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EPCardiac41

**Bicarbonate Purge Solution To Support Impella Devices For Patients With Clinically Suspected Or Confirmed Heparin-induced Thrombocytopenia**

**Jeremy Moretz**, PharMD<sup>1</sup>, Soumen Das, PhD<sup>1</sup>, Craig Beavers, PharMD<sup>2</sup>, Doug Jennings, PharMD<sup>3</sup>, Jenna F. Cox, PharMD<sup>4</sup>, Robert DiDomenico, PharMD<sup>5</sup>, Steve Dunn, PharMD<sup>6</sup>, Long To, PharMD<sup>7</sup>, Toby Trujillo, PharMD<sup>8</sup>, Phillip Weeks, PharMD<sup>9</sup>, Scott Corbett, PhD<sup>1</sup>; <sup>1</sup>Abiomed, Danvers, MA, USA, <sup>2</sup>University of Kentucky College of Pharmacy, Lexington, KY, USA, <sup>3</sup>Long Island University College of Pharmacy, Brooklyn, NY, USA, <sup>4</sup>Prisma Health Richland Hospital, Columbia, SC, USA, <sup>5</sup>UIC College of Pharmacy, Chicago, IL, USA, <sup>6</sup>University of Virginia Health System, Charlottesville, VA, USA, <sup>7</sup>Henry Ford Health System, Detroit, MI, USA, <sup>8</sup>University of Colorado Skaggs School of Pharmacy, Aurora, CO, USA, <sup>9</sup>Memorial Hermann Texas Medical Center, Houston, TX, USA

**Study:** The Impella catheter is a transvalvular, micro-axial left ventricular assist device that provides temporary mechanical circulatory support and requires a heparin-containing purge solution to reduce the risk of biomaterial deposition in the purge gaps and also maintain proper pump function. For patients with suspected or confirmed heparin-induced thrombocytopenia (HIT), direct thrombin inhibitors (DTI) have been proposed as an alternative to heparin in the purge, but have been associated with pump failure requiring temporary tPA in the purge solution to normalize pump function. In this report, we review HIT patients supported with a sodium bicarbonate-based purge solution (BBPS).

**Methods:** Patients with suspected or confirmed HIT on Impella support using sodium bicarbonate (25 mEq in 1L D5W solution) in the purge from September 2020 to January 2021 were reviewed. Case data were obtained from Impella Quality (IQ) database for those supported with a BBPS and clinically suspected or confirmed HIT. Purge pressures and purge flows were evaluated from the Automated Impella Controller (AIC).

**Results:** Ten patients were supported with a BBPS during this period. Impella support was begun either with no anticoagulant (n=5), DTI (n=2), or heparin (n=3) and then switched to BBPS. Impella run time using a BBPS ranged from 1-14 days; five pumps had a run time with a BBPS > 10 days (Figure 1). Systemic DTI use was used in five cases along with a BBPS. No purge pathway thrombosis or bleeding events were observed, along with no changes in purge flow or purge pressures observed. In conclusion, preliminary experience suggests the use of BBPS in the setting suspected or confirmed HIT patients supported with an Impella is safe and effective and may provide a useful therapeutic option for heparin intolerant patients. Future work should investigate mechanisms and purge reliability of BBPS in this setting.

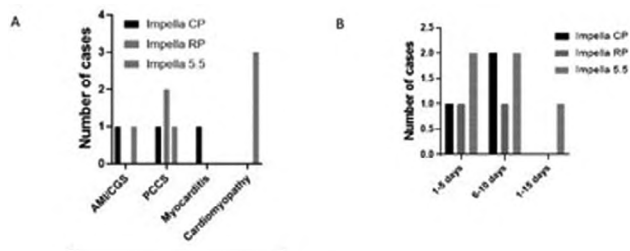


Figure 1: (A) Clinical indication, and (B) Duration of use across different Impella pump types supported with bicarbonate in the purge

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**Percutaneous Access Device For Preventing LVAD Driveline Infection**

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**Study:** A durable left ventricular assist device (LVAD) requires long-term circulatory support capability, yet driveline infection (DLI) due to the percutaneous driveline access is an inevitable adverse event, which is one of the major causes of hospital readmission impeding the patient quality of life. Totally implantable system with a percutaneous energy transmission system may be an ultimate solution for this adverse event, but another potential approach historically attempted is a percutaneous access device (PAD).

**Methods:** PAD prototypes were fabricated for the in-vitro fitting tests, handling feasibility, and, in-vivo implantation tests. Control smooth surface (non-textured titanium surface), blasted rough surface, multiple sintered beads surface, and 3D-titanium sponge material was evaluated in tissue healing and integrity between skin-titanium interface. To identify the optimal animal model and chronic study protocol, working prototypes with sealed mechanism were designed based upon an anatomical fitting study (on the bovine study) and evaluated with goat and swine models (Mexican hairless and Göttingen mini pig) for chronic implantation. After termination, histopathology analysis was performed.

**Results:** Non-textured titanium surface developed poor tissue adhesion and developed epidermal down-growth. Titanium beads (spherical/asymmetrical) sintered surface establish better tissue ingrowth but inflammatory cell infiltration was sustained around the skin interface. Titanium sponge structure appeared to develop stable skin and subcutaneous healing without the evidence of active inflammation and infection on the Göttingen minipig model up to 60 days chronics implantation. Histopathology study demonstrated tight tissue adhesion and micro vascularization. Skin button PAD may be a potential technology for preventing DLI by offering mechanical barriers for the driveline exit site avoiding bacterial invasion from the interface between the driveline and adjacent tissue.

