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Major article

Comparison of clinically relevant benchmarks and channel sampling methods used to assess manual cleaning compliance for flexible gastrointestinal endoscopes

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Background: The objectives of this study were to recommend sample collection method(s) based on relative soiling in patient-used gastrointestinal (GI) endoscopes and determine whether the published benchmarks for protein, bioburden, and adenosine triphosphate (ATP) remain relevant for pump-assisted manual cleaning.

Methods: Patient-used gastroscopes, duodenoscopes, and colonoscopes were sampled before and after manual cleaning and assessed for protein, bioburden, and ATP levels. The biopsy port (BP) to distal end (D) sample was collected using 20 mL of sterile reverse-osmosis water. After a 200-mL flush, the umbilical (UM) to BP portion was sampled by flushing 40 mL from the UM to the D.

Results: The BP to D portion of the suction biopsy channel contained 83% of ATP residuals. Despite cleaning with brushing and a flushing pump, 25% of gastroscopes exceeded the ATP benchmark of 200 relative light units (RLU), whereas all duodenoscopes and colonoscopes had <200 RLU after cleaning. The protein and bioburden residuals after pump-assisted cleaning were consistently lower than existing benchmarks.

Conclusion: Sampling the suction biopsy channel from BP to D detected the most residuals from patient-used GI endoscopes. The protein and bioburden benchmarks for pump-assisted cleaning can be lowered, but 200 RLU is still adequate for ATP.

The reprocessing of flexible endoscopes is a complex, multistage process prone to human error. Ofstead et al[1] documented that all stages of manual reprocessing were performed correctly in only 1.4% of the 69 endoscopes that they evaluated. The main areas of concern in their study were the brushing stage of manual channel cleaning and the use of forced air to dry channels before storage. The overall compliance for automated endoscope cleaning and disinfection (75.4%) was significantly better than that for manual cleaning combined with automated disinfection.[1] The need to ensure adequate reprocessing of flexible endoscopes (especially at the manual cleaning stage) has been well emphasized in various published guidelines.[2-5]

Despite such guidelines, the recent report of infection transmission due to contaminated duodenoscopes by Carbonne et al[6] demonstrated a transmission rate of 45% and an infection rate of 11% for multidrug-resistant *Klebsiella pneumoniae*. Reports such as that conclusively document that despite advances in flexible endoscope design and the development of guidelines that emphasize reprocessing,[2-5] there is significant evidence suggesting that the problem of flexible endoscopes causing infection transmission remains a concern. One factor contributing to this ongoing problem with flexible endoscopes is that visual inspection is insufficient to confirm cleaning adequacy, because visualization of the narrow channels is not possible.

Although adenosine triphosphate (ATP) testing has long been used to monitor environmental cleaning in the food and drug industry,[7] the first adaptation of this methodology to monitor cleaning of flexible endoscopes was reported by Sciortino et al[8] in

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2004. In this early assessment, biofilm formation within the channels of older flexible endoscopes clearly resulted in persistent elevated relative light unit (RLU) levels after disinfection and alcohol flushing. The authors performed ATP testing after storage of endoscopes and, based on their data, concluded that the older flexible endoscopes likely developed biofilm within the channels that persisted and proliferated during storage. A limitation of this study was that only swab tests were available for use, and as such, the entire length of the endoscope channel could not be sampled.

A number of subsequent studies have evaluated the feasibility of using ATP-based testing from various manufacturers to assess the cleaning of flexible endoscopes.[9-13] Hansen et al[9] and Fushimi et al[11] both used swabs to sample the exterior of endoscopes for ATP monitoring of cleaning. Channel sampling was reported by Obee et al,[10] who used channel brushes, and by Fushimi et al,[11] who used 10 mL of sterile water flushed from the biopsy port to the distal end of gastroscopes. Considering that these studies used different methods for evaluating flexible endoscope channel cleaning, comparing results is difficult. However, in all studies, ATP testing was reported to be a useful method for monitoring manual cleaning.

Recent studies have demonstrated a highly variable limit of detection for different ATP test kits and luminometers.[14,15] As such, it is important for the manufacturer of each ATP test kit to provide specific sample collection protocols and indicate the level of RLU can be expected when proper cleaning is achieved (ie, validated cutoff for a test that differentiates unacceptable from acceptable manual cleaning). Using samples collected by flushing sterile reverse-osmosis (sRO) water through each channel, Alfa et al[12,13] provided validated RLU cutoff values for the 3M ATP test kit from all flexible GI endoscope channels (excluding gastroscope channels). They demonstrated that these cutoffs can be achieved in routine clinical use, although they reported that the elevator guidewire channel was the most difficult to clean adequately.[12,13] Although some of the published studies used RLU cutoffs to differentiate between “clean” and “dirty,” none assessed whether the optimal sample collection is from the entire endoscope channel from umbilical to distal or whether samples collected from the biopsy port to distal end are adequate for their ATP testing method. Furthermore, the different sample collection methods used in these studies has hindered determination of the clinically relevant cutoffs for ATP compared with bioburden and protein.

The objectives of the present study were (1) to determine whether most of the organic and bioburden residuals from patient-used GI endoscopes was found in the biopsy port to distal portion or the umbilical to biopsy port portion of the suction-biopsy (SB) channel, to help determine optimal sample collection strategies, and (2) to compare the levels of ATP, protein, and bioburden residuals to evaluate whether the previously established benchmarks for adequate channel cleaning remain valid.

MATERIALS AND METHODS

Flexible endoscopes

The following flexible endoscopes, all from Olympus (Center Valley, PA), were used in this study: colonoscope models CF-Q180AL and CF-H180AL, duodenoscope model TFJ-160VF, and gastroscope models GIF-Q180 and GIF-H180.

Sample collection

All patient-used flexible endoscopes received routine bedside precleaning and were then transported to the reprocessing area, where sample collection was performed. Only the SB channel was evaluated, with the aim of comparing the organic and bioburden loads in different sections of this channel. The 2 sections of the SB channel were compared by taking samples from the biopsy port (BP) to the distal end (D) and from the umbilical end (UM) to the distal end (D). The first sample was collected by flushing 20 mLs of sRO water through the channel from the BP to the D.

Because the samples from the UM to the D had to pass through the BP-to-D portion of the BP channel, the protocol included a pump-assisted flushing step to ensure that once the BP-to-D sample was collected, this section of the BP channel was thoroughly flushed with 200mL of sRO water before the second sample from the UM-to-D portion was collected. Samples were taken from the BP-to-D portion of the sample after the pump-assisted flushing and showed that virtually no material remained in this section of the SB channel before the UM-to-D sample was collected (data not shown).

After this flushing stage of the BP-to-D portion of the channel, the second sample was collected by flushing 40 mL of sRO water from the UM-to-D portion of the SB channel. Samples were also taken from fully reprocessed endoscopes (called baseline) to ensure that there was no buildup of material over repeated uses (20 mL for the BP-to-D sample and 40 mL for the UM-to-D sample).

Clinical study

An overview of the sample collection in relationship to precleaning and postcleaning is given in Table 1. The patient-used flexible endoscopes all received bedside cleaning before sample collection (as described above). The 10 precleaning samples were taken from different patient-used endoscopes than the 20 postcleaning samples.

Precleaning phase

All samples were collected on receipt of the scope into the reprocessing room before full manual cleaning.

Postcleaning phase

The endoscopes were leak tested followed by full manual cleaning. As part of this manual cleaning, the Endo-Flush (EFP-500; PCI Medical, Deep River, CT) was used to ensure the channels of each endoscope were flushed with enzymatic detergent during the cleaning phase and tap water during the rinsing phase. The EFP-500 was regularly calibrated as per the manufacturer’s instructions to ensure it was delivering the correct flushing volume. Once the endoscope had been fully manually cleaned, the SB channel was sampled again as described previously (ie, BP to D, as well as UM to D).

Assays for ATP, protein, and bioburden quantitation

Each of the channel samples collected from patient-used endoscopes was tested to determine the amount of protein, bioburden and ATP. The 3M Clean-Trace ATP Water test kit (3M, Saint Paul, MN) along with the handheld Clean-Trace luminometer were used (as per the manufacturer’s instruction) for testing channel samples for ATP as measured by relative light units (RLUs). There are no existing validated ATP manufacturer’s instructions for endoscope sample collection. Experiments were performed in triplicate and results were presented as the average RLUs/sample.

The channel samples collected were also assayed for protein using the QuantiPro BCA assay kit based on bicinchoninic acid (Sigma-Aldrich, St Louis, MO). The kit includes a bovine serum albumin protein standard and was performed in accordance with the manufacturer’s instructions (limit of detection, 5 μg/mL). For bioburden quantitation the samples were serially diluted 1:10 in