VELETRI® (epoprostenol)
Aerosolized Administration of VELETRI

SUMMARY

- The safety and efficacy of inhaled VELETRI has not been established in clinical trials.
- Specific concerns regarding the use of inhaled VELETRI include the use of arginine as an excipient and the pH of the reconstituted solution.[1-3]
- A search of the published medical and scientific literature identified several articles describing the aerosolized administration of inhaled epoprostenol (iEPO).[4-27]

CLINICAL DATA

In vitro data implicate arginine, an excipient in VELETRI for injection, in metabolic processes involved in both bronchodilation and bronchoconstriction, inflammation, cytotoxicity and fibrosis.[1-3] There are no data available investigating the use of inhaled arginine in pulmonary arterial hypertension (PAH), acute respiratory distress syndrome (ARDS), or the perioperative setting.

Information From the Literature

Randomized Trial

Ghadimi et al[4] conducted a health system-funded, randomized, blinded, parallel-designed, equivalence clinical trial that investigated whether the use of VELETRI will lead to similar rates of severe/grade 3 primary graft dysfunction (PGD-3) after adult LT (lung transplant) when compared with use of inhaled nitric oxide (iNO).

Ghadimi et al[5] conducted a health-system funded, randomized, double-blind controlled trial that evaluated if iEPO and iNO led to similar rates of postoperative right ventricular (RV) failure development and other outcomes after major cardiac surgery.

Retrospective Studies

Ammar et al[6] analyzed critically ill patients admitted to the intensive care unit who received iEPO through noninvasive routes of ventilator support systems. Improvements in respiratory status and hemodynamic parameters were evaluated.

Li et al[7] conducted an in-vivo and in-vitro study to compare high versus low concentrations of VELETRI in adult intubated patients. The in-vitro study was a retrospective study that enrolled adult patients who received VELETRI via invasive ventilation to treat refractory hypoxemia, pulmonary hypertension, or right ventricular failure between August 2015 and December 2019.

Li et al[8] conducted a retrospective review of adult patients who received VELETRI via high-flow nasal cannula (HFNC) to treat PH and/or right ventricular dysfunction between July 2015 to October 2019.

Richards et al[9] conducted a retrospective review of patients with severe hypoxemic respiratory failure or right heart failure treated with iEPO prior to transport from May 2017 through June 2019. The primary outcome was the change in oxygen saturation (SpO_2) from the start of the iEPO transport to the time of handover of care at the receiving institution. The secondary outcome was the change in the mean arterial pressure (MAP).

Additional retrospective studies, including patients with COVID-19 infection, are included in the REFERENCES section for your review.[10-21]

Case Reports

Held et al[22] reported a case of RV infarction presenting with new right bundle branch block (RBBB), and therapeutic use of inhaled epoprostenol to reduce RV afterload and augment cardiac output during refractory cardiogenic shock.

Foster et al[23] reported a series of four cases that occurred from August through October 2018 of adult patients with severe hypoxemic respiratory failure from Legionnaires' disease transported on iEPO to extracorporeal membrane oxygenation (ECMO) centers.

Additional case reports are included in the REFERENCES section for your review.[24-26]

Prospective Study

Abe et al[27] conducted a prospective study that provided the first comparative evaluation of the effects of inhaled prostacyclin and nitric oxide on pulmonary hemodynamics, systemic hemodynamics, and gas exchange in patients developing residual pulmonary hypertension after pulmonary endarterectomy.

LITERATURE SEARCH

A literature search of MEDLINE®, EMBASE®, BIOSIS Previews®, DERWENT® (and/or other resources, including internal/external databases) was conducted on 8 March 2024

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