CONCISE COMMUNICATION

Effectiveness of Flexible Gastrointestinal Endoscope Reprocessing

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The practice of reprocessing endoscopes and its effectiveness was evaluated in 37 services. Contamination of at least 1 endoscope could be identified in 34 (91.6%) of 37 services. Bacteria, fungi, and/or mycobacteria were isolated from 84.6% (33/39) of the colonoscopes (110–32,000 colony-forming units [CFUs]/mL) and from 80.6% (50/62) of the gastroscopes (100–33,000 CFUs/mL). Not all services followed recommended guidelines. Therefore, patients who underwent gastrointestinal endoscopies were exposed to diverse pathogens.

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The gastrointestinal endoscope becomes contaminated after direct contact with the mucosa of the gastrointestinal tract and must subsequently be cleaned and undergo high-level disinfection or sterilization.[1] The complex design of this equipment and changes in the integrity of their surfaces resulting from frequent use can hinder the removal of dirt and microorganisms during reprocessing.[2] Although cleaning and disinfection procedures for gastrointestinal endoscopes are well described in manufacturer equipment cleaning manuals and professional guidelines,[3,4] contamination of this equipment has been a major cause of infection in patients undergoing gastrointestinal endoscopy, mainly because of inadequate reprocessing.[5]

Thus, it is necessary to understand and evaluate the reprocessing of such equipment by microbiological analyses that include not only the suction/biopsy channels, as most studies have done, but also the air/water channels. This study aimed to evaluate the effectiveness of the reprocessing of colonoscopes and gastroscopes by microbiological analyses as well as to evaluate the practices associated with reprocessing this equipment.

METHODS

After approval by the ethics committee, this study was conducted from August 2010 to March 2011 in gastrointestinal endoscopy services in the capital city of Belo Horizonte, Minas Gerais, Brazil, a city of approximately 2.4 million inhabitants. The criteria for inclusion were performance of colonoscopy and/or gastroscopy for diagnostic exams and/or therapeutic exams in adult individuals.

Thirty-seven services (61.7%) agreed to participate; 21 (56.8%) were private, 10 (27%) were public, and 6 (16.2%) were nonprofit. Eighteen (48.6%) were located in hospitals, 10 (27%) in clinics, 7 (18.9%) in doctors' offices, 1 (2.7%) in emergency medical care, and 1 (2.7%) in the center specialty treatment area. Data were collected both by means of a questionnaire and by the collection of samples from channels of gastroscopes and colonoscopes.

Questionnaire. The questionnaire was administered by the researcher to 1 staff member assigned to reprocess the gastrointestinal endoscopes from each service. Through this instrument, data on monthly use frequency of gastroscopes and colonoscopes, equipment reprocessing practices from precleaning to storage, availability of protocols in the services, and frequency of training of professionals were obtained.

Collection of samples from the air/water and suction/biopsy channels of colonoscopes and gastroscopes. It was estimated that for a confidence level of 95% with an error of 3% a sample of 93 gastrointestinal endoscopes would be required. Samples from the air/water and suction/biopsy channels of 62 gastroscopes and 39 colonoscopes, which accounted for 61.4% and 62.9% of the total number of devices available from the 37 services, respectively, were collected for microbiological analysis. The number of endoscopes sampled was directly proportional to the number of available endoscopes for each service.

After reprocessing, samples were collected using aseptic technique, opting preferentially for the flush-brush-flush method. Each endoscope channel was flushed separately with 10 mL of double-distilled water, and samples of that fluid were saved in a sterile conical tube. Each channel was then cleaned with a separate sterile endoscopy cleaning brush if technically feasible. The distal aspect of that brush was placed in the same tube with the corresponding flush sample, followed by flushing with 10 mL of double-distilled water, and samples of that fluid were saved in a sterile conical tube. The flush method was adopted to collect samples of the air/water channels of Olympus and Fujinon equipment because of the impossibility of creating friction within these channels. After the washes were collected, the samples were kept on ice and transported to the microbiology laboratory.

Processing of samples from the air/water and suction/biopsy channels of colonoscopes and gastroscopes. In the laboratory, the test tubes containing the washes were subjected to sonication for 5 seconds at 42 KHz (Branson 2510 sonicator), followed by shaking in a vortex during the same period. Immediately after these procedures, 1.0 mL of each sample was placed in trypticase soy broth and incubated for 48 hours at 35°C and 100 rpm. Each sample was assessed for turbidity,

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TABLE 1. Percentage of Services That Adopted Gastrointestinal Endoscope Reprocessing Recommendations, Belo Horizonte, 2011

Reprocessing practice	Site of gastrointestinal endoscope		
	Outer surface (n = 37)	Air/water channel (n = 37)	Suction/biopsy channel (n = 37)
Precleaning	27 (73)	26 (70.8)	29 (78.4)
Inserting the cleaning solution into the channels	NA	20 (54.1)	32 (86.5)
Rinsing after cleaning	37 (100)	33 (89.2)	37 (100)
Drying before immersing in disinfectant	27 (73)	17 (45.9)	16 (43.2)
Filling the channels with disinfectant solution	NA	19 (51.4)	28 (75.7)
Final rinse	37 (100)	34 (91.9)	37 (100)
Final drying	36 (97.3)	24 (64.9)	26 (70.3)

NOTE. Data are no. (%). NA, not applicable.

and 0.1-mL aliquots were placed on blood, MacConkey, Sabouraud dextrose, and Lowenstein-Jensen agar.

The samples inoculated on blood agar and MacConkey agar were incubated aerobically at 35°C for 48 hours or at 28°C for 3 days for the investigation of significant pathogens, such as *Pseudomonas* species. The agar plates of the Lowenstein-Jensen medium and Sabouraud dextrose agar were incubated at 35°C for 12 days. Previous experiments have indicated that sonication is not associated with the loss of cell viability in suspension (data not shown).

Appropriate biochemical tests were performed to identify the genera and species of the recovered microorganisms. The identification of contaminating microorganisms such as *Bacillus* species, *Corynebacterium* species, *Mycobacteria* species, *Streptococcus* α-hemolytic, *Aspergillus* species, and *Penicillium* species was performed by manual testing. Microorganisms such as Enterobacteriaceae, *Staphylococcus* species, nonfermentative bacteria, and yeasts were identified using the bioMérieux Vitek 2 system, GNI cards, and GPI YBC9 automated equipment.

Because of technical constraints, microbial load for each sample was assessed 2–4 months later using refrigerated samples. These samples were seeded in broth and replated as described previously, and the number of colonies per sample were expressed as colony-forming units (CFUs) per milliliter.

Samples were considered contaminated according to microbial growth regardless of microbial loads, bearing in mind that, after high-level disinfection, all organisms, except for spores, must be eliminated.[1] Questionnaire and microbiological data were analyzed using descriptive statistics from SPSS, version 15.0.

RESULTS

In 91.2% (34/37) of the services, contamination of at least 1 endoscope was identified. Microbial loads presented below refer to the sum of the loads detected in the air/water and suction/biopsy channels of the equipment.

Microbiological analysis of samples from colonoscopes. Thirty-three colonoscopes (84.6%) were found to be contaminated. A predominance of gram-negative bacteria (Enterobacteriaceae) was observed, with *Pseudomonas aeruginosa* (27%), *Escherichia coli* (15%), *Klebsiella pneumoniae* (13.6%), and *Acinetobacter baumannii* (9.1%) representing the most prevalent microorganisms. In 8 samples (12.1%) gram-positive bacteria (*Enterococcus faecalis* and *Staphylococcus aureus*) were detected, while 4 (6.1%) contained mycobacteria (*Mycobacterium fortuitum* and *Mycobacterium chelonae*) and 3 (3%) contained yeast (*Candida albicans*).

The amount of microorganisms varied from 110 to 32,000 CFUs/mL (median, 2,100 CFUs/mL) among the endoscopes from different services and within the same service when samples were collected from more than 1 colonoscope.

Microbiological analysis of samples from gastroscopes. Fifty gastroscopes (80.6%) were found to be contaminated. *E. coli* (19%), *P. aeruginosa* (18%), and *K. pneumoniae* (11%) were the most prevalent microorganisms. Although *E. faecalis* tends to belong to intestinal microbiota, this bacterium was isolated from 9 gastroscopes (6%) that had come into contact with the gastric tract. In addition, mycobacteria (*M. fortuitum* and *Mycobacterium kansasii*) and fungi (*C. albicans* and *Aspergillus* species) were isolated from 5 (3.1%) and 4 (2.5%) samples, respectively.

The amount of microorganisms varied from 100 to 33,000 CFUs/mL (median, 2,100 CFUs/mL) among the endoscopes from different services and within the same service when samples were collected from more than 1 gastroscope.

Reprocessing practices for gastrointestinal endoscopes in 37 services. No differences could be observed in the reprocessing of colonoscopes and gastroscopes in any of the analyzed services. In all services, only manual cleaning methods, not automated cleaning methods, were adopted. Tables 1 and 2 describe the percentage of services that adopted gastrointestinal endoscope reprocessing recommendations.

By means of the questionnaire it was determined that a high-level disinfection process was the main stage of reprocessing for which recommendations were followed. Tap water was used for rinsing after cleaning and disinfection in 31 (83.8%) services, while 6 (16.2%) used filtered water.

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TABLE 2. Compliance with Gastrointestinal Endoscope Reprocessing Recommendations, Belo Horizonte, 2011

Recommendation for reprocessing gastrointestinal endoscopes	Compliance, proportion (%)
Reprocessing is performed with the endoscopes disconnected from the light	24/37 (64.9)
A sealing test is performed at least daily to detect leaks in the equipment	30/37 (80.1)
Enzymatic detergents are used	32/37 (86.5)
Endoscopes are immersed in detergent for the time recommended by the manufacturer	12/32 (37.5)
Adaptors recommended by the manufacturers are used to fill channels with cleaning solutions[a]	2/20 (10)
High-level disinfection is performed after cleaning	36/37 (97.3)[b]
Endoscopes are completely immersed in the disinfectant solution	12/36 (33.3)
Endoscope are exposed to the disinfectant for 30 minutes[c]	
Peracetic acid	0/6 (0)
Glutaraldehyde	18/30 (60)
Adaptors recommended by the manufacturers are used to fill channels with disinfectant solutions[a]	1/19 (5.3)
Adaptors recommended by the manufacturers are used to fill channels with water when rinsing[a]	1/33 (3)
Service has written protocols for the reprocessing of gastrointestinal endoscopes	31/37 (83.8)
Professionals who are responsible for the reprocessing of endoscopes receive training at least annually	5/37 (13.5)

[a] Manufacturers recommend that adaptors be connected to the ports of air/water and suction valves to ensure that channels are completely filled with cleaning solutions, disinfectants, and water.
[b] In 1 service (2.7%), gastrointestinal endoscopes were only cleaned.
[c] Time recommended by national standards.

DISCUSSION

Our findings regarding the nonadherence to recommendations for reprocessing endoscopes at all stages may be related to the lack of periodic training of professionals responsible for this activity, as noted by 86.5% (32/37) of the services analyzed. In addition, the possibility of human error cannot be ruled out, bearing in mind that all services used a nonautomated method. This finding is supported by other studies that point to a low rate (1.4%) of adherence to guidelines for reprocessing when only the manual method was used, compared with 75.4% adherence to guidelines when the automated method was used.[6]

Cleaning solution, disinfectant, and water possibly did not come in contact with the entire inner surface of the channels, bearing in mind that adapters were not used for the purpose recommended by manufacturers and/or regulators.[3,4] Failure with regard to exposure time, temperature, and complete immersion of equipment in the detergent enzyme was found, in accordance with the findings of other studies,[7,8] and may have compromised the effectiveness of cleaning and, consequently, the other stages of reprocessing.

Use of 2% glutaraldehyde was found to be prevalent in the services included in this study (29/36), as has also been reported in other countries.[9] It is noteworthy that among glutaraldehyde products approved by the US Food and Drug Administration, a minimum concentration of 2.4% at a temperature specific for each product is necessary to achieve effectiveness,[10] but a concentration of 2% is permitted in the country of study. Noncompliance with the exposure time of endoscopes to high-level disinfection for the time recommended on the label of the products was demonstrated in this study and is in accordance with the findings of other studies.[8,11]

It was found that the majority of recommendations aimed at high-level disinfection were followed by the professionals responsible for reprocessing. Nevertheless, it is important to note that paying attention only to the disinfection process did not necessarily ensure the absence of contamination or safe devices for use in patients. This statement is based on the finding that the failure to apply the procedures that precede disinfection, such as precleaning, cleaning, rinsing, and drying, can severely compromise the disinfection process itself.

The definition of an acceptable microbial load after the reprocessing of gastrointestinal endoscopes is still controversial.[12,13] Therefore, in this study samples were considered to be contaminated when microorganisms were present regardless of the microbial load. However, it should be noted that 96.6% and 97.1% of gastroscopes and colonoscopes, respectively, were contaminated even when adopting a cutoff point of 100 CFUs/mL, as has been suggested in the literature.[12]

The level of contamination of this equipment poses a major challenge for reprocessing considering that the average microbial burden after examination approaches 10^5 CFUs/mL for colonoscopes and 10^1–10^4 CFUs/mL for gastroscopes. The challenge for appropriate processing and decontamination of gastroscopes may be even greater, as they are used 3-fold more often per month than colonoscopes. The high frequency of use presents a directly proportional relationship between this factor and contamination of gastrointestinal endoscopes.[14] Furthermore, the small diameters of the suction/biopsy and air/water channels of gastroscopes compared with colonoscopes surely present a challenge to decontamination.

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The recovery of predominantly gram-negative microorganisms is supported by the literature.[11] Some microorganisms, such as *P. aeruginosa*, *E. coli*, *K. pneumoniae*, and *A. baumannii*, are common constituents of the gastrointestinal tract flora, particularly among patients in the hospital and those with significant healthcare exposure, but they also could be acquired from environmental water sources. Detection of microorganisms of the microbiota of the lower gastrointestinal tract, such as *E. faecalis*, in gastroscopes and of the upper gastrointestinal tract (as well as *C. albicans* and *Candida glabrata*) in colonoscopes may reflect that cleaning and disinfection of both devices may occur together using common vessels, brushes, and other accessories.

This study concludes that high rates of contamination of gastroscopes (80%) and colonoscopes (84.6%) were strongly related to noncompliance with daily gastrointestinal endoscope reprocessing procedures, which is in accordance with the findings of several studies.[7,11,14] Although 80% of services had protocols in place, the procedures for reprocessing did not reflect their use. Therefore, the importance of training and direct supervision of the professionals who perform the reprocessing of endoscopes is emphasized to ensure that recommendations for this procedure are followed, which in turn promotes lowering or eliminating the risk of transmission of microorganisms to patients undergoing gastrointestinal endoscopies.

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REFERENCES

1. Spaulding EH, Emmons EK. Which solution to use and how to use it are influenced more by the types of bacteria to be destroyed than they are by the instrument or object to be disinfected. *Am J Nurs* 1958;58:1238–1242.
2. Pajkos A, Vickery K, Cossart EY. Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and contamination? *J Hosp Infect* 2004;58:224–229.
3. Sociedade Brasileira de Enfermagem em Endoscopia Gastrointestinal (SOBEEG). *Manual de Limpeza e Desinfecção de Aparelhos Endoscópios.* São Paulo: SOBEEG, 2005.
4. Beilenhoff U, Neumann CS, Rey JF, et al; European Society of Gastrointestinal Endoscopy Guidelines Committee. ESGE-ESGENA guideline: cleaning and disinfection in gastrointestinal endoscopy. *Endoscopy* 2008;40:939–957.
5. Aumeran C, Poincloux L, Souweine B, et al. Multidrug-resistant *Klebsiella pneumoniae* outbreak after endoscopic retrograde cholangiopancreatography. *Endoscopy* 2010;42:895–899.
6. Ofstead CL, Wetzler HP, Snyder AK, Horton RA. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. *Gastroenterol Nurs* 2010;33:304–311.
7. Alfa MJ, Olson N, Degagne P, Jackson M. A survey of reprocessing methods, residual viable bioburden, and soil levels in patient-ready endoscopic retrograde choliangiopancreatography duodenoscopes used in Canadian centers. *Infect Control Hosp Epidemiol* 2002;23:198–206.
8. Barbosa JM, Souza ACS, Tipple AFV, Pimenta FC, Leao LSNO, Silva SRMC. Endoscope reprocessing using glutaraldehyde in endoscopy services of Goiânia, Brazil. *Arq Gastroenterol* 2010;47:219–224.
9. Zhang X, Kong J, Tang P, et al. Current status of cleaning and disinfection for gastrointestinal endoscopy in China: a survey of 122 endoscopy units. Dig Liver Dis 2011;43:305–308.
10. FDA-cleared sterilants and high-level disinfectants with general claims for processing reusable medical and dental devices—March 2009. Food and Drug Administration website. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm. Accessed May 5, 2012.
11. Machado AP, Pimenta ATM, Contijo PP, Geocze S, Fischman O. Microbiologic profile of flexible endoscope disinfection in two Brazilian hospitals. *Arq Gastroenterol* 2006;43:255–258.
12. Alfa MJ, Sepehri S, Olson N, Diploma AW. Establishing a clinically relevant bioburden benchmark: a quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes. *Am J Infect Control* 2012;40:233–236.
13. Beilenhoff U, Neumann CS, Rey JF, Biering H, Schmidt V; European Society of Gastrointestinal Endoscopy Guidelines Committee. ESGE-ESGENA guideline for quality assurance in reprocessing: microbiological surveillance testing in endoscopy. *Endoscopy* 2007;39:175–181.
14. Bisset L, Cossart YE, Selby W, et al. A prospective study of the efficacy of routine decontamination for gastrointestinal endoscopes and the risk factors for failure. *Am J Infect Control* 2006;34:274–280.

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