COMMENTARY

Monitoring of Endoscope Reprocessing: Accumulating Data but Best Practices Remain Undefined

Bret T. Petersen, MD[1]

(See the article by Visrodia et al, on pages 987–994.)

The reprocessing of flexible gastrointestinal endoscopes between uses requires continuous vigilance by staff and managers in hospitals and ambulatory facilities. Despite federal guidance[1] and widespread adoption of multisociety guidelines for cleaning and high-level disinfection,[2] these practices are often referred to as the Achilles heel for safety in our gastrointestinal endoscopy suites. Current guidelines advise sequential steps, encompassing the following: (1) bedside precleaning by removal of visible external soil and suction of a large volume of detergent solution through the working channels of the endoscope; (2) manual washing with full submersion in detergent solution, further scrubbing of all exposed surfaces (including access ports, elevators, and channel entries), plus repeated flushing and brushing of accessible channels until all visible soil is removed; (3) high-level disinfection (HLD) according to manufacturers' guidelines, using approved HLD solutions, most commonly in an automated reprocessor that has been cleared for HLD of flexible endoscopes by the US Food and Drug Administration; and (4) complete drying, generally employing an alcohol flush followed by forced air drying and storage in a straight upright dangling position, enabling further drip drying if any moisture remains or collects in internal channels. When performed diligently, these measures appear to work remarkably well, despite the complexity of flexible endoscopes, which are not currently designed for either chemical or autoclave sterilization. Indeed, transmission of clinical infection appears to be extremely rare and is generally attributable to lapses in accomplishing these reprocessing steps. Such lapses are certainly understandable, however, given the repetitive nature of reprocessing tasks that are often relegated to employees with limited training or healthcare expertise. Occasional lapses in disinfection practices are widely publicized, and suspicions exist that less clinically obvious lapses may occur frequently.[3] Hence, as called for in the recent multisociety guideline, well-validated means toward ensuring the adequacy of reprocessing are sorely needed. Various investigators,[4] organizations,[5] and others have touted use of an assortment of tests for assessing the outcome of either intermediate steps in the reprocessing sequence or terminal HLD results. Most of the intermediate testing methods employ rapid assessment for the presence of blood, protein, or adenosine triphosphate (ATP), an organic constituent of both living and dead life forms. Terminal testing options include the same studies of blood, protein, or ATP plus surveillance cultures, which should be a more definitive test for risk of infectivity. Gastroenterology organizations in Europe, New Zealand, and Australia all recommend performance of intermittent post-HLD surveillance cultures, primarily for quality assurance and guidance regarding training and staff performance. This approach is limited, however, by the delay in availability of culture results, questions regarding notification and testing of potentially exposed patients between sequential surveillance tests, and lack of standardization of sampling techniques, culture methods, or interpretation of results, which often include common environmental contaminants.

In this issue, Visrodia et al[6] report a study of several rapid indicators for detection of organic residue before and after manual cleaning of gastrointestinal endoscopes, with an eye toward which of these methods might serve to guide training, quality monitoring, and quality improvement efforts in endoscope reprocessing. Dipstick tests for blood and protein and both swab- and water-based bioluminescence tests for ATP were employed. Samples were variably obtained from the control handles, distal surfaces, biopsy ports, and channels of 10 endoscopes (6 upper endoscopes, 2 colonoscopes, and 2 duodenoscopes) after 14 procedures (10 esophagogastroduodenoscopies, 2 endoscopic retrograde cholangiopancreatographies [ERCPs], and 2 colonoscopies). The authors noted significant correlations between visible soil after precleaning and ATP levels but not between visible residue and protein or blood tests from the distal tips or channel samples of precleaned endoscopes. Hence, they confirm long-standing presumptions that significant quantities of organic soil re-

Affiliation: 1. Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, Minnesota.

Received May 22, 2014; accepted May 24, 2014; electronically published June 20, 2014.

© 2014 by The Society for Healthcare Epidemiology of America. All rights reserved. 0899-823X/2014/3508-0009$15.00. DOI: 10.1086/677323

https://doi.org/10.1086/677323 Published online by Cambridge University Press

main on endoscopes following bedside precleaning and that visual inspection alone is an insufficient guide to the adequacy of manual cleaning prior to high level disinfection. Not surprisingly, after manual cleaning—and before high-level disinfection—at least 1 rapid indicator was positive on at least 1 endoscope component in 82% of reprocessing cycles. ATP levels exceeded the nominal benchmark of 200 relative light units on at least 1 endoscope component after cleaning in 8 of 14 reprocessing cycles (57%), including 7 of 10 samples at the biopsy ports, which appeared to be the site of greatest potential risk for persistent contamination. Further review of the data suggests that testing the exterior of the distal end of the endoscope or the handle and control knobs appears fruitless, since the only positive sample from these areas was coupled with more strongly positive samples from other areas, in particular the biopsy port and the endoscope channels. Testing for blood also appeared to yield limited benefit, since it was rarely employed for the exposed surfaces, commonly positive in the channels after precleaning (10/14 cycles), and never positive after manual washing (0/14). While protein tests were positive after manual washing on 5 occasions, 2 of these were from the low-risk exposed distal ends (1 with a concurrent high ATP level from a biopsy port), 1 was from the elevator channel of a duodenoscope (with a concurrent high ATP level at the same site), and 2 were associated with concurrent high ATP tests from other areas. Overall, positive protein levels in high-risk sites were only identified without the concurrence of any ATP elevations on 2 of 5 occasions. Given the lack of solid data validating an association between these intermediate test results and terminal culture outcomes, it is hard to espouse adopting the authors' guidance to employ multiple different tests of cleaning adequacy. The most important take-home point appears to be that the long narrow channels and the biopsy ports of endoscopes are areas of highest risk and, hence, are the most useful sites for assessment during cleaning and high-level disinfection. Second, compared with protein or blood testing, ATP assays via rapid handheld luminometers appear to identify the greatest proportion of high or unacceptable results following manual cleaning.

This study relies on several assumptions that warrant further consideration. Most important is that detection of ATP levels above the currently accepted nominal threshold of 200 relative light units in this particular device (Biotrace luminometers, 3M)—or of any blood or protein following manual cleaning but before HLD—correlates with the presence of infective organisms and risk for transmission of infection following completion of high-level disinfection and endoscope drying. This has not been directly demonstrated. This absence of data is not particularly reassuring, however, since results of testing during the intermediate steps of reprocessing could just as well underestimate the risk of infectious transmission as overstate it. Validation studies of ATP testing have demonstrated that ATP levels following manual cleaning correlate with concurrent residual protein, hemoglobin, and artificial bioburden levels after manual soiling and cleaning in a lab setting.[7] Studies employing ATP testing of these intermediate steps in reprocessing and terminal culturing are sorely needed and should be encouraged and funded by organizations and agencies with oversight for these practices.

A number of reprocessing challenges have presented in recent years. Most concerning are several clusters of carbapenem-resistant Enterobacteriaceae transmission during ERCP that have been attributed to persistent contamination on duodenoscopes despite presumably appropriate performance of all reprocessing steps.[8] Presumably, these infections occur as a result of established biofilms that are resistant to standard reprocessing steps. Biofilm may be more prone to develop in complex instruments, such as those with mechanical elevators activated by cables sealed in minimally or nonaccessible channels, but they have also been attributed to prior reprocessing lapses even in basic endoscope designs. In the absence of highly susceptible anatomy (such as obstructed bile ducts) and particularly resistant organisms that come to attention as a consequence of their rarity, we have few data regarding how rare or commonplace this occurrence may be. Given the commonplace role of gastrointestinal endoscopy and the low but uncertain potential for transmission of clinical disease or subclinical alteration of the gut microbiome, research funding in all aspects of endoscope reprocessing and industry efforts for redesign of the most complex instruments should become high priorities.

ACKNOWLEDGMENTS

Potential conflicts of interest. B.T.P. reports consulting for Olympus America and the American Cancer Society outside the submitted work. He also reports serving on the governing board of the American Society for Gastrointestinal Endoscopy (ASGE), for which he is an ad hoc representative to discussions with the Centers for Disease Control and Prevention regarding duodenoscope- and endoscopic retrograde cholangiopancreatogram–related transmission of infection. While serving as chair of the ASGE Quality in Endoscopy Committee, he was the primary author of the Multisociety Guideline on Reprocessing of Flexible Gastrointestinal Endoscopes, 2011. All authors submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest, and the conflicts that the editors consider relevant to this article are disclosed here.

Address correspondence to Bret T. Petersen, MD, Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN 55902 (petersen.bret@mayo.edu).

REFERENCES

1. Rutala WA, Weber KJ; Healthcare Infection Control Practices Advisory Committee. *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.* Atlanta: Centers for Disease Control and Prevention, 2008. http://www.cdc.gov/hicpac/pdf/guidelines/disinfection_nov_2008.pdf. Accessed May 14, 2014.
2. Petersen BT, Chennat J, Cohen J, et al. Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011. *Gastrointest Endosc* 2011;73:1075–1084.
3. Dirlam Langlay AM, Ofstead CL, Mueller NJ, et al. Reported

https://doi.org/10.1086/677323 Published online by Cambridge University Press

gastrointestinal endoscope reprocessing lapses: the tip of the iceberg. *Am J Infect Control* 2013;41:1188–1194.
4. Alfa MJ, Fatima I, Olson N. The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels. *Am J Infect Control* 2013;41:249–253.
5. Beilenhoff EU, Neumann CS, Rey JF, et al; ESGE Guidelines Committee. ESGE-ESGENA guideline: cleaning and disinfection in gastrointestinal endoscopy: update 2008. *Endoscopy* 2008;40:939–957.
6. Visrodia KH, Ofstead CL, Yellin HL, Wetzler HP, Tosh PK, Baron TH. The use of rapid indicators for the detection of organic residues on clinically used gastrointestinal endoscopes with and without visually apparent debris. *Infect Control Hosp Epidemiol* 2014;35:987–994 (in this issue).
7. Alfa MJ, Fatima I, Olson N. Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels. *Am J Infect Control* 2013;41:245–248.
8. Frias M, Tsai V, Moulton-Meissner H, et al. Notes from the field: New Delhi metallo-β-lactamase–producing *Escherichia coli* associated with endoscopic retrograde cholangiopancreatography—Illinois, 2013. *MMWR Morb Mortal Wkly Rep* 2014;62;1051–1051.

https://doi.org/10.1086/677323 Published online by Cambridge University Press