

High-level disinfection of gastrointestinal endoscope reprocessing

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Abstract

High level disinfection (HLD) of the gastrointestinal (GI) endoscope is not simply a slogan, but rather is a form of experimental monitoring-based medicine. By definition, GI endoscopy is a semicritical medical device. Hence,

such medical devices require major quality assurance for disinfection. And because many of these items are temperature sensitive, low-temperature chemical methods, such as liquid chemical germicide, must be used rather than steam sterilization. In summarizing guidelines for infection prevention and control for GI endoscopy, there are three important steps that must be highlighted: manual washing, HLD with automated endoscope reprocessor, and drying. Strict adherence to current guidelines is required because compared to any other medical device, the GI endoscope is associated with more outbreaks linked to inadequate cleaning or disinfecting during HLD. Both experimental evaluation on the surveillance bacterial cultures and in-use clinical results have shown that, the monitoring of the stringent processes to prevent and control infection is an essential component of the broader strategy to ensure the delivery of safe endoscopy services, because endoscope reprocessing is a multistep procedure involving numerous factors that can interfere with its efficacy. Based on our years of experience in the surveillance of culture monitoring of endoscopic reprocessing, we aim in this study to carefully describe what details require attention in the GI endoscopy disinfection and to share our experience so that patients can be provided with high quality and safe medical practices. Quality management encompasses all aspects of pre- and post-procedural care including the efficiency of the endoscopy unit and reprocessing area, as well as the endoscopic procedure itself.

Key words: Automated endoscope reprocessor; Bacterial culture; Gastrointestinal endoscopy; High-level disinfection; Liquid chemical germicide

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Core tip: High-level decontamination processes to ensure iatrogenic infection prevention in the delivery of high-quality gastrointestinal (GI) endoscopy services

are essential. There are three important steps that must be highlighted: manual washing, automated endoscope washer reprocessing and adequate drying/storage after rinsing. Our experimental data demonstrated that surveillance culture monitoring that can detect unsuccessful decontamination provides a much greater assurance of quality control for high level disinfection. This monitoring should be taken into account in order to ensure safety when a patient receives GI endoscope service. Randomized surveillance culture monitoring of the reprocessing process in each month is important for quality control and in ensuring patients' safety.

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INTRODUCTION

Gastrointestinal (GI) endoscopy is a widely performed for the diagnosis and treatment tool in the patients with gastrointestinal diseases not only, but also in the healthy people with requests for physical exams or checkups. Because of the instruments are complicated in structures and reusable in the clinical practice, a standard disinfection procedure is requested^[1]. It is an essential requirement for patient safety during the medical service. Inadequate reprocessing of endoscopes or endoscopic accessories may result in infection outbreak. Although the incidence of iatrogenic infection during gastrointestinal endoscopy was only about 1/1.8 million procedures in the United States from the year 1988 to 1992^[2], outbreak of bacterial/viral infection complicated with contamination of endoscopes and washer-disinfector instrument was also been individually reported^[3-6]. To supply a high quality medical environment, our institution adopt an idea of patient-centered approach, deliver a safety medical service, and we encourage innovations in teaching on the young physicians, new advance basic and clinical research and wonderful services in medical requirement. Herein, we would like to share with our years of experience on the surveillance of the culture monitoring of endoscopic reprocessing in our GI endoscope unit, particularly the detail process of the disinfection procedure of the GI endoscopes.

In the British Society of Gastroenterology guidelines (2008) and Public Health Agency of Canada and the Canadian Association of Gastroenterology (2010) emphasized the important of manual brushing all of the working channels in addition to decontamination with automatic endoscopic reprocessor^[1,7,8]. Adequate disinfection and decontamination of GI endoscopes involves manual cleaning and automatic high-level disinfection (HLD) followed by 75% ethanol rinsing and then hang-

Table 1 Disinfection classification of gastrointestinal instruments

Category	Lever of disinfection	Gastrointestinal device
Critical	High-level	Argon plasma coagulation device Aspiration Biopsy Needles Banding ligation device Biopsy forceps Biopsy valves Cytology curettes Dilation balloon Distal attachments Electrical knife Foreign body retrieval Injection needle Manometry device Mouthpieces Snare Spray catheter
Semicritical	Intermediate-level	Gastroendoscope Small intestinal scope Colonoscope Sigmoidoscope Endoscopic ultrasonography scope Endoscopic retrograde cholangiopancreatography scope Naso-gastroendoscope
Noncritical	Low-level	Cautery plates Electrodes Stethoscopes Vital sign monitor

ing for endoscope drying before storage.

Disinfection classification of gastrointestinal instruments

According to the Spaulding classification^[9,10], the GI endoscope belongs to the class of semicritical devices because the instruments may touch with mucous membranes during clinical procedure, thus bearing a relative degree of infection risk if contamination occurs during use. At the very minimum, they should receive HLD. In our previous large medical cohort study, we found that the average biopsy rate was 17.3%, which meant about 200 thousand endoscopic procedures over 14.5 years^[11]. Furthermore, biopsy forceps or injection needles, for example, also require proper sterilization given that they frequently enter sterile tissues or the vascular system, and thus carry an absolute degree of infection risk if contaminated during use^[12]. The critical, semicritical and noncritical level of infection risks in GI instruments are listed on the Table 1. All of the GI endoscopes, including gastroendoscope, small intestinal scope, colonoscope, sigmoidoscope, endoscopic ultrasonography scope, and the more complicated structure such as endoscopic retrograde cholangiopancreatography scope and magnified endoscope have been recommended to receive HLD. It is vital to monitor adequate disinfection of endoscopes and to avoid an iatrogenic infection in patient after endoscopic service. The cautery plates and electrodes, however, belong to noncritical-level medical devices.

Table 2 High-level disinfection of gastrointestinal endoscope reprocessing in Kaohsiung Chang Gung Memorial Hospital

Procedure room	Manual washing Precleaning (Enzymatic detergent cleaning) Wipe the outer surface by gauze Cleaning the channel by suction Cleaning (Brushing working channels) (Figure 1) Long brush cleaning inner channels Immersion detergent solution
Disinfection room	High-level disinfection Leak test (Figure 2) Automated endoscope reprocessor Normal relief valve pressure is $1.85 \pm 0.05 \text{ kgf/cm}^2$ Water supply is 17 liter/minute Liquid chemical germicide Rinsing
Store room	Drying Flushing 75% ethanol Storage by vertical hanging



Figure 1 Manual cleaning procedure for flexible endoscopes including brushing and irrigation of the internal channels with enzymatic detergent solution that should be performed before disinfection.

Reprocessing of gastrointestinal endoscopy

In recently, both of the American Multisociety Guideline and World Gastroenterology Organization Global Guideline are emphasize multistep in medical endoscopic reprocessing that includes not only the cleaning, disinfection and drying, but also the precleaning before the cleaning, first rinsing after the cleaning, followed by disinfection, and the second rinsing after disinfection, drying and then storage^[10]. These can be summarized into three important processes of GI endoscopic reprocessing step by step: manual washing including precleaning and cleaning, automated endoscope reprocessor (AER) with HLD and liquid chemical germicide (LCG), and drying/storing (Table 2). Under the recommendations for infection control, the GI endoscopic procedure room as a contaminated zone needs to be separated from the clean zone disinfection room, which requires suitable room ventilation with more than 12 air exchanges per hour for the prevention of toxic materials from leaking and endoscopic associated disease^[13,14]. This means that the GI endoscopic procedure room and GI endoscopic disinfection room are separated by an adequate distance, and that the hand case must be covered before it is transfer from the contaminated zone to the clean zone^[15].

MANUAL WASHING IN THE PROCEDURE ROOM

This process consists of the two important phases of precleaning and cleaning (Table 2). The beginning step is manual washing endoscopic instruments and should be performed at the procedure room. Precleaning focuses on enzymatic detergent washing to remove organic debris, such as blood, feces, mucus *etc.*. In contrast to the precleaning, cleaning focuses on the brushing process with enzymatic detergent solution of the all the working channels, such as the biopsy, air and water channels of the

GI endoscope. This step is also only to be performed at the GI endoscopic procedure room. Inadequate cleaning causing blood clot, body tissue retention in the GI endoscopes, it should be frequently contaminated with microorganisms transmission during the next endoscopic service. Our recent studies showed the importance of adequate cleaning with brushing processes for the longer small intestinal endoscopes and the more frequently contaminated colonoscopies^[16,17].

Precleaning

After being taken from a patient, the outer surface of the GI endoscope is wiped immediately with enzymatic detergent gauze. Alternatively, 10-15 s of air and water flushing prevents leakage of mucus and blood from the dirt bucket. Enzymatic detergent cleaning solution needs to be suctioned until the suction tube returns clean, non-turbid, water. Water rinsing of the entire surface of the endoscope is very important. Immersion in enzymatic detergent solution for longer than 20 min is recommended if there is suspicion of highly infectious cases such as tuberculosis or human immunodeficiency virus^[4,16].

Cleaning

The endoscope should be inspected for damage and a water-resistant cap should be attached. All active buttons, plugs, apex protection ring should be dismantled and manual washed with a soft bristle brush. Water irrigation and attract conduit working channels, then gauze and a soft short bristle brush with enzymatic detergent solution should be used to brush the orifices of the biopsy channel and to clean the air and water channels. For the cleaning of the longer and contaminated anus route scope for the small intestine, a long scrub brush with repeated and adequate brushing is very important due to the high rate of bacterial culture^[16]. Repeated cleaning with the brush head of a long scrub brush of at least 3 or more times is needed for all of the internal channel included biopsy channel, suction channel and air channel, and from the channel orifice to the fore-end of the endoscope^[18].



Figure 2 A manual leak test is conducted to examine any damage in and out of the gastrointestinal endoscope. It is very important to protect the endoscope from damage from the cleansing solution. No air bubbles should appear after attaching the water-resistant cap.

AUTOMATIC ENDOSCOPIC REPROCESSOR IN THE DISINFECTION ROOM

Leak test

After initial manual washing, the GI endoscope should be moved to the disinfection area by a carrying case with cloth covered to prevent contamination of the clean zone. The disinfection room is separated into two isolated rooms, the lower GI endoscopic disinfection room and the upper GI endoscopic disinfection room each with a separate entrance. The first step in the disinfection is the leak test. The endoscope is an electronic instrument must be protect to prevent water damage. Therefore, a leak test must be completely inspected first of all before disinfection^[19,20]. The leak test consists of a manual leak test (Figure 2) and an automatic leak test in the AER. It is a very important step to protect the electronic endoscope fatal damage from the cleansing solution. No air bubbles should appear after the water-resistant cap is attached. Forgetting to attach the water-resistant cap when conducting the leak test is a very critical concern in the training of new nurses in clinical practice. The potential to reduce the cost of endoscope repairs with an AER device by reducing the amount of manual handling during reprocessing has been estimated at 34%; use of AER devices can result in fewer opportunities for the scope to be inadvertently mishandled^[21].

Automatic endoscope reprocessor

AERs are strongly recommended by the World Gastroenterology Organization for the reprocessing of all GI endoscopic instruments to absolute complete all of the decontamination processes and to prevent the chemical contamination of the instruments^[22,23]. In our case, manual cleaning is performed by a trained GI endoscopic nurse before HLD. The AER was processed with Olympus ER-30 model (Aizu Olympus Co. Ltd, Fukushima, Japan) in our disinfection room. There are two important checking

issues in the AER reprocessing. The first one is the inflow and outflow pressure monitor. According to the operator manual of Olympus ER-30 model, $1.85 \pm 0.05 \text{ kgf/cm}^2$ of the normal relief valve pressure and 17 Liter/min in inflow water are required. The second checking issue is the concentration of LCG used in reprocessing. LCG is an effective disinfecting chemical agent for most of the microorganisms and spores. It is widely be used in the disinfection reprocess because of the no expensive in price, and no evidence for endoscope or equipment damage^[22]. Hence, AER with LCG can certainly be considered HLD. One of the most commonly used LCGs is 2.4% alkaline glutaraldehyde. In the AER, the endoscopes are soaked in this disinfectant for 20 min in every reprocess cycle. In our unit, alkaline glutaraldehyde is stored at 15 °C-30 °C in the disinfection room. Depends on the reprocess loading, it will be replaced every 2 wk or less. The disinfectant is monitored by the GI endoscopic nurse every morning and every 5 cycles of AER process using test strips. The concentration is effective for the AER process if the test strip is purple in color. The disinfectant is discarded immediately or within 2 wk when the test strip change to yellow. It is represent that the concentration of LCG drops below the minimum effective concentration. We performed a bacterial culture for surveillance monitoring. When a culture-positive to have determined, the numbered GI endoscope is no longer be clinical service, and the AER is reprocessed and can only be put back into clinical use when the re-culture becomes negative. In the AER, the LCG is forced and filled all of the working channels. The endoscopes are subsequently flushed with sterile distilled water and dried with 75% alcohol and forced air in the AER automatically. One important issue should be emphasized here: the servicing of the AER is carried out regularly, specifically every 3-6 mo, in our GI endoscope unit. Given that the longstanding use of the machine results in elasticity sclerosis and damage, the valve pressure can diminish beyond the standard value and the reduced amount of inflow sterilized water may not be able to disinfect the internal channel thoroughly in spite of the standard reprocessing procedure. Positive surveillance culture may put the quality of the HLD at risk^[24]. At the end of the disinfection, discarded the rinse water after each reprocess cycle, 75% ethanol rinsing the AER, disinfected and sterilized the water bottles at least once a day^[25].

DRYING/STORAGE IN THE STORE ROOM

Drying

Mechanical drying all of the working channels with 75% ethanol rinsing, 25 L/min in airflow and 60 psi in blowing pressure of the GI endoscope is one of the important step at the end of HLD in the AER. In every cycle of the GI endoscope HLD, the endoscope is manually flushed with 30c.c. of 75% ethanol into the internal channel of the GI endoscopes for at least 2 min. At the end of the working day, the endoscope should be flushed with 200 c.c.

Table 3 Positive surveillance culture after automatic endoscope reprocessor with high-level disinfection

Gastrointestinal instrument	Positive rate	Ref.
Colonoscope ¹	71.40%	[24]
Colonoscope	20.8%	[17]
Small intestinal scope, anal route	19.2%	[16]
Gastroendoscope	10.7%-14.3%	[17,24]
Small intestinal scope, oral route	12.9%	[16]
AER reprocess to gastroendoscope ²	2%	[17,27]
AER reprocess to colonoscope ³	0.8%	[17,27]

¹AER was damaged in reprocessing; ²case size was 6/300; ³case size was 1/120. AER: Automatic endoscope reprocessor.

of 75% ethanol into the AER, and then forced air should be used for at least 10 min to dry the GI endoscope and to disinfect the AER. After the GI endoscope is removed from the AER, the outer surface needs to be carefully dried with a clean dry towel, and then the whole GI endoscope and lens should be wiped with a gauze with 75% ethanol. In our recent study, positive surveillance swab culture of the AER was still found incidentally after a full cycle HLD. In a high loading endoscopic unit with short drying cycle, GI endoscopes could be dry used with high pressure air jet blowing. At the end of the working day, an overnight endoscope hanging for completely drying should be required^[22,26]. This means that the drying of the AER overnight is also an important step that should not be overlooked for a standard HLD^[27].

Storage

After a full reprocessing cycle, the cleaned GI endoscopes need to vertically hang in the of endoscopic protection cabinet in order to prevent residual water droplets from impacting on patient health. Overnight hanging for GI endoscope drying is necessary. For maintenance disinfection and decontamination of the GI endoscopes, storage with a dust-free drying cabinet is a major impact factor and should be recommended^[22].

Surveillance culture for monitoring the quality of HLD

The recent study showed that the impact factor of the iatrogenic infection is the number of biofilm growth inside the endoscope in addition mucosa damage during endoscopic service especially in case with immune compromise^[28]. Therefore, microbiological surveillance is very important for monitoring the quality of the endoscope disinfection, and one of the best way to supply safely medical service in an academic teaching hospital^[29]. According to our experience, the surveillance culture is used with 50 mL sterile distilled water manual flushed the working channels under an aseptic procedure and preparation^[16,24]. The rinse sample is collected in a sterile container and plated on blood agar, MacConkey agar, and Lowenstein-Jensen medium for the endoscopic surveillance culture monitoring. At the same time, a swab culture is performed from the inside of the AERs at the end of

the working day for the AER disinfection monitoring in every month. We used the liquid thioglycollate broth for swab culture^[17,27]. All of the culture are determined with colony forming units (CFU) with plate count method and incubated for 30 h at 37 °C and culture identified for aerobic and anaerobic bacteria and *mycobacterium tuberculosis* after 24 h, 48 h, and 6 wk. By the definition, the bacterial culture plate counts greater than 10³ CFU/mL is so-called culture-positive, in contrast or less is culture-negative. In our recent study, the trimean biopsy rate was about 19.29% of 199877 GI endoscope procedures over a period of 14.5 years^[11]. Since endoscopic biopsy is very frequent procedure in the clinical practice^[30], the biopsy channel is one of the most common contamination parts of the GI endoscope. It is thus very important that the surveillance microbiological culture from the biopsy channel be monitored for the quality of the HLD of GI endoscope reprocessing^[17]. In terms of the different clinical approaches of the GI endoscope, the complicated structure with the elevator design of the endoscopic retrograde cholangiopancreatography and the longer approach of double balloon small intestinal scope makes disinfection difficult. In our recent study, the positive culture rate was significant difference between the oral route (12.9%) and the anal route (19.2%) of the double balloon small intestinal scope^[16]. There was a linear trend observation between the positive culture rate and the length of the GI endoscopes: gastroendoscope, colonoscope, oral route and then anal route of the double balloon small intestinal scope (Table 3). The average positive surveillance culture of the upper GI tract was between 10.7% to 14.3%^[16,17,24]. The positive swab culture from the AER was 2.0% (6/300) for gastroendoscope and 0.8% (1/120) for colonoscope reprocessing; among the cultures from gastroendoscope reprocessing, 50% (3/6) were positive for aerobic bacteria, while the remaining 50% (3/6) showed fungal contamination. The positive culture rate was around 0.8% to 2.0% in our experiences^[17,27] (Table 3). Therefore, the surveillance culture from the AER may also benefit for the monitoring of the quality of the disinfection end point of the reprocessing. It should be kept in mind that 200 c.c. of 75% ethanol flushing should be used and the AER should be dried overnight at the end of the reprocessing of an endoscopic unit. The endoscope expertise recommended that the AER needs to be cleaning if the endoscopic procedures more than 50 times a week^[31]. Monthly regular randomized surveillance culture monitoring of the high quality endoscope service is very important for safety in endoscopic procedures.

In conclusion, for GI endoscope disinfection, there are three important steps that must be highlighted: manual washing, automated endoscope washer reprocessing and adequate drying/storage after rinsing. Our experimental data demonstrated that surveillance culture monitoring that can detect ineffective decontamination provides a much greater assurance of quality control for HLD. This monitoring should be taken into account in order to en-

sure safety when a patient receives GI endoscope service.

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