Communication from the ASGE Technology Committee

REPORT ON EMERGING TECHNOLOGY

Technologies for monitoring the quality of endoscope reprocessing

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent preclinical and clinical studies on the topic, and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but, in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. For this review, the MEDLINE database was searched through September 2013 by using the keywords "endoscope reprocessing," "endoscope disinfection," "endoscope cleaning," "high-level disinfection," "surveillance cultures," and "ATP bioluminescence." Reports on Emerging Technologies are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the governing board of the ASGE. These reports are scientific reviews provided solely for educational and informational purposes. Reports on Emerging Technologies are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

BACKGROUND

Strategies for reprocessing medical devices are based on the risk of infection associated with use of the device. The Spaulding classification categorizes medical devices into 3 classes (critical, semicritical, and noncritical) based on their site of body contact and the associated risk of infection. Flexible endoscopes come in contact with mucous membranes and are categorized as semicritical devices.[1] High-level disinfection (HLD) is required for the reprocessing of semicritical devices after use. HLD is defined as the destruction of all vegetative microorganisms, mycobacteria, small and medium viruses (lipid or nonlipid), fungal spores, and some bacterial spores.[1]

Endoscope reprocessing comprises manual cleaning steps followed by HLD, then by rinsing and drying steps. Meticulous manual cleaning is imperative to achieve subsequent HLD. This usually comprises bedside cleaning and suctioning of enzymatic detergent followed by manual washing, flushing, and brushing of accessible channels to remove all residues. These processes were detailed in the 2011 Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes.[2] HLD may be performed manually or by automated endoscope reprocessors (AERs).[3] AERs allow for automation and standardization of several reprocessing steps and thereby minimize the risk and impact of human error.

It is estimated that more than 20 million endoscopies are performed in the United States annually.[4] Despite the large number of procedures performed, transmission of infection via endoscopes is very rare, with an estimated incidence of only 1 in 1.8 million endoscopies.[5] Reported infections have usually been associated with a failure to follow established multisociety guidelines for reprocessing or attributed to defective equipment.[6] The manual component of reprocessing appears most prone to error.[7] Periodic surveillance may potentially help reduce such errors by reinforcing adherence to the many steps in reprocessing. Routine microbial surveillance is recommended by the European Society of Gastrointestinal Endoscopy (ESGE), the European Society of Gastroenterology and Endoscopy Nurses and Associates committee (ESGENA), and the Gastroenterological Society of Australia. Currently, there are no recommendations for monitoring the efficacy of reprocessing of flexible endoscopes in the United States.[2] This report highlights the status of current technology for monitoring the efficacy of flexible endoscope reprocessing.

EMERGING TECHNOLOGY

Effective surveillance of flexible endoscope reprocessing ideally requires testing methods that allow for rapid assessment of compliance with current reprocessing standards. However, the lack of both widely accepted bioburden/microbial benchmarks and widely validated

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means of assessing these have limited implementation of such strategies. Potential methods for surveillance include the following.

Microbial culture

The ESGE recommends surveillance cultures of reprocessed endoscopes at intervals of not more than 3 months.[8] The ESGE-ESGENA guideline states that the maximal total microbiological count should be less than 20 colony-forming units (cfu) for fluid collected after flushing the endoscope channels with 20 mL of sterile saline solution with placing of 1 mL of the fluid on each agar plate.[9] However, culturing for bacterial load is impractical for many endoscopy centers that may not have easy access to microbiology laboratories. In addition, the slow turnaround time (minimum 24 hours) for results does not allow for rapid reuse of the tested endoscope.[8,10,11] Furthermore, viruses such as hepatitis B and C and HIV cannot be cultured by using standard methods.[2] Alfa et al[12] performed a prospective study of the bacterial and fungal burden in endoscopes after reprocessing and storage over a weekend, in an effort to identify a practical benchmark for microbial burden. The authors tested 141 endoscopes and 383 channels and found that 99.5% of all endoscopes demonstrated less than 100 cfu/mL of microbial growth and proposed this as a reliable and routinely attainable benchmark.

Bioburden assays

Currently available methods allow rapid evaluation of residual bioburden and organic matter from the endoscope channels (eg, Scope-Check; Valisafe America, Tampa, Fla and EndoCheck and ChannelCheck; HealthMark Industries, Fraser, Mich). Scope-Check is a test for protein residue on the surface of endoscopes, EndoCheck is able to detect protein and blood residues within the biopsy channel of endoscopes while ChannelCheck is able to detect protein, blood and carbohydrate residues within the biopsy channel of endoscopes.

Methodology. All of the above tests are easily and rapidly performed. For the Scope-Check test, a swab of the surface of the endoscope is obtained and dropped into a vial containing test reagent. If protein is present, the reagent turns blue within 10 seconds. The deepness of the blue color and the speed of the color change provide a semiquantitative measure of the amount of protein on the test swab. The test is able to detect as little as 1 μg of protein residue. The EndoCheck test uses a long probe with a swab attached to its tip. The probe is inserted into the endoscope's biopsy channel, and a swab of the channel is obtained. The swab is then cut off the probe and dropped into a test vial containing the test reagent and shaken. The presence of blood or protein residue is displayed by a color change in the reagent.

The ChannelCheck test offers the advantages of ease of test sample collection, simple test methodology using a test strip similar to a urine dipstick, as well as detection of a wider range of biological soils. The assay uses test strips with 3 pads that allow detection of residual carbohydrate, protein, and hemoglobin. The endoscope's biopsy channel is flushed with 10 mL of sterile deionized water, followed by 10 mL of air to promote expulsion of the water from the distal end of the endoscope. This water is collected into a sample collection container, and the test strip is immersed within it for 10 seconds. The 3 test pads on the test strip indicate the presence of residual carbohydrate, protein, and hemoglobin by a color change within 90 seconds. The colors on the test strip are compared with those on a color indicator chart provided on the test strip bottle.

Studies. Proposed benchmarks for organic and bioburden residuals after proper manual cleaning and before HLD include less than 6.4 $\mu g/cm^2$ of protein, less than 1.2 $\mu g/cm^2$ of carbohydrate, and less than 2.2 $\mu g/cm^2$ of hemoglobin.[13,14] A simulated-use study evaluating a prototype test strip validated its ability to detect improperly cleaned endoscopes that exceeded these proposed bioburden benchmarks.[14] A Canadian clinical study was then performed at 44 endoscopy centers using the test strip.[14] Of a total of 1489 endoscope channels tested, 96.6% tested negative, suggesting that the proposed benchmarks were reasonable and attainable.

Adenosine triphosphate bioluminescence

Adenosine triphosphate (ATP) bioluminescence is present in microorganisms and human cells and therefore offers a means of testing for microbial and biological residue. ATP bioluminescence testing provides results within a few minutes. The technique uses the light-producing reaction between ATP, luciferin, and luciferase to estimate the levels of ATP in a sample. Luminometers convert the number of photons released in the reaction into relative light units (RLUs). ATP bioluminescence was first used for measuring the cleanliness of surfaces in hospitals.[15] Recent studies have demonstrated the measurement of ATP to be effective in monitoring HLD of flexible endoscopes.[13,16-19]

Methodology. Described endoscope sampling techniques have included surface sampling and channel sampling. Surface sampling has been performed by using swabs taken from the distal end of the endoscope. For channel sampling, techniques have included (1) brushing of the endoscope channel followed by rinsing of the brush in 25% Ringer's solution, (2) combining channel flushing with brushing/sponging, and (3) flushing of channels only. The flushing-only method offers the advantage of simplicity, and results are comparable to those with other more labor-intensive techniques.[14,16] Collection of flushing fluid takes approximately 2 minutes per endoscope channel, and the ATP bioluminescence test takes approximately 1 minute to perform.

TABLE 1. Currently available bioburden and ATP test kits

Assay	Manufacturer	Description	Testing	Cost, US$
Bioburden test kits				
Scope Check	Valisafe America, Tampa, Fla	25 vials per box	Test for protein residue	141
EndoCheck	HealthMark Industries, Fraser, Mich	12 test kits per box. Different boxes based on diameter and length of endoscope lumen	Separate kits for detection of protein and hemoglobin residue	102-210
ChannelCheck	HealthMark Industries	2 boxes of 50 test strips, with control	Strips detect residual carbohydrate, protein, and hemoglobin	104
ATP test kits				
Clean-Trace	3M (St. Paul, Minn)	ATP assay kit and luminometer	Surface and channel flush	5187
Glomax 2020	Promega (Madison, Wisc)	ATP assay kit and luminometer	Surface and channel flush	2789
Pallchek	Pall Corp (Port Washington, NY)	ATP assay kit and luminometer	Surface and channel flush	23,383
Lumat	Berthold Tech (Oak Ridge, Tenn)	Luminometer only	Works with most assays	8475
Millipore	EMD Biosciences (Darmstadt, Germany)	ATP assay kit only	Surface and channel flush	369
Ultrasnap	Hygiena (Camarillo, Calif)	ATP assay kit only	Surface and channel flush	485

ATP, Adenosine triphosphate.

The test has been performed after manual cleansing steps only (ie, before HLD) as an audit tool to determine the adequacy of cleaning and/or after complete reprocessing (ie, after manual cleaning and HLD). The rationale for monitoring after the manual cleaning steps only is that thorough manual cleaning is a necessary prerequisite for subsequent effective HLD.

Studies. Alfa et al[12] recently validated the Clean-Trace (3M Inc, St. Paul, Minn) water-flush method and assessed the correlation of residual ATP with organic and bioburden residuals after manual cleaning. This simulated study using artificial test soil to perfuse channels of a duodenoscope identified that proposed bioburden and organic benchmarks after manual cleaning were achieved when bioluminescence readings were less than 200 RLUs. Therefore, they proposed that if the ATP bioluminescence is more than 200 RLUs, the residual organic and bioburden levels may be too high for effective HLD after manual cleaning. A further study assessed whether this benchmark was achievable in a busy endoscopy center.[13] The authors evaluated 40 patient-used colonoscopes and duodenoscopes and found that after manual cleaning, 96% of tested channels had fewer than 200 RLUs by using the ATP method and would thus satisfy acceptable benchmarks for bioburden and protein.[13] The 5 channels, which did not meet this benchmark, were all in duodenoscopes because of inadequate cleaning of the elevator/wire channel.

In a further study, ATP bioluminescence was compared with conventional microbial cultures (criterion standard) in 108 flexible endoscopes. Every plate with bacterial growth was considered positive, regardless of the number of colony-forming units. The sensitivity and specificity of ATP bioluminescence were determined at a range of threshold RLUs from 30 to 100 RLUs. The sensitivity and specificity of ATP bioluminescence were 0.75 and 0.43 for a threshold of 30 RLUs, respectively, and 0.46 and 0.81, respectively, for a threshold of 100 RLUs.[18] Although these data indicate that conventional microbial culture is more sensitive than ATP bioluminescence, the sensitivity rate may have been affected by the authors decision to consider any growth as a positive result, rather than using the ESGE-ESGENA benchmark of 20 cfu/mL. A more recent study assessed ATP bioluminescence, microbial cultures, and residual protein in channel rinsates before and after manual cleaning and before HLD.[20] Manual cleaning alone led to a reduction in mean ATP from 30,281 to 104 RLUs/sample ($P = .011$), a reduction of mean microorganism colony counts from 95,827 to 14 cfu/sample ($P = .001$), and a reduction in protein from 36 to 20 μg/sample ($P = .078$) in channel flush samples. Similar reductions in ATP and microorganism colony counts were noted for endoscope surfaces.

Overall, these data suggest that ATP bioluminescence is potentially an effective tool for surveillance of the manual

steps of endoscope reprocessing. The ability to obtain immediate results is a significant advantage of ATP bioluminescence over standard microbial cultures.[20]

Currently, there are multiple ATP measurement tools available on the market (Table 1).

POTENTIAL CLINICAL APPLICATIONS

Minimizing the potential for transmission of pathogens by using flexible endoscopes is an important issue for facilities at which endoscopy is performed. These technologies offer endoscopy units the ability to implement surveillance strategies, which may potentially improve the quality of endoscope reprocessing.

Research agenda

The available data regarding technology for monitoring the efficacy of endoscope reprocessing are limited. The efficacy data for available techniques to measure residual organic material or ATP are noncomparative and small in sample size. Areas for future research include the following:

- Establishment and validation of standardized bioburden/microbial benchmarks and ATP bioluminescence thresholds after reprocessing of flexible endoscopes.
- Assessment of cost-effectiveness of implementing surveillance strategies for monitoring the quality of endoscope reprocessing.
- Large prospective studies to assess the relative clinical and cost-effectiveness of different available surveillance technologies as well as their impact on reducing the transmission of clinically significant infections.
- Potential for incorporating bioburden/microbial assessments into AERs.

SUMMARY

Transmission of infection via endoscopes remains very rare. Reported infections have usually been associated with a failure to follow established multisociety guidelines for reprocessing or defective equipment. The manual components of reprocessing are prone to human error. Emerging technologies for monitoring the quality of endoscope reprocessing offer the ability to perform rapid surveillance, which may potentially help reinforce adherence to the many steps in reprocessing. Bioburden/microbial benchmarks need to be established and validated widely, and the relative ease of use, costs, and relative efficacies of different methodologies need to be studied further before recommendations regarding widespread adoption of these technologies. Further studies are needed to determine whether surveillance strategies including ATP monitoring can effectively identify failures of cleaning, disinfection, or storage that are not detected by process monitoring and that create a risk of transmission of infection.

DISCLOSURE

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Abbreviations: AER, automated endoscope reprocessor; ATP, adenosine triphosphate; ESGE, European Society of Gastrointestinal Endoscopy; ESGENA, European Society of Gastroenterology and Endoscopy Nurses and Associates; HLD, high-level disinfection; RLU, relative light units.

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