repositioned, it will be performed only by the interventional cardiologist or cardiovascular surgeon.
- The ICU nurse should notify the interventional cardiologist and the intensivist if cardiac index is <2.2 or CPO/CPI <0.6/<0.32 or PAPI <1 during use of Impella device.

Hemodynamic management

For most patients in the ICU will target a MAP ≥65 mmHg or SBP ≥90 mmHg, CVP <10 to 15 mmHg, PCWP <18 mmHg, CI ≥2.2 L/min, CPO/CPI ≥0.6/0.4, UO ≥0.5 ml/Kg/h and lactate <2, although this will be individualized.

- MAP will be supported by maintaining pump performance (P) level between P3-P8 to achieve established target hemodynamics. P8 is the recommended maximum performance level.
- Vasopressors and inotropes will be minimized to achieve targeted hemodynamics and promote lactate clearance and improved end-organ function.
- Acidosis may interfere with appropriate blood pressure response to vasoactive medications, therefore, will attempt to correct significant acidemia (pH <7.3).
- Diuretics can be used to optimize hemodynamics and relieve congestion to achieve PCWP of <18 mm Hg and CVP <15 mm Hg.
- Consider additional volume if any of the following are observed in the presence of a CVP <10 or PCWP or PAD <10 (will use crystalloid 250-500 ml or albumin 5% 250 ml IV bolus as a first step and reassess).
    - Presence of hemolysis
        - Hb drop, elevated LDH, increased indirect bilirubin.
            - If necessary, we will consider send-out sample for measuring plasma free Hb (it is the most specific clinical indicator of hemolysis).
        - Hematuria due to hemoglobinuria.
    - Suction alarms or motor current drops indicative of suction events.
    - Inability to run at P-levels required for adequate support without suction alarms.
    - Lower than expected flows for a given P-level.
- Will monitor Impella positioning with the use of limited echocardiography in the setting of any of the following clinical changes
    - Suction alarms on the controller
    - Worsening patient hemodynamics
    - Hemolysis
    - Ventricular arrhythmias
    - Suspected mechanical complications
        - Device-related cardiac perforation, aortic valve or mitral chordal/leaflet injury (LV Impella), and pump thrombosis.

Suspected hemolysis

- First, will address and correct any malposition or suction alarms
- If malposition is excluded consider hypovolemia or reduced RV function
    - Hypovolemia
        - Lower cardiac filling pressures
        - The LV pressure waveform on the console can provide information as normal systolic and low diastolic pressures indicate low filling status
    - Reduced RV function – low PAPI
- If malposition, hypovolemia and reduced RV function are excluded, pump thrombosis should be considered, as a clot will enhance shear stress and induce hemolysis
    - Evidence for pump thrombosis includes elevated purge pressures and a recent history of insufficient anticoagulation
    - Pump exchange is recommended when pump thrombosis is suspected
- Together with the etiologic investigation
    - Consider lowering the P level as much as tolerated.

    - If lower support is not sufficient, pump exchange or upgrade to another MCS will be considered
- If hemolysis cannot be controlled, device removal should be considered

Weaning from MCS/Impella - Stepwise approach

- Will do daily assessments to determine readiness to wean and begin weaning with the intention of removing the MCS/Impella once myocardial recovery is achieved with improvement of end-organ hypoperfusion on minimal IV inotropic support.
- Weaning of Impella/MCS will be performed in a step by step manner usually with a minimum support of 48 hours.
    - In some circumstances such as when significant complications arise from ongoing MCS support, weaning may need to be initiated before the patient has been fully optimized. In these situations, the benefits of MCS support need to be balanced against the risks of continued complications related to the MCS device.
- After a period of hemodynamic stability and organ perfusion is improving, vasopressors and inotropes can be started to be weaned.
    - Will consider using a low-dose inotropic (dobutamine or milrinone) or vasopressor (norepinephrine) support to facilitate weaning of MCS.
- Once there is minimal requirement of inopressor support, CPO/CPI >0.6>0.4, and PAPI >1 , SvO_2 >60%, acceptable oxygenation, no signs of residual myocardial ischemia and electrical stability, the weaning of MCS/Impella support will be initiated:
    - Will progressively decrease the performance flow every 2 to 4 hours with the goal to remove the Impella/MCS once performance flow P2 is achieved, according to the criteria established by the interventional cardiologist.
    - Will not reduce the flow performance to less than P2 when weaning.
- If weaning is successful, defined by stable clinical, hemodynamic, and laboratory findings on low levels of support, will proceed with device explantation and liberation from MCS as an interdisciplinary decision.
    - MCS/Impella will be removed by interventional cardiologist or cardiovascular surgeon.
        - It will be done in the ICU or in the cath lab per the interventional cardiologist or cardiovascular surgeon discretion. For removal of Impella 5.5 the patient may need to go to operating room.
    - Once removed the RN must follow protocol for sheath removal and document within the Post Invasive Procedure flow sheet.
- After removal of Impella/MCS, the PA catheter will remain in place at least 24 hours and the patient will be co-managed according to the usual ICU protocols.

Escalation of support

If patient remains with end organ hypoperfusion despite MCS/Impella with P flow of 8, and inotropes and vasopressors adjustments, will discuss with the interventional cardiologist, cardiovascular surgeon, and PCP the following options:

- If evidence of severe LV dysfunction with CPO/CPI <0.6/0.4, PCWP >18, CVP <15, CVP/PCWP ratio <0.63, and PAPI ≥1
    - Impella CP in place.
        - Placement of Impella 5.5 attempting better cardiac output and a more complete LV unloading.
    - Impella 5.5 in place
        - Transfer to tertiary center.
- If evidence of severe biventricular dysfunction with CPO/CPI <0.6/0.4, PCWP >18, CVP >15 and PAPI <1.
    - Impella CP in place.
        - Placement of Impella 5.5.

    - Impella 5.5 in place
        - Transfer to tertiary center.
- If evidence of severe RV dysfunction with PCWP <18, CVP >15, CVP/PCWP ratio >0.63, and PAPI <1.
    - Impella RP placement for RV unloading.
    - If no improvement, transfer to tertiary center.

Cardiac arrest

If a patient with MCS/Impella has a cardiac arrest, the decision to perform CPR will be based on standard criteria

- Will reduce flow to P2 during manual compressions.
- If ROSC occurs, we will check MCS/Impella position with echocardiogram and resume previous P flow with adjustments as needed.

Defibrillation

If a patient with MCS/Impella requires defibrillation

- No need to reduce P flow.
- Avoid touching MCS/Impella system at time of shock.

Establishment of goals of care

If patient does not regain myocardial recovery within 3-5 days or have persistent end-organ hypoperfusion despite full MCS/Impella support, will discuss with interventional cardiologist and PCP transfer to tertiary center for potential LVAD/transplant center or consideration for palliative care.

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