MOCK TRANSFUSION OF BOVINE BLOOD TO DETERMINE THE RATE OF HEMOLYSIS USING A 1o2® VALVE

Introduction

A new drug delivery valve by ICU Medical is evaluated in this study to determine its performance when used with blood. Concerns in clinical practice are commonly directed toward the use of a product and whether it functions well with, or is compatible for use with applications involving the administration of blood. ICU Medical has designed the 1o2 to be safe and effective for use with blood. An independent study was completed at The North American Science Associates (NAMSA) of Irvine California to determine the rate of hemolysis for blood delivery through the 1o2 valve.

ASTM Hemolysis Study

The independent study was conducted at NAMSA where all readings were done with the use of a spectrophotometer and obtained according to ASTM standards for statistical evaluation of laboratory data. Ten Abbott Laboratories blood transfusion sets (Catalog No. 9155-68) with standard male luer lock fittings were used to access 500cc bags of whole citrated blood. The blood transfusion sets were hung at 72" head height to simulate clinical use. The Abbott set alone was used as the control to demonstrate the best case clinical scenario where blood would be delivered through the open ended male luer with a direct hub connection to the venous access device.

Procedure

Ten samples of the single valve 1o2 were attached to the ten blood delivery sets at the sideport of the 1o2. The control group was setup in the same method excluding the 1o2 device. 500cc of blood was delivered through the control and study group over a period of two hours and samples were taken at 250cc and 475cc. The spectrophotometer was used to measure the mean average for the absorbance and concentration of both plasma hemoglobin and blood hemoglobin independently. The test results are shown in table one.

TABLE ONE

	1o2	Control
Plasma Hemoglobin Absorbance (ABS)	0.00	0.00
Plasma Hemoglobin Concentration (mg/mL)	0.00	0.00
Blood Hemoglobin Absorbance (ABS)	0.348	0.402
Blood Hemoglobin Concentration (mg/mL)	132.403	156.875

Conclusion

The adjacent graph illustrates how the 1o2 compares to an open ended male luer in regards to the rate of hemolysis.

The 1o2 performs significantly as well in preventing the incidence of hemolysis as using the open ended luer (no connector). Using t-Test P(T<=t) one tail with a P score of greater than 0.05 with a 95% confidence level, in all cases this study demonstrates that no significant hemolysis occurs with the use of the 1o2 valve.