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

Laura E. Seiberlich MS (Clinical Research Manager) [a], Vanessa Keay BN, RN (Registered Nurse) [b], Stephane Kallos MD (Research Associate) [c], Tiffany Junghans BA (Research Coordinator) [c], Eddy Lang MD, CCFP-EM (Academic and Clinical Department Head for Emergency Medicine) [c], Andrew D. McRae MD, PhD, FRCPC (Clinician-Scientist and Research Director) [c,*]

[a] Smiths Medical, ASD, Inc., 1265 Grey Fox Road, St. Paul, MN 55112, USA
[b] Department of Emergency Medicine, Foothills Medical Centre, 1403 29 Street NW, Calgary, Alberta, Canada T2N 2T9
[c] Department of Emergency Medicine, University of Calgary and Alberta Health Services, 1403 29 Street NW, Calgary, Alberta, Canada T2N 2T9

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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

* Corresponding author. Department of Emergency Medicine, Foothills Medical Centre, Rm C231, 1403 29 St NW, Calgary, AB, Canada T2N 2T9. Tel.: +1 403 210 8835; fax: 403 944 2419.
E-mail address: amcrae@ucalgary.ca (A.D. McRae).

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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