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Inadequate Decontamination Procedures: Sepsis Following Uneventful Endoscopy

Ellyn A. Smith, Kimberly J. Chaput and Berhanu M. Geme

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Abstract

Exogenous infection following endoscopy remains rare, however, recent attention in the media and the rise of antibacterial resistant strains of bacteria have emphasized the importance of proper sterilization techniques involved in the reprocessing of endoscopes and accessory devices. This chapter serves as comprehensive review into the epidemiology of exogenous infections as well as basic reprocessing techniques and guidelines for all medical professionals that treat patients that would benefit from endoscopy.

Keywords: endoscopy, reprocessing, exogenous infection, sterilization

1. Clinical vignette

A 51 year old Caucasian female, with a past medical history of hypertension, was admitted to the hospital with the diagnosis of gallstone pancreatitis. At the time of admission, the patient had an elevated lipase at 14,528, an abdominal ultrasound demonstrating gallstones with a common bile duct measuring 7 mm without choledocholithiasis. In addition, she was noted to have an elevated total bilirubin, without leukocytosis or fever. Patient was admitted with gastroenterology consultation.

The next hospital day, the patient underwent endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy and sludge removal. Post procedure her pain was improved and she was tolerating a clear liquid diet. Forty-eight hours after the procedure, the patient was noted to have a temperature of 101.8°F, and a leukocytosis of 15,600 per mL. Two blood cultures drawn at the time of fever resulted in carbapenem-resistant Enterobacteriaceae (CRE). Infectious disease consultation was obtained and the patient was treated with tigecycline plus gentamicin.

Within two weeks another patient at the same facility was diagnosed with CRE bacteremia following ERCP, prompting investigation into the technique involved in endoscopy sterilization.

2. Introduction

Although the overall risk of exogenous infection from endoscopy and flexible bronchoscopy remains rare, increased concern and awareness has recently been stimulated by outbreaks reported in the literature and newspapers. In 2015, the United States Food and Drug Administration (FDA) released a safety communication about duodenoscopes, after an outbreak of carbapenem-resistant Enterobacteriaceae (CRE) infections were diagnosed following procedural intervention with duodenoscopes. The communication outlined the close monitoring the association between reprocessed endoscopes and multidrug-resistant bacterial infections caused by CRE, such as *Klebsiella* species and *Escherichia coli* [1]. Subsequently, the increased awareness as well as the emergence of “super-bugs” and anti-bacterial resistant strains of bacteria has emphasized the importance of proper sterilization techniques involved in the reprocessing of endoscopes and accessory devices.

2.1. Epidemiology

Infection following endoscopy can be divided into three broad categories: exogenous infection, endogenous infection, and infection transmitted between patient and endoscopy personnel or vice versa [2]. Exogenous infection involves the spread of bacteria via contaminated equipment between one patient and another. Endogenous infection is not due to contaminated equipment, but rather, the translocation of bacteria from the gastrointestinal tract as a result of the endoscopic procedure. An example of an endogenous infection would be a patient that develops bacteremia secondary to traumatic tissue injury during the endoscopy. Lastly, infection may be transmitted from the patient to the endoscopy personnel and vice versa if proper technique and personal protective equipment are not utilized.

The benefit of endoscopy when compared to the risks has been clearly demonstrated throughout literature [3]. Despite the large number of GI endoscopic procedures performed, estimated at over 24 million procedures in 2004 in the United States alone, instances of infectious complications remain rare [4, 5]. Infectious complications are estimated at frequency of 1 in 1.8 million procedures [6]. The majority of infections following endoscopy are endogenous infections, with exogenous infections occurring even less frequently [7].

2.2. Equipment

Endoscopies are performed in a variety of facilities throughout the United States, including the hospital, ambulatory surgical center as well as physician offices. The term endoscope is a broad term encompassing any instrument used to visualize a hollow viscus. Endoscopes can be used to perform a variety of procedures including bronchoscopy, esophagogastroduodenoscopy, sigmoidoscopy, and colonoscopy as well as a variety of others. The equipment of the endoscope is similar, although slight variations exist to facilitate the performance of one procedure over another.

The majority of modern day endoscopes are video-endoscopes. These, although technically similar to the original fiber-endoscopes, which utilized fiber optical viewing bundles, conversely utilize a charged couple device (CCD) “chip” and electronics at the tip of the scope to generate an image that can be viewed upon a screen [8]. This advancement in technology has allowed for changes in instrument design, and limited the need for the endoscopist to place their eye close to the instrument. This has obvious hygienic advantages and minimizes the risk of infection transmitted between patient and endoscopy personnel.

Endoscopes are divided into several sections. In general, the scope has a light source, a “universal cord” which is plugged into the light source and the video processor, a the head of the instrument which contains a variety of switches and valves that control many scope functions and positions, and the “insertion tube” which includes the objective lens and the light guide lens. It is just behind the objective lens that the charge-coupled device (CCD) is located. An understanding of the basic equipment as well as the portion of the scopes which may be removed is important to ensure the adequate cleaning and reprocessing of the endoscope (**Figure 1**).

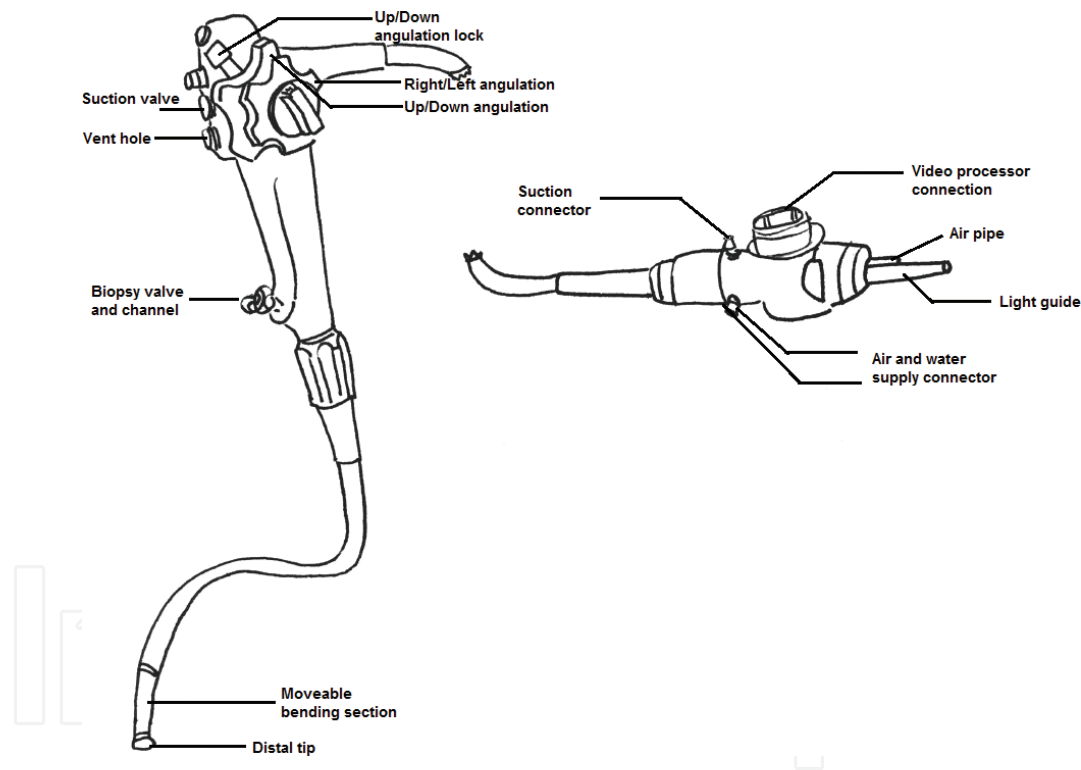


Figure 1. Structure of flexible endoscope.

3. Terminology: critical, semi-critical, noncritical, cleaning, disinfection, and sterilization

A variety of terms exist to describe the different processes and levels of sterilization involved in reprocessing endoscopes. An understanding of these terms is imperative. In general, there are three levels of disinfection of medical equipment. These include sterilization, high-level

disinfection and low-level disinfection, and are based upon the whether the equipment is labeled as critical, semi-critical, or noncritical [2, 9, 10]. A definition of each team, an example and the associated level of sterilization is displayed in **Table 1**.

The classification and terminology involved in the associated level of sterilization and disinfection is based on the ability to eliminate microbial life. Sterilization refers to the process of complete elimination of all microbial life. Conversely, high-level disinfection destroys all vegetative bacteria, mycobacteria, fungi, enveloped and nonenveloped viruses. High-level disinfection, however, does not necessarily eliminate bacterial spores. Low-level disinfection kills most vegetative bacteria, some fungi, and enveloped viruses (e.g., HIV, and hepatitis B, C) but does not kill mycobacteria or bacterial spores [11]. Cleaning is often the first step in removing the microbial burden from a device. It refers to the physical removal of debris.

3.1. Established protocols

All endoscopy units and facilities should have strict procedural guidelines that exist to ensure the correct reprocessing of equipment. Unit personnel should be proficient with the guidelines and methods unique to that institution and procedural monitoring should also be in place to ensure the method is being carried out effectively. Adherence to guidelines is a critical component of reducing infection.

3.2. Pre-cleaning

Following an endoscopy, biomaterial and microorganisms are present on the endoscope. The first step in endoscope reprocessing is an attempt to eliminate as much of the biomaterial as possible. Begin by wiping the insertion tube from the control section to the distal tube with a moist cloth or sponge. Then, all channels and working sites must be cleaned and flushed with detergent/and or water as recommended by the manufacture. This includes channels that are not used, due to the distal end being exposed to material and fluid. We recommend removing the material immediately after the procedure to minimize the risk of the material becoming dry, adherent and hard on the scope. If a delay of over an hour occurs between the endoscopy and pre-cleaning the scope should be soaked within the manufacture recommended detergent [12].

	Definition	Example	Associated level of sterilization and disinfection
Critical	A device that <i>penetrates</i> mucus membranes, blood vessels or body cavities	<ul style="list-style-type: none"> • Biopsy forceps • Sphincterotomes • Snares 	Sterilization
Semi-critical	A device that comes in <i>contact, but does not penetrate</i> mucus membranes	<ul style="list-style-type: none"> • Endoscopes • Dilators 	High-level disinfection
Noncritical	Objects that <i>do not come into contact</i> with patients	<ul style="list-style-type: none"> • Endoscopy control cart 	Low-level disinfection

Table 1. Terminology of endoscope reprocessing.

3.3. Leakage test

Prior to immersing an endoscope in any fluid, a leakage test should be completed to ensure that the device is air and fluid tight. This is important in the maintenance of the equipment as well as infection control. Begin by ensuring that the water resistant cap is properly attached then, remove the suction valve, air-water channel, cleaning channel, biopsy valve and auxiliary water tube if present. The scope should then be emerged in clean water, with the leakage test device on. Any evidence of continuous bubbles coming from the scope or while moving the control dials indicates a leak and should not be immersed in detergent and reprocessed. The endoscope should be repaired at this point. If no leaks are observed the scope may be removed the water and reprocessed [13].

3.4. Mechanical cleaning

Mechanical cleaning is a multistep process that utilizes equipment such as tubes, brushes and additional flushing devices to reduce bioburden and reduce the risk of cross contamination [14]. Effective cleaning will remove more than 99.9% of the bioburden from the endoscope [15]. For specific details regarding endoscope mechanical cleaning protocols please see the manufacturing guidelines for cleaning. In general, a basin of detergent solution should be prepared. It is important to ensure that this detergent is freshly prepared at the specific concentration and temperature recommended. Never re-use a solution. The endoscope should be completely immersed within the solution and using a soft sponge or brush to clean the endoscope all working channels, valves and portions of the endoscope should be cleaned. Ensure that any brush that is utilized to facilitate the cleaning process is not damaged. Replace any damaged brush.

3.5. Alcohol flushing

The use of flushing the endoscope channel with alcohol promotes drying and inhibits the growth of water born microorganisms. Utilizing 70% Ethyl or Isopropyl alcohol, immerse the injection tube within the beaker of solution. Then flush the solution through the air/water channel as well as the suction port. Complete this step by flushing copious amounts of air through each port with air from a syringe [13].

3.6. Endoscope storage

Once the endoscope has been reprocessed and it is dry, it should be stored vertically, in a well ventilated cabinet. The scope should be labeled or sealed with a date of when it was reprocessed. Ensure that all valves have been removed prior to storage. Angulation locks should also be placed in the "free" position. The distal tip should hang freely, and as straight as possible avoiding contact with other instruments.

The interval of storage between reprocessing and use has been an area of debate and investigation. According to the "American Society of Gastrointestinal Endoscopy Multi-society guideline for reprocessing flexible gastrointestinal endoscopes" it remains an issue requiring

further studies [10]. Data suggests that intervals of 7 to 14 days have negligible contamination and is typically related to skin organisms rather than pathogenic bacterial growth [16–18]. The data for maximal duration of re-use is currently undetermined.

3.7. Precautionary measures and occupational exposure

All personnel involved in handling of endoscopy equipment that has been used is in danger of transmission of bacterial infections to themselves. Personal protective equipment should be worn at all times while handling soiled equipment for reprocessing. This includes gowns, gloves and eye protection [10]. Occupational Safety and Health Administration (OSHA), and manufacture guidelines should be observed while handling any specific detergents, with an importance placed on diluting detergents per protocol. The proper disposal of all products that is not reprocessed is also recommended to decrease the risk of infection among personnel.

3.8. Exogenous infection after endoscopy

With more than 19 million gastrointestinal endoscopies and bronchoscopies performed each year within the United States [19], the overall risk of exogenous infections, or infections involving the spread of bacteria from one patient to another, remain relatively low. However, the importance of proper reprocessing remains fundamental in reducing the transmission risk, particularly in the time of bacterial resistance and the emersion of “superbugs.” The variability of endoscopy cleanliness and reprocessing protocols has been shown to be significant. In a study published in 2013 approximately 15% of hospitals within the United States failed to achieve an acceptable level of cleanliness [20]. The specific type of endoscopy impacted the results with a higher level of duodenoscopes being unacceptable than other gastrointestinal endoscopes [20]. The suspected rationale for the inadequate reprocessing of endoscopies has been outlined in a study published in 2003, **Figure 2** [21]. A systemic review of published literature between 1966

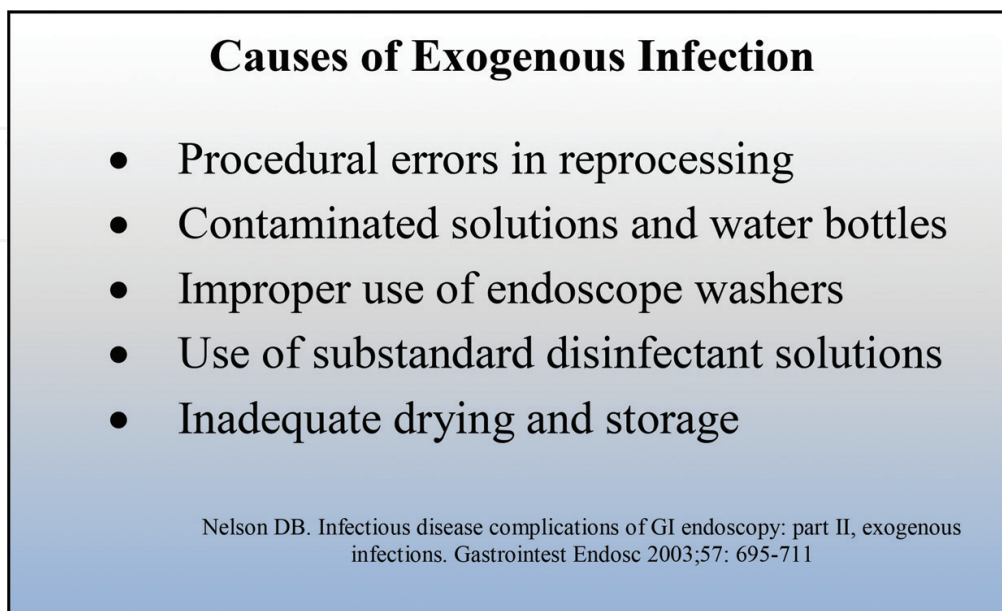


Figure 2. Causes of exogenous infection.

and 2005 revealed only 70 outbreaks of infection reported within 64 articles [22]. This number may underestimate the amount of infections, due to under-reporting. The recognition of exogenous infection risk and adequate reprocessing techniques is imperative to all personnel and staff involved in endoscopy. Proper reprocessing could reduce the number of infections.

4. Key points

- The three main types of infection following endoscopy include exogenous infections, endogenous infections and infection spread between patient and medical personnel.
- Sterilization, high-level disinfection and low-level disinfection are distinct terms used to clarify the level of sterilization based on the ability to eliminate microbial life. Sterilization refers to the process of complete elimination of all microbial life for critical pieces of equipment.
- All personnel should understand the decontamination and reprocessing protocols within their institution. Protocols should be based off specific equipment protocols by the manufacturer.
- The main steps of endoscope reprocessing include; pre-cleaning, performing leak test, mechanical cleaning, alcohol flushing and proper storage.
- Exogenous infections, though rare, have increased clinical significance given the rise of antibiotic strains of bacteria. All efforts should be made to prevent the exogenous infections from endoscopes.

5. Conclusions

Increased concern and awareness of infections after endoscopies has gained much attention in the literature in recent times. The rise of superbugs and transmission of potentially lethal microbes has led to an increased awareness of the necessity for proper reprocessing of all endoscopes. An understanding of the specific equipment, protocols within each institution and each manufacture guidelines is essential. Also as important, is the implementation of system of periodic and random review of policies and methods, to ensure that all protocols are being followed as intended. In the future, automated endoscope reprocessors, AERs, which are beginning to emerge from a variety of manufacturers have been proposed to enhance the efficiency, consistency and reliability of endoscope reprocessing and may reduce the potential human error associated reprocessing [23].

Acknowledgements

This chapter is meant to provide education in the form of a comprehensive review and act as a guideline all medical professionals that treat patients that would benefit from endoscopy. This guideline should not be mistaken for a legal standard of care. Clinical judgment should be considered in all circumstances, and may vary based on endoscopist and facility.

Author details

Ellyn A. Smith*, Kimberly J. Chaput and Berhanu M. Geme

*Address all correspondence to: ellyn.smith@sluhn.org

St. Luke's University Health Network, Bethlehem, PA, USA

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