Technology Review

Cleaning, Disinfection, and Sterilization of Gastrointestinal Endoscopes: Approaches in the Office

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Techniques of flexible proctosigmoidoscopy and colonoscopy have become available to family physicians during the 1980s. Little has been published, however, describing the proper cleaning, disinfection, and sterilization processes for gastrointestinal endoscopes. In fact, many clinicians cannot accurately define these terms. In practice this problem is compounded by conflicting recommendations from vendors of endoscopic equipment, disinfectant solution salesmen, nursing associations, and others. Most of the early (1973–1981) recommendations for endoscopic cleaning, disinfection, and sterilization were arbitrary and without proven efficacy. As more studies have been performed, the process of minimizing the risk of infection for patients has become more scientific.[1] This paper defines key terms and discusses the how, when, and why of various disinfection agents and techniques. Allowing for differing practice styles and community standards, reasonable and safe protocols are discussed, and specific recommendations are made. Manufacturers and clinicians are encouraged to take the steps needed to organize and further improve their own protocols.

Control of nosocomial infections is extremely important in light of anxiety regarding the potential iatrogenic spread of acquired immunodeficiency syndrome (AIDS) and hepatitis.[2,3] While infections caused by endoscopy are rare, such events may be underrecognized and underreported. Documented transmission of *Pseudomonas* and *Salmonella* has occurred with upper gastrointestinal endoscopy.[4] One survey revealed 17 infections in 211,000 upper gastrointestinal tract examinations.[5] In contrast to upper gastrointestinal tract examinations, however, there are few reported cases of infection regarding lower gastrointestinal tract examinations. A 1982 survey by the American Society of Gastrointestinal Endoscopists reported only one case in 57,000 procedures. When underrecognition and underreporting are accounted for, the estimated risk of acquiring an infection by means of a lower gastrointestinal tract endoscopic examination is about 1 in 1000 to 1 in 10,000.[6] In the literature reporting thousands of lower gastrointestinal endoscopy procedures, few transmissible infections are documented. In fact, others agree that despite heterogeneous cleaning and disinfection methods, endoscopically transmitted infections have occurred with remarkable rarity.[7] Many of these cases have occurred as a result of poor mechanical cleansing or a lack of a disinfectant cycle.

Several endoscopically transmitted infections were attributed to a suboptimal disinfectant solution. Solutions such as hexachloraphene, chlorhexidene, and quaternary ammonium compounds have a poor spectrum of activity against gram-negative bacteria.[5,7] Identical disinfection techniques are recommended for both lower and upper gastrointestinal endoscopes. Even though infection is rare, the physician's duty is to protect the patient.

Historically, formal recommendations for medical equipment cleaning and disinfecting protocols have been developed by the Centers for Disease Control (CDC) and have been subject to approval by the Environmental Protection Agency (EPA). The Food and Drug Administration (FDA) has also added another level of definition to these protocols. Note that 1981 CDC recommendations for endoscopic equipment disinfection "strongly recommended" gas sterilization or 30 minutes of high-level disinfection with either 2% glutaraldehyde or 6% hydrogen peroxide following each use. These guidelines, based upon CDC studies performed on disinfection of respiratory tract equipment, were extrapolated to include flexible endoscopes. Subsequent independent studies have refuted the necessity of such rigorous cleaning methods for endoscopes.[8] As a result, the CDC now agrees that "liquid chemical germicides used in laborato-

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ries and health-care facilities have been shown to kill HTLV III/LAV (ie, HIV) at concentrations much lower than are used in practice,"[9] and their recommendations have become less stringent. More recently, they recommended that "medical devices or instruments that require sterilization or disinfection be thoroughly cleansed before being exposed to the germicide, and the manufacturer's instructions for use of the germicide should be followed."[10] Thus, endoscopists are currently left to interpret manufacturer's cleaning and disinfection protocols and to select the most appropriate "germicide" by themselves.

The following criteria must be considered when designing processes for effective cleaning and disinfection of endoscopes:

1. The endoscope may be needed within 10 to 20 minutes for the next patient examination.
2. The endoscopes contain heat-labile materials and cannot be sterilized in the autoclave.
3. The endoscopes may be damaged by certain disinfectants.
4. The narrow channels and recesses are difficult to clean and disinfect.
5. The endoscopes are expensive and people are unwilling to send them to central areas to be cleaned.
6. The process must be so simple that it is readily performed in the office.
7. The process must be safe for the attendant staff.
8. The following definitions must be understood:

Cleaning: A mechanical process that removes all feces, blood, mucus, and material from the endoscope.

Disinfection: A chemical process that removes all vegetative forms of bacteria from the endsocope (may also include removal of some viruses and spores).

Sterilization: A chemical or physical process that removes or kills all microorganisms including viruses and spores.

Cleaning

Careful cleaning is very important because the effectiveness of the disinfection process depends on the degree of precleaning that occurs. There appears to be relatively little controversy regarding techniques for cleaning. One recommended cleaning procedure is described in this paper under Final Recommendations. Other acceptable

procedures exist also. It should be noted that some procedures introduce a low-sudsing, protein-dissolving soap such as chlorhexidene gluconate (Protozyme or Hibiclens) in the cleaning phase.[11] Such an agent is unnecessary, however, if careful attention is made to remove all mucus, feces, and debris with a thorough tap water cleansing.

While the cleaning process is not difficult to complete, the clinician must understand it thoroughly and should be able to perform it. Effective cleaning will require staff with appropriate training, time, and motivation.

Disinfection

The number of microorganisms to be destroyed chemically depends to a large extent on the thoroughness of the cleaning. In an attempt to abandon arbitrary recommendations and identify the proper agent and length of exposure, several authors have studied various agents and exposure times. The major characteristics of each of these disinfection agents are listed in Tables 1 and 2.

Table 3 summarizes the most important aspects of various disinfection solutions. From these data it is obvious that, while no perfect agent is available, alkaline glutaraldehyde comes closest. Its major disadvantage is sensitivity reactions among workers. In one survey of British endoscopy centers, 37% of the centers reported sensitivity reactions using the 2% solution.[5] Because many currently consider alkaline glutaraldehyde the agent of choice, efforts have been made to decrease its risks. The manufacturers of Cidex (Surgikos) have developed a specially designed container to reduce fumes in a poorly ventilated work area. Successful attempts have been made to prove the efficacy of shorter disinfecting times, from 30 minutes several years ago to as few as 2 to 5 minutes now.[4–6,20,22] A recent study looking at contamination of endoscopes used in AIDS patients found no viral activity after disinfection for only 2 minutes in 2% alkaline glutaraldehyde.[23] In fact, some even recommend 1-minute disinfecting times between patients.[18]

The manufacturers of Sporicidin have decreased the concentration of alkaline glutaraldehyde to 0.125% and combined it with an active phenolic buffer in an attempt to decrease sensitivity reactions and thereby increase acceptance by office staff.[14] The search for even more effective and less toxic agents has led Meuwissen and MacLaren[18] to recommend a mixture of 0.5% glutaraldehyde, 0.75% formaldehyde, and 0.6% alkyldimethylbenzylammonium chloride (known as 1% Tegodor in Europe), but its efficacy and safety are as yet unproven.

Table 1. Glutaraldehyde Disinfectants

Compound	Duration	Efficacy	Hazards	Remarks
0.125% Alkaline glutaraldehyde (Sporicidin)	1–10 min	Same as 2.0% alkaline glutaraldehyde; inactivates HIV[12,13]; active phenolic buffer "boosts" effectiveness of lower glutaraldehyde concentration	Risk of dermatitis, sinusitis, and conjunctivitis to examiner much less than in 2% solution; prolonged exposure not found to damage scope.[14]	Nonflammable; noncorrosive; easy penetrability, easily rinsed from scope; must be changed every 14 d; many recommend 30 d
2% Alkaline glutaraldehyde (Cidex)	1–10 min	Very effective against all bacteria, including *Salmonella*[5], *Pseudomonas*, and *Clostridium difficile*,[15] hepatitis B virus and HIV[12,16]; maintains rapid, high-level germicidal activity in presence of organic soil; more active than acid glutaraldehydes against spores. Resistant spore-forming organisms, such as *Clostridium*, are rare and not clinically significant	Risk of dermatitis, sinusitis, and conjunctivitis to examiner; prolonged exposure (>30 min) may damage scope	Nonflammable; noncorrosive; easy penetrability; easily rinsed from scope; must be changed every 7–14 d
Acid glutaraldehyde	Unknown (20 min?)	Probably similar to alkaline glutaraldehyde against bacteria; unknown against hepatitis B virus and HTLV-III virus	May corrode scope	

Povidine-iodine compounds are effective, but their tendency to stain the lens yellow limits their usefulness.

Many manufacturers will call for very detailed and intricate cleaning steps, but fail to require a disinfection cycle between patients or at all. It should be noted that disinfection is a very important step that cannot be ignored by clinicians.

Sterilization

Cleaning and disinfection only are preferred and adequate for most situations, but if sterilization is desired, gas sterilization is available. The accessory instruments may be sterilized in the autoclave, but the endoscopes will not stand steam under any pressure and cannot be

Table 2. Other Disinfectants

Compound	Duration	Efficacy	Hazards	Remarks
Povidine-iodine	2–10 min	Effective, but inactivated rapidly by organic soil and hard water; proper concentration necessary for efficacy; may still harbor *Pseudomonas*[17]; inactivates HIV	Allergic reactions by staff described[18]; yellow stains may occur; safe for equipment if limited to 2–4 min soak; longer soaks not recommended, but may be needed to inactivate HIV	Can be very difficult to rinse from equipment; sticky
Hypochlorites	20–30 min	Germicidal and hepatovirucidal, but inactivated rapidly by organic soil; inactivates HIV[19]; unstable at low concentrations	May corrode scope	
Chlohexadene and hexachlorophene		Ineffective; has been implicated in *Pseudomonas* sepsis and death		
70% Alcohol		Ineffective; bacterial contamination persists; generally not antiviral or sporicidal[17], but does inactivate HIV[19]	Flammable; may damage lens cement	Very useful as a drying agent
Quaternary ammonium compounds		Studies to date disappointing; *Pseudomonas* sepsis with death reported in upper gastrointestinal endoscopy cases[5]		
Succine dialdehyde		Effective against bacteria and hepatitis B virus	Unacceptably toxic to staff	

Table 3. Disinfectant Properties

Agent	Acts Quickly	-Cidal Activity				Inactivated by Soil	Hazards		Easily Rinses
		Bacteria	Spores	Hepatitis B	AIDS		for Staff	for Scope	
Alkaline glutaraldehyde (Sporicidin) 0.125%	3	3	3	3	3	0	1	0	3
Alkaline glutaraldehyde (Cidex) 2%	3	3	3	3	3	0	3	0	3
Povidine-iodine	3	3	3	3	3	3	1	1	0
Acid glutaraldehyde	2	3	1	3	?	0	2	2	3
Hypochlorites	1	3	3	3	3	3	0	2	3
Chlorexadene	1	1	1	?	?	2	0	0	3
70% alcohol	1	1	1	?	3	1	1	1	3
Quaternary ammonia compounds	1	1	1	?	2	1	0	0	3
Succine dialdehyde	2	3	2	3	?	1	3	0	3

Scale: 3 = strong, 2 = moderate, 1 = weak, 0 = none.

placed in an autoclave. Gas sterilization is a prolonged, hospital-based process that uses ethylene oxide—a very toxic, explosive, and potentially mutagenic and teratogenic agent. It may cause severe burns and may induce spontaneous abortions. Its inhalant toxicity is similar to ammonia.[5] Furthermore, repeated use of ethylene oxide may shorten the life of the endoscope.[24] Following 30 minutes of sterilization with ethylene oxide, the scope must be aerated for 10 to 24 hours.[5,24]

Thus, there is no routine role for ethylene oxide. In certain clinical situations, however, sterilization of the endoscope and accessory instruments may empirically be considered under the following conditions: (1) following the examination of any patient known to have positive test results for hepatitis B surface antigen, AIDS, active tuberculosis (pulmonary or extrapulmonary), or salmonellosis; and (2) before the examination of any patient known to have significant increased risk of acquiring bacterial infections (eg, active cancer).

As noted in Tables 1, 2, and 3, certain disinfectants have adequate activity against hepatitis B and human immunodeficiency viruses (HIVs). In nine prospective studies summarized by O'Connor and Axon,[5] 230 patients were inadvertently examined with an endoscope previously used on Hb_sAg-positive patients. The endoscopes had received routine cleaning and disinfection only. None of the patients developed clinical disease, only one became antibody positive, and none became chronic carriers. Thus, while some authors recommend gas sterilization after examination of a known Hb_sAg-positive or HIV-positive patient, its necessity is unproven. Certainly, it is not necessary to prescreen all endoscopy patients for Hb_sAg or HIV. Even following

examination of high-risk patients whose Hb_sAg positivity or HIV status is unknown, only cleaning and disinfection are necessary. This standard of care is currently acceptable for prevention of iatrogenic viral infections.

Final Recommendations

Cleaning and disinfection are two necessary and equally important steps to prevent transmission of infection from patient to patient by the endoscope and its accessories. Complete sterility is not believed to be necessary in the usual situation, but the degree of disinfection that ensures clinical safety is unknown. Based on current information, the following recommendations (which closely correspond to several manufacturers' recommendations) are made.

Cleaning is performed at the beginning of each session and after each case as follows:

1. The external sheath is washed with a sponge and a mild detergent solution. (One author [W.M.R.] uses a tap water scrub if debris is minimal.)

2. The cleaning brush is pushed through the biopsy channel first to minimize the amount of debris suctioned through the inner scope. This action may help to avoid clogged channels.

3. Tap water is suctioned through the endoscope to remove secretions. Sterile water is not necessary.

4. The biopsy valve and distal hood (if present), as well as suction, air, and water valves, are removed (some authors believe that removing the air valve is unimportant). The channel openings, valves, and hoods are vig-

orously cleaned with a cotton-tipped applicator and mild detergent solution.

5. The control head is cleaned with gauze that is dampened with detergent; care must be taken not to immerse the control head on some older instruments.

6. The entire length of the biopsy channel is cleaned with the channel cleaning brush and aspirated detergent solution, followed by an aspiration rinse with water.

A *disinfection* cycle then follows cleaning. Despite its shortcomings, alkaline glutaraldehyde appears to be the best agent available and is the consensus choice of authors. A lower concentration in combination with an active buffer (Sporicidin) is believed to be as effective as a higher concentration (Cidex) and may help avoid the sensitivity reactions. Gloves should be worn during the entire process. A recommended protocol follows.

Short Cycle Disinfection:

1. Approximately 50 mL of disinfectant is suctioned through the suction biopsy channel.

2. The water insufflation bottle (if present) is then partially filled with the disinfectant, and it is flushed into the air-water channel. Some feel this step is optional.

3. The endoscope is then left to soak in the disinfectant tray for 2 to 10 minutes, taking care to avoid immersion of the control head.

4. Any necessary equipment (eg, biopsy equipment) is mechanically cleaned, then soaked for 10 minutes in alkaline glutaraldehyde, then carefully rinsed. Biopsy forceps and cytology brushes can be placed in an autoclave, which some experts also recommend for the accessories.[25]

5. The biopsy channel is flushed by aspirating water through it for 30 to 60 seconds.

6. The water bottle is then rinsed and filled with water, and the air-water channel is flushed with water for 30 to 60 seconds.

7. The exterior of the endoscope is rinsed thoroughly with water, taking care to avoid splashing water on the head of the instrument.

8. The endoscope sheath is dried by air or an alcohol swab.

9. The umbilical cord is wiped with alkaline glutaraldehyde, then with water.

After the last case of the day, proceed with steps 10 to 13:

10. Air is suctioned through the biopsy channel for 60 seconds.

11. The water connector tube is disconnected from the umbilical cord, the port is covered, and air is flushed through the air-water channel for 60 seconds.

12. The water bottle is dried and left open to air dry.

13. The endoscope is hung vertically in open air to dry overnight. Do not hang in an enclosed space, such as cupboard or closet.

Summary

Bacterial contamination of endoscopes can be clinically significant. While current data suggest that flexible sigmoidoscopy may entail fewer risks than upper endoscopy, these data are too incomplete to draw this conclusion. Careful cleaning and disinfection after each procedure are recommended. Gas sterilization of the endoscope and gas or heat sterilization of accessory equipment may be necessary in certain clinical situations. It must be remembered that hundreds of thousands of endoscopic procedures were performed in the 1970s using cleaning only without substantial health risk.

The processes do not have to be complicated or difficult. Staff must be well trained and must understand the potential risks of working with disinfecting agents such as alkaline glutaraldehyde. It is recommended that the clinician fully understand the cleaning and disinfection steps and be able to perform them. It is important that office procedures be based on efficacy, not convenience.

The procedures developed to date are not ideal and the ideal disinfectant has yet to be found. Cleaning and disinfecting machines have been developed, but they are expensive and their efficacy and safety are no better than hand-performed methods. An alternative approach to reducing transmission of infections by endoscopes may be to seek less adherent plastic substances for the endoscope sheath.[26] The introduction of immersible endoscopes has helped with cleaning, but their use may also give rise to a false sense of security. Diligent attention to cleaning and disinfection is still necessary.

Despite the remaining uncertainty over risk of endoscopically transmitted infection, the clinician can be reassured by the substantial clinical experience that suggests a wide safety margin for those who rigorously follow, at a minimum, the aforementioned cleaning and disinfection procedures.

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