Remember, interventional EUS is performed using an elevator-containing scope as well

Siyu Sun, Caixia Wang, Sheng Wang
Endoscopic Center, Shengjing Hospital of China Medical University, Shenyang 110001, Liaoning Province, China

Despite the low incidence of infection from gastrointestinal (GI) endoscopy, the cleaning and disinfection of GI endoscopes have recently drawn considerable attention. Increasing patient safety through duodenoscope reprocessing has become a strong focus, especially after several reports\(^1,2\) confirmed outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) infection following ERCP, leading to significant morbidity and mortality. In 2014, the Centers for Disease Control and Prevention (CDC) investigated and reported the largest outbreak of CRE infection in the history of the United States, which occurred the previous year at a hospital in Chicago.\(^2\) This investigation determined that 28 and 10 patients in the hospital had been colonized by and infected with CRE, respectively. Another independent inspection of infection control practices by the Centers for Medicare and Medicaid Services\(^1\) stated that (1) the CRE outbreak in 2013 was associated with the use of the same three types of duodenoscopes; (2) at least two of the ten patients infected with the strain of CRE from this outbreak died; and (3) the CDC recovered three strains of CRE from this event. However, this inspection of the hospital’s CRE outbreak did not identify any obvious breaches in the protocol for reprocessing ERCP endoscopes during its investigation of the hospital’s CRE outbreak. Despite not finding specific breaches of protocol, they concluded that the hospital had “failed to reprocess ERCP endoscopes as recommended by the endoscope manufacturer.”

The CDC further clarified that the duodenoscope’s complex physical design “might pose a particular challenge for cleaning and disinfection.”\(^3\) The special structure of a duodenoscopic tip includes an elevator, its controlling wires, and both closed and semi-closed wire channels, which are difficult to clean and disinfect. Although the controlling wire channels of some types of duodenoscopes have been designed to be flushable, the wires are not removable and the channels cannot be brushed. This problem is analogous to cleaning a toilet: a simple flush without a toilet brush is insufficient if the stool is too sticky. Moreover, the highly irregular shape of the elevator creates a recessed dead end. We all know that it is difficult to completely clean small nooks and crannies.

Therefore, to prevent nosocomial infections after ERCP, in 2015, the US Food and Drug Administration (FDA) emphasized that manual cleaning before disinfection or sterilization is critical for effective reprocessing.\(^3\) The
FDA communicated with manufacturers and stressed that duodenoscopes should be designed to enable meticulous cleaning and disinfection or sterilization. They further urged manufacturers to update their duodenoscope reprocessing instructions to include additional brushing of the elevator recess area using a new cleaning brush with smaller bristles. According to the FDA recommendations, in addition to strict adherence to manufacturers’ duodenoscope reprocessing instructions, the following supplemental measures may further reduce the risk of infection associated with the use of duodenoscopes: (1) microbiological culturing; (2) ethylene oxide sterilization; (3) use of a liquid chemical sterilant processing system; and (4) repeated high-level disinfection (HLD). Many endoscopy centers have adopted a “culture and hold” policy, in which duodenoscopes are cultured after disinfection and held until culture results are negative. Some centers have turned to ethylene oxide gas sterilization, which is an optimal but costly endoscope sterilization method. Other centers have started to use a repeated HLD process, including our center, because among these recommendations, it is one of the cheapest and fastest options. However, in a randomized trial comparing single- and double-HLD of elevator-containing endoscopes by standard automated reprocessing, Bartles et al. reported that double-HLD did not reduce culture positivity rates compared with single-HLD in facilities that already had low positive culture rates.

When the transmission of infections through ERCP became a concern, few have worried about echoendoscope reprocessing. Initially, EUS was designed for diagnosing GI submucosal tumors or pancreatic lesions. Since the introduction of curved linear array (CLA) echoendoscopes, they have been widely applied in interventional procedures for many conditions, including GI diseases and lesions surrounding the GI tract. Under EUS guidance, we can perform fine-needle aspiration, fine-needle injection, drainage, radiofrequency ablation, and stenosis stenting. The interventional indications of EUS include tumor biopsies, tumor ablation, biliary stenosis, gallstones, common bile duct stones, infected pseudocysts, and abscesses. As such, there is a significant overlap between the indications of EUS and ERCP. However, for the convenience of puncture, almost every type of CLA echoendoscope has been designed with an elevator [Figure 1]. Therefore, the complex structures of echoscopes are very similar to those of duodenoscopes.

Although very few EUS-related infection cases have been reported, some experts have become concerned about it. For example, Chapman et al. evaluated the risk of infection transmission by curvilinear array echoendoscopes through a prospective reprocessing and culture registry. In that study, 21 of 521 primary cultures (4.2%), obtained from 18 CLA echoendoscopes after standard HLD and reprocessing, were positive for Gram-negative bacilli. Eleven different bacteria were isolated, although there were no documented cases of CRE. However, this study only evaluated Olympus CLA echoendoscopes, and the risk of EUS-transmitted infections for Pentax and Fujifilm scopes should not be overlooked. Clinicians should consider applying the

![Figure 1.](image-url)
FDA recommendations for duodenoscope reprocessing to elevator-containing echoendoscopes to ensure patient safety.

In the past, echoendoscopes have been mainly applied for imaging diagnosis. In recent years, EUS-guided interventional procedures, utilizing needles and other instruments that enter the tissue, have become more common. Such procedures, sometimes involving infected pancreatic fluid collections and abdominal abscesses, may involve multi-drug resistant bacteria (MDRBs) or CRE. MDRBs are especially common in cases of infected walled-off necrosis, in which patients with severe pancreatitis have just returned from an Intensive Care Unit. After the drainage of pus from these infected lesions, echoendoscopes used in these procedures may have extremely high bacterial loads.

Therefore, we should pay more attention to the disinfection of CLA echoendoscopes and should remember that CLA echoendoscopes contain elevators. Endoscopists and infection control professionals should cooperate with manufacturers to help design new CLA echoendoscopes, with elevators and controlling wires that are convenient to remove, thus enabling the channel to be brushed. Furthermore, we need to develop new reprocessing strategies for both duodenoscopes and CLA echoendoscopes. Before achieving this dream, we should at least apply the current FDA recommendations for duodenoscope reprocessing to CLA echoendoscopes.

REFERENCES

1. Muscarella LF. Risk of transmission of carbapenem-resistant Enterobacteriaceae and related “superbugs” during gastrointestinal endoscopy. World J Gastrointest Endosc 2014;6:457-74.
2. Centers for Disease Control and Prevention (CDC). Notes from the field: New Delhi metallo-β-lactamase-producing Escherichia coli associated with endoscopic retrograde cholangiopancreatography – Illinois, 2013. MMWR Morb Mortal Wkly Rep 2014;62:1051.
3. US. Food and Drug Administration. Infections Associated with Reprocessed Duodenoscopes. Updated 26 February, 2018. Available from: https://www.fda.gov/medicaldevices/productsandmedicalprocedures/reprocessingofreusablemedicaldevices/ucm454630.htm. [Last accessed on 2018 Mar 03].
4. Bajolet O, Ciocan D, Vallet C, et al. Gastroscopy-associated transmission of extended-spectrum beta-lactamase-producing Pseudomonas aeruginosa. J Hosp Infect 2013;83:341-3.
5. Kovaleva J, Peters FT, van der Mei HC, et al. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev 2013;26:231-54.
6. Ha J, Son BK. Current issues in duodenoscope-associated infections: Now is the time to take action. Clin Endosc 2015;48:361-3.
7. Bartles RL, Leggett JE, Hove S, et al. A randomized trial of single versus double high-level disinfection of duodenoscopes and linear echoendoscopes using standard automated reprocessing. Gastrointest Endosc 2018. pii: S0016-5107 (18) 30130-5.
8. Bhutani MS, Koduru P, Joshi V, et al. The role of endoscopic ultrasound in pancreatic cancer screening. Endosc Ultrasound 2016;5:8-16.
9. Chapman CG, Siddiqui UD, Manzano M, et al. Risk of infection transmission in curvilinear array echoendoscopes: Results of a prospective reprocessing and culture registry. Gastrointest Endosc 2017;85:390-70.
10. Guo J, Saltoiu A, Vilmann P, et al. A multi-institutional consensus on how to perform endoscopic ultrasound-guided peri-pancreatic fluid collection drainage and endoscopic necrosectomy. Endosc Ultrasound 2017;6:285-91.