

Minimizing Hemolysis During Blood Infusion 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 Needlefree Neutral Displacement Connector 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. 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 Clave Neutron on the cellular composition of blood infused 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 Clave Neutron to cause hemolysis during a blood infusion procedure by measuring the % hemolysis of blood samples infused through ten Clave Neutron test articles (total of twenty samples), and blood samples infused through an open luer.

Materials and Methods

For the study, Clave Neutron 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 (B30137) to a 500 mL bag of whole porcine blood. The blood bag was hung at a height of 72 in. to simulate clinical use.

Control articles were collected by opening the clamped line and allowing a 3 mL aliquot of blood to drain at a rate of approximately 250 mL per hour. The clamp was then closed and a Clave Neutron test article was attached to the open end of the set. The clamp was re-opened at the same rate of 250 mL per hour and approximately 3 mL of blood (from the same blood bag used for the control article) was collected after approximately 250 mL and 450 mL of the blood had been drained from the blood bag. This was repeated with each of the ten test articles for a total of twenty samples.

Both the control and Clave Neutron test samples 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.

The mean % hemolysis for each volume (250 mL and 450 mL) was calculated by averaging the % hemolysis values for each of the ten test articles. The mean % hemolysis for the control article was calculated by averaging the % hemolysis values for each of the ten samples taken from the control article.



Test Article
Clave Neutron
Needlefree Neutral
Displacement
Connector

Results

The mean % hemolysis for the open luer control samples was 0.29%. In comparison, the mean % hemolysis for the Clave Neutron connector test article after approximately 250 mL and 450 mL of blood was infused through the device was 0.25% and 0.28%, respectively.

Table

Test/Blood bag	Control Article Percent Hemolysis Values	Test Article ~250 mL Percent Hemolysis Values	Test Article ~450 mL Percent Hemolysis Values
#1	0.20371	0.19522	0.19098
#2	0.21276	0.18773	0.18773
#3	0.28086	0.28717	0.29979
#4	0.22512	0.23105	0.26067
#5	0.31669	0.13210	0.14395
#6	0.17999	0.16874	0.17811
#7	0.28595	0.26668	0.32130
#8	0.22844	0.27739	0.26651
#9	0.41958	0.35414	0.45615
#10	0.59374	0.41388	0.53572
Mean % Hemolysis	0.29%	0.25%	0.28%

Conclusion

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