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Epidemiologic Review of Carbapenem-Resistant Enterobacteriaceae, Duodenoscopes, and Endoscopic Ultrasonography in the Department of Veterans Affairs

Recent investigative reports have described transmission of carbapenem-resistant Enterobacteriaceae (CRE) infections linked to duodenoscopy procedures (ie, endoscopic retrograde cholangiopancreatography [ERCP]) or endoscopic ultrasonography (EUS).[1–6] Accordingly, the US Food and Drug Administration issued an executive summary[7] and a safety communication[8] on this subject in 2015. In response, the Department of Veterans Affairs (VA) conducted a retrospective review to determine whether veterans could have developed CRE infection after ERCP or EUS procedures.

VA data warehouses were queried for hospital number, patient identifiers, procedure date, Current Procedural Terminology codes, and *International Classification of Diseases, Ninth Revision* procedure codes for ERCP and EUS procedures performed (Supplementary Table 1) at VA or non-VA medical centers (paid by VA) and positive cultures for CRE (any specimen type or anatomic site) collected at VA medical centers from January 1, 2010, through February 28, 2015. CRE were identified using Centers for Disease Control and Prevention definitions: positive for Enterobacteriaceae genus meeting the following criteria: (1) nonsusceptible to 1 carbapenem (doripenem, meropenem, or imipenem) and (2) resistant to all of the following third-generation cephalosporins tested: ceftriaxone, cefotaxime, and ceftazidime.[9]

CRE were isolated using standard microbiologic methods according to local VA medical center practice. Patients having ERCP/EUS at medical centers that reported either carbapenem nonsusceptibility or third-generation cephalosporin resistance (but not both) were evaluated as described above (medical center was contacted for additional information). Results from patients with ERCP/EUS procedure codes and at least 1 positive culture for CRE were merged. Additional information

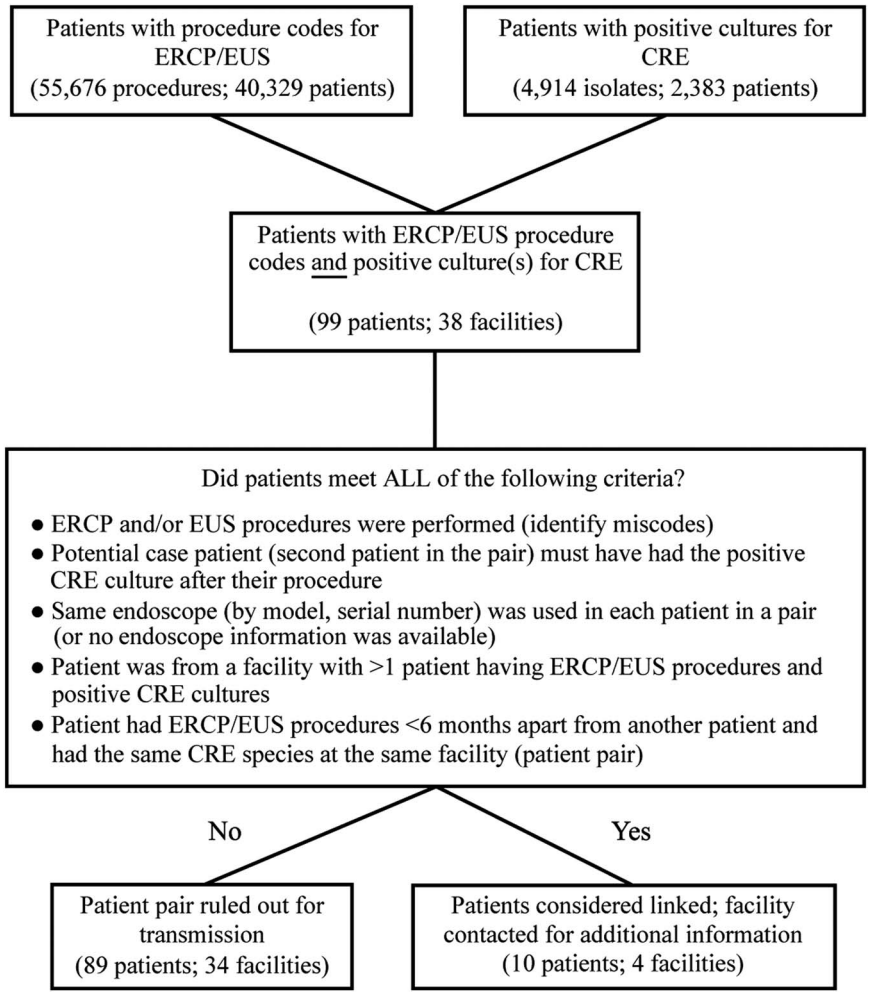

FIGURE 1. Flow chart in epidemiologic review of carbapenem-resistant Enterobacteriaceae, duodenoscopes, and endoscopic ultrasonography in the Department of Veterans Affairs. CRE, carbapenem-resistant Enterobacteriaceae; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasonography. Time interval of < 6 months apart was decided upon in conjunction with CDC.

including endoscope make, model, and serial number was obtained from electronic health records (Figure 1). For patients with postprocedure CRE isolates only, we determined infection or colonization status on the basis of provider decision to treat or not treat.

To assess possible transmission, patients having ERCP/EUS procedures within a 6-month period of another patient (time interval selected in consultation with the Centers for Disease Control and Prevention) at the same VA or non-VA medical center and who had positive cultures for the same CRE bacterial species were identified. Patients were considered linked if they had ERCP/EUS procedures in the defined time-frame, the same CRE bacterial species was identified (potential case patient had CRE isolated after his or her procedure), and the same endoscope was used. If endoscope information did not match, CRE transmission was ruled out. If information was not documented or was unavailable in electronic health records, the VA medical center was contacted for further information.

Of 55,676 ERCP/EUS coded procedures (40,329 patients) and 4,914 CRE isolates (2,383 patients), 99 patients had ERCP/EUS procedure codes and at least 1 positive CRE culture. CRE was found in urine (2,915 [59%]), respiratory tract (821 [17%]), blood (412 [8%]), gastrointestinal/abdominal (76 [2%]), and other sites (690 [14%]). After eliminating 18 *International Classification of Diseases, Ninth Revision*/Current Procedural Terminology procedure miscodes, 81 patients had positive pre- and/or postprocedure CRE cultures: 17 preprocedure only, 57 postprocedure only, and 7 pre- and postprocedure.

Of 57 patients with postprocedure isolates only, 47 and 10 were determined to be infections and colonization, respectively. Median number of days from ERCP/EUS procedure to CRE isolation was 129 and 212 days for infected and colonized patients, respectively (Table 1). Thirty-two patients had expired, 28 with infection, 4 with colonization; the median number of days from procedure to death was 279 and 588 days, respectively.

Ten patients (7 pairs, 4 facilities) had procedures less than 6 months apart, same CRE organism isolated at that facility,

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TABLE 1. Characteristics of Carbapenem-Resistant Enterobacteriaceae (CRE) Infection and Colonization in Patients With Postprocedure Isolates Only

Variable	Infections (n = 47)	Colonization (n = 10)
Site		
Respiratory tract	14	2[a]
Urine	10	7[a]
Bile/gallbladder	7	0
Blood	6	0
Peritoneal fluid	6	0
Other	4	2
Organism		
Klebsiella	25	8
Enterobacter	16	1
Escherichia	2	0
Serratia	2	0
Citrobacter	1	0
Morganella	0	1
Providencia	1	0
Time from procedure to CRE isolation, median (range), d	129 (11–1,683)	212 (12–1742)
Number of deaths[b]	28	4
Time from procedure to death, median (range), d	279 (11–1,701)	588 (309–1,812)

[a]1 patient was colonized in urine and sputum.
[b]CRE was not necessarily the principal or contributing cause of death.

and documentation of the same endoscope (or endoscope information was unavailable). For 3 of the 10 patients (3 pairs, 1 facility), endoscope information was unavailable (procedures were not performed in VA). The procedure dates for the 3 patient pairs were 68, 75, and 143 days apart. For the remaining 7 patients (4 pairs, 3 facilities), the same endoscope was used at their respective 3 facilities. These procedure dates were 82, 85, 108, and 120 days apart for each pair. The same endoscopes were used on multiple other patients during the time interval between the pairs, and no documented CRE infections or colonization was found in these patients.

In general, infections associated with transmission from duodenoscopes have occurred within 30 days after duodenoscopy.[5,6] Median time from endoscopy to CRE infection in VA was approximately 4 months. On the basis of this finding and our observation of the same endoscope being used in other patients between these pairs, it appears CRE infection resulting from transmission of CRE from endoscope transmission is unlikely, but we cannot definitely rule out transmission.

Cleaning endoscopes is complex. Residual bacteria associated with infection are thought to be harbored within the distal end elevator mechanism and may persist even after appropriate cleaning and disinfection.[2,4,7,8,10] The VA has policies and procedures in place requiring all VA facilities to assess competency and ensure cleaning guidelines and manufacturer's instructions are rigorously followed.

There were limitations to this retrospective analysis. CRE isolates and endoscopes were unavailable for culture/epidemiologic testing, some microbiology data were unavailable, susceptibility testing/reporting practices were variable across VA, microbiology data were limited to VA facilities, some endoscope information was unavailable, and procedure miscoding was identified. Also, reprocessing practices were not assessed. Currently, VA is not routinely screening and/or culturing for CRE before or after ERCP/EUS. Thus, we were unable to determine whether colonization was associated with endoscopy before infection occurred, and there are likely undetected cases.

In conclusion, we did not find convincing evidence of CRE transmission related to ERCP/EUS in the VA during the analyzed timeframe. Given limitations of this review, the possibility that some transmission may have occurred cannot be completely excluded.

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SUPPLEMENTARY MATERIAL

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Factors Affecting Adherence to a Preoperative Surgical Site Infection Prevention Protocol

Reasons for the lack of treatment regimen adherence (ie, the extent to which patients follow healthcare provider-prescribed instructions[1]) are likely multifactorial, including health status, belief systems, social supports, economic factors, and regimen complexity.[1] In chronic diseases such as pediatric asthma, socioeconomic status (SES) has been associated with readmission and has been thought to represent a marker of adherence to chronic disease management.[2] The role of SES in adherence to acute processes is not well understood.

Surgical site infection (SSI) prevention protocols include preoperative patient and family actions.[3,4] However, factors that contribute positively or negatively to task execution are unknown. Assuming that nonadherence contributes to higher SSI rates, identifying and addressing such factors is a priority. We sought to identify such factors for a locally developed SSI prevention protocol and to test the effect of SES on adherence.

METHODS

This retrospective analysis was approved by our institutional review board and included patients undergoing spinal fusion over 27 months (July 1, 2012, through October 31, 2014, excluding July 2014) utilizing a preoperative SSI prevention protocol. We used the earliest procedure for patients with >1 eligible procedure during the study period. Protocol adherence was measured as described elsewhere.[5] Briefly, patients were given verbal and written instructions for 2–5 protocol tasks preoperatively (eg, bathing and decolonization) based on screening results. All-or-nothing adherence was measured based on self-report.[6]

The patient variables we considered included age at surgery, sex, race, and insurance, obtained from the electronic medical record (EMR), and number of complex chronic condition (CCC) categories obtained from the Pediatric Health Information System.[7] We excluded technology dependence and other congenital or genetic defects from the CCC categorization because ~90% of included patients were positive for 1 or both, presumably due to a fusion procedure and/or scoliosis diagnosis (data not shown).

Included clinical characteristics were scoliosis diagnosis, surgical history, months since protocol initiation, and number of protocol tasks assigned; these data were obtained from the EMR and orthopedic patient databases. Scoliosis diagnoses were categorized as idiopathic, neuromuscular, or other, and surgical histories were categorized as any previous spinal surgery, any previous nonspinal surgery, or no previous surgery. For SES, we used census-tract percentage of individuals with income below the federal poverty level from the most recent US Census American Community Survey[8] and categorized these data into tertiles: high (meaning more individuals in poverty), medium, and low.

Univariate logistic regression was used to identify potential patient characteristics associated with protocol nonadherence ($P < .1$). The initial multivariate logistic regression model included the retained patient characteristics and the clinical characteristics of scoliosis diagnosis, surgical history, months since protocol initiation, and number of protocol tasks. Variables with $P \geq .1$ were removed to give the most