Duodenoscope reprocessing surveillance with adenosine triphosphate testing and terminal cultures: a clinical pilot study

Kavel Visrodia, MD,[1] Yuri Hanada, MD,[1] Kelly M. Pennington, MD,[1] Pritish K. Tosh, MD,[2] Mark D. Topazian, MD,[1] Bret T. Petersen, MD[1]

Rochester, Minnesota, USA

Background and Aims: Recent reports of infectious outbreaks linked to duodenoscopes have led to proposals for duodenoscope surveillance culturing, which has inherent limitations. We aimed to assess the feasibility of real-time adenosine triphosphate (ATP) testing after manual cleaning and its ability to predict reprocessing adequacy, as determined by terminal duodenoscope cultures.

Methods: Clinically used duodenoscopes underwent reprocessing per current guidelines. After manual cleaning, ATP samples were obtained from the elevator, within the proximal biopsy port, and by flushing of the biopsy channel. After high-level disinfection (HLD), aerobic cultures of the elevator and biopsy channel were obtained using sterile technique. Duodenoscopes with any ATP sample $\geq$200 relative light units underwent repeated cycles of cleaning, ATP testing, HLD, and terminal culturing.

Results: Twenty clinically used duodenoscopes were included; 18 underwent a second reprocessing cycle, and 6 underwent a third reprocessing cycle because of detection of high ATP. After the initial reprocessing cycle, 12 of 20 (60%) duodenoscopes had positive culture results, most commonly yielding gram-negative bacilli (GNB, n = 11 from 9 duodenoscopes), and catalase-positive gram-positive cocci (CP-GPC, n = 7 from 7 duodenoscopes), suggesting staphylococcal organisms. Ambient environmental controls also showed GNB and CP-GPC growth. The overall sensitivity and specificity of ATP testing compared with terminal cultures were 30% and 53%, respectively.

Conclusions: ATP sampling appears to correlate poorly with terminal culture results and cannot be recommended as a surrogate for terminal cultures. The performance and interpretation of cultures remains complicated by the potential recovery of environmental contaminants. (Gastrointest Endosc 2017;86:180-6.)

INTRODUCTION

Several recent reports have linked infectious outbreaks involving multidrug-resistant organisms (MDRO) to reprocessed duodenoscopes.[1,2] Unlike previous events, these endoscope-related outbreaks occurred even though the duodenoscopes had been reprocessed in accordance with the manufacturer's instructions and professional guidelines. A definitive solution to this problem has not yet been defined, but the U.S. Food and Drug Administration (FDA) has encouraged supplemental measures to improve the safety of duodenoscope reprocessing in the interim, including surveillance cultures of patient-ready endoscopes after high-level disinfection (HLD).[3,4] However, data supporting the usefulness or feasibility of this strategy in the setting of a clinical endoscopy unit are lacking.

Abbreviations: AER, automatic endoscopic reprocessor; ATP, adenosine triphosphate; CDC, Centers for Disease Control and Prevention; CFU, colony forming units; CP-GPC, catalase-positive gram-positive cocci; FDA, Food and Drug Administration; GNB, gram-negative bacilli; HLD, high-level disinfection; MDRO, multidrug-resistant organisms; RLU, relative light unit; ROC, receiver operating characteristic.

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Current affiliations: Division of Gastroenterology and Hepatology (1), Division of Infectious Diseases (2), Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota, USA.

Reprint requests: Bret T. Petersen, MD, Division of Gastroenterology and Hepatology, Mayo Clinic, 200 First Avenue, Southwest, Rochester, MN 55905.

Moreover, cultures are costly, difficult to perform well and interpret, require access to a microbiology laboratory, and are inherently limited by a 1- to 2-day delay for the results.[5]

BACKGROUND

Various tests have been investigated for their ability to rapidly evaluate endoscopes for the presence of residual bioburden in real time. Testing for adenosine triphosphate (ATP), which is present in microorganisms as well as human cells, has been used in monitoring environmental cleaning for many years, and more recently has been applied to endoscope reprocessing.[6,7] Although terminal ATP testing does not correlate well with concurrently obtained endoscope cultures after HLD,[8] there may be a role for ATP testing in assessing organic residue after manual cleaning. In a simulated-use study, investigators demonstrated that effective manual cleaning of endoscope channels, as determined by microbiological cultures (<4 $\log_{10}$ colony forming units [CFU]/cm^2), was associated with an ATP measurement of less than 200 relative light units (RLU).[9] The impact of this threshold on terminal cultures after HLD of clinically used duodenoscopes is not known but it could serve to immediately identify high-risk duodenoscopes without the need for cultures. Thus, the aim of this pilot study was to assess clinically used duodenoscopes and whether this benchmark for manual cleaning correlated with microbiological cultures obtained after HLD.

METHODS

Setting

This study was conducted in the Mayo Clinic endoscopy and reprocessing unit for advanced and complex procedures, where approximately 40 endoscopic procedures are performed daily. Patients scheduled for ERCP provided consent for enrollment as permitted by the workflow in the endoscopy and reprocessing unit. Duodenoscope reprocessing was performed in accordance with the manufacturer's recommendations and professional guidelines by dedicated reprocessing technicians.[10] This study was approved by the Institutional Review Board and patient consent was obtained in the event clinical data were abstracted.

ERCPs were performed using Olympus model TJF-Q180V duodenoscopes (Olympus America, Center Valley, Pa). After the procedure, duodenoscopes underwent immediate bedside precleaning in the endoscopy room, including flushing of the biopsy channel with an enzymatic cleaner and wiping the exterior endoscope to remove visible debris. In a dedicated reprocessing room, reprocessing technicians manually cleaned the duodenoscope, which consisted of leak testing, brushing internal channels and components, and use of an irrigation system to flush detergent and water through the channels. This was followed by HLD using an automatic endoscope reprocessor (AER) (Medivators, Inc, Minneapolis, Minn). The AER sequence included a final flush with isopropyl alcohol, after which duodenoscopes were dried with forced air and hung vertically in a storage cabinet.

Duodenoscope sampling was performed by 3 trainee physicians, each with a designated role (duodenoscope facilitator, duodenoscope sampler, and data recorder). Personal protective equipment, including hair coverings, face masks with shields, and sterile surgical gowns and gloves were worn. Each investigator had previously undergone formal training in sterile technique. Duodenoscope sampling occurred in a designated corner of the reprocessing room with reduced traffic and away from vents and other potential sources of contamination. Samples for ATP were obtained after manual cleaning with the duodenoscope lying on a mobile cart dressed with a sterile sheet. Samples for cultures were obtained after HLD with the duodenoscope still in the AER before drying.

Sampling protocol

Each duodenoscope underwent at least 2 sampling encounters. The first encounter followed manual cleaning, at which time the duodenoscope components (proximal biopsy port, elevator, and biopsy channel) were sampled for ATP. The second encounter followed HLD, at which time the elevator and biopsy channel were sampled for culturing using the Centers for Disease Control and Prevention (CDC) duodenoscope sampling and recovery protocol implemented for investigation outbreaks.[11] After sampling, duodenoscopes underwent a repeat cycle of HLD before drying and returning to storage for clinical use. In cases where ATP sampling after manual cleaning revealed that any duodenoscope component measured beyond the proposed ATP benchmark, the duodenoscope underwent HLD and culture sampling but was then returned to the reprocessing technician for repeated cycles of manual cleaning, ATP sampling, HLD, and culture sampling until the duodenoscope components met the benchmark ATP. Culturing was repeated for up to 1 repeat reprocessing cycle and ATP sampling for up to 2 repeat reprocessing cycles, after which duodenoscopes with persistently high ATP were sent for sterilization by ethylene oxide (EtO). Although the ATP benchmark of fewer than 200 RLU has only been validated for sampling of the suction channel,[9] we proposed the same cutoff for the biopsy port and elevator regions. When the proposed ATP thresholds were met, duodenoscopes qualified for return to clinical use and were not quarantined while awaiting culture results.

ATP testing and cultures

ATP levels were assessed using Clean-Trace Surface ATP and Clean-Trace Water ATP tests together with a