ORIGINAL ARTICLE

Caveat Emptor: The Role of Suboptimal Bronchoscope Repair Practices by a Third-Party Vendor in a Pseudo-Outbreak of *Pseudomonas* in Bronchoalveolar Lavage Specimens

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(See the commentary by Weber and Rutala, on pages 230–234.)

OBJECTIVE. To describe a pseudo-outbreak associated with loose bronchoscope biopsy ports caused by inadequate bronchoscope repair practices by third-party vendors and to alert healthcare personnel to assess bronchoscope repair practices.

DESIGN. Outbreak investigation.

SETTING. A 925-bed tertiary care hospital in Baltimore, Maryland.

PATIENTS. Patients who underwent bronchoscopy with certain bronchoscopes after they had been repaired by a third-party vendor.

METHODS. An epidemiologic investigation was conducted to determine the cause of *Pseudomonas putida* growth in 4 bronchoalveolar lavage (BAL) specimens within a 3-day period in May 2008. All bronchoscopes were inspected, and cultures were obtained from bronchoscopes and the environment. Bronchoscope cleaning and maintenance practices were reviewed. Microbiologic results from BAL specimens and medical records were reviewed to find additional cases.

RESULTS. All 4 case patients had undergone bronchoscopy with one of 2 bronchoscopes, both of which had loose biopsy ports. Bronchoscope cultures grew *P. putida*, *Pseudomonas aeruginosa*, and *Stenotrophomonas*. The *P. putida* strains from the bronchoscopes matched those from the patients. Specimens from 12 additional patients who underwent bronchoscopy with these bronchoscopes grew *P. putida*, *P. aeruginosa*, or *Stenotrophomonas*. No patients developed clinical signs or symptoms of infection, but 7 were treated with antibiotics. Investigation revealed that the implicated bronchoscopes had been sent to an external vendor for repair; examination by the manufacturer revealed irregularities in repairs and nonstandard part replacements.

CONCLUSIONS. Third-party vendors without access to proprietary information may contribute to mechanical malfunction of medical devices, which can lead to contamination and incomplete disinfection.

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Outbreaks associated with bronchoscopes have been associated with failures in cleaning and disinfection,[1-3] malfunctioning parts,[4-6] and damage that occurs during use.[7,8] Damage usually occurs during procedures rather than during cleaning and disinfection, most commonly in the form of tears and ruptures of the covering of the inner channel from instruments placed in the channel.[9] Such incidents are costly, resulting in repairs that cost approximately $3500–$4000 (2009 dollars) per incident, or about $35–$50 (2009 dollars) per procedure when amortized over 1 year, because the instruments require specialized repair.[9-12] Optimally, repairs are performed by the manufacturer, who has proprietary knowledge regarding the structure of the scope and the design of its parts. Because of the high cost, it is common practice for institutions to use less expensive third-party vendors for maintenance and repair of bronchoscopes (Olympus America, personal communication).

In this report, we describe the investigation of a cluster of 4 patients whose bronchoalveaolar lavage (BAL) cultures grew *Pseudomonas putida* over 3 days in May, 2008, leading to the discovery that bronchoscope repairs made by a third-party vendor may have contributed to bronchoscope damage and

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subsequent contamination. We propose an approach to assess patients at risk after detection of a damaged bronchoscope.

METHODS

Setting

The Johns Hopkins Hospital is a 925-bed tertiary care hospital in Baltimore, Maryland. Approximately 1,000 bronchoscopy procedures are performed annually in the endoscopy suite, the operating rooms, and the intensive care units.

Surveillance

At our institution, an outbreak of *Pseudomonas aeruginosa* respiratory-tract infections (RTIs) was associated with a contaminated recalled loose bronchoscopy biopsy port in 2001.[6] Since then, surveillance to detect unusual patterns of organisms isolated from respiratory tract specimens has been implemented. In May 2008, the microbiology lab reported the growth of *Pseudomonas putida* from 4 separate BAL specimens obtained in a 3-day period. We queried our microbiology database to determine whether other BAL specimens had grown *P. putida* in the preceding 6 months.

Inspection and Culturing of Bronchoscopes

The 2 bronchoscopes used on the 4 patients were removed from service immediately. Elective bronchoscopy procedures were cancelled. All bronchoscopes in the endoscopy unit were inspected for evidence of loose ports or other defects, and culture samples were obtained by instilling sterile saline into the distal (biopsy) port and collecting samples in both an anterograde and a retrograde manner from the biopsy channel as previously described.[6]

Evaluation of Bronchoscope Cleaning Procedures and Environmental Culturing

The endoscopy unit cleans bronchoscopes according to manufacturers' recommendations and national guidelines.[6,13] The cleaning and disinfection processes, as well as bronchoscope maintenance and repair records, were evaluated. Culture samples were obtained from the ortho-phthalaldehyde liquid germicide (Cidex OPA, Advanced Sterilization Products), bronchoscope washers, water from the washers during the cycle, filters from the washers, the bronchoscope storage cabinet, antifog solution, and the sinks and drains.

Microbiology Methods

Bronchoscope and environmental samples were plated onto MacConkey agar. All organisms were identified using the Phoenix automated instrument (Becton Dickinson). Further identification of *P. putida* was performed by cell wall fatty-acid analysis using gas liquid chromatography (MIDI). Pulsed-field gel electrophoresis (PFGE) was performed on available isolates. DNA was digested with SpeI (New England Biolabs), and gels were analyzed visually and with Molecular Analyst Fingerprinting Plus software (Bio-Rad). Isolates were considered genetically related if their PFGE patterns differed by 3 or fewer bands and if the similarity index was 90% or higher on the dendrogram.[14]

Outcomes

Patients potentially at risk were identified by means of a log of bronchoscopy cases and the serial number of the bronchoscope used in the procedure. Patient medical records were reviewed for respiratory tract colonization or infection possibly related to the bronchoscopy and whether antibiotic therapy was initiated. RTIs were defined according to the Centers for Disease Control and Prevention criteria and were attributable to the bronchoscopy if they occurred within 14 days of the procedure.[15] Each patient at risk was contacted by an attending physician to assess for any respiratory problems following bronchoscopy. The institutional review board at Johns Hopkins University approved this study and waived informed consent (JHM-IRBX, NA_00026444).

RESULTS

Investigation of Bronchoscopes

The 4 patients with BAL specimens growing presumptive *P. putida* had undergone bronchoscopy with 1 of 2 bronchoscopes. Inspection of all bronchoscopes revealed that these 2 bronchoscopes had biopsy ports that were easily loosened by hand and had sludge accumulation at the port site (bronchoscopes A and B, both model BF160, Olympus America). The biopsy port on a third bronchoscope could be loosened only with a hemostat forceps; no sludge accumulation was noted (bronchoscope C, model BFQ180, Olympus America). No other bronchoscopes had loose ports. Samples taken in an anterograde and a retrograde manner from the biopsy channels of bronchoscopes A and B grew *P. putida* as well as *P. aeruginosa.* In addition, samples taken in an anterograde manner from bronchoscope B and those taken in a retrograde manner from bronchoscope A grew *Stenotrophomonas maltophilia.* No cultures from bronchoscope C or the other 15 bronchoscopes grew organisms.

Investigation of Bronchoscope Cleaning, Disinfection, and Maintenance Practices

No clinically important deviations in the cleaning and disinfection process were noted. However, while an informal protocol for training and competency assessment was in place, no written protocol was available. Bronchoscopes were not examined routinely for loose ports at the time of cleaning or prior to each procedure. In addition, the bronchoscopy unit had begun using a third-party vendor for repair and maintenance of bronchoscopes, rather than sending them to the manufacturer, in August 2007. The biopsy channels of bronchoscopes A, B, and C had last been replaced 10–22 weeks prior to occurrence of the index cases. One other bron-

choscope had been repaired by the third-party vendor; it was out for repair at the time of the initial investigation and subsequently did not have a loose biopsy port. None of the other 15 bronchoscopes had been repaired by the third-party vendor. Examination of the implicated scopes by the manufacturer revealed irregularities in repairs and nonstandard part replacements.

Cultures from 3 of the filters removed from the bronchoscope washers grew *P. putida*; however, the PFGE types were different from those of the organisms isolated from the patients and bronchoscopes. Cultures taken during the washer cycles did not grow organisms. Cultures taken by composite swabs from areas around the bronchoscope washers grew small amounts of *P. aeruginosa*; other environmental cultures were negative.

Investigation of Patients

We assessed all patients who had undergone bronchoscopy with the implicated bronchoscopes since their return from repair by the third-party vendor, as we judged this to be the period during which patients were potentially at risk. Seventy-seven patients had 82 bronchoscopies, and episodes were stratified into 4 risk categories (Figure 1): group 1, BAL culture grew an organism isolated from cultures of the bronchoscopes (*P. putida*, *P. aeruginosa*, or *S. maltophilia*; 12 patients in addition to the 4 index case patients); group 2, BAL culture grew fewer than 10,000 gram-negative rods that were not speciated (9 patients, including 1 patient whose BAL culture was available for speciation and grew *P. putida*); group 3, BAL culture was not performed at the time of the procedure because culture was not indicated (15 patients); and group 4, BAL cultures did not grow organisms (3 patients) or grew organisms that were not of interest (42 patients). No further evaluation of patients in group 4 was undertaken; they were believed to be at low risk for subsequent infection if the implicated organisms did not grow from cultures taken through the potentially contaminated ports.

A total of 8 patients grew *P. putida* from the BAL fluid. These were the 4 index case-patients, 1 patient whose BAL specimen grew fewer than 10^4 non–lactose-fermenting gram-negative rods that were subsequently identified to species level, and 3 patients who underwent bronchoscopy with bronchoscope A at the end of December, 2007. These 3 cases may represent an earlier, undetected cluster. Although none of these patients went on to develop an RTI, 4 were treated with antibiotics directed at *P. putida*. All isolates were susceptible to all tested antipseudomonal agents except aztreonam.

Seven patients in group 1 grew only *P. aeruginosa* from the BAL fluid. Two had existing colonization, and 1 had existing pneumonia. Three of the remaining 4 patients had underlying lung disease (2 lung transplants and 1 interstitial lung disease) and could have had either existing colonization or contamination from the bronchoscope; 3 were treated with antibiotics. The last patient underwent bronchoscopy to rule out

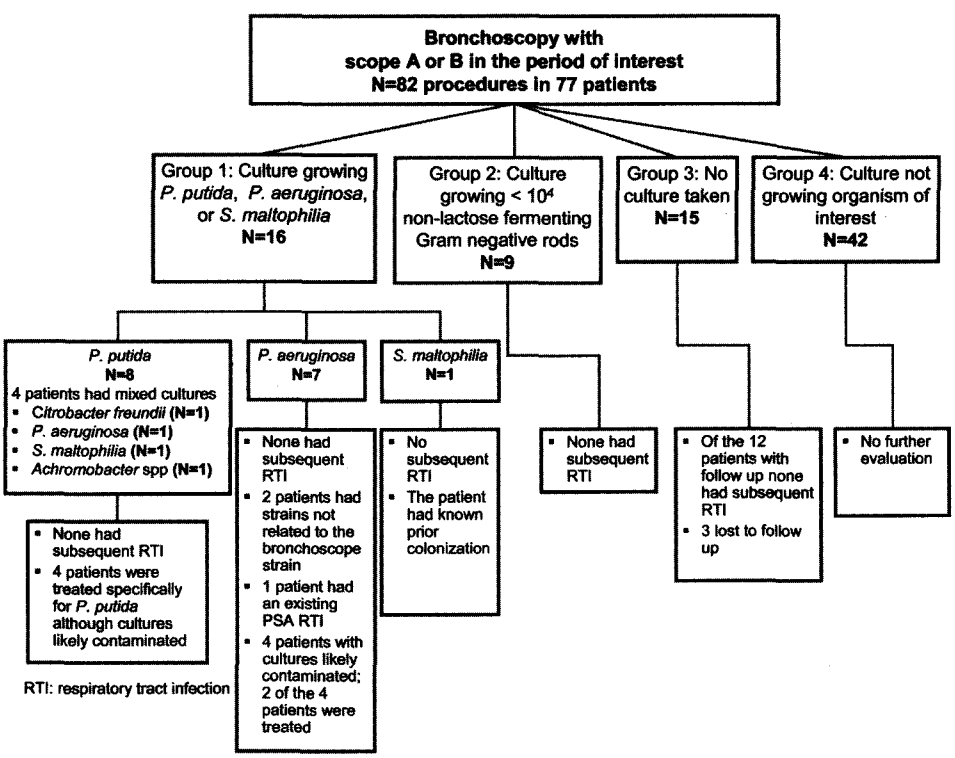

FIGURE 1. Stratification of case patients into infection risk groups and case outcomes.

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Pneumocystis jirovecii pneumonia and was not treated for *P. aeruginosa*, which was believed to be a contaminant. None of these patients had evidence of a new RTI in the 14-day period after the bronchoscopy. A culture from 1 patient in group 1 grew only *S. maltophilia*. This patient had existing colonization with the organism and had no subsequent evidence of a new RTI following bronchoscopy.

None of the 9 patients in group 2 (BAL culture growing fewer than 10,000 gram-negative rods) had evidence of a new RTI following bronchoscopy, and none were treated with antibiotics for RTI. None of the 12 patients in group 3 (BAL culture not performed at the time of bronchoscopy) who had follow-up had evidence of a new RTI; 3 of the patients were lost to follow-up.

PFGE subsequently revealed two different *P. putida* strains that were isolated from bronchoscopes A and B. Patients 1 and 2, who underwent bronchoscopy with bronchoscope A, both grew the same strain (strain 2), and patients 3–5, who underwent bronchoscopy with bronchoscope B, all grew the same strain (strain 1; Figure 2).

Termination of the Outbreak

No further cases of *P. putida* were identified in BAL cultures after the implicated bronchoscopes were removed from service. Maintenance of all bronchoscopes by the manufacturer was reinitiated, and all bronchoscopes were examined by the manufacturer. Endoscopy staff now record in the bronchoscopy log that biopsy ports have been checked for tightness at the time of cleaning and immediately before use. A written standard operating procedure for cleaning and disinfection of bronchoscopes was developed; competency training and its documentation are required annually. Finally, the tracking system for bronchoscopes in the institution was enhanced to include detailed logs of the location of all bronchoscopes in the institution as well as repair records.

DISCUSSION

In 2001, our institution discovered *P. auruginosa* contamination associated with bronchoscope biopsy ports that were loose because of a manufacturing defect. This new report differs in that rather than a manufacturing defect, inadequate repair practices performed by a third-party vendor led to the loose biopsy ports. We describe a cluster of *P. putida*, *P. aeruginosa*, and *S. maltophilia* in BAL cultures associated with these loose biopsy ports. This report demonstrates several critical issues that all institutions should address with regard to maintenance of bronchoscopes. The loose ports occurred in bronchoscopes that had been the subject of a recall for loose biopsy ports with associated microbial contamination in November 2001; all bronchoscopes had been repaired by the manufacturer at that time and had undergone routine maintenance with the manufacturer until August 2007, when a third-party vendor was employed to perform maintenance and repairs. The manufacturer detected several defects in the bronchoscopes that had been serviced by the third-party vendor. Third-party vendors without access to proprietary information may contribute to mechanical malfunction of bronchoscopes, which may lead to contamination and incomplete disinfection. Currently, in the United States, there is no regulation of third-party vendors that would establish minimum standards with regard to their maintenance and repair practices. Because of such unintended consequences, institutions should exercise caution before employing the services of third-party vendors for repair of equipment.

In addition, bronchoscopy areas must establish and maintain systems to assess scopes for loose ports and other problems before each use. They must develop standardized written protocols for cleaning and disinfection and ensure that all staff are appropriately trained in these protocols and maintain competency over time.

An association between loose biopsy ports, bronchoscope

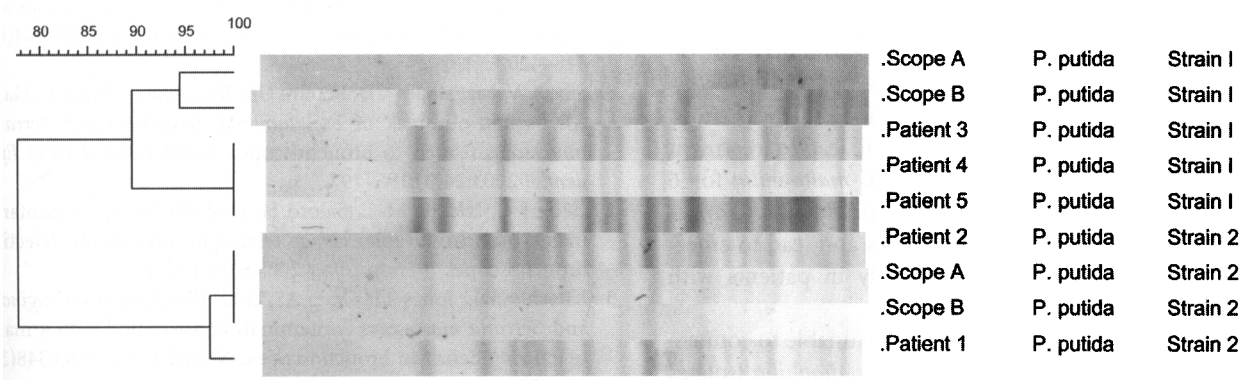

FIGURE 2. Pulsed-field gel electrophoresis–generated dendrogram for *Pseudomonas putida* isolates, comparing the isolates from 5 patients and the affected bronchoscopes, A and B. Isolates were considered genetically related if the similarity index was 90% or higher. The isolates from patients 1 and 2 were related or identical to strain 2 recovered from both scopes. The isolates from patients 3–5 were related to or identical to strain 1 recovered from both scopes.

contamination, and BAL cultures growing organisms has been described in previous reports.[5,6] The findings of the same strain types of *P. putida* in the patients' cultures and in cultures from bronchoscopes with grossly loose ports, while cultures from bronchoscopes without loose ports had negative results, provides strong evidence for this association. The surface area under the loose ports likely created a nidus in which organisms that are routinely found in water were able to lodge. The finding of *P. putida* growing in the washer filters and *P. aeruginosa* growing around the washers indicates that these organisms were present in the environment. No organisms were isolated from the washers during washing cycles, suggesting that there was no contamination of the washers themselves that could lead to contamination of properly functioning bronchoscopes. Indeed, bronchoscopes with normally functioning parts were found not to be contaminated.

Like *P. aeruginosa*, *P. putida* has been associated with outbreaks involving contaminated water and fluids, including contamination of a commercial antifog solution used to prevent condensation from forming on endoscopes, contamination of heparin flush made in a hospital pharmacy, and contamination of tap water in a pediatric oncology unit.[16-18] The organism is of low virulence, which may explain why our patients did not develop pneumonia or other RTIs after exposure.

We propose an approach by which institutions can stratify patients on the basis of the risk of contamination in the event of discovery of a contaminated bronchoscope. A database containing the serial numbers of bronchoscopes used for each patient was instrumental in allowing rapid assessment of which patients had been exposed. At-risk patients were then grouped according to available culture data. While patients whose cultures grow the organisms of interest are obvious candidates for further assessment, it is important to assess all patients who might be at risk, specifically those with uncharacterized or unidentified non–lactose-fermenting gram-negative rods and those who have not had cultures taken but could have had organisms introduced into the respiratory tract during the procedure.

We did not find clear evidence that any patients went on to develop RTI after undergoing bronchoscopy with the contaminated bronchoscopes; thus, we consider this a pseudo-outbreak. However, the positive cultures did lead to treatment directed at *P. putida*, *P. aeruginosa*, or *S. maltophilia* for 6 patients who likely did not need antibiotic therapy. Unnecessary antibiotic use can cause side effects and lead to emergence of resistant organisms, particularly in patients with underlying pulmonary disease.

This report has some limitations. We are unable to confirm that the *P. putida*, *P. auruginosa*, and *S. maltophilia* isolates from patients who underwent bronchoscopy before the cluster was detected in early May 2008 were of the outbreak strains, as these isolates were not available for strain typing. In addition, we do not know the exact time that the biopsy ports became loose and were contaminated, although we suspect that it occurred at the time of repair by the third-party vendor. Thus, the full extent of this cluster is unknown. In performing the investigation, we opted to include all potentially affected patients so as not to miss any clinically significant complications.

Continued vigilance for clusters of unusual organisms in patients undergoing bronchoscopy, via both electronic surveillance approaches and an engaged microbiology lab, is critical. Despite the many safeguards in place to ensure proper functioning of complex equipment in the healthcare setting, failure of devices or of processes to maintain these devices can still occasionally occur and is a significant threat to patient safety.

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