Hub disenfection and its impact on Catheter-Related Infections

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Catheter-related bloodstream infections (CR-BSI) are now a significant public health problem in the United States, with estimates ranging from 200,000 to 400,000 incidences annually. This could represent as many as 62,500 deaths, result in approximately 3.5 million additional hospital days needed for treatment, and add $3.5 billion to the annual costs of healthcare.[1-3]

It has long been recognized that the sources of catheter-related infection include hematogenous seeding, infusate contamination, skin surface, and hub colonization.[1,4] While the first two causes are rarely documented or relatively uncommon,[4] the patient's skin and the catheter hub are well documented to be significant sources of these pathogens.

The patient's skin is thought to be the major source of microorganisms when the infection presents within 10 days after insertion of an intravenous (IV) catheter.[2] In such a case, preventive strategies typically focus on the use of maximal aseptic barriers at the insertion site, adherence to sterile technique during routine site care, the addition of subcutaneous cuffs and tunnels to the device, and choosing IV catheters that have anti-infective coatings on their cannulae.

When a CR-BSI occurs later than the initial 10 days that an IV catheter has been indwelling, the hub of the catheter is considered the most likely (and significant) source of the contamination. As early as 1984 researchers began to suspect hub manipulation as a major source of CR-BSI.[5] Preventive approaches for these cases include ensuring that there are secure junctions between the catheter hub and any attached pieces of external tubing, using catheters with as few lumens (and hence hubs) as possible, limiting the use of side ports and stopcocks, and extending the life of administration sets in order to reduce the frequency of hub manipulation.[6]

Defining Our Actions

Aseptic hub manipulation and hub cleaning are recommended as important strategies to reduce the load of microorganisms introduced intraluminally. Although recognized as a strong need, many questions remain about the practical aspects of how we really accomplish hub cleaning.

Before we discuss the logistical aspects, we need to agree on the taxonomy, or language, used to describe what we are trying to accomplish. Many studies use the words disinfection and antisepsis interchangeably, even though they are very different processes. Antiseptic agents are chemical germicides formulated for use on skin or tissue, and they are not used to decontaminate inanimate objects.[7]

To that end, cleaning and sterilization represent opposite ends of a continuum. While cleaning is the removal of foreign material from an object (including organic material such as blood), sterilization is the complete elimination or destruction of all forms of microbial life from an object. Since this term has an absolute meaning, not a relative one, it cannot be applied to components once they are in use. For example, catheters, dressings, and many other products may begin as sterile products but they cannot be considered "sterile" while actually indwelling in or in contact with the patient. Therefore, failure to clean or remove accumulated organic material is likely to render the disinfection or sterilization process ineffective.[7]

Disinfection is any process that eliminates many or all pathogenic microorganisms, with the exception of bacterial spores, from inanimate objects. This usually is accomplished by either the application of liquid

chemicals or wet pasteurization. The efficacy of the chosen process depends upon previous cleaning of the object, the organic load on the object, the type and level of microbial contamination, the concentration of and exposure time to the germicidal agent, the physical configuration of the object (*e.g.*, the presence of indentations and crevices), and the temperature and pH of the disinfectant agent.[7]

Regulation of disinfectant agents depends upon the devices for which the solution is intended. The Food and Drug Administration (FDA) regulates agents used on critical devices, devices used to enter tissue or the vascular system, semi-critical devices, or those devices that touch mucous membranes, such as endoscopes. The Environmental Protection Agency (EPA) regulates agents used on non-critical objects that touch intact skin, such as stethoscopes.[7]

Based upon the standard definition of "disinfection" and considering the devices for which these disinfecting solutions are intended and the guidelines for their use, an intriguing question is whether the hub of an indwelling catheter actually can be disinfected or are we really just cleaning the hub's surfaces? Typically written guidelines for disinfection address objects that are used for a short period and then removed and disinfected for subsequent use. Rarely do they address the disinfection processes appropriate for a product *in situ*.

Disinfectant Agents

Disinfectant agents in general use include alcohols, chlorine and chlorine

Catheter Manufacturing Processes

While we know the microbicidal activity of disinfectant solutions, we often do not have the same level of knowledge about the interaction between these chemicals and the materials used in their construction. The catheter body is made of silicone or polyurethane and polycarbonates are often used for the catheter hub.

Silicone and polyurethane are biostable polymers and resins characterized by biocompatibility and physical strength. Polycarbonates, on the other hand, have physical properties of heat resistance and strength, even though chemical resistance is limited.

Catheters made of polyurethane can withstand sterilization processes and harsh environments. Manufacturing processes include injection molding, blow molding, and extrusion, and their critical processes necessary for manufacturing catheters include proper drying and cooling methods, along with ensuring uniform wall thickness and reducing sharp corners. Testing during and after their assembly includes such stresses as flexing and stretching of the cannula, and measuring light transmission through the catheter itself. However, no matter how strong the tests show the device components to be, applying povidone-iodine, isopropyl alcohol or lipids can result in property loss of up to 30%, depending upon the specific type of polyurethane used in the manufacturing.[9]

Questions about the negative effects of iodine on silicone have been raised, but no published documentation has appeared. In fact, the published information reveals the exact opposite. For instance, iodine has been studied as an additive to silicone to add anti-infective properties since iodine can pass freely into and out of the silicone matrix.[10] Iodine also has been combined with polyurethane to create a class of self-sterilizing plastics.[8]

During manufacturing, the molding processes for catheter hubs aim to eliminate points of stress by making hub walls uniformly thick, reducing sharp corners, and ensuring uniform cooling of the material in all areas of the mold. In contrast, clinical use creates points of stress by pinching, clamping, and twisting of the hub, and the cleaning techniques used. When any points of stress resulting from the molding process are combined with the stresses of clinical use, product integrity suffers. In addition, when certain chemicals are applied to some polymers, the hub or catheter body may swell at the points of stress concentration, thus causing cracking of the component.

For many years we have read manufacturer's warning about the application of acetone to the cannulae and hubs of IV catheters. At low levels of stress, polycarbonates are susceptible to an effect from the presence of acetone. While other chemicals may not cause the same level of changes to the polymer, as does acetone, there are some changes. After 7 days exposure to certain chemicals, all polycarbonate samples show some loss in tensile strength. For example, in one study exposure to isopropyl alcohol resulted in a 52% loss of tensile strength of the cannula while exposure to povidone-iodine caused a 20% loss of strength and fracturing of the cannula resulted with exposure to 10% bleach and 20% lipids.[11]

Environmental stress cracking or crazing can result when cleaning solutions contact the polymer. These solutions act as solvents and penetrate the polymer, causing it to swell. The occurrence of crazing depends upon a combination of many factors, including the degree of attraction or repulsion between the solvent and the polymer; the complexity of the stress applied to the catheter part; exposure time and temperature; the part design and its geometry; and the processing conditions used during manufacturing.

Failure of catheters in clinical use is a serious problem and presents many challenges for healthcare providers and patients. Although these situations can be frustrating, it is important for healthcare professionals to work with the manufacturer to identify the problem and its cause. Failure analysis of polymeric medical devices is in its infancy due to a relatively brief history of polymer science and biomedical engineering.[12] Types of failures include misuse, poor design or improper material selection, and errors in manufacturing and/or quality control. To completely investigate the problem, the manufacturer will need thorough information about the patients, their diagnosis, and types of therapies; the length of use for the catheter; and specific techniques used to care for the catheter, such as cleaning, dressing and tubing changes, and any other stresses placed on the catheter. ❤

compounds, and iodines. Although these may sound similar to common antiseptic solutions, their formulations as disinfectant agents are different.

Ethyl and isopropol alcohols are not considered high-level disinfectants, although they are used extensively to disinfect small surfaces, such as rubber-stoppered vials. They are rapidly bactericidal, viricidal, fungicidal, and tuberculocidal, but they neither destroy bacterial spores nor penetrate protein-rich material, such as blood. The optimum concentration of the alcohol used ranges from 60% to 90%.

Chlorine and chlorine compounds have a broad spectrum of antimicrobial activities, including bactericidal, fungicidal, tuberoculocidal, sporicidal, and viricidal actions. Although the mechanism of action is not clear, it is postulated that these compounds produce enzymatic reactions within the cell that result in protein denaturation and inactivation of the nucleic acids. An example of this type of solution is Amukin 50%, which is used to clean connection sites on hemodialysis and peritoneal dialysis catheters.

Iodine solutions have significantly more free iodine when formulated as disinfectants, since free iodine is required for microbicidal activity. Interestingly, iodophors, such as povidone-iodine, combine iodine with polyvinylpyrrolidone and the resulting complex diminishes the amount of free iodine available to kill germs. As a result, many clinicians question its effectiveness as an antiseptic and such a complex could have very little effect as a disinfectant.[8] There could be a more significant risk associated with repeated use of povidone-iodine in a manner that would allow this solution to gain entrance into the catheter lumen. There are numerous reports of serious thyroid, hepatic, and renal impairment, including organ failure, when povidone-iodine has been used for irrigation of surgical wounds or when one packs wounds with gauze soaked in this solution.[8] Based upon these reports, it probably would be wise to avoid introducing povidone-iodine into the catheter lumen and bloodstream.

Hub Cleaning Techniques

Healthcare professionals know the risk of contaminated hubs, what can happen with use of the various solutions, and that cleaning is necessary. However there are many questions yet to be answered about specific techniques for hub cleaning. The concerns include being able to reach all catheter and hub surfaces and if one introduces the cleaning solution and/or swab fibers into the catheter lumen while cleaning the device.

Typically the exposed surfaces of an IV catheter are easy to reach with a swab or swabstick. As there also can be dried blood on the posterior side of the catheter when in contact with the skin, one needs to remove the tape or securement device and lift the catheter in order to reach these surfaces. Securement with sutures may prohibit reaching these surfaces easily.

The type of administration tubing connected to the catheter hub can either allow or prohibit reaching the external surfaces of the hub. In order to reduce accidental disconnection while a device is indwelling, a luer-lock connection is required when connecting items to all central venous catheters. As a result, blood, drug precipitate, and other cellular debris can accumulate on these locking surfaces and make it can be difficult to access such regions. If the tubing has a luer-lock with a spin collar, one can "unlock" this collar and retract it up the tubing, while leaving the slip luer connection to fill the catheter lumen. This technique permits one to clean all of the exterior hub surfaces without inadvertently introducing the cleaning solution into the catheter's lumen.

In the absence of luer-lock connections with a spin collar, the only method available to reach all of the hub surfaces is to disconnect the tubing completely from the catheter. In such a case, precautions for preventing air emboli must be employed. Also, with the catheter hub open, one must be aware of the potential to introduce foreign substances into the lumen of the catheter. Materials that could enter the lumen in this way include the cleaning solution, cotton fibers from the swab used to apply the solution, and organic debris that had collected on the hub over time. Once inside the catheter hub, these substances can enter the bloodstream when the catheter is flushed or infusion is resumed.

In order to assess the capacity of various agents to disinfect catheter hubs, suspensions of *Staphylococcus epidermidis, Pseudomonas aeruginosa*, and *Candida parapsilosis* were infused into the lumens of 20 gauge short peripheral IV catheters and incubated overnight.[13] The next day the researchers swabbed the hubs of these IV catheters with either 1% chlorhexidine in 70% ethanol, 1% chlorhexidine in water, 97% ethanol, or normal saline. After swabbing the hub, 1 ml normal saline was flushed through the lumen of the catheters and

Commonly Used Agents for Disinfection of Surfaces

Ethyl & Isopropol Alchol
- Bactericidal, Viricidal, Fungicidal, and Tuberculocidal
- Will not destroy bacteria spores and will not penetrate protein-rich materials, such as blood
- Optimal concentration ranges from 60% to 90%

Chlorine & Chlorine Compounds
- Bactericidal, Viricidal, Fungicidal, Sporicidal, and Tuberculocidal
- Work to denature cell proteins and inactivate nucleic acids

Iodine Solutions
- Wide microbiological activity when formulated as free iodine
- Iodophors, such as povidone-iodine, combine iodine with polyvinylpyrrolidone, with the resultant complex thought to reduce the amount of free iodine available to kill microbes.

into a petri dish, where upon the fluid was examined for the presence of cotton fibers. In the ethanol group, 3 ml of normal saline was flushed through the lumen to measure the amount of ethanol recovered with such a wash.

It was noted that while all disinfectants were effective in reducing colony counts of these bacteria, the ethanol was the most effective agent. Interestingly, only the use of saline removed greater than 99% of the total number of microorganisms, suggesting that the mechanical action of a fluid passing over a surface alone may be beneficial. In the wash from 180 hubs, three strands were found in the petri dishes that resembled cotton fibers. Based upon the amount of ethanol present in the effluent solution, the level of ethanol in the blood was calculated to be minimal— in a 500-gram neonate, 1 ml of ethanol would result in a serum level of 0.38 mg/dl.[13]

Implications for Practice

In the absence of well-designed research to guide our clinical practice, we must rely on general principles. First, clinicians need to closely follow manufacturers' instructions for use for IV catheters. While in general polyurethane catheters cannot tolerate contact with alcohol, this is not true for all formulations of polyurethane, so catheters made with newer formulations may not carry the same restrictions on alcohol use. Therefore, one must refer to the printed instructions for use for the specific catheter brands being used.

Unfortunately, with so many IV catheters on the market, nurses in alternate care settings will find such a recommendation challenging because they receive patients with a wide variety of catheter brands indwelling. In addition, this makes it difficult for institutions to establish written procedures that will cover all patient care situations.

Second, clinicians must know the chemical composition of solutions being used, as chlorahexidine gluconate and povidone-iodine can both be combined with alcohol. If problems develop, it is important for the clinician to make careful notes about the specific solutions used, the types of infusates delivered via the catheter, and any other instruments, such as hemostats, that were used to disconnect the tubing.

Finally, collaboration among healthcare professionals, researchers, and medical device design engineers is critical. Research investigating the methods of reducing catheter contamination cannot be conducted without consideration of the plastics used in the construction of the IV catheter. Published reports of studies need to include details of the devices and products used because there is so much variation in these plastics. Similarly, device manufacturers must know the types of solutions and chemicals that will be applied to their products in routine clinical practice and provide information about any potential problems or interactions.

Until clinical studies have reported on these issues, we must rely on the latest information available about reduction in the incidence of catheter-related bloodstream infections and the research on the various polymers used to make all components of IV catheters. Using both sets of information will enhance clinical practice decisions. ❤

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