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Major Article

Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: Results of visual inspections, biochemical markers, and microbial cultures

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Background: Flexible endoscopes are currently reused following cleaning and high-level disinfection. Contamination has been found on endoscopes, and infections have been linked to gastrointestinal, respiratory, and urologic endoscopes.

Methods: This longitudinal study involved visual inspections with a borescope, microbial cultures, and biochemical tests for protein and adenosine triphosphate to identify endoscopes in need of further cleaning or maintenance. Three assessments were conducted over a 7-month period. Control group endoscopes reprocessed using customary practices were compared with intervention group endoscopes subjected to more rigorous reprocessing.

Results: At final assessment, all endoscopes (N = 20) had visible irregularities. Researchers observed fluid (95%), discoloration, and debris in channels. Of 12 (60%) endoscopes with microbial growth, 4 had no growth until after 48 hours. There were no significant differences in culture results by study group, assessment period, or endoscope type. Similar proportions of control and intervention endoscopes (~20%) exceeded postcleaning biochemical test benchmarks. Adenosine triphosphate levels were higher for gastroscopes than colonoscopes ($P = .014$). Eighty-five percent of endoscopes required repair due to findings.

Conclusions: More rigorous reprocessing was not consistently effective. Seven-day incubation allowed identification of slow-growing microbes. These findings bolster the need for routine visual inspection and cleaning verification tests recommended in new reprocessing guidelines.

Guidelines for reprocessing flexible endoscopes currently permit reuse following cleaning and high-level disinfection (HLD), which theoretically eliminates all bioburden except small numbers of bacterial spores.[1-5] However, organic residues often remain after manual cleaning[6-10] and endoscope contamination has persisted in institutions with documented adherence to reprocessing guidelines.[9,11-13] The presence of residual material after cleaning reduces HLD effectiveness,[14] and researchers have recovered nonspore-forming microbes on 8%-64% of patient-ready endoscopes following HLD.[9,11-13,15-17]

Although inadequate reprocessing is commonly found during endoscopy-associated outbreak investigations,[1,5,18] infections have also occurred when guidelines were followed.[12,19] Outbreaks involving duodenoscopes have illuminated challenges specific to cleaning their elevator mechanisms,[12,20,21] but infections have also been linked to endoscopes without elevators, including gastroscopes,[22] colonoscopes,[23] bronchoscopes,[18,24] and urologic endoscopes.[25,26] Studies using advanced microscopy have found that residual protein and biofilm are not completely removed from channels during reprocessing, even with multiple rounds of cleaning.[27,28] In 3 outbreaks, surface damage and biofilm were found when implicated endoscopes were examined by manufacturers.[12,21,29]

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Conflicts of interest: CLO is employed by Ofstead & Associates, Inc, which has received research funding and speaking honoraria related to infection prevention from 3M Company, Medivators, HealthMark Industries, STERIS Corporation, Boston Scientific, and Invendo Medical. HPW, OLH, EAJ, and JEE, are employed by Ofstead & Associates, Inc.

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To identify endoscopes needing additional cleaning or maintenance, new reprocessing guidelines recommend that more emphasis be placed on conducting visual inspections. They recommend using lighted magnification[2-4] and borescopes,[2] which are small cameras for inspecting endoscope channels and ports. New guidelines also recommend routine tests for biochemical markers such as protein, hemoglobin, and adenosine triphosphate (ATP) be conducted to verify cleaning effectiveness.[2,3]

In a previous study, repeated attempts to remove residue on highly contaminated colonoscopes and gastroscopes were not sufficient to meet benchmarks for manually cleaned endoscopes.[9] Most of these endoscopes had been in use for more than 4 years and had been used for more than 2,000 procedures (data on file in possession of the authors). The findings raised the possibility that organic residue and biofilm accumulation could be associated with factors such as endoscope age, procedure volume, and repair history.

This longitudinal study was designed to evaluate the feasibility and utility of visual inspections combined with biochemical tests and microbial cultures to identify endoscopes in need of further cleaning or maintenance. Researchers assessed endoscope surfaces and contamination levels over time and evaluated the influence of more rigorous methods on reprocessing effectiveness.

MATERIALS AND METHODS

Setting

This prospective study was conducted in an ambulatory surgery center where researchers documented adherence to reprocessing guidelines during 10 unannounced audits (1 prestudy and 9 during the study). Researchers had previously conducted reprocessing effectiveness studies[9-11] and received training from clinical educators employed by borescope and biochemical test manufacturers. The Institutional Review Board granted a waiver because the research subjects were flexible endoscopes, no human subjects were involved, and no patient health data were collected.

Study design

Researchers compiled data on endoscope age, procedure volume, and repair history. Endoscopes were visually inspected and assessed for residual contamination at baseline, 2 months, and final assessments in April, June, and October 2015, respectively. Following baseline, researchers evenly distributed endoscopes to control and intervention groups using their serial numbers and data regarding endoscope type, acquisition date, and procedure volume (supplementary Table S1). To maintain similar group sizes and characteristics, additional endoscopes acquired during the study were assigned to groups using the characteristics described above.

Reprocessing methods

The facility's usual reprocessing practices included bedside precleaning, which involved wiping external surfaces and flushing channels with detergent immediately after procedures, followed by leak testing, manual cleaning, and HLD with 2.5% glutaraldehyde in automated endoscope reprocessing (AER) machines (Intercept Bedside Kit, Intercept detergent, Pull-Thru Cleaning Device, Scope Buddy Endoscope Flushing Aid, and DSD 201 AER; Medivators Inc, Minneapolis, MN) in a reprocessing room.

Control group endoscopes were reprocessed in accordance with the protocol described above. For the intervention group, bedside precleaning, leak testing, and manual cleaning were performed as described above before reprocessing in a different AER that performed automated cleaning before HLD with 5% peracetic acid (PA) (Advantage Plus, Medivators Inc). The change to PA was based on evidence that glutaraldehyde can cause protein fixation and PA's ability to remove buildup from glutaraldehyde use.[1] For every intervention endoscope, reprocessing technicians verified the effectiveness of manual cleaning by conducting biochemical tests for ATP on biopsy ports (BPs) and in suction-biopsy channels (SBCs) (CleanTrace ATP Surface and ATP Water; 3M Company, St Paul, MN). Intervention endoscopes were recleaned whenever results exceeded the "clean" benchmark of 200 relative light units (RLUs).[6,30] When ATP levels remained high after recleaning, endoscopes were subjected to 2 AER cycles, with repeat testing after the first cycle.

To aid in drying, both types of AERs performed alcohol flushes (30 mL) and forced-air purges after HLD. The AER air-purge cycle was set for 1 minute at baseline. The cycle time was increased to 6 minutes in both groups after the baseline assessment identified residual fluid in several endoscopes. Following removal from AERs, endoscopes were wiped with lint-free towels and hung vertically in closed, ventilated cabinets.

Visual inspections

At baseline, 2 months, and final assessments, visual inspections were performed on patient-ready endoscopes. External surfaces were photographed using an 8-megapixel digital camera (iSight; Apple Inc, Cupertino, CA) whenever defects, irregularities, or debris were identified. The distal end and the interior of the air–water port, suction port, BP, and SBC were examined using a 3.2 mm borescope with 17× magnification (Flexible Inspection Scope; HealthMark Industries, Fraser, MI). To facilitate longitudinal comparisons and determine whether there were visible surface changes over time, borescope photographs were captured at specific locations inside every endoscope and whenever irregularities were observed. Videos were recorded when there were lengthy segments of abnormalities and when fluid or debris occluded the channel or moved when disturbed by the borescope. Endoscope serial numbers, photograph or video location, and comments about irregularities were documented.

Biochemical tests and microbial cultures

Samples were collected using aseptic technique in a procedure room dedicated for research use. At the final assessment, samples were collected from BPs and SBCs after manual cleaning and again after an AER cycle. First, BPs were sampled for microbial cultures using sterile swabs that were placed immediately in liquid Amies media to support microbial viability (480c ESwabs; COPAN Diagnostics Inc, Murrieta, CA). Then the flush-brush-flush technique[9,10,19] was used with 35 mL sterile water for obtaining SBC effluent that was used for microbial cultures, ATP tests (CleanTrace ATP Water), and protein tests (ProCheck-II; HealthMark Industries). Following the collection of channel effluent, the biopsy port was sampled again with a sterile swab for ATP testing (CleanTrace ATP Surface). The ATP and protein tests were conducted in accordance with manufacturers' instructions, and published benchmarks were used to evaluate results (6.4 μg/mL protein; 200 RLU ATP).[6,30]

Positive and negative controls (a precleaned gastrointestinal endoscope and a sterilized cystoscope, respectively) were tested to verify aseptic technique and validate results. A sterilized cystoscope was used as a negative control because samples could be obtained using methods that were similar to the process for sampling gastrointestinal endoscopes. Results were expected to be negative, and were compared with findings from a precleaned gastrointestinal endoscope to verify that the biochemical tests were functioning properly.