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.

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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.