An experimental method for detecting blood splatter from retractable phlebotomy and intravascular devices

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Background: This study was designed to evaluate the safety of retractable intravascular devices in terms of their potential to produce blood splatter. A method for measuring this blood splatter designed by the research team was used to evaluate 3 specific intravascular devices.
Methods: Scientific filters were positioned around the retraction mechanisms of the devices and weighed with an analytical scale, both before and after activation, in a simulated vein containing mock venous blood. The difference in filter mass was used as the primary unit of analysis to detect blood splatter. In addition, the filters were visually inspected for the presence or absence of blood.
Results: A paired *t*-test revealed significant differences in the prefilter and postfilter groups for 2 of the 3 devices tested ($P < .0001$). In addition, visible blood was detected on 23% to 40% of the scientific filters for 2 of the devices.
Conclusions: Our findings indicate a potential for bloodborne pathogen exposure with the use of intravascular devices with a retractable mechanism. This experiment may serve as a model in the design and implementation of future sharps device evaluation protocols to validate the threat of bloodborne pathogen exposure.

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Over the past few decades, many bloodborne pathogens have emerged that have chronic, debilitating effects on infected individuals. Consequently, a new high-risk group for bloodborne transmission of these pathogens has been identified: the health care worker (HCW). The known average risk of infection after a needlestick injury (NSI) from a source patient in a susceptible individual is 6% to 30% for hepatitis B virus (HBV), 1.0% to 7.0% for hepatitis C virus (HCV), and 0.3% for HIV.[1] In addition to these 3 viruses, more than 20 other disease-causing pathogens can be transmitted via NSI.[2]

In 1987, the Centers for Disease Control and Prevention (CDC) published recommendations for Universal Precautions in an attempt to protect HCWs from bloodborne and body fluid–borne diseases like HIV, HBV, and HCV.[3] The CDC recommended applying Universal Precautions to blood and other body fluids containing visible blood, because occupational transmission of HIV and HBV to HCWs has been documented.[3-5] Before the advent of devices with engineered sharps injury protection (ESIPs), NSIs constituted a major portion of health care–related exposures to bloodborne pathogens.[1] Hollow-bore needles have been implicated in the majority of NSIs (63%), and 90% of CDC-documented cases of HCWs contracting HIV after NSIs involved a hollow-bore needle.[1]

In an effort to protect health care workers from NSIs and reduce the risk of transmission of bloodborne pathogens, Congress passed the Needlestick Safety & Prevention Act in November 2000.[6] Moreover, the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogen Standard was amended to include the adoption of devices with engineering controls as an important aspect of NSI prevention.[7] The adoption of these devices has significantly reduced the risk of NSIs associated with recapping needles, transferring body fluid between containers, and improperly disposing of sharps.[8] The first safer needle devices were patented in the 1970s; however, only 15% of US hospitals used safer devices before state and federal laws for use of such devices were implemented.[9]

Since the passage of the Needlestick Safety & Prevention Act, numerous mechanical devices have been developed to help reduce the risk of exposure to bloodborne pathogens. Of particular importance are intravascular devices with retractable mechanisms, which when activated retract out of the blood vessel and into a protective sheath. This design feature reduces the risk of NSIs associated with recapping

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needles and improperly disposing of used needles. Many such retractable devices are finding applications in phlebotomy and intravenous (IV) access, as well as in administration of drugs and fluids. The parameters used to evaluate the efficacy of these devices include reductions in the incidence of NSIs and in the transmission of bloodborne pathogens.[9]

However, these devices themselves may present a risk of exposure to and transmission of bloodborne pathogens. The rapid retraction mechanism may cause microaerosolization of residual blood (ie, blood splatter), a potential source of exposure to bloodborne pathogens. A review of the current literature revealed no data on the incidence of blood splatter due to the retraction of such devices.

The extensive use of engineered safety devices in health care settings makes it imperative to explore all avenues of potential bloodborne pathogen exposure, including the possible microaerosolization of blood from safety devices. The present study was designed to evaluate the safety of retractable intravascular devices in terms of their potential to produce blood splatter. A method of measuring blood splatter, designed by the research team, was used to evaluate 3 specific intravascular devices.[10] This current report describes this laboratory-based evaluation.

METHODS

Materials

In this study, 100 each of 3 devices (a phlebotomy device, an IV catheter, and a winged butterfly set) were tested. The phlebotomy device had an automated vacuum tube mechanism that, when activated, rapidly retracted the needle into its plastic holder. The IV catheter used an automated rapid retraction mechanism. The butterfly phlebotomy device/IV catheter required manual retraction by the user. The experiment was conducted in a controlled laboratory environment designed to simulate the health care setting. An injectable extended antecubital fossa (ACF) pad (a soft tissue pad that represents the antecubital fossa of the arm and is used for venipuncture and the introduction of cannulae; Limbs & Things, Bristol, UK), attached to a blood bag containing mock venous blood and infusion tubing, was used to represent the venous system in accordance with the manufacturer's recommendations. Scientific filters composed of Kendall Versalon all-purpose sponges (prefolded 4-ply, 4'' × 4,'' prelabeled ''1a, 1b,'' etc up to ''100''; Mansfield, MA) and heavy-duty Kimberly-Clark heavy particulate arresters (tested at ≥ 0.3 μ, prelabeled; Neenah, WI) were used to capture blood splatter from the retracting needle. A Daigger analytical scale calibrated to 1/1000 g was used to weigh the filters before and after activation of each device. The experiment was conducted inside a tissue culture hood, which provided a controlled environment free from contamination and any sudden changes in air pressure.

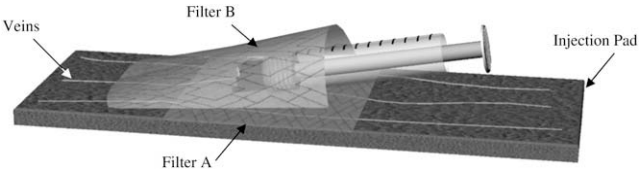

Figure 1. Illustration of the experimental setup.

A prevalidation test was performed to determine the reliability of the scale. A total of 100 filters were weighed using 4 different variables theorized to alter the weights in the clinical setting (ie, with a gloved hand, with a nongloved hand, after being placed immediately on the scale, and after being moved outside and then back onto the scale). Based on the analysis of the results, the scale was determined to be reliable to 0.001 g.

For each experiment, the ACF pad was premarked and numbered with 100 injection sites. The injection sites were placed such that they were rotated and not adjacent to subsequent sites. Absorbent material (ie, a 4.0'' × 6.0'' × 0.02'' pad with both cotton and plastic facing on opposite sides) was placed on the ACF pad distal to each insertion site to provide additional protection from any seepage that could occur from the insertion sites when the device was removed from the ACF pad. The level of mock blood in the blood bag was monitored and maintained between 400 to 500 mL.

In all 3 devices, the scientific filters were designated filter A and filter B. An independent testing protocol for capturing blood splatter was developed for each of the 3 devices. The amount of mock venous blood that moved into the device on each insertion was not measured; instead, the procedure was strictly timed and standardized throughout the experiment, to limit the variables inherent in intravascular access procedures. The specific protocol was based on the retraction mechanism, its activation, and the manufacturer's instructions for use. Activation was defined as the motion (specific for each device) resulting in removal of the needle from the injection site through its retraction into the barrel of the device.

One HCW tested 100 each of a retractable phlebotomy device, an IV catheter, and a butterfly device. The weights of the scientific filters (2 for each device tested) were measured on the analytical scale and recorded on a spreadsheet as the first step. The filters were then positioned around the retraction mechanism, with care taken to ensure that they did not come in contact with the retracting needle. For all 3 devices, filter A was placed on the ACF pad under the

Table 1. Test statistics for detection of blood splatter from retractable IV access devices before and after activation, by filter weight (in mg) and conversion to blood volume (in mL), n = 100 for each device

Device	Mean weight difference, mg	Standard deviation, mg	Weight range, mg	Converted mean blood volume, mL	Converted blood volume range, mL	Weight difference *P* value
Phlebotomy device						
Filters A and B	−0.0141	0.3	−0.5 to 0.9	−0.00001	−0.00050 to 0.00090	.5867
IV catheter						
Filter A	0.03	0.1	−0.4 to 0.4	0.00003	−0.00040 to 0.00040	.0387
Filter B	0.5	0.6	−0.3 to 3.1	0.00050	−0.00030 to 0.00311	< .0001
Butterfly device						
Filter A	0.2	0.2	−0.2 to 1.0	0.00020	−0.00020 to 0.00100	< .0001
Filter B	0.3	0.6	−0.3 to 2.5	0.00030	−0.00030 to 0.00251	< .0001

device's insertion point, and filter B was positioned around the retraction point (Fig 1).

After device activation, filter weights were once again measured on the analytical scale and recorded on a spreadsheet. The difference in filter mass before and after device activation was the primary unit of analysis for detecting blood splatter. Additional data recorded included the presence or absence of mock venous blood on the filters, absorbent pads, and gloves. These items were visually inspected after each trial, and findings were recorded for each of the parameters as a dichotomous outcome. Descriptive and paired (Student *t*-test) statistics were used to analyze all of the data collected.

RESULTS

The paired Student *t*-test was used to compute the mean (± standard error) of the differences in the weight of filters before and after activation, and also to determine the probability that the absolute value of the mean difference was > 0 by chance alone. The mean, range, and *P* values of weight differences were recorded. Table 1 summarizes the results. For the phlebotomy device, the mean difference between the preactivation and postactivation filter weights was -0.0141 mg ($P = .5867$). In contrast, the results for the IV catheter devices demonstrated a positive mean weight difference, equal to 0.03 mg for filter A. The postactivation weights were higher than the preactivation weights ($P = .0387$), and the mean weight difference was positive, 0.50 mg ($P < .0001$). Of those filters in which a weight increase was found, 13% of the increases were > 1.0 mg, with a range of +1.0 to +3.1 mg. In addition, 23% of the filter B's used with the IV catheter exhibited visible blood, whereas blood was not detected on any filter A's. The mean difference in the butterfly device's filter A's was positive (0.2 mg), as was that in the filter B's (0.3 mg). Paired *t*-tests revealed significant differences in preactivation and postactivation weights ($P < .0001$) for both filter A and filter B. Thus, for the butterfly device, the filter mass was higher postactivation than preactivation. The probability of this difference occurring by chance in both cases (filters A and B) was < .0001, whereas the difference was statistically significant at $\alpha = .05$. Of those filter B's in which a weight increase was detected, 11% of the increases were > 1.0 mg, with a range of -0.3 to +2.5 mg. In addition, 14% of the filter A's and 40% of the filter B's used with the butterfly device displayed visible blood.

The mean weight of 1 mL of the mock venous blood was 0.99618 mg. Using this information, the weight differences were converted to blood volume values (in mL). The blood volume values for the 3 devices ranged from -0.00001 to 0.00050 mL (mean, 0.00020 mL).

DISCUSSION

Two of the 3 devices tested in this experiment exhibited a measurable filter weight difference and a positive visual identification of blood droplets on the filter. These results indicate that blood splatter emanated from these devices and was captured using the study protocol, thereby suggesting the possibility of blood splatter exposure from the retracting needle to the mucous membranes of individuals in the proximity.

To date, no study has specifically investigated the potential issue of blood splatter from retractable syringes. However, several published reports provide evidence that small blood splashes can cause HBV and HCV infection in HCWs.[11-13] Taylor found that the mucous membranes of the mouth, eyes, nose, and ears are potential routes of transmission from minute amounts of infected blood (in some cases, amounts invisible to the naked eye).[14] That study's results clearly indicate that residual blood on medical instruments poses a potential health risk to both patients and HCWs, especially if it were to become aerosolized.

Our study has several strengths. First, a single HCW (a licensed physician) conducted all of the intravascular device insertions, minimizing variations. Second, each of the 3 protocols underwent numerous iterations to minimize environmental effects and hone the capture process. Once the protocols were finalized, they were strictly adhered to in each trial, to ensure

standardization. Third, the research team comprised individuals from diverse scientific backgrounds, including occupational infection control, medicine, mechanical engineering, and biostatistics. Fourth, the materials and methods in the laboratory were designed to closely replicate the conditions of the health care setting. Finally, and perhaps most importantly, this is the first study specifically designed to evaluate blood splatter associated with retractable intravascular devices.

Several factors limit the generalizability of our results, however. First, in contrast to the filters for the IV catheter and butterfly device, the filters for the phlebotomy device were not weighed separately (as filters A and B), but rather were weighed together (see Table 1). This variation in methodology possibly could account for the negative weight difference (lower combined weight of filters A and B postactivation) found for the phlebotomy device. Second, the products were not tested on humans. Third, it is important to mention that these experiments did not measure the distance or direction of the splatter, but only evaluated whether or not blood splatter occurred. Future studies to determine the amount, direction, and distance of potential blood splatter should be undertaken, along with studies using human subjects.

Thus study has several implications. The findings reinforce the recommendation that HCWs use personal protective equipment (eg, goggles, masks) while performing phlebotomy and IV catheterization.[15] In addition, HCWs' perceptions regarding the risk of exposure from intravascular procedures may be heightened. In the absence of obvious blood and body fluid exposure, HCWs do not have the protection of postexposure prophylaxis, which is a part of the Exposure Control Plan.[7] Thus, the use of personal protective equipment is the only available control measure to prevent seroconversion after exposure in such instances. Thus, the onus is on HCWs to adequately protect themselves against blood splatter from these retractable devices.

CONCLUSION

The findings of this study indicate a potential for exposure to bloodborne pathogens associated with the use of intravascular devices with retractable mechanisms. The findings pose important implications regarding the need for splatter protection when devices with retraction mechanisms (a characteristic of several devices with ESIP) are used to access the intravascular system. The extensive use of retractable needle devices in a wide variety of health care settings makes it important to explore all possible occupational exposures to bloodborne pathogens associated with their use. Scientifically sound studies on occupational health exposures, such as those dealing with blood splatter, are essential to improve current practices to enhance the safety of HCWs. This study may serve as a model for the design and implementation of future evaluation protocols to validate the threat of bloodborne pathogen exposure associated with devices that have ESIP.

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