An Investigational Study on the Use of a Sporicidal Disinfectant to Decontaminate Hazardous Drug Residues on IV Bags

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ABSTRACT

Introduction

It is best practice to wipe down surfaces of supplies such as intravenous (IV) bags and vials packaged in cardboard boxes with a disinfectant before bringing the supplies into classified areas of a clean room. Effective decontamination of hazardous drug residues on containers such as IV bags may reduce the risk of occupational exposure. It is critical to understand the risk of penetration of any potential disinfecting or decontaminating agent into the IV bags.

Methods

The ability of 4 types of IV bags to resist penetration by an EPA-registered sporicidal disinfectant based on peracetic acid and hydrogen peroxide (PAA/HP) was determined by 2 methods: A standard method used to measure barrier properties of gowns and gloves in a closed-loop system and analysis for trace levels of hydrogen peroxide in the IV fluids after immersion of the bags in a solution of the disinfectant. The 4 IV container materials studied were polyvinyl chloride, ethylene vinyl acetate, polypropylene, and ethylene propylene copolymer. The reduction of residues from 3 antineoplastic drugs on the outside of 1 type of IV bag was assessed after wiping the surface of the bags once with the disinfectant followed by isopropyl alcohol utilizing a commercially-available wipe sampling product.

Results

No migration (<5 ppm) of the PAA/HP disinfectant through the 4 types of IV bags was detected through 8 hours of exposure in a closed-loop system. No hydrogen peroxide (<31 ppb) was detected in the IV fluids after immersing the bags for 1 hour in the disinfectant. Dried residues from 3 antineoplastic drugs were reduced by at least 99.97% after wiping the surface of IV bags with the sporicidal disinfectant and then isopropyl alcohol.

Conclusion

Using a PAA/HP sporicidal solution to disinfect and decontaminate IV bags does not result in penetration or leaching of the PAA/HP into the bags, even after prolonged contact. Results also indicate that a single pass with PAA/HP-saturated wipes, followed by isopropyl alcohol, can effectively reduce common hazardous drug residues from the outside surface of IV bags.

Keywords: IV bags, sporicidal, disinfectant, decontamination, hazardous drugs

Introduction

Containers for compounded sterile preparations (e.g., IV bags, syringes, elastomeric pumps) are subject to intense quality control by manufacturers, including sterility validations for the absence of foreign matter or substances. However, once they are received into health care organizations, the responsibility to maintain their integrity and hygiene during compounding and administration shifts to pharmacy and nursing personnel.

PeridoxRTU® Sporicidal Disinfectant Cleaner (PAA/HP) is a sporicidal, fungicidal, and bactericidal 1-step disinfectant registered with the Environmental Protection Agency. The product is commonly used to disinfect surfaces in compounding pharmacies and clean rooms. Additionally, some facilities that compound hazardous drugs (HDs) use a wiping or mopping protocol with chemical agents such as PAA/HP to decontaminate surfaces that may harbor HD residues. Results of previous studies using PAA/HP with wipes or mop pads on surfaces such as stainless steel, plastic, and vinyl have demonstrated reductions exceeding 99.99% of several marker HDs.[1] However, decontamination of residual HDs by wiping final compounded sterile preparation (CSP) containers with PAA/HP has not been studied previously.

IV bags often are composed of multiple layers of polymers, including polyvinyl chloride (PVC), ethylene vinyl acetate (EVA), polypropylene (PP), polyethylene, or a combination of these polymers. The goal for design and construction of bags is to maximize puncture resistance and maintain sterility while ensuring the materials are safe to contact the IV fluids for a prolonged duration.[2] Design features also include the use of materials that can be sterilized while minimizing the cost and complexity of manufacturing. The bags may be supplied empty or prefilled with different IV fluids. Most, but not all, IV bags also are sealed inside an outer bag called an overwrap. The overwrap reduces fluid loss from the IV bag due to osmosis, and further protects the bag and its contents from physical damage or contamination during shipping.

Many facility standard operating procedures (SOPs) require that all supplies be wiped to decrease microbial bioburden before entering the buffer room or crossing the segregated compounding area (SCA) perimeter line. Additionally, compounding pharmacies also wipe final hazardous drug CSP doses after compounding HDs to remove potentially hazardous drug residue. This wiping step can reduce the risk of spreading HD residue outside the negative compounding spaces during transport and exposure during administration. Although HD residue on the outside of IV bags and other containers has been examined in several previous studies, the risk level is unclear.[3-10] Regardless, IV bags used for HDs are handled in several steps through compounding, transportation, and administration. Strategies for breaking the chain of transmission of these drug residues to reduce occupational exposure can use many of the same methods employed for decreasing transmission of microbial contamination in health care settings. Thus, it is desirable to explore if a simple protocol such as wiping the bag with a readily available chemical agent can effectively decontaminate HD residues without posing a risk to the fluids inside the bag.

Methods

Although the polymers used in personal protective equipment (PPE) like gloves or gowns may differ from those used in IV bags, a method used to understand penetration resistance for PPE can be applied to IV bags. The most common protocol for testing the chemical resistance of plastics and textiles is ASTM F-739 "Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact."[11] This method describes most of the experimental design and details needed to test any type of flat material for resistance to different chemical agents, including disinfectants and HDs. As described below, this standard method was adopted to test the penetration resistance of 4 container materials used for IV bags (Table 1) to prolonged exposure to PAA/HP.

The studies were conducted at the Akron Rubber Development Lab, a laboratory that specializes in

TABLE 1 | Container Material of IV Bags in ASTM F-739 Test Protocol to Determine Penetration Resistance

Container material	Brand (manufacturer)	Diluent	Container volume	Catalog reference
Polyvinyl chloride	Viaflex® (Baxter)[12]	NS[a]	1,000 mL	2B1324X
Propylene ethylene copolymer	Excel™ (B. Braun)[13]	NS[a]	1,000 mL	L8000
Polypropylene	E^3™ (B. Braun)[14]	NS[a]	1,000 mL	E8000
Ethylene vinyl acetate	Pinnacle™ CP0500(B. Braun)[15]	None	500 mL	2112347

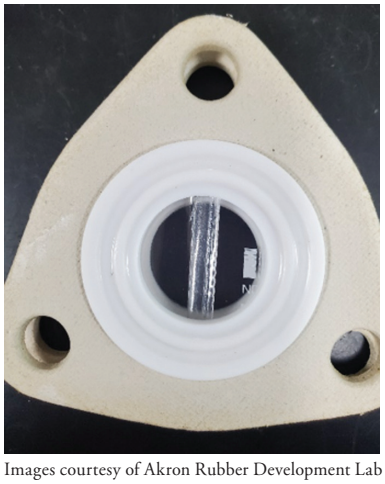
[a]NS: Sodium chloride 0.9% solution

testing the penetration resistance of PPE. IV bags were removed from the overwrap, if present, and emptied of fluid. An initial study measured penetration resistance of 3 randomly selected areas (5 cm^2) of the 4 types of IV bags, some of which may have included the seams. A second study consisted of single samples (5 cm^2) that focused on the seams of each bag (Figure 1A). In each case, the outer face of the IV bag was positioned within the exposure test chamber (Figure 1B) to contact the solution of PAA/HP.

Over 8 hours, a fresh solution of PAA/HP was recirculated across the surface of the IV bags through a closed-loop system. A blank solution of distilled water was recirculated on the other side of the IV bag sample. It was measured continuously with UV-Vis absorption spectrometry to detect penetration of the PAA/HP solution through the sample. The minimum detection level was 5 parts-per-million (ppm) of PAA/HP solution.

The penetration resistance of IV bags after immersion in a solution of PAA/HP also was determined with a different procedure. This colorimetric assay uses spectrophotometry to measure trace levels of hydrogen peroxide after reaction with a mixture of ferric iron with xylenol orange (PeroxiDetect™ Kit, Sigma-Aldrich). In Europe, several studies have utilized this sensitive assay for peroxides to assess if vapor-phase peracetic acid or hydrogen peroxide can penetrate IV bags during disinfection of isolators and devices used to reconstitute HDs.[16-17] This test included samples of IV bags like those listed in Table 1. The Baxter Viaflex® bags used in this study were smaller (250 mL; REF 2B1322) than the bags used in the penetration studies using ASTM Method F-739. The Pinnacle™ EVA bags were prefilled with 500 mL sterile water before the test. The exposure method involved immersing triplicate bags in a solution of PAA/HP up to, but not covering, the septa. After

FIGURE 1A
Sample Holder with a Sample of IV Bag Containing a Seam Before Placing into the Test Chamber



Images courtesy of Akron Rubber Development Lab

FIGURE 1B
Exposure Test Chamber

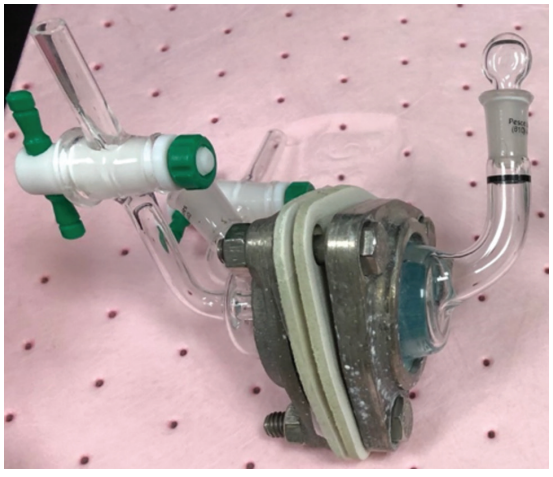


TABLE 2 | Hazardous Drug Dilution for Surface Application and Decontamination Testing of IV Bags

Drug	Diluent	Concentration/ reconstituted	Dilution for test and Control (1/10 dilution)	Amount applied to container surface[a]
Cyclophosphamide	Sodium chloride 0.9%	20 mg/mL	2.0 mg/mL	0.0500 mg
Methotrexate	Sodium chloride 0.9%	25 mg/mL	2.5 mg/mL	0.0625 mg
5-Fluorouracil	Sterile Water for Injection	50 mg/mL	5.0 mg/mL	0.1250 mg

[a]Protocol: 0.025 mL in 4 droplets of approximately 6.25 microliters each, applied across a 7.6 cm by 10.2 cm (3-inch by 4-inch) area on the container surface.

immersing the bags for 1 hour at room temperature, the IV solutions inside the bags were assessed for levels of hydrogen peroxide using the test kit.

An additional study was performed to determine the decontamination of HD residues from the outside of IV bags using wipers wetted with the PAA/HP solution. The outer surface, 7.6 cm x 10.2 cm (3 inches x 4 inches area) of 2 sets of triplicate PVC bags were intentionally contaminated with dilutions of 3 different HDs using a 1 mL syringe/needle as described in Table 2.

Drug solutions were allowed to dry on the outside surface of the bag for 30 minutes inside the containment primary engineering control (CPEC). One set of triplicate samples was used as controls to determine recovery efficiency of the sampling process. The other set of triplicate samples was used to measure the efficacy of decontamination. The decontamination procedure involved wiping each contaminated bag using a single pass with a sterile quarter-folded 9 inch x 9 inch polyester-cellulose wipe saturated with PAA/HP. After 3 minutes, each bag was wiped with a sterile quarter-folded 9 inch x 11 inch polypropylene wipe pre-saturated with sterile 70% isopropyl alcohol/30% water (sIPA). After drying, the area of contamination on each of the 6 bags was sampled using the swabbing technique prescribed in a commercial HD sampling kit.[18]

Results

As shown in Table 3, the results of testing using ASTM F-739 on 4 types of polymeric films used in IV bags indicated no penetration or leaching (< 5 ppm) of PAA/HP solution through 8 hours of exposure in either study 1 (3 different areas, some may have contained seams) or study 2 (single samples that included bag seams).

The resistance of the IV bags to penetration from the PAA/HP solution was further substantiated by

TABLE 3 | Penetration of PAA/HP through Container Material of IV Bag over an 8-Hour (480 min.) Exposure Using a Procedure Based on ASTM Test Method F-739

Container material	Average breakthrough detection time (minutes)
Polyvinyl chloride	>480
Propylene ethylene copolymer	>480
Polypropylene	>480
Ethylene vinyl acetate	>480

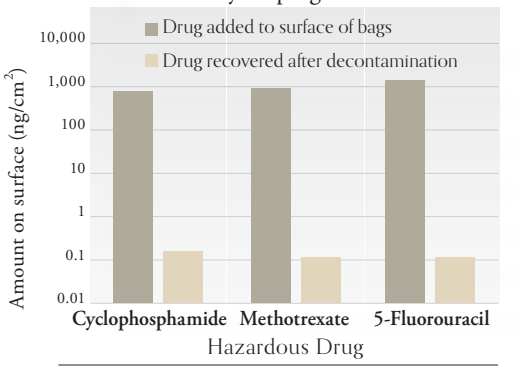
the results of testing using a commercially available assay for trace levels of hydrogen peroxide. As shown in Table 4, after soaking the 4 types of IV bags in the PAA/HP solution for 1 hour, the average concentrations of hydrogen peroxide recovered from the fluids inside the bags were below the minimum detection level of the method (<0.9 nanomoles/mL or 31 ppb). Although all the levels were below the minimum test threshold, the sodium chloride 0.9% from the 250 mL bags composed of PVC contained the highest concentration of peroxide of all the bag types. However, it was impossible to determine whether the increased levels were due to bag composition or to the smaller volume of the PVC bags.

TABLE 4 | Concentration of Hydrogen Peroxide Measured in IV Bag Diluents after 1 Hour of Immersion in PPA/HP Solution using a Colorimetric Assay[a]

Container Material	Container Volume	Mean Concentration of Hydrogen Peroxide[b] (SD)
Polyvinyl chloride	250 mL	26 (13)
Propylene ethylene copolymer	1,000 mL	20 (15)
Polypropylene	1,000 mL	10 (5)
Ethylene vinyl acetate	500 mL	9 (1)

[a]The minimum detection level of the method is <31 ppb.
[b]Measured in parts-per-billion (ppb)

FIGURE 2 Reduction of Hazardous Drug Residues on the Outside of PVC IV Bags after Wiping with PAA/HP Solution Followed by Wiping with sIPA[a]



[a]The corresponding percent reductions were 99.97% (cyclophosphamide), >99.98% (methotrexate) and >99.99% (5-fluorouracil).

Decontamination of 3 common hazardous drugs was accomplished by wiping the bags once with the PAA/HP solution, waiting 3 minutes, then wiping the bags with sIPA (Figure 2). The average recovery efficiency of the HDs from the control bags (no wiping with PAA/HP) using the commercial HD sampling kit was approximately 78% (data not shown). With the test IV bags, a single pass of PAA/HP on quarter-folded wipes, followed by wiping with sIPA, reduced the average level of drugs by at least 99.97%. With all but 1 replicate with cyclophosphamide, no residual HDs (<10 ng per 7.6 cm x 10.2 cm area (3 inches by 4 inches) were detected after the decontamination protocol. The minimum detection level in these tests was 0.13 ng/cm^2.

Discussion

Results of this study indicate minimal risk of penetration of an EPA-registered disinfectant based on peracetic acid and hydrogen peroxide through several common types of IV bags. Studies to measure the potential penetration of the PAA/HP solution into IV bags were performed under extreme conditions where the bags (including seams) were exposed to the PAA/HP solution over an 8-hour period. Results of additional studies that measured levels of hydrogen peroxide concentrations in the IV solutions after immersion for 1 hour also represent a worst-case scenario. Even if bags are wiped repeatedly, whether to disinfect, or to remove HD residues, the total duration of exposure would only be a few minutes. These results indicate that wiping IV bags with the PAA/HP solution poses minimal risk to the fluids inside the bags or the overall integrity of commonly used container closure devices.

Previous studies have examined the migration or leaching of disinfectant solutions into IV bags that might occur during vapor-phase sterilization processes.[16,17,19-21] Interestingly, the active ingredients used for these sterilization processes are the same actives used in the PAA/HP solution: peracetic acid and hydrogen peroxide. However, the sterilization processes use 10-100 times higher concentrations of these 2 chemicals and for a much longer duration of exposure when compared with a simple surface application of PAA/HP. Some of these previous results revealed differences in the amount of migration into IV bags depending on the type of polymeric film used in the bags.[16,20] Although the levels of trace hydrogen peroxide measured in this study were all below the stated sensitivity of the test kit, it is interesting to note that the levels of hydrogen peroxide detected inside PVC bags were higher than with other types of IV bags. Although penetration through the overwrap was not tested here, results of previous studies by other researchers indicated no detectable migration into IV bags if they were exposed to the sterilization process while still contained in the overwrap.[16,17,19-21]

As mentioned above, considering that PAA/HP would be in contact with the IV bags only for a few minutes to accomplish disinfection of microbes or decontamination of HD residues, it appears the risk of leaching of PAA/HP into the IV bags is extremely low. In cases where the outer packaging (overwrap) is disinfected with PAA/HP, the risk of IV fluid contamination from PAA/HP would be even lower since the PAA/HP is not directly contacting the IV fluid bag at that time. If wiping the IV bags themselves (instead of the overwrap), it is recommended to wipe with sIPA at some point after PAA/HP to remove any visible dried residues that might cause concerns from nurses or patients.

While the results described above demonstrate the penetration resistance of IV bags to PAA/HP, further discussion and studies elucidate the suitability of PAA/HP to both disinfect microorganisms and decontaminate hazardous drug residues on the external container surface of the IV bags. Most facility SOPs for bringing supplies into the negative pressure buffer room or beyond the perimeter line of the SCA require wiping materials with a disinfectant to decrease microbial bioburden on the surfaces

of supplies. This practice is based on the guidance in both the current and recent revisions of USP <797> Pharmaceutical Compounding – Sterile Preparations and the recognition that cardboard and paper packaging often can harbor significant levels of bacterial and fungal spores. The revisions of USP <797> published in 2019 and 2021 (but not yet finalized) clarify that EPA-registered disinfecting agents must be allowed to dwell, with the surface remaining wet, for the contact time. The PAA/HP solution is registered with the EPA to disinfect various surfaces, including the same type of polymeric films used in IV bags. As shown on the EPA master label, the contact times for the PAA/HP disinfectant range from 1 to 2 minutes for fungi and vegetative bacteria and 3 minutes for bacterial endospores.[24]

Regarding decontamination of hazardous drug residues on IV bags containing HD CSPs, the results of this study indicate that a wiping protocol utilizing PAA/HP with appropriate textiles, followed by wiping with sIPA, is a viable option to reduce the risk of HD migration. Numerous guidance documents from the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), the American Society of Health-System Pharmacists (ASHP), and others mention IV bags as a potential source of occupational exposure to HDs. As described above, several published studies have examined the occurrence of HD residues found on the surfaces of IV bags (also called infusion or intravenous containers in the literature). While a recent large study conducted in 8 Dutch hospital pharmacies found no detectable contamination of 5-Fluorouracil on the outside of IV bags, several other studies have recovered substantial levels of HDs from the outside of IV bags.[3,4-10] The occurrence of HD contamination likely depends on variables like compounding technique, the use of robotics and closed-system transfer devices (CSTDs), the level of contamination on the outside of vials provided from manufacturers, and the robustness and frequency of decontamination, cleaning, and disinfection procedures. Since many of these factors are challenging to control and may be both variable and highly operator-dependent, it may be a best practice to wipe the outside of the final HD CSPs before they are removed from the CPEC and packaged for transport. The current study did not consider other types of containers used for HD CSPs, such as plastic syringes and elastomeric pumps. However, these containers are composed of similar polymers as many IV bags. Future studies should investigate the resistance to penetration and impact of HD decontamination of these containers using the PAA/HP solution.

Conclusion

The surfaces of supplies such as IV bags should be disinfected to reduce the transfer of viable microorganisms into classified areas of compounding clean rooms. For sterile compounding of hazardous drugs, decontamination of potential drug residues on the external surfaces of final CSP containers can reduce the risk of occupational exposure during transport and administration. Results of this study indicate that a 1-step sporicidal disinfectant and cleaner based on peracetic acid and hydrogen peroxide can effectively reduce hazardous drug residues on the container surfaces of IV bags without posing a risk that the disinfectant ingredients penetrate through the bags.

Disclosures

Mark Wiencek and Lauren Pernot are employees of Contec, Inc.

Michael Bedenbaugh is a consultant on retainer with Contec, Inc

Kate Douglass is a consultant on retainer with Contec, Inc.

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