Editorial

Lessons From Outbreaks Associated With Bronchoscopy

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Bronchoscopy is currently the most commonly employed invasive procedure in the practice of pulmonary medicine.[1] An estimated 497,000 bronchoscopy procedures were performed in the United States in 1996.[2] Current and new applications include bronchoscopic ultrasound, laser therapy, brachytherapy, electrocautery, cryotherapy, placement of airway stents, and balloon dilatation to relieve airway obstruction caused by airway lesions.[3] Flexible endoscopes also are widely used in other medical disciplines. For example, more than 10,000,000 gastrointestinal endoscopies are performed each year.[4]

Endoscopes represent the medical devices most commonly linked to nosocomial outbreaks and pseudo-outbreaks.[5] Flexible endoscopes present a challenge for low-temperature sterilization or high-level disinfection, because they have long narrow lumens, cross-connections, mated surfaces, sharp angles, springs and valves, occluded dead ends, absorbent material, and rough or pitted surfaces.[6,7] Failure to eradicate contamination that occurred during use may lead to person-to-person transmission of pathogens (eg, *Mycobacterium tuberculosis);* failure to prevent contamination during disinfection or storage may lead to outbreaks or pseudo-outbreaks from environmental microbes (eg, nontuberculous mycobacteria, or *Rhodotorula rubra).* In this issue, Sorin and colleagues[8] describe the nosocomial transmission of an imipenem-resistant strain of *Pseudomonas aeruginosa,* and Kressel and Kidd[9] describe a pseudo-outbreak involving organisms relatively resistant to glutaraldehyde (ie, *Mycobacterium chelonae* and *Methylobacterium mesophilicum)* associated with the use of contaminated bronchoscopes.

Prevention of endoscope-related infections requires strict adherence to current guidelines for cleaning and disinfection. Guidelines for disinfection of flexible endoscopes, including bronchoscopes, have been published by the Association for Professionals in Infection Control and Epidemiology, Inc.[10,11] To date, nosocomial outbreaks have not been reported in which all current recommendations were followed scrupulously. These guidelines are based on sound scientific principles generated from several sources of data: first, studies on the natural bioburden of endoscopes and efficacy of cleaning; second, studies on the in vitro efficacy of recommended high-level disinfectants and low-temperature sterilization methods; third, studies of disinfection of simulated endoscopes or experimentally inoculated endoscopes; fourth, studies of the effectiveness of current high-level disinfection and sterilization methods in actual practice; and finally, lessons learned from outbreaks and pseudo-outbreaks involving endoscopes.

Only limited data are available on the bioburden present on bronchoscopes following use. Alfa and Sitter reported the average load on bronchoscopes before cleaning was 6.4×10^4 colony-forming units (CFUs)/mL, with streptococci and normal upper respiratory flora being reported.[12] The bioburden on used gastrointestinal endoscopes is higher, ranging from 10^6 to 10^7 CFUs for upper gastrointestinal endoscopes and 10^8 to 10^{10} CFUs for colonoscopes.[13] Cleaning has been demonstrated to reduce the bioburden on endoscopes in most studies by more than 4 logs.[13] Cleaning also removes organic and inorganic debris that may compromise the disinfection and sterilization process. For example, Alfa and colleagues tested several low-temperature sterilization methods (ie, ethylene

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TABLE 1
STEPS IN THE DISINFECTION PROCESS AND MECHANISMS FOR FAILURE

Disinfection Component	Reasons for Component	Mechanisms for Failure
Cleaning	Reduce bioburden	Inadequate policies
	Remove interfering substances: blood, salt	Inadequate staff training
Appropriate disinfectant	Inactivation of contaminating microbes (demonstrated efficacy and effectiveness)	Ineffective disinfectant
		Inadequate concentration
		Inadequate duration
Contact between disinfectant and contaminating microbes	Requirement for killing	AER: failure to use channel connectors
		AER: wrong channel connectors
		Occluded lumen
		Torn or damaged lumen
Sterilization of biopsy forceps	Eliminate contaminating microbes	Inadequate policies
		Inadequate staff training
Rinse	Remove potentially toxic chemicals (eg, glutaraldehyde, hydrogen peroxide)	Mucous membrane damage (eg, colitis)
Prevention of recontamination	Prevent contamination with environmental microbes	Tap water rinse without subsequent alcohol rinse
		Failure to air dry scope
		Contaminated AER
		Placement of scope in contaminated container

Abbreviation: AER, automatic endoscope reprocessor.

oxide, hydrogen peroxide gas plasma, and vaporized hydrogen peroxide) and reported that none could eradicate 10^6 CFUs of all bacterial strains inoculated on a carrier placed in a narrow lumen in the presence of 10% serum and 0.65% salt.[14]

Currently, the Food and Drug Administration has cleared several chemical sterilants listed as high-level disinfectants for reprocessing endoscopes.[15] These include: ≥2.4% glutaraldehyde, 0.55% ortho-phthalaldehyde, a 0.95% glutaraldehyde with 1.64% phenol/phenate, 1.0% hydrogen peroxide with 0.08% peracetic acid, 7.35% hydrogen peroxide with 0.23% peracetic acid, and 7.5% hydrogen peroxide.[15,16] Although all of these products have excellent antimicrobial activity, 7.5% hydrogen peroxide and 1.0% hydrogen peroxide with 0.08% peracetic acid have limited use, because they cause cosmetic and functional damage to the endoscope. The two products most commonly used for reprocessing endoscopes in the United States are glutaraldehyde and the automated chemical sterilization process that uses peracetic acid (STERIS SYSTEM 1, Mentor, OH).[17] The advantages and disadvantages of the chemical sterilant, peracetic acid (STERIS SYSTEM 1), and high-level disinfection methods have been reviewed.[7]

The importance of allowing the sterilant to come into contact with an inoculated carrier has been demonstrated by two studies that investigated the peracetic acid immersion system (ie, STERIS SYSTEM 1). Alfa and coworkers demonstrated excellent activity of the peracetic acid immersion system against three test organisms using a narrow-lumen device.[18] In these experiments, the lumen test object was connected to channel connectors, which ensured that the sterilant had direct contact with contaminated carriers. The effectiveness was achieved by the combination of organism wash-off and peracetic acid inactivation of the test organisms. Data reported by Rutala and colleagues demonstrated failure of the peracetic acid immersion system to eliminate *Bacillus stearothermophilus* spores completely from an inoculated carrier placed in a stainless steel lumen test unit.[19] In these experiments, the lumen test unit was not connected to channel connectors. The failure of the peracetic immersion system was felt to be attributed to the inability of the peracetic acid to diffuse into the center of a 40-cm–long, 3-mm–diameter tube, possibly due to an air lock or air bubble formed in the lumen that would impair flow.[20,21] We have since repeated our experiments using a channel connector specially designed for our 1-, 2-, and 3-mm lumen test units, with the result that the STERIS SYSTEM 1 was completely effective in eliminating an inoculum of 10^6 *B stearothermophilus* spores (WAR, unpublished data, October 2000). Both Sorin and colleagues[8] and Kressel and Kidd[9] demonstrate the clinical relevance of these findings.

Experimental contamination of flexible bronchoscopes with *Mycobacterium gordonae*[22] and gastrointestinal endoscopes with duck hepatitis B virus[23] has demonstrated the importance of cleaning and validated current disinfection recommendations. The importance of cleaning also has been demonstrated in studies evaluating gastrointestinal endoscopes contaminated with *Helicobacter pylori*.[24] Simulated-use trials with the STERIS SYSTEM 1 have demonstrated excellent microbicidal activity, and three clinical trials have demonstrated both excellent microbial killing and no clinical failure leading to infection.[7]

Failure to follow current disinfection recommendations (Table 1) has led to multiple outbreaks[8,25-35] (Table 2)

TABLE 2
NOSOCOMIAL OUTBREAKS VIA BRONCHOSCOPES DUE TO EXOGENOUS CONTAMINATION OR PERSON-TO-PERSON TRANSMISSION

Reference	Year	Pathogen*	Mechanism of Contamination
Webb et al[25]	1975	*Serratia marcescens*	Inadequate disinfectant (70% alcohol)
Hussain[26]	1978	*Pseudomonas*	Contaminated biopsy suction attachment (soaked in antiseptic)
Markovitz[27]	1979	*Pseudomonas pseudomallei*	Not specified
Leers[28]	1980	*Mycobacterium tuberculosis*	Inadequate cleaning and disinfectant (povidone-iodine)
Nelson et al[29]	1983	*M tuberculosis*	Inadequate disinfectant (povidone-iodine/70% ethanol)
Pappas[30]	1983	*Mycobacterium chelonei*	Two bronchoscopes with punctured suction channels
Wheeler et al[31]	1989	*M tuberculosis*	Contaminated suction valve
Agerton et al[32]	1997	MDR *M tuberculosis*	Inadequate cleaning, failure to use leak-test equipment, no potency testing of glutaraldehyde, failure to immerse scope fully, terminal tap water without subsequent alcohol rinse
Blanc et al[33]	1997	*Pseudomonas aeruginosa*	AER: contaminated unit
Michele et al[34]	1997	*M tuberculosis*	Failure to use enzymatic cleaner, immerse scope fully, or sterilize biopsy forceps
Kramer et al[35]	2001	*P aeruginosa*	AER: contaminated disinfectant (0.04% glutaraldehyde) due to inadequate concentration (concentration mistakenly set too low)
Sorin et al[8]	2001	*P aeruginosa*	AER: inappropriate channel connectors

Abbreviations: AER, automatic endoscope reprocessor; MDR, multidrug-resistant.
* Species as listed by investigator; may not reflect current taxonomy.

and pseudo-outbreaks[9,36-64] (Table 3) involving bronchoscopes. The pathogen most commonly associated with outbreaks has been *M tuberculosis,* a finding that is not surprising in that only bacteria endospores are relatively more resistant than mycobacteria to disinfectants. Outbreaks associated with automatic endoscope reprocessors (AERs) commonly involve *P aeruginosa,* as was the case with the report by Sorin and colleagues.[8] Pseudo-outbreaks most commonly involve nontuberculous mycobacteria or other water-derived environmental microbes such as *Legionella, R rubra,* and *P aeruginosa.* Pseudo-outbreaks also have resulted from use during bronchoscopy of contaminated medications or devices.[65] For example, pseudo-outbreaks have resulted from the use of an anesthetic contaminated with *M gordonae*[66] or fungi,[67] and atomizers contaminated with nontuberculous mycobacteria[68] or *M tuberculosis.*[69]

Lessons learned from outbreaks reported in the literature include the following. First, cleaning must precede disinfection or sterilization. Second, ineffective disinfectants such as iodophors, 30% to 70% alcohol, or inadequate concentrations of disinfectant may result in outbreaks. Third, contact of all internal and external surfaces with the disinfectant is crucial. Outbreaks have resulted from failure to immerse the scope fully, disassemble valves, or repair rips or tears in internal channels. The outbreak reported by Sorin and coworkers[8] and pseudo-outbreaks reported in the literature[61,62,64] suggest that the proper use of channel connectors to ensure flow through an endoscope's inner channels is essential. If an AER is used, one must ensure that all channel connectors are attached according to the AER's manufacturer. Fourth, following disinfection, a sterile water rinse followed by forced-air drying or a tap water rinse followed by forced-air drying and a 70% alcohol rinse must be used to prevent recontamination. The disinfected endoscope must be stored so as to prevent recontamination. Failure to rinse the scope fully also may result in mucositis following use of the scope on another patient, if either glutaraldehyde[70] or hydrogen peroxide is used as the disinfectant. AERs offer several advantages to manual reprocessing, including automation and standardization of several important reprocessing steps,[71-73] which reduce the likelihood that an essential reprocessing step will be skipped, and reduction of personnel exposure to high-level disinfectants. However, failure of AERs has been linked to bronchoscopy-related outbreaks (Table 2) and pseudo-outbreaks (Table 3), in part because the water filtration system may not reliably be able to provide sterile rinse water.[74] It is critical that personnel rigorously adhere to the current recommendations for the use of AERs.[11] We agree with Sorin and colleagues that random bacterial surveillance cultures of endoscopes to assure appropriate disinfection should be done as part of a comprehensive program in quality assurance.

In conclusion, there is a need for further development and redesign of AERs[75] and endoscopes,[6] so that they do not represent a potential source for infection. Newly developed disposable-component endoscope systems may be able to improve the ease of cleaning and disinfection and so reduce the risk of infection. Recommendations for the cleaning and disinfection of endoscopic equipment should be followed strictly. Unfortunately, audits have shown endoscopic personnel often fail to adhere to guidelines on disinfection.[76-78] To ensure that persons responsible for reprocessing are properly trained, there should be initial and annual competency testing for such personnel.[79,80]

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TABLE 3
NOSOCOMIAL PSEUDO-OUTBREAKS VIA BRONCHOSCOPES DUE TO EXOGENOUS CONTAMINATION OR PERSON-TO-PERSON TRANSMISSION

Reference	Year	Pathogen*	Mechanism of Contamination
Weinstein et al[36]	1977	*Proteus* species	Inadequate disinfection (30% alcohol)
Dawson et al[37]	1982	*Mycobacterium intracellulare*	Inadequate disinfection of plastic tubing for collecting specimens
Sammartino et al[38]	1982	*Pseudomonas aeruginosa*	Inadequate disinfectant (povidone-iodine)
Goldstein and Abrutyn[39]	1985	*Bacillus* species	Contaminated automatic suction valve
Siegman-Igra et al[40]	1985	*Serratia marcescens*	Inadequate disinfection (alcohol)
Richardson et al[41]	1986	*Bacillus* species	Contaminated suction valves, terminal tap water rinse
Hoffmann et al[42]	1989	*Rhodotorula rubra*	Contaminated channel cleaning brushes and leak-test tub water
Wheeler et al[31]	1989	*Mycobacterium avium*	Contaminated suction valve
Nye et al[43]	1990	*Mycobacterium chelonae*	Contaminated tap water rinse
Fraser et al[45]	1992	*M chelonae*	AER: contaminated AER. No terminal ethanol rinse and scopes not forced-air dried
Gubler et al[46]	1992	*M chelonae*	AER: contaminated AER
Nicolle et al[47]	1992	*Blastomyces dermatitidis*	Inadequate disinfection of bronchoscope
Whitlock et al[48]	1992	*R rubra*	Failure to air dry scope, contamination of suction and biopsy valves
Bryce et al[49]	1993	*Mycobacterium tuberculosis*	AER: contaminated suction valves and faulty wash/disinfect switch
Vandernbroucke-Grauls et al[50]	1993	*S marcescens*	Inadequate immersion time (2 min), terminal tap water rinse, stored without drying
Bennett et al[51]	1994	*Mycobacterium xenopi*	Inadequate disinfectant (0.13% glutaraldehyde-phenate) and exposure time, rinsed with contaminated tap water, inadequate drying
Campagnaro et al[52]	1994	*M chelonae*	AER: contaminated suction valve, terminal tap water rinse
Kolmos et al[53]	1994	*P aeruginosa*	Failure to clean suction and biopsy channels, inexperienced bronchoscopy staff
Maloney et al[54]	1994	*M abscessus*	AER: contaminated AER
Petersen et al[55]	1994	*M abscessus*	AER: contaminated AER
Hagan et al[56]	1995	*R rubra*	Contaminated suction channel, inadequate drying
Takigawa et al[57]	1995	*M chelonae*	AER
Wang et al[58]	1995	*M chelonae*	AER: contaminated suction channel
Mitchell et al[59]	1997	*Legionella pneumophila*	Use of contaminated tap water for rinse, failure of 70% ethanol flush
Wallace et al[60]	1998	*M abscessus*	AER and manual disinfection procedure
Wallace et al[60]	1998	*M abscessus*	AER
Wallace et al[60]	1998	*Mycobacterium fortuitum*	AER
CDC[61]	1999	*M tuberculosis*	AER: failure to replace biopsy port cap before loading in AER
CDC[61]	1999	*Mycobacterium avium-intracellulare*	AER: use of channel connectors provided by bronchoscope manufacturer rather than connector kit produced by AER manufacturer
Strelczyk[62]	1999	Acid-fast bacilli	AER: inadequate channel connectors provided by bronchoscope manufacturer
Wilson et al[63]	2000	*Aureobasidium* species	Reuse of single-use stopcocks disinfected by an AER
Larson et al[64]	2001	*M tuberculosis*	AER: errors in cleaning, incompatible AER
Kressel and Kidd[9]	2001	*M chelonae, Methylobacterium mesophilicum*	AER: biofilm buildup in AER, no alcohol flush, organisms relatively resistant to glutaraldehyde

Abbreviations: AER, automatic endoscope reprocessor; CDC, Centers for Disease Control and Prevention.
* Species as listed by investigator; may not reflect current taxonomy.

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