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## Endoscope Reprocessing: Update on Controversial Issues

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Several issues concerning endoscope reprocessing remain unresolved based on currently available data. Thus, further studies are required to confirm standard practices including safe endoscope shelf life, proper frequency of replacement of some accessories including water bottles and connecting tubes, and microbiological surveillance testing of endoscopes after reprocessing. The efficacy and cost-effectiveness of newer technology that allows automated cleaning and disinfection is one such controversial issue. In addition, there are no guidelines on whether delayed reprocessing and extended soaking may harm endoscope integrity or increase the bioburden on the external or internal device surfaces. In this review, we discuss the unresolved and controversial issues regarding endoscope reprocessing. **Clin Endosc 2015;48:356-360**

**Key Words:** Reprocessing; Endoscopy; Disinfection

### INTRODUCTION

Gastrointestinal (GI) endoscopy is an important tool for the diagnosis and management of GI tract disorders. GI endoscopic procedures are performed in body cavities that are heavily colonized with microorganisms; thus, during use, endoscopes become heavily contaminated with bioburdens including blood, body fluids, and other potentially infectious materials. Endoscope reprocessing requires multiple steps, including pre-cleaning, cleaning, disinfection, rinsing, drying, and storage.<sup>1</sup> Although automated endoscope reprocessors (AERs) have been used during the disinfection step in the past few decades, reprocessing still primarily involves manual handling.

A number of current guidelines provide standards and recommendations for endoscope reprocessing.<sup>2-7</sup> In 1995, the Korean Society of Gastrointestinal Endoscopy (KSGE) devel-

oped cleaning and disinfection guidelines for GI endoscopes that were subsequently revised and republished in November 2009, August 2012, and March 2015.<sup>8</sup> However, real practices for endoscope reprocessing may differ among sites, and alterations to protocols and deviations from standard procedures may occur over time.<sup>9</sup> In addition, several studies reported a lack of compliance with established guidelines for endoscope reprocessing.<sup>10-13</sup> An increased risk of infection transmission has been associated with endoscope and AER flaws as well as human error, including inadequate or delayed reprocessing, failure to sterilize accessory equipment, incorrect selection of disinfectants, and improper drying.<sup>13</sup>

Although rare, media reports of infectious complications following GI endoscopy persist. Outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) in the United States were recently reported in patients who had undergone endoscopic retrograde cholangiopancreatography (ERCP) or duodenoscopy.<sup>14</sup> An elevator wire hinge of side-view duodenoscopy used during ERCP cannot be reached by the brushes used to perform the manual component of the high-level disinfection. The remaining organic debris could lead to the potential for bacterial transmission. Although no study to date has reported duodenoscopy-associated outbreak of CRE in Korea, safe and effective reprocessing of all endoscopic equipment is imperative to prevent infection transmission during GI endoscopy.

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Several issues concerning endoscope reprocessing remain unresolved based on currently available data and necessitate further studies to confirm standard practices.<sup>2</sup> The first issue is endoscope “hang time” or “shelf life”; that is, the time for which a reprocessed endoscope can be stored and reused without further reprocessing. The second issue is the optimal frequency of replacing clean water bottles and connecting tubes. Another issue is microbiological surveillance testing of endoscopes after reprocessing, during storage, or before use. Recommendations from current international guidelines for these issues are inconclusive. KSGE guidelines have no recommendation for controversial issues. In addition to above unresolved issues, there are other issues regarding the efficacy of new technologies for fully automated cleaning and disinfection, and delayed reprocessing. A review of microbiological surveillance testing is beyond the scope of the present article. In this review, we discuss the unresolved and controversial issues surrounding endoscope reprocessing.

## ENDOSCOPE SHELF LIFE

Although protocols for endoscope reprocessing are highly effective when applied assiduously, safe shelf life is not known due to limited research evidence, and the recommendations from many guidelines are not uniform. Current U.S. Multi-Society guidelines make no recommendation for endoscope shelf life.<sup>2</sup> The European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology Nurses and Associates (ESGNA) states that “local policies must be in place that define for how long a reprocessed endoscope can be used before it needs re-disinfection.”<sup>4</sup> Australian guidelines recommend stricter storage time of 12 to 72 hours before additional reprocessing depending on endoscope type.<sup>6</sup> The Society of Gastroenterology Nursing and Associates has not made any recommendation for the interval of storage due to limited investigations.<sup>5</sup> The most recent recommendation from the Association of periOperative Registered Nurses states that endoscopes may be stored up to 5 days without additional reprocessing before use if thoroughly dried and stored properly.<sup>3</sup>

Available data from several studies suggest that the contamination of reprocessed endoscopes during appropriate storage for intervals of 7 to 14 days is negligible, occurs only on the exterior of endoscopes, and involves only common skin organisms.<sup>15-20</sup> Endoscope contamination in these studies was assessed by flushing endoscope channels with sterile water at various time points and culturing the samples to determine the presence of microorganism contamination. Rejchrt et al.<sup>17</sup> evaluated the contamination of three different types of endoscopes (gastrosopes, duodenoscopes, and colonoscopes)

stored in a clean cabinet after disinfection. The results showed that skin bacteria were the only contaminants on the endoscope surfaces during the subsequent 5-day testing period. None from fluid flushed thorough the biopsy channels were contaminated. A simulated study demonstrated that colonoscopes remained free of potentially pathogenic contamination for up to 1 week after high-level disinfection.<sup>16</sup> In a prospective observational study involving 23 endoscopes, including gastrosopes, duodenoscopes, colonoscopies, and endoscopic ultrasound (EUS) scopes, endoscopes were microbiologically sampled before the first procedure of the day ( $n=200$ ).<sup>18</sup> The results showed a nonpathogenic contamination rate of 15.5% and a pathogenic rate of 0.5%. The most frequently detected environmental nonpathogenic organism was coagulase-negative *Staphylococcus*. A pathogenic organism, yeast, was cultured in only one case when incubation was extended to 7 days. In another study, four duodenoscopes and three colonoscopes were cultured after high-level disinfection every day for a period of 2 weeks, but no potential pathogens were found.<sup>19</sup> A recent study by Ingram et al.<sup>20</sup> tested four colonoscopes over an 8-week period but found no medically significant microbiological growth; however, fungal cultures were not performed.

Most recently, Brock et al.<sup>21</sup> reported that endoscopes can be stored for as long as 21 days after standard reprocessing with a low risk of pathogenic microbial colonization. In this prospective observational study, the researchers tested four duodenoscopes, four colonoscopes, and two gastrosopes. After reprocessing, each endoscope was hung vertically without valves in a dust-free ventilated cabinet with a removable drip tray. Microbiological samples were collected from each endoscope channel by irrigation with 30 mL of sterile water on days 0, 7, 14, and 21 that was then cultured. A total of 33 positive cultures from 28 of the 96 sites tested were obtained. Almost all of the isolates (29 of 33) were typical skin or environmental contaminants and, thus, considered clinically insignificant. The other four isolates were potential pathogens, including *Enterococcus*, *Candida parapsilosis*,  $\alpha$ -hemolytic *Streptococcus*, and *Aureobasidium pullulans*. However, the findings were also clinically insignificant because all isolates were found in low concentrations and each was only recovered at one site and time point. This study provides evidence to expand endoscope shelf life after reprocessing to up to 21 days, which would result in considerable cost savings. These cost savings would be mainly in reduced staffing resources required as well as decreased use of disinfectants and AERs. However, these recommendations can be applied only when endoscopes are properly reprocessed, dried, and hung vertically in a clean, well-ventilated cabinet (Fig. 1). In addition, further studies are necessary to evaluate whether these findings apply to other



**Fig. 1.** Correct endoscope storage after reprocessing. Endoscopes are hung vertically in a clean, well-ventilated cabinet without caps, valves, and other detachable components to facilitate drying.

reprocessing systems and disinfection agents.

## WATER BOTTLES AND CONNECTORS

There is limited research evidence to recommend the proper intervals for the replacement of water bottles, air insufflation tubes, lens wash water, waste vacuum canisters, and suction tubes used in endoscopy. Water bottles and connecting tubes have been implicated in the transmission of infection by inadequate cleaning, lack of sterilization, or the use of tap water instead of sterile water.<sup>22,23</sup> Several guidelines including those of the KSGE provide a recommendation that water bottles and connecting tubes be steam sterilized and the bottles changed each session.<sup>4,6,24</sup> All non-autoclavable bottles and connectors should be replaced with those that can be autoclave-sterilized. The water bottles should be filled with sterile water and new bottles should be exchanged after each session. In addition, microbiological testing of water bottles must be

included in regular quality control measures.<sup>4</sup> The safety and potential risk per procedure versus the daily exchange of these accessory items should be further investigated

## NEW TECHNOLOGIES FOR HIGH-LEVEL DISINFECTION

AERs, which were designed to replace some manual reprocessing steps, are widely used worldwide and provide reliable and effective high-level disinfection. The ESGE/ESGNA strongly recommend the use of AERs for cleaning and disinfection.<sup>4</sup> AERs allow a standardized and validated reprocessing cycle in a closed environment, automatic documentation of the process steps, and highly reliable reprocessing. In addition, their use can minimize contact between chemicals and between contaminated equipment and staff as well as prevent environmental contamination. A variety of capabilities have been developed and incorporated into the available AERs. These capabilities are summarized in a technology status evaluation report of the American Society of Gastrointestinal Endoscopy.<sup>25</sup> All models have disinfection and wash cycles, and some feature detergent cleaning, alcohol flush, and/or a drying cycle using filtered air. Additional characteristics or designs may include the following: variable cycle times; printed process documentation; low-intensity ultrasound waves; disinfectant vapor recovery systems; heating to optimize disinfectant efficacy; a variable number of endoscopes reprocessed per cycle; automated leak testing; automated detection of channel obstruction; and table-top, floor-standing, and cart mounted models.<sup>25</sup>

The manual cleaning step is a critical part of endoscope reprocessing that is vulnerable to human error.<sup>12,26,27</sup> Possible human errors during manual cleaning may include: failing to clean channels because endoscope reprocessing personnel were unaware of them, failing to properly assess whether channels are leaking or blocked, or not flushing adequate amounts of fluid through all channels.<sup>28</sup> These errors may cause inadequate high-level disinfection that allows hazardous microorganisms to survive and be transmitted to the next patient. Recently, one newer AER (EVOTECH Endoscope Cleaner and Reprocessor [ECR]; ASP, Irvine, CA, USA) received an U.S. Food and Drug Administration cleared cleaning claim for use after bedside pre-cleaning only without the need for manual cleaning and channel brushing before high-level disinfection.<sup>25</sup> Alfa et al.<sup>28</sup> performed simulated-use testing as well as a clinical study to evaluate the efficacy of ECR cleaning for flexible colonoscopes. ECR cleaning consists of a flush with enzymatic detergent solution through all channels and wiping the exterior of the insertion tube with a cloth soaked with the same enzymatic detergent. The results of this

study showed that the use of an ECR to clean endoscopes met or exceeded standards set for routine manual cleaning in 99% to 100% of cleaning cycles. The authors concluded that ECR is an effective automated method that ensures adequate cleaning of the channels and surfaces of flexible endoscopes after having only a bedside pre-cleaning. In addition to cleaning endoscopes, ECR provide an automated wet and dry leak test, alcohol flushing before cycle completion to promote drying, and complete monitoring of critical cycle parameters including minimum effective concentration of the disinfectant, disinfection time, channel blockage detection, pressure, temperature, and time to ensure process compliance.<sup>29</sup>

Another recent study performed an economic evaluation to determine the cost efficiency of the ECR versus AER methods of endoscope reprocessing in an actual clinical setting.<sup>30</sup> The results showed that ECR was more efficient and less expensive than manual cleaning followed by AER disinfection. Although the expenditures of consumable supplies required to reprocess endoscopes was slightly higher than manual cleaning plus AER, the value of labor time saved by ECR compensated for the difference. However, ECR cannot be used to reprocess two-channel endoscopes or EUS scopes. In addition, in cases in which endoscopes have been used for emergency procedures or where endoscope reprocessing has been delayed for more than 1 hour, endoscopes should be manually cleaned before placement within the ECR. Further studies are required to determine if the increased efficiency with ECR would allow further cost-savings in low-volume endoscopy units.

## DELAYED REPROCESSING

Current endoscope reprocessing guidelines recommend reprocessing immediately after use. Delayed endoscope reprocessing, in which the endoscope is allowed to sit idle and is soiled for an extended period of time, sometimes hours, before being reprocessed is another important problem because it can pose an increased risk of disease transmission and result in endoscopic damage.<sup>31</sup> If endoscope reprocessing is delayed, body fluids or other potentially infectious materials can begin to dry on the surface and internal channels of the endoscope; thus, biofilm can form on the inner wall of the extension pipe of the endoscope and render the standard reprocessing procedures less effective. Delays in reprocessing usually occur in the setting of emergency endoscopy when the endoscopes are left for proper reprocessing the next business day. When immediate reprocessing is not possible, an alternative strategy is to soak the endoscope in the proper enzymatic detergent according to the manufacturer's recommendations until it can be mechanically cleaned and high-level disinfection can be performed.<sup>32</sup> However, the optimal soaking period

is not stated, and the importance of pre-cleaning with enzymatic detergent is not clearly mentioned.

There are currently no standards or guidelines on whether delayed reprocessing and extended soaking may harm endoscope integrity or increase the bioburden on its external or internal surfaces. An extended soak in detergent should be 2 to 5 hours up to 10 hours.<sup>31</sup> Extended soaking longer than the recommended duration may result in increased bioburden, potential biofilm formation, and endoscope damage due to moisture, especially if it was not first leak-tested.<sup>33</sup> A recent study performed a web-linked survey to determine staffing and practice patterns for after-hours and emergency endoscopy.<sup>34</sup> Of 168 endoscopists, 20 (12%) reprocessed the endoscopes themselves or with the help of a resident. To prevent the transmission of microorganisms during endoscopy, such physicians should receive adequate and regular training for all of the reprocessing components. Even if endoscope reprocessing is delayed, pre-cleaning should always be performed at the bedside immediately after use according to current standards of practice. Further studies should be designed to better define the importance of immediate reprocessing.

## CONCLUSIONS

Endoscope contamination due to improper reprocessing is associated with more outbreaks of hospital-acquired infection than any other medical device. Current international guidelines and KSGE guidelines have no recommendations or standards for practice regarding some issues, including safe endoscope shelf life, the optimal replacement frequency of some accessories, and microbiological surveillance testing of endoscopes after reprocessing. In the absence of evidence-based guidelines for unresolved issues, every effort should be made in a timely and efficacious manner to ensure patient safety.

### Conflicts of Interest

The authors have no financial conflicts of interest.

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