Evaluation of the clinical effectiveness of a bivalirudin-based anticoagulation protocol for ECMO patients in the cardiac surgery ICU at a large academic medical center

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Purpose/Background: Extracorporeal membrane oxygenation (ECMO) is a therapeutic option for refractory respiratory and/or cardiac failure. While systemic anticoagulation with heparin is routinely administered, the use of heparin may trigger heparin-induced thrombocytopenia (HIT) or heparin resistance which can result in thrombotic complications. In the case of HIT or heparin resistance during ECMO, alternative anticoagulation strategies may be necessary. Bivalirudin, a direct thrombin inhibitor, may be a valid option for anticoagulation in ECMO; however, there is limited data for its use in this population. At our institution, a nurse-driven protocol is used to titrate bivalirudin for anticoagulation in ECMO patients.

Objective: The primary objective of this study was to evaluate adherence to the bivalirudin ECMO protocol in the Cardiac Surgery ICU. Secondary objectives of this study were to evaluate the effectiveness and safety of the bivalirudin ECMO protocol.

Methods: A historical cohort of 213 ECMO patients from January 2013 to July 2017 was evaluated. Adult patients (18 years or older) were included in the analysis if they were on ECMO for at least 24 hours and received bivalirudin for anticoagulation. Pregnant or incarcerated patients were excluded. Thirty-seven ECMO patients (22 VV and 15 VA-ECPR) were retrospectively analyzed via chart review. The primary outcome variables were the type and number of protocol deviations. Secondary outcome variables included time to target aPTT range, mean bivalirudin dose while in target aPTT range, aPTT variations > 20% outside of goal range, and number of dose adjustments required to achieve goal range. Safety endpoints included thrombotic complications (patient and circuit thrombosis), bleeding complications (cerebral and spontaneous tissue bleeding), and transfusion requirements. Primary and secondary outcomes were analyzed using descriptive statistics.

Results: For the primary outcome of adherence to the bivalirudin ECMO protocol, all patients in both the VV and VA-ECPR groups had at least one protocol deviation. The mean number of protocol deviations per patient was 1.8 ± 0.85 and 1.5 ± 0.74 in the VV and VA-ECPR groups, respectively. The time to target aPTT was 29.0 ± 23.8 hours in the VV group and 12.4 ± 15.3 hours in the VA-ECPR group. The mean dose of bivalirudin used to achieve and maintain a goal aPTT was 0.150 ± 0.125 mg/kg/hr in the VV group and 0.058 ± 0.053 mg/kg/hr in the VA-ECPR group. In the VV group, 2 patients experienced deep vein thromboses, 1 patient had a documented circuit thrombosis, and 3 patients had spontaneous tissue bleeds. In the VA ECPR group, 2 patients had documented circuit thrombosis and 2 patients had spontaneous tissue bleeds.

Conclusion: The adherence to the current bivalirudin ECMO protocol is poor in the cardiac surgery ICU, which may contribute to the extended time required to achieve goal aPTT levels. After the current analysis, re-education of the nursing and medical staff is recommended in order to ensure understanding, compliance, and appropriate documentation of the bivalirudin ECMO protocol. Additionally, based on the secondary endpoints describing the effectiveness and safety of the protocol, the current protocol will be re-evaluated to determine if revisions to the protocol are necessary.