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Evaluation of a new venous catheter blood draw device and its impact on specimen hemolysis rates

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ABSTRACT

Objectives: Blood collections from peripheral intravenous catheters offer several benefits to patients, including reduced needle punctures and patient discomfort, but they risk reducing the quality of blood specimens analyzed by the laboratory. In an effort to balance analytical quality of test results with patient-centered care initiatives, a needle-less blood collection device called PIVO™ was evaluated at two institutions. The primary objective of this study was to assess the ability of the PIVO™ device to provide high-quality blood specimens for laboratory testing compared to current blood collection methods.

Methods: Blood specimens drawn using the PIVO™ device were prospectively flagged. A retrospective review was performed comparing the degree and rate of hemolysis for PIVO™ blood collections to both concurrent and historical hemolysis rates for other collection methods.

Results: Approximately 7600 PIVO™ blood draws were performed across the two institutions. The hemolysis rates of samples collected with PIVO™ were evaluated using 2380 flagged collections, containing approximately 1200 test orders requiring hemolysis index measurements. The hemolysis rate of PIVO™-flagged samples (1.8%) was statistically superior to the venipuncture and central line blood collection methods (3.3%), reducing the risk of hemolysis during a venous blood draw by 39%.

Conclusions: PIVO™ collections facilitated improvement in the rate and degree of sample hemolysis when compared to venipuncture and central line blood collections. These findings suggest that PIVO™ is capable of delivering samples that are superior to current blood collection methods in terms of hemolysis rate as well as reducing the number of invasive venipunctures required for laboratory testing.

1. Introduction

Hemolysis, defined as the breakdown of red blood cells and the release of hemoglobin and intracellular contents into the plasma, is a frequent occurrence in blood samples submitted to clinical laboratories for testing. The estimated prevalence of hemolyzed specimens is approximately 3% of routine samples and they make up approximately 60% of specimens classified as unsuitable for analysis [1]. Higher rates of hemolysis are typically seen in the acute care setting, such as the emergency department and intensive

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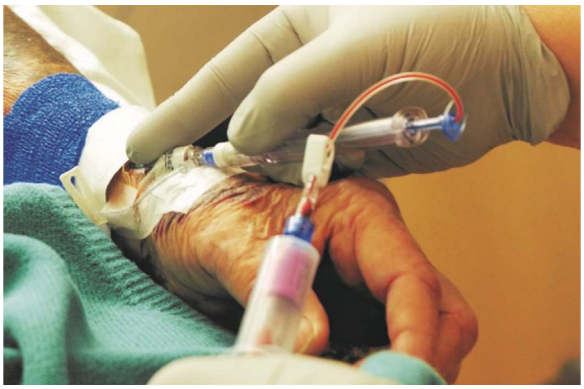

Fig. 1. PIVO™ device collecting blood.

care units, with some literature reports as high as 32% [1,2]. Sample hemolysis is a patient safety concern because it can lead to inaccurate laboratory results, the need for specimen recollection, and potential delays in diagnosis and treatment. There are several laboratory tests that can be impacted by hemolysis with varying levels of interference observed based on the degree of hemolysis and the specificity of the method being used. The risks associated with analyzing hemolyzed specimens have been recognized and efforts made toward creating more robust assays and facilitating consistent high quality specimen collections.

Previous research has extensively explored the causes of hemolysis including patient inherent factors, collection techniques, collection devices, and specimen transport. Collection from a peripheral IV is one of the most commonly cited causes of hemolysis and is associated with decreased specimen integrity as compared to venipuncture due to increased mechanical shearing of the red blood cells [3–5]. In fact, one study found that specimens drawn though an IV catheter were more than 3 times as likely to be hemolyzed than those drawn by venipuncture [4]. Not surprisingly, the highest rates of hemolyzed specimens are observed in acute care settings where collections through peripheral IV catheters are most common [1]. The patient populations in these units often consist of individuals in which double needle punctures are avoided to improve efficiency and patient experience such as pediatric patients or adults with difficult venous access, presence of bleeding disorders, or the need for serial testing [6]. Efforts to reduce hemolysis rates in these settings have largely been focused on standardization of blood collection practices, staff training initiatives to improve technique, and in recent years the development of new blood collection devices.

In 2016, the clinical laboratories of Dixie Regional Medical Center (DRMC, a 130-bed level II trauma center) and University Hospitals Cleveland Medical Center (UHCMC, a 1100-bed level I trauma center) each embarked on an evaluation of a new needle-free blood collection technology. PIVO™ (Velano Vascular Inc.) is a single-use, FDA-cleared blood collection device that connects to the hub of a peripheral IV catheter (PIVC) extension set and advances a polymer cannula through the PIVC into the vein to collect a blood specimen (Fig. 1). The goal of this evaluation was to assess if the needle-free blood collection method could deliver blood specimens of equivalent integrity to venipuncture. The hemolysis rate from nearly 1200 PIVO™ blood collections across both institutions was compared to concurrent and historical venipuncture hemolysis rates using the specimen integrity check feature of the automated chemistry analyzers. This large, statistically significant sample set was taken from real clinical usage of the product at these institutions and used to validate PIVO™ as a beneficial option to both the laboratory and patients.

2. Materials and methods

2.1. Blood collection materials

BD Vacutainer Safety-Lok Blood Collection Sets (Becton Dickinson, Franklin Lakes, NJ) with pre-attached holders were used for venipuncture at DRMC and UHCMC. DRMC also utilized BD Eclipse needles with holders and UHCMC used Greiner Bio-One Vacuette tubes (Greiner Bio- One, Monroe, NC). Central line collections used the same holders as the venipunctures at each hospital. The PIVO™ blood collection device was used for blood draws from a peripheral IV catheter. Prior to the PIVO™ collection, the IV catheter was flushed with 5 mL normal saline. The PIVO™ device was attached to the needle-less valve and actuated through the IV catheter into the blood stream. Standard vacuum tubes or a syringe were used at the back end of the device to collect blood samples. The blood collections were typically performed with a tourniquet above the PIVC. A discard volume of 1 mL was collected through PIVO™ prior to the required specimen collection based on research by Baker [7]. After the PIVO™ collection the device was retracted, removed, and disposed of. The IV catheter was again flushed with 5 mL normal saline.

2.2. Laboratory instrumentation and indices

Patient testing was performed on the Siemens Dimension Vista at UHCMC prior to June 25, 2016 and on the Beckman Coulter AU5800 thereafter. The Abbott Architect ci8200 was used for patient testing at DRMC. Specimen integrity was checked by the semi-quantitative, spectrophotometric assessment of hemolysis in human serum and plasma on these automated chemistry analyzers. Only