ORIGINAL ARTICLE

Comparison of Visual versus Microscopic Methods to Detect Blood Splatter from an Intravascular Catheter with Engineered Sharps Injury Protection

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OBJECTIVE. To determine whether retractable intravenous devices produced blood splatter and whether blood splatter frequency differed between visual and microscopy detection methods.

METHODS. In this laboratory-based experiment, 105 venipunctures were performed in a simulated brachial vein containing mock venous blood. The retraction mechanism was activated in a testing chamber with precut fabric filters, placed at 3 different locations, to capture blood splatter. Differences in filter mass, visual inspection, and microscopic analysis for presence of blood on filters were the units of analysis. Descriptive statistics, paired Student t tests, and κ statistics were used for data analysis.

RESULTS. Blood splatter was detected visually and microscopically as follows: filter A, 70% and 71%, respectively; filter B, 12% and 9%, respectively; and filter C, 13% and 10%, respectively. A statistically significant difference was observed in the mean mass of filter A between before and after activation when confirmed by the naked eye ($P = .014$) and microscopically ($P = .0092$). Substantial agreement between methods was observed for filter A ($\kappa = 0.78$ [95% confidence interval, 0.64–0.92]), filter B ($\kappa = 0.73$ [95% confidence interval, 0.51–0.95]), and filter C ($\kappa = 0.75$ [95% confidence interval, 0.55–0.96]). However, blood was detected by microscopy and not by the naked eye in 7 instances (7%).

CONCLUSIONS. Our findings demonstrate that splatter, which can potentially expose healthcare workers (HCWs) to bloodborne pathogens, is associated with the activation of intravascular catheters with retraction mechanisms. HCWs may not detect this splatter when it occurs and may not report a splash to mucous membranes or nonintact skin. The need to wear personal protective equipment when using such devices is reinforced.

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Efficacy evaluations of devices with engineered sharps injury protection (ESIP) for reducing bloodborne pathogen (BBP) exposures to healthcare workers (HCWs) include not only reduction in incidence of needlestick injuries (NSIs),[1,2] but also whether blood splash following activation of the retractable safety mechanism of some ESIP devices occurs.[3] Blood splatter poses a risk of aerosolization of and the potential risk of mucocutaneous exposures to BBP.[1] Cases of HCWs who have contracted a BBP because of blood splash have been reported around the world.[4] The most commonly implicated pathogens are hepatitis B and C viruses, human immunodeficiency virus (HIV), and, less frequently, syphilis.[5] Ippolito et al reported 2 cases of hepatitis C virus transmission resulting from a blood splash to the conjunctiva.[6] Mucocutaneous HIV exposures have an estimated risk of seroconversion of 1 (0.03%) in 300 (95% confidence interval [CI], 0.006%–0.19%).[7] The probability of infection after mucocutaneous exposure of persons susceptible to BBP depends on the route of exposure, viremia level, and amount of blood.[5] Nevertheless, the overall risk of BBP transmission through blood splatter in general is still believed to be very small (less than 0.1%, depending on the source).[8,9]

Although the estimated frequency of NSIs associated with the use of ESIP devices is approximately 2.05 injuries per 100,000 ESIP devices purchased,[10] the incidence of blood splatter from use of devices with ESIP and the risk of infection from this route remain unknown. Although infections have not been reported, there is evidence that blood splatter occurs when ESIP devices are activated.[1,11-14] Haiduven et al designed a visual method to evaluate the potential of blood splatter

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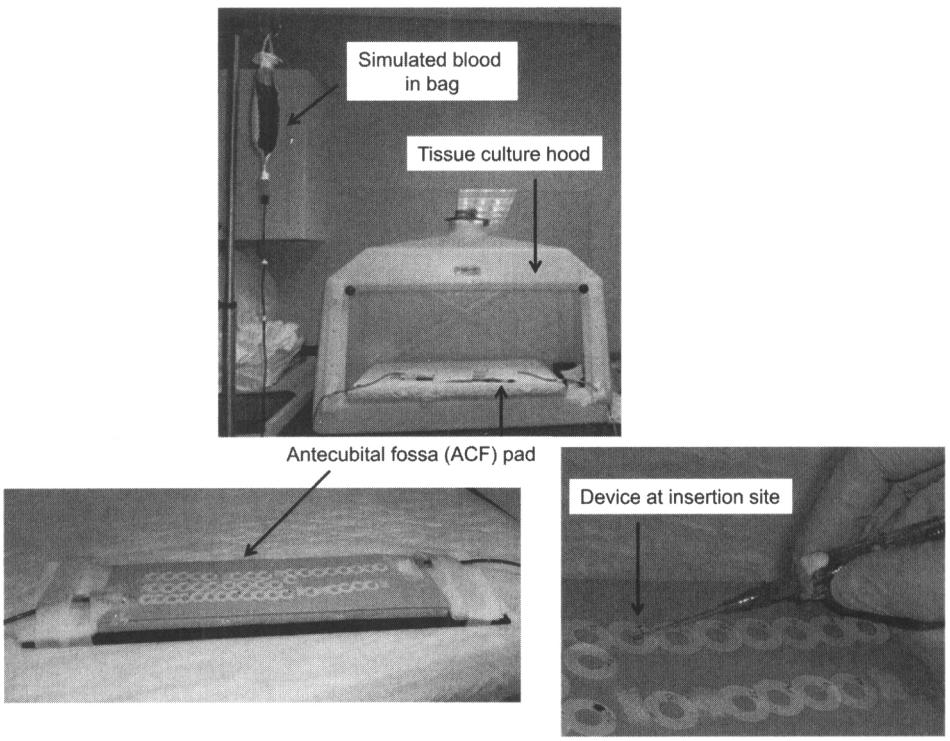

FIGURE 1. Experimental setup for detection of blood splatter. A color version of this figure is available online.

with ESIP devices.[1] They found a significant difference in the weight of the filters before and after activation of ESIP intravenous catheters as a result of blood splatter, with a mean (± standard deviation [SD]) weight difference of 0.5 ± 0.6 mg (range, −0.3 to 3.1 mg; $P < .0001$).[1] In that study, microscopic analyses were not used to detect blood splatter, possibly providing valuable information to improve the design of ESIP devices, such as the number of microscopic drops and the distance and direction of the splatter. In this study, we evaluate the potential of retractable intravascular devices for producing blood splatter and compare direct visual inspection with microscopic assessment by asking (1) whether the device produces measurable blood splatter, (2) whether splatter frequency differs between methods, and (3) whether there is a difference in blood capture between filter locations.

METHODS

Materials

The retractable intravascular safety device tested was Becton Dickinson's Insyte AutoGuard with a 20-gauge, 1.1 × 25-mm needle and an automated mechanism that, when activated, rapidly retracts the needle into its barrel. The experiment was conducted inside a ductless containment hood (Sentry Air Systems; Houston, TX), which provided a controlled environment free from contamination and any sudden changes in airflow. One injectable extended antecubital fossa (ACF) pad (a soft-tissue pad that simulates the ACF of a human right arm) was attached to a blood bag containing mock venous blood and infusion tubing. The mock venous blood used in this experiment was made to the correct color and viscosity of human venous blood (Limbs and Things; Savannah, GA). An intravenous catheter was inserted into the top portion of the ACF pad (blood entrance site) and another catheter was inserted into the distal end of the venous system of the ACF pad (venous blood exit site). Each ACF pad was premarked and numbered with 50 insertion sites (1–50 and 51–100, respectively; an additional 5 sites were tested on a third pad). A sequence pattern was established so that the insertion sites into the 3 simulated veins were not consecutively placed. Each new insertion site was not adjacent to the previous insertion site; instead, the sites rotated in location. The insertion of the catheter into each nonconsecutive site with the blood bag continuously connected was based on the manufacturer's directions for simulating an intravenous insertion (Figure 1).

The activation chamber was a custom-designed apparatus to hold the retractable intravascular device for the purpose of device activation and the detection of blood splatter at the activation site and the immediate vicinity. This chamber was used to collect any blood splatter resulting from activation of the device after the catheter was removed from the ACF pad and placed in the chamber, as shown in Figure 2. Fabric filters composed of heavy-duty coverall particulate arrester material with a maximum particulate barrier capacity were

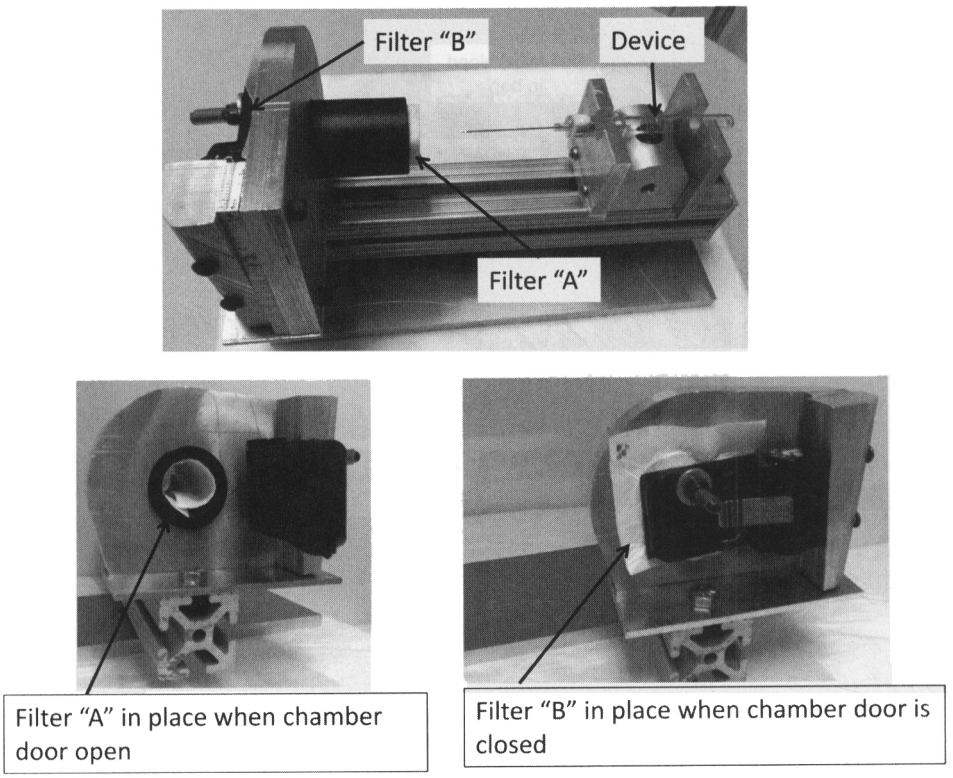

FIGURE 2. Activation chamber showing filter A with the retractable device in place and the location of filter B when the door of the activation device is closed. A color version of this figure is available online.

used to capture blood splatter from the retracting device (Kimberly Clark Healthcare; Roswell, GA). The filters were designated A, B, and C, respectively, and differed from each other in size and shape to fit their location and function. Filter A was positioned inside and around the activation chamber's cylinder, and filter B was positioned anterior to the retractable intravascular device. Filter C was used to wipe the back section of the chamber, the researcher's glove, and the outside of the intravascular device (Figure 2). The testing procedure involved 10 validation trials and 105 test trials, each time using 3 filters that were weighed before and after the trial.

An analytical scale (Ohaus; Pine Brook, NJ) calibrated to 1/1,000 g was used to weigh the filters before and after activation of each device. A prevalidation protocol was performed to determine the reliability of the scale. The weights of the 3 filters used for each retractable intravascular device were measured in milligrams on the analytical scale and recorded on a spreadsheet. A stereoscopic microscope with digital camera and 40× magnifications (Microscope Store; Roanoke, VA), using Motic Image Plus 2.0 software (Motic; Xiamen, China) was used. The entire filter was systemically perused with the low-power objective (10×) starting at the left upper corner in a pattern that resembled the method for scanning a direct wet film preparation. This allows for overlapping of the fields when looking under the microscope and reduces the chances of missing an area of the filter. Any suspicious material was further examined using the high-power objective.

Statistical Methods

The units of measurement for this experiment were (1) the difference in filter mass between before and after activation, (2) the presence or absence of visible blood on filters, and (3) visual versus microscopic examination of filters for the presence of blood splatter. These values were entered into an Excel spreadsheet using triple data entry. One researcher read the data values while another entered them into the Excel spreadsheet. The 2 researchers then switched their roles to recheck the data. Finally, the principal investigator rechecked all of the entries with one of the researchers, thus completing triple data entry. Descriptive statistics, paired Student t tests to assess filter weights before and after activation, and κ statistics were used to analyze the data. The κ statistic was calculated to compare the degree of agreement between filter examination results with the naked eye versus microscopy with respect to the presence or absence of blood for each filter.[15] Statistical tests of comparison were 2-tailed with a Type I error rate fixed at 5% using SAS, version 9.1 (SAS Institute) to perform all analyses.

RESULTS

The data set encompassed a total of 105 experimental trials of a single specific design of a retractable intravascular device. Data from 5 trials that involved breaks in the protocol (eg, dropping a filter on the floor and conducting steps out of sequence) were excluded to prevent any compromise to the validity, leaving a total of 100 trials retained for the final analysis. The first 2 research questions were whether retractable intravascular devices produce measurable blood splatter and whether there was a difference in blood capture between the 3 filter locations. Table 1 illustrates the number of filters with blood detected through microscopic examination versus through examination with the naked eye for filters A, B, and C. For filters A, B, and C, the number and percentage of filters with detectable blood were 70 (70%), 12 (12%), and 13 (13%), respectively, when examined by the naked eye and 71 (71%), 9 (9%), and 10 (10%), respectively, when examined by microscopy. Compared with filter A, a smaller number of filters B and C contained detectable blood.

Table 1 also illustrates the mean mass differences for each filter type by detection method. A paired Student *t* test was used to compute the mean (± standard error) mass difference for filters A, B, and C before and after activation. The results indicate that there was sometimes negative mean mass difference using both detection methods for filter A, but not for filters B and C. The difference between the mean (± SD) mass of filter A before (0.3701 ± 0.010154 mg; range, 0.3466–0.3921 mg) and after activation (0.3699 ± 0.010145 mg; range, 0.3618–0.3917 mg) was statistically significant for the proportion of filters with blood detected by the naked eye (mean mass difference before and after activation for filter A, −0.0013 mg; $P = .0140$) and microscopically (mean mass difference before and after activation for filter A, −0.00014 mg; $P = .0092$). However, there was no statistically significant difference between the mean mass of filters B and C before and after activation using either detection method. Thus, there was measurable blood splatter from this device detected, and splatter detection was greater at the filter A location. The difference between microscopic and visible blood detection was 0.0001 mg for filter A, 0.000131 mg for filter B, and 0.000085 mg for filter C.

The third research question was whether there was a difference in blood detection by the naked eye versus microscopic examination. Table 2 shows the level of agreement and 95% CIs between these 2 methods of detection for the presence of visible blood on filter A and the absence of visible blood on filters B and C. The associated frequency data for filter A show that, in 66 of 70 cases, there was agreement that visible blood was present, and in 25 of 30 cases, there was agreement that visible blood was not present. The frequency data for filters B and C show similar agreement with respect to the presence of visible blood (8 of 12 and 9 of 13, respectively) and the absence of visible blood (87 of 88 and 86 of 87, respectively). Assessing agreement between the 2 detection methods for the presence of visible blood resulted in a κ statistic of 0.78 (95% CI, 0.65–0.92) for filter A. Assessing

TABLE 1. Mean Mass Difference for Filter Weights before and after Activation for Naked Eye versus Microscopy Blood Splatter Detection

Visible blood	Filter A[a]	Filter B[b]	Filter C[c]
By naked eye			
No. of tests with blood detected	70	12	13
Mass difference			
Mean[d]	−0.00013	0.000025	0.000115
SD	0.000431	0.000569	0.000580
95% CI	−0.00023 to −0.00003	−0.00034 to 0.000387	−0.00024 to 0.000466
P[e]	**.0140**	.8818	.4869
By microscopy			
No. of tests with blood detected	71	9	10
Mass difference			
Mean[d]	−0.00014	0.000156	0.000200
SD	0.000447	0.000525	0.000643
95% CI	−0.00025 to −0.00004	−0.00025 to 0.000559	−0.00026 to 0.000660
P[e]	**.0092**	.3997	.3509

NOTE. Weight in milligrams for 100 tests and 300 filters. Statistically significant *P* values are indicated in boldface type. CI, confidence interval; SD, standard deviation.

[a] Filter A was positioned around the needle at the point of insertion into the antecubital fossa pad.

[b] Filter B was positioned ahead of the needle insertion site and covering the chamber door.

[c] Filter C was used to wipe the device first, the gloves of the healthcare worker second, and the area holding the back edge of the device, after activation.

[d] Analysis of mean mass difference for each filter was conducted including only those observations where blood was detected on the specified filter.

[e] Mean mass difference of specified filters as assessed by Student *t* test with significance level of $P < .05$.

TABLE 2. Level of Agreement between Blood Detection Measures (Naked Eye and Microscopy) for Presence of Visible Blood on Filter A and Absence of Visible Blood on Filters B and C

Filter type	No. of filters with presence of visible blood	Total no. (%) agreement on presence of visible blood	No. of filters with absence of visible blood	Total no. (%) agreement on absence of visible blood	κ (95% CI)[a]
A	70	66 (94)	30	25 (83)	0.78 (0.65–0.92)[b]
B	12	8 (67)	88	87 (99)	0.73 (0.51–0.96)[c]
C	13	9 (69)	87	86 (99)	0.75 (0.55–0.96)[c]

NOTE. CI, confidence interval.

[a] κ of 0.41–0.60 denotes moderate agreement and 0.61–0.80 denotes substantial agreement.

[b] Denotes agreement between both methods with regard to the presence of visible blood.

[c] Denotes agreement between both methods with regard to the absence of visible blood.

agreement between the 2 methods for the absence of visible blood resulted in κ statistics of 0.73 (95% CI, 0.51–0.96) for filter B and 0.75 (95% CI, 0.55–0.96) for filter C. These results show that there is substantial agreement between detection methods regarding the presence or absence of visible blood for each of the filter types. Furthermore, the CIs show that the degree of agreement was statistically significant using a weighted κ procedure.

Despite the overall agreement on the presence of visible blood between methods of detection, 7 separate trials did not detect blood by the naked eye but did show evidence of blood splatter under the microscope. Blood was detected by microscopy but not with the naked eye on filter A in 5 trials and on filters B and C in 1 trial each. Thus, 7% of the trials exhibited blood microscopically that was not visible to the naked eye (Figure 2). The range of weight difference for filter A was −0.0001 to 0.0001 mg. For the filter B and filter C instances, the weight differences were −0.0003 and 0.0003 mg, respectively.

DISCUSSION

The device evaluated in this study is designed to protect the user from sharps injury exposures by retracting the needle into the device barrel. Our study does not dispute this fact but instead focused on the potential for blood exposure from devices with retraction mechanisms.

Regarding the negative mean mass difference in weights for filter A between before and after activation of the device, there are 2 possible explanations. First, there may be a loss of thin fibers during the process of wiping, transporting, and examining the filters. Second, a loss of moisture from the filters might have occurred during the time period between before and after activation of the device. The loss of fibers that may have contained visible blood might also be a possible explanation for the number of times blood was detected by the naked eye and not by microscopy.

Regarding visual versus microscopic blood splatter detection, there was a high degree of agreement between the 2 methods. However, in 7 instances (7%) there was microscopic but not visual evidence of blood splatter ranging in weights of absolute value between 0.0001 and 0.0003 mg. HIV, hepatitis C virus, and hepatitis B virus contain 10^0–10^3, 10^0–10^6, and 10^3–10^8 viral particles per milliliter of blood, respectively.[16] Whether amounts in this study could result in infection after exposure depends upon the infectious dose of the pathogen, the level of viremia, and the route of exposure and requires additional study.

Filter A was positioned around the needle, and capture of blood splatter on this filter was a result of the needle mechanism retracting into the barrel of the catheter. Filter B was located further forward than filter A, and capture of blood splatter on this filter implies a further forward projection of blood after the needle was retracted. Presence of blood on filter C was the result of blood splatter onto either the device, the gloves of the healthcare worker, or the back chamber behind the catheter. The blood splatter on filter C, resulting from wiping the catheter or gloves, reinforces the need for HCWs to wear gloves when using these devices to prevent blood exposures to nonintact skin on the hands. Our findings suggest the need for HCWs to wear face protection (eg, masks and safety goggles or shields) when performing procedures involving placement of intravascular catheters with retraction mechanisms. However, because this study did not measure the distance or direction of blood splatter, future studies will need to employ methods to characterize these 2 parameters to better inform the issue of face protection.

There have been others who assessed blood splatter from this particular device using different methods than our own. Asai et al[12,13] tested the BD Insyte AutoGuard in 2 studies. Blood contamination was measured by counting the number of drops on the researcher inserting the device, the assistant, the patient, the device, and the holding tray after removal of the device from the patient. When comparing this device with its conventional version, there was a statistically significantly lower incidence of splatter onto personnel or the device in the AutoGuard group than in the conventional group ($P < .001$) and no incidence of blood contamination on the holding tray.[12] In their second study, 2 safety-engineered devices, the BD Insyte AutoGuard and the Johnson and Johnson Protective Acuvance catheter, were compared with a conventional device for 50 venous cannulations using the same methods used in their previous study. Blood contamination of the staff,

patient, and equipment occurred in more cases among the AutoGuard group than among the other 2 groups, although the difference was not significant. However, there were only 2 instances (4%) in which blood stains were noted on the holding tray in the AutoGuard group, which was statistically significantly fewer instances ($P < .001$) than with the other safety-engineered device and the conventional catheter.[13]

Ford and Phillips[14] developed a method of detecting blood splatter from intravascular devices using a closed pressurized simulated venous system containing fluorescein solution. The catheter was inserted into the tubing and withdrawn over a piece of paper that was subsequently examined under a UV light to detect fluid droplets. Of the 7 devices evaluated (including the BD Insyte AutoGuard), none produced blood splatter.

Our study has demonstrated that blood splatter does occur with this particular device, and our methods show that it occurs more frequency than reported by other studies. Notably, microscopic examination was not used in any of the other reported evaluations.[12-14]

One limitation of this study is that it did not involve human subjects. For humans, device activation would occur while the needle is in the vein, whereas in this study, device activation occurred away from the site of insertion, perhaps resulting in findings not reflective of what occurs in the clinical setting. The transportation of the device may have resulted in a loss of blood droplets, which means the risk may be underestimated. Alternatively, there is the possibility that the experimental design aspect of the study could lead to an overestimation of splatter compared with in-vein activation. However, anecdotal evidence from observations of healthcare workers indicates that retractable devices are not always activated while in the patient, despite the manufacturers' recommendations to do so.[17,18] Sometimes they are removed and then activated. This would create a blood splatter hazard to others in the immediate area. In addition, even when activated outside the vein, the device contains simulated blood in its lumen. A second limitation is that the analysis of the mass difference for each filter included only those instances in which blood was detected on the specified filter by the naked eye or microscopically. Thus, information regarding weight differences for filters without blood detection is not provided.

The results demonstrate splatter of blood detectable by the naked eye and microscopically and potential spread of bloodborne pathogens to HCWs associated with the activation of intravascular devices with retraction mechanisms. Microscopic examination enhanced the ability to detect minute amounts of blood splatter, but measurement of filter weights did not. Because HCWs may not be able to detect blood splatter when it occurs, potential blood exposure might go undetected. This reinforces the need for HCWs to wear personal protective equipment when using intravascular catheters with ESIP.[19] This study should be replicated with all brands of intravascular catheters with ESIP, and methods should be developed to measure the direction and distance of splatter. Finally, manufacturers should consider this issue in future designs of such devices.

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