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Original Article

Endoscopic retrograde cholangiopancreatography and endoscopic ultrasound endoscope reprocessing: Variables impacting contamination risk

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Abstract

Objective: To evaluate variables that affect risk of contamination for endoscopic retrograde cholangiopancreatography and endoscopic ultrasound endoscopes.

Design: Observational, quality improvement study.

Setting: University medical center with a gastrointestinal endoscopy service performing ~1,000 endoscopic retrograde cholangiopancreatography and ~1,000 endoscopic ultrasound endoscope procedures annually.

Methods: Duodenoscope and linear echoendoscope sampling (from the elevator mechanism and instrument channel) was performed from June 2020 through September 2021. Operational changes during this period included standard reprocessing with high-level disinfection with ethylene oxide gas sterilization (HLD–ETO) was switched to double high-level disinfection (dHLD) (June 16, 2020–July 15, 2020), and duodenoscopes changed to disposable tip model (March 2021). The frequency of contamination for the co-primary outcomes were characterized by calculated risk ratios.

Results: The overall pathogenic contamination rate was 4.72% (6 of 127). Compared to duodenoscopes, linear echoendoscopes had a contamination risk ratio of 3.64 (95% confidence interval [CI], 0.69–19.1). Reprocessing using HLD-ETO was associated with a contamination risk ratio of 0.29 (95% CI, 0.06–1.54). Linear echoendoscopes undergoing dHLD had the highest risk of contamination (2 of 18, 11.1%), and duodenoscopes undergoing HLD-ETO and the lowest risk of contamination (0 of 53, 0%). Duodenoscopes with a disposable tip had a 0% contamination rate (0 of 27).

Conclusions: We did not detect a significant reduction in endoscope contamination using HLD-ETO versus dHLD reprocessing. Linear echoendoscopes have a risk of contamination similar to that of duodenoscopes. Disposable tips may reduce the risk of duodenoscope contamination.

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In the early 2010s, multiple studies described infections attributed to duodenoscopes contaminated with multidrug-resistant pathogens during endoscopic retrograde cholangiopancreatography.[1,2] This patient safety risk may be due to inadequate reprocessing or an intrinsic risk of the endoscope design because duodenoscope features may harbor pathogens despite appropriate manual cleaning and the use of automated endoscope reprocessors.[3]

The US Food and Drug Administration (FDA) recommends that facilities perform microbiologic surveillance of duodenoscopes to detect the adequacy of reprocessing. The FDA also recommends that facilities consider repeating high-level disinfection (ie, double high-level disinfection or dHLD), performing high-level disinfection followed by ethylene oxide gas sterilization (HLD-ETO), or use of a liquid chemical sterilant.[4] Additionally, the FDA recommends the use of duodenoscopes with disposable components.[5] Prior studies have not resolved uncertainty regarding the
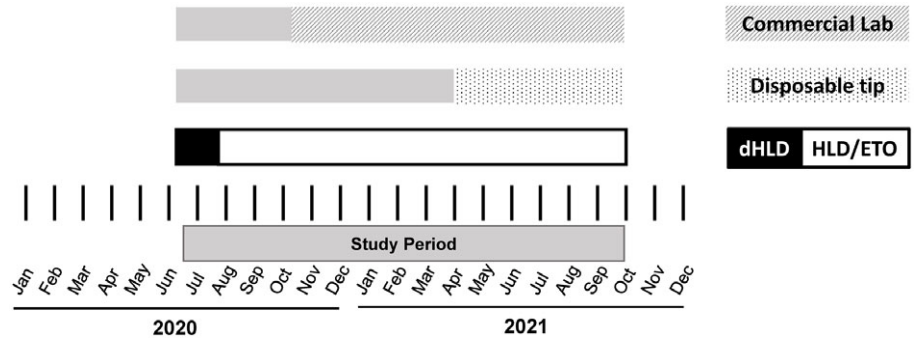
Fig. 1. Analysis periods for duodenoscope contamination, including by method of reprocessing, change to duodenoscope with disposable tip, and change from clinical to commercial laboratory. Note. dHLD, double high-level disinfection; HLD-ETO, high-level disinfection/ethylene oxide gas sterilization.

optimal method for reprocessing because endoscope contamination may persist even with dHLD or HLD-ETO reprocessing.[6]

Limited data are available regarding the comparative effectiveness of reprocessing methods in reducing contamination of linear echoendoscopes used for endoscopic ultrasound (EUS), which have similar design features as duodenoscopes, including the elevator mechanism. Several studies have reported the risk of contamination of linear echoendoscopes.[7–10] Existing studies among linear echoendoscopes have only been performed following standard high-level disinfection (sHLD) or dHLD; the rate of contamination following alternative reprocessing methods has not been described.

Real-world observational data can help providers understand the risk of scope contamination by device type and reprocessing method. A natural experiment may be derived from an unplanned change in clinical practice. At our institution, a temporary pause in the availability of ETO provided the opportunity to understand differences in contamination rates among both duodenoscopes and linear echoendoscopes. We evaluated the difference in contamination between dHLD and HLD-ETO for both duodenoscopes and linear echoendoscopes. As a quality improvement intervention, we concomitantly assessed other factors that may affect the interpretation of the contamination rates of these endoscopes. Here, we have described differences in contamination rates when the definition of pathogen is varied, contamination risk among samples from the elevator mechanism and instrument channel, and contamination among duodenoscopes with a disposable tip.

Methods

Setting and study population

UPMC Presbyterian Gastrointestinal Endoscopy service maintains a fleet of 26 duodenoscopes and 20 linear echoendoscopes to perform ~1,000 endoscopic retrograde cholangiopancreatography and ~1,000 EUS procedures annually. Specific devices may be temporarily or permanently replaced due to inspection, repair, or upgrade. The duodenoscopes in this analysis included model number TJF-180V (Olympus Medical Systems, Tokyo, Japan) prior to March 2021. These were subsequently and simultaneously all replaced with model number TJF-Q190V (Olympus Medical Systems), a device with a detachable and disposable tip (Fig. 1). The linear echoendoscopes were model number GF-UC140P-AL5 (Olympus Medical Systems).

Reprocessing of duodenoscopes is performed in the gastrointestinal (GI) endoscopy laboratory by trained GI technicians according to the manufacturer's instructions for use. The sequential steps of reprocessing are summarized as follows: (1) application of a pretreatment immediately after use (Pre-Klenz, Steris Healthcare,

Mentor, OH); (2) visual inspection and manual cleaning (Prolystica, Steris Healthcare) using single-use brushes; (3) ultrasonic cleaning, detergent cleaning, rinsing, high level disinfection with acetic acid (5%), paracetic acid, hydrogen peroxide disinfectant (Acecide-C, Best Sanitizers, Penn Valley, CA); (4) rinsing, air purge, alcohol flushing, and a final air purge, all performed using an automated reprocessor (Olympus OER Olympus Medical Systems [Tokyo, Japan]); (5) drying for a minimum of 2 hours; and (6) storage in a facility-built, ventilated, closed cabinet.

Individuals performing reprocessing are trained by qualified experts and undergo competency re-evaluation annually. Quality control for automated disinfection is performed according to the manufacturer's specifications; no deviations were noted during the study period. The quality of manual disinfection was verified using biologic sampling (ChannelCheck, Olympus, Tokyo, Japan); no failures occurred during the study period.

Reprocessing methods

Duodenoscopes and linear echoendoscopes undergo reprocessing as described above and are then wrapped in sterile blue packaging and delivered to the central processing department where ETO is performed (3M Ethylene Oxide Sterilization Monitoring, St. Paul, MN). After ETO sterilization, the scopes are returned in sterile packing to the GI laboratory where they are stored maintaining sterility. During a planned shutdown of the ETO sterilizer from June 16, 2020 through July 15, 2020, reprocessed duodenoscopes and linear echoendoscopes underwent a repeated cycle of HLD (ie, double HLD or dHLD) without removing the device from the reprocessor in place of ETO sterilization (Fig. 1).

Definitions

In this study, endoscope was defined as a unique duodenoscope and linear echoendoscope sampled 1 or more times. An endoscope culturing event was defined as obtaining a sample for culture from the instrument channel and elevator mechanism (or in few cases, either the instrument channel or elevator mechanism). This metric was the denominator for frequency of endoscope contamination. Sample site refers to either the instrument channel or elevator mechanism, and the sample refers to the specimen obtained from the instrument channel or the specimen obtained from the elevator mechanism. The resulting endoscope culturing event culture refers to the combined outcome for the instrument channel and elevator mechanism (eg, positive from 1 or both samples).

Outcomes

The primary outcome was the comparison of the pathogenic contamination rate identified from culturing events among

endoscopes reprocessed by either dHLD or HLD-ETO. The coprimary outcome was the comparison of the pathogenic contamination rate between duodenoscopes and linear echoendoscopes processed by either reprocessing method.

Moreover, 5 secondary analyses were performed using the pathogenic contamination rate unless otherwise noted (eg, outcome of ≥1 pathogenic bacteria present in a sample of the elevator mechanism or instrument channel). We performed the primary analysis stratified by duodenoscopes and linear echoendoscopes type to assess effect modification by device type in the relationship between reprocessing method (HLD-ETO vs dHLD) and the frequency of contamination. Among duodenoscopes, we compared the frequency of contamination among standard model duodenoscopes and those with a detachable and disposable endoscope tip to determine whether this design modification resulted in a lower contamination rate. The primary outcome was compared to samples from the instrument channel and the elevator mechanism to understand the relative and independent contributions to duodenoscope contamination from these sampling sites. An analysis varying the outcome definition was performed to estimate the additional potential risk of endoscope contamination and transmission when fungal pathogens were considered in addition to bacterial pathogens. In these analyses, we qualitatively compared the primary analysis with alternate outcomes of pathogenic bacteria plus *Candida* spp and pathogenic bacteria plus any fungi. Lastly, we compared the frequency of the primary outcome among samples processed at a clinical microbiology laboratory versus a commercial environmental culture laboratory to validate the consistency of very similar microbiologic methods between these 2 laboratories. The change to a commercial laboratory occurred several months after dHLD use concluded (Fig. 1). Therefore, the comparison of outcomes between clinical and commercial laboratory processing was restricted to endoscopes reprocessed by HLD-ETO.

In a routine investigation, we followed a culture-positive endoscope (>1 CFU pathogenic bacteria or >10 CFU of any other bacteria or fungi). Endoscope use data were obtained from the automated reprocessor. Electronic health record review of patients who had a procedure with the affected endoscope within the prior 3 months or after the endoscope was last surveillance culture negative was performed to identify microbiologic laboratory findings with a culture matching or potentially matching the endoscope-cultured isolate. At the time of endoscope culture positivity, reprocessing practices were reviewed for potential breaches in reprocessing protocols, but none were found during this investigation.

Microbiologic methods

Samples were obtained for this study over a 15-month period from June 2020 through September 2021 (Fig. 1). Endoscopes were sampled after dHLD and drying or following ETO. As a quality assurance measure, we sampled every endoscope at least once per quarter and a minimum of 1 endoscope was cultured once each week based on the availability of the endoscope (ie, convenience sampling). The frequency of endoscope culturing increased to 3 culturing events per day, 4 days per week during the period when dHLD was performed in place of HLD-ETO for reprocessing

The sampling procedure was adapted from the FDA–CDC–ASM protocol[11] with the following modifications: The elevator mechanism and instrument channel samples were processed separately. The use of alcohol swab and sampling of the external surface was omitted. The sample processing method was modified.

The full sampling protocol is provided in the Supplementary Appendix (online). Sampling was performed by 2 people, including a trained infection prevention team member and GI technologist.

Prior to November 4, 2020, cultures were processed at a UPMC clinical laboratory, and after that time environmental cultures were processed in a commercial environmental sampling laboratory (Fig. 1). Summary microbiology methodologies for both laboratories are reported in the Supplementary Appendix (online). The gross contamination rate was defined as the number of endoscope cultures positive for growth of ≥1 colony-forming units (CFU) of ≥1 pathogenic organism or the growth of any bacteria or fungal organism in a quantity >10 CFU divided by the number of endoscopes cultured. The pathogenic contamination rate was defined as the number of endoscope cultures positive for the growth of ≥1 CFU of ≥1 pathogenic organism in either the elevator mechanism or instrument channel specimen divided by the number of endoscopes cultured. Pathogenic bacteria were defined as Enterobacteriaceae, *Pseudomonas* spp, *Pantoea* spp, *Acinetobacter* spp, *Stenotrophomonas* spp, *Enterococcus* spp, *Streptococcus* spp, and *Staphylococcus aureus*.[11] As an additional analysis of the findings, the definition of pathogenic organism was modified in 2 ways: (1) this list of pathogenic bacteria or growth of *Candida* spp and (2) this list of pathogenic bacteria or any fungal growth. As part of our institutional guidelines, when an endoscope culture became positive with either >1 CFU pathogenic bacteria or >10 CFU of any other bacteria or fungi, the sampled endoscope was removed from use, reprocessed, and recultured before reuse. The repeated culture events were included in this analysis.

Statistical analysis

All data were collected using Excel (Microsoft, Redmond, WA), and statistical analyses were performed using Stata version 15.1 software (StataCorp, College Station, TX). Risk ratios were calculated (including 95% confidence intervals) for the coprimary outcomes of frequency of contamination between duodenoscopes and linear echoendoscopes and between reprocessing with dHLD versus HLD-ETO. The Pearson χ^2 test of independence was used in the stratified analysis of frequency of contamination by endoscope type and reprocessing method. For all analyses, a $P \leq .05$ was considered statistically significant. The remainder of comparisons to accomplish secondary aims were exploratory in nature, and no effect estimates or statistical tests of significance were derived. For this quality improvement investigation, the sample size was defined by the period the interventions were undertaken and endoscope sampling performed. This study was approved by the UPMC Quality Improvement Review Committee (project no. 2791).

Results

Overall, 127 endoscope culturing events were completed between June 2020 and September 2021, of which 45 (35.4%) were linear echoendoscopes and 82 (64.6%) were duodenoscopes. Among all duodenoscopes, 27 (21.3%) had disposable tips. Of the 127 endoscope culturing events, 47 (37%) occurred after reprocessing with dHLD and 80 (63%) occurred after reprocessing with HLD-ETO. The 127 endoscope culturing events included 250 samples: 126 (50.4%) from the elevator mechanism and 124 (49.6%) from the instrument channel.

The study included 25 unique duodenoscopes (some had been sent for repair or had been replaced), and 11 (44.0%) of these had

Table 1. Frequency of Contamination with ≥1 Pathogenic Bacteria on Elevator Mechanism or Instrument Channel of Cultured Duodenoscopes, by Duodenoscope Type and Reprocessing Method

Duodenoscope Type	Reprocessing Method	Frequency of Pathogenic Bacteria (Positive/Total Cultured)	%	Risk Ratio (95% CI)	*P* Value
Duodenoscope or linear echoendoscope	dHLD or HLD-ETO	6/127	4.7	. . .	
Duodenoscope or linear echoendoscope	dHLD	4/47	8.5	Reference	
Duodenoscope or linear echoendoscope	HLD-ETO	2/80	2.5	0.29 (0.06–1.54)	.12
Duodenoscope	dHLD or HLD-ETO	2/82	2.4	Reference	
Linear echoendoscope	dHLD or HLD-ETO	4/45	8.9	3.64 (0.69–19.1)	.10
Duodenoscope	dHLD	2/29	6.9	. . .	
Duodenoscope	HLD-ETO	0/53	0	. . .	
Linear echoendoscope	dHLD	2/18	11.1	. . .	
Linear echoendoscope	HLD-ETO	2/27	7.4	. . .	

Note. CI, confidence interval; dHLD, double (repeat) high-level disinfection; HLD, high-level disinfection; ETO, ethylene oxide.

disposable tips. In addition, the study included 20 unique linear echoendoscopes. The 25 duodenoscopes in use during the study period were cultured a median of 3 times (range, 1–10). The 11 duodenoscopes with detachable tips were cultured a median of 2 times (range, 1–5). Lastly, the 20 linear echoendoscopes were cultured a median of 2 times (range, 1–5) (Supplementary Figs. S1 and S2 online).

All organisms identified are described in Supplementary Table S1 online). The most common bacterial pathogens were *Klebsiella pneumoniae*, *Pantoea* spp, and *Staphylococcus aureus*. A *Candida* sp was isolated in 32 (6.4%) of cultured endoscopes.

The pathogenic contamination rates among all endoscope culturing events were 6 (4.72%) of 127. The pathogenic contamination rate for the coprimary outcome comparisons of duodenoscopes versus linear echoendoscopes and HLD-ETO versus dHLD as well as the stratified analysis by endoscope type and reprocessing method are presented in Table 1. Contamination was highest with linear echoendoscopes undergoing dHLD (2 of 18, 11.1%), and was lowest in duodenoscopes undergoing HLD-ETO (0 of 53, 0%), including 27 endoscopes with disposable tips and 26 with nondisposable tips. The results of a post hoc analysis of these outcomes, excluding endoscope culturing events performed to confirm resolution of a pathogenic bacteria, is presented in Supplementary Table S2 (online).

The pathogenic contamination rate was 2.4% (2 of 82) for all models of duodenoscopes disinfected by either dHLD or HLD-ETO. For models without a detachable tip, the pathogenic contamination rate was 3.6% (2 of 55). The pathogenic contamination rate was 0% (0 of 27) for models with a detachable tip

For 3 culturing events, the elevator channel was sampled but the instrument channel sample could not be processed. For 1 culturing event, the instrument channel was the only site sampled. All 4 of these instances were due to sample leak during transport to the laboratory. The pathogenic contamination rate from elevator mechanism samples was 4.8% (6 of 126), and the pathogenic contamination rate from instrument channel samples was 2.4% (3 of 124). Moreover, 9 culturing events were positive for ≥1 pathogenic bacteria on the instrument channel or the elevator channel. Among them, 3 cultures were positive on both the instrument channel and elevator mechanism samples; 3 cultures were only positive from the instrument channel sample; and 3 cultures were only positive from the elevator mechanism sample. Of the 3

endoscope cultures positive from both the elevator mechanism and instrument channel, 1 was identified as having the same pathogen on both, which was *Klebsiella pneumoniae*. In the other 2 samples, a different species of pathogen was identified from each sample. In both cases, *Acinetobacter* sp was identified from the instrument channel and *Staphylococcus aureus* from the elevator mechanism.

The gross contamination rate among all endoscope culturing events was 71.7% (91 of 127). The gross contamination rate varied from 70.0% to 74.5% among duodenoscopes and linear echoendoscopes reprocessed by dHLD or HLD-ETO (Supplementary Table S3 online).

The overall pathogenic contamination rate increased from 4.7% to 10.2%. when including *Candida* spp and to 14.2% when including all pathogenic fungi with pathogenic bacteria (when the definition of significant pathogen was broadened). The frequency of pathogen contamination using these 2 alternative definitions by endoscope type and reprocessing method is described in Supplementary Table S4 (online).

The gross contamination rate identified at the clinical microbiology laboratory (N = 67) versus a commercial environmental laboratory (N = 60) did not change appreciably for culturing events overall (71.6% and 71.7%, respectively) (Supplementary Table S5 online). Absolute differences stratified by endoscope type and reprocessing method were <7%. The gross and pathogenic contamination rate among endoscope samples, by endoscope sampling location, are presented in Supplementary Table S6 (online). No patient had a clinical infection attributable to a culture-positive endoscope.

Discussion

In this observational study of duodenoscope and linear echoendoscope contamination, overall contamination with ≥1 pathogenic bacteria on the instrument channel or elevator mechanism of duodenoscopes was 4.7%. Linear echoendoscopes had a higher though statistically nonsignificant contamination rate than duodenoscopes (8.9% vs 2.4%), and the overall risk of contamination after HLD-ETO was lower than following reprocessing with dHLD (2.5% vs 8.5%), also not a statistically significant difference. The use of a duodenoscope with a disposable tip may decrease the risk of duodenoscope contamination after reprocessing. Adding

Candida spp to the definition of potential pathogens transmitted by duodenoscope may significantly increase the estimate of reprocessing failure.

Even though there was some difference between ETO and dHLD, ETO does not eliminate contamination. A meta-analysis showed that switching to either ETO or dHLD led to an estimated contamination rate of 9.2%, which is within the range of the contamination rates we observed.[1] Evaluations of other interventions are needed to help decrease transmission risk.

Disposable tips on duodenoscopes have been suggested to improve contamination rates. In our study, disposable tips eliminated the positivity rate in duodenoscopes, but the sample size was small. To date, this study is the first to evaluate the contamination rates of endoscopes designed with a disposable tip. Further study is warranted to validate the lower contamination risk.[12,13]

Linear echoendoscopes have been underappreciated as an additional risk for contamination. The FDA and other organizations have focused their efforts on the contamination rate of duodenoscopes.[4] Previous studies have noted rates of contamination in linear echoendoscopes comparable to our findings.[7,14] In our study, we concurrently cultured both duodenoscopes and linear echoendoscopes to provide a more direct comparison of the relative risk of linear echoendoscope contamination. We found contamination rates to be comparable to those observed in duodenoscopes. Linear echoendoscopes should be included in microbiologic surveillance to ensure high-quality reprocessing.

Our findings support assessing risk beyond bacterial contamination. *Candida* and pathogenic fungi have not been correlated with duodenoscope-associated infections to date but have been shown to have significant outcomes on patients who develop infection.[15] In this study, we identified no clinically significant infections resulting from endoscope transmission. However, more information is needed to establish the clinical risk of positive endoscopes. Increasing the microbiologic methods of culturing to include fungal contamination could show possible unidentified prior risk.

This observational study had several limitations. Our comparison of HLD-ETO and dHLD was not randomized and covered different periods because this was a natural experiment based on an involuntary switch that affected only reprocessing without changing other practices. This study was a quality improvement project; it was underpowered for power calculations and did not include predetermined sample sizes. The small sample sizes made it difficult to demonstrate statistically significant differences in the effectiveness of dHLD versus HLD-ETO. However, this study was conducted in a real-world setting in a healthcare facility.

Contamination rates with pathogenic bacteria remained ~5% in this observational quality improvement study even after all manufacturer recommendations for reprocessing were followed. Risk was not eliminated with the use of ETO sterilization. Incorporating linear echoendoscopes into facilities risk assessments is vital to decreasing risk. Expanding risk to incorporate fungi will be vital in understanding current unknown risk. Additional information is needed to determine the value of disposable tips and the decision on dHLD versus HLD-ETO.

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