ORIGINAL ARTICLE

Impact of cleaning monitoring combined with channel purge storage on elimination of *Escherichia coli* and environmental bacteria from duodenoscopes

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Background and Aims: We aimed to determine whether monitoring of duodenoscope cleaning by rapid adenosine triphosphate (ATP) combined with channel-purge storage could eliminate high-concern microorganisms.

Methods: In a simulated-use study, suction channels, as well as lever recesses, from 2 duodenoscopes models and the unsealed elevator guidewire (EGW) channel from 1 of these 2 duodenoscopes (the other model has a sealed EGW) were perfused with ATS2015 containing approximately 8 Log_{10} colony-forming units (CFU)/mL of both *Enterococcus faecalis* and *Escherichia coli*. Pump-assisted cleaning was monitored by rapid ATP testing. Duodenoscopes exceeding 200 relative light units (RLUs) were recleaned. Clean duodenoscopes were processed through an automated endoscope reprocessor and then stored in a channel-purge storage cabinet for 1 to 3 days. Cultures of EGW channel and instrument channel combined with the lever recess (IC-LR) were taken after storage. The impacts of extended cleaning and alcohol flush were evaluated.

Results: *E coli* was reliably eliminated in IC-LR and EGW channels of 119 duodenoscope tests (59 with sealed EGW and 60 with nonsealed EGW). However, actionable levels of *E faecalis* and environmental bacteria persisted. Neither alcohol flush nor extended cleaning resulted in a reduction of actionable levels for these organisms. Identification of isolates indicated that residual organisms in duodenoscope channels were hardy Gram-positive bacteria (often spore formers) that likely originated from environmental sources.

Conclusions: These data indicate that high-concern Gram-negative bacteria but not *E faecalis* or environmental bacteria can be reliably eliminated by use of the manufacturer's instructions for reprocessing with ATP monitoring of cleaning and channel-purge storage conditions. (Gastrointest Endosc 2018;■:1-11.)

Abbreviations: AER, automated endoscope reprocessor; ATP, adenosine triphosphate; CDC, Centers for Disease Control; CFU, colony-forming unit; CP cabinet, channel-purge storage cabinet; EGW, elevator guidewire; IC-LR, instrument channel–lever recess; MALDI-TOF, matrix-assisted laser desorption/ionization-time of flight; MIFU, manufacturer's instructions for use; RLU, relative light unit; sRO, sterile reverse osmosis; SS1E, Steris System 1E.

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The worldwide outbreaks of multiantibiotic-resistant bacteria transmitted by contaminated endoscopes have raised concerns about the adequacy of endoscope reprocessing.[1-9] Recent clinical studies have shown variable results, with some sites having no or low levels of detectable bacteria after disinfection or sterilization[10-15] and others having 35% to 60% of endoscopes growing organisms of concern.[16-19] This variability could be due to the use of different culture sample collection procedures such as the use of friction to collect samples, the type of sample collection fluid used, the use of neutralizer and sample concentration methods for culture, all of which are important variables.[16,17,20] Clinical studies using friction for sample collection, neutralizer, and sample concentration methods often report higher levels of contamination of endoscopes.[16-19] The precleaning contamination level of patient-used endoscopes varies depending on the scope type, the procedure type and duration, and the underlying condition of the patient. In addition, wet storage conditions are more widespread than previously recognized, inasmuch as up to 95% of endoscopes assessed after alcohol flush and drying still had visible drops of fluid in them after overnight storage.[21,22] Part of this wet storage may be related to the use of simethicone, which is insoluble in water and has been observed as liquid or crystals in patient-ready endoscopes. (Note: simethicone is not frequently used for ERCP with duodenoscopes.)[21,23,24]

The ability of channel-purge storage cabinets (CP cabinets) to limit proliferation of bacteria in endoscope channels has been shown by simulated-use studies[25] and for patient-used endoscopes.[17] Despite these published data, the use of CP cabinets in North America is limited. Although the human factors study by Ofstead et al[26] indicated that cleaning and drying are the steps most often not done properly, there are no systematic simulated-use or clinical studies to determine whether cleaning monitoring combined with channel-purge storage after disinfection is adequate to ensure reliable eradication of concerning microorganisms.

The objective of the current study was to undertake a simulated-use study to determine whether cleaning monitoring combined with storage in a CP cabinet after disinfection would reliably eradicate high levels of organisms of concern from duodenoscopes by the use of what are currently considered the most sensitive sample collection and culture procedures.

MATERIALS AND METHODS

Duodenoscopes and automated endoscope reprocessors

The duodenoscopes used for this study were Olympus JF-140F, TJF-160V, and TJF-Q180V models (Olympus America, Center Valley, Penn). The JF-140F and TJF-160V models had unsealed elevator guidewire (EGW) channels, and the TJF-Q180V model had a sealed EGW channel. The TJF-160V and TJF-Q180V were used as demonstration units before being lent by Olympus for this research project. Before experimental testing, the TJF-Q180V duodenoscope had been submitted to the Olympus repair facility to have the O-ring replacement completed in accordance with the Olympus recall. The JF-140F was donated to the research laboratory many years earlier, and there was no record of its prior history, although in the research laboratory no accessory devices were passed through the instrument channels of these duodenoscopes other than the bristle brushes used for cleaning according to manufacturer's instructions for use (MIFU). There was no internal assessment from Olympus or from our research testing regarding any internal damage to the instrument channels of the 3 duodenoscopes used in this study; however, immersion leak testing was regularly performed during the course of the research project. Before experimental testing was begun, both the JF-140F and TJF-Q180V duodenoscopes passed immersion leak testing and had thorough cleaning and disinfection in the Steris System 1E (SS1E). Baseline cultures showed no *Enterococcus faecalis* and no *Escherichia coli*. (There were low levels of, eg, bacilli and diphtheroids in the instrument channel–lever recess [IC-LR] of both duodenoscopes and no growth in the EGW of the JF-140F duodenoscope.) When the JF-140F duodenoscope had a major leak that was deemed irreparable by the Olympus repair facility, it was replaced with a TJF-160V duodenoscope that also had an unsealed EGW channel. (Olympus indicated that they did not have any JF-140F duodenoscopes that could be lent for the research project.) Before use in experiments, this TJF-160V duodenoscope passed immersion leak testing and had cleaning followed by disinfection with the SS1E, but no baseline culture was done. The JF-140F duodenoscope was used for the first 15 tests, and the TJF-160V duodenoscope was used for the remaining 45 tests for duodenoscope with an unsealed EGW.

The Steris System 1E (SS1E) (Steris Inc, Mentor, Ohio) was the automated endoscope reprocessor (AER) used for this study. This AER has recently been revalidated by Steris[27] and cleared by the U.S. Food and Drug Administration as appropriate for reprocessing of duodenoscopes. Biological indicators were run weekly, and chemical indicators were included in every run in accordance with the AER MIFU.

Inoculation of duodenoscopes

E coli (ATCC 25922) and *E faecalis* (ATCC 29212) were suspended in ATS2015 (Healthmark Industries, Fraser, Mich) supplemented with 20% defibrinated sheep blood to achieve an approximate concentration of 10^8 colony-forming units (CFU)/mL as described by Alfa and Olson.[28] This test soil has been shown to mimic the secretions that duodenoscopes are exposed to during patient use[28] and as such is an appropriate test soil for simulated-use studies.