Adenosine triphosphate bioluminescence for bacteriologic surveillance and reprocessing strategies for minimizing risk of infection transmission by duodenoscopes

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Background and Aims: Recent outbreaks of duodenoscope-transmitted infections underscore the importance of adequate endoscope reprocessing. Adenosine triphosphate (ATP) bioluminescence testing allows rapid evaluation of endoscopes for bacteriologic/biologic residue. In this prospective study we evaluate the utility of ATP in bacteriologic surveillance and the effects of endoscopy staff education and dual cycles of cleaning and high-level disinfection (HLD) on endoscope reprocessing.

Methods: ATP bioluminescence was measured after precleaning, manual cleaning, and HLD on rinsates from suction-biopsy channels of all endoscopes and elevator channels of duodenoscopes/linear echoendoscopes after use. ATP bioluminescence was remeasured in duodenoscopes (1) after re-education and competency testing of endoscopy staff and subsequently (2) after 2 cycles of precleaning and manual cleaning and single cycle of HLD or (3) after 2 cycles of precleaning, manual cleaning, and HLD.

Results: The ideal ATP bioluminescence benchmark of <200 relative light units (RLUs) after manual cleaning was achieved from suction-biopsy channel rinsates of all endoscopes, but 9 of 10 duodenoscope elevator channel rinsates failed to meet this benchmark. Re-education reduced RLUs in duodenoscope elevator channel rinsates after precleaning (23,218.0 vs 1340.5 RLUs, $P < .01$) and HLD (177.0 vs 12.0 RLUs, $P < .01$). After 2 cycles of manual cleaning/HLD, duodenoscope elevator channel RLUs achieved levels similar to sterile water, with corresponding negative cultures.

Conclusions: ATP testing offers a rapid, inexpensive alternative for detection of endoscope microbial residue. Re-education of endoscopy staff and 2 cycles of cleaning and HLD decreased elevator channel RLUs to levels similar to sterile water and may therefore minimize the risk of transmission of infections by duodenoscopes. (Gastrointest Endosc 2017;85:1180-7.)

The reprocessing of flexible endoscopes after use is a complex, multistage process. The broad steps include point-of-use precleaning, manual cleaning, and high-level disinfection (HLD) followed by alcohol flushing and drying.[1] The manual component of reprocessing appears to be most prone to error.[2] Although periodic microbial surveillance is recommended by the European Society of Gastrointestinal Endoscopy and the Gastroenterological

Abbreviations: ATP, adenosine triphosphate; HLD, high-level disinfection; RLU, relative light unit; SPD, Sterile Processing Department.

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Society of Australia,[3,4] no such recommendations exist in the United States.[1]

One reason for the prior lack of a regulatory mandate for surveillance in the United States is that transmission of infection related to endoscopic procedures was assumed to be very rare,[5,6] with estimated infection transmission rates ranging from 1 in 1.8 million to 1 in 10 million procedures[6,7] and with reported cases of infection largely attributed to defective equipment or to breaches in following multisociety guidelines on endoscope reprocessing.[1,8,9]

A major development over the last decade has been the worldwide emergence of carbapenem-resistant Enterobacteriaceae.[10] These organisms cause serious illness and are associated with a high mortality rate.[10] Several recent outbreaks of infection with carbapenem-resistant Enterobacteriaceae associated with duodenoscope use have forced a reassessment of the risk of transmission of infection related to endoscopic procedures, particularly ERCP, and have highlighted a need for endoscopy units to create a surveillance program to ensure adequate HLD of their endoscopes.[11,12] After these outbreaks of infection, the Centers for Disease Control and Prevention suggested an interim protocol for surveillance cultures of duodenoscopes to evaluate for bacterial contamination but did not make a firm recommendation because of a lack of published data.[13] However, using cultures or other laboratory-based polymerase chain reaction surveillance methods such as multiplex real-time polymerase chain reaction–based detection of *Klebsiella pneumoniae* carbapenemase and New Delhi metallo-β-lactamase genes[14] presents several logistical difficulties,[15] particularly for endoscopy units without microbiology laboratory access.

There is a need for a rapid surveillance method to proactively monitor compliance with the various phases of flexible endoscope reprocessing.[4,16,17] Testing for adenosine triphosphate (ATP) bioluminescence, measured as relative light units (RLUs), offers a practical, rapid, and low-cost approach.[18,19] ATP is present in microorganisms and in human cells, and its presence indicates microbial/biologic residue in endoscopes.[20] Several commercial systems are available. ATP testing is typically performed after manual cleaning and before HLD, because adequate manual cleaning is a prerequisite for attaining HLD.[21,22] Studies performed by Alfa et al[22,23] suggest that ATP bioluminescence of <200 RLUs after completion of all manual cleaning steps correlate with acceptable residual bioburden benchmarks, which would allow for effective subsequent HLD. It is important to note that values from one commercial brand of ATP testing kit may not be compared directly with bioluminescence values obtained from another kit.[24]

Our study was designed to assess the utility of ATP bioluminescence as a method for surveillance of flexible endoscopes during and after the HLD process, with specific attention to duodenoscopes. Our specific objectives were (1) to verify whether the ATP bioluminescence benchmark of 200 RLUs after manual cleaning was routinely achievable in rinsates from the working channels of all endoscopes used in the busy endoscopy suite of a U.S. tertiary care hospital and (2) to specifically evaluate rinsate ATP bioluminescence values from the elevator channels of duodenoscopes and linear echoendoscopes. Although not planned a priori, based on our initial data, we also added 2 additional objectives: (3) to evaluate the impact of re-education and scrutiny/supervision on duodenoscope elevator channel ATP bioluminescence values and (4) to evaluate the impact of 1 versus 2 back-to-back cleaning and HLD cycles on duodenoscope elevator channel ATP bioluminescence values.

METHODS

Flexible endoscopes tested

This study received Stanford University Institutional Review Board approval (protocol number 38212). This study was performed at the Stanford University Hospital in an endoscopy suite that performs >50 GI endoscopy procedures each day. Consecutive, patient-used endoscopes were tested for ATP bioluminescence after precleaning, manual cleaning, and HLD. The endoscopes tested were manufactured by the Olympus Corporation of the Americas (Center Valley, Pa), including gastroscope models GIF-160, GIF-H180, and GIF-Q180; colonoscope models CF-Q180AL, CF-H180AL, PCF-160AL, PCF-H190, and PCF-Q180; echoendoscope models GF-UE160, GF-UE160-AL5, and GF-UC140; and duodenoscope model TJF-160VF, and by Pentax of America (Montvale, NJ), including gastroscope models EG-2990I and EG-3490K, colonoscope models EC-3890LI and EC-3490LI, and echoendoscope models EG-3670URK and EG-3870URK.

In the preintervention phase of this study, patient-used gastroscopes (n = 10), colonoscopes (n = 10), duodenoscopes (n = 10), linear echoendoscopes (n = 10), and radial echoendoscopes (n = 8) were tested. In the postintervention phases, only duodenoscopes (n = 10) were tested.

Endoscope reprocessing

Point-of-use precleaning. All endoscopes underwent precleaning as per the endoscope manufacturer's instructions.[25,26] The endoscopes were then immediately transported in closed plastic containers to the Sterile Processing Department (SPD) for subsequent reprocessing steps.

Manual cleaning. All endoscopes underwent manual cleaning as per the endoscope manufacturer's instructions,[25,26] commencing within 15 minutes of completion of endoscopy.

High-level disinfection. In the preintervention cycle of testing, endoscopes underwent HLD using an automated endoscope reprocessor (Custom Ultrasonics, Warminster, Pa). For subsequent study cycles, HLD was performed using a Medivators Advantage Plus (Minntech, Minneapolis, Minn) automated endoscope reprocessor.

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