American Journal of Infection Control 43 (2015) 794-801

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major article

Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines

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Key Words:
Endoscope reprocessing
Reprocessing medical devices
High-level disinfection
Epidemiology
Gastrointestinal endoscopy
Colonoscope

Background: Pathogens have been transmitted via flexible endoscopes that were reportedly reprocessed in accordance with guidelines.
Methods: Researchers observed reprocessing activities to ensure guideline compliance in a large gastrointestinal endoscopy unit. Contamination was assessed immediately after bedside cleaning, manual cleaning, high-level disinfection, and overnight storage via visual inspection, aerobic cultures, and tests for adenosine triphosphate (ATP), protein, carbohydrate, and hemoglobin.
Results: All colonoscopes and gastroscopes were reprocessed in accordance with guidelines during the study. Researchers collected and tested samples during 60 encounters with 15 endoscopes. Viable microbes were recovered from bedside-cleaned (92%), manually cleaned (46%), high-level disinfected (64%), and stored (9%) endoscopes. Rapid indicator tests detected contamination (protein, carbohydrate, hemoglobin, or ATP) above benchmarks on bedside-cleaned (100%), manually cleaned (92%), high-level disinfected (73%), and stored (82%) endoscopes. Visible residue was never observed on endoscopes, but it was often seen on materials used to sample endoscopes. Seven endoscopes underwent additional reprocessing in response to positive rapid indicators. Control endoscope channels were free of biologic residue and viable microbes.
Conclusion: Despite reprocessing in accordance with US guidelines, viable microbes and biologic debris persisted on clinically used gastrointestinal endoscopes, suggesting current reprocessing guidelines are not sufficient to ensure successful decontamination.

Gastrointestinal (GI) endoscopes are complex instruments that become highly contaminated during use. Endoscope reprocessing is a multistep process consisting of cleaning and high-level disinfection (HLD).[1] Manual (mechanical) removal of debris from external surfaces and interior channels is a fundamental step of reprocessing.[1-3] Residual substances not removed during cleaning may interfere with disinfectants.[3-5] Biofilm, an accumulation of biomass containing microbes and other material, adheres to surfaces, forms

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Funding/Support: Supported by 3M, which provided funding and materials to Ofstead & Associates for this study. Additional research support was provided by Mayo Clinic and Ofstead & Associates.
Disclaimer: 3M did not have access to the data and was not involved in the preparation of this manuscript. No monetary compensation was received by the physicians at Mayo Clinic or the University of North Carolina (P.K.T., K.H.V., and T.H.B.) or their departments for participating in the research or writing of this manuscript.
Conflicts of interest: C.L.O. is employed by Ofstead & Associates, which has received research funding and speaking honoraria related to endoscopic procedures from 3M, Advanced Sterilization Products, Medivators, Invendo Medical, Boston Scientific, and Steris. E.M.D., C.K.R., and H.P.W. are employed by Ofstead & Associates and have no other disclosures to report. K.H.V., T.H.B., and P.K.T. have no disclosures to report.

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http://dx.doi.org/10.1016/j.ajic.2015.03.003

a matrix that may be difficult to remove during subsequent reprocessing,[5] and may prevent disinfectants from inactivating microbes.[5]

An accurate estimate of the infection risk associated with endoscopic procedures has yet to be determined.[6] Most infectious outbreaks linked to endoscopes have been associated with documented breaches of reprocessing.[7-9] Recently, outbreaks involving multidrug-resistant organisms (MDROs) occurred after endoscopes were reportedly reprocessed according to guidelines.[10-13] Investigators from the US Centers for Disease Control and Prevention recently concluded that the endoscopes implicated in an outbreak of an MDRO served as an efficient means of transmission, with colonization identified in 39% of exposed patients who were tested in an institution where reprocessing guidelines were followed.[10]

Rapid indicators may be useful in verifying the removal of viable organisms and organic residue from endoscopes during reprocessing.[14-17] Benchmarks for adenosine triphosphate (ATP), protein, carbohydrate, and hemoglobin levels have been established to ensure proper cleaning has been completed prior to endoscope disinfection,[4,18] but these have not been incorporated into current guidelines. A recent validation study determined that thorough manual cleaning decreased bioburden and residual organic debris levels to below the established limits (ie, ATP <200 relative light units [RLU], protein <6.4 μg/cm^2, hemoglobin <2.2 μg/cm^2, and microbial bioburden <4 log10 colony forming units [CFU]/cm^2).[18] Using an ATP indicator, one institution found manual cleaning initially failed to meet established benchmarks 37% of the time. After the establishment of a quality improvement program involving staff training and a revised cleaning algorithm, failure rates after manual cleaning (based on ATP thresholds) were reduced to 5% over 6 months.[19] Because ATP is present in viable organisms and nonviable organic debris, researchers have evaluated the association between ATP levels and microbial cultures.[15,17,20] Both decrease significantly after cleaning.[17,18] A linear association has been described[20]; however, this association is less clear in the context of low microbial burden.[18] As such, measurement of multiple indices of contamination (eg, ATP, protein, hemoglobin, cultures) may be needed to fully characterize residual bioburden on reprocessed endoscopes. The lack of national standards regarding cleaning verification does not provide technicians with any benchmarks to verify cleaning effectiveness.

We sought to determine whether colonoscope and gastroscope contamination caused by clinical use persists despite reprocessing in accordance with current guidelines by performing microbial cultures and rapid indicator tests for ATP, protein, hemoglobin, and carbohydrate residue.

METHODS

Setting

This study was conducted at Mayo Clinic, Rochester, Minnesota, where 30,000 endoscopic procedures are performed annually. Data were collected in an endoscopy unit that reprocesses approximately 100 endoscopes each business day. A waiver was granted by the Mayo Clinic Institutional Review Board because this study did not involve human subjects or protected health information.

Colonoscopy and gastroscopy were performed using Olympus colonoscopes and esophagogastroduodenoscopes (EGDs) (Olympus America, Center Valley, PA), which do not have elevator channels. During this study, reprocessing consisted of several steps. These included bedside cleaning in the procedure room by a technician who flushed enzymatic solution through suction/biopsy (SB) and auxiliary water (AUX) channels and used disposable wipes to clean exterior components. This was followed by leak testing and manual cleaning in dedicated reprocessing rooms. Manual cleaning involved wiping external surfaces, brushing channels and components, and using an irrigation system (Scope Buddy Endoscope Flushing Aid; Medivators, Minneapolis, MN) to flush detergent (Endozime; Ruhof, Mineola, NY) and water through channels. An automated endoscope reprocessor (Medivators SSD-102LT Single Basin AER; Medivators, Minneapolis, MN) was used for HLD (MetriCide OPA Plus; Metrex, Orange, CA). The disinfectant's temperature and minimum effective concentration were verified before cycle initiation. Disinfected endoscopes were stored vertically after drying with isopropyl alcohol and forced air.

Endoscope testing was performed in a dedicated room adjacent to the procedure room, which allowed for rapid sampling and testing. Barrier separation between procedural, reprocessing, data collection, and testing activities minimized potential for environmental cross-contamination. Extensive measures to ensure aseptic environmental conditions during data collection included use of disinfectant wipes on surfaces, use of disposable absorbent pads, and restricting room access. Researchers wore gloves, impervious gowns, face masks with splash protection, hair nets, and shoe covers. Gloves were changed between sampling, and gowns were changed between endoscope encounters.

Sampling

Each instance where samples were obtained from an endoscope was considered an encounter. Samples were collected during a minimum of 4 encounters with each clinically used study endoscope. An endoscope was included when researchers and a technician were available and a GI procedure was completed. Endoscope encounters occurred sequentially after each reprocessing step (ie, bedside cleaning, manual cleaning, HLD) and after overnight storage to assess contamination levels throughout reprocessing. After post-HLD sampling, another cycle of HLD was performed before storage. Components sampled at each encounter included control handles, suction and air and water valves, biopsy ports and caps, distal ends, SB channels, and AUX channels and ports. Tests were conducted to detect protein, carbohydrate, hemoglobin, ATP, and viable microbes.

Visual inspection was performed on all external endoscope components and channel effluent and sampling instruments. External surfaces were individually sampled with sterile swabs. Interior channels were assessed by testing effluent samples obtained via the flush-brush-flush method with 20 mL of sterile water and a 6-mm brush.[18,21] The effluent was divided into 3 sterile collection tubes for microbiologic culturing and rapid indicator testing.

Rapid indicator tests and cultures

Multiple rapid indicators (ie, ATP, protein, hemoglobin, carbohydrate) were used.[18,21] ATP has been validated for assessing endoscope contamination.[17,18] Residual protein is an indicator of inadequate cleaning and can interfere with HLD efficacy.[5] Blood, frequently found within endoscopes after patient use,[16] and sodium ions in blood can inhibit the microbiocidal activity of HLD.[4] Carbohydrate is an energy source for microbes and allows adherence to surfaces.[22]

ATP levels were tested using Clean-Trace Surface ATP and Clean-Trace Water ATP tests (3M, Saint Paul, MN).[23,24] A luminometer quantified ATP expressed in RLU.[20] In accordance with a validated benchmark for clean SB endoscope channels,[18] a cutoff of 200 RLU was applied to evaluate channels and external surfaces. Protein was assessed on control handles and ports (biopsy and air and water) using Clean-Trace Surface Protein-High Sensitivity swabs (3M, Saint