Use of a Novel Bicarbonate-Based Impella 5.5 Purge Solution in a Coagulopathic Patient

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ABSTRACT

The Impella 5.5 with SmartAssist (Abiomed; Danvers, MA) is a life-saving treatment option in acute heart failure which utilizes a continuous heparin purge solution to prevent thrombosis. In patients with contraindications to heparin, alternative anticoagulation strategies are required. We describe the stepwise management of anticoagulation in a coagulopathic patient with persistent cardiogenic shock following a coronary artery bypass procedure who underwent Impella 5.5 placement. A direct thrombin inhibitor-based purge solution was utilized while evaluating for heparin-induced thrombocytopenia. Use of a novel bicarbonate-based purge solution (BBPS) was successfully used due to severe coagulopathy. There were no episodes of pump thrombosis or episodes of severe bleeding on the BBPS and systemic effects of alkalosis and hypernatremia were minimal.

INTRODUCTION

The Impella 5.5 with SmartAssist (Abiomed; Danvers, MA) transvalvular micro-axial left ventricular assist device (VAD) is a life-saving treatment option in acute heart failure. To prevent thrombosis, the Impella device requires a purge line that traditionally uses a continuous heparin infusion (1). Patients with contraindications to heparin require alternative anticoagulation strategies. We describe the stepwise management of anticoagulation in a patient with multiple contraindications to a traditional heparin purge solution including use of a bicarbonate-based purge solution (BBPS).

CASE

The patient, a 41-year-old female with history of poorly managed type I diabetes and polysubstance abuse, presented to an outside facility with severe chest pain as a result of Non-ST-Elevation Myocardial Infarction with a peak troponin of 26 ng/mL. A transthoracic echocardiogram demonstrated a Left Ventricular Ejection Fraction (LVEF) of 60% with normal right ventricular (RV) systolic function. A Left heart catheterization demonstrated severe three vessel coronary artery disease. At the outside facility, the patient underwent an on-pump coronary artery bypass procedure including endarterectomy of the left anterior descending (LAD) coronary artery. This procedure was complicated by a massive infarction of the LAD territory with subsequent acute heart failure. Prior to sternal closure, an Impella 5.5 was implanted through a graft on the ascending aorta which was brought out suprasternally. The Impella was managed with a traditional heparin purge. Postoperative echocardiogram demonstrated a LVEF of 13% with an appropriately placed Impella 5.5 and moderately reduced RV systolic function.

Due to the severity of her heart failure, the patient was transferred to our quaternary facility for advanced mechanical circulatory support and transplant evaluation. Upon arrival to our facility, the patient was noted to have thrombocytopenia to 132 x 10^9/L from a preoperative value of 408 x 10^9/L. Due to concern for heparin-induced thrombocytopenia (HIT), all heparin products were discontinued, and purge solution was switched to argatroban (50 mg in 1 L of 5% dextrose) per our facility's protocol.

Platelet Factor 4 (PF4) Absorbance and Serotonin Release Assay (SRA) were sent and resulted as negative for HIT. Patient was subsequently switched back to a heparin purge solution once the platelet count rebounded after 17 days on an argatroban purge solution.

Her hospital course was complicated by development of an acute kidney injury with volume overload and RV systolic dysfunction requiring aggressive renal replacement therapy. With dialysis and careful fluid management, the patient recovered renal function. She remained on the centrally placed Impella 5.5 until postoperative day 33 at which time a peripheral Impella 5.5 device was placed through a right axillary approach to enable formation of a tracheostomy. While on both heparin and argatroban purge solutions, patient was noted to have multiple episodes of severe bleeding from central line sites. Her aPTT was labile (range 26-107 sec) despite receiving no additional systemic anticoagulation. In consultation with the device manufacturer, on postoperative day 56, the patient was placed on a BBPS of 25 mEq sodium bicarbonate in 1 L of 5% dextrose. While on a BBPS purge solution, there were no episodes of pump thrombosis or severe bleeding events. Systemic effects were limited, with no hypernatremia and mild systemic alkalosis (pH range 7.41-7.57). She remained on a BBPS for 7 days until postoperative day 63 when the device became dislodged during patient transfer requiring emergent placement of an intra-aortic balloon pump. After further volume optimization and RV recovery, she underwent uneventful placement of an intracorporeal VAD on postoperative day 75.

COMMENTARY

The Impella 5.5 temporary axial flow VAD has been established as an effective tool for management of cardiogenic shock. It can be used as a bridge to recovery, to an intracorporeal device, or to transplantation (2). To prevent blood from entering the device motor, a dextrose-based purge solution provides a counter current pressure gradient (figure 1). To prevent buildup of biomaterial within the purge gaps, the purge solution is formulated with heparin (25-50 units/mL) in a dextrose solution of varying concentrations (5-20%). This purge solution prevents thrombosis through direct inhibition of the coagulation cascade with the dextrose concentration adjusted to optimize fluid viscosity. In addition to heparin within the purge solution, systemic heparin or alternative anticoagulant may be administered for prophylaxis (1,3).

As demonstrated with this patient, post-cardiotomy thrombocytopenia complicates management of anticoagulation. While some degree of thrombocytopenia is common following cardiac surgery, a diagnosis of HIT can be devastating (4). In addition, the hypercoagulable state of HIT places patients with a mechanical support device at elevated risk for pump thrombosis. Per our facility's protocol, heparin products are discontinued after an observed fall of more than 50% from baseline or total platelet count less than 100×10^9/L and immediate labs sent for PF4 absorbance and SRA. The patient is then managed with an argatroban-containing purge solution pending these results. Switching back to heparin is considered if PF4 and SRA testing is negative for HIT.

As argatroban and other direct thrombin inhibitors (DTI) lack a known reversal agent and bleeding complications are possible with both DTIs and heparin, there is a need for an alternative purge solution. In addition, the highly variable delivery of anticoagulation to the systemic circulation as autoregulated by the Impella system in a hemodynamically labile patient increases this risk (1). While its use as a systemic anti-coagulant is limited, sodium bicarbonate has been successfully used as a hemodialysis catheter lock solution (5). The proposed mechanism whereby a BBPS inhibits thrombosis is through

bicarbonate chelation of calcium and alterations of pH (6). This functions by suppressing fibrin assembly, improving protein stability, and lysing biobuildup.

Due to its effect on pH in critically ill patients, monitoring for systemic alkalosis and hypernatremia is necessary. In this patient, the BBPS infusion rate ranged from 13-13.9 ml/hr. As this case demonstrates, the risk of either alkalosis or hypernatremia is minimal. Importantly, no pump thrombosis events were noted and severe bleeding at percutaneous access sites improved.

CONCLUSION

Prolonged anticoagulation in cardiac surgery patients is problematic due to both bleeding and thrombotic events. This is particularly evident in the setting of temporary ventricular support devices in critically ill patients. While DTI therapy may be considered for HIT, an alternative agent that does not increase bleeding risk is attractive. We demonstrate in this case report the stepwise management of an Impella 5.5 purge solution, including the use of a BBPS in a coagulopathic patient. We believe further investigation is warranted to evaluate its efficacy and safety particularly among patients with contraindications to traditional anticoagulation.

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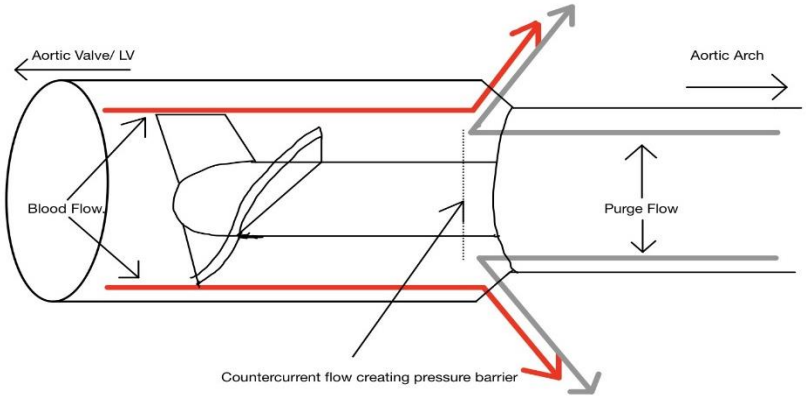

Figure 1. Impella outlet. Countercurrent pressure from the purge line creates a pressure gradient to direct blood flow away from the motor housing.