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Major Article

Duodenoscope hang time does not correlate with risk of bacterial contamination

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Background: Current professional guidelines recommend a maximum hang time for reprocessed duodenoscopes of 5-14 days. We sought to study the association between hang time and risk of duodenoscope contamination.

Methods: We analyzed cultures of the elevator mechanism and working channel collected in a highly standardized fashion just before duodenoscope use. Hang time was calculated as the time from reprocessing to duodenoscope sampling. The relationship between hang time and duodenoscope contamination was estimated using a calculated correlation coefficient between hang time in days and degree of contamination on the elevator mechanism and working channel.

Results: The 18 study duodenoscopes were cultured 531 times, including 465 (87.6%) in the analysis dataset. Hang time ranged from 0.07-39.93 days, including 34 (7.3%) with hang time ≥7.00 days. Twelve cultures (2.6%) demonstrated elevator mechanism and/or working channel contamination. The correlation coefficients for hang time and degree of duodenoscope contamination were very small and not statistically significant (–0.0090 [$P = .85$] for elevator mechanism and –0.0002 [$P = 1.00$] for working channel). Odds ratios for hang time (dichotomized at ≥7.00 days) and elevator mechanism and/or working channel contamination were not significant.

Conclusions: We did not find a significant association between hang time and risk of duodenoscope contamination. Future guidelines should consider a recommendation of no limit for hang time.

Recent outbreaks of infections due to multidrug-resistant bacterial pathogens associated with contaminated endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes have intensified interest in practices that mitigate the risk of duodenoscope contamination. These outbreaks have been described with and without evidence of a lapse in reprocessing techniques, and in some cases have prompted empirical use of ethylene oxide (ETO) gas sterilization.[1,2] Parts of the duodenoscope are difficult to access for cleaning and disinfection, including removal of biofilm. The inherent design of these devices has been proposed as a possible mechanism for persistent contamination, and thus growth while the duodenoscope is stored following reprocessing.[3] Therefore, an important aspect of managing duodenoscope reprocessing that has been subject to debate is the hang time (also known as shelf life), or the duration of time between duodenoscope reprocessing and use.

Current guidelines recommend reprocessing ERCP duodenoscopes if not used (ie, hang time) within 5-14 days.[4,5] However, uncertainty in this duration has been acknowledged, and the possibility cannot be excluded that there is no additional growth for hang times exceeding this duration.[6] A recent systematic review identified 10 studies investigating hang time for flexible endoscopes, with no change in the rate of contamination over the hang time duration studied (at least 2-7 days, including up to 56 days).[7] The 4 studies specifically investigating duodenoscopes included a total of 19 duodenoscopes and 88 samples.[7-10] However, hang time only exceeded 7 days in a single of these studies.[10] Available data

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investigating markedly longer hang times among duodenoscopes and other endoscopes demonstrate a low to zero rate of culture positivity, although for a limited sample size.[11,12]

In this study, we sought to characterize the risk of bacterial contamination among ERCP duodenoscopes, particularly with a hang time longer than 5-14 days.

MATERIALS AND METHODS

Study setting

This study was undertaken as a secondary analysis of data collected during the DISINFECTS study (Duodenoscope Infection Surveillance IN Functioning automated Endoscope reprocessors in Conjunction with eThylene oxide Sterilization; NCT02611648), which was reviewed and approved by the institutional review board of the study institution. The study was conducted at a tertiary care center performing approximately 1,500 ERCP procedures annually. Briefly, the DISINFECTS study was a prospective, randomized trial investigating 3 methods of reprocessing ERCP duodenoscopes: standard high-level disinfection (sHLD), sHLD with a repeated (double) cycle of disinfectant exposure (dHLD), and sHLD followed by ETO gas sterilization (sHLD/ETO).[13] During the study, the 18 ERCP duodenoscopes were assigned to a reprocessing arm for the duration of the study (sHLD, dHLD, or HLD/ETO in a 5:5:8 ratio) and were selected using a block randomization scheme for clinical use in a procedure when the need for an ERCP duodenoscope was anticipated. All 18 ERCP duodenoscopes were the same model and manufacturer (model TJF-Q180V; Olympus, Shinjuku, Tokyo, Japan), of which 7 (38.9%) were purchased shortly before study initiation (ie, 2015; new duodenoscopes) and 11 (61.1%) were previously acquired during 2012 (in-service duodenoscopes).

ERCP duodenoscopes were cultured in a highly standardized fashion after reprocessing and before anticipated use, including a swab sample of the elevator mechanism and a flush-brush-flush sampling of the working channel. ERCP duodenoscopes not used within 1 calendar day subsequent to culture or not used during the procedure were sent for reprocessing. During the study investigators selected, when feasible, a duodenoscope for culturing and use that was least recently reprocessed, resulting in an asymmetric distribution of hang time ≥7 days and <7 days. Otherwise, the hang time of a duodenoscope was not influenced by observable factors and occurred in an as-practiced or stochastic fashion.

ERCP duodenoscope reprocessing and microbiologic methods

Immediately following the completion of each procedure, ERCP duodenoscopes received a manual wipe of the exterior and a flush of the working channel with enzymatic solution (EmPower; Metrex, Orange, CA). Manual reprocessing then took place within 1 hour of procedure completion consistent with the manufacturer's guidelines for use, and included the use of a brush specific to the elevator mechanism as well as manual wire brush cleaning of the working channel.[14] Reprocessing was completed using automated endoscope reprocessors (System 83 Plus 9; Custom Ultrasonics, Ivyland, PA) with orthophthalaldehyde (MetriCide OPA Plus; Metrex) disinfectant followed by flushing with alcohol and then compressed air. ERCP duodenoscopes are hung vertically for drying in a cabinet without circulated or ventilated air. ETO gas sterilization was performed with a Steri-Vac Sterilizer/Aerator (3M, Maplewood, MN). Dedicated cleaning technicians and specialty nurses are trained in the process according to the manufacturer's instructions for use, with periodic competency re-evaluations.

The culturing process was adapted from the procedure recommended by the Centers for Disease Control and Prevention and included the sampling of the working channel and elevator mechanism.[15] Sampling was performed with the researcher wearing bouffant cap, face mask with shield, sterile gown, and sterile gloves over a field prepped with a sterile surgical drape. A dry flocked swab (ESwab with liquid Amies media; Copan Diagnostics, Murrieta, CA) was used to sample under the elevator, the top and the bottom of the elevator, and over the face of the duodenoscope tip, using a swirling motion. The working channel was sampled using sterile water and a sterile wire brush in a flush-brush-flush method: the channel was flushed with a standardized volume of sterile water; a sterile channel brush was inserted the entire length of the duodenoscope, removed, and the brush tip was agitated in the collected sterile water for 10 seconds; and finally a second standardized volume of sterile water was flushed through the duodenoscope and collected with the first flush and brush-agitated specimen. After sampling, air was forced through the scope to promote drying.

Elevator mechanism and working channel specimens were processed in the study laboratory directly after collection or after refrigeration (at temperatures 2°C-8°C) in transport media or phosphate-buffered solution for no more than 72 hours.[16] Elevator mechanism swabs were vortexed in transport media and the subsequent virtual pellet was plated and incubated aerobically on Mueller-Hinton agar plates. Working channel samples were vortexed and a pellet was withdrawn twice in sequence and then plated to Mueller-Hinton agar. Bacterial growth (in colony forming units) was quantified after overnight incubation.

Statistical analysis

The exposure of interest in this analysis was hang time, defined as the duration of time in days between ERCP duodenoscope reprocessing and sampling of elevator mechanism and working channel for culture. Observations with incomplete data or observations following procedures in which the duodenoscope did not have patient contact (eg, would not be at risk for contamination from the gastrointestinal tract) were excluded. Hang time was dichotomized at the commonly used and guideline-commensurate cutoff of <7.00 days and ≥7.00 days. Exact reprocessing times were not available at our institution; therefore, we estimated the start of hang time using the preceding procedure end date and time, because the time elapsed between procedure end and reprocessing (within 1 hour) and time to complete reprocessing was short and relatively fixed.

The primary outcome was the relationship between hang time and risk of bacterial contamination, calculated as a correlation coefficient between hang time and colony forming units, for each elevator mechanism and working channel in serial. Additionally, we characterized the relationship between a dichotomized exposure (hang time ≥7.00 days) and outcome (significant contamination, defined as the presence of ≥10 CFU aerobic bacterial growth on either the elevator mechanism or working channel[17]) by calculating an odds ratio (OR) with 95% confidence intervals and *P* values using logistic regression. Because the probability of persistent contamination may differ based on the sampled location on the duodenoscope, an OR was also calculated for the relationship between hang time ≥7 days and elevator mechanism and working channel contamination, respectively. Additionally, we hypothesized that duodenoscope age (new vs in-service duodenoscopes) may serve as an effect modifier of the relationship between hang time and duodenoscope contamination. Therefore, we calculated stratified OR among cultures performed on previously owned versus newly purchased duodenoscopes. We also hypothesized that study arm (dHLD and HLD/ETO, compared with sHLD) may confound the relationship between hang time and duodenoscope contamination, and we therefore calculated an adjusted OR for hang time in a multivariable logistic regression that included study arm. *P* values < .05 were considered significant. Analyses were performed using STATA version 12.1 (StataCorp, College Station, TX).