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Major Article

Microbiologic assessment of flexible gastrointestinal endoscope reprocessing using a pump-assisted sampling technique: an investigation involving all endoscopy units in Tianjin, China

Xue-Yue Ji MM [a,*], Pei-Yong Ning MB [b,1], Wei Zhang MM [b], Dong-Jing Yang MM [b], He Liu MM [a], Jun Liu MM [a], Jia Song MB [a], Chun-Nan Fei MM [a]

[a] Department of Infectious Disease, Tianjin Centers for Disease Control and Prevention, Tianjin, China
[b] Pathogenic Microbiology Institute, Tianjin Centers for Disease Control and Prevention, Tianjin, China

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Background: Microbiologic surveillance of flexible gastrointestinal endoscopes is recommended in several guidelines as the primary means of identifying reprocessing failures. This study aimed to evaluate the contamination level and prevalence of bacteria of post-reprocessing endoscopes and to access whether using a pump-assisted sampling method (PASM) improves the sensitivity of culture.

Methods: All 59 endoscopy units in Tianjin, China, were investigated. The PASM and the conventional flushing sampling method (CFSM) were used to compare the results of the microbial culture. Logistic regression analysis was used to identify the influencing factors.

Results: One hundred four (56.52%) flushing channel samples of gastrointestinal endoscopes were positive for culture, and the maximum bacterial concentration was 14,100 colony-forming units (CFU)/channel. One hundred fifty-one (82.07%) flushing samples were qualified according to the national standard of China (≤ 20 CFU/channel). The qualified rate of the samples collected by PASM was significantly lower than the qualified rate by CFSM (65.52% vs 89.68%). Using PASM (odds ratio [OR]: 4.257; 95% confidence interval [CI]: 1.870–9.690) would increase the sensitivity of culture. The use of purified water (OR: 0.288; 95% CI: 0.102–0.814) could reduce the risk of endoscope reprocessing failure.

Conclusion: Many endoscopes fail to meet the national standard for microbial culture after reprocessing. Our results suggest that using a pump-assisted method could increase the sensitivity of the test.

Gastrointestinal endoscopes are widely and increasingly used for minimally invasive diagnostic and therapeutic interventions. They are semi-critical devices because they contact with mucosal membranes during these procedures, which can result in microbial contamination on the surface and within the channels of the endoscope.[1] The sophisticated design incorporates several systems (eg, water, electricity, and air), and the unique coated materials, narrow and long lumens, and various joints make flexible gastrointestinal endoscopes difficult to clean and disinfect.[2] Although endoscopes should not develop biofilm if they are adequately disinfected, the failure of endoscope reprocessing, incomplete drying, and improper storage can lead to the survival of pathogens, to biofilm forming inside the endoscope channels, and to increased risk of infection.[3] It has been reported that manual cleaning that does not adhere to disinfection protocols is prone to human error.[4] A recent report by Robertson et al[5] indicated that a nosocomial outbreak of *Salmonella enteritidis* that affected 4 inpatients who underwent endoscopic retrograde cholangiopancreatography (ERCP) was linked to inadequate cleaning and drying of gastrointestinal endoscopes. Evidence shows that after processing a "dry cycle" in an automatic endoscope reprocessor (AER), up to 95% of endoscopes still have visible water in the channel after being stored overnight.[6] The presence of this water can lead to the growth of bacteria. Therefore, irrespective of whether gastrointestinal endoscopes were cleaned manually or with AERs, endoscope reprocessing failures have been reported, although the incidence of infection associated with the use of flexible endoscopes has been reported to be very low (~1 in

* Address correspondence to Xue-Yue Ji, MM, Department of Infectious Disease, Tianjin Centers for Disease Control and Prevention, No.6 Huayue Road, Hedong District, Tianjin, China.
E-mail address: jixueyue@163.com (X.-Y. Ji).

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[1] Co-first authors.

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1.8 million procedures).[7] Ofstead et al[8] found that this low estimate of endoscopy-associated infections was neither reliable nor representative of actual infection risk and that the risk might be substantially higher than current estimates. Recent studies have examined post-endoscopy symptoms (fever, diarrhea, and abdominal pain) with incidence rates ranging from 0.5% to 3.4%.

The use of microbiologic surveillance to detect early endoscope contamination can possibly prevent cross-contamination and infection in patients.[9] Guidelines[10-12] issued by many countries and organizations recommend routine monitoring of endoscopes with microbial culture methods. The sampling technique recommended by each guideline is different. Only flushing the biopsy channel with sterile saline as the sampling method was represented by Europe[12] and Belgium.[11] The flush-brush-flush method was represented by Netherlands,[13] Australia,[14] Canada,[15] and the United States.[16]

In theory, few organisms will be obtained from flushing alone if the endoscope is reprocessed in adherence with disinfection protocols.[16] Some evidence suggests that brushing of the biopsy channel with a sterile brush is more likely to release viable organisms attached to the inner lumen of the channel and is therefore a more sensitive sampling technique.[17] However, Chinese national standard[18] do not recommend the use of brushes for endoscope microbial culture. In addition to using the flushing method, the use of a peristaltic pump for sampling as an alternative method was approved according to Chinese national standard.[18]

The primary objectives of this study were to investigate the microbial level of post-disinfection endoscopes in all endoscopy units in Tianjin, China; to compare the sampling technique between flushing and pump-assisted flushing; and to analyze the influencing factors of endoscope reprocessing on microbiologic culture.

MATERIAL AND METHODS

Ethical approval

This study was approved by the Institutional Ethics Review Board of Tianjin Centers for Disease Control and Prevention.

ENDOSCOPY UNITS

A total of 59 hospitals, located in all 16 districts of Tianjin, China, all of which perform gastrointestinal endoscope examination and treatment, were included in this study. Two hundred thirty-eight gastroscopes and 149 colonoscopes were distributed over these 59 endoscopy units. Not all endoscopy units had both gastroscopes and colonoscopes. Five endoscopy units had more than 10 gastroscopes. In contrast, only 2 endoscopy units had more than 10 colonoscopes. The largest number of gastroscopes in 1 unit was 42, and the largest number of colonoscopes was 20. The median number (quartile [Q] 1, Q3) of endoscopes per unit was 3 (Q1, 3; Q3, 6) for gastroscopes and 2 (Q1, 1; Q3, 3) for colonoscopes.

Sampling technique

Sampling and testing were conducted according to the Hygienic Standard for Disinfection in Hospital (GB15982-2012),[18] which is the Chinese national standard promulgated by the Chinese National Health and Family Planning Commission.

Two sampling techniques were used to sample flexible gastrointestinal endoscopes: (1) the conventional flushing sampling method (CFSM) and (2) the pump-assisted sampling method (PASM). The two sampling techniques both used 50 mL of fluid containing a neutralizer to flush the channel. Different fluid should be used for sampling. The main components of the fluid (1% peptone [w/v], 0.85% NaCl [w/v], 0.1% Tween 80 [w/v], 0.283% disodium hydrogen phosphate anhydrous [w/v], and 0.136% monopotassium phosphate [w/v]) were the same. The main difference was that if the disinfectant used for endoscope reprocessing was glutaraldehyde (GA) or orthophthalaldehyde (OPA), 0.5% glycine [w/v] was added to the fluid. If electrolyzed-oxidizing water (EOW), peracetic acid (PAA), or chlorine disinfectant was used in reprocessing, 0.5% sodium thiosulfate [w/v] was added to the fluid.

The CFSM used a syringe to draw 50 mL of neutralizing fluid, inject it into the biopsy channel, and used a sterilized bottle to collect the fluid at the distal point.

The PASM used a peristaltic pump (HTY-601, Zhejiang Tailin BioEngineering Co, Ltd, China) connected to the distal point with a sterilized silica gel taper joint. A collection cup (FC501, Zhejiang Tailin BioEngineering) with a filter membrane (0.45 μm) was connected to the peristaltic pump. Under the action of the peristaltic pump, the fluid was extracted and stopped at a certain frequency in the endoscope channel and absorbed into the collection cup. In 4 hours, the sample water was transported to the laboratory for testing.

Testing technique

The water collected was mixed thoroughly. One mL of water was taken and mixed with 15–20 mL per plate of ordinary nutrient agar cooled to 40°C –45°C and incubated at 36°C ± 1°C for 48 hours. After incubation, the colonies were counted and calculated as colony-forming units (CFU)/plate. The remaining water was collected by CFSM under aseptic conditions using a filter unit (Microsart @filter, Sartorius, Germany) to concentrated. Conversely, the remaining water collected by PASM was concentrated by the filter device (HTY-101, Zhejiang Tailin BioEngineering) that was matched with the collection cup.

The filter membrane obtained by the 2 sampling methods was aseptically removed, transferred to the nutrient agar plate, and incubated at 36°C ± 1°C for 48 hours. After incubation, the colonies were counted and calculated as CFU/membrane.

When the bacterial colonies on the filter membrane were too numerous to count, the result was reported as CFU/channel = CFU/plate × 50. When the colonies on the filter membrane could be counted, the result was reported as CFU/channel = CFU/plate + CFU/membrane.

The results were compared with the threshold value (20 CFU/channel) established by the Hygienic Standard for Disinfection in Hospital. A VITEK 2 (Vitek2 compack30; Biomerieux, Marcy-l'Etoile, France) analyzer was used to identify Gram-negative and Gram-positive aerobic bacteria.

Data collection

After each sampling, a questionnaire designed by the authors of more than 10 variables was completed by the medical staff of the sampling endoscopy units. The variables were recorded and coded as follows: location of hospital (1 = downtown area; 2 = rural area); level of hospital (1 = level 1; 2 = level 2; 3 = level 3); final rinse water (1 = municipal water; 2 = purified water; 3 = simple filter water; 4 = purchased bottled water); disinfectant (1 = GA; 2 = OPA; 3 = EOW; 4 = PAA; 5 = chlorine dioxide; 6 = ozone); drying method (1 = only compressed air; 2 = alcohol also used); hospital self-inspection (1 = adherence to GB15982; 2 = nonadherence to GB15982); AER available (1 = yes; 2 = no); and reprocessing method (1 = manual cleaning; 2 = AER). Endoscope identification and sampling date were recorded for each water sample.