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Current Issues in Duodenoscope-Associated Infections: Now Is the Time to Take Action

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A duodenoscope has a very complex structure that contains many small parts which make reprocessing more challenging. The difficulty in cleaning duodenoscopes contributes to a higher risk of infection than that of conventional gastrointestinal endoscopes. However, a duodenoscope shares similar disinfection process with other gastrointestinal endoscopes. Recent outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) infections associated with duodenoscopes used for endoscopic retrograde cholangiopancreatography procedures have raised many concerns worldwide. Duodenoscope-associated infections involving CRE or other multidrug-resistant bacteria pose a great threat to patients undergoing procedures using duodenoscopes and should be dealt with a great concern. Updated guidelines regarding cleaning and disinfection of duodenoscope needs to be developed urgently to prevent transmission of infection and ensure patient safety. Meanwhile, healthcare staff should pay special attention to thorough cleaning and disinfection of duodenoscopes. **Clin Endosc 2015;48:361-363**

Key Words: Duodenoscopes; Cholangiopancreatography, endoscopic retrograde; Endoscope reprocessing; Carbapenem-resistant Enterobacteriaceae

INTRODUCTION

A duodenoscope is a flexible, lighted tube used during endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and treatment of a variety of conditions of the biliary tree and pancreas, including ductal obstructions, stones, and malignancy. In Korea, the number of procedures involving duodenoscope use is increasing each year since ERCP is one of the best ways of resolving various problems caused by cancer, gallstones, or other conditions in the pancreatic and biliary ducts. However, physicians have not paid much attention to duodenoscope-related infection so far. Recent reports regarding duodenoscope-related infections raised many concerns to healthcare community worldwide. The purpose

of this article is to review recent reports on duodenoscope-related infections and to discuss important issues on its etiology and prevention.

CURRENT ISSUES IN DUODENOSCOPE-ASSOCIATED INFECTIONS

A duodenoscope has a very complex structure that contains many small parts such as an elevator and elevator channel, which make reprocessing more challenging. The difficulty in cleaning duodenoscopes contributes to a higher risk of infection than that associated with conventional gastrointestinal endoscopes. However, the importance of duodenoscope-related infections has been somewhat underestimated so far, with few guidelines specifically dealing with reprocessing of duodenoscopes. A duodenoscope has a similar disinfection process as that of other gastrointestinal endoscopes; the process comprises eight steps of pre-cleaning, leakage testing, cleaning, rinsing, disinfection, rinsing, drying, and storage.

The emergence of multidrug-resistant organisms, including carbapenem-resistant Enterobacteriaceae (CRE) such as

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Escherichia coli and *Klebsiella pneumoniae*, is a serious concern at home and abroad. Recent outbreaks of CRE bacterial infections associated with duodenoscopes used for ERCP procedures have raised many concerns worldwide. Incidents of duodenoscope-associated CRE infection have been reported in Canada and the United States.¹ Investigations of these outbreaks identified the cause as poor reprocessing technique and failure to follow guidelines on cleaning and disinfection of endoscopes. However, more recently reported outbreaks are more disturbing because investigations revealed that the infections occurred despite strict adherence to recommended reprocessing procedures.^{2,3} These reports have attracted much attention of healthcare professionals worldwide regarding the adequacy of current guidelines on cleaning and disinfection of endoscopes.

The United States Food and Drug Administration (FDA) finally issued a safety communication on duodenoscope cleaning on February 19, 2015, which stipulated that the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing and that duodenoscope-related infection might still occur even when the manufacturer's reprocessing instructions are followed.⁴

Therefore, instructions for reprocessing of duodenoscopes are essential for reducing the risk of duodenoscope-related infections among medical facilities. In other words, the importance of duodenoscope reprocessing, especially pre-cleaning, cannot be over-emphasized. Establishing the method of reprocessing specific to duodenoscopes is essential since a duodenoscope has unique structures such as an elevator and elevator channel, which present a challenge for cleaning and disinfection. Currently, the elevator area is cleaned by brushing manually. However, moving parts in the elevator mechanism contain crevices that might not be reached by cleaning brushes and thus body fluids and organic debris might remain in those crevices and might act as a reservoir for serious infections.

The methods and materials used for disinfection for duodenoscopes need to be reevaluated. The materials comprising duodenoscopes are heat labile and require thorough disinfection with chemical agents or low-temperature sterilization.⁵ The most widely used disinfectants today are glutaraldehyde, peracetic acid, hydrogen peroxide, and electrolyzed acid water. However, since recent outbreaks of CRE infections occurred after thorough cleaning and disinfection, the efficacy of disinfection is questionable. Recently, the Centers for Disease Control and Prevention in the United States reported that high-level disinfection of ERCP endoscopes with ethylene oxide (EtO) sterilization stopped the outbreak of CRE infection.⁶ However, other studies indicate that disinfection with widely used disinfectants such as peracetic acid is fully

effective against multidrug-resistant bacteria.⁷⁻⁹ As the studies show conflicting results, more studies are needed to evaluate the efficacy of EtO sterilization and other disinfectants. Thus far, there are no data to recommend EtO sterilization for disinfection of duodenoscopes.

In addition, the complex structure of a duodenoscope causes difficulty in cleaning and disinfection of the duodenoscope. Therefore, redesigning its structure to facilitate reprocessing is a long and time-consuming but an important step toward preventing duodenoscope-associated infections. Further studies on failure modes of duodenoscope-related infection will help to identify flaws in duodenoscope design and possibly aid in redesigning the instrument.

CONCLUSIONS

Duodenoscope-associated infections involving CRE or other multidrug-resistant bacteria pose a great threat to patients undergoing procedures using duodenoscopes and should be dealt with great concern. Updated guidelines regarding cleaning and disinfection of duodenoscope need to be developed urgently to prevent transmission of infection and ensure patient safety. Meanwhile, healthcare staff should pay special attention to thorough cleaning and disinfection of duodenoscopes. Healthcare professionals should strictly follow the cleaning instructions provided by the duodenoscope's manufacturer, especially the instructions for brushing the area around, near, and behind the elevator located at the distal end of the duodenoscope. Reusable items such as biopsy forceps should also be regularly cleaned and disinfected. The cleaning and disinfection process should be more frequently monitored on a regular basis. High-level disinfection, using an FDA-cleared aldehyde-based disinfectant or an oxidizing agent, should be carried out with proper protocol.

Conflicts of Interest

The authors have no financial conflicts of interest.

REFERENCES

1. Dirlam Langlay AM, Ofstead CL, Mueller NJ, Tosh PK, Baron TH, Wetzler HP. Reported gastrointestinal endoscope reprocessing lapses: the tip of the iceberg. *Am J Infect Control* 2013;41:1188-1194.
2. Epstein L, Hunter JC, Arwady MA, et al. New Delhi metallo-beta-lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. *JAMA* 2014;312:1447-1455.
3. Wendorf KA, Kay M, Baliga C, et al. Endoscopic retrograde cholangiopancreatography-associated AmpC *Escherichia coli* outbreak. *Infect Control Hosp Epidemiol* 2015;36:634-642.
4. U.S. Food and Drug Administration. Design of endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes may impede effective

- tive cleaning: FDA safety communication [Internet]. Silver Spring: U.S. Food and Drug Administration; 2015 [updated 2015 Mar 4; cited 2015 Sep 7]. Available from: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm>.
5. Rutala WA, Weber DJ. Healthcare Infection Control Practices Advisory Committee. Guidelines for disinfection and sterilization in healthcare facilities, 2008 [Internet]. Atlanta: Centers for Disease Control and Prevention; 2015 [updated 2009 Dec 29; cited 2015 Sep 7]. Available from: http://www.cdc.gov/hicpac/Disinfection_Sterilization/6_0disinfection.html.
 6. Centers for Disease Control and Prevention (CDC). Notes from the field: New Delhi metallo-beta-lactamase-producing *Escherichia coli* associated with endoscopic retrograde cholangiopancreatography: Illinois, 2013. MMWR Morb Mortal Wkly Rep 2014;62:1051.
 7. Aumeran C, Poincloux L, Souweine B, et al. Multidrug-resistant *Klebsiella pneumoniae* outbreak after endoscopic retrograde cholangiopancreatography. Endoscopy 2010;42:895-899.
 8. Clorox Healthcare. Clorox Healthcare Bleach Germicidal Cleaners. Testing results [Internet]. Oakland: Clorox Healthcare; c2015 [cited 2015 Sep 7]. Available from: <http://www.cloroxprofessional.com/products/clorox-healthcare-bleach-germicidal-cleaners/efficacyclaims/>.
 9. PURE Bioscience, Inc. Technical report and efficacy statement. PURE Hard Surface spray disinfectant [Internet]. Bolivar: Nilodor, Inc.; c2014 [cited 2015 Sep 7]. Available from: http://www.nilodor.com/Member/nilodor/Images/ImageGallery/flyers/pure_hard_surface_disinfectant.pdf.