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Major Article

Improper positioning of the elevator lever of duodenoscopes may lead to sequestered bacteria that survive disinfection by automated endoscope reprocessors

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High-level-disinfection
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Background: Some outbreaks associated with contaminated duodenoscopes have been attributed to biofilm formation. The objective of this study was to determine whether bacteria within an organic matrix could survive if the elevator lever was improperly positioned in the automated endoscope reprocessor (AER) after 1 round of reprocessing.

Methods: Duodenoscope lever cavities with an open or sealed elevator wire channel were inoculated with 6-7 Log_{10} of both *Escherichia coli* and *Enterococcus faecalis* in ATS2015 (Healthmark Industries, Fraser, MI) and dried for 2 hours. The duodenoscopes with the lever in the horizontal position were processed through 2 makes of AERs. The cavity was sampled using a flush-brush-flush method to determine the quantity of surviving bacteria.

Results: *E faecalis* (range, 21-6 Log_{10} CFU) and *E coli* (range, 0-3 Log_{10} CFU) survived disinfection of sealed or unsealed elevator wire channel duodenoscopes in 2 different AERs with and without cleaning cycles.

Conclusion: If bacteria in organic residue are under the improperly positioned lever, then just 1 round of use is sufficient for bacteria to survive both liquid chemical sterilization and liquid chemical HLD regardless of whether or not the AER had a cleaning cycle.

Despite numerous reviews of the outbreaks of multiantibiotic-resistant organisms transmitted through contaminated endoscopes[1-4] and manufacturer instructions regarding lever position,[5] there are no recommendations that staff document the lever position when duodenoscopes are placed into an automated endoscope reprocessor (AER) for disinfection.[6] Alrabaa et al[7] reported the presence of visible debris under the elevator lever in fully reprocessed patient-used duodenoscopes that were culture-positive for carbapenemase-producing *Escherichia coli* despite having undergone high-level disinfection (HLD). A critical question that remains unanswered is, How much accumulated material is necessary to cause failure of disinfection in the elevator lever cavity such that bacteria can survive HLD? The objective of this study was to determine whether 1 round of sequestered bacteria within a clinically relevant organic matrix[8]

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Conflicts of interest: MJA has acted as a consultant and received research funds from 3M, Olympus, Karl Storz, Novaflux, and Steris. She receives royalties from the University of Manitoba for license of a patent to Healthmark Industries and has been an invited conference speaker sponsored by Olympus, 3M, and Sealed Air. HS is on the advisory board of Pendopharm and Ferring Canada, and has received research funds from Merck Canada. DRD is on the advisory board of Shire Canada.

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could survive HLD if the elevator lever was in the wrong position (horizontal) in the AER.

MATERIALS AND METHODS

Simulated-use study: Duodenoscopes AERs

The Olympus duodenoscopes (Olympus Corporation of the Americas, Center Valley, PA) used included a JF-140F model (unsealed elevator guide wire) and a TJF-Q180V model (sealed elevator guide wire). The Steris System 1E (SS1E) (Steris Inc, Mentor, OH) and the Advantage Plus (AP) (Medivators Inc, Minneapolis, MN) AERs were used. The AP AER has a cleaning cycle that used Intercept (Medivators Inc) as the detergent.

Inoculation of duodenoscope lever cavity

E coli (ATCC 25922) and *Enterococcus faecalis* (ATCC 29212) were suspended in ATS2015 (Healthmark Industries, Fraser, MI) supplemented with 20% defibrinated sheep blood to achieve an approximate concentration of 10^8 CFU/mL as described by Alfa et al.[8] Then, 0.1 mL suspension was placed behind the lever as shown in Figure 1. The lever was then moved down and up 3 times. After worst-case drying for 2 hours (ie, 1 hour dry followed by 1 hour using gentle vacuum) the lever was placed in the horizontal position (Fig 1) and the inoculated duodenoscope was processed (without any cleaning) in either the SS1E or AP AER.

Sample collection from duodenoscope lever cavity

The fully processed duodenoscope was aseptically removed from the AER (gown, face shield, and sterile gloves) and the endoscope control head was secured by clamping it to a stand and the distal end was placed on a large piece of sterile foil. A sterile plastic transfer pipette (Fisherbrand, Ottawa, ON, Canada) and a tiny white brush (Olympus brush MAJ-1888) were used to collect the sample as described in Figure 1 using a flush-brush-flush technique. An equal volume (2 mL) of neutralizer[9] was added to the sample. The sample was sonicated for 5 minutes and then mixed for 1 minute. Serial 1:10 dilutions in sterile phosphate buffered saline were prepared and 0.1 mL direct sample and each dilution were spread over the surface of blood agar plates and incubated aerobically at 35°C for 48 hours and then colonies were counted. All testing was performed in triplicate.

Statistical analysis

The 2-tailed Student *t* test was used to compare the levels of residual colony forming units after disinfection.

RESULTS

Variable levels of both bacteria survived the disinfection process for duodenoscopes with sealed (ie, TJF-Q180V) or unsealed (ie, JF-140F) elevator wire channels (Table 1). The number of surviving *E faecalis* colonies was consistently higher than for *E coli* for all testing, but only achieved significantly higher levels in the JF-140F duodenoscope processed through the SS1E AER ($P = .004$). There were more *E coli* residuals remaining in the JF-140F duodenoscope compared with the TJF-Q180V duodenoscopes, but this was statistically significant only for the SS1E AER ($P < .001$) and marginally nonsignificant for the AP AER ($P = .07$).

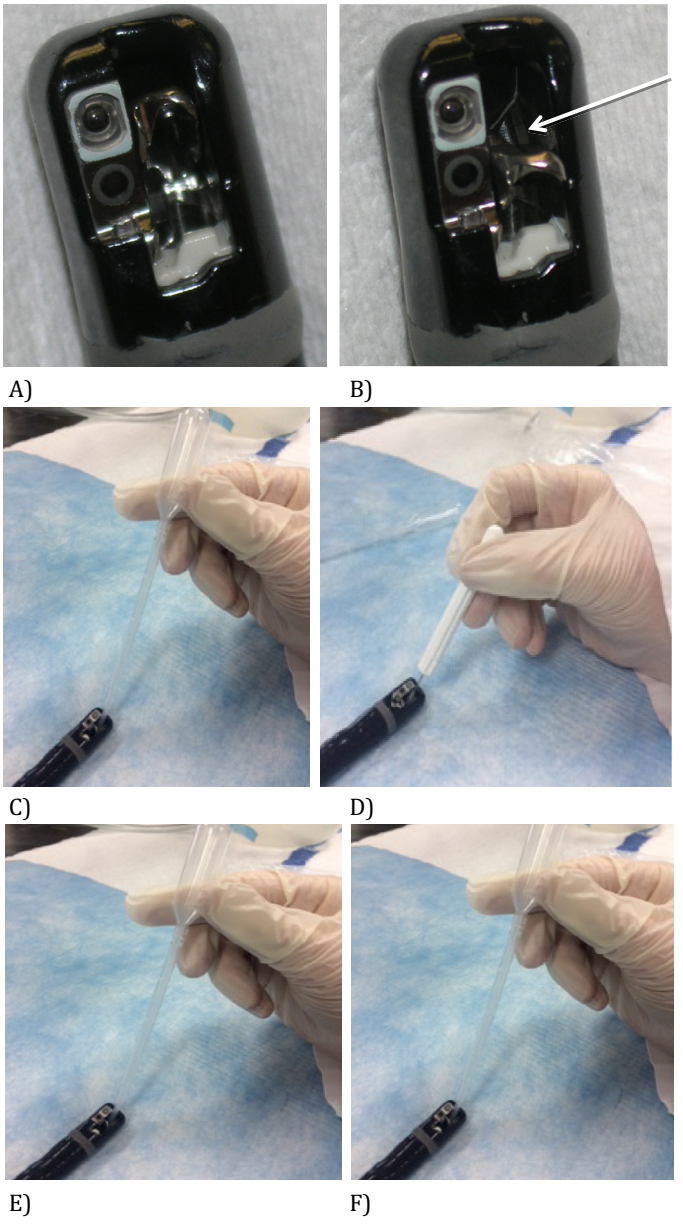

Fig 1. Inoculation and sample collection from the elevator lever cavity of a duodenoscope. The lever position of a TJF-Q180V duodenoscope is shown in the (A) horizontal (B) vertical position. The white arrow indicates where the 0.1 mL inoculum (approximately 10^7 Log_{10} CFU in 0.1 mL ATS-2015 [Healthmark Industries, Fraser, MI]) was placed and allowed to dry. Before placing the inoculated duodenoscope into the automated endoscope reprocessor, the lever was positioned in the horizontal position (A). After high-level disinfection, a sterile plastic transfer pipette (C) was used to instill sterile reverse osmosis water into the cavity and then a tiny bristle brush was used to brush above and below the lever and the lever cavity (D) and the tip of the brush was cut into the sample collection container. Then a plastic transfer bulb (C) was used to aspirate the fluid from the cavity and transfer it to the collection container (Flush 1). A second flushing (Flush 2) of the cavity (E) was also done (no brushing) and the fluid was transferred to the collection container.

DISCUSSION

Our simulated use study provides the first published data showing that if the elevator lever is in the incorrect position (ie, in the horizontal position instead of the 45° position), the AER disinfection cycle cannot provide the expected 6 Log_{10} kill if bacteria are

Table 1
Survival of bacteria in simulated-use testing when duodenoscope elevator lever was in incorrect position in the automated endoscope reprocessor (AER)

	Number of bacteria recovered after disinfection Log_{10} CFU/lever sample*	
Duodenoscope tested	*Enterococcus faecalis*	*Escherichia coli*
	Processed through Steris System 1E	
JF-140F	6.18	1.71
	5.74	1.62
	6.71	0.0
Mean ± standard deviation	6.21 ± 0.48	1.11 ± 0.96
TJF-Q180V	3.13	0.0
	2.48	0.0
	6.25	0.0
Mean ± standard deviation	3.95 ± 2.01	0.0 ± 0
	Processed through Advantage Plus	
JF-140F	3.03	1.71
	2.82	0.0
	5.24	3.36
Mean ± standard deviation	3.69 ± 1.34	1.69 ± 1.68
TJF-Q180V	2.86	1.79
	1.49	0.0
	1.31	0.0
Mean ± standard deviation	1.89 ± 0.85	0.60 ± 1.03

*The inoculum placed in the lever cavity of both JF-140F and TJF-Q180V endoscopes was 7.21 Log_{10} CFU *E faecalis* and 6.93 Log_{10} CFU of *E coli* for the SS1E (Steris Inc, Mentor, OH) AER testing and 7.13 Log_{10} CFU *E faecalis* and 7.69 Log_{10} CFU *E coli* for the Advantage Plus (Medivator, Minneapolis, MN) AER testing. Negative controls (uninoculated duodenoscopes [triplicate tests] processed through the SS1E or Advantage Plus AERs) showed no detectable growth. All mean Log_{10} colony forming units data in Table 1 represent 3 replicates (each replicate used a separate fully reprocessed duodenoscope). The value 0 represents less than the limit of detection for the culture method (limit of detection was Log_{10} 1.30 CFU/cavity sample) and for calculation of mean ± standard deviation Log_{10} 0 was set to 0. There was no significant difference in the level of surviving *E coli* or *E faecalis* in the lever cavity of either duodenoscope type processed through the SS1E compared with Advantage Plus AER. There were more *E coli* residuals remaining in the JF-140F duodenoscope compared with the TJF-Q180V duodenoscope, but this was statistically significant only for the SS1E AER ($P < .001$ for SS1E and $P = .07$ for Advantage Plus AER).

sequestered under the lever within an organic matrix regardless of whether or not the AER has a cleaning cycle. One might argue that there would always be some cleaning of the lever cavity before placement in an AER. However, Alrabaa et al[7] reported visible debris under the duodenoscope lever in patient-used duodenoscopes after HLD, confirming that there are instances where worst-case persistent soiling may occur in clinical practice. Our data extend the findings of Alrabaa et al[7] and show that even 1 round of improper positioning of the elevator lever may result in bacteria survival. ATS2015 has been shown to mimic human secretions that duodenoscopes are exposed to during clinical use, so it is a relevant organic challenge.[8] Our data highlight the narrow margin of safety because neither repeated rounds of improper lever positioning or biofilm formation were needed for bacteria to survive HLD in AERs. This emphasizes the need to thoroughly train reprocessing staff regarding the meticulous cleaning and proper lever position when placed into an AER. We recommend that the lever position be rechecked and documented when a duodenoscope is removed from the AER. If the lever position is incorrect, the duodenoscope should have HLD repeated (or if visible debris is observed under the lever, then both cleaning and HLD should be repeated).

Limitations of our study include small sample size and that we did not test inoculated simulated-use endoscopes with the lever in the correct position. Further studies are needed to determine the margin of safety of the AERs by testing duodenoscopes inoculated with 7 Log_{10} bacteria in an organic matrix with the lever in the correct position (ie, can the AER compensate for improperly cleaned lever cavities when the lever is correctly positioned?).

CONCLUSIONS

Our simulated-use data demonstrate that 1 round of improper elevator lever position was sufficient to sequester bacteria in organic residue and thereby allow them to survive both liquid chemical sterilization and liquid chemical HLD regardless of whether or not the AER had a cleaning cycle. We recommend that endoscopy clinics using duodenoscopes with elevator levers should ensure thorough training of reprocessing staff about the narrow margin of safety regarding lever position when a duodenoscope is placed in an AER. Furthermore, documentation of the duodenoscope lever position in the AER would be a useful quality assurance measure.

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