Clinical case study

Investigating the failure of repeated standard cleaning and disinfection of a *Pseudomonas aeruginosa*–infected pancreatic and biliary endoscope

Lijun Qiu, Zhihui Zhou, Qifang Liu, Yuhua Ni, Feng Zhao, Hao Cheng MD

*Address correspondence to Hao Cheng, MD, 3 Qingchun East Rd, 310016 Hangzhou, Zhejiang Province, China. E-mail address: lz_chenghao@126.com (H. Cheng).

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Digestive endoscopy is an important technique for the diagnosis and treatment of digestive system disease. Similar to many other high-precision medical devices, a digestive endoscope is a device with a complex structure, special building materials, and reusability. To assure medical safety, a digestive endoscope must be cleaned and disinfected before its use in an operation on the next patient. The most common treatment procedure on a digestive endoscope is high-level disinfection. According to current literature reports, digestive endoscopic examination–related pathogen spread is caused by the following: incompliance of the guidelines for endoscope cleaning and disinfection procedure; use of a defective device; or biofilm formation on endoscope tubes leading to failure of the cleaning and disinfection. The potential risk associated with digestive endoscopes is always the focus of endoscopic management in clinical practice. In this study, a polluted pancreatic and biliary endoscope after surgery was cleaned and disinfected multiple times with the standard procedure but still tested positive for *Pseudomonas aeruginosa* culture, which is very rare and has not been reported in China or abroad.

**CASE REPORT**

**Case 1**

An 82-year-old man was admitted to the hospital because of epigastric pain for 2 days. The physical examination results showed a temperature of 36.8°C, pulse of 96 beats per minute, respiration of 18 breaths per minute, blood pressure (BP) of 102/60 mm Hg, complete blood count (CBC) of 17.9 × 10^9/L, no clear yellow stain or bleeding spot on the systemic skin mucous membrane, no enlargement for either cervical or supraclavicular lymph nodes, positive Murphy sign, soft abdomen, and active bowel sounds. Abdominal B ultrasound suggested acute cholecystitis, calculus incarcerated in the neck of the gallbladder, multiple gallbladder stones, and the upper section with common bile duct stones accompanied by extrahepatic biliary dilatation. The patient was diagnosed with acute obstructive suppurative cholangitis and was given emergent endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic retrograde biliary drainage. The patient started to have a fever on day 3 after the surgery, with a maximum
Body temperature of 39°C. Bile culture for *P. aeruginosa* tested positive. Blood culture for both *Klebsiella pneumoniae* and *Escherichia coli* also tested positive.

**Case 2**

An 80-year-old man was previously admitted to the hospital in January when he was 79 because his skin and sclera turned yellow accompanied with weight loss. The physical examination results showed a temperature of 36.7°C, a pulse of 70 beats per minute, respiration of 18 breaths per minute, BP of 106/58 mm Hg, and CBC of 3.5 × 10^9/L. The sclera and systemic skin clearly exhibited a yellow stain. The superficial lymph nodes, heart, and lungs were normal. The abdomen was soft without tenderness or rebound pain. The Murphy sign was negative, and bowel sounds were normal. An upper abdominal noncontrast enhanced computed tomography scan and magnetic resonance cholangiopancreatography showed a widespread expansion of the intra- and extrahepatic bile duct, a common bile duct obstruction, and a dilated pancreatic duct. In addition, the ultrasound result from another facility suggested the following: a low echo occupied the low part of the common bile duct; cancer; chronic cholecystolithiasis; dilatation in the common bile duct, intrahepatic bile duct, and main pancreatic duct; multiple gallbladder stones; biliary sludge; and a filled spleen. The patient was diagnosed with common bile duct obstruction and possible pancreatic head cancer or ampullary cancer. The patient was given ERCP, endoscopic sphincterotomy, and endoscopic biliary stent implantation (2 days after the previous patient). The patient developed a fever on day 2 after the surgery, with a maximum body temperature of 39.2°C. Bile culture of *P. aeruginosa* tested positive. Blood culture of both *K pneumoniae* and *E coli* tested positive.

**Case 3**

A 40-year-old man was admitted to the hospital because of recurrent fever and abdominal pain for 20 days and exacerbated conditions for 4 days. The physical examination showed the following: temperature of 37.5°C, pulse of 98 beats per minute, respiration of 19 breaths per minute, BP of 91/53 mm Hg, and CBC of 12.0 × 10^9/L. No skin superficial lymph node enlargement was observed. The abdomen was soft without intestinal or gastric peristalsis. The left lower abdomen showed tenderness without rebound pain or muscle tension. The Murphy sign was negative, and bowel sounds were normal. The patient was given an auxiliary examination of the abdomen and Bartholin, Urethral, and Skene glands; the result showed multiple small stones in the gallbladder, cholecystitis, hepatic adipose infiltration, and a lower left abdominal cystic mass with possible abscess. High-sensitivity C-reactive protein tested at 81.7 mg/L. The patient was diagnosed with gallbladder stones and common bile duct stones. ERCP was performed to remove the stones, and nasobiliary drainage was given (3 days after the ERCP operation on the previous patient). This patient developed a fever on day 4 after the surgery, with a maximum body temperature of 39°C. Bile culture of *P. aeruginosa* tested positive. Blood culture tested negative.

**Treatment and monitoring of endoscope**

Preventive monitoring and investigation on multidrug-resistant bacteria infection by the department of infectious disease discovered that the infection of 3 patients occurred after ERCP surgery. The entire process of ERCP in the endoscopy center was investigated immediately. The procedures, including patient documentation, operation environment, the device, and endoscopic-related equipment, were inspected. Compliance with the cleaning and disinfection technical standard for endoscope operations, such as the rinse of the lifting clamp channel of the pancreatic and biliary endoscope and infection control chain inside the hospital, was also investigated. The results revealed that the same pancreatic and biliary endoscope was used in operations on the 3 patients sequentially. This pancreatic and biliary endoscope was suspended immediately, and biologic inspection was performed on the device. Bacteria culture of *P. aeruginosa* tested positive. Pulsed-field gel electrophoresis revealed a high homology between the *P. aeruginosa* from the endoscope and those from the 3 patients (Fig 1). This endoscope was again cleaned and disinfected in compliance with the standard protocol followed by a biologic inspection. The *P. aeruginosa* culture still tested positive. This endoscope was cleaned and disinfected using the standard procedure for a third and fourth time. In addition, various high-level disinfectants were used in the immersion disinfection process, including 2% glutaraldehyde, o-Phthalaldehyde (made in China), o-Phthalaldehyde (imported), and 24% glutaraldehyde (imported). Biologic inspection was carried out again after each disinfection procedure, and the *P. aeruginosa* culture still tested positive. The endoscope was cleaned with the standard procedure for the fifth time and soaked in 2% glutaraldehyde for 13 hours to sterilize. Biologic inspection was performed again and the *P. aeruginosa* culture still tested positive, but the colony count decreased by 50% when compared with the previous samples. The endoscope was sent to the Olympus endoscopic repair station at Shanghai, China. After being sterilized with epoxynethane, the entire endoscopic channel of the endoscope was dismantled and sent to the Laboratoire Biotech-Germande (Marseille, France) for examination. Microbiologic analysis was performed on the sample retrieved from the 4 tubes of the endoscope, and the report showed that the level of polymorphic nonpathogenic bacteria was higher than the allowed interference level in the standard guideline recommended by the hospital Committee of Technical Infection. The endoscope was cleaned and disinfected with a standard procedure and stored for 24 hours. Samples taken from the endoscope still tested positive with polymorphic nonpathogenic bacteria. In addition, the number of bacteria at the biopsy-suction tube and lifting clamp tube was higher than the allowed interference level in the standard guideline recommended by the hospital Committee of Technical Infection. Measurement of the protein and total organic carbon contents excluded the possible existence of bacterial biofilm in the various tubes. In the end, the repair center replaced the internal tubes of the endoscope on dismantlement of various components. The endoscope was then cleaned and disinfected with the standard protocol at the hospital endoscopy center and sent for biologic inspection. The bacteria culture this time was negative after 2 tests.

**DISCUSSION**

The completeness of endoscope cleaning and disinfection is crucial for medical safety and is highly regarded by hospital and endoscope management staff nationwide. The Chinese Department of Health published *Guidelines for Cleaning and Disinfecting Endoscopes* (2004 version), in which rule 34 in chapter 5 stated that after cleaning and disinfecting with the standard procedure, gastrointestinal endoscopy, pancreatic and biliary endoscope require a quarterly biologic inspection. In our hospital a standard precleaning, cleaning, and disinfection of the endoscope is managed under World Gastroenterology Organization (WGO)/OMGE—Organization Mondiale de Gastroenterologie (OMGE)/the World Organization of Digestive Endoscopy (OMED) *Practice Guideline Endoscope Disinfection* (2005 version). Considering the narrow lifting clamp tube and complex structure of the pancreatic and biliary endoscope, it is harder to clean and disinfect than other endoscopes. Since 2011,
the endoscopy center of our hospital has adopted a policy that biologic inspections for pancreatic and biliary endoscope be performed every 4 weeks based on the recommendation from the Gastroenterological Society of Australia in Guidelines Infection Control in Endoscopy (3rd ed). In this report, a pancreatic and biliary endoscope in our hospital was used in an ERCP operation on a patient with bile duct infection. After standard cleaning and disinfection, the endoscope was used for ERCP operations on another 2 patients and resulted in the *P. aeruginosa* infection of these 2 patients. Even though a previous study reported that the probability of pathogen spread during endoscopic examination operation was 1 in 1.8 million,1 some other studies have suggested that with the compliance of infection control guidelines, the endoscope prepared for patients still showed a >2% bacterial infection rate.2 The infection risk was hard to evaluate for various reasons. The blood culture and bile culture of the 3 patients reported in this study were not completely the same, which suggested a potential source of endogenous infection. However, the 3 cases showed a surprisingly similar bile culture result and bacteria homology, which indicated the relevance between the *P. aeruginosa* infection and the endoscope used in the process. The standard cleaning and disinfection procedures on the endoscope plus a standard cleaning and sterilizing procedure were performed, but the biologic inspection result still came back positive for *P. aeruginosa*. However, the biofilm tested negative. The bacteria culture tested negative until the endoscope was dismantled and replaced with new internal tubes. All the 3 patients were under the treatment with antibiotics before and after the endoscopic examination for cholecystitis and were given nasobiliary drainage. Therefore, no special treatment for *P. aeruginosa* infection was given. Case patients 1 and 3 recovered afterward. Case patient 2 went to a local hospital for further treatment after the infection was under control.

The failed cleaning and disinfection for this endoscope might be the result of the following. *P. aeruginosa* could have developed a resistance to disinfectants, especially aldehyde disinfectants. Even though no direct evidence was found in this study, a previous study suggested that atypical mycobacteria showed complete resistance to glutaraldehyde.3 Also, this endoscope was used for 6 years, and its inner tubes might have been damaged and left with a rough or uneven surface and cracks. During the ERCP operation on patients with bile duct infection, bacteria easily accumulated in the irregular connections, cracks, or ruptures of the internal channel surface and were hard to clean up.4 The final explanation is formation of biofilm. Biofilms consist of substrates from different types of bacteria and extracellular polysaccharides secreted by the bacteria that are attached to the surface of the endoscope. With the growth of bacteria in the biofilm-covered channels, even though the standard cleaning and disinfection procedure is executed, the damaged channel with bacteria attached would potentially prevent the disinfectant from killing the bacteria. The infecting bacteria in this study were *P. aeruginosa*, which is a typical biologic organism that can easily develop biofilms. In addition, this type of biofilm is very difficult to remove from the channel components and damaged endoscopic tubes, therefore increasing the infection risk to the next patient even after a standard cleaning and disinfection procedure. The examination of the biofilm was based on stochastic selection of the remaining samples for endoscopic biologic inspection, which indicated the possibility of missed detections. Therefore, even though no biofilm was detected during the biologic inspection process in this study, it was still difficult to exclude the possibility of biofilm formation. It is necessary to improve the standard cleaning and disinfection methods for *P. aeruginosa*-infected endoscopes. For example, an automatic endoscope washer with an ultrasonic oscillation function and the application of detergent with good biofilm removing efficiency could more effectively remove the attached bacteria.5 In this case, cross-infection and in-hospital infection could be reduced, and medical safety could eventually be assured.

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Fig 1. Pulsed-field gel electrophoresis revealed a high homology between the *Pseudomonas aeruginosa* from the endoscope (307) and those from the bile cultures of the 3 patients (309, 310, 305).
CONCLUSION

ERCP is the endoscopic operation with the highest postsurgical infection rate.6-10 According to the endoscopic treatment experiences of the authors of this report, after an endoscopic examination or treatment was performed on a patient with a high infection risk, a biologic inspection after the standard cleaning and disinfection of the endoscope is very critical. It is recommended to perform an immediate bacteria culture after any endoscopic operation on a patient with a suspected bile duct infection. In addition, biologic inspection is still necessary even after cleaning and disinfection. The endoscope should only be used again on the confirmation of a negative bacteria culture result.

References