STUDY SUMMARY

Minimizing Hemolysis During Blood Draws With The Clave™ Neutron™ Needlefree Neutral Displacement Connector

Report of a study commissioned by ICU Medical, Inc. and conducted by NAMSA

Background

The Clave Neutron catheter patency device is designed to prevent fluid displacement resulting from the four known causes of displacement associated with needlefree connectors: connection or disconnection of a luer, syringe plunger compression, patient vascular pressure changes (e.g. coughing or sneezing), and IV solution container run-dry which may cause multiple forms of reflux into a catheter. The Clave Neutron connector utilizes a bidirectional silicone valve, which remains closed unless it is being accessed for aspiration or infusion, in combination with an internal bellows feature, which gives the Clave Neutron connector the unique ability to absorb and physically compensate for pressure variations that typically result in blood reflux into a catheter.

In order to properly evaluate the effect of the Clave Neutron connector on the cellular composition of blood drawn through the device, ICU Medical independently contracted with NAMSA of Northwood, Ohio to perform an in vitro hemolysis study. The results of this study are reported herein.

Purpose

The purpose of this study was to evaluate the potential for the Clave Neutron connector to cause hemolysis during a blood draw procedure by measuring the % hemolysis of blood samples withdrawn through two Clave Neutron connector test articles (five samples each), blood samples withdrawn through two control articles (EDTA vacutainer tubes with luer adapters), and one positive control sample (Sterile Water for Injection (SWFI)).

Test Article Clave Neutron Needlefree Neutral Displacement Connector

Materials and Methods

For the study, the Clave Neutron connector was evaluated according to procedures based partly on ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials, and ISO 10993-4, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood.

A test apparatus was prepared by attaching the sponsor-provided tubing set (B1002) to a 500 mL bag of whole porcine blood. The B1002 was primed by attaching a 5 cc syringe to each open line, opening the clamps, and withdrawing 5 cc of blood. Each line was re-clamped and the syringes discarded.

EDTA vacutainer blood collection tubes were then attached to the two open ends of the B1002. The clamps on each line were opened to collect a single sample of 5 mL of blood for each control article. The clamp was closed and the control articles were removed from the B1002.

The Clave Neutron connector test articles were then attached to the two open lines. After connecting the Clave Neutron connector test articles, a luer adapter was attached, followed by an EDTA vacutainer blood collection tube. A 5 mL aliquot of blood was withdrawn into the tube for both ends for each test article. This was repeated five times for each test article (ten samples in total).

The positive control was prepared by taking a 10 mL aliquot of SWFI and mixing with 0.2 mL of the whole porcine blood.

Samples from the Clave Neutron connector test articles, open luer control articles, and positive control were centrifuged at 700-800 x g for 15 minutes. A 1.0 mL portion of each supernatant was added to separate tubes containing 1.0 mL of Drabkin's reagent. The test and control tubes stood at room temperature for 15 minutes and the absorbances were read at 540 nm using a spectrophotometer.

Control Article Marketed EDTA Vacutainer Tube

The average % hemolysis was then calculated by averaging the % hemolysis values for each of the two test articles (five samples of each article) and by averaging the two samples taken from the control articles (one sample from each).

Results

The mean % hemolysis for Clave Neutron connector test articles 1 and 2 was 0.29% and 0.28%, respectively. Comparatively, the mean % hemolysis for the open luer control articles was 0.29%.

Table

Sample	Absorbance	% Hemolysis	Mean % Hemolysis	Standard Deviation
Sponsor Provided Control (1)	0.127	0.31	0.29	0.0
Sponsor Provided Control (2)	0.109	0.27		
Positive Control	0.942	116.89	N/A	N/A
Test Article 1: Aliquot 1	0.142	0.35	0.29	0.0
Test Article 1: Aliquot 2	0.111	0.27		
Test Article 1: Aliquot 3	0.110	0.27		
Test Article 1: Aliquot 4	0.120	0.29		
Test Article 1: Aliquot 5	0.114	0.28		
Test Article 2: Aliquot 1	0.116	0.28	0.28	0.0
Test Article 2: Aliquot 2	0.117	0.28		
Test Article 2: Aliquot 3	0.112	0.27		
Test Article 2: Aliquot 4	0.120	0.29		
Test Article 2: Aliquot 5	0.114	0.28		

Conclusion

The results of this study indicate that the Clave Neutron catheter patency device does not increase the rate of hemolysis compared to an open luer. Consequently, using Clave Neutron to reduce catheter reflux during blood draws may help clinicians reduce thrombotic occlusions and lower the risk of bloodstream infection without increasing the risk of hemolysis of red blood cells drawn through the device.