Bivalirudin Anticoagulation Guideline for Temporary Mechanical Circulatory Support (tMCS)

Site Applicability

St. Paul's Hospital (SPH) Cardiac Surgery ICU (CSICU

Practice Level

Specialized: Nursing, Clinical Pharmacist & providers who have received supplemental education and work in PHC CSICU can manage patients on tMCS

Requirements

The MRP and Clinical Pharmacy Specialist must collaboratively review the patient's case and determine that anticoagulation with bivalirudin versus with a standard anticoagulation protocol (i.e. heparin) is appropriate.

This protocol applies to the following tMCS:

- Extracorporeal Membrane Oxygenation (ECMO) (Venoarterial)
- Abbott CentriMag blood pump ventricular assist device (Left or Right)
- LivaNova centrifugal blood pump circuit configured as ventricular assist device (Left or Right)

*Excluded tMCS system: Abiomed Impella (Left or Right)

Need to Know

Patients with tMCS require systemic anticoagulation given the inflammatory cascade from critical illness that may lead to thrombosis. Thrombosis can cause adverse effects such as oxygenator failure, pump malfunction, hemolysis, and thromboembolic events (e.g. limb ischemia or stroke) (Sy et al, 2017). There are clinical scenarios where the risk of anticoagulation use outweighs the benefit (e.g. severe bleeding, thrombocytopenia); the MRP should determine appropriateness of anticoagulation therapy and evaluate this daily while the patient is supported by tMCS.

Heparin remains the standard choice of anticoagulation for patients on tMCS at St. Paul's Hospital, Cardiac Surgery ICU (CSICU). Heparin however, has its disadvantages and may not be the appropriate for all patients.

Risks of intravenous heparin

- Bleeding
- Heparin-induced thrombocytopenia
    - HIT occurs in up to 5% of patients requiring heparin therapy for more than 4 days, and risk is increased in those undergoing cardiovascular surgery or requiring ECMO support
- Heparin resistance
    - Requires antithrombin III in order to enact anticoagulant effects; antithrombin III is often reduced in patients receiving ECMO

Bivalirudin for ECMO:

Bivalirudin indications: currently only approved by Health Canada for use as an anticoagulant in patients undergoing percutaneous coronary intervention, or for patients with, or at risk of heparin-induced thrombocytopenia undergoing percutaneous coronary intervention or cardiac surgery.

Emerging data is showing potential benefits of using bivalirudin in tMCS patients including: more time spent within therapeutic range, less bleeding, less in-hospital mortality, less blood products use, and no difference in thromboembolic events compared to Heparin (Ranucci et al, 2011; Rivosecchi et al, 2021; Seelhammer et al, 2021; Sheridan et al, 2022

Benefits of bivalirudin

- Inhibits plasma and clot-bound thrombin reducing clot stabilization via thrombin-activated platelets
    - Activity is independent of antithrombin
- Quick onset of action (less than 5 minutes), short half-life (25 minutes)

Risks of bivalirudin

- No antidote
- Mostly cleared by circulating proteases, but does have renal clearance
    - Elimination reduced in those with renal impairment

Guideline

The following should be considered when determining if IV bivalirudin is appropriate (either as switch from heparin, or as starting agent):

- Hemostasis achieved & no planned surgery within 24 to 48 hours, <u>in addition to at least one</u> of the following criteria:
    - Centrally cannulated intermediate LVAD and or RVAD
    - Confirmed or suspected heparin-induced thrombocytopenia with or without thrombosis
    - Inability to achieve stable target aPTTs within 24 to 48 hours of initiating heparin, OR aPTT remains unstable on Heparin
    - Suspected or measured low anti-thrombin III levels

- Thrombosis is noted in the patient or in the tMCS circuit while on IV heparin

MRP to order drug via Electronic Health Record and should use the **bivalirudin for Heparin Induced Thrombocytopenia PowerPlan (Module)**.

Also refer to the Parenteral Drug Therapy Manual (PDTM) in instruction for use & administration of bivalirudin

If patient is deemed appropriate for bivalirudin and has started on therapy but unplanned surgery arises; MRP with anesthesia is to discuss plans for timing of discontinuation with or without a change of anticoagulation strategy that is tailored to the patient's clinical status and circumstances.

Suggested time range for discontinuation; at minimum:

- 4 hours for patients with normal renal function
- 8 hours for patients with renal dysfunction

Documentation

Decision and indication to use bivalirudin (versus standard therapy), after discussion and review of this protocol should be documented in Cerner EMR by the MRP. Daily review of the appropriateness of bivalirudin therapy should be recorded on the critical care rounds notes by the MRP.

Patient and Family Education

Patient (if clinically stable and able to comprehend information) and their family should be provided information and education about the use of bivalirudin, the purpose of using bivalirudin versus standard anticoagulation, the effects and side effects, as well as how it is routinely monitored for its safety and effectiveness.

Related Documents

1. B-00-13-10207 - Extra Corporeal Membrane Oxygenation (ECMO): Care of the Patient Receiving Veno-Arterial ECMO
2. Heparin – (PDTM)
3. Bivalirudin - PDTM
4. CentriMag Blood Pump, Abbott, Instructions For Use
5. Bivalirudin for Heparin Induced Thrombocytopenia (HIT) PowerPlan

References

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Persons /Groups Consulted

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