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Cleaning, Disinfection and Sterilization of Heat-Sensitive Endoscopes

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Additional information is available at the end of the chapter

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1. Introduction

High level disinfection is a process that kills high numbers of all types of vegetative non-spore forming bacteria (Gram-positive and Gram-negative), fungi, all types of viruses (hydrophylic and lipophylic), and mycobacteria (TB), but not necessarily high numbers of bacterial spores in the relatively brief exposure time for disinfection. Sterilization is a process that kills all types of microbes including highly resistant bacterial spores. Sterilization usually requires a much longer exposure time than disinfection. Gastrosopes, colonoscopes, urethrosopes, and cystoscopes normally do not break the barrier between non-sterile areas of the body and sterile areas, and therefore high level disinfection is the commonly accepted practice for these endoscopes. Bronchoscopes are a possible exception as they may enter into the sterile bronchioles, although they make that entrance through the non-sterile nasal passages where they likely become contaminated with the flora of the oral-nasal body cavities. Endoscopists, and certainly patients, all agree that endoscopes and their accessories such as biopsy forceps should be thoroughly cleaned of all body fluids and any possible microbes between patients, even if not technically sterilized.

2. Methods

Unless endoscopes can be completely dried after disinfection, creating an environment where microbes cannot survive or multiply, or there is laboratory culturing evidence that endoscopes still contain very few or no microbes, they should be disinfected and rinsed again in the morning before first use. Any microbes that might remain in the endoscopes after disinfection, or be introduced into the endoscopes by means of non-sterile rinse water, could multiply overnight

or over a weekend or holiday to unsafe numbers, or begin to form a biofilm within the channels of the endoscope. Certain microbes such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, or *Escherichia coli* can divide every 60 minutes or faster in dark, moist, and warm conditions. Just 10 or 20 microbes remaining in an endoscope at 4:00 PM can multiply to about one million colony forming units by the time of the 1st case at about 8:00 AM the next day, and many more if the starting number is higher than “just 10 or 20” if there is enough substrate to sustain a population that size. The hospital laboratory or a contract laboratory/microbiologist can be a valuable ally to know by testing how many microbes are in the channels of an endoscope after a cleaning/disinfecting procedure, or after a storage interval. It takes only a few minutes for a microbiologist to flush recovery solutions through an endoscope, and then assay those fluids to validate the numbers, if any, of microbes within the channels of an endoscope. At intervals of about three or four months, or after newly trained personnel begin to process and disinfect endoscopes, or the disinfecting procedure is modified, a sampling of the endoscopes should be cultured to validate that the endoscopes are indeed disinfected, and any numbers of bacteria in the endoscopes are very low. B.T. Petersen, et. al. is another publication regarding methods for reprocessing flexible endoscopes [1].

3. Cleaning endoscopes

The initial cleaning step happens in the Procedure Room when the insertion tube is removed from the patient and wiped with a gauze pad saturated with a disinfectant, and the internal air, suction, and water channels are flushed with water. This initial cleaning step removes much of the organic soil and probably removes and kills at least 99% of any microbes on the endoscope. The endoscope is then transported in a plastic bin to the reprocessing room and tested for possible leaks. The control valves are removed, and the endoscope and all parts (valves) are submerged in a deep stainless steel sink (or plastic basin) with about two or three gallons of warm tap water with a disinfectant-detergent solution. The endoscope should be cleaned within about 30.0 min of leaving the procedure room, and not allowed to dry. Organic soil and microbes are much more difficult to remove and to kill after they become dry than when they are wet. A disinfectant-detergent cleaning solution is a concentrate of a low-foaming surfactant (detergent) and disinfectant. These disinfectant-detergent cleaning solutions are concentrates intended and labeled to be diluted in the range of 1:16 to 1:32. The label will give the exact dilution to be used, and also identify that the solution will kill Gram-positive and Gram-negative bacteria, fungi, and hydrophylic and lipophylic viruses, (and possibly even mycobacteria and some spores or spore-forming bacteria, depending on the particular disinfectant-detergent chosen). Labels that use the scientific names of microbes can be difficult for non-microbiologists to understand. The hospital laboratory, or any microbiologist, can help to translate the label into common terms such as Gram positive or Gram negative bacteria, fungi, and viruses. The disassembled valves should be flexed and lightly brushed with the disinfectant-detergent cleaning solution (cleaning solution), the exterior of the endoscope should be wiped with a soft cloth saturated with the cleaning solution, and the biopsy or working channel of the endoscope should be filled with the cleaning solution and brushed the entire length several times with a tight-fitting brush. Insert the

brush into the channel until the brush emerges from the channel. Brush the channel repeatedly about three or four times. Allow the brush to emerge from the channels submerged within the cleaning solution to avoid a splattering of microbes in the air. The air-water channel is too small to brush, and care should be taken to ensure that this small channel is not blocked and is filled with the cleaning solution. This wiping and brushing of all parts of the endoscope with the cleaning solution should continue for about 5.0 min which allows the disinfectant to kill many of any contaminating microbes. This cleaning procedure is completed by triple-rinsing all parts and sections of the endoscope with fresh warm tap water. Some cleaning solutions contain enzymes, and enzymes are not antimicrobial, and are not compatible with disinfectants. Enzymes require at least body temperature (35 °C) and many minutes to function. Enzymes are proteins, and it is proteins such as blood and tissues that are being removed from the endoscopes. For those reasons, especially the fact that enzyme-detergent combinations are not antimicrobial, and are not compatible with disinfectants, these enzyme-detergent combinations are not recommended by this author for cleaning endoscopes. Enzyme products are useful as a soak to dissolve clogged air/water channels that are too narrow to be brushed. The purpose of using a disinfectant-detergent cleaning solution during this cleaning stage is to remove organic soil (blood, mucous, fecal matter), and lower the number of microbes on the endoscope in advance of the final stage of disinfecting or sterilizing, and to protect the technician and the environment from a splattering of wash water containing potentially infectious microbes.

4. High level disinfection of the endoscope

After the endoscope and all of its parts have been cleaned as described above in a disinfectant-detergent cleaning solution, and thoroughly triple-rinsed with tap water to remove the disinfectant-detergent, the rinsed endoscope should then be soaked in a high level disinfectant at the labeled exposure time and temperature for any particular high level disinfectant. A high level disinfectant is a disinfectant that is labeled to kill all Gram-Positive and Gram-Negative vegetative bacteria, all fungi, all mycobacteria (TB), and all types of viruses, hydrophylic and lipophylic, within the labeled exposure time and temperature. High level disinfectants are also able to kill bacterial spores and spore-forming bacteria, although it takes a longer time to kill high numbers of bacterial spores than to kill vegetative microbes. After the initial disinfection and rinse in the procedure room, and the procedure of cleaning the endoscope with the disinfectant-detergent cleaning solution, the number of spore-forming bacteria on the endoscope should be very low, and thus this disinfecting procedure will also remove and kill many bacterial spores.

5. Sterilization of an endoscope

The procedure to sterilize an endoscope contains all the steps for cleaning and high level disinfection of an endoscope as described above, but the exposure time for sterilization is

longer than for disinfection in order to kill spores and spore-forming bacteria [2]. The label of the high level disinfectant will identify the sterilization soak time, which can be many hours. Also, the final rinse should be with sterilized water rather than ordinary tap water. Air should be forced through the internal channels with a syringe to dry them, and the endoscope should be stored in some sterile manner such as covering the endoscope with a sterile wrap or cloth. Hang the endoscope so it can further drip dry.

6. Protective clothing

Although care is taken to not splash contaminated water from an endoscope during reprocessing, there will be some splash and splatter as brushes emerge from the internal channels, and otherwise. Personnel should wear a plastic face shield covering the eyes, nose, and mouth; hair covering; elbow-length rubber gloves; and long-sleeved, waterproof gowns or coats.

7. Examples of disinfectant-detergent cleaning solutions

A disinfectant-detergent cleaning solution will be a concentrate intended to be diluted with tap water, usually 16- or 32-fold. The detergent should be anionic or non-ionic, low foaming, and easily rinsed from the endoscope. Use the lowest concentration (highest dilution) recommended to facilitate rinsing and removal of the disinfectant-detergent solution. There are dozens of these disinfectant-detergents listed on the US Environmental Protection Agency (EPA) web site. Local Sales Representatives will also be able to provide written descriptions and access to disinfectant-detergent concentrates. They contain modified phenolic chemicals (phenylphenol, amylphenol, etc); quaternary ammonium chemicals (dimethyl benzyl ammonium chloride); sodium hypochlorite/bleach; iso- or ethyl alcohol; or other common disinfectants. These disinfectant-detergents are being used in the cleaning stage to clean organic material from the endoscopes by way of the detergent, to lower the bioburden of microbes on the endoscope by way of the disinfectant, and to provide some respite to the environment and to the operator from the microbes inevitably splashed with the cleaning water. Several endoscopes can be cleaned in a basin filled with the diluted disinfectant-detergent at one time. Discard/drain the disinfectant-detergent cleaning solution after each endoscope cleaning procedure. The basin could be repeatedly drained and filled with tap water to triple rinse the endoscopes, or additional basins could be used for rinse water.

8. Examples of high level disinfectants

High level disinfectants are able to kill high numbers of all vegetative bacteria, fungi, viruses, and mycobacteria within a relatively brief exposure time such as about 10.0 min to

20.0 min at temperatures of about 20 °C to about 25 °C. The label of the high level disinfectant will have an exposure time and temperature. However, if the cleaning procedure used a disinfectant-detergent which would have killed large numbers of microbes, the high level disinfectant exposure time can be shortened to 20.0 min. With a longer exposure time such as hours, a high level disinfectant can also kill highly resistant forms of bacterial spores. Alkaline glutaraldehyde solutions (Cidex Solution), solutions of glutaraldehyde enhanced with isopropanol (Aldahol High Level Disinfectant), and peracetic acid solutions are high level disinfectants. The sterilization time for Ortho-Phthalaldehyde (OPA) is 32 hours, which is not practical, and OPA is not labelled as a sterilant. Alkaline glutaraldehyde solutions with and without isopropanol, and peracetic acid solutions are highly soluble in water, and thus are easily rinsed from endoscopes. OPA has a low solubility in water, and is difficult to rinse away from endoscopes with any practical number of rinses [3]. Trade names of some high level disinfectants are Cidex Activated Dialdehyde Solution, Aldahol High Level Disinfectant [4], Rapicide High Level Disinfectant, Resert XL HLD, and Acecide High Level Disinfectant.

9. Automatic endoscope reprocessing machines

Automatic endoscope reprocessing (AER) machines are available. Some of these AER machines also claim to be able to clean the endoscopes as well as to disinfect them. The cleaning action of the cleaning solution for these AER machines is by force rather than by brush, and this author is skeptical that such forceful rinsing is able to clean the channels of endoscopes as well as a brush. If an AER machine is used, the endoscope should be manually brushed before it is placed into the machine. Duodenoscopes have an elevator wire channel that must be manually cleaned regardless of a final clean in a machine.

10. Protection from irritating disinfectant vapors

Glutaraldehyde solutions, glutaraldehyde-isopropanol solutions, and peracetic acid solutions all have irritating and sensitizing chemical vapors. These solutions should be contained and used in a manner to protect workers from the irritating and sensitizing chemical vapors. This can be done by soaking the cleaned endoscope in a covered container of the disinfectant, and/or working in a hood that ventilates the chemical vapors through a filter to remove the vapors, or ventilates the vapors to outside air. If a hood is not available, a small fan can be positioned to blow the chemical vapors away from the operator. Any spilled high level disinfectant should be immediately cleaned up. Serious and effective efforts must be made to ventilate and eliminate and protect personnel from the vapors of glutaraldehyde, OPA, and peracetic acid.

11. Biofilms

The interior channels of endoscopes can be convoluted, and the air-water channel is too narrow to brush. Therefore it is possible over time for the channels of an endoscope to develop a film of microbes, called a biofilm. Endoscope channels that contain a biofilm cannot be disinfected [5]. Detection of a biofilm is one reason why endoscopes should be periodically cultured. Biofilms can be removed by soaking the endoscope and all of its channels in an enzyme detergent for a prolonged period of time such as one or two hours, followed by vigorous brushing of the channels. After this prolonged soaking, brushing and rinsing procedure, the endoscope should again be cultured to determine that the biofilm has been removed. The hospital laboratory or a contract microbiologist can be the Endoscopists best friend, and the only way to know for certain that procedures lead to a disinfected endoscope is to culture the endoscope, at least periodically.

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