Clinical Practice Guidelines for the Endoscope Reprocessing

Hyun Jin Oh, Jin Su Kim,

Division of Gastroenterology, Department of Internal Medicine, College of Medicine, The Catholic University of Korea, Seoul, Korea

Running Title: Comparison of Endoscope Reprocessing

Correspondence: Jin Su Kim, MD.

Division of Gastroenterology, Department of Internal Medicine, Seoul St. Mary's Hospital, College of Medicine, The Catholic University of Korea, 222 Banpo-daero, Seocho-gu, Seoul 137-701, Korea; Tel: 82-2-2258-2044; Fax: 82-2-2258-2089; E-mail: jinsu23@naver.com
Abstract

Gastrointestinal endoscopy is effective and safe for the screening, diagnosis and treatment of gastrointestinal disease. However, issue about endoscope-transmitted infections are emerging. Many countries have established and continuously revise guidelines for the endoscope reprocessing to prevent infections. While there are common processes of endoscope reprocessing, differences exist among these guidelines. It is important that reprocessing of GI endoscopes should be carried out at each step and in line with recommendations.

Key words: Endoscopy; Reprocessing; Guideline
Introduction

Endoscopy is used worldwide for screening, diagnosis and treatment of Gastrointestinal (GI) diseases. It enables early detection and treatment of malignant GI diseases. Despite its efficacy, there are several reported concerns about infections that are transmitted via endoscopy.\(^1^\)\(^-^\)\(^3^\) Consequently, several countries have revised evidence-based guidelines on the use of endoscopy in order to reduce infection and improve safety. Recently, the Korean Medical Association released in March 2015 its 3\(^{rd}\) revision on guideline of endoscopic reprocessing. In this paper, we discuss reprocessing protocols of GI endoscopes and recently revised guidelines of medical associations around the world including Multisociety guideline, The European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) guideline, British Society of Gastroenterology (BSG) Guideline and World Gastroenterology Organization (WGO) Guideline.

Common reprocessing protocol of GI endoscopes

There are seven steps involved in reprocessing of GI endoscopes: precleaning, cleaning, rinsing, disinfection, rinsing, drying and storage. These steps are similar across various guidelines.\(^4^\)\(^-^\)\(^8^\)

1. Precleaning is the first step of the reprocessing, and should be done at the bedside immediately after finishing the endoscopic procedure. Precleaning involves the removal of visible debris by wiping the exterior of the endoscope with an appropriate detergent solution. Air and solution should be passed through the biopsy channel repeatedly. After precleaning, endoscopes need to be transported to other room for disinfection process. The container for endoscopes should be closed, if the room is not adjacent.

2. Cleaning is the next step. Before cleaning the endoscopes, a leak test should be performed and all detachable parts should be separated. Clean the external surface of the endoscope with detergent, by using soft cloths, sponge or brushes. Flush and brush all accessible channels to remove the debris and other contaminants. Hard to clean areas or accessories should be cleaned by an ultrasonic cleaner. After cleaning, rinse with clean water to remove the detergent on the endoscopes.
3. Rinsing means flushing the endoscope, channels and all accessories with sterile water.

4. High-level disinfection is recommended after the cleaning and rinsing process. The endoscope and its components should be completely immersed in high-level disinfectant solution ensuring that all channels are well perfused. Selection of high-level disinfectants should be based on FDA (CE or KFDA) approval. Appropriate exposure time and temperature for high-level disinfection is different according to the disinfectants and its concentration. An automated endoscope reprocessor can be used for high-level disinfection.

5. Following disinfection, final rinsing the endoscope, channels and all accessories with sterile water.

6. Dry the endoscopic channels by flushing the forced air and ethyl or isopropyl alcohol 70–90%.

7. Storage means keeping endoscope in a safe and sterile condition usually hang the endoscopes in vertical position without touching the floor

Korean Guideline of endoscopic reprocessing

The Korean Society of Gastrointestinal Endoscopy had established the first endoscopic reprocessing guideline in 1995. Since then, the guideline has been revised in August 2009, August 2012 and March 2015. The latest, 3rd revision included assessment criteria regarding reprocessing not only in certification of individual medical facilities but also in quality assessment of national cancer endoscopic screening. The overall process of endoscopic reprocessing is same as the common reprocessing protocol.

The main change of the recent updated guideline was on the issue of endoscope accessories reprocessing. It is no longer acceptable to reuse single-use (disposable) forceps and needles after sterilization. Korean National Health Insurance Service (NHIS) have not provided appropriate reimbursement for single usage of forceps up to date. Therefore, many clinicians have had practical limitations to use single-use forceps. As above, Korean endoscopy society updated and clarified the recommendation about endoscope accessories in 3rd revision. Thanks to their efforts, the reasonable cost of the biopsy forceps claims are made possible.

There are several different details from other guidelines about reprocessing endoscopes. For example, unlike
BSG and ESGE-ESGENA guidelines, there is no recommendation for microbiological surveillance. Also, water bottle and connectors should receive high-level disinfection every day and the water should be sterilized.

Multisociety guideline

In 2003, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America (SHEA) has developed an initial guideline for reprocessing GI endoscopes. This guideline was updated in 2011 together with additional discussions on evolving issues and latest literature citations. The guideline uses CDC system to categorize recommendations, from “Category IA” to “no recommendation”.  

For instance, “Category IA” recommendations about high-level disinfectants include as follow:

High-level disinfectants should be selected with FDA approval. There are six approved disinfectants: glutaraldehyde, orthophthalaldehyde, peracetic acid, hydrogen peroxide, electrolyzed acid water, and peracetic acid/hydrogen peroxide blend. The guideline mentions that when glutaraldehyde is used, it should be at 2% concentration level at 25°C for 20 to 90 minutes. Also, minimum effective density of active ingredient should be present in high level disinfectants and the solution must also be checked every day before use. The solution should be discarded, when the concentration of the solution is less than the minimal effective density.  

Unlike other guidelines, this guideline emphasizes the protection of those who participate in reprocessing from exposure to hazards and chemicals with varying recommendations. All participants should wear personal protective equipment and be in a safe environment (Category IB and IC). They should also be educated about hazards properly (Category IC).  

In addition, they use the Spaulding classification of medical device, which is used by the US FDA, CDC, epidemiologists and many other international organizations to determine the disinfection or sterilization. As endoscopes are classified as “semicritical” device, they should undergo at least high level disinfection. High-level disinfection is the destruction of mycobacteria, microorganisms, viruses, fungal spores and some, but not all, bacterial spores. Biopsy forceps, needles and cutting instruments such as sphincterotomes, which penetrate
the sterile tissue of the vascular structure, are classified as “critical” and should be sterilized.\textsuperscript{13,14}

There are two more contents that updated in the 2011 guidelines.

1. Before High-level disinfection, complete cleaning of endoscopes is more strongly required.

2. Hand hygiene, reprocessing tubing with one-way valves and endoscopic channels are considered the potential source of infection.

In addition, the following four unresolved issues are discussed.

1. How long endoscopes can be stored between use. Association of periOperative Registered Nurses (AORN) recommends 5 days, while the Association for Professionals in Infection Control and Epidemiology (APIC) recommends 7 days before reprocessing

2. How long water bottles, tubing for insufflations of air, lens wash water, waste vacuum canisters and suction tubing replacement could be used before replacements. AORN recommends changing after each procedure.

3. How long endoscopes could be used before replacement. Figuring out durability and longevity of endoscope requires additional research.

4. Whether microbiological surveillance testing is required after reprocessing, during storage, before use of endoscopes. Gastroenterological Society of Australia and the guideline of the combined European Society of Gastrointestinal Endoscopy and the European Society of Gastroenterology and Endoscopy Nurses and Associates committee recommends this measure. But this has not been advised in current american standards. Environmental microbiological testing of endoscopes for quality assurance has not been routinely established but this warrants further study.

ESGE-ESGENA guideline

In 1994, the ESGE–ESGENA Guideline Committee of the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) established the guideline for infection control of GI endoscopes. In 2008, ESGE-ESGENA updated the guideline for cleaning and disinfection of GI endoscopes.\textsuperscript{4}
Apart from the seven steps of endoscope reprocessing similar with other guidelines, they provided detailed information for the three different available reprocessing methods. Automated washer-disinfectors, automated disinfection devices and manual reprocessing followed by precleaning and manual cleaning. Automated washer disinfector includes all the processing steps from leakage test to drying. Automated disinfection devices include the rinsing, disinfection with final rinsing and drying. ESGE and ESGENA strongly recommend the use of washer-disinfectors including cleaning and disinfection. Compared with manual reprocessing, automated reprocessing provides a standardized and validated reprocessing cycle. In addition, it ensures highly reliable reprocessing, minimal staff hazard and lowers the risk of scope damage.

According to European (EN) standard 14885, disinfectants are effective at room temperature when they are used manually or in automated disinfection devices. They present the aldehyde group which includes glutaraldehyde, formaldehyde, and orthophthalaldehyde and the oxidizing substances include chlorine dioxide, hypochlorous acid and peracetic acid and its salts.

Biliopancreatic procedures require the usage of sterile accessories. Reusable devices should be autoclavable. Balloons for this matter, cannot be autoclaved and the use of reprocessed balloons increases the risk of biliopancreatic duct infection. Injection needles likewise should only be used once and in no circumstance should be reprocessed because dismantling of needles is dangerous and the lumen of the needle is inaccessible to clean.

They recommend the process validation and microbiological surveillance. Manufacturer’s instructions should be followed when performing process validation for washer disinfectors. Regular microbiological surveillance test, at intervals less than 3 months, is recommended. Washer disinfector, endoscopes, and the water used in endoscopy should be tested at the same time. Moreover, Regular quality control must include testing of water bottles.

British Society of Gastroenterology (BSG) Guideline
The 2008 guideline was updated in 2014. The process of reprocessing is described in two parts: First is the manual cleaning, which include precleaning, cleaning and rinsing. Second is the automated disinfection by using endoscope washer disinfectors (EWD), followed by drying and storage.

The reprocessing of endoscopes requires almost the same process as other guidelines. But there are several details which differ from other or previous guidelines. The use of enzymatic detergents on manual cleaning process to digest mucus and other biological material from endoscopic channel are no longer recommended, due to reports of occupational asthma and skin reactions.\textsuperscript{18,19}

This guideline does not consider manual disinfection method at all. They only recommend EWD as automated disinfection device. They strongly recommend the EWD for disinfection process, following manual cleaning. Glutaraldehyde-based disinfectant, a widely used disinfectant, is no longer used in United Kingdom. They mention two reasons for this. First is the issue of occupational safety concerns, an example of such is as asthma. Second is the potential risk of cross-link residual protein or prion material. There are four other disinfectants which can be used for reprocessing of endoscopes: Ortho-phthalaldehyde(0.55%), peracetic acid 0.2–0.35%, chlorine dioxide, and electrolytically generated hypochlorous acid.\textsuperscript{20}

For reprocessing of accessories, those that pass through the working channel of endoscopes should only be used once. For example, cytology brushes, polypectomy snares, injection needles, biopsy forceps and most ERCP accessories.\textsuperscript{21,22} Currently most biopsy forceps are reused but the discovery of variant Creutzfeldt-Jakob Disease has led the shift towards the single use. Accessories that are not passed through the working channel could be reused when sterilized, such as bottles and bougies. Heater probes also can be reused and should be sterilized.\textsuperscript{21}

BSG also recommend the microbiological surveillance test for assurance. The final rinse water should be sampled from the EWD and tested weekly for its microbiological quality in accordance with the current relevant European (EN) Standard, Health Technical Memorandum (HTM) or Choice Framework for local Policies and Procedures (CFPP).\textsuperscript{23-26}

World Gastroenterology Organization (WGO) Guideline

8
The committee of WGO is composed of Europe, America, Japan and they updated the guideline of reprocessing endoscopes in 2011. WGO guideline introduced the standard procedures with alternatives options that could be used when there are certain external limitations, in order to improve compliance. For example, cleaning process should be done with enzymatic detergent, but it could be done with non-enzymatic detergent in the limited condition. Also, if they cannot rinse the endoscopes and valves with filtered water, rinse them under running tap water of drinking-water quality. Endoscope Accessories which penetrate the mucosal barrier should be used only once or sterilized between each patient use. However, single-use is more preferred. If disposable accessories are to be reused in limited clinical setting, they should be perfectly sterilized. Microbiological surveillance testing is recommended. Samples of final rinse water from the automatic reprocessor should be subjected to microbiological testing at least weekly.

Conclusion

Guidelines for reprocessing of GI endoscopes are similar to each other, but they also have subtle differences (Table 1). Reprocessing of GI endoscopes should be carried out according to each step and in line with recommendations, whether they use the manual or automated methods. Many associations are trying to develop evidence-based guidelines on reprocessing of GI endoscopes. Evolution of disinfectants and automated machines for reprocessing is required to ensure endoscopic safety. Lastly, guidelines should reflect the evolution and practical limitation.

Conflicts of interest

The authors have no financial conflicts of interest.
Reference


30. Nurses AopR. Recommended practices for cleaning and processing endoscopes and endoscope accessories. AORN journal 2003;77:434.

<table>
<thead>
<tr>
<th>Country</th>
<th>Update</th>
<th>Disinfectants</th>
<th>Single use or reuse of accessories</th>
<th>Microbiological surveillance test</th>
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<tbody>
<tr>
<td>Multisociety America 2011</td>
<td>Glutaraldehyde, orthophthalaldehyde, peracetic acid, hydrogen peroxide, electrolyzed acid water, peracetic acid/hydrogen peroxide blend.</td>
<td>Penetrate mucosa: single use or sterilize</td>
<td>Contact with mucosa: at least high-level disinfection</td>
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<tr>
<td>ESGE-ESGENA Europe 2008</td>
<td>Formaldehyde, glutaraldehyde, orthophthalaldehyde, hypochlorous acid, chlorine dioxide, peracetic acid and its salts.</td>
<td>Biliary and pancreatic accessories sterilize except balloon</td>
<td>Rinse samples culture for channels and water bottle, Swab culture from outer surface, Test no longer than 3 months</td>
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<tr>
<td>BSG United Kingdom 2014</td>
<td>Orthophthalaldehyde(0.55%), peracetic acid 0.2~0.35%, chlorine dioxide, electrolytically generated hypochlorous acid</td>
<td>Passing through the working channel: single use</td>
<td>Final rinse water from the EWD, Tested weekly</td>
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<tr>
<td>WGO Europe, America 2011</td>
<td>Glutaraldehyde, orthophthalaldehyde,</td>
<td>Penetrate the mucosa: single use or sterilize</td>
<td>Final rinse water from the EWD,</td>
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ESGE, European Society of Gastrointestinal Endoscopy; ESGENA, European Society of Gastroenterology and Endoscopy Nurses and Associates; BSG, British Society of Gastroenterology; WGO, World Gastroenterology Organization