The Addition of a Silicone Valve to a Peripheral Intravenous Catheter Hub Does Not Increase Blood Hemolysis

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Abstract

The ViaValve™ Safety I.V. Catheter (Smiths Medical, ASD, Inc.) is an active safety peripheral intravenous catheter (PIVC) that has a new silicone valve integrated into the catheter hub to minimize blood exposure upon catheter insertion. The purpose of this study was to evaluate the potential of the ViaValve™ Safety I.V. Catheter to produce hemolysis as compared to the ProtectIV™ Plus Safety I.V. Catheter, from which the ViaValve™ catheter was designed, and other non-valved (BD Insyte™ Autoguard™ Shielded IV Catheter and B. Braun Intracath Safety IV Catheter) products at gauge (g) sizes 14, 20, and 24. Samples were taken from units of pooled red blood cells by different methods of removal and pull speeds (0.1mL/s, 0.25mL/s, Vacutainer®) by the various catheter types and sizes. Samples were tested for plasma hemoglobin and potassium levels which are known to signify hemolysis.1 The ViaValve™ Safety I.V. Catheter was equivalent to other catheters tested in the ability to induce a minimal degree of hemolysis under all other test conditions.

Objectives

• Determine if the addition of the valve within the ViaValve™ Safety I.V. Catheter hub has any significant impact on the occurrence of hemolysis.
• Evaluate the amount of hemolysis that occurs with the ViaValve™ Safety I.V. Catheter (ViaValve) compared to the ProtectIV™ Plus Safety I.V. Catheter (ProtectIV), the BD Insyte™ Autoguard™ Shielded IV Catheter (Autoguard) and the B. Braun Intracath Safety IV Catheter (Intracath) by measuring plasma hemoglobin and potassium levels.

Methods

Simulated patient blood draws from fresh donor blood bags were performed with the ViaValve, ProtectIV, Autoguard, and Intracath PIVCs. Table 1 describes the testing methods performed for each catheter type. Control blood samples (gravity drip with no catheter) were also taken at the start of the study, after every 36 samples were collected, and at the end of the study. A total of 324 test samples were obtained.

<table>
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<th>Table 1: Test Configuration Matrix</th>
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Results

There were no statistically significant differences in blood plasma hemoglobin levels among all catheter types and sizes tested.

The results were consistent for the combined analyses of Blood Pools 1 and 2 (Group A) and for Blood Pool 3 (Figures 1 and 2). The control blood did not hemolyze across all samples collected. Irrespective of catheter type, some groups had significantly higher levels of hemolysis than the drip control. Particularly, the 14g catheters with the Vacutainer® produced the largest amount of hemolysis in all catheter types tested. The variation of the 14g samples was very large, which did not allow the ability to distinguish the signal from the error. The ViaValve 20g vacutainer samples also had a large amount of variability, but the results was not statistically different from the other catheter types. The 24g catheters were considered too small for Vacutainer® use and were not tested.

Blood plasma hemoglobin levels, the results across all experimental series (PIVC types and sizes) for a given blood pool were not significantly different and were similar in number (9.2mmol/L-11.1mmol/L for Pool 1 and 13.1mmol/L-14.2mmol/L for Pool 2). Blood Pool 3 was not measurable due to levels that exceeded the machine’s upper limit of 20mmol/L, which was expected since potassium is known to leak out of cells at a rate of 1mmol/L per day.

Conclusion

Blood plasma hemoglobin values over 20-40mg/dL could cause an increase in bilirubin and LDH levels and be considered clinically significant.1 The ViaValve™ Safety IV Catheter was equivalent to other catheters tested in their ability to minimize the degree of hemolysis under all test conditions. Therefore, the addition of the integrated valve in ViaValve™ does not have a significant impact on the occurrence of hemolysis compared to other PIVCs.

References


Figure 1: Group A Mean Plasma Hemoglobin Levels by Gauge Size and Pull Speed

Figure 2: Blood Pool 3 Mean Plasma Hemoglobin Levels by Gauge Size and Pull Speed