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A Novel Needle-Free Blood Draw Device for Sample Collection From Short Peripheral Catheters

Caprice Cadacio, MD • Irving Nachamkin, DrPH, MPH, FAAM, FIDSA

ABSTRACT

A new US Food and Drug Administration-cleared needleless blood collection device (PIVO; Velano Vascular, San Francisco, CA) for short peripheral catheters was compared with conventional venipuncture for collecting blood samples for routine laboratory analysis from adult healthy volunteers. The PIVO device was comparable with venipuncture in terms of providing high-integrity samples (no hemolysis or clotting), equivalent laboratory values, and better patient experience as assessed by pain scores. Further studies to assess the overall utility of the PIVO device are warranted.

Key words: blood collection devices, laboratory testing, needleless blood collection, peripheral intravenous catheter, phlebotomy, short peripheral catheter, venipuncture

BACKGROUND

Blood draws by venipuncture are 1 of the most commonly performed hospital procedures in the world, affecting nearly every hospitalized patient daily.[1] As a case in point, at the Hospital of the University of Pennsylvania (HUP), a regional referral and teaching institution, more than half a million inpatient blood collections are ordered in a single year.[2] Nearly every inpatient in the hospital's care typically receives at least 1 daily blood collection, with 25% of admissions receiving 3 or more collections per day.[2] Over the course of an admission, approximately 3% of patients receive more than 100 blood collections during their stay.[2]

Frequent blood draws have unwanted consequences, namely patient discomfort, provider sharps injuries, ecchymosis, and even iatrogenic anemia.[3–5] As such, the movement to reduce venipunctures and their associated unwanted sequelae has become a significant hospital procedural improvement initiative nationwide.[6] Institutional enhancements have focused on elimination of unnecessary tests and movement toward drawing samples based on clinical need rather than a routine schedule.[6] Central vascular access devices may be used for blood collection but their general use is only justified in a certain patient population.[7] Even then, the use of central vascular access for blood draw purposes needs to be weighed against the risk of jeopardizing contamination and luminal patency[8] and the inherent risks of catheter placement such as central line-associated bloodstream infections (CLABSIs), thrombosis, and pneumothorax.[9,10] Alternatively, providers are able to obtain blood draws from short peripheral catheters (SPCs), and these samples are largely comparable with venipuncture samples,[11-13] although they are at higher risk

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of hemolysis.[14] The Infusion Nurses Society's *Infusion Therapy Standards of Practice* (the *Standards*) advise that only pediatric patients, adults with difficult vascular access, and patients with bleeding disorders or a need for serial tests have blood taken from SPCs.[7(S87)] Thus, SPC blood draws currently are not a widespread practice. New technology, such as the PIVO blood collection device (Velano Vascular; San Francisco, CA), may leverage SPCs for blood draws to provide reliable blood samples and change the clinical culture around this technique.

The primary objective of this study was to assess the ability of PIVO, a new US Food and Drug Administration-cleared needle-free blood collection device, to aspirate nonhemolyzed, high-integrity blood samples via SPCs both at the time of placement and soon after. The secondary objective was to assess patient pain and provider experience.

METHODS

Study Device

The PIVO blood collection device is a single-use blood collection apparatus that connects to the hub of a T-shaped SPC extension set (Figure 1a). The user actuates a plunger on the device, which advances a polymer cannula through the SPC hub and past the end of the SPC tip into the vein (Figure 1b). Standard vacuum tubes or a syringe are used at the back end of the study device to collect blood samples (Figure 1c).

Study Design

A prospective, nonrandomized study design was used for the current evaluation. Healthy adult subjects (>21 years of age) were recruited to the outpatient Clinical and Translational Research Center (CTRC) at HUP to participate. Exclusion criteria were severe needle phobia or a history of syncope, panic attacks, or hypotension with venipuncture or intravenous catheter placement; renal disease or a history of hemodialysis; arteriovenous fistulas or vascular grafts; a current indwelling vascular device (peripherally inserted central catheters, ports, SPCs); morbid obesity (body mass index [BMI] >35); deformity or injury to either of the participant's arms or hands; a history of valvular heart disease, endocarditis, or cardiovascular prosthesis; use of aspirin in the last 2 weeks; pregnant women (a urine pregnancy test was done after consent); any condition that the investigator thought might limit the volunteer's ability to complete the study protocol; and hemolytic disorders (eg, sickle cell disease). All subjects underwent informed consent to participate. The study was approved by the Institutional Review Board of the University of Pennsylvania.

Each participant served as his or her own control, receiving 2 paired blood draws to compare the blood samples and patient experience of the study device versus traditional venipuncture. On an alternating basis, 30 subjects were assigned to receive draws comparing either 21-gauge needle venipunctures to study device draws through a 20-gauge SPC or comparing 23-gauge needle venipunctures to study device draws through a 22-gauge SPC (Figure 2).

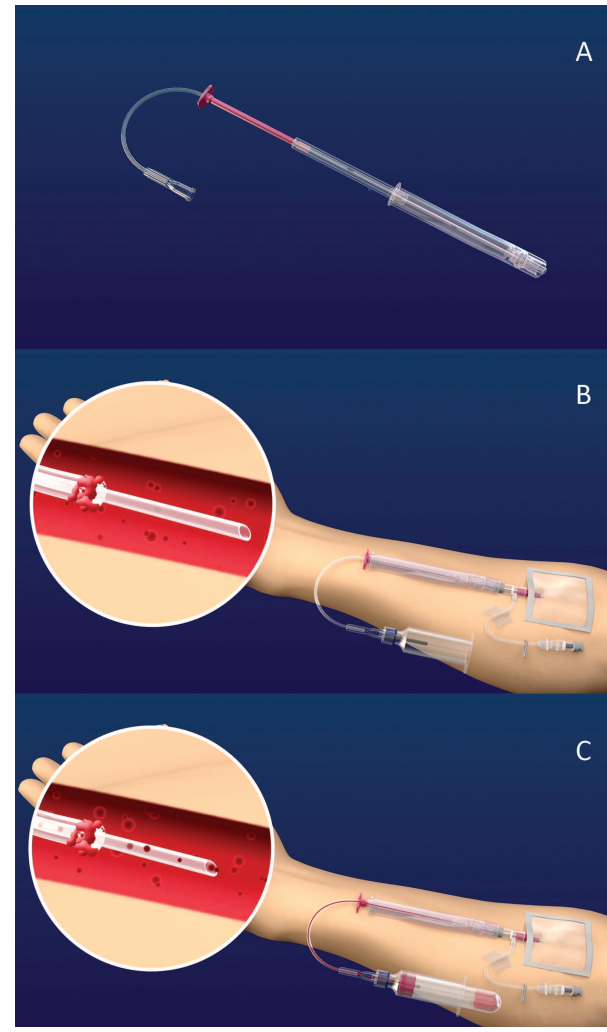

Figure 1 A, PIVO device. B, PIVO device advanced into vein. C, PIVO device collecting blood.

All study procedures were performed by experienced nursing staff exclusive to the CTRC. A total of 5 nurses performed draws; however, nearly 50% were performed by 1 nurse. Nurse selection was driven solely by availability during scheduled visits.

Each patient had an SPC (BD; Franklin Lakes, NJ; Insyte Autoguard IV 20 gauge, 22 gauge) placed in 1 arm followed by a flush of 5 mL normal saline and a 10-minute wait. The first venipuncture (BD Vacutainer Safety-Lok Wingsets, 21 gauge, 23 gauge) was performed in the non-SPC arm and immediately followed by a study device draw through the SPC. After the study device draw, the SPC was again flushed with 5 mL normal saline and another 10 minutes were allowed to pass. A second venipuncture was performed in the non-SPC arm immediately followed by a study device draw through the SPC. After the second device draw, the SPC was removed. Patient and providers were asked to rate or comment on their experiences after each draw.

Venipunctures followed standard clinical practice, including skin antisepsis, use of a tourniquet, and puncture of veins of the antecubital fossa.[7] During venipuncture, nurses

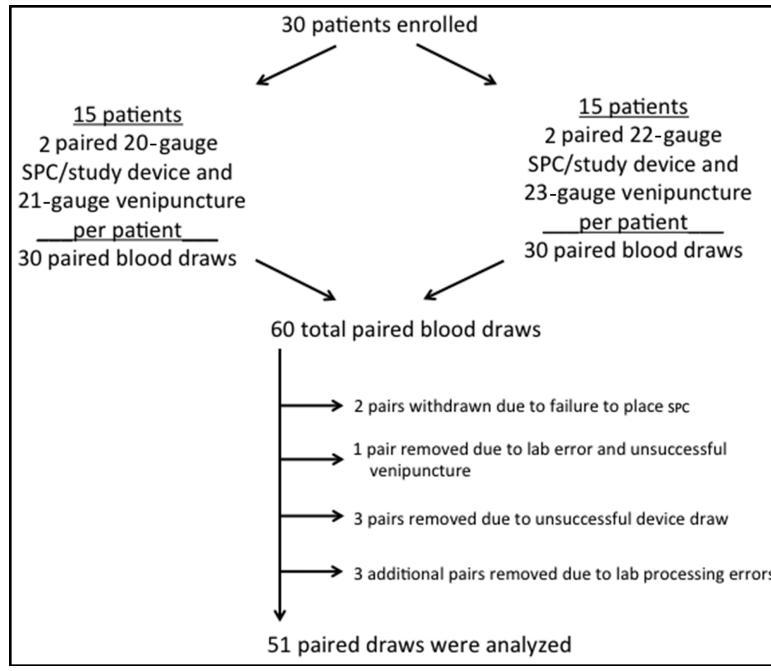

Figure 2 Protocol flowchart and patient allocation. *Abbreviation: SPC, short peripheral catheter.*

collected 3 requisite tubes of blood for coagulation (BD Vacutainer Buffered Sodium Citrate [0.105 M, 3.2%], 4-mL blue top tube), chemistry (BD Vacutainer Clot Activator/Polymer Gel, 4-mL gold top tube), and complete blood count (BD Vacutainer K2EDTA 7.2-mg, 4-mL lavender top tube) laboratory analysis in that order. No waste tube was drawn during venipunctures, in keeping with local clinical practice.

Blood draws with the study device began with antisepsis of the needleless connector. No tourniquet was used for device collections. Each study device draw first collected a 3-mL waste tube followed by the same tubes in the same order as during venipuncture. All study draws were collected directly into vacuum tubes.

Both venipunctures and device collections each were allowed 2 attempts to complete the collection. Each tube was uniquely labeled to indicate the collection. At the end of all draws, all tubes were sent simultaneously to the core laboratory at HUP for processing, and results were reported using the assigned unique labels.

Laboratory Testing

A clinically high-quality blood specimen was defined as not having spurious hemolysis or extrinsic hemostatic activation. Samples were analyzed to detect spurious hemolysis by comparison of potassium, hemoglobin, lactate dehydrogenase (LDH), aspartate aminotransferase (AST), and the spectrographic hemolysis index.[15] Spurious hemostatic activation was assessed by platelet count, international normalized ratio (INR), and fibrinogen comparisons. Laboratory analysis was performed in the Core Laboratory of the Department of Pathology and Laboratory Medicine at HUP, a clinical laboratory certified by Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists.

Survey of Participants

After the SPC insertion, each venipuncture, and each PIVO device draw, the subjects indicated their level of discomfort on a 0 to 10 Likert-type scale with 0 indicating "no discomfort" and 10 indicating "extreme discomfort." Qualitative feedback on device and procedural experience was gathered using a comment form from the study nurses.

Statistical Analysis

Paired laboratory values comparing venipuncture with device draws were analyzed by Bland-Altman limits of agreement analysis. This technique is used to assess agreement between 2 methods of clinical measurement. Limits of agreement analysis uses the mean of the differences between 2 sets of samples and their standard deviations to calculate an upper and lower bound within which the true difference of means lies with a set 99% certainty. If the upper and lower bounds fall within the interval of difference created by predefined total allowable error, then the 2 methods of measurement can be considered equivalent.[16] Acceptable performance was based on proficiency testing criteria for acceptable performance as established by CLIA.[15]

RESULTS

Subject Population

This study recruited self-reported healthy adults from the population in proximity to the CTRC. The subjects were 60% male, with a mean age of 36 (range of 20-65) and mean BMI of 27.5 (range of 19.6-39.9). Laboratory values from the venipuncture draws were reviewed for results out

of the normal range, and patients were contacted by the investigator, as clinically necessary. Six total subjects had values outside the laboratory's normal range that required investigator notification. Four subjects were anemic. Two subjects had an elevated creatinine, and 2 participants had an elevated bilirubin. No adverse events related to the study device were reported.

Blood Collection

Consent was obtained from 30 enrolled volunteers. One subject was withdrawn because the nurse could not place an SPC after 3 attempts. Six additional subjects required 2 attempts to place the SPC. One venipuncture draw was unsuccessful after 2 attempts (overall 98% success), and the corresponding study device draw was not processed because of a laboratory labeling error. One additional venipuncture required a second attempt to complete. Three device draws were unsuccessful after 2 attempts (overall 95% success). One additional device draw required a second attempt to complete. In 3 instances, the specimen was not processed because of an error in the laboratory's labeling system. Overall, of 120 expected draws, 102 were analyzed and reported, resulting in 51 paired comparisons of the device draw to a corresponding venipuncture (Figure 2).

Blood Specimen Integrity: Spurious Hemolysis

Spurious hemolysis of samples collected by the study device and venipuncture were compared using potassium, hemoglobin, LDH, AST, and the spectrographic hemolysis index. Hemolysis index was reported on a scale of 0 to 4, with 0 being no hemolysis, 1 being slight hemolysis, and 2 or greater triggering a sample rejection. All samples collected by both the study device and venipuncture showed no hemolysis per the hemolysis index. As shown in Table 1, the calculated Bland-Altman upper and lower limits of agreement for potassium, LDH, and AST between the venipuncture and device draws were within the total allowable error. The authors considered the venipuncture and device draws equivalent in terms of spurious hemolysis.

Blood Specimen Integrity: Hemostatic Activation

Spurious hemostatic activation was assessed by comparing the resulting values for platelet count, INR, and fibrinogen. As shown in Table 1, the Bland-Altman upper and lower limits of agreement are within the total allowable error, so all laboratory values of hemostasis are considered equivalent between the venipuncture and device draw.

Laboratory Test Precision

Because of the study design, whereby study device draws were done after venipuncture and all samples were sent to the laboratory simultaneously, some clinical variability was expected between collection methods. It was expected that very little variability would be seen within the 2 venipuncture draws performed on each person. However, comparable variability was seen within paired venipunctures (Table 2) as was seen when comparing venipuncture to study device draws (Table 1), indicated by similar Bland-Altman upper and lower bounds.

TABLE 1

Comparison of Laboratory Results From Device Draw and Venipuncture

Laboratory Test	Device Draw		Venipuncture		Bias/Difference (Device - VP)			B-A Limits of Agreement		Total Allowable Error (+/-)	Comparison
	Mean	SD	Mean	SD	Mean	SD	*P* value	LB	UB		
Hemolysis											
Hemolysis Index	0	0	0	0	0	0					Equivalent
Potassium (mmol/L)	4.0	0.2	4.1	0.3	-0.12	0.20	0.00	−0.56	0.32	0.50	Equivalent
LDH (IU/L)	143	22	146	23	−3.11	9.010	0.05	−22.44	16.32	29.26	Equivalent
AST (IU/L)	19.5	9.0	19.8	9.3	−0.28	0.89	0.31	−3.27	2.69	3.96	Equivalent
Activation											
Hemoglobin (g/dL)	13	1	14	1	−0.21	0.28	0.00	−0.87	0.45	0.96	Equivalent
Platelets (10^3/μL)	238	38	242	43	−3.93	8.52	0.04	−25.44	17.52	60.51	Equivalent
INR	1.1	0.1	1.1	0.1	0.01	0.04	0.19	−0.09	0.11	0.17	Equivalent
Fibrinogen (mg/dL)	301	61	295	59	3.81	14.31	0.10	−24.82	32.43	59.00	Equivalent

Abbreviations: AST, aspartate aminotransferase; B-A, Bland-Altman limits of agreement; see Statistical Analysis section; INR, international normalized ratio; LB, lower bound; LDH, lactate dehydrogenase; SD, standard deviation; UB, upper bound; VP, venipuncture.

TABLE 2

Comparison of Laboratory Values From First and Second Paired Venipuncture Draws

Laboratory Test	2nd VP		1st VP		Bias/Difference (2nd VP - 1st VP)			B-A Limits of Agreement		Total Allowable Error (+/-)
	Mean	SD	Mean	SD	Mean	SD	*P* value	LB	UB	
Hemolysis										
Hemolysis Index	0	0	0	0	0	0				
Potassium (mmol/L)	4.1	0.2	4.1	0.3	-0.03	0.24	0.50	−0.51	0.44	0.50
LDH (IU/L)	145	22	146	25	-1.29	7.08	0.38	−15.17	12.59	29.26
AST (IU/L)	20.0	9.6	19.9	9.2	0.08	1.02	0.69	−1.91	2.08	3.96
Activation										
Hemoglobin (g/dL)	14	1	14	1	−0.13	0.24	0.01	−0.60	0.34	0.96
Platelets (10^3/µL)	240	41	242	45	−1.79	10.23	0.40	−21.84	18.25	60.51
INR	1.1	0.1	1.1	0.1	−0.01	0.05	0.43	−0.11	0.09	0.17
Fibrinogen (mg/dL)	288	47	293	58	−4.38	12.48	0.12	−28.84	20.08	59.00

Abbreviations: AST, aspartate aminotransferase; B-A, Bland-Altman limits of agreement; please see Statistical Analysis section; INR, international normalized ratio; LB, lower bound; LDH, lactate dehydrogenase; SD, standard deviation; UB, upper bound; VP, venipuncture.

Subject and Provider Assessment

Perceptions of procedural discomfort and device performance, as reported by both study subjects and study nurses, respectively, were assessed. Seventy-nine percent of device draws were reported as having no sensation by the subject with a reported score of 0 on a pain scale between 0 (no pain) and 10 (very uncomfortable). Overall, average device draw discomfort was a reported 0.4 of 10, whereas average venipuncture draw discomfort was a reported 1.8 of 10 (Table 3). This difference was statistically significant using a paired *t* test ($P < .05$). As a benchmark, SPC placement was rated as a 2.1 of 10 by the study participants.

Providers subjectively reported similar flow rates from the device versus needle and no significant difficulty in device use. Total time to fill 3 tubes of blood was compared between the device and venipuncture. In the case of the device draws, time to fill a waste volume was not measured or incorporated. The comparison of draw times was not analyzed for statistical significance and is reported as a descriptive comparison only. Overall, the average tube fill times were longer in the PIVO draws than with venipuncture draws with the exception of the second draw in the 21-gauge needle and 20-gauge PIVO/SPC groups (Table 4). When comparing draw times between corresponding groups the maximum time difference was 31 seconds longer in the 22-gauge PIVO/SPC versus the 23-gauge needle group (first draw). Some of this time difference may be attributable to slower flow inherent to smaller gauges. The smallest time difference was 5.3 seconds longer in the 22-gauge PIVO/SPC versus the 23-gauge needle group (second draw).

DISCUSSION

The new PIVO blood collection device was evaluated as an alternative to venipuncture for patients with indwelling SPCs. Overall, the study device showed high blood collection

TABLE 3

Comparison of Subject Procedural Survey Feedback Using 0 to 10 Likert-type Scale

Group	Mean	Median	Range
SPC placement (n = 29)	2.1	2.0	0–5
Venipuncture (n = 58)	1.8	2.0	0–7
Device draws (n = 58)	0.4	0.0	0–4

Abbreviation: SPC, short peripheral catheter.

TABLE 4

Comparison of Draw Times

	Venipunctures			Device Draws	
Needle Gauges	First Draw (seconds)	Second Draw (seconds)	SPC Gauges	First Draw (seconds)	Second Draw (seconds)
21 G	42.3	67.4	20 G	54.2	62.6
23 G	68.4	73.4	22 G	99.4	78.7

Abbreviation: G, gauge; SPC, short peripheral catheter.

success, equivalent sample integrity and analyte results to venipuncture, and satisfaction from both patients and providers. The findings suggest 3 potential benefits of the PIVO blood collection device in comparison with classic venipunctures blood collection. First is the avoidance of painful venipunctures and their associated hematomas[17] and risks and costs of provider sharps injuries.[18,19] The study device exhibited nearly painless draws for patients. This could benefit patients who require frequent blood draws. Second is the implementation of a simple procedure to draw quality samples from an SPC. The study device draws matched the quality of venipuncture draws while demonstrating ease of use from clinicians. Lastly, given the ease of use of the PIVO and needleless construction, accidental needlesticks may be avoided.

There were limitations to the study design. First, there was preanalytic handling variation between various nurses and variable time to deliver and process the specimens at the laboratory that was not controlled or measurable. Second, the subjects in this study were self-reported healthy volunteers. The self-selected population of patients may have affected reported pain scores and subjects' inherent vein integrity. Last, the device was studied using a recently placed SPC. Additional studies are required to fully understand the study device's interactions with longer indwelling SPCs.

Overall, the study suggests this novel PIVO blood collection device offers the benefits of relatively pain-free blood collection without compromising sample integrity in comparison with the practice of venipuncture. The results further suggest benefit of the PIVO device to patients and providers and prompt further investigation into its ability to draw blood from indwelling SPCs in an inpatient population.

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