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Concise Communication

Identification and control of two outbreaks of unrelated New Delhi metallo-β-lactamase–producing carbapenem-resistant *Escherichia coli* traced to the same endoscope defect

Halima K. Dabaja-Younis MD, MPH[1,2], Vered Schechner MD[3,4], Ibrahim Firan RN[1], Iyad Khamaysi MD[2,5], Gabrielle D. Levi[3], Mor N. Lurie-Weinberger[3], Avi Weissman MD[2,6], Yuri Guriel RN[5], Yuval Geffen PhD[2,7] and Khetam Hussein MD[1,2]

[1]Infection Control and Prevention Unit, Rambam Health Care Campus, Haifa, Israel, [2]The Ruth & Bruce Rappaport Faculty of Medicine, Technion–Israel Institute of Technology, Haifa, Israel, [3]National Institute for Antibiotic Resistance and Infection Control, Ministry of Health, Tel Aviv, Israel, [4]Sackler Faculty of Medicine, Tel Aviv University, Israel, [5]Gastroenterology Unit, Rambam Health Care Campus, Haifa, Israel, [6]Hospital Management, Rambam Health Care Campus, Haifa, Israel and [7]Microbiology Laboratory, Rambam Health Care Campus, Haifa, Israel

Abstract

We report 2 outbreaks of genetically unrelated carbapenem-resistant New Delhi metallo-β-lactamase–producing *Escherichia coli* caused by contaminated duodenoscopes. Using endoscopes with disposable end caps, adherence to the manufacturer's reprocessing instructions, routine audits, and manufacturer evaluation are critical in preventing such outbreaks.

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Endoscopic retrograde cholangiopancreatography (ERCP) is a widely used procedure. Bacteremia or infection are a known complication of ERCP.[1] The rate of ERCP-related infections is 15.2%.[2] Duodenoscopes contain many small functional parts, so proper reprocessing and disinfection is essential to prevent endoscope-related infections.[3,4] However, several outbreaks of multidrug-resistant organisms (MDROs) have been reported after ERCP even though the manufacturers' reprocessing instructions were strictly followed.[5,6]

We describe 2 ERCP-related outbreaks of carbapenem-resistant New Delhi metallo-β-lactamase (NDM)–producing *Escherichia coli* that occurred 7 months apart at Rambam Health Care Campus (RHCC), a 1,000-bed, university-affiliated hospital in Haifa, northern Israel. Approximately 500 patients undergo ERCP at RHCC each year. At the time of the outbreaks, 2 types of duodenoscopes were in use: TJF-Q190V (with disposable end cap) and TJF-Q180V (with fixed end cap). Carbapenem-resistant *Enterobacteriaceae* screening guidelines at RHCC are listed in Supplementary Table 1 (online).

Author for correspondence: Dr. Khetam Hussein, Infectious Control and Prevention Unit Rambam Health Care Campus, PO Box 9602, Haifa 31096, Israel. E-mail: k_hussein@rambam.health.gov.il

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First outbreak

On day 1 and day 3, *E. coli* NDM was detected in 2 patients hospitalized at the surgical department during routine surveillance. Remarkably, *E. coli* NDM was extremely rare in our hospital, so the infection prevention and control (IPAC) staff initiated an epidemiological investigation, which revealed that both patients had undergone ERCP procedures in our hospital 1 week earlier.

On day 18, a third patient was admitted to the hospital with septic shock secondary to *E. coli* NDM 3 days after ERCP. The 3 cases raised immediate concern that the infections were related to recent ERCP procedures.

Second outbreak

On day 214, 7 months later, a rectal screening of a 2-year-old patient performed after transfer from the pediatric intensive care unit yielded a positive result for *E. coli*-NDM. A rapid investigation revealed that he had undergone an ERCP procedure 3 days earlier (day 211). Also, 8 days earlier (day 203), a known carrier of *E. coli*-NDM (index case 2) had been treated with the same endoscope (endoscope 2-TJF-Q180V, serial no. 2507365) (Table 1).

Methods

In both investigations, the medical records of all patients who had undergone an ERCP procedure up to 45 days before the mentioned events were reviewed. The IPAC team observed the endoscope's reprocessing techniques. All involved endoscopes were sampled and returned to the manufacturer for evaluation.

Table 1. Patients Positive for Carbapenem-Resistant *Enterobacteriaceae*, NDM β-Lactamase

Patient No.	Hospital Admission Date	Status on Admission	Screening Date	Date of ERCP	Date of Acquisition	Device No.	Carriage/ Clinical Infection	Outcome
Index case 1	Day (−44)	Positive	Day (−44)	Day (−30)	Day (−127)	2507371	Screening for known carrier (positive gall bladder fluid from August)	Death (unrelated to ERCP procedure)
Patient 1	Day (−10)	Negative	Day 1	Day (−10)	Day 1	2507371	Routine screening	No consequences
Patient 2	Day (−11)	Unknown	Day 3	Day (−8)	Day (−1)	2507371	Routine screening	No consequences
Patient 3	Day 15	Unknown	NA	Day 15	Day 18	2507371	BSI bacteremia	Sepsis
Index case 2	Day 223	Positive	Day 190	Day 223	Day 190	2507365	Known carrier	No consequences
Patient 4	Day 230	Negative	Day 234	Day 231	Day 234	2507365	Routine screening	No consequences

Note. NDM, New Delhi metallo; ERCP, endoscopic retrograde cholangiopancreatography; N/A, not available.

Results

First investigation

The 3 patients underwent procedures with the same endoscopic device (endoscope 1-TJF-Q180V, serial no. 2507371). Another endoscope was used to re-examine one of the patients (endoscope 2-TJF-Q180V, serial no. 2507365). Both endoscopes were immediately taken out of service, and ERCP procedures at the hospital were discontinued.

An investigation revealed that a known *E. coli* NDM carrier with *E. coli* NDM detected in his gallbladder aspirate underwent ERCP with the first endoscope 42 days before day 1. This patient was presumably the index case 1 (Table 1).

All patients who had undergone an ERCP procedure with endoscope 1 (16 patients) after the index case or with endoscope 2 (7 patients), which was used to re-examine one of the patients, were invited for rectal screening. All 23 patients were screened at least once; 9 were screened twice at least 1 month apart. All results were negative.

Deficiencies in cleaning and storage of endoscopes were noted. Reprocessing of the duodenoscopes was performed according to manufacturer's instructions and included immediate manual wiping of the outside of the duodenoscope and leak testing, then soaking with an enzymatic solution and manual reprocessing within an hour of completion of the procedure, followed by automated reprocessing with HLD, and finally vertical hanging for drying in an unventilated cabinet. The process of cleaning and storing clean endoscopes occurred in the same room without separation between clean and contaminated zones.

After the outbreak, cleaning and disinfection processes of duodenoscopes were moved to the main gastroenterology cleaning unit that work according to infection prevention and control standards. Clean endoscopes were stored in standardized lockers in a separate room adjacent to the ERCP unit.

Affected endoscopes were sampled and *E. coli*-NDM grew in cultures from 3 channels of the first endoscope. Cultures from the second endoscope and the brushes were sterile. Molecular typing revealed that all organisms had carbapenemase gene $bla_{\text{NDM-19}}$. All isolates were *E. coli* ST167 with the same resistance profile and antibiotic resistance genes. According to the phylogenetic tree, the 5 isolates were very closely related (Supplementary Fig. 1 online). In addition, all samples appeared to contain the same plasmid, IncX3. After laboratory confirmation, all 5 endoscopes used in the ERCP unit were immediately sterilized with ethylene oxide gas.

The endoscopes were revised by the manufacturer and showed numerous cracks and corrosion damage to the insertion tube and protector, the control unit connector, and the distal end cap. The damage was repaired before they were reused.

For devices used in patients known to be MDRO carriers, a cleaning protocol with double reprocessing cycles was implemented. Small brushes that fit on the tip of the elevator portion of the endoscope were procured to clean inaccessible parts of the endoscopes.

Second investigation

E. coli-NDM was detected in cultures from the endoscope 2. However, 5 patients who had undergone ERCP with this endoscope after the index case were screened for CPE and the culture results were negative. Positive samples from the index case, the child, and endoscope 2, were sent to the referral microbiology laboratory for molecular identification.

Molecular typing revealed that all samples had the carbapenemase gene $bla_{\text{NDM-1}}$. All isolates were *E. coli* ST115 with the same resistance profile, which was different from the isolates of the first outbreak (Supplementary Table 2 online). According to the phylogenetic tree, the 3 isolates were very closely related (Supplementary Fig. 1 online). Similarly, all samples appeared to contain the plasmid ColpVC.

Inspection by the manufacturer revealed numerous cracks and deformations in the distal end cap. The TJF-Q180V endoscopes were not returned to service due to nonusability, and all endoscopes were replaced with PENTAX duodenoscopes. The ED34-i10T2 video duodenoscope from PENTAX Medical (Montvale, NJ) has a sterile disposable elevator cap that is easily replaced and improves the cleanability of the duodenoscope. No additional cases have been reported since the second outbreak (28 months).

Discussion

We report here 2 genetically unrelated outbreaks of *E. coli*-NDM transmission via ERCP endoscopes. The occurrence of 2 unrelated events within a few months despite improvement in HLD compliance supports our hypothesis of contamination from inaccessible parts of the elevator channels. Contamination rates can be as high as 5.7% despite double HLD or ethylene gas sterilization,[2] underscoring the difficulty of cleaning and supporting our decision to use endoscopes with disposable elevator end caps. This action is supported by the recent US Food and Drug Administration

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recommendation to switch to disposable end caps, which allows more effective reprocessing of endoscopes.[7]

Awareness of violations in the cleaning process needs to be heightened, and audits should be conducted regularly.[8] Manual bedside cleaning and leak testing should be performed immediately after the procedure. Proper manual cleaning of endoscopes with special brushes compatible with the internal channels and detachable parts of the endoscope is critical to remove debris and to prevent biofilm formation.[9]

Small cracks in the internal canals of duodenoscopes could serve as escape points for organic materials and bacteria and subsequent biofilm formation. Thus, annual compatibility testing by the manufacturer may be warranted.

In addition, microbiologic surveillance of duodenoscopes should be performed at specific intervals, as recommended by the Center for Disease Control and Prevention.[10] In the case of repeated positive cultures, evaluation by the manufacturer is warranted.[8,10] The investigations of these outbreaks were conducted after the detection of a very rare MDRO infection. Our findings may suggest that other events caused by more common pathogens may go unnoticed.

In conclusion, regular review of duodenoscope reprocessing procedures by IPAC teams is essential, even in the absence of visible deficiencies. However, strict adherence to manufacturers' reprocessing guidelines is probably not sufficient to prevent all ERCP-related infections. Endoscopes should be inspected regularly for the presence of internal cracks or damage that could promote biofilm formation and that duodenoscopes be used with disposable end caps to ensure optimal cleaning.[10]

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/ice.2023.21

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