Abstract # 1194

Efficacy of shortened high-level disinfection (HLD) protocols for GI duodenoscopes with disposable tips used for endoscopic retrograde cholangiopancreatography (ERCP)

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Abstract

Background: The most efficient combination of manual washes (MW) and high-level disinfection (HLD) cycles for the reprocessing of duodenoscopes used for ERCP is unknown. The FDA recently announced the national recommendation for transition to duodenoscopes with disposable components.

Methods: We studied contamination rates of Pentax Medical duodenoscopes with disposable tips used for ERCP. Duodenoscopes were cleaned and disinfected following removal of the disposable tip. First, one manual wash was performed with detergent and brushes that fit into the suction channel, air/water valves, cylinder, and elevator chamber. Afterward, the duodenoscope underwent HLD with an automated endoscope re-processor. Our study evaluated the success of an abbreviated cycle of one MW followed by one HLD (MW-HLD) cycle compared to a pair of MW-HLD cycles. Each duodenoscope was sampled in 4 locations after the first MW-HLD cycle and the second: 1) The elevator tab, 2) elevator channel distal opening, 3) composite duodenoscope tip, and 4) the elevator channel (Figure 1). Samples 1-3 were collected with flocked swabs. Swabs were plated on routine medias for relevant enteric pathogens. The 4th was collected by flushing 25 mL of neutralizing buffer through the elevator channel, then scrubbing the channel with a brush, followed by another 25 mL flush. The 50 mL eluent was vacuum filtered through a 0.22-micron filter and plated on TSA. Antibiotic resistance was assessed via PCR. CFU and proportion of contaminated scopes were compared between MW-HLD cycles.

Results: 46 duodenoscopes were sampled from September 2021 through March 2022 resulting in 92 sample events and 368 total samples. After one MW-HLD cycle, 19 of 46 (41%) duodenoscopes remained contaminated, including 5 (11%) with VRE (Table 1). After two MW-HLD cycles, 11 (24%) remained contaminated and 0 (0%) with VRE (p=0.08, 0.02, respectively). Results were similar at the sample location level (p=0.03, 0.01, respectively).

Conclusion: Our data demonstrate that 1 MW-HLD cycle is insufficient at decontaminating duodenoscopes with disposable tips but do support the use of two MW-HLD cycles. VRE was identified after one MW- HLD cycle, but not after two MW-HLD cycles. Further studies are needed to determine the optimal combination of MWs and HLDs while minimizing HLD staff time.

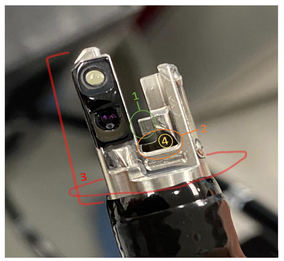
Background

- FDA recommended transition to duodenoscopes with disposable components or entirely disposable (2019)
- Prior reprocessing studies focused on reusable scopes and recommend 1 manual wash (MW) and 1 high-level disinfection (HLD) cycle
- DUHS: 1) Scopes with disposable end caps 2) SOP: (MW-HLD) x 2
- Objective: Can we safely reduce to (MW-HLD) x 1?

Methods

- Prospective observational study, Duke University Health System, of contamination of Pentax duodenoscopes with disposable tips used for ERCP. 9/2021 – 3/2022
- Evaluated an abbreviated cycle of one MW followed by one HLD (MW-HLD) cycle compared to a pair of MW-HLD cycles
- Each study scope was sampled after one MW-HLD cycle, and again after a 2nd MW-HLD cycle
- Microbiological Cultures: 1) The elevator tab, 2) elevator channel distal opening, 3) composite duodenoscope tip, 4) the elevator channel (Figure 1)
  - 1-3 collected with flocked swabs
  - 4th collected by flushing 25 mL of neutralizing buffer through the elevator channel, then scrubbing the channel with a brush, followed by another 25 mL flush
  - Processed via standard microbiological lab techniques

Figure 1. Duodenoscope tip



- Cultures were assessed for any bacterial flora as well as *C. difficile*, Gram-negatives, and *Enterococci spp.*
- Antibiotic resistance was assessed via PCR. CFU and proportion of contaminated scopes were compared between MW-HLD cycles

Results

Size: 46 duodenoscopes, 92 sample events and 368 total samples

One MW-HLD cycle: 19 of 46 (41%) duodenoscopes remained contaminated, including 5 (11%) with VRE (Table 1)

Two MW-HLD cycles: 11 (24%) remained contaminated and 0 (0%) with VRE (p=0.08, 0.02, respectively)

Results similar at the sample location level (p=0.03, 0.01, respectively).

Table 1. Proportion of duodenoscopes contaminated with any flora and Vancomycin-resistant Enterococcus spp.

	Total n (%) N = 92		MW-HLD x1 n (%) N = 46		MW-HLD x2 n (%) N = 46		p value MW-HLD x1 vs x2	
	Flora	VRE	Flora	VRE	Flora	VRE	Flora	VRE
Duodenoscope	24 (26)	5 (5)	19 (41)	5 (11)	11 (24)	0 (0)	0.08	0.02
Sample Location								
Elevator Tab	9 (10)	2 (2)	6 (13)	2 (4)	3 (7)	0 (0)	0.29	
Elevator Channel Opening	8 (9)	2 (2)	5 (11)	2 (4)	3 (7)	0 (0)	0.46	
Composite	10 (11)	2 (2)	8 (17)	2 (4)	2 (5)	0 (0)	0.04	
Flush Output	12 (13)	0 (0)	7 (15)	0 (0)	5 (11)	0 (0)	0.54	
Total	39 (11)	6 (2)	26 (14)	6 (3)	13 (7)	0 (0)	0.03	0.01

Conclusions

- 1 MW-HLD cycle was insufficient at decontaminating duodenoscopes with disposable tips compared to two MW-HLD cycles
  - 41 vs. 24% contaminated overall
  - VRE was identified after one MW- HLD cycle (11%), but not after two MW-HLD cycles
- Further studies are needed to determine the optimal combination of MWs and HLDs while minimizing HLD staff time