Endoscope storage time: assessment of microbial colonization up to 21 days after reprocessing

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Background: Insufficient data exist for how long endoscopes can be stored after reprocessing. Concern about possible microbial colonization has led to various recommendations for reprocessing intervals among institutions, with many as short as 5 days. A significant cost savings could be realized if it can be demonstrated that endoscopes may be stored for as long as 21 days without risk of clinically significant contamination.

Objective: To demonstrate whether flexible endoscopes may be stored for as long as 21 days after reprocessing without colonization by pathogenic microbes.

Design: Prospective, observational study.

Setting: Tertiary care center.

Endoscopes: Four duodenoscopes, 4 colonoscopes, and 2 gastroscopes.

Intervention: Microbial testing of endoscope channels.

Main Outcome Measurements: Culture results at days 0, 7, 14, and 21.

Results: There were 33 positive cultures from 28 of the 96 sites tested (29.2% overall contamination rate). Twenty-nine of 33 isolates were typical skin or environmental contaminants, thus clinically insignificant. Four potential pathogens were cultured, including *Enterococcus*, *Candida parapsilosis*, α-hemolytic *Streptococcus*, and *Aureobasidium pullulans*; all were likely clinically insignificant as each was only recovered at 1 time point at 1 site, and all grew in low concentrations. There were no definite pathogenic isolates.

Limitations: Single center.

Conclusion: Endoscopes can be stored for as long as 21 days after standard reprocessing with a low risk of pathogenic microbial colonization. Extension of reprocessing protocols to 21 days could effect significant cost savings. (Gastrointest Endosc 2015;81:1150-4.)

Endoscopes are cleaned ("reprocessed") to prevent transmission of infection from 1 patient to another. They are categorized as semicritical medical devices by the Spaulding classification system, meaning that they contact mucosal surfaces but do not breach sterile environments.[1] As such, they require at least high-level

Abbreviation: CFU, colony-forming unit.

DISCLOSURE: *All authors disclosed no financial relationships relevant to this article. This study was supported by institutional funds for quality improvement at the Medical University of South Carolina.*

See CME section; p. 1237.

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0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2014.09.053

Received June 30, 2014. Accepted September 22, 2014.

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disinfection, as espoused by multiple societies.[1] Proper reprocessing became widespread when multisociety guidelines for standardized endoscope reprocessing were first established 1988. Since that time, there have been very few reports of transmission of infection during GI endoscopy, and they are almost exclusively related to breaches in disinfection protocol or the use of defective equipment.[2]

Although disinfection protocols are highly effective when applied assiduously, it is not known how long instruments may be stored before microbial colonization may occur. Because of this paucity of data, current U.S. multisociety guidelines make no recommendation for how long endoscopes may be stored after reprocessing ("shelf life").[1] This has led to variability in reprocessing intervals among institutions, with many using 5-day intervals, likely based on earlier society guidelines.[1] Other organizations, such as the Gastroenterological Society of Australia, call for even more stringent intervals, with storage times between 12 and 72 hours, depending on type of endoscope.[3] The few studies that address this issue indicate that shelving instruments for 5 to 14 days is associated with a low risk of contamination,[4-8] with 1 small study of colonoscopes only showing this for up to 8 weeks.[9] We aimed to demonstrate whether duodenoscopes, gastroscopes, and colonoscopes may be stored for as long as 21 days without microbial colonization by potential pathogens.

METHODS

This was a prospective, observational study conducted at the Medical University of South Carolina from August to October 2013. The endoscopes used in this study were in active use in our unit before the study and only taken out of circulation for the duration of the study. They included 4 duodenoscopes, 4 colonoscopes, and 2 gastroscopes (Olympus Medical, Center Valley, Pa). All personnel in this unit responsible for endoscope reprocessing are certified endoscopy technicians and follow standard of care protocols for mechanical cleaning and high-level disinfection by using an automated endoscope reprocessor. This study did not include human subjects or identifiers and was thus given exempt status by the Institutional Review Board of the Medical University of South Carolina.

Endoscope reprocessing

Each endoscope was cleaned per institutional protocol, in accordance with published guidelines.[10] This involves manually wiping the endoscope with enzymatic detergent (Intercept; Medivators Inc, Minneapolis, Minn) at the bedside until all visible debris is removed. The endoscope is then suctioned with the same solution. The endoscope is then transported to a dedicated reprocessing area where each channel as well as the length of the endoscope is leak tested with clean water. If no leaks are present, the channels are brushed with detergent and the endoscope is again manually cleaned with enzymatic detergent. The endoscope is then connected to a sink that purges each channel at specified pressures. Subsequently, the endoscope and each channel are rinsed with filtered water. Air is then blown through each channel to dry. All surfaces of the endoscope are then visually inspected. After this, the endoscope is placed into the automated reprocessor (Medivators DSD-201; Medivators Inc) and undergoes high-level disinfection with a 2.5% glutaraldehyde solution (Rapicide; Medivators Inc). At the end of the 27-minute disinfection cycle, the endoscope is flushed with filtered water, followed by alcohol and then air. It is then stored hanging vertically without valves in a dust-free, ventilated cabinet with a removable drip tray (InnerSpace 4000 Series Metal Roll Top Scope Cabinet; Stanley Healthcare, Grand Rapids, Mich). This cabinet also included endoscopes that were in active use and was left open during the day but closed at night for security.

Sample collection

All microbiological samples were collected by 2 registered nurses, 1 of whom is a certified gastroenterology registered nurse of 13 years, with 12 years of previous experience as an endoscopy technician (J.F.) and the other an infection control practitioner (B.G.). The samples were collected immediately after high-level disinfection on day 0, then stored hanging in a dust-free cabinet until they were removed (but not reprocessed) for sample collection on days 7, 14, and 21.

Before collecting samples, each nurse performed hand hygiene and donned a sterile gown and gloves. Samples were collected from each endoscope channel on days 0, 7, 14, and 21, making a total of 96 samples. For duodenoscopes, samples were first collected from the elevator wire channel, followed by the suction channel and biopsy port, the latter 2 being in the same order for colonoscopes and gastroscopes. For the elevator channel, 3 mL of sterile water was irrigated via a 3-mL Luer lock syringe (Becton, Dickinson, Franklin Lakes, NJ) 3 times, for a total collection of 9 mL. The sample collection technique for the suction and biopsy ports was the same, whereby they were first irrigated with 30 mL of sterile water. Next, a sterile brush was inserted through the channel and advanced 2 inches beyond the endoscope tip. Sterile scissors were then used to cut the brush, allowing it to drop into a sterile specimen cup.

Microbial testing

A 1-mL aliquot of each well-mixed sample was inoculated onto trypticase soy agar with 5% sheep blood (blood agar), thioglycollate broth, a CDC anaerobic blood agar plate, and Sabouraud dextrose agar (for yeast and molds). All media were incubated at 25° to 35° Celsius for 7 days.

TABLE 1. Nonpathogens

Microbe	Total positive cultures	C-scope	D-scope	G-scope	Suction channel	Biopsy channel	Elevator
CNS	18	2	4	3	4	11	3
Micrococcus	6	2	2	0	2	3	1
Bacillus	3	1	1	1	1	2	0
Corynebacterium	1	0	1	0	0	1	0
Propionibacterium acnes	1	0	1	0	0	1	0

C-scope, Colonoscope; *D-scope*, duodenoscope; *G-scope*, gastroscope; *CNS*, coagulase-negative *Staphylococcus*.

TABLE 2. Potential pathogens

Microbe	Total positive cultures	Endoscope	Channel	Day	Concentration
Enterococcus	1	Colonoscope	Biopsy	7	1 CFU/mL
Candida parapsilosis	1	Duodenoscope	Biopsy	21	1 CFU/mL
α-Hemolytic *Streptococcus*	1	Gastroscope	Biopsy	14	Thio broth only*
Aureobasidium pullulans	1	Colonoscope	Biopsy	1	1 CFU/mL

CFU, Colony-forming unit.
*Thio broth only is considered to be <1 CFU/mL.

Organisms were identified by using standard microbiological techniques; results were reported in colony-forming units (CFU) per milliliter.

Data analysis

Numbers and percentages of positive cultures were calculated in total and by type of endoscope, organism, channel, and day.

RESULTS

There were 33 positive cultures from 28 of the 96 sites tested (29.2% overall contamination rate). Most positive cultures grew 1 CFU/mL or less (ie, grew in thio broth only). The majority of isolates, 29 of 33, were typical skin or environmental contaminants, thus clinically insignificant (Table 1). The most common of these was coagulase-negative *Staphylococcus* (n = 18), followed by *Micrococcus* (n = 6), *Bacillus* (n = 3), *Corynebacterium* (n = 1), and *Propionibacterium acnes* (n = 1). Only 3 cultures grew more than 1 CFU/mL: 1 culture grew 5 CFU/mL *Corynebacterium*, a second culture grew 8 CFU/mL of coagulase-negative *Staphylococcus*, and 1 culture, a duodenoscope elevator, grew 49 CFU/mL of *Micrococcus*. There was only 1 instance where the same microbe was isolated on the same channel of the same endoscope at different time points (1 CFU/mL *Micrococcus* on days 7 and 21 on the biopsy channel of a colonoscope).

Four isolates represented potential pathogens (4.2% of 96 sites tested). These included *Enterococcus*, *Candida parapsilosis*, α-hemolytic *Streptococcus*, and *Aureobasidium pullulans* (Table 2). All were found in low concentration and only at 1 site and time point. One was isolated on day 0, 1 on day 7, 1 on day 14, and 1 on day 21 (Table 2).

The 4 potential pathogens were cultured from 2 colonoscopes, 1 duodenoscope, and 1 gastroscope, all from the biopsy channel (Table 2). This was also the most common site for all positive cultures (22 of the 33) (Table 3).

DISCUSSION

Exogenous transmission of infection via endoscopy is a rare event when proper high-level disinfection techniques are used, but the shelf-life before virulent microbial colonization may occur is not currently known. In this study, we provide evidence that a storage time of 21 days is likely safe.

Our results are consistent with and complement those of previous reports. One study demonstrated no clinically significant growth on gastroscopes, colonoscopies, and duodenoscopes at 5 days.[6] Two reports evaluating colonoscopes alone demonstrated no clinically significant contamination at 7 days.[4,5] A larger study involving 23 endoscopes, including gastroscopes, duodenoscopes, colonoscopies, and EUS endoscopes showed no potentially

TABLE 3. Isolates by endoscope

Scope	No. of positive cultures	Biopsy channel	Suction channel	Elevator	Day 0	Day 7	Day 14	Day 21
C1	3	3	0	n/a	0	1	1	1
C2	3	2	1	n/a	1	1	1	0
C3	5	4	1	n/a	1	1	2	1
C4	1	1	0	0	0	0	1	0
D1	4	2	1	1	1	0	0	3
D2	6	4	1	1	0	2	1	3
D3	2	1	0	1	0	1	0	1
D4	4	1	2	1	1	0	2	1
G1	1	1	0	n/a	0	0	0	1
G2	4	3	1	n/a	0	2	1	1
Total	33	22	7	4	4	8	9	12

C, Colonoscope; *n/a*, not applicable; *D*, duodenoscope; *G*, gastroscope.

or true pathogenic microorganisms at 5 days, and only 1 (yeast) when incubation was extended to 7 days.[7] A study from 2007 recovered no pathogens or potential pathogens on 3 colonoscopes and 4 duodenoscopes at 14 days.[8] A more recent study evaluated 4 colonoscopes over an 8-week period, finding no pathogens[9]; however, this study was limited to colonoscopies, and fungal cultures were not obtained.

In this study, we found a large number of positive cultures with nonpathogenic microbes. This is likely attributed to contamination while obtaining and/or inoculating samples and thus not clinically significant. We also identified 4 potential pathogens (*Enterococcus*, *Candida parapsilosis*, α-hemolytic *Streptococcus*, and *A pullulans*), although the clinical significance of these isolates is questionable because each was only identified at 1 time point and at 1 site (ie, not identified on repeated cultures from the same or different sites). Additionally, although no established clinically relevant bioburden has been reached, the growth rate in each instance fell well below the proposed threshold of 100 CFU/mL (3 cultures with 1 CFU/mL and 1 thio broth only).[11] Moreover, none of these pathogens have been documented in any reported cases of endoscopic transmission of infection.[12] Finally, the random distribution of time points of these pathogens (0, 7, 14, and 21 days) makes them most likely contaminants given the previous studies demonstrating the low risk of potentially pathogenic species for as long as 8 weeks after reprocessing.[4-9]

We elected to sample the endoscope channels but not the surface. It has been noted that the channels (particularly the biopsy channel) are the best means of assessing microbial colonization because they are more likely to harbor microorganisms than is the surface.[13] This is because of the lower accessibility of the channels to cleaning equipment, subsequent biofilm collection, as well as the increased damage incurred in these areas during use.[13]

This is the first study that evaluates colonization of gastroscopes, colonoscopes, and duodenoscopes for as long as 21 days after reprocessing. Evidence is now accruing that we can safely shelve flexible endoscopes after standard disinfection for longer durations than are currently practiced. It is uncertain what the maximum duration is, but for now, extending beyond the 5 to 7 days that is practiced in many units could result in considerable cost savings. Specifically, less-frequent processing would decrease the amount of endoscopy staff time required, the use of disinfectants, and the use of processors. Additionally, less-frequent intervals may facilitate endoscopy unit throughput and minimize delays in procedures because of the lack of available endoscopes. Future studies with extended cultures beyond 21 days would be critical to understand the maximum shelf-life of flexible endoscopes after reprocessing.

It should be emphasized that our conclusions and recommendations clearly apply only when endoscopes are reprocessed and stored in optimal fashion. It is conceivable that short shelf-times may occasionally have minimized the potential adverse effects of inadequate reprocessing at some centers and that lengthening the time in such circumstances could be detrimental. Finally, other similar studies are needed to assess whether the conclusions apply to other reprocessing systems and disinfection agents.

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