Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak

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Background and Aims: Carbapenem-resistant Enterobacteriaceae (CRE) outbreaks have been implicated at several medical institutions involving gastroenterology laboratories and, specifically, duodenoscopes. Currently, there are no specific guidelines to eradicate or prevent the outbreak of this bacteria. We describe ethylene oxide (ETO) gas sterilizations of duodenoscopes to address this issue.

Methods: A complete investigation of the gastroenterology laboratory and an evaluation by the Centers for Disease Control and Prevention concluded that no lapses were found in the reprocessing of the equipment. With no deficiencies to address, we began a novel cleaning process using surgical ETO gas sterilizers in addition to standard endoscope reprocessing recommendations and guidelines, all while trying to eradicate the CRE contamination and prevent future recurrences. We also instituted a surveillance system for recurrence of CRE contamination via monthly cultures of the duodenoscopes.

Results: Between October 2013 and April 2014, 589 ERCPs were performed with 645 ETO gas sterilizations of 6 duodenoscopes. Given the extra 16 hours needed to sterilize the duodenoscopes, our institution incurred costs resulting from purchasing additional equipment and surveillance cultures. Four duodenoscopes sustained damage during this period; however, this could not be directly attributed to the sterilization process. Furthermore, after an 18-month success period we encountered a positive CRE culture after sterilization, albeit of a different strain than originally detected during the outbreak. The duodenoscope underwent additional ETO gas sterilization, with a negative repeated culture; all potentially exposed individuals screened negative for CRE.

Conclusions: Proper use of high-level disinfection alone may not eliminate multidrug-resistant organisms from duodenoscopes. In this single-center study, the addition of ETO sterilization and frequent monitoring with cultures reduced duodenoscope contamination and eliminated clinical infections. As such, ETO gas sterilization may provide benefit in further decontamination of duodenoscopes, but further investigation is necessary. (Gastrointest Endosc 2016;84:259-62.)

Carbapenem-resistant Enterobacteriaceae (CRE) increasingly has become one of the most discussed medical topics in the news. Since its initial detection in 2001, cases including the presence of this bacterium have been reported in nearly every state in the United States.[1] Since 2012, there have been approximately a half-dozen outbreaks affecting several prominent medical institutions. One of the initial outbreaks occurred at our facility, a 600-bed community teaching hospital (part of a 10-member system) located in Park Ridge, Illinois. Similar to the other outbreak sites, we linked the spread of the infection to the use of ERCP endoscopes, ie, duodenoscopes.

As outlined in the original article titled "New Delhi metallo-β-lactamase–producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes,"[2] our institution, and, specifically, the

Abbreviations: CRE, carbapenem-resistant Enterobacteriaceae; ETO, ethylene oxide; HLD, high-level disinfection.

DISCLOSURE: *All authors disclosed no financial relationships relevant to this publication.*

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2016.01.055

Received September 28, 2015. Accepted January 27, 2016.

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gastroenterology laboratory, underwent extensive evaluation, including a visit by the Centers for Disease Control and Prevention. The gastroenterology laboratory underwent culturing in many of its areas, including procedure rooms, endoscope storage cabinets, cleaning areas, and sinks. After finding no other areas of CRE contamination and no lapses in the technique for disinfection of the duodenoscopes, and given the lack of guidelines for eradication of such multidrug-resistant bacteria, we adopted what we thought to be the most aggressive modality in an effort to eliminate the presence of CRE: the addition of ethylene oxide (ETO) gas sterilization.

METHODS

Sterilization in the surgical field has been the primary modality in preventing the spread of infections. As such, in August 2013, we proceeded to change the reprocessing of our 6 duodenoscopes (model ED-3490TK; Pentax Medical, Montvale, NJ) from automated high-level disinfection (HLD) to combined HLD followed by ETO gas sterilization of all the duodenoscopes, as well as additional precleaning steps. To help reduce the visible bioburden, each duodenoscope was precleaned (First Step Bedside PreClean Kit; Cygnus Medical, Branford, Conn) immediately after patient use before transport for reprocessing. The duodenoscope was then brought to the cleaning room, where it was manually cleaned with multi-enzyme detergent/cleaner (CST-404C Surg-ENZ; Complete Solutions Technologies, Moorestown, NJ) using manufacturer recommendations. After this, the duodenoscope was placed into a washer/disinfector (System 83 Plus; Custom Ultrasonics, Ivyland, Pa) for reprocessing using a high-level disinfectant (MetriCide OPA Plus; Metrex Research, Orange, Calif). All the recommendations and guidelines provided by the endoscope manufacturer, as well as the manufacturers of the cleaning/disinfecting solutions and equipment, were closely followed. After HLD, the duodenoscope was then brought to the surgical sterilization facility. The Pentax-proposed guidelines for ETO gas sterilization of duodenoscopes were closely followed, along with, as suggested by Pentax, the guidelines of the sterilizer manufacturer.[3]

Our institution was already equipped with 4 dual-cycle 100% ETO gas sterilizers (Steri-Vac sterilizer/aerator model 8XL; 3M, St Paul, Minn) for use on surgical equipment, including endoscopes used during surgical procedures. Guidelines recommended by the Association for the Advancement of Medical Instrumentation as well as the manufacturers of the equipment were strictly followed. Each duodenoscope was placed into a disposable wrap (Halyard Health, Alpharetta, Ga), then placed into the sterilizer chamber along with surgical equipment. The sterilization process consisted of machine start-up, 1-hour automated sterilization with a 100% ETO single-use cartridge (3M), and a 12-hour aeration cycle, totaling at least 15 to 16 hours (this did not include HLD time). The duodenoscope was then brought to the gastroenterology department, where it was removed from the sterilized wrapper and visually inspected. If not immediately used, the duodenoscope was hung in a nonsterile storage cabinet (model 20000; Custom Ultrasonics) with medical air aeration. If the duodenoscope was not used in 5 days, it underwent reprocessing with HLD as described previously herein.

Because of the lack of guidelines, we began monthly culturing of each duodenoscope specifically for CRE 4 months after initiating the sterilization process. Culturing of all duodenoscopes was performed at the same time; therefore, a duodenoscope may have been cultured after HLD but before ETO sterilization, immediately after ETO sterilization, or any time after ETO or additional HLD before its use (ie, the timing of culture was random during each duodenoscope sterilization cycle). As previously identified as the culprit for contamination and the potential nidus for organic debris,[4] the elevator mechanism of the duodenoscope was cultured in the up and down position (ESwab collection kit; ACL Laboratories, Rosemont, Ill). Culturing was performed under sterile technique, which included disinfection of the counter and the use of gowns, face masks/shields, hair covering, and sterile gloves. After appropriate preparation, the outer tip of the duodenoscope was sanitized with an alcohol pad, using caution not to wipe the elevator mechanism and lens face at the distal end that was to be sampled with the ESwab; the duodenoscope was air-dried before sampling. The duodenoscope was placed in a tray with a sterile pad/liner for sampling. The ESwab was dipped in the medium of the transport container to premoisten it, and excess fluid was pressed from the ESwab inside the inner walls of the container. The ESwabs were held above the red mark on the shaft because that was the part of the shaft that was broken off and discarded; the shaft below the red mark was not touched. One ESwab was used for both the up and down elevator positions. The inside of the elevator mechanism, the recess, and the channel in the down position were sampled. Next, the same ESwab was used to sample the elevator mechanism and the recess in the up position and to scrub the face of the lens. The ESwab was then placed into the transport tube, which was tightened and labeled as indicated. After culture, the specimen was sent to ACL Laboratories, and the duodenoscope was reprocessed with HLD. At that time, awaiting the results of cultures did not preclude use of the duodenoscopes.

RESULTS

For 18 months (October 2013 to April 2015), after 589 ERCPs and 84 random cultures, no recurrence of