International Emergency Nursing 25 (2016) 59–64

Contents lists available at ScienceDirect

International Emergency Nursing

journal homepage: www.elsevier.com/locate/aaen

Clinical performance of a new blood control peripheral intravenous catheter: A prospective, randomized, controlled study

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ARTICLE INFO

Article history:
Received 23 April 2015
Received in revised form 18 August 2015
Accepted 20 August 2015

Keywords:
Emergency nursing
Peripheral intravenous catheters
Blood exposure
Mucocutaneous exposure
Blood control
Safety valved catheter
Closed system
Needlestick injury reduction

ABSTRACT

Introduction: The performance of a new safety peripheral intravenous catheter (PIVC) that contains a blood control feature in the hub (blood control) was compared against the current hospital standard without blood control (standard).
Methods: In this prospective, non-blinded trial, patients were randomized 1:1 to receive either device. Insertions were performed and rated by emergency room nurses. Primary endpoints included clinical acceptability, incidence of blood leakage, and risk of blood exposure. Secondary endpoints were digital compression, insertion success, and usability.
Results: 15 clinicians performed 152 PIVC insertions (73 blood control, 79 standard). Clinical acceptability of the blood control device (100%) was non-inferior to the standard (98.7%) ($p < 0.0001$). The blood control device had a lower incidence of blood leakage (14.1% vs 68.4%), was superior in eliminating the risk of blood exposure (93.9% vs 19.1%) and the need for digital compression (95.3% vs 19.1%), while maintaining non-inferior insertion success rates (95.9% vs 93.7%) and usability ratings ($p < 0.0001$).
Discussion: In comparison with the hospital-standard, the new safety PIVC with integrated blood control valve had similar clinical acceptability ratings yet demonstrated superior advantages to both clinicians and patients to decrease blood leakage and the clinician's risk of blood exposure, during the insertion process.

1. Introduction

The peripheral intravenous catheter (PIVC) is the most commonly used device for gaining vascular access in the clinical setting. Nearly 300 million PIVCs are used in United States hospitals alone each year (Maki, 2008; Maki et al., 2006). Use of PIVCs places health care workers at risk for exposure to blood and possible transmission of a number of pathogens, including hepatitis B and C and human immunodeficiency virus (HIV). Exposure may occur because of needlestick injuries (NSIs) and/or blood that is back-flowing through the open end of the catheter hub.

The incidence and need for reduction of NSIs among providers inserting PIVCs have been a subject of study globally (Elmiyeh et al., 2004; Mallin and Sinclair, 2003; Porta et al., 1999; Saia et al., 2010; Sharma et al., 2010; Yang and Mullan, 2011). Comparatively, less attention has been paid to accidental mucocutaneous blood exposure, and the impact of risks in in curred through such exposures, that can occur through catheter leakage, backflow at the hub, or splatter that originates when needle-safety mechanisms are activated during PIVC insertion. One study assessing the safety of PIVCs found that blood exposure occurred in 10%–27% of all PIVC insertions – either on the clinician's skin, gloves, mask or clothes or on the surrounding environment (Prunet et al., 2008). Another study demonstrated that the very small droplets of blood (<1 nL) from PIVC spatter confer negligible risk of transmittable diseases such as hepatitis B and C and HIV (Wittmann et al., 2013). However, results from a conflicting study indicated that spatter contamination, along with "oozing" of blood from the device, deposits particles that could

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http://dx.doi.org/10.1016/j.ienj.2015.08.005

potentially cause transmission of blood-borne viruses (Roff et al., 2014). Regardless of these contradictory conclusions, investigators of both studies emphasized the importance of instituting improvements for reducing mucocutaneous blood exposures among health care workers during PIVC insertions.

Both risk of NSIs and blood exposure have the potential to be greatly reduced, if not eliminated, with the advent of improved PIVC technology. For PIVCs with blood control, there are three main categories of devices: active, passive, and closed systems. The closed system, or integrated closed intravenous catheter systems (CICS), includes a pre-attached stabilization platform and extension set, and represents the most expensive of the blood control devices. The "active" safety blood control catheters are less expensive and do not include a pre-attached extension set. These devices have a safety mechanism within the catheter itself that must be activated by the clinician for the needle guard to lock over the introducer needle, as well as an integrated blood control valve within the catheter hub. The "passive" safety blood control devices are generally the least expensive blood control device, also do not have a pre-attached extension set, and the safety mechanism engages during the normal use of the product.

Recently, three studies have been published evaluating the ease of insertion and the effectiveness of both active and passive safety catheters in reducing staff's risk of accidental needlestick, in reducing the occurrence of abnormal blood reflux, and in reducing staff exposure to patients' blood (Onia et al., 2011; Prunet et al., 2008; Tamura et al., 2014). However, no such studies have been published evaluating a new active safety catheter that also contains a blood control feature in the catheter hub, and no studies have examined PIVC usage in an emergency department (ED) setting. Therefore, the purpose of this study was to assess the clinical performance of a new blood control catheter compared with the current hospital standard in ED patients requiring PIVC insertion. Primary outcomes of the study were to assess device acceptability ratings, incidence of blood leakage, and risk of blood exposure, and the secondary outcomes evaluated use of digital compression during the insertion process, PIVC insertion success rates, and clinical usability.

2. Methods

2.1. Study design and devices

This was a prospective, non-blinded, randomized, controlled, single-center post-market study conducted in the ED of Alberta Health Services' Foothills Medical Centre in Calgary, Alberta, Canada. Subject insertions were randomized 1:1 by participating clinicians to either the blood control device or to the standard-of-care control. The study was reviewed and approved by the hospital's Research Ethics Board (REB) and made publicly available on clinicaltrials.gov (NCT02119351) prior to subject recruitment. All insertions were performed per hospital requirements following standard precautions.

The blood control device for the study was the ViaValve® Safety I.V. Catheter (Smiths Medical, St. Paul, MN), and the standard device was the ProtectIV® Safety I.V. Catheter (Smiths Medical, St. Paul, MN), the current standard of care for the hospital. Clinicians participating in the study used the straight hub version of the standard device during the study to appropriately compare with the blood control device performance; however, the primary configuration used at the hospital outside of the study was the standard winged product. Both study devices are active safety PIVCs, and the functional difference between the 2 products is that the blood control device includes a valve that is designed to restrict blood flow back out of the catheter hub upon initial venepuncture. The blood control device also contains a window within the introducer needle of the 20–24 G sizes for early confirmation of vessel entry.

2.2. Study population

Licensed ED nurses at least 18 years of age inserting at least 2 PIVCs per week for a minimum of 3 months were eligible for study inclusion. All eligible individuals in the ED were asked to participate in the study. Those interested and eligible provided informed consent and baseline demographic information about their medical and PIVC insertion experience. After being trained on the protocol and blood control device, the clinicians performed 20 practice insertions into vein pad models before beginning study insertions on subjects.

All patients who were indicated to receive a PIVC and were willing and able to sign an informed consent were eligible for enrollment as a study subject. Indicated use of a PIVC was defined as: the need to gain access to a vein or artery to sample blood, monitor blood pressure, or administer intravenous fluids as part of treatment.

2.3. Data collection

Study clinicians collected and recorded all data. After obtaining subject informed consent, baseline demographic information was collected, and the subject was then randomized to receive either the blood control or standard device. For each PIVC insertion attempted, the study clinicians were allowed a total of 3 venepuncture attempts to gain vascular access. Data collection about the PIVC insertion continued until PIVC removal for all successful insertions (if possible) or stopped at the time an insertion failure status was reached. Study subjects were able to have 1 or more PIVCs inserted by 1 or more clinicians, depending upon the subject's medical needs and participating clinicians' availability.

For each successful PIVC insertion, clinicians answered questions regarding clinical acceptability, blood exposure risk, blood leakage, use of digital compression, insertion success, securement, and clinical usability (ease of use) of the assigned PIVC. Once a clinician completed all study insertions, an overall assessment of the performance of both PIVCs was collected. Data were also collected for clinician or subject withdrawal, adverse events related to the PIVC insertion, and deviations from the clinical protocol.

2.4. Statistical analysis

The primary endpoints were clinical acceptability, incidence of blood leakage, and risk of blood exposure. Secondary endpoints included the need for digital compression, insertion success, and clinical usability. For all of the primary and secondary endpoints except the measurement of blood leakage, clinicians indicated their agreement with provided statements using a 6-point Likert scale and were grouped into 2 categories of Agree (Strongly Agree, Agree, and Somewhat Agree) and Disagree (Somewhat Disagree, Disagree, and Strongly Disagree).

The unit of observation was the insertion of an intravenous catheter. The study was initially designed to enroll 30 clinicians, with each clinician performing a total of 10 insertions, 5 with each device (300 insertions total). The sample size was based on the primary outcome of clinical acceptability and the planned non-inferiority comparison of the blood control device to the standard device, with a non-inferiority margin of 15%, 90% power, at a one-sided alpha of 0.05, and an anticipated acceptability rating of 95% (Blackwelder, 1982). With 10 observations per clinician, a modest intra-clinician correlation of 0.2, and a low attrition rate (5%), a total of 300 insertions were planned. However, because of clinician availability, 15 clinicians were targeted to perform a maximum of 20 insertions each, with a target of at least 150 insertions total.

Statistical analyses were performed using SAS, version 9.2 (SAS Institute, Cary, NC). Study subject data were summarized using descriptive statistics. Two-sided 95% confidence intervals were

calculated for event-rate differences between the standard and blood control devices. For inferential assessments between the two groups, Fisher's exact test was used for binary variables, and a t-test was used for continuous variables. A p-value of <0.05 was considered statistically significant. As there were multiple observations per clinician and to account for potential correlations within clinicians, generalized estimating equations (GEE) with the exchangeable correlation structure for within-clinician correlations were used.

3. Results

A total of 15 ED nurses and 150 subjects were enrolled in the study. Two clinicians withdrew before performing any insertions, and 1 subject withdrew from the study after the initial attempt to place the assigned PIVC was unsuccessful. Tables 1 and 2 provide descriptive summary statistics of the demographic data for participating clinicians and subjects, respectively. Two of the participating subjects received 2 insertions, bringing the total number of study insertions to 152. There were a total of 4 PIVC-related adverse events reported during the study. All events were hematomas, 2 for each catheter type, and both resolved with observation.

A total of 73 insertions were attempted or successfully placed using the blood control device and 79 using the standard device. Despite the complete range of sizes made available (14–24 g), the device sizes selected for insertion were primarily the 18 g × 1¼″ (46/73 blood control and 41/79 standard insertions) and 20 g × 1¼″ (27/73 blood control and 33/79 standard insertions). There were 4 standard device insertions where an 18 g was used for the first venepuncture and 20 g for the second, and one 14 g × 1¼″ standard device was also used. As the setting was the ED, the indwell times were either of short duration (mean approximately 2 hours) or unknown due to patients being moved to an inpatient status. Table 3 provides additional summary statistics for the PIVC insertion data for both devices, including insertion technique, vessel adequacy, insertion location, number of venipunctures per subject, and catheter dislodgement during needle withdrawal.

Table 1
Clinician demographics summary.

Characteristic	N = 13 clinicians
Age (year)	
Mean (SD)	35.8 (7.3)
Median (min, max)	34.0 (25.0, 51.0)
Gender	
Female	9/13 (69.2%)
Male	4/13 (30.8%)
Number of years inserting IV catheters	
Mean (SD)	10.5 (5.3)
Median (min, max)	9.2 (3.3, 20.3)
Average number of IV catheter insertions each week	
Mean (SD)	18.1 (12.2)
Median (min, max)	10.0 (10.0, 40.0)
Normally use digital compression for preventing blood leakage	
No	1/13 (7.7%)
Yes	12/13 (92.3%)

Table 2
Patient demographic summary.

Characteristic	N = 150 subjects
Age (year)	
Mean (SD)	46.2 (18.0)
Median (min, max)	44.2 (17.8, 98.6)
Gender	
Female	89/150 (59.3%)
Male	61/150 (40.7%)
BMI (kg/m^2)	
Mean (SD)	25.9 (5.2)
Median (min, max)	25.1 (14.4, 44.5)
PIVC insertion indication	
Sample blood	138/150 (92.0%)
Monitor blood pressure	2/150 (1.3%)
Fluid infusion	90/150 (60.0%)
Medication administration	74/150 (49.3%)

Table 3
PIVC insertion summary.

Measure	Blood control N = evaluable insertions	Standard N = evaluable insertions
Type of approach used for insertion	**N = 67**	**N = 75**
One handed	42/67 (62.7%)	31/75 (41.3%)
Two handed	25/67 (37.3%)	44/75 (58.7%)
Assess the overall vessel adequacy	**N = 72**	**N = 78**
Clearly visible and easily palpable	51/72 (70.8%)	41/78 (52.6%)
Visible and palpable	10/72 (12.6%)	11/78 (14.1%)
Barely visible and palpable	9/72 (12.5%)	18/78 (23.1%)
Visible but not palpable	1/72 (1.4%)	1/78 (1.3%)
Neither visible nor palpable	1/72 (1.4%)	7/78 (9.0%)
Final location of the IV catheter	**N = 69**	**N = 76**
Right/left hand	10/69 (14.5%)	14/76 (18.4%)
Right/left forearm	32/69 (46.4%)	41/76 (53.9%)
Right/left antecubital fossa	24/69 (34.8%)	17/76 (22.4%)
Other	3/69 (4.3%)	4/76 (5.3%)
Number of venipunctures per subject	**N = 73**	**N = 79**
1	66/73 (90.4%)	65/79 (82.3%)
2	7/73 (9.6%)	12/79 (15.2%)
3 or 4	0/73 (0.0%)	2/79 (2.5%)
Catheter dislodge from vessel during withdrawal	**N = 69**	**N = 71**
No	69/69 (100%)	69/71 (97.2%)
Yes	0/73 (0.0%)	2/71 (2.8%)

3.1. Clinical acceptability

Clinicians rated the clinical acceptability of each PIVC insertion with the statement, "The PIVC was clinically acceptable for the purpose of intravenous or arterial insertion." Table 4 presents the summary statistics by device and the results of the statistical comparisons of superiority of the blood control PIVC compared to the standard device for the pre-specified endpoints. The clinical acceptability of the blood control device was statistically non-inferior to the standard, with 72/72 of the evaluable blood control insertions (100%) and 76/77 standard insertions (98.7%) receiving a clinical acceptability rating of somewhat agree or above (non-inferiority margin = 15%; $p < 0.0001$). The predominant response was "strongly agree" – 64/72 for the blood control device (88.9%) and 67/77 for the standard device (87.0%). There was 1 rating of somewhat disagree, which was reported from use of the standard catheter. A test for superiority of the blood control device to the standard device for clinical acceptability was performed and was not significant.

3.2. Blood exposure

Clinicians reported blood leakage through a yes/no response to the question, "During the process of catheter insertion, withdrawal of the needle and connection of the Luer, did you observe blood leaking from the catheter hub?" Of the 152 total insertions, 62 instances of blood leakage were reported, 10 using the blood control device (14.1%) and 52 using the standard device (68.4%) (Table 4). The results demonstrated that the blood control device was superior to the standard device in preventing blood leakage ($p < 0.0001$).

In addition to reporting blood leakage, clinicians assessed overall blood exposure risk of each insertion by providing a Likert-scale rated

Table 4
Endpoint analyses.

Outcome measured	Blood control device N = evaluable insertions	Standard device N = evaluable insertions
Clinical acceptability (insertions rated clinically acceptable[a])	N = 72	N = 77
Number rated clinically acceptable (%)	72 (100%)	76 (98.7%)
95% CI (non-inferiority p-value)	95.0, 100.0 (p < 0.0001)	93.0, 100.0
Blood leakage events (reports of blood leaking from catheter hub)	N = 71	N = 76
Number of blood leakage events (%)	10 (14.1%)	52 (68.4%)
95% CI (superiority p-value)	7.0, 24.4 (p < 0.0001)	56.7, 78.6
Blood exposure risk reduction (insertions with agreement that blood exposure risk was eliminated[a])	N = 64	N = 68
Number of blood leakage events (%)	60 (93.8%)	13 (19.1%)
95% CI (superiority p-value)	84.8, 98.3 (p < 0.0001)	10.6, 30.5
Digital compression (insertions with agreement that need for digital compression was eliminated[a])	N = 64	N = 68
Number of blood leakage events (%)	61 (95.3%)	13 (19.1%)
95% CI (superiority p-value)	86.9, 99.0 (p < 0.0001)	10.6, 30.5
Insertion success (ability of clinician to successfully place the PIVC in the subject with three or fewer venipunctures total)	N = 73	N = 79
Number of successful insertions (%)	70 (95.9%)	74 (93.7%)
95% CI (non-inferiority p-value)	88.5, 99.1 (p = 0.0003)	85.8, 97.9

[a] Defined as all responses rated "somewhat agree," "agree," or "strongly agree".

response to the question, "During the process of catheter insertion, withdrawal of the needle and connection of the Luer, the PIVC eliminated the risk of blood exposure." For the blood control device, 60 of the 64 evaluable insertions (93.8%) were rated "somewhat agree" or above, compared with 13 of 68 evaluable insertions (19.1%) for the standard device (p < 0.0001) (Table 4). The results demonstrated that the blood control device was superior to the standard device in eliminating the perceived risk of blood exposure during the catheter insertion process (Fig. 1).

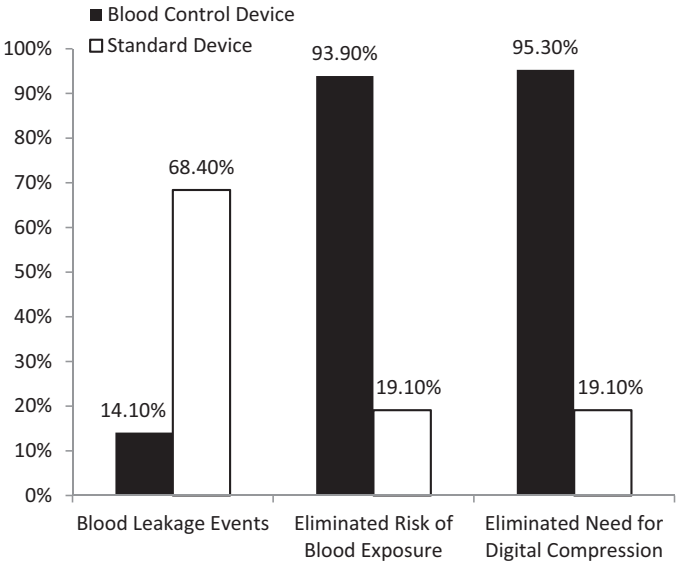

Fig. 1. Benefits observed from the blood control device.

3.3. Need for digital compression

Digital compression was assessed by providing a Likert-scale rated response to the question, "During the process of catheter insertion, withdrawal of the needle and connection of the Luer, the PIVC eliminated the need for digital compression to prevent blood leakage from the catheter hub". For the blood control device, 61 of the 64 (95.3%) evaluable insertions were rated "somewhat agree" or above, compared with 13 of the 68 (19.1%) evaluable insertions from the standard device (p < 0.0001) (Table 4). The results demonstrated that the blood control device was superior to the standard device in eliminating the clinician's need to use digital compression during catheter insertion (Fig. 1).

3.4. Insertion success

Insertion success was defined as the ability of the clinician to successfully place the PIVC in the subject with ≤3 venepunctures total (maximum of 2 attempts and 1 successful insertion). For the blood control device, 70 of the 73 insertions (95.9%) were reported as successful, compared with 72 of the 79 insertions for the standard device (93.7%) (Table 4). Of the successful insertions, the blood control device had 2 instances where 2 venipunctures were required for successful placement, whereas the standard device had 9 instances requiring 2 venepunctures and 1 requiring 3 venepunctures. The overall "first stick" success rate of the blood control device was 90.4% compared with 81.0% for the standard device or 1.06 and 1.15 venepunctures per successful insertion, respectfully. In examining the first stick success rates by device size, the 18 g rate was 93.5% (43/46) and 90.2% (37/41) respectively for the blood control and standard devices; whereas the 20 g was 85.2% (23/27) and 75.8% (25/33). While the results successfully demonstrated that the insertion success rate of the blood control device is non-inferior to that of the standard device (non-inferiority margin = 15%; p = 0.0003), the blood control device did not demonstrate superiority (p = 0.7209).

3.5. Clinical usability and overall assessment

Clinical usability was a term encompassing a number of statements that assessed performance parameters of the PIVCs after each insertion. Clinicians submitted Likert-scale rated responses to 7 clinical usability questions. Table 5 presents the summary statistics by device for the percent of clinicians who agreed (strongly agree, agree, somewhat agree) and disagreed (somewhat disagree, disagree, strongly disagree) with the statements. Eleven of the 13 clinicians also completed an overall assessment of the performance of both devices. Overall, the clinical usability ratings were positive for both devices. Clinicians stated that the blood control device would have the same or better likelihood of insertion success as the standard device, and all clinicians agreed that they would recommend use of the blood control device over other catheters they have used. Both devices were rated overall as clinically acceptable by all clinicians.

4. Discussion

This study demonstrates the ability of a new blood control catheter to decrease the observed blood leakage and risk of blood exposure to both clinicians and patients, while maintaining the same level of performance and clinical acceptability as the catheter type currently being used as the hospital standard of care. Reducing the amount of blood exposure observed during the insertion process is beneficial for both the clinicians, in terms of potential bloodborne pathogens, but also to the patients' comfort or level of anxiety if having to observe blood leakage. Although not evaluated in this study, first stick success may also impact patient comfort or satisfaction,

Table 5
Clinical usability of the standard and blood control PIVCs.

Clinical usability[a]	Blood control device		Standard device	
	% Agree (strongly, agree, somewhat)	% Disagree (somewhat, disagree, strongly)	% Agree (strongly, agree, somewhat)	% Disagree (somewhat, disagree, strongly)
Blood flashback easily seen	100% (62, 9, 0)	0% (0, 0,0)	98.7% (48,23, 4)	1.3% (0,0, 1)
Needle and catheter easily advanced	95.8% (57,10, 1)	4.2% (2, 1,0)	97.3% (51,19, 3)	2.7% (0,1, 1)
Needle easily withdrawn	98.6% (53,15, 1)	1.4% (0, 0,1)	98.7% (52,18, 4)	1.3% (0,0, 1)
Risk of needlestick injury reduced by needle retraction mechanism	98.6% (57,10, 3)	1.4% (1, 0,0)	85.5% (41,18, 5)	4.5% (0,0,11)
Connection between catheter hub and Luer easily performed	88.7% (38,18, 7)	11.3% (2 ,5,1)	86.7% (41,13,12)	13.3% (4,4, 2)
Clinically acceptable flushing of the IV catheter	98.6% (62, 8, 0)	1.4% (0, 1,0)	98.7% (58,14, 2)	1.3% (0,0, 1)
Catheter easily secured to patient	98.6% (39,20,10)	1.4% (0, 1,0)	97.3% (50,19, 4)	2.7% (2.0, 0)

[a] Insertions evaluated 'unable to rate' by the clinicians were excluded from the analysis.

as both pain and anxiety have been previously described being associated with peripheral IV cannula insertion (Deguzman et al., 2012; McNaughton et al., 2009; Winfield et al., 2013). Differences in first stick success rates were primarily observed between the 20 g devices, and the blood control 20 g device has the window for early blood visualization.

Although the blood control device demonstrated superiority in reducing the number of observed blood leakage events, more blood leakage events were reported using both products than was initially anticipated. Requiring clinicians to switch from a winged product to a catheter with a straight hub likely elevated the blood leakage incidence due to a change in the technique for how the catheter hub is held during the insertion process. Despite changing back and forth between two devices and switching to a product without wings, the first stick success rate of 1.06 for the blood control device was lower than the standard device and the US national average of 2.2 sticks per successful insertion per patient (LaRue, 2000).

Some users also reported not using digital compression with the standard device, a technique that is necessary to prevent blood leakage in standard devices. However, despite using the compression in that group, blood leakage was still observed. Having a blood control feature allows clinicians to modify their insertion technique, freeing up their second hand to focus on becoming more efficient with completing the cannula insertion and securement.

In addition, it was noted that the Luer connection forces were different between the two devices in order to pass through the valve of the blood control catheter. Additional practice insertions requiring Luer connection, as well as consistently using the same device for consecutive insertions rather than switching between two devices for randomization, may lead to an even lower rate of blood exposure with the blood control device.

4.1. Limitations

There were some limitations to the study that could have affected the results. Because the clinicians were able to contribute to the endpoint multiple times, overall ratings of each device could have been skewed. The general estimating equation (GEE) analysis was performed to take into account the correlation among observations from each clinician. In addition, the number of insertions performed by each clinician varied from nurse to nurse. This lack of uniformity in the number of product uses could have introduced variability in the overall ratings; for example, it is possible that those performing the greatest insertions could have become more comfortable with the device, prompting more positive ratings. Also, the study was designed to collect data from 30 clinicians performing 300 insertions but was completed and analyzed with 15 clinicians and 152 insertions due to clinician availability. Finally, the fact that the study could not be designed as a double-blind investigation lent some inherent, albeit unavoidable, clinician bias to the results.

5. Conclusion

The blood control PIVC achieved a clinically meaningful reduction in blood leakage and blood exposure events with similar overall acceptability to standard PIVCs. This offers ED nurses an important reduction in the risk of occupational blood-borne illness exposure.

Additional research comparing performance of multiple blood control PIVCs in a clinical setting would help differentiate performance between the available products; however, the insertion technique for each device is different and would be challenging to evaluate in a randomized non-biased design.

Acknowledgements

The authors would like to thank all study participants and ED nurses who participated in the study. The authors would like to specifically acknowledge Peggy Pereda and Wei Cao at Regulatory and Clinical Research Institute, Inc. for their statistical planning, analysis, and expertise and Smiths Medical for funding the study.

Conflict of interest

This study was designed and funded by Smiths Medical, the manufacturer of both the blood control and standard PIVCs that were evaluated. The data were collected by emergency nurses who did not have any affiliation with the study Sponsor, and the statistical analyses were also performed independently by Regulatory and Clinical Research Institute, Inc. The co-author, Laura Seiberlich, is an employee of the study Sponsor; all other authors have no financial conflicts to report.

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