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A Case Study of SANGUINATE™ in a Patient with a Comorbidity due to An Underlying Hemoglobinopathy (4/13/2014)

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Corresponding Author:	Deven Parmar, MD Prolong Pharmaceuticals South Plainfield, NJ UNITED STATES
Corresponding Author's Institution:	Prolong Pharmaceuticals
Order of Authors:	Deven Parmar, MD

Background

SANGUINATE™ (pegylated carboxyhemoglobin bovine)**,** 40 mg/mL for intravenous infusion, is an investigational product under development for treatment of the consequences of vascular ischemia and hemolysis associated with SCD. Under an Emergency IND, SANGUINATE was administered to a patient with a life-threatening comorbidity of SCD.

Method (Patient)

A 61-year-old female patient (past medical history of hypothyroidism, SC/thalassemia trait, two severe SC crises, hypotension, intraductal papilloma and atypical ductal hyperplasia of left breast/post-raloxifen) was admitted for Altered Mental Status/lethargy. Due to religious beliefs, the patient and her family on her behalf refused blood transfusion. The workup was negative for cerebral vascular aneurysm but revealed an abnormal EEG consistent with encephalopathy. The patient gradually worsened with hemoglobin dropping from 8.6 to 6.5 g/dL, a very low platelet count and possible thrombotic thrombocytopenia purpura (TTP), causing intravascular hemolysis and potentially complicating cerebral ischemia. Sepsis workup was negative. BP progressively decreased, and vasopressors and volume expanders were administered. She was in near-comatose condition and unresponsive to voice, with stable vital signs and a pre-infusion brain oxygen saturation level of 48%. Emergency IRB approval was obtained and one 500 mL bag of SANGUINATE (290 mg/kg dose at 69 kg mass) was administered via 2-hour intravenous infusion.

Results/Outcome

SANGUINATE was tolerated with no acute toxicity. Within 12 hours post-infusion, the brain oxygen saturation level rose to 60%. The patient became responsive to verbal commands.

The next day, the patient experienced acute respiratory failure and anemia secondary to SC crisis with possible TTP. At this time, the hemoglobin level had not improved and bradycardia developed. A second infusion of SANGUINATE was administered. The pre–infusion brain oxygenation saturation level was 51%. The post–infusion brain oxygenation saturation level was also 51%.There were no study related or possibly related acute toxicities noted post- infusion. The patient continued to show poor response to routine therapy with severe hypotension and progressive acute renal failure.

After respiratory extubation, the patient's blood pressure and heart rate declined and subsequently stopped. Autopsy was refused. The event of death was judged by the study investigator as not related to study drug.

Conclusion

This is the first case to illustrate the potential of SANGUINATE to treat hypoxia associated with SCD comorbidities. A Phase II trial is planned to test the safety and efficacy of SANGUINATE in patients with vaso-occlusive crisis due to SCD.