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Major Article

Assessment of test methods for evaluating effectiveness of cleaning flexible endoscopes

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Background: Strict adherence to each step of reprocessing is imperative to removing potentially infectious agents. Multiple methods for verifying proper reprocessing exist; however, each presents challenges and limitations, and best practice within the industry has not been established. Our goal was to evaluate endoscope cleaning verification tests with particular interest in the evaluation of the manual cleaning step. The results of the cleaning verification tests were compared with microbial culturing to see if a positive cleaning verification test would be predictive of microbial growth.

Methods: This study was conducted at 2 high-volume endoscopy units within a multisite health care system. Each of the 90 endoscopes were tested for adenosine triphosphate, protein, microbial growth via agar plate, and rapid gram-negative culture via assay. The endoscopes were tested in 3 locations: the instrument channel, control knob, and elevator mechanism.

Results: This analysis showed substantial level of agreement between protein detection postmanual cleaning and protein detection post–high-level disinfection at the control head for scopes sampled sequentially.

Conclusions: This study suggests that if protein is detected postmanual cleaning, there is a significant likelihood that protein will also be detected post–high-level disinfection. It also infers that a cleaning verification test is not predictive of microbial growth.

BACKGROUND

Recent outbreaks related to contaminated endoscopes have pressed health care organizations, endoscope manufacturers, and professional organizations to reevaluate guidelines and recommendations related to the cleaning and disinfection of endoscopes and verification of those functions.[1-7] In 2015, the U.S. Food and Drug Administration issued several notifications to health care facilities regarding reprocessing of duodenoscopes.[8] The Centers for Disease Control and Prevention also issued several statements, including a proposed protocol for culturing these devices for microbial contamination.[9] During this time frame the Association for the Advancement of Medical Instrumentation,[10] Society of Gastroenterology Nurses and Associates,[11] American Society for Gastrointestinal Endoscopy,[2] and other industry standards groups also released new and revised standards for reprocessing. Finally, the manufacturers of these endoscopes (Olympus, Center Valley, PA, Pentax, Montvale, NJ, and Fujifilm, Stamford, CT) issued new and revised instructions for reprocessing, including new tools for more effective cleaning.[3] Although there is a clear need for evaluation of the effectiveness of endoscope reprocessing, health care organizations struggle with an undefined standard method of verification of readiness for use.

Strict adherence to each of the multiple steps of reprocessing is imperative to removing potentially infectious agents from the endoscope. Precleaning at the point of use, leak testing, manual cleaning, and finally high-level disinfection or liquid chemical sterilization are 4 distinct steps that can be evaluated using various methods. Steps prior to high-level disinfection must be taken to ensure soil and proteinaceous material is removed from the endoscope. Failure to do so can interfere with the disinfection and sterilization process' ability to kill or inactivate organisms and may lead to the development of biofilm. Several studies have been performed to evaluate the effectiveness of endoscope reprocessing that led to the development of cleaning verification tests for frontline clinician use.[4-6] Such methods included tests that detected organic soils in the form of adenosine triphosphate (ATP),[7] blood, protein, and carbohydrates.[12] Microbiologic culturing has also been used, but long incubation periods, the labor intensive process, and meticulous protocols have made this practice prohibitive as a method for use en masse by frontline staff reprocessing the endoscopes.

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The purpose of the study was to evaluate multiple point-of-use reprocessing verification tests with particular interest in the evaluation of the manual cleaning step. In addition to evaluating point-of-use tests, microbiologic culturing was also performed. The team compared results of the various verification methods at the manual cleaning and high-level disinfection steps. Furthermore, we assessed if the use of the cleaning verification tests could be incorporated into a quality assurance process in the future.

MATERIALS AND METHODS

Setting

This study was conducted at 2 high-volume endoscopy units within a large, multisite health care system located in the Midwestern United States. Prior to this study, the locations were evaluated for endoscope reprocessing practices and both were found to be compliant with each manufacturers' most recent instructions for reprocessing.

Olympus flexible gastrointestinal endoscopes and duodenoscopes were tested. At each facility, 45 endoscopes were sampled (15 in storage, 15 postmanual cleaning, and 15 post–high-level disinfection using an automated endoscope reprocessor), for a total of 90 scopes. A total of 8 unique, individual duodenoscopes and a total of 25 unique, individual flexible gastrointestinal endoscopes were tested. The in-storage samples were collected at the beginning of day, before the clinic opened. The in-process samples were randomly collected as the endoscopes progressed through the reprocessing room. The endoscopes to be sampled were chosen based on availability of the staff that were collecting and samples and in a manner that did not impede patient flow. In some instances, an endoscope was sampled more than once in the event it reappeared in the course of clinic use and reprocessing. Each of the 90 endoscopes were tested for ATP, protein, microbial growth via agar plate (traditional culturing), and rapid gram-negative culture via assay. The rapid gram-negative test was only performed on the instrument channel because the test is designed only for testing via flushing. The endoscopes were tested in 3 specific locations on the endoscope itself: the instrument channel (via flushing), control knob (via swab), and elevator mechanism (for duodenoscopes only). A total of 666 samples were taken.

Sample collection

Instrument channel samples were collected via flushing with sterile water and recapturing at the distal tip. Samples of the recaptured liquid were then drawn off and tested separately for protein, ATP, gram-negative rapid culture, and microbial culture via plating. Samples were collected using aseptic technique, and steps were taken to prevent contamination.

Control knob samples were collected via swabbing around the control knob of the endoscope and testing for protein, ATP, and microbial culture via plating. The cotton swab was moistened with sterile water prior to sampling. Swabbing was performed behind the up and down angulation control knob. Three samples needed to be taken from this physical location (ATP, protein, and microbial culturing). Once a surface is swabbed, repeated swabbing in the exact location is likely to result in an inaccurate representation because the previous swab could potentially remove or wipe away any bioburden. For this reason, a different place on each endoscope's control head was sampled using a method that viewed the control knob as the face of a clock. For example, the 12 o'clock position might be used for the ATP sample, the 3 o'clock position for the protein sample, and the 6 o'clock position for the microbial culture sample.

Elevator mechanisms on duodenoscopes were swabbed and tested for protein, ATP, and microbial culture via plating. The cotton swab was moistened with sterile water prior to sampling. A single swab was used to sample this area. The area was swabbed around the elevator mechanism and while it was raised and lowered, swabbing in all 3 positions.

Assays for ATP, protein, rapid gram-negative culture, and microbiologic culturing

A total of 4 test methods were selected: ATP detection, protein detection, rapid (overnight) gram-negative bacteria test, and microbiologic culturing.

ATP

ATP testing had originally been designed for the food production industry and has been used for environmental cleaning assessment; however, researchers have determined that ATP could be detected in manually cleaned endoscopes. The ATP system from Charm Sciences (Lawrence, MA) was chosen because of its high degree of sensitivity. Its relative light unit scale is orders of magnitude higher than most other systems on the market. ATP levels of >200,000 relative light units were considered positive or inadequate for patient use per Charm Scientific's instructions for use. This brand allowed for greater granularity to the results, but it can cause confusion because the values that would trigger alerts or action levels on competing systems are well below the threshold for concern with the Charm Scientific system.

Protein

Although residual contamination can be detected by the very sensitive protein detection system (EndoCheck; Healthmark Industries, Fraser, MI) used (down to 1 μg of protein), the more likely trigger for a positive result is bodily fluids and other organic soils from the patient. Two methods were used for capturing samples for protein. For flushing the biopsy channel, 1 mL of the collected sample was drawn off and mixed with the reagent. This was then placed in a spectrophotometer (DR 1900; Hach, Loveland, CO) and read for telltale protein (340-800 nM). The second method was to swab (control head and elevator mechanism). Once a sample was collected, the swab was added to the liquid assay and a wait time of 5 minutes for protein detection elapsed. Color change of the liquid or the swab to blue-green indicated a positive result. No color change after 5 minutes was recorded as negative.

Rapid gram-negative test

The rapid gram-negative test (NOW! Test; Healthmark Industries) used has a sensitivity of <10 colony forming units of gram-negative bacteria. It uses a reagent that reacts with the enzymes produced by gram-negative bacteria. In this way, it is able to provide a rapid result. Once the fluid is recaptured from the endoscope, a growth medium is added, and the sample is incubated overnight (≥12 hours). Once the incubation period is complete, the reagent is added, and the sample is placed in a fluorometer that reflects and detects light at a set frequency indicating the presence of the enzyme produced by viable gram-negative bacteria. The reading takes 10 minutes after adding the reagent; therefore, the minimum time to a result is 12 hours. The test was used only for channel flush samples in this study.

Microbial culturing

In the case of microbial culturing (culturing services provided by Nelson Laboratories, Salt Lake City, UT), blood agar culture plates were selected. Once collected, samples were incubated for 48 hours prior to counting colonies. In the instance of 60 endoscopes that