

The Flexible Sigmoidoscope as a Potential Vector of Infectious Disease, Including Suggestions for Decontamination of the Flexible Sigmoidoscope

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Received September 4, 1985

The flexible fiberoptic sigmoidoscope has gained widespread acceptance as a diagnostic tool in the detection and diagnosis of colorectal disease. Since its introduction nearly a decade ago, studies have thus far indicated that in the hands of experienced physicians, flexible sigmoidoscopy is a safe procedure affording greater patient comfort, greater depth of insertion, and a higher yield of neoplastic lesions than rigid sigmoidoscopy, with surprisingly few associated risks. Although reported infrequently, infection is an acknowledged risk of flexible sigmoidoscopy and other endoscopic procedures. The most efficient means of preventing endoscopy-associated infection is uncompromising aseptic practice. Clinical and experimental data obtained from studies designed to investigate endoscopic transmission of infectious organisms and from our own and others' experiences are reviewed. Guidelines for achieving high-level disinfection of the flexible fiberoptic sigmoidoscope are included.

INTRODUCTION

The past decade has seen the development of a wide array of fiberoptic instruments and accessories for gastrointestinal endoscopy. These complex instruments have proven to be invaluable in diagnosing and treating many gastrointestinal disorders. Along with their indisputable advantages, there are risks associated with their use. Infection must be acknowledged as one such risk. Because special thermolabile materials are used in the construction of fiberoptic instruments, heat sterilization is not feasible. Since an alternative method of decontamination must be employed, and ethylene oxide gas sterilization is not a practical alternative, chemical disinfection is the option most often selected. Although chemical disinfection is deemed a safe method of decontamination, in most settings it can offer no guarantee that all pathogens have been destroyed. With the increased use of endoscopy in recent years as a diagnostic and therapeutic modality, the danger of transmitting infectious organisms by this route has also increased. Although endoscopes have clearly been identified as potential vectors of infection, the likelihood of transmitting disease by this route is minimal, if proper cleaning and disinfection regimens are adhered to consistently [1].

BACTERIAL INFECTIONS

Bacterial infections associated with gastrointestinal endoscopy have occurred from a variety of organisms, including *Pseudomonas aeruginosa*, *Serratia marcescens*, *Mycobacterium tuberculosis*, and several species of salmonella [2]. Endoscope-related cross-infection has been demonstrated in two ways: directly, as in patient-to-patient

transmission and, more indirectly, by inoculation of opportunistic organisms such as *Pseudomonas* into patients after colonization has occurred in endoscopic equipment. Opportunistic bacteria multiply quickly in warm moist environments, making the endoscope water bottle and other accessories suitable targets for microorganisms to colonize. If an instrument contaminated in this manner is introduced into a susceptible patient, serious infection may result [3].

Clinically, bacterial complications of sigmoidoscopy are manifested either as gastrointestinal infection or bacteremia. Bacteremia, as associated with endoscopy, is usually transient and of little consequence. Goldman et al. investigated the frequency of bacteremia accompanying flexible sigmoidoscopy. Blood samples for aerobic and anaerobic cultures were drawn before, during, and after flexible sigmoidoscopy in 100 patients. Transient bacteremia with *Streptococcus intermedius* was demonstrated in one patient. The patient was symptom-free post-sigmoidoscopy [4]. Nonetheless, the American Heart Association recommends antibiotic coverage for endoscopy in patients with valvular heart disease, prosthetic heart valves, and other cardiac abnormalities, as these patients are theoretically at increased risk for endocarditis [1].

HEPATITIS B VIRUS

Until recently, endoscopic transmission of hepatitis B virus had not been demonstrated, though it was widely believed to be a hazard of gastrointestinal endoscopy. Recently, Birnie et al. [5] reported a case of Type B viral hepatitis which was probably acquired at endoscopy. The instrument suspected of transmitting the virus had been used on the previous day to endoscope a patient who was incubating type B hepatitis virus. Although this case report strongly suggests a causal relationship, another recently published study supported the opposite contention that endoscopic transmission could not be established. This prospective controlled study, conducted by Villa et al. [6] investigating the importance of the different endoscopic procedures in the transmission of hepatitis B, supported the view that transmission of hepatitis B is not associated with gastrointestinal endoscopy. Although reason may exist to question a causal relationship, most consider Hbs Ag-positive patients, at this time, to be a high-risk group for transmitting infection and institute special precautions to minimize the risk of cross-infection.

AIDS

Acquired immune deficiency syndrome is characterized by immunodeficiency which predisposes the host to opportunistic infections that are ultimately fatal. Mortality approaches 100 percent. The transmission of AIDS (HTLV III virus) to patients or personnel is a potential risk of gastrointestinal endoscopy. Indirect or direct exposure to infected blood or blood products is an established mode of transmission for the HTLV III virus. A sigmoidoscope is unavoidably contaminated with blood and stool during a procedure. While the HTLV III virus has been identified in body fluids other than blood, it has not been ascertained whether exposure to these fluids poses a threat of acquiring the disease [2]. Until the uncertainties surrounding the AIDS epidemic have been resolved, aggressive preventive measures seem prudent to insure personnel and patient safety.

Special precautions need to be observed when endoscopic very high-risk or known AIDS patients. To protect personnel, double gowns, double gloves, masks, and goggles

are recommended when endoscoping a suspected or known AIDS patient. To prevent possible endoscopic transmission of the disease, patients known to have AIDS should have a separate, sterilized endoscope designated for their exclusive use. It must be recognized here that the latter practice is not sufficiently practical to allow for routine compliance. In instances where a separate endoscope is not accessible, the AIDS patient should be endoscoped as the last patient of the day, and the endoscope and accessories used should be subjected to vigorous mechanical cleaning followed by ethylene oxide gas sterilization. Wet-proof disposable covers should be used when possible to minimize contamination to surfaces with which the infected endoscope or accessories come in contact [2]. The precautions outlined above may prove to be disproportionate to the actual risk of endoscopic transmission of the HTLV III virus; however, the efficacy of less aggressive infection control measures has yet to be demonstrated.

CROSS-INFECTION

Logically, for endoscopic cross-infection to occur, a variety of contributing factors must coexist. Obviously necessary are an index patient, a pathogenic organism, a susceptible host, and a contaminated endoscope or accessory [1]. Recent evidence suggests that bacterial adherence to plastics, which are used in the construction of fiberoptic endoscopes, may play a role in endoscope-transmitted infection. Botta et al. [7] reported a strong adherence of bacteria to polyethylene, a plastic used in the construction of fiberoptic endoscopes. *In vitro* studies indicated that polyethylene had a high affinity for the bacteria tested and that, at the end of the washing process, high numbers of microorganisms remained on the endoscope. The virulence of the organism and possibly the incubation time between procedures are additional elements to be considered when studying the pathogenesis of endoscope-associated infection. When evaluating all factors, it becomes obvious that the only reliable means of reducing the risk of endoscopic cross-infection is thorough and aggressive cleaning of the endoscope after each use.

CLEANING AND DISINFECTION

The prime objective of any cleaning and disinfection method is to eliminate the risk of infection. The process which will most certainly achieve this objective is sterilization. As previously discussed, however, fiberoptic endoscopes are constructed using special materials, such as synthetic resins and special rubbers and plastics, which will not tolerate heat sterilization. As an alternative method, ethylene oxide gas sterilization may be employed, but in most situations it is time-consuming, not readily available, and felt, by most authorities, to be unnecessary. Chemical disinfection seems to offer the most practical and, when properly performed, efficient means of minimizing the risk of infection [2]. The contact time and effectiveness of chemical disinfectants vary. Specific properties of selected classes of disinfectants are delineated in Table 1.

Gerding et al. [8] evaluated methods of cleaning and disinfecting endoscopes. The results clearly indicated that mechanical cleaning alone was insufficient (Table 2), as it did not adequately preclude the risk of transmitting infection. Chemical disinfection with 2 percent alkaline glutaraldehyde for 5–20 minutes combined with forced-air drying before storage resulted in 94 percent of all endoscopic cultures being negative (Table 3). Additional glutaraldehyde immersion time did not significantly alter these results. Although infection control experts often recommend glutaraldehyde for its

TABLE 1
Properties of Selection Classes of Disinfectants

Class	Effectiveness	Recommended Concentration	Other Properties and Remarks
Ethylene oxide	High	450 to 800 mg/l (at 55°-60°C)	Toxic gas. Dry spores not destroyed. Does not corrode surgical or optical instruments.
Glutaraldehyde, alkaline aqueous	High	2%	Destroys <i>Mycobacterium tuberculosis</i> in 10 minutes and most spores in 30 minutes. Toxic unstable solution. Does not corrode optical instruments.
5% alkaline glutaraldehyde plus alkaline phenate buffer	High	2% with recommended dilution for sterilization of 1:16	Inactivates hepatitis B virus in 10 minutes; inactivates herpes virus in 10 minutes. Hypoallergenic solution, does not yellow or sensitize skin.
Formaldehyde/alcohol	High	8% and 70%	Sporicidal, toxic, harmful, irritating fumes, corrosive and volatile.
Formaldehyde, aqueous	Intermediate to high	3% to 8%	Sporicidal, toxic, harmful, irritating fumes.
Iodine + alcohol	Intermediate	0.5% + 70%-80%	Corrosive, stains skin/fabric, flammable.
Alcohols	Intermediate	70% to 90%	Corrosive, irritate skin, flammable.
Chlorine compounds	Intermediate	0.05% to 0.5% (= 500 to 5,000 ppm of available chlorine)	Corrosive, irritate skin, inactivated by organic matter.
Phenolic compounds	Intermediate	0.5% to 3% (final dilution)	Corrosive, irritate skin, stable, little activation by organic matter.
Iodine aqueous	Intermediate	1%	Corrosive, stains skin/fabrics.
Iodophors	Low to intermediate	0.0075%-0.015% (= 75 to 100 ppm available)	Corrosive, stain skin/fabric, some activation by organic matter.
Quaternary ammonium compounds	Low	0.1%-0.2%	Inactivated by soap/anionic solutions. Absorbed by fabric, noncorrosive.

Hexachlorophene	Low	1% to 3%	Insoluble in water, soluble in alcohol, nonactivated by soap, noncorrosive.
Mercurial compounds	Low	0.1% to 2%	Inactivated by organic matter.

Modified from [2]

TABLE 2
Culture Results from a Comparison of Endoscope Cleaning (C) Alone
and Cleaning Plus Five-Minute Glutaraldehyde (C + 5G) Immersion^c

Cultures Taken	Group Studied	Number of Positive Cultures	Mean Bacterial Count (log ₁₀ CFU/ml)	Range of Positive Cultures (log ₁₀ CFU/ml)
Immediately after patient use	C alone	13/13	3.3	1.1–6.3
	C + 5G	10/10	3.6	1.7–6.1
		NS ^a	NS ^b	
Immediately after cleaning alone or cleaning plus disinfection	C alone	11/14	2.3	1.5–5.3
	C + 5G	5/11	1.0	1.4–3.0
		NS ^a	<0.04 ^b	
After storage	C alone	23/29	3.4	1.0–6.3
	C + 5G	8/26	1.4	2.7–5.7
		<0.01 ^a	<0.002 ^b	

NS = not significant

^aProbability using X² or Fisher's exact test

^bProbability using Mann-Whitney U Test, two-tailed

^cForced-air drying was not performed after cleaning or disinfection.

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rapid high-level germicidal activity, its use may pose problems. A recent survey found a 37 percent incidence of sensitivity reactions, including dermatitis, conjunctivitis, and sinusitis among personnel using it [3]. It has also been reported that endoscope lenses may become cloudy from the crystallization of residual glutaraldehyde over a period of time. In addition, the fixation of protein-containing residues by glutaraldehyde in the air-water channel over a period of time has been observed and may result in serious damage to the endoscope [9]. Glutaraldehyde-phenate solutions (Table 1) reportedly offer the same high-level disinfection, with fewer sensitivity reactions and a lesser incidence of endoscope damage [9].

NEW INSTRUMENTATION

“Endoscope Processors” and other automatic closed-system methods of cleaning and disinfecting endoscopes are now commercially available. Although expensive, they permit high-level cleaning and disinfection of inner channels and offer the security of a consistent cleaning regimen which is difficult to duplicate manually. In addition, because of decreased exposure to potentially irritating vapors of chemical disinfectants, the risks of sensitivity reactions among personnel are minimized.

Recently, totally immersible instruments have been developed and introduced as a potential solution to the problem of cross-infection. The provision of easy-to-clean removable valves and a system of irrigating and disinfecting all channels now permits easier cleaning between patients and offers a more reliable means of endoscope cleaning and disinfection. Easier accessibility and total immersibility are not, however, the whole answer to the problem of endoscope-related infection. Daily endoscope care by well-trained, conscientious individuals is essential to obviate the risk of transmitting infectious disease endoscopically.

TABLE 3
 Culture Results from a Comparison of Endoscope Cleaning Plus Five-Minute Glutaraldehyde (C + 5G) Immersion
 and Cleaning Plus Twenty-Minute Glutaraldehyde (C + 20G) Immersion

Cultures Taken	Group Studied	Number of Positive Cultures	Mean Bacterial Count (log ₁₀ CFU/ml)	Range of Positive Cultures (log ₁₀ CFU/ml)
Immediately after patient use	C + 5G	10/10	3.7	0.7-6.3
	C + 20G	8/12	2.4	0.6-5.6
Immediately after disinfection	C + 5G	NS ^a	NS ^b	
	C + 20G	2/10	0.3	0.7-2.8
After storage	C + 5G	0/13	—	
	C + 20G	NS ^a	NS ^b	
	C + 5G	1/21	0.2	5.0
	C + 20G	1/19	0.3	6.0
		NS ^a	NS ^b	

NS = Not significant

^aProbability using X² or Fisher's exact test

^bProbability using Mann-Whitney U Test, two-tailed

^cForced-air drying after disinfection was added to both groups.

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GUIDELINES FOR DECONTAMINATION

Manufacturers' recommendations for mechanical cleaning should be followed carefully and should be implemented immediately after use to prevent drying of secretions.

A cleaning agent should be selected which is specifically formulated to dissolve protein-containing material.

Because instruments may be used on patients with unrecognized infections, instruments should be cleaned and disinfected in the same manner after each use.

Chemical disinfection is the method most frequently employed to decontaminate fiberoptic endoscopes after routine use. Two percent alkaline glutaraldehyde or glutaraldehyde-phenate solutions are most often recommended. Recommended immersion time is usually 5–20 minutes. The Center for Disease Control recommends that endoscopes which touch mucous membranes be subjected to a sterilization process before each use and, if this is not practical, they should ideally receive a 30-minute immersion in a high-level disinfectant [10].

Thorough rinsing should follow chemical disinfection to minimize the risk of introducing potentially irritating toxic residues into the patient.

To minimize the risk of opportunistic infection, the external surfaces of the endoscope, as well as the inner channels, should be dried before storing. Inner channels may be forced-air dried either by the use of commercially available compressed air or by attaching suction to the distal tip of the endoscope for five minutes.

Valves for forceps openings are particularly difficult to clean and disinfect adequately. This process may be accomplished by inserting a pipe cleaner/cotton-tipped swab through the valve opening and immersing in disinfectant. Due to the spring-like configurations, accessories such as biopsy forceps are also extremely difficult to clean and disinfect. It is recommended that these accessories as well as the valves for forcep openings be purchased in sufficient quantity to allow for ethylene oxide sterilization or for prolonged disinfection by a chemical agent.

Suction tubing should be washed/disinfected between procedures and replaced at least daily.

Water bottles should be washed and disinfected between patients.

REFERENCES

1. Vennes JA: Infectious complications of gastrointestinal endoscopy. *Dig Dis Sci* 26:608–648, 1981
2. Berkowitz DM: Disinfection and Sterilization. *Endo Rev* 1:28, 1984
3. O'Connor HJ, Axon AT: Gastrointestinal endoscopy: Infection and disinfection. *Gut* 24:171, 1983
4. Goldman GD, Miller SA, Furman DS, Brock D, Ryan JL, McCallum RW: Does bacteremia occur during flexible sigmoidoscopy? *American J Gastroenterology* 80:621, 1985
5. Birnie GG, Quisley EM, Clements GB, Follet EAC, Watkinson G: Endoscopic transmission of hepatitis B virus. *Gut* 24:171, 1983
6. Villa E, Pasquinelli C, Rigo G, Ferrari A, Perini M, Ferretti I, Gandolfo M, Rubbiani L, Antonioli A, Barchi T, Manenti F: Gastrointestinal endoscopy and HBV infection: No evidence for a causal relationship. *Gastrointes Endo* 30:15, 1984
7. Botta GA, Costa AG, Puqliese V: Bacterial adherence to plastics: A role in endoscope-transmitted infections. *Lancet* i:398–399, 1984
8. Gerding DN, Petersen LR, Vennes JA: Cleaning and disinfection of fiberoptic endoscopes: Evaluation of glutaraldehyde exposure time and forced air drying. *Gastroenterology* 83:613–618, 1982
9. Kennedy M: Evaluation of a glutaraldehyde-phenate solution used to disinfect endoscopes and instruments in a freestanding surgical facility. *JORRI* 3:8, 1983
10. Messner RL: Infection control in gastrointestinal endoscopy. *SGA Journal* 8:21, 1985