Multicenter Study of Needle-Free Blood Collection System for Reducing Specimen Error and Intravenous Catheter Replacement

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ABSTRACT

Inpatient hospital settings require access to high-quality blood specimens and durable peripheral intravenous (IV) catheters for patient care. The most common standard-of-care method for acquiring each blood specimen—venipuncture—often results in a non-negligible preanalytical error rate, patient discomfort, and tissue inflammation. In a 2-year, multicenter (23 hospitals) retrospective study, a novel blood collection system that collects blood specimens through existing inpatient IVs without a needle (PIVO, Velano Vascular) was compared with the current standard of care, in regards to its effect on specimen quality and IV catheter longevity. Using the PIVOTM device for blood collection decreased the rate of preanalytical errors by 56% compared with other collection methods, including venipuncture and conventional line draws. In addition, peripheral IV catheters that were used with PIVO™ for blood draws also had a 19% lower rate of replacement compared with those that did not. This is the largest study to date of PIVO use and demonstrates significant quality improvement outcomes compared with the current standard of care in blood collection, providing an opportunity to innovate inpatient hospital care.

Keywords: PIVO, needle-free blood draw, blood specimen preanalytical error, peripheral intravenous catheter replacement

Introduction

Inpatient blood collection is the most common invasive procedure performed in hospital settings. The standard method of collection is venipuncture, which inflicts pain on patients, exposes health practitioners to occupational needlestick injuries, and predisposes specimens to hemolysis, leading to preanalytical error.1 Preanalytical errors cost hospitals $208 per event, with an estimated financial waste from preanalytical error of $1.1 million per year per hospital, or approximately 1% of operating costs for a 650-bed hospital.2 Preanalytical errors may also lead to downstream adverse effects, malpractice, and delayed medical care.3,5

Current alternative methods of blood collection include draws from central venous catheters or arterial lines, but are generally considered too invasive to benefit the typical non-intensive care unit inpatient hospitalization.6,7 Another practice is to collect specimens from peripheral intravenous (IV) catheters, which are typically placed during inpatient hospitalizations for fluid and medication delivery. Despite the common practice of aspirating a blood specimen from a newly inserted IV catheter before fluids are infused, aspirating blood from the IV catheter during the remainder of its dwell has been historically unreliable and associated with higher rates of preanalytical error compared with venipuncture.7,9 In addition, sampling blood from an IV catheter has been associated with a myriad of changes to the IV catheter and vessel physiology, which develop shortly after insertion. These changes lead to restricted blood flow at the IV catheter tip and the inability to access downstream collateral circulation because of venous valves preventing retrograde blood flow to the IV catheter.10,11

The development of needle-free technology designed specifically for the purpose of drawing
higher-quality blood specimens from peripheral IVs (PIVO™, Velano Vascular) prompts an assessment of the device’s impact on blood specimen quality and IV longevity. This single-use device temporarily attaches to an indwelling peripheral IV catheter and deploys a flexible cannula approximately 3 cm downstream into the vein, where normal blood flow is usually reconstituted (see Figure, Supplemental Digital Content 1, http://links.lww.com/JHQ/A148 that diagrams PIVO use compared with standard venipuncture). The specimen is then withdrawn, and the device is detached and discarded. Previous studies have demonstrated that daily use of PIVO through IV catheters did not affect catheter dwell time, that laboratory results obtained from specimens drawn using PIVO were equivalent to those obtained by venipuncture, and that PIVO-acquired blood specimens had a lower hemolysis rate compared with venipuncture. Because approximately 60–70% of all blood samples require venipuncture for collection, PIVO, an alternative to venipuncture, may greatly affect the landscape of blood collection methods.

To more broadly assess the impact of PIVO on the quality of blood specimens collected and peripheral IV catheter longevity on a larger sample size, we conducted a retrospective study at a multicenter hospital system comprising 23 hospitals and 2,300 beds, which draws roughly 900,000 inpatient blood specimens annually. In this expanded setting, we test the hypothesis that PIVO use for routine blood collection decreases the specimen error rate and improves IV catheter longevity compared with other blood collection methods, including venipuncture.

Methods

Study Design
Retrospective quantitative causal/comparative study design was performed between January 2017 and December 2018 at a U.S. multicenter hospital system that implemented PIVO to evaluate two primary hypotheses: (1) PIVO use in blood collection decreased specimen error rates compared with the standard of care, and (2) PIVO use decreased peripheral IV catheter replacement rates compared with nonuse. A secondary hypothesis within the study design posited that anatomical location of peripheral IV catheters affected dwell times.

Ethical Considerations
The primary aim of this project was quality improvement within the target health system to address a care improvement opportunity. Institutional review board approval was obtained through the health system’s privacy board (Ref Number: 026825) for this retrospective analysis. All patient data were deidentified to protect confidentiality.

Sample and Setting
Blood collection and IV replacement data were obtained from inpatient settings at 23 hospitals (approximately 2,300 total beds) between January 2017 and December 2018.

Inclusion criteria for blood collection data include inpatient stays greater than 8 hours and less than 60 days, blood collection less than 8 hours before admission, blood collection less than 1 hour after discharge, and blood collections that fall within the window of IV dwell time. Data that fell within the first 20 days of the study and IV dwell times that exceeded 60 days were excluded. Total sample size was 2,013,290 blood specimens from non-PIVO collection methods such as central line draws and venipuncture and 140,999 specimens from PIVO use.

Inclusion criteria for intravenous replacement data include inpatient stays greater than 8 hours and less than 60 days, IV placement less than 8 hours before admission, IV removal at or before discharge, and IV dwell times greater than 0 days and less than 60 days. Data that fell within the first 20 days of the study and IV dwell times that exceeded 60 days were excluded. Total sample size was 136,809 IV placements before PIVO introduction and 131,573 IV placements after PIVO introduction. IV replacement was defined as a single event within a defined dwell time interval.

Inclusion criteria for IV replacement data by anatomical site: inpatient admissions between 18 and 72 hours and patients greater than 20 years of age with an 18-, 20-, or 22-gauge (G) IV catheter. Pediatric and maternity patients were excluded. Admissions under 18 hours were too short to assess IV replacement because all IVs—regardless of status or indication—were removed before discharge and thus were excluded. Admissions greater than 72 hours were also excluded to avoid confounding outliers and presumably appropriate peripheral IV catheter restarts for long admissions. Total sample size was 66,052 forearm, 23,314 hand, and 83,844 antecubitus (AC) IV placements. IV replacement was defined as a single event within the defined dwell time interval.

Procedures
PIVO method of use: The PIVO blood collection device is a single-use blood collection apparatus that
connects to the hub of a T-shaped IV extension set. The user pushes a slider on the PIVO device that advances a flexible polymer cannula through the hub and past the end of the IV catheter tip approximately 3 cm into the vein. Standard vacuum tubes or a syringe is used at the back of the device to collect blood specimens. Although no waste volume is required before specimen collection,5 per manufacturer’s recommendations, 1–2 mL of blood volume is drawn and discarded before PIVO collection.

Intravenous setup and training: Each of the 23 hospitals within the multicenter system received training for the PIVO-compatible IV setup and PIVO use 2 weeks before launch. Users received 1 hour of classroom education led jointly by local nursing staff and vendor clinical educators. After launch, the vendor provided direct on-site shadowing of users for 1–2 weeks.

Data Collection
Blood draws were tracked using handheld computers at the point of care. At the end of each draw, phlebotomists selected their “method of collect” from a drop-down menu, then data were fed into the systemwide laboratory information system (LIS), Sunquest. Error, also obtained through Sunquest LIS, was defined as any specimen that was rejected by Sunquest. Error, also obtained through Sunquest systemwide laboratory information system (LIS), Sunquest. Error, also obtained through Sunquest LIS, was defined as any specimen that was rejected by the clinical laboratory because of hemolysis, contamination, dilution, insufficient quantity, clotting, or lacking proper documentation from introduction of a new process into the healthcare workflow.

Intravenous gauge sizes, anatomical location, placement, and replacement events were logged by nursing staff and collected from the Cerner electronic medical record (EMR) system. For IV placement events that corresponded with PIVO use, blood draw method data from Sunquest LIS and IV replacement data from Cerner EMR were cross-referenced, and only events marked by both PIVO use and IV placement data were used.

All data were deidentified to protect patient confidentiality while maintaining data integrity for analysis. Institutional in-house quality control system verified all data collected.

Data Analysis
Data analysis was performed by a third-party consulting firm. Chi-squared tests for comparison of proportions were performed for statistical analysis between proportions observed between two independent groups, with significance defined as p value <.05. A 95% confidence interval was defined as one SD from the mean. Least squares model was used to correct underlying longitudinal trends in IV replacement rates irrespective of PIVO use.

Results
Use of PIVO for Blood Draws Reduces Preanalytical Error Rate
A total of 140,999 PIVO-based laboratory draws and 2,013,290 specimens drawn by standard-of-care methods, including venipuncture, were collected across all hospitals that conducted greater than 5,000 total PIVO draws during the study’s observation period. The preanalytical error rate for blood specimens drawn by PIVO was 0.40%, compared with 0.92% for standard-of-care methods, an absolute difference of 0.52% (95% CI 0.48–0.55%, p <.0001), and a relative reduction rate of 56% (Figure 1; Table 1).

Use of PIVO Reduces Peripheral Intravenous Catheter Replacement Rates
The “closed” IV catheter (e.g., BD Nexiva™) previously in use across the hospital system had preattached extension tubing that was unable to be exchanged for a PIVO-compatible IV extension set. The health system then moved to more commonly used “open” IV catheters (e.g., BD Insyte™ Autoguard™ and B.Braun Intracan Safety™). Given this widespread peripheral IV product change across the system, we first wanted to establish that IV replacement rates before and after introduction of PIVO-compatible IV setups remained equivalent. A total of 136,809 closed IVs before introduction of PIVO-compatible extension setups and 131,573 open IVs with the PIVO IV extension setup after introduction were assessed across all institutions within the multicenter system; replacement rates were unchanged between closed and open IV setups (16.13% vs. 16.27%, respectively; 95% CI for difference 0.10–0.37%, p >.05) (Figure 2A; Table 1).

After the introduction of PIVO-compatible open IV setups, we then compared the effect of PIVO use on peripheral IV replacement rates. IVs in which PIVO was used had a replacement rate of 15.45%, compared with 19.00% for IVs without PIVO use. PIVO use in compatible open IV setups reduced IV replacement rate by an absolute difference of 3.54% (95% CI 3.82–3.96, p <.0001) and a relative reduction rate of 19% (Figure 2B; Table 1).

Peripheral Intravenous Catheter Location Affects Replacement Rate
During the study’s observation period, we incidentally noted that anatomical location of peripheral IV
placement affected replacement rates. A closer examination for all peripheral IVs placed in adult patients with inpatient admissions between 18 and 72 hours demonstrated that IV replacement rates were 7.09% for forearm, 8.43% for hand, and 10.76% for AC (Figure 3; Table 1).

Limitations
As with any new technology, operator-based proficiency may confound early data collection. This was mitigated by including only hospitals within the multicenter system that already performed more than 5,000 total PIVO draws and excluding data within the first 20 days of the study. Existing trends of IV replacement rates were also considered to potentially skew results. For example, replacement rates in the 2 years before PIVO use demonstrated a very gradual increase over time of 0.00008 per week. To assess the impact of the new IV technology on replacement rates, this trend was extrapolated for dates after PIVO introduction at each hospital, and a least squares error model was used to adjust the replacement rates.

Discussion
This is the largest multicenter study to date evaluating the rate of preanalytical error with the use of needle-free PIVO blood specimen collection. The results support the hypothesis that using PIVO decreases the preanalytical error rate compared with the standard of care. Our findings are consistent with a previous, smaller, multicenter study that reviewed...

### Table 1. Numerical Comparison of Preanalytical Error and IV Replacement Rates Between Groups Described in Figures 1–3

| Description                                                                 | Absolute reduction difference (%) | 95% confidence interval | p   | Relative reduction (%) |
|----------------------------------------------------------------------------|----------------------------------|--------------------------|-----|------------------------|
| Preanalytical error rate between standard venipuncture and needle-free PIVO (Figure 1) | 0.52                             | 0.48–0.55                | <.0001 | 56.18                  |
| IV replacement rate before and after PIVO-compatible IV setups (Figure 2A) | (−) 0.14                        | (−) 0.37–(+0.10          | >.05 | (+) 0.086               |
| IV replacement rate without and with PIVO use (Figure 2B)                  | 3.54                             | 3.31–3.95                | <.0001 | 18.65                  |
| IV replacement rate between AC and forearm placement (Figure 3)           | 3.67                             | 3.38–3.96                | <.0001 | 34.11                  |
| IV replacement rate between hand and forearm placement (Figure 3)         | 1.34                             | 0.94–1.75                | <.0001 | 15.90                  |
| IV replacement rate between AC and hand placement (Figure 3)              | 2.33                             | 1.91–2.74                | <.0001 | 21.65                  |

CI, confidence interval; IV, intravenous.

Figure 1. PIVO blood collection reduces preanalytical error rates compared with standard of care. The preanalytical error rate, defined as sample rejection, for blood specimens drawn by PIVO was 0.40% (black), compared with 0.92% for standard of care (white), an absolute difference of 0.52% (95% CI 0.48–0.55%, p < .0001), and a relative reduction rate of 56%. Error bars represent 95% confidence interval of the preanalytical error rate difference between the two methods. CI, confidence interval.
approximately 1,200 PIVO draws and found a 39% relative reduction in hemolyzed specimens compared with other collection methods. In addition, previous studies have demonstrated that quantitative laboratory values from nonrejected specimens obtained by PIVO are accurate. Determining the mechanism by which PIVO reduces the preanalytical error rate in blood collection will require further study.

Peripheral IV replacement often results in patient dissatisfaction and is a potential source of adverse events, such as needlestick injury and healthcare-acquired infections. In addition, peripheral IV replacement on average costs $28–36 per event. Our finding that PIVO use (i.e., one or more instances of blood collection using PIVO) reduced the rate of IV replacement has broad implications for the reduction of adverse events and operating costs associated with IV replacement.

Because PIVO is a new device that accesses peripheral IVs for blood collection, PIVO may have an effect on IV dwell times. Although we did not directly measure dwell times in this study, IV replacement data were used as a corollary for IV duration because IV replacements were easily trackable as discrete events with fewer confounding factors in data recording within the Cerner EMR, compared with IV dwell time data. Indeed, patients who received PIVO draws, which correlated with lower IV replacement rates, on average, had slightly longer lengths of stay compared with controls. This was consistent with a previous
randomized controlled study that demonstrated daily use of PIVO did not affect IV dwell time and suggests that PIVO may prolong IV duration. Further study will be needed to rigorously explore the relationship between PIVO use and IV dwell times.

Incidentally, during the study, we also observed that forearm placement of peripheral IVs had lower rates of replacement compared with other anatomical locations, independent of type of IV setup or use of PIVO. This finding is consistent with the recommendations from the 2021 Infusion Nurses Society Standards of Practice for IV insertion, which states to avoid areas of flexion and ideally choose an insertion site on the forearm. In standard venipuncture, there are differences in blood specimen collection confidence and quality among healthcare professionals. When performing standard venipuncture, healthcare professionals with different types of training (e.g., nurses vs. phlebotomists) yield different specimen qualities and also experience different degrees of confidence in performing the procedure. As the use of PIVO expands, future studies will assess whether PIVO proficiency could bridge this difference among healthcare professionals.

Conclusions
During the 2-year study period, the introduction of a noninvasive, needle-free method of blood collection from peripheral IV catheters (the PIVO system) in a large, multicenter hospital system demonstrated a 56% relative reduction in the specimen preanalytical error rate and a 19% relative reduction in IV replacement rate. This is the largest study to date of PIVO use and demonstrates quality improvement compared with the current standard of care in blood collection and IV placement.

Implications
One of the primary drivers for PIVO adoption is reduction of venipuncture for blood collection. Because each preanalytical error incurs a repeat needlestick, reducing preanalytical error through PIVO use will also, as a logical consequence, reduce the number of needlesticks to the patient and the risk of needlestick injury to the provider. During the early phase of implementation, we tracked PIVO reliability to draw a specimen for more than 3,600 collections by one of our hospital system’s phlebotomy teams. They reported a 94.8% draw success rate with PIVO, whereas standard venipuncture can vary from 72 to 88%. In addition, during the 2-year study period as PIVO was rolled out across the health system, well over 100,000 needlesticks were removed from patient care. This practice has the potential to remove hundreds of thousands of needles and patient needlesticks annually in our health system. Further research will be needed to fully quantify the relationship between PIVO use and both needlestick reduction and fewer specimen recollections.

Needle-free PIVO innovation represents an advance in blood specimen quality and IV replacement compared with the current standard of care and has been adopted by other multicenter hospital systems. As this novel technology continues to be implemented by other hospital systems, we anticipate that PIVO will have a durable impact on quality improvement and harm reduction in inpatient hospital settings.

Authors’ Biographies
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