TRANSESOPHAGEAL ECHOCARDIOGRAPHY, INSUFFICIENT CLEANING PRACTICES AND LAX EQUIPMENT MAINTENANCE, AND *ESCHERICHIA COLI* - A BREAKDOWN IN INFECTION CONTROL

INTRODUCTION

Escherichia coli (*E. coli*) is a rod-shaped, gram-negative bacillus normally found in the lower gastrointestinal tract and is part of the normal intestinal flora. In hospital settings, *E. coli* most commonly causes urinary tract infections. Respiratory tract infections due to *E. coli* are uncommon, though there have been several published reports that chronicle *E. coli* pneumonia in the pediatric intensive care unit (ICU) [1]. Outbreaks of respiratory tract infections with gram-negative organisms have been increasingly reported due to contamination of medical equipment including bronchoscopes which are directly inserted into the respiratory tract. Transesophageal echocardiography (TEE) is normally done by inserting the instrument into the gastrointestinal tract (the esophagus) and is used during cardiac surgery to better visualize the posterior of the heart. The gastrointestinal tract is considered “dirty” and medical equipment should receive high-level disinfection.

On May 30, 2006, Los Angeles County (LAC) Department of Public Health, Acute Communicable Disease Control (ACDC) Program received a report from the hospital infection control professional that nine cardiac surgery patients were culture positive (blood or sputum) with *E. coli* infections that occurred in early May 2006. The positive cultures occurred from 1 to 4 days after surgery. This report describes the ensuing investigational study to determine the source of the outbreak.

METHODS

Setting: The study was conducted in a 370-bed acute care hospital in LAC which specializes in cardiology and orthopedic care.

Cohort Study: This was a hospital-based cohort study of individuals who underwent valve replacement, coronary artery bypass graft (CABG), both or any other cardiac procedure in May 2006. During this period, a total of 26 cardiac procedures were performed.

Cases were defined as patients who had a cardiac procedure in May that tested positive for *E. coli* within seven days of the procedure and had either a matching pulsed-field gel electrophoresis (PFGE) pattern or matching antibiotic susceptibility pattern. Controls were defined as patients who had a cardiac surgery procedure in May and did not test positive for *E. coli*.

A standardized chart abstraction tool was developed to collect information on demographics; culture results; pre-operative, operative, and post-operative procedures; surgical staff, medications, bed location, and ICU staff during and after the operation until the first positive culture for *E. coli* (cases) or for four days after surgery (controls).

The antibiotic susceptibility profiles of the *E. coli* infections in the cases were reviewed. Susceptibility to amikacin, cefazolin, cefepime, cefotaxime, ceftazidime, imipenem, nitrofurantoin and piperacillin/tazobactam was tabulated.

Environmental: Environmental surveillance cultures of the cardio-vascular ICU (CVICU) were obtained by hospital infection control staff from May 26 to June 2, 2006 and by Public Health staff. Cultures of the TEE equipment were obtained by hospital staff and LAC Public Health Laboratory (PHL) staff.

Laboratory Investigation: Available *E. coli* isolates from cardiac surgery patients and from environmental surveillance were submitted to the LAC PHL for microbiological analysis.

The LAC PHL completed PFGE analysis on *E. coli* clinical (case and control) and environmental isolates. PFGE was performed using the standardized methods of the PulseNet USA protocol [2]. PFGE pattern

comparisons were performed visually and using BioNumerics software, version 4.0 (Applied Maths, Belgium).

Statistical Analysis: Data were analyzed using SAS, version 9.1 (Statistical Analysis Software, Cary, NC). Logistic regression was used to generate relative risks (RRs) and corresponding 95% confidence intervals (CIs) to evaluate potential risk factors. χ^2 test was used to compare groups while Fisher's exact test was used when appropriate. The mean surgery time was calculated and compared between cases and controls. A two-tailed *P* value of 0.05 or less was considered statistically significant.

Infection Control Measures/Investigation of Implicated Re-useable Medical Device: After the first site visit on May 31, 2006, ACDC issued interim recommendations including adding antibiotic coverage from gram-negative organisms for cardiac surgery patients, collecting surveillance cultures (sputum) on all intubated CVICU patients, collecting environmental cultures, and culturing the TEE equipment and removing it from use. CVICU and operating room procedures, infection control standards, and procedures for cleaning the TEE equipment were all assessed. When not in use, the TEE probe is stored in a closed case on top of the refrigerator in the cleaning room of the CV operating room (CVOR) office. The TEE equipment was visually inspected and the manufacturer was contacted regarding routine maintenance provided.

RESULTS

Cohort study: Of the nine case-patients seven had positive sputum cultures, one had a positive blood culture, and one had both a positive sputum and blood culture for *E. coli*. All the cultures occurred 1 to 4 days after surgery. All were treated with antibiotics after positive culture.

The distribution of ages and gender was similar between cases and control (Table 1). However, more controls were at home prior to surgery, had elective surgery than cases (Table 1), and did not have valve replacements. Cases also had a longer mean duration of surgery time (p=0.06) (Table 3).

Table 1. Characteristics of Post-Cardiac Surgery Patients with *Escherichia coli* Infection (Cases) versus without (Controls)

Variable	Cases (n=9)		Controls (n=17)		p-value
	n	(%)	n	(%)	
Age					
<50	-	-	1	5.9	0.1319
50-59	3	33.3	4	23.5	
60-69	2	22.2	6	35.3	
70-79	3	33.3	4	23.5	
80+	1	11.1	2	11.8	
Sex					
Male	4	44.4	13	76.5	0.1167
Female	5	55.6	4	23.5	
Prior Surgery Location					
Home	-	-	4	23.5	<0.0001
Ward	5	55.6	10	5.8	
Emergency Room	1	11.1	2	11.8	
Intensive Care Unit	2	22.2	-	-	
Other	1	11.1	1	5.9	
Procedure Type					
Valve	1	11.1	3	17.7	0.014
CABG	4	44.4	9	52.9	
Valve + CABG	2	22.2	-	-	
Other	2	22.2	5	29.4	
Status					
Urgent	2	22.2	3	17.6	<0.0001
Emergent	1	11.1	-	-	
Elective	4	44.4	12	70.6	
Other	-	-	1	5.9	
Missing	2	22.2	1	5.9	

* Values may not add up to totals due to missing values.

Table 3. Comparison of Procedure Duration for Cases and Controls

Procedure Duration	Cases	Controls	p-value
Mean (minutes)	351.4	270.8	0.055
Median	343	297	
Range	(300,455)	(75,414)	

Data for potential risk factors collected for cases and controls was analyzed to yield RRs and 95% CI (Table 2). None of the analyzed risk factors were statistically significant. Surgical staff, including surgeons, assistants, anesthesiologists, nurses, perfusionists, respiratory therapists and CVICU nurses were also analyzed, but no particular staff member emerged as a source of the infection. Pharmacy data for cases and controls was also analyzed, but did not yield a medication that may potentially be associated with the infection.

Table 2. Risk Ratios and Corresponding 95% Confidence Intervals (CI) For Potential Risk Factors for Patients with *Escherichia coli* Infection (Cases) versus without (Controls)

Risk Factor	RR	95% CI	P-value
Procedure Type			
Valve+CABG*	2.40	0.18,32.9	0.5122
CABG	1.33	0.10,17.1	0.8253
Valve	Referent	-	-
TEE			
Yes	0.47	0.08,2.6	0.3905
No	Referent	-	-
Bronchoscopy			
Yes	1.07	0.08,13.9	0.9579
No	Referent	-	-
OR Room			
14	1.80	0.29,11.2	0.3905
12	Referent	-	-
Surgery Status			
Urgent or emergent	3.00	0.42,21.3	0.2720
Elective	Referent	-	-
Vancomycin			
Yes	2.15	0.2,23.2	0.5268
No	Referent	-	-
TEE Post Surgery			
Yes	0.72	0.06,8.5	0.7956
No	Referent	-	-

* Includes "Other" category

Environmental Cultures: Twenty-three environmental cultures were collected by hospital staff, including the TEE probe, which was cultured on June 2 and again on June 8. The TEE probe tested positive for Klebsiella pneumoniae on June 2 and tested positive for *E. coli* on June 8. Four additional cultures were taken from the TEE probe, TEE gel, gel cap, and outside of the cap by PHL staff. All samples were sent to the PHL. All environmental cultures were negative for *E. coli* except for the TEE probe.

Laboratory: Thirteen clinical specimens (from *E. coli* positive CVICU patients in May and June) and one environmental specimen (TEE) were submitted to the PHL for PFGE testing. PFGE was performed using the standardized methods of the PulseNet USA protocol [2]. PFGE pattern comparisons were performed visually and using BioNumerics software, version 4.0 (Applied Maths, Belgium). Strain typing analysis revealed that three patient isolates and one infection control isolate (TEE) had an indistinguishable PFGE pattern with *Xba*I and *Bln*I enzymes. Three patient isolates were subtypes of the predominant strain type, differing by a total of one to four bands, and six isolates had band differences of $\geq$7, indicating that these six are not part of the outbreak [3].

Infection Control Review: The hospital had one TEE probe dedicated to the two cardiac surgery operating rooms. Cardiac surgery patients regularly had the TEE inserted at the beginning of a procedure and the scope remained inserted for the entire duration. The TEE probe was cleaned between each patient with disinfectant and recorded; however, incorrect recording and poor disinfection technique was observed. Visual inspection revealed cracks in the ring of the TEE (Figure 1, 2). The TEE probe was removed from patient care and returned to the manufacturer.

Figure 1.

Figure 2.

DISCUSSION

Reports of *E.coli* infections acquired in hospitals are typically described in the context of urinary tract [3] or ventilator-associated infections [4]. Respiratory tract infections due to *E. coli* are uncommon.

Here, a hospital outbreak of *E. coli* respiratory infections among post-cardiac patients due to a reusable medical device, the TEE probe, was described. After an extensive literature search, this is the only other outbreak due to the TEE equipment that could be gathered.

The TEE equipment is used to visualize the posterior aspect of the heart during cardiac surgery. Professional organizations, medical equipment manufacturers and disinfectant manufacturers all provide instructions on the cleaning and disinfection of these items. Reprocessing of flexible endoscopes is standard practice in many health care settings, and the appropriate cleaning, disinfection, storage and maintenance of these devices can be a lengthy and complicated process. Frequently, endoscopes have been linked to nosocomial outbreaks [5-7].

It is the responsibility of the facility to ensure that reusable medical devices are properly cleaned and disinfected prior to each patient use. In addition, staff must be trained (and retrained) in the proper use, cleaning, storage and maintenance of the device. Staff knowledge is crucial to the infection control bottom line, and annual competency should be documented.

It is critical that reusable medical devices are properly cleaned prior to disinfection. Rutala and Weber reference the Spaulding classification for reusable medical items as critical, semi-critical and non-critical on the basis of the degree of risk of infection [8]. The TEE equipment is considered a semi-critical item since it is in contact with mucous membranes, and high level disinfection using chemical disinfectants is the minimum requirement. Prior to disinfection, the item should be rinsed with sterile water, filtered water, or tap water, followed by an alcohol rinse. The item should be thoroughly dried prior to storage.

The hospital has a policy and procedure “Cleaning TEE Transducer” outlining the appropriate cleaning principles such as “…the transducer must be cleaned and inspected before and after each transesophageal echocardiography examination…should be inspected for perforations or tears in the outer casing…”.

The TEE equipment consists of a transducer probe and a motor housing with articulation knobs followed by a cable ending at the connector. The probe is covered by a hard, black, smooth plastic with depth markings. The CVOR transducer showed visible fraying and deterioration in the area surrounding the outer aspect of the transducer probe neck, and fraying with a white string protruding from the inner aspect.

ACDC was initially told that the TEE is inspected quarterly on-site by the manufacturers’ representative. However, the hospital was unable to provide documentation of the manufacturers’ quarterly maintenance.

The Centers for Disease Control and Prevention (CDC) Guidelines for Environmental Infection Control in Health Care Facilities Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) 2003 advises that “manufacturers should provide care and maintenance instructions specific to their equipment” [9].

After reviewing the literature, other than 1 report of 2 cases of *Legionella* after TEE, no other report of respiratory, or other infections, associated with TEE was found. Nosocomial infections in ICUs are almost always associated with the use of an invasive device [1]. Richards et al. found that infections at three major sites represented 68% of all reported infection (primary bloodstream, 28%; pneumonia, 21%; and UTIs, 15%); 84% of all episodes of nosocomial pneumonia were related to mechanical ventilation [1]. In another study, device-related sources were responsible for 43% of all hospital-acquired bacteremia [10].

In the analysis of the data, no one particular factor emerged as a probable risk factor. This was surprising, since after obtaining the PFGE results, which implicated the TEE probe as the point source, it was expected to be confirmed by the statistical analysis. A possible explanation may be that the results of the analysis depend solely on the quality of the data. Because of the busy nature of the OR and the many surgical procedures, procedures such as TEE may not be documented and recorded in patient medical charts. As a result, upon chart review, data may be inaccurate and may thus reflect in the final analysis. Since PFGE is the gold standard method and has high reproducibility and discriminatory power [11], the interpretation relied on the PFGE results, which were used for the typing of *E. coli* isolates.

The TEE probe was implicated as the cause of this outbreak due to multiple reasons, including the matching PFGE isolates from the TEE and the cardiac patients exposed to the TEE, the epidemiology of *E. coli* infection in the cardiac patients, the cracked surface of the TEE which would have allowed safe harbor for bacteria even during disinfection, and the correlation between exposure duration to TEE and the increased likelihood of *E.coli* infection.

Interestingly, though post-cardiac surgery patients began developing *E. coli* infections in the beginning of the year at this facility, the PFGE only showed that half of the patients with the same antibiotic resistance profile had the same PFGE. Additionally, two patients had one strain that matched exactly the outbreak strain and another isolate that differed by two bands. This may be attributed to multiple strains of *E. coli* that survived on the TEE; however, there were only one culture because the TEE was removed from use and cleaned by the time it was cultured.

Other notable findings include the rapidity of the *E. coli* growth; many patients were positive within a day of surgery. However, it is still not clear how the bacteria migrated from the esophagus or oropharynx to the trachea/bronchi given that the patients were intubated during the time that the TEE was in the patient and for those who remained intubated, there should have been a sufficient seal with the TEE to block the spread of oropharyngeal flora to the lungs. For those who were extubated, it is possible that their oropharynx was so contaminated by the bacteria with the TEE passing through their mouth that it was able to gain access to their lungs.

This study has several limitations. As previously mentioned, the quality of a study depends on the accuracy of its data. Selective survival bias may also exist in this study. The longer surgery time might be a function of the emergent nature of the surgeries for the case patients, who might have been more likely to have surgery after ICU stay, resulting in an increased susceptibility to *E. coli* infection.

This study highlights the importance of a close relationship between hospitals and their local health departments. ACDC was notified of the outbreak by an astute hospital infection control practitioner. Due to complete cooperation and frequent communication, the point source of the outbreak was quickly identified and suggested control measures were implemented, thereby preventing additional infections. This study also demonstrates the necessity for hospitals to maintain better surveillance, especially in this case where *E. coli* infections are unusual in cardiac surgery patients. It is also necessary for hospitals to review infection control policies and procedures for “semi-critical” equipment, since such equipment has been linked to outbreaks of extended-spectrum beta-lactamase, hepatitis B and C [12,13]. Lastly, hospitals need to examine their equipment for deterioration per the manufacturers’ recommendations and hospital policy. In fact, once the TEE was identified as the source of the outbreak, the hospital visually inspected other scopes at the facility and found that some had evidence of erosion that had not been reported previously and were removed from patient use.

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