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State of the Science Review

A systematic review of adenosine triphosphate as a surrogate for bacterial contamination of duodenoscopes used for endoscopic retrograde cholangiopancreatography

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Background: Bacterial culture is the accepted standard to measure the adequacy of high-level disinfection (HLD) of duodenoscopes. Adenosine triphosphate (ATP) bioluminescence assays have been suggested as an alternative method of evaluating the quality of reprocessing. We systematically reviewed published research describing the correlation between ATP and bacterial cultures.

Methods: The primary outcome was the correlation or concordance between concomitantly sampled ATP and bacterial contamination obtained from the instrument channel and/or elevator mechanism of the duodenoscope. A secondary outcome included the reduction in ATP measurements between paired samples before and after stages of duodenoscope reprocessing.

Results: Ten studies were included in the analysis. Four studies reported the relationship between concomitantly sampled ATP and cultures. Three studies reported receiver operating characteristic curves (1 study additionally reported a Wilcoxon rank sum test), and 1 study reported Spearman correlation coefficients and paired dichotomous measurements of ATP and bacterial contamination. All analyses suggested a poor relationship between the 2 measures. Studies measuring ATP before and after manual cleaning and before and after HLD reported a reduction in ATP after the reprocessing stage.

Conclusion: Current research does not support the direct substitution of ATP for bacterial culture surveillance of duodenoscopes. Serial ATP measurement may be a useful tool to evaluate the adequacy of manual cleaning and for training of endoscopic reprocessing staff.

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BACKGROUND

Endoscopic retrograde cholangiopancreatography (ERCP) has a significant risk of contamination with enteric pathogens during a procedure.¹ The duodenoscope differs from other types of endoscopes in that its design is highly elaborate: the tip of the duodenoscope has an elevator plate that raises components passed through the instrument channel into the field of view to facilitate interventions. This complex design makes thorough cleaning and disinfection of these instruments very difficult. Published reports

of outbreaks of invasive infections due to multidrug-resistant bacteria attributed to contaminated duodenoscopes have focused interest on the adequacy of duodenoscope reprocessing.²⁻⁶

The Centers for Disease Control and Prevention (CDC) has issued interim guidelines advocating for routine surveillance culture of duodenoscopes for early detection of contamination.⁷ Although published experience suggests culture surveillance may be inadequate to reliably detect duodenoscope contamination, the current standard to assess for duodenoscope contamination is culture of the device, including the elevator mechanism and instrument channel. The method of using aerobic bacterial cultures is resource intensive and requires time for both processing of the sample and sequestration of the duodenoscope pending the findings. The 2015 CDC guidelines state that non-culture methods, including adenosine triphosphate (ATP), may be useful to detect residual organic material after cleaning. However, "more work is needed to interpret their results since non-culture methods lack consistent correlation to bacterial concentrations."⁷

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The ATP molecule is found in all living organisms and may be used as an indirect indicator of microbial contamination. ATP is measured using 1 of several proprietary bioluminescence assays that use a luciferine/luciferase reaction with the detection of ATP (measured in relative light units [RLUs]).⁸ These simple-to-use assays provide point-of-testing results and have been implemented in food safety and to evaluate environmental cleaning in the healthcare setting.⁹⁻¹²

In this study, we systematically reviewed published evidence characterizing the relationship between measurement of ATP and bacterial contamination of ERCP duodenoscopes. Specifically, we sought to identify studies that concomitantly measured ATP and bacterial contamination, to estimate (a) the correlation or concordance between the 2 surveillance methods sampled from duodenoscopes and (b) the change in ATP levels before and after the manual and automated duodenoscope reprocessing stages.

METHODS

Search strategy

This literature review was conducted in accordance with Preferred Reporting Items of Systematic Reviews and Meta-Analyses guidelines.¹³ The review was limited to ERCP duodenoscopes, since they have been a focus of recent published outbreaks, investigations, and specific guidance for surveillance. Moreover, experts have hypothesized that the complexity of their design—specifically, the elevator mechanism—may predispose these devices to contamination.^{7,14} To minimize heterogeneity, linear echoendoscopes were not included in the analysis. The review was limited to English-language articles. An experienced medical librarian (J.W.) conducted the literature search, with input from the research team. We searched the following databases from inception to May 2017: PubMed/MEDLINE (National Center for Biotechnology 1966–2017), EMBASE (Elsevier 1974–2017), Web of Science (Thomson 1900–2017), and CINAHL ~1984–2017. Keywords were combined with the relevant index terms from each database, including permutations of the terms “endoscope,” “duodenoscope,” and “adenosine triphosphate.” The complete detailed search strategy is outlined in Table A1 of the supplement. EndNote software (version X7; Thomson Reuters, Toronto, ON) was used for reference management.

Study selection and outcomes

Titles, abstracts, and articles were screened by a study investigator (L.B.O.). Studies were included in the analysis if they reported measurement of ATP and bacterial contamination from ERCP duodenoscopes, sampled from any area of the device, without regard to how the investigators quantified the measurements or the microbiologic methods used to characterize bacterial contamination. Data were included only from studies in which duodenoscope sampling followed routine clinical use and reprocessing (as opposed to simulated contamination or reprocessing). The analysis focused on ERCP duodenoscopes.

The primary outcome was the correlation of ATP (quantified as RLU) and bacterial contamination (quantified as colony-forming units [CFUs]) as continuous measures and the concordance of ATP and CFU as dichotomized measures, among concomitantly obtained paired measurements of ATP and bacterial contamination, from the instrument channel¹ and/or elevator mechanism (including samples

from the sealed elevator channel¹⁵). Specific cutoffs for dichotomization of ATP and CFU measurements were analyzed as defined in the publication. The secondary outcome was the difference in ATP measurements between paired samples (from any area of the device) before and after manual reprocessing and before and after high-level disinfection (HLD) with an automated endoscope reprocessor.

Data extraction and synthesis

Data were abstracted and recorded into a custom-designed data extraction sheet and included the following fields: first author; year of publication; study setting; study objective; duodenoscope manufacturer; ATP bioluminescence assay manufacturer and model; sampling time relative to reprocessing stage; duodenoscope sampling location and technique; summarized concomitant ATP and microbiologic sampling results; ATP and CFU cutoff criteria to define clean for dichotomized measures; proportion of sampled duodenoscopes meeting ATP and CFU cutoff criteria; method of assessing correlation and/or concordance relationship; effect estimate (and confidence intervals and *P* values) of correlation and/or concordance; summary measurements of ATP RLU before and after reprocessing stage; and summary measurements of CFU before and after the reprocessing stage. Due to the anticipated heterogeneity of study methods and analysis on this topic, a meta-analysis of the data was not planned.

RESULTS

A total of 191 non-duplicate studies published as manuscripts, abstracts, or conference proceedings were considered for analysis. A detailed assessment was performed on 17 studies, of which 10 met the criteria for inclusion in this review (Fig 1). These 10 studies were published between 2005 and 2017 and included 9 articles and 1 abstract. Additional publication details, including the intended objective of each study and pertinent findings, are described in Table A2 of the supplement.

The study setting, devices, and sampling strategy of the 10 studies in this analysis are presented in Table 1. In 5 of 10 (50%) studies, the duodenoscope used was manufactured by Olympus (Center Valley, PA); for the remaining studies the duodenoscope manufacturer could not be identified. The ATP manufacturer was 3M Inc. (St. Paul, MN) in 7 (70%) studies, HyServe (Uffing, Germany) in 1 study, Charm Science (Lawrence, MA) in 1 study, and not reported in 1 study. The sampling time relative to the duodenoscope reprocessing stage differed among the studies, with 6 (60%) studies reporting sampling prior to manual cleaning, 6 (60%) studies reporting sampling after manual cleaning, and all studies reporting sampling after HLD (reported as either after HLD [7] or after storage [3]). All studies sampled the instrument channel either by flushing the channel to obtain the sample (8 studies, 80%) or by using the flush-brush-flush method (2 studies, 20%). The elevator mechanism was swabbed in 3 (30%) of the studies, flushed in 1 (10%) study, and not sampled in 6 (60%) studies.

Table 2 describes the primary outcome, including reported correlation or concordance between ATP and microbiologic sampling of duodenoscopes after all cleaning and disinfection procedures. Two (20%) studies did not provide data regarding bacterial contamination that would allow an assessment of the relationship between the 2 methods. Four (40%) studies provided the distribution of ATP and CFU but no direct assessment of the relationship between paired data. Of the remaining 4 (40%) studies, 2 reported only receiver operating characteristic (ROC) curves, 1 reported ROC curves as well as a “nonparametric Wilcoxon test,” and 1 reported paired dichotomous measurements of ATP and bacterial contamination as well as a Spearman correlation coefficient.

¹The terms instrument channel, suction-biopsy channel, and working channel are used synonymously within cited publications. For simplicity, this endoscope channel is referred to as “instrument channel” in this publication.

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