

Efficacy of high-level disinfectants for reprocessing GI endoscopes in simulated-use testing

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Background: There has been recent public concern regarding the adequacy of current practices for flexible endoscope reprocessing. High-level disinfection is defined by the Food and Drug Administration (FDA) as a minimum of 6-log reduction of mycobacteria under a worst-case scenario. Several agents are currently approved by the FDA, but published data on their relative efficacies against mycobacteria are lacking. The objective of this study was to determine the efficacy of these agents for high-level disinfection.

Methods: In simulated-use testing, video endoscopes (5 colonoscopes and 5 duodenoscopes) were each inoculated with 9.0×10^7 colony-forming units of *Mycobacterium chelonae*. Cleaning was performed by using a standardized protocol. Each endoscope was then subjected to chemical disinfection with Cidex (2.0% glutaraldehyde) at 20°C for 20 minutes, Sporox (7.5% hydrogen peroxide) at 20° for 30 minutes, and Steris 20 (0.2% peracetic acid) at 50°C to 56°C for 12 minutes using the Steris System 1 processor. Although not FDA-approved, tests were also conducted by using 70% isopropyl alcohol at 20°C for 20 minutes. These results were compared with disinfection with ethylene oxide gas. All channels were sampled for *M chelonae* before and after manual cleaning and after disinfection.

Results: Cleaning alone resulted in an average log reduction of 3. Cidex, Sporox, Steris 20, ethylene oxide gas, and isopropyl alcohol, in combination with manual cleaning, each achieved a 6-log or greater reduction of the mycobacterial inoculum. No organisms were recovered from any channel after reprocessing with ethylene oxide and Steris 20.

Conclusions: Commercially available high-level disinfectants are equally efficacious for reprocessing flexible GI endoscopes when used in conjunction with cleaning and in accordance with recommended guidelines. (Gastrointest Endosc 2001;53:456-62.)

Flexible GI endoscopes invariably become contaminated with microorganisms during clinical use. The complex and delicate construction of modern endoscopes and the rapid turnover requirements of most endoscopy centers pose a difficult challenge to endoscope reprocessing because safety, efficacy, and expediency must all be balanced. Although the reported rates of infection transmission during flexible endoscopy are low,¹ public concerns have been expressed in the media regarding the adequacy of current practices for reprocessing of reusable medical devices.^{2,3}

The reprocessing guidelines for all semi-critical medical devices require that flexible endoscopes

should be subjected to high-level disinfection (HLD),⁴ which is defined by the Food and Drug Administration (FDA) as a 6-log reduction of mycobacteria under a “worst-case” scenario.⁵ Several liquid disinfectants have been approved by the FDA for use as high-level disinfectants. Glutaraldehyde-based solutions are the prototypical liquid high-level disinfectants and are the most widely used in the United States for reprocessing endoscopic equipment.⁶ The FDA has determined that to achieve HLD with Cidex (Johnson & Johnson Medical, Inc., Arlington, Tex.), endoscopes must be exposed to a 2% solution at 25°C for a minimum of 45 minutes. When Sporox is used (Reckitt & Colman, Montvale, N.J.), endoscopes must be exposed to a 7.5% solution at 20°C solution for 30 minutes. Steris 20 (Steris Corp., Mentor, Ohio) has been approved as a liquid chemical sterilant when endoscopes are reprocessed at 50°C to 56°C for 12 minutes inside the Steris System 1 processor. These recommendations are based on a “worst-case” scenario that assumes no cleaning is performed before disinfection.⁵

The relative efficacies of the above disinfectants against mycobacteria are not known because there have been no comparative studies to date. Furthermore, the significance of the exclusion of cleaning is

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Table 1. Colony counts after manual cleaning and disinfection*

Type of endoscope	Serial number	Cidex (2.0% glutaraldehyde)	Sporox (7.5% hydrogen peroxide)	Steris 20 (0.2% peracetic acid)	70% Isopropyl alcohol	Ethylene oxide gas
Duodenoscope						
JF130	2410594	23	40	0	11	0
JF130	2400118	12	44	0	16	0
TJF130	2100347	30	31	0	29	0
TJF130	2721630	8	16	0	15	0
TJF130	2351236	20	87	0	37	0
Colonoscope						
CF100L	2245042	3	0	0	4	0
CF100L	2361348	0	14	0	8	0
CF100TL	2574204	13	17	0	0	0
CF100TL	2573651	16	80	0	42	0
CF100TL	2574094	5	71	0	28	0

*The starting inoculum used in each experiment was 9.4×10^6 .

a matter of debate because theoretically the surface contact time necessary for adequate disinfection becomes impractical unless the proteinaceous biofilm that builds up with routine clinical use is first mechanically dislodged and removed. Several studies have shown that "adequate cleaning" reduces the time needed to disinfect endoscopes.⁷⁻¹⁰ The revised guidelines for glutaraldehyde use issued by most endoscopic societies, including the American Society for Gastrointestinal Endoscopy (ASGE), recommend immersion in 2% glutaraldehyde for 20 minutes at room temperature provided this is preceded by thorough instrument cleaning.

The purpose of this study was to compare the relative efficacies of Cidex, Sporox, and Steris 20 against mycobacteria when used in conjunction with a standardized, validated manual cleaning protocol. Although not FDA-approved, tests were also conducted with 70% isopropyl alcohol as a disinfectant at 20°C for 20 minutes. Previous testing confirmed the disinfectant properties of 70% isopropyl alcohol, which is commonly used as a drying agent after the disinfection process.¹¹ These results were compared with disinfection achieved with ethylene oxide gas.

MATERIALS AND METHODS

There were no human participants in this study. Endoscope contamination was simulated by inoculation of a known concentration of *Mycobacterium chelonae*, an atypical organism with historically similar resistance to high-level disinfectants as *M tuberculosis* but with less infectious potential. The methodology has been previously published by the present investigators.¹² *M chelonae* was obtained from American Type Culture Collection (No. 14472, Rockville, Md.) and grown on Middlebrook 7H11 agar (Difco Laboratories, Detroit, Mich.). A subculture was suspended in Middlebrook 7H9 broth (Difco Laboratories) for use in contaminating the endoscopes. A standardized concentration of *M chelonae* was used for inoculation and was confirmed by both plate count methodology

and spectrophotometry. Spectrophotometry was used to verify initial bacterial counts by comparing the optical density of the inoculant against a known standard.^{13,14} The optical density (0.013) at 520 nm was equal to approximately 1.6×10^6 colony-forming units (cfu) per mL.

Various flexible video endoscopes (Olympus America Inc., Melville, N.Y.) that had been in clinical use for 1 to 5 years and in good working order were tested: 5 colonoscopes (2 CF100L and 3 CF100TL) and 5 duodenoscopes (2 TJF130 and 3 TJF130). Each endoscope was subjected to a standardized method of inoculation, manual cleaning, and disinfection.

To simulate contamination that might occur clinically, each endoscope was inoculated by immersing the insertion tube in the mycobacterial suspension and suctioning a 60-mL aliquot through the accessory (suction) channel. Because the initial concentration of bacteria was approximately 1.5×10^6 cfu/mL, the total number of mycobacteria suctioned through each endoscope was calculated to be 9.0×10^7 cfu.

$$1.5 \times 10^6 \text{ cfu/mL} \times 60 \text{ mL} = 9.0 \times 10^7 \text{ cfu}$$

To confirm adequate inoculation of at least 10^6 cfu per endoscope, a separate set of control experiments were conducted in which each endoscope was sampled for the organism after inoculation but without undergoing cleaning or disinfection. This control value was then used as the starting point for calculating the log reduction of mycobacterial colonies after cleaning and disinfection experiments.

Inoculation was confirmed by collecting samples from the air channel, water channel, accessory (suction) channel, auxiliary water inlet channel (colonoscopes), and elevator channel (duodenoscopes) with the Ott/Mayo Channel Sampling Kit (Ruhof Corp., Valley Stream, N.Y.). To sample the air channel, 5 mL of sterile phosphate buffer solution (PBS) was injected through the air/water connection of the umbilical with the operator placing a finger over the air valve on the control section to force the PBS down the insertion tube and out the tip while an assistant collected samples from the tip. To sample the water channel, the operator completely depressed the air/water valve while injecting the PBS through the endoscope in a similar manner as for

Table 2. Summary of efficacy of disinfection methods studied

Disinfectant	Time (min)	Temp (Celsius)	HLD achieved? (yes/no)	Average cfu recovered per scope (\pm SD)*
Cidex (2.0% glutaraldehyde)	20	20	Yes†	13 (\pm 10)
Sporox (7.5% hydrogen peroxide)	30	20	Yes†	40 (\pm 30)
Steris 20 (0.2% peracetic acid)	12	50-56	Yes†	0 (\pm 0)
70% isopropyl alcohol	20	20	Yes†	19 (\pm 14)
Ethylene oxide gas	N/A	N/A	Yes†	0 (\pm 0)

HLD, High-level disinfection; cfu, colony forming units; SD, standard deviation; N/A, not applicable.

*Starting inoculum used in each experiment was 9.4×10^6 .

†In conjunction with manual cleaning.

the air channel collection. To sample the instrument channel, 5 mL of sterile PBS was suctioned through the endoscope, and the effluent was collected in a sterile suction trap canister connected to the suction port of the umbilical cord. The elevator channel of the duodenoscope and the auxiliary water inlet channel of the colonoscope were sampled by injecting 5 mL of sterile PBS through the channel and collecting the effluent at the tip of the insertion tube. Two additional syringes of air were used to recover most of the fluid from each channel.

Experiments were conducted inside a laminar flow equipped Bioguard hood with Hepa filter (model B-600-2, The Baker Co., Sanford, Me.). This hood is equipped with a wall suction port and the mycobacterial suspension was suctioned through the endoscope into an overflow-protected canister.

A standardized, previously validated manual cleaning protocol was used for all experiments.¹² The inoculated endoscope was immersed in a solution containing 1 ounce of Enzol enzymatic detergent (Johnson & Johnson Medical Inc.) mixed with 1 gallon of sterile water. The exterior surface of the insertion tube was wiped 3 times with a sterile EndoZyme sponge (Ruhof Corp.). The channel openings of the endoscope (suction valve housing, air/water valve housing, and instrument channel port) were brushed 5 times back and forth across the mouth of each opening with a sterile channel-opening cleaning brush (MH-507, Olympus) soaked in Enzol solution. The duodenoscope elevator was also brushed 5 times with a simple in-and-out motion in both the unlocked and locked positions. A sterile, single-use endoscopic cleaning brush (Teleded Systems, Inc. Marlborough, Mass.) soaked in Enzol solution was passed through the proximal end of the suction channel (on the control section) down the length of the insertion tube and out the distal tip as well as up through the umbilical. This was performed 5 times with a simple in-and-out motion, dipping the brush into the Enzol solution after each pass. The instrument channel was brushed 5 times through the proximal end and out the distal tip. Because the elevator channel and the auxiliary water inlet channel are too small to allow passage of a brush, a 10-mL syringe containing Enzol solution was used to rinse each of these channels through the proximal end of the endoscope. To remove any residual bacteriostatic Enzol, a total of 180 mL of sterile water was then forced through each of the air, water, instrument, and auxiliary water inlet channels, and the eleva-

tor channel was irrigated with 10 mL of sterile water. Cultures were obtained from each channel to determine the reduction of bacterial colony counts achieved by manual cleaning alone.

The endoscope was then completely immersed in a freshly activated bath of disinfectant. Each endoscope was subjected to 2% glutaraldehyde (Cidex) at 20°C for 20 minutes, 7.5% hydrogen peroxide (Sporox) at 20°C for 30 minutes, 0.2% peracetic acid (Steris 20) at 50°C to 56°C for 12 minutes inside the Steris System 1 processor, 70% isopropyl alcohol at 20°C for 20 minutes, and ethylene oxide gas during separate experiments. Disinfectant immersion, where applicable, was accomplished without agitation with the exception of Steris 20, which is automatically cycled through the Steris System 1 processor. Cultures were obtained to demonstrate the reduction of bacterial colony counts achieved by each disinfection process.

Although each channel was individually sampled for *M chelonae*, the samples obtained from various sites were combined for each endoscope to determine the colony counts. The collected samples were serially diluted to allow quantification of colonies. The samples were injected through a 0.45 μ m membrane filter (Micron Separations, Inc., Westboro, Mass.) and the filter was plated on Middlebrook 7H11 agar and incubated at 37°C for 7 days.

RESULTS

The *M chelonae* inoculum used to contaminate each endoscope was calculated to be 9.0×10^7 cfu. In a separate set of control experiments, each endoscope used in these experiments was sampled for *M chelonae* after contamination to confirm adequate inoculation. The average number of organisms recovered from the endoscopes in these control experiments was 9.4×10^6 cfu. This control value was then used as the starting point for calculating log reduction of mycobacterial colonies. After manual cleaning alone, the average number of residual colonies was 9.9×10^3 cfu, a 3-log reduction. The number of colonies recovered from each endoscope after disinfection is listed in Table 1. The efficacy of each disinfectant method is summarized in Table 2. Disinfection with ethylene oxide gas and Steris 20 resulted in zero recovery of mycobacteria, although all disinfectants tested met the FDA definition for

HLD. The experimental results for colonoscopes and for duodenoscopes were similar.

DISCUSSION

Reprocessing of reusable medical devices remains a major concern among health care institutions as well as the public. The complex and delicate construction of modern GI endoscopes makes them poor candidates for traditional steam-based sterilization methods and has provided the driving force for the development of new low-temperature liquid disinfectant technologies. Since June of 1993, the FDA has had regulatory oversight for liquid chemicals used to reprocess semi-critical devices such as GI endoscopes. In April 1994, Johnson & Johnson Medical, Inc. received the first written 510(k) certification from the FDA for their glutaraldehyde-based disinfectant products (Cidex line). In September 1994, the makers of Cidex altered their package insert as required by the FDA to specify that the time required for high-level disinfection was 45 minutes at 25°C. When evaluating a high-level disinfection claim for a germicide, the FDA currently does not take precleaning of instruments into consideration because this is not within the agency's purview. However, these specifications pose several problems: first, there is a larger potential health hazard to personnel from exposure to disinfectant fumes when glutaraldehyde is heated to 25°C. Second, given the limited number of endoscopes in the inventory at most endoscopy centers and the need for rapid turnover of these expensive instruments, there are economic penalties associated with prolonged disinfectant immersion times. Most importantly, during clinical use blood, fecal matter, mucus, and other biologic substances can be expected to adhere to the endoscope and its channels. Theoretically, microorganisms embedded within this biofilm could be sheltered from the effects of the disinfectant and inadequate cleaning may yield suboptimal results. Current guidelines from the Association for Practitioners in Infection Control (APIC) and the ASGE suggest that a 20-minute immersion time in 2% glutaraldehyde at room temperature is adequate for endoscopic disinfection provided that thorough instrument cleaning is first performed.^{1,15} The reported rate of endoscopically transmitted infection since 1988 is only 1 in 1.8 million,¹ which favors the position taken by the professional societies that the current guidelines and practices are in fact adequate and safe for the patient, although public concern regarding this issue persists.³ Recently, the ASGE has been compelled to respond to the claim that "the number of reported cross-infections is so small because no one is really investigating."²

Ambiguity surrounding what constitutes high-level disinfection is a factor that may contribute to the ongoing skepticism regarding the adequacy of current reprocessing standards. A commonly held definition for HLD is the complete eradication of all microorganisms with the exception of high numbers of bacterial spores.¹⁶⁻¹⁸ This definition, however, does not take into account the initial microbial load in the instrument. For example, complete elimination of all microorganisms in a contaminated instrument with a starting inoculum of only 10^3 cfu cannot be considered the equivalent of complete microbial elimination when the starting inoculum is greater than 10^{12} cfu. To further confound the issue, the complex design of the modern flexible endoscope, as well as the "cracks and crevices" that develop inside an endoscope with use, is such that a few organisms will inevitably escape detection despite the most vigorous sampling technique. Therefore, elimination of all microorganisms cannot be proven unequivocally and a more realistic endpoint is needed. More specifically, the FDA accepts a 6-log reduction of microorganisms, with the exception of high numbers of bacterial spores, as proof of high-level disinfection.⁵ "Sterilization" is often used interchangeably with "disinfection" in medical publications when, in fact, a sterilization claim requires demonstration of a minimum of 12-log reduction in bacterial spores. Concern has been raised that failure to achieve "sterilization" of flexible endoscopes may be associated with an increased risk of disease transmission. However, current data suggest that high-level disinfection provides the same degree of safety as sterilization because the spores that tend to survive HLD are non-pathogenic.¹⁹⁻²²

The results of our study confirm the adequacy of current endoscope reprocessing guidelines. In the wake of glutaraldehyde's 510(k) certification, other liquid high-level disinfectants have become commercially available. In addition to Cidex (glutaraldehyde), the investigators were able to validate the efficacy of Sporox (hydrogen peroxide) and Steris 20 (peracetic acid). Although also approved by the FDA, the investigators were unable to obtain sufficient quantities of Cidex PA (Advanced Sterilization Products, Irvine, Calif.), formerly marketed as Peract 20 (0.08% peracetic acid and 1.0% hydrogen peroxide) for testing. Interestingly, 70% isopropyl alcohol, which is commonly used to flush the endoscope channels to facilitate drying after disinfection, proved to be an equally effective disinfectant against mycobacteria. The disinfectant properties of isopropyl alcohol against a variety of microorganisms have been previously reported in *in vitro* zone of inhibition studies, but this is the first report of its

Table 3. Comparison of liquid chemical disinfectants

	Glutaraldehyde (2.0%)	Hydrogen peroxide (7.5%)	Peracetic acid (0.2%)
Trade name	Cidex	Sporox	Steris 20
HLD claim	20°-25° at 20-90 min	20° at 30 min	N/A
Sterilization claim	20°-25° at 10 h	20° at 6 h	50° at 30 min
Activation	Yes	No	No
Reuse life	14-30 d	21 d	Single use
Shelf-life stability	2 y	2 y	6 mo
Disposal restrictions	Local*	No	No
Materials compatibility	Excellent	Good	Fair
Safety	Respiratory	Serious eye damage	Serious eye and skin damage
Processing	Manual or auto	Manual or auto	Automated
Sterilant cost	\$10.40/gal	\$24.99/gal	\$4.95/container
Cost profile (per cycle)	\$0.25 manual, \$1.49 auto	\$0.40 manual, \$2.38 auto	\$4.95 automated

Adapted from Rutala WA, Weber DJ. Disinfection of endoscopes: review of new chemical sterilants used for high-level disinfection. *Infect Control Hosp Epidemiol* 1999;20:69-76.

N/A, Not applicable.

*No US Environmental Protection Agency regulations, but some states and local authorities have additional restrictions.

efficacy against mycobacteria in simulated-use testing of endoscopes. Although isopropyl alcohol is inexpensive, environmentally safe, and easy to obtain, prolonged soaking of endoscopes in isopropyl alcohol is currently not recommended because of the ability of alcohol to break down the adhesives used by manufacturers to affix the endoscopic lenses to their mounts. Its limited activity against hydrophilic viruses also precludes an HLD classification, although it remains useful as the final drying step in the reprocessing protocol.

One possible criticism of this and previous studies^{23,24} is that a biological soil to simulate the blood, fecal matter, and mucus that is encountered in the clinical setting was not included in the inoculum. The presence of such a soil would probably further highlight the importance of cleaning as an indispensable step in the reprocessing protocol. Because of their relative resilience against germicides, efficacy against mycobacteria is accepted by the FDA as evidence in support of a high-level disinfection claim. *M chelonae*, the organism used in this study, has generally been considered to have a similar resistance to chemical disinfectants as *M tuberculosis* or *M bovis*. However, a more recent study²⁵ published after the completion of our study suggests that *M chelonae* may be more susceptible to inactivation than other mycobacterium species. It is possible that the estimates of tuberculoid activity obtained from our data may not be predictive of activity against other mycobacteria.

Although all disinfectants tested were adequately effective, the decision to use one disinfectant over another may be influenced by factors other than data presented in studies such as this one. All the products evaluated in this study have limitations. Glutaraldehyde has the advantage of being the most

well studied and is also the most inexpensive to use (Table 2). Unfortunately, it is less environmentally friendly and its vapors are irritating to the eyes, nose, throat, and respiratory airways. The latter can be minimized by using an automated endoscope reprocessor with a "closed system" or by reprocessing endoscopes in a room fitted with the appropriate negative ventilation. Prolonged contact with the chemical may cause contact dermatitis, asthma, and rhinitis.^{26,27} Failure to rinse disinfected equipment thoroughly has led to serious mucosal damage in patients.²⁸ Hydrogen peroxide (Sporox) results in environmentally friendly byproducts and does not produce noxious fumes; however, it is more expensive to use than glutaraldehyde and there are material compatibility problems with brass, zinc, copper, and nickel or silver plating, which may require modification of plumbing devices. One manufacturer has recently released a technical bulletin citing field reports and laboratory studies indicating that Sporox (and presumably Sporox II) causes damage to the insertion tube clear coat, glues, and some paints.²⁹ Steris 20 when used with the Steris System 1 processor is unique among the agents tested because it has been granted a sterilant claim by the FDA although the investigators did not attempt to validate this claim in this study. It produces no significant odors or noxious fumes although it had the highest processing costs per endoscope of any of the disinfectants studied (Table 3). It is also the only disinfectant studied that must be used in a dedicated automated processor resulting in a higher initial investment. Furthermore, in a study by Fuselier and Mason²² of urologic endoscopic equipment, the use of the Steris System 1 compared with high-level disinfection with glutaraldehyde led to increased costs with respect to endoscopic repairs (\$6037 vs \$445).

Although these liquid chemicals were found to be effective, there is room for further refinement of high-level disinfection methods. There is also growing concern for emerging pathogens resistant to glutaraldehyde.¹¹ New agents currently being evaluated may provide more suitable alternatives. Orthophthalaldehyde, a high-level disinfectant most recently approved by the FDA, contains 0.55% 1,2-benzenedicarboxaldehyde. Studies have shown superior mycobactericidal activity compared with glutaraldehyde (5-log reduction of mycobacteria in 5 minutes).^{30,31} Furthermore, it produces no noxious fumes, requires no activation, and is stable at a wider pH range of 3 to 9.³² Other emerging technologies include vapor phase disinfectants (hydrogen peroxide, peracetic acid), ozone sterilization, gaseous chlorine dioxide, and ionizing radiation.³³ Although these technologies are already in use by other industries, studies are underway to adapt them to flexible endoscope reprocessing. These technologies are potentially capable of sterilizing endoscopes without the adverse effects seen with traditional steam sterilization methods because reprocessing occurs at low temperatures.

In summary, current guidelines for reprocessing of flexible endoscopes are sufficient to satisfy the criteria for high-level disinfection as defined by the FDA. It must also be emphasized that, irrespective of the FDA labeling, these chemicals cannot be relied on to achieve high-level disinfection of flexible GI endoscopes unless rigorous cleaning is performed.

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