Evaluation of Abbreviated HLD Protocols for Duodenoscopes with Disposable Tips

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Duodenoscopes with disposable tips are an intermediary between reusable and disposable endoscopes.

We asked if disposable tips decreased the need for 2 cycles of high-level disinfection, as is currently recommended by the FDA.

Based on our evidence, duodenoscopes contaminated by vancomycin-sensitive and resistant *Enterococcus spp* require 2 cycles of HLD for decontamination, despite disposable tips.

INTRODUCTION

- Recent observational studies suggest duodenoscopes with disposable tips have lower rates of bacterial contamination compared to fully reusable duodenoscopes
- However, it is unclear if the reprocessing of duodenoscopes with disposable tips can be abbreviated without compromising disinfection efficacy

STUDY DESIGN

- Two-phase prospective observational study utilizing an abbreviated protocol for the disinfection of Pentax Medical ED34-i10T2 duodenoscopes with disposable tips

METHODS

1. Phase 1 (P1) Oct 2021 - Mar 2022: Abbreviated Protocol
   - One manual wash (MW) prior to one cycle of high-level disinfection (HLD)
2. Phase 2 (P2), Apr - May 2022: Standard HLD Protocol
   - samples obtained after two MWs and one HLD

**Each duodenoscope was sampled in 4 locations (Figure 1)*

- Samples were plated on routine medias for enteric pathogens including *Clostridium difficile* and *Enterococcus spp.* Antibiotic resistance was assessed via PCR for Vancomycin sensitive or resistant *Enterococcus* (VSE/VRE)
- One-sided Fisher's exact test was done to assess for differences in bacterial growth at each sample site between study phases

RESULTS

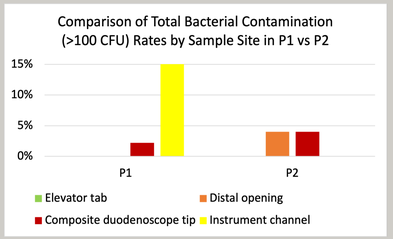
Contamination was defined by >100 CFU raw growth and >1 CFU *C difficile* and VSE and VRE (per FDA)

P1: 46 duodenoscopes were sampled at 4 sites resulting in 184 sample events. 8 of 184 sites (4.3%) (8 unique duodenoscopes) had raw growth >100 CFU. 11 sites (6.0%) (8 unique scopes) grew VRE or VSE. None grew *C difficile*.

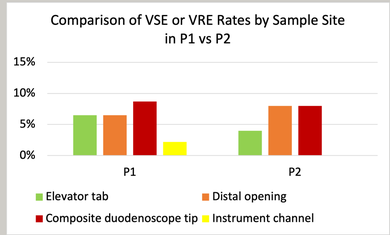
P2: 25 duodenoscopes were sampled at 4 sites resulting in 100 sample events. 2 of 100 sites (2%) (2 unique duodenoscopes) had raw growth >100 CFU. 5 sites (5%) (4 unique duodenoscopes) grew VRE. None grew *C difficile*.

P1 vs P2:
There were no significant differences in total bacterial or VSE/VRE presence for all sample sites.

Figure 1. Sample locations:
1) The elevator tab
2) instrument channel distal opening
3) composite duodenoscope tip
4) the instrument channel



	P1 N= 46 (95% CI)	P2 N= 25 (95% CI)
Elevator tab	0 (0%) (0%, 7.7%)	0 (0%) (0%, 13.7%)
Distal opening	0 (0%) (0%, 7.7%)	1 (4.0%) (0.1%, 20.4%)
Composite Tip	1 (2.2%) (0.1%, 11.5%)	1 (4.0%) (0.1%, 20.4%)
Instrument Channel	7 (15.2%) (6.3%, 28.9%)	0 (0.0%) (0%, 13.7%)



	P1 N= 46 (95% CI)	P2 N= 25 (95% CI)
Elevator tab	3 (6.5%) (1.4%, 17.9%)	1 (4.0%) (0.1%, 20.4%)
Distal opening	3 (6.5%) (1.4%, 17.9%)	2 (8.0%) (1.0%, 26.0%)
Composite Tip	4 (8.7%) (2.4%, 20.8%)	2 (8.0%) (1.0%, 26.0%)
Instrument Channel	1 (2.2%) (0.1%, 11.5%)	0 (0.0%) (0%, 13.7%)

DISCUSSION

- In our study, one MW did not grow significantly more bacteria compared with two MW prior to HLD
- This suggests that one MW may be sufficient in achieving adequate HLD in duodenoscopes with disposable tips
- However, the upper CI limit for 3 sites after two MW included higher rates of contamination, likely explained by the small sample size, or by two MW causing more biofilm disruption

CONCLUSIONS

- Duodenoscopes with disposable components appear to have decreased bacterial contamination but bacteria do remain
- Our data provide impetus for larger studies of abbreviated HLD protocols and the development of technologies that expedite the HLD process