American Journal of Infection Control ■■ (2017) ■■-■■

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

The effectiveness of sterilization for flexible ureteroscopes: A real-world study

Cori L. Ofstead MSPH *, Otis L. Heymann BA, Mariah R. Quick MPH, Ellen A. Johnson BAS, John E. Eiland MS, RN, Harry P. Wetzler MD, MSPH

Ofstead & Associates, Inc, Saint Paul, MN

Key Words:
Borescope
Reprocessing
Microbial
Cultures
Contamination

Background: There are no guidelines or quality benchmarks specific to ureteroscope reprocessing, and patient injuries and infections have been linked to ureteroscopes. This prospective study evaluated ureteroscope reprocessing effectiveness.

Methods: Reprocessing practices at 2 institutions were assessed. Microbial cultures, biochemical tests, and visual inspections were conducted on sterilized ureteroscopes.

Results: Researchers examined 16 ureteroscopes after manual cleaning and sterilization using hydrogen peroxide gas. Every ureteroscope had visible irregularities, such as discoloration, residual fluid, foamy white residue, scratches, or debris in channels. Tests detected contamination on 100% of ureteroscopes (microbial growth 13%, adenosine triphosphate 44%, hemoglobin 63%, and protein 100%). Contamination levels exceeded benchmarks for clean gastrointestinal endoscopes for hemoglobin (6%), adenosine triphosphate (6%), and protein (100%). A new, unused ureteroscope had hemoglobin and high protein levels after initial reprocessing, although no contamination was found before reprocessing.

Conclusions: Flexible ureteroscope reprocessing methods were insufficient and may have introduced contamination. The clinical implications of residual contamination and viable microbes found on sterilized ureteroscopes are unknown. Additional research is needed to evaluate the prevalence of suboptimal ureteroscope reprocessing, identify sources of contamination, and determine clinical implications of urinary tract exposure to reprocessing chemicals, organic residue, and bioburden. These findings reinforce the need for frequent audits of reprocessing practices and the routine use of cleaning verification tests and visual inspection as recommended in reprocessing guidelines.

A large proportion of gastrointestinal endoscopes harbor residual contamination.[1-6] Outbreaks have been linked to contaminated duodenoscopes, gastroscopes, bronchoscopes, and cystoscopes.[7-12] In a cystoscopy-associated outbreak involving 23 patients in New Mexico, investigators found myriad breaches of endoscope reprocessing guidelines. These included delayed reprocessing, failing to fully immerse the cystoscope in high-level disinfectant (HLD), inadequate HLD exposure time, and reusing the same rinse water for 2 weeks or until it "began to smell."[10] In a gastroscopy-associated outbreak of multidrug-resistant *Pseudomonas aeruginosa* in France, technicians were reportedly following the French reprocessing guidelines, but investigators observed suboptimal manual cleaning (eg, only 1 size of brush used; <10 minutes invested in brushing and flushing channels), inadequate drying, and horizontal storage. The pathogen was found in the gastroscope channel, and the outbreak was ended by improving reprocessing practices.[7] On the other hand, recent outbreaks associated with duodenoscopes have occurred even when guidelines were followed.[8,11]

Injuries and infections have also been attributed to contaminated or damaged ureteroscopes, including those with broken wires, plastic coatings, and linings.[13-16] Ureteroscopes are frequently repaired due to functional problems identified during procedures.[17-19]

* Address correspondence to Cori L. Ofstead, MSPH, Ofstead & Associates, Inc, 400 Selby Ave, Suite V, Blair Arcade West, Saint Paul, MN 55102.

E-mail address: cori@ofsteadinsights.com (C.L. Ofstead).

Supported by a research grant from Boston Scientific. Supplies and materials were provided by HealthMark Industries, which provided a borescope, hemoglobin tests, and protein tests, and 3M Company, which provided the adenosine triphosphate testing devices and swabs. The companies were not involved in designing the study, collecting data, interpreting results, or preparing the manuscript. Ofstead & Associates Inc, provided research support.

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, Advanced Sterilization Products, and Invendo Medical. OLH, MRQ, EAJ, JEE, and HPW are employed by Ofstead & Associates, Inc.

http://dx.doi.org/10.1016/j.ajic.2017.03.016

Manufacturer's instructions for use (IFUs) recommend conducting a multistep inspection before each procedure, and removing ureteroscopes with defects from service.[20-23] Guidelines for reprocessing flexible endoscopes recommend conducting visual inspections and leak tests during every reprocessing cycle, along with routine monitoring of cleaning effectiveness.[24,25]

To date, no published study has systematically assessed the extent of damage and residual contamination in patient-ready flexible ureteroscopes. This study used lighted magnification to identify ureteroscope damage or debris, measured residual contamination, and evaluated the association between ureteroscope characteristics (eg, age, number of uses, and repair history) and the presence of visible irregularities or residual contamination.

MATERIALS AND METHODS

Setting and design

This prospective study was conducted at 2 large multispecialty health care facilities in the mid-western United States. A waiver was granted by the institutional review boards at both sites because no human subjects were involved. Data regarding ureteroscope models, acquisition dates, procedural use, and repair histories were collected by site personnel. Site visits were conducted to examine patient-ready ureteroscopes and observe reprocessing practices in June (site A) and August (site B) 2016.

Sampling for biochemical tests and microbial cultures

Researchers collected samples from every patient-ready ureteroscope in use at each facility. Sampling was done in operating rooms using aseptic technique. Sterile swabs (482c ESwabs; COPAN Diagnostics Inc, Murrieta, CA) moistened with sterile, deionized water were used to obtain microbial culture samples from channel ports. Swab tips were placed in vials containing 1 mL Amies solution. The flush-brush-flush technique was used with 4 mL sterile, deionized water and a sterile channel swab to obtain channel effluent. The tip of this channel swab was removed and placed in a vial containing 2 mL effluent and 2 mL Amies solution for microbial cultures. The remaining 2 mL effluent was tested for adenosine triphosphate (ATP) (CleanTrace ATP Water; 3M Company, St Paul, MN), protein (ProCheck-II; HealthMark Industries, Fraser, MI), and hemoglobin (HemoCheck-S; HealthMark Industries). Surface ATP samples were obtained by swabbing the distal tip and the entire length of the insertion tube (CleanTrace ATP Surface; 3M Company). ATP levels were measured using a luminometer. Protein and hemoglobin levels were read using a spectrophotometer (DR 1900 Portable Spectrophotometer; Hach Company, Loveland, CO). Due to the lack of published benchmarks for permissible levels of organic residue on reprocessed ureteroscopes, researchers used published benchmarks for residue on manually cleaned gastrointestinal endoscopes (ATP: 200 relative light units [RLU], protein: 6.4 μg/mL, and hemoglobin: 2.2 μg/mL).[26,27] Samples for microbial culturing were transported in coolers to an external laboratory (Biotest Laboratories, Inc, Brooklyn Park, MN). The laboratory filtered samples through 0.22 μm nitrocellulose filters before plating on blood agar. Samples were incubated at 26°C-30°C for 24 hours and then at 34°C-36°C for 5-7 days to foster growth of bacteria and fungi.

At each site, 2 positive control tests were performed on clinically used endoscopes before they underwent manual cleaning. Two negative control tests were conducted at each site using sterile items (brand new ureteroscope, autoclaved surgical steel instrument, and sterile water).

Visual examinations

After sampling, ureteroscopes were recleaned and sterilized before visual examination. External surfaces were systematically photographed using an 8-megapixel digital camera (iSight; Apple Inc, Cupertino, CA). Predetermined locations inside distal ends, ports, and channels were examined with a 0.8 mm fiber optic borescope (Ultra-Thin HQ Micro Borescope; Medit Inc, Winnipeg, Canada) to facilitate comparisons between ureteroscopes. Additional photographs were captured when irregularities were observed.

Risk assessment protocol

Before site visits, researchers and site personnel established a risk assessment protocol to address issues identified as a result of study activities. Under this protocol, researchers alerted site personnel whenever residual contamination exceeded benchmarks, substantial irregularities (eg, deep scratches; residual debris) were observed during visual examinations, or microbial cultures had any growth. Decisions to re-reprocess ureteroscopes, quarantine them, or send them out for repair were made by site personnel.

RESULTS

Ureteroscope characteristics

Researchers received administrative data for 13 ureteroscopes at site A (A-1 through A-13) and 4 ureteroscopes at site B (B-1 through B-4) (Table 1). The mean ureteroscope age was 2.1 years (range, 0.21-5.6 years) at site A and 2.2 years (range, 1.0-2.8 years) at site B. Ureteroscopes at both sites were used infrequently (average <1/week). Sites documented a total of 49 repairs before the study. Ureteroscopes required repair after an average of 14 uses at site A and 42 uses at site B. Common reasons for repair included leaks identified by reprocessing technicians (19 repairs) and inadequate image quality (15 repairs) (Table 1).

Reprocessing practices

According to sterile processing department (SPD) managers at both sites, institutional reprocessing protocols included immediate bedside precleaning; transportation to SPD; leak testing; manual cleaning with enzymatic detergent followed by rinsing; drying with air purges, alcohol flushes, and forced air; and sterilization with hydrogen peroxide gas. The reprocessing protocols described by SPD managers are consistent with recommendations described in reprocessing guidelines.[24,25] Before sterilization, the reprocessing protocol at site A also required each endoscope to undergo automated cleaning and HLD in an automated endoscope reprocessor. Enzymatic detergent was used for the automated cleaning cycle, and peracetic acid was used for HLD before sterilization. At site B, the protocol included conducting routine tests to verify cleaning effectiveness using an indicator for protein, hemoglobin, and carbohydrates (ChannelCheck; HealthMark Industries) after manual cleaning. The site B protocol specified that ureteroscopes should be recleaned whenever the cleaning verification test detected contamination. In addition, the image quality was assessed immediately after each procedure and again before packaging for sterilization.

During both site visits, no bedside precleaning was done by operating room personnel, who acknowledged that they did not customarily perform this step before sending ureteroscopes to the SPD for reprocessing. SPD and operating room employees reported occasional delays between procedure completion and the initiation of manual cleaning, and there was no protocol for reporting delayed reprocessing so that it could be addressed in