Is bacteriologic surveillance in endoscope reprocessing stringent enough?

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Endoscopes, including duodenoscopes, are medical devices that are frequently associated with outbreaks of nosocomial infections. We investigated an outbreak of multidrug-resistant Pseudomonas aeruginosa sepsis affecting three patients after endoscopic retrograde cholangiopancreatography (ERCP). Epidemiologic investigation supplemented by molecular typing revealed that one ERCP scope was the source of infection with P. aeruginosa. No contamination with this microorganism was found after screening of washer-disinfectors, connecting tubes, and environmental surfaces in the endoscopy center. Pseudomonas isolates from blood and endoscope channels before gas sterilization with ethylene oxide (ETO) were characterized by molecular typing as “linked isolates”. Though the current surveillance system did not prevent the infections in three patients, our microbiological surveillance protocol with routine culturing of endoscopes was helpful in detecting the source of contamination and probably avoided numerous cross-contaminations in other patients who underwent ERCP procedures with endoscopes.

Introduction

Flexible endoscopy is a widely used diagnostic and therapeutic procedure. Despite the large number of endoscopies that are performed annually, documented data suggest that iatrogenic infections due to flexible endoscopy are rare. In gastrointestinal endoscopy, the estimated rate of transmission of infectious organisms is approximately one in 1.8 million procedures [1]. However, the actual transmission during endoscopy may go unrecognized because of technically inadequate surveillance, low frequency of surveillance, no surveillance at all, or the absence of clinical symptoms [2].

Endoscopic retrograde cholangiopancreatography (ERCP) is the only endoscopic procedure which has been associated with a significant rate of procedure-induced infection [3]. Biliary sepsis is one of the major complications of ERCP, and although it occurs in only 0.4%–0.8% of ERCPs, it is associated with an 8%–20% mortality rate [4]. The microorganisms most frequently associated with iatrogenic transmission during endoscopy are Gram-negative bacteria (P. aeruginosa, Serratia marcescens and Salmonella species), mycobacteria [2,3] and yeasts [5]. These microorganisms can be transferred from previous patients or contaminated cleaning sources (automated reprocessing equipment, water supply lines) by contaminated endoscopes or accessories including biopsy forceps, cytology brushes, and snares [2].

Currently used flexible endoscopes cannot be heat-sterilized and contain multiple channels and ports which are exposed to body fluids and are difficult to clean and disinfect [2,6]. The ability of bacteria to form biofilms on the inner channel surfaces, especially when these surfaces become damaged, can contribute to failure of the decontamination process [6].

Various organizations have published endoscope reprocessing and infection-control guidelines [3,7,8] and, under controlled conditions, these measures are adequate. At the University Medical Centre Groningen (UMCG) in the Netherlands, a microbiological surveillance protocol for evaluation of the efficacy of endoscope reprocessing was applied [5].

We report an outbreak of multidrug-resistant P. aeruginosa sepsis after ERCP in three patients and describe the importance of the surveillance procedure for microbiological safety.
Case report

Patient 1
A 73-year-old woman underwent ERCP because of obstructive jaundice due to distal common bile duct stenosis. On July 8, 2008, 6 days after ERCP she developed high fever and had an elevated serum C-reactive protein (CRP) of 108 mg/L (normal < 5 mg/L). A multidrug-resistant *P. aeruginosa*, sensitive to tobramycin and polymyxins and resistant to beta-lactam antibiotics and fluoroquinolones was isolated from several sets of blood cultures and from a rectal swab. Intravenous antimicrobial combination therapy with meropenem (1 g, three times daily) and vancomycin (1 g twice daily) was initiated. At 2 days later vancomycin was discontinued and the patient became febrile after a few days. Therapy was completed in 2 weeks and the patient was discharged from the hospital.

Patient 2
A 54-year-old man underwent ERCP on July 17, 2008 with placement of an endoprosthesis in the distal common bile duct because of stenosis. After ERCP he had several episodes of CRP elevated up to 142 mg/L without fever. At 6 weeks later, the patient complained of chills and sweats. His temperature rose to 39.8°C. No apparent focus of infection was found and empirical treatment with piperacillin-tazobactam was started. The treatment was changed to colistin, intravenously 6 mg/kg per day, after isolation of a multidrug-resistant *P. aeruginosa* from two blood cultures. The susceptibility pattern was similar to that of the strain isolated from patient 1. After 4 weeks of therapy, the patient became febrile again and had blood cultures positive for *P. aeruginosa* with the same susceptibility pattern. The persistent *Pseudomonas* sepsis was treated with colistin, 6 mg/kg per day, intravenously. No tobramycin was added because of serious renal decompensation. The clinical condition of the patient improved and he was discharged.

Outbreak investigation
At the time when patient 2 developed pseudomonas sepsis it was noticed that the same endoscope had been used for the ERCP procedures in both patients 1 and 2. This ERCP scope, introduced in our hospital in April 2008, demonstrated contamination with *P. aeruginosa* in two surveillances (in July and September) and in three consecutive samples (in October), despite intensive high-level disinfection (HLD) procedures. Surveillance samples from the endoscope channels after ethylene oxide (ETO) sterilization were verified as “different” in comparison with other strains (similarity 80%) [9].
the endoscope and samples from the three patients with sepsis after undergoing ERCP procedures in which that same endoscope was used.

Following gas sterilization in November 2008, the implicated endoscope was found to have P. aeruginosa-negative cultures and was reintroduced into service. However, 4 months later, it was found to be again contaminated with P. aeruginosa. The endoscope was sent to the manufacturer for repair. Structures suggesting the presence of biofilm were found on the inner surface of the undamaged endoscope channels. The endoscope channels were changed.

The available P. aeruginosa strains were subjected to molecular typing by repetitive DNA sequence-based polymerase chain reaction (rep-PCR) using the DiversiLab System for DNA fingerprinting (BioMérieux, France). The isolates from the three patients and from the endoscope channels, obtained before ETO sterilization, were characterized as “linked isolates” (similarity above 95% and two or fewer peak changes) (Fig. 2).

Two Pseudomonas strains from the endoscope channels after gas sterilization were verified as “different” in comparison with other strains (similarity 80%) [9].

We reviewed the recalls ordered in accordance with our protocol [5] in 2007 and 2008 of flexible endoscopes due to repetitive contaminations. Two endoscopes underwent ETO sterilization because of contamination with Stenotrophomonas maltophilia and P. aeruginosa after three consecutive HLD procedures. On six occasions endoscopes were removed from use due to repetitive positive cultures (three times Candida parapsilosis was involved; two times C. parapsilosis in combination with S. maltophilia; and once Candida guilliermondii). After either two or three HLD procedures, cultures remained negative.

**Surveillance protocol and retrograde sampling**

According to our microbiological surveillance protocol [5], all therapeutic endoscopes undergo microbiological surveillance testing once a month and diagnostic endoscopes once every 3 months. If any contamination is found, an intensive HLD procedure of the contaminated endoscope will be performed. Endoscopes with positive cultures for the same clinically important microbial species in two consecutive tests after HLD will be taken out of use and undergo ETO sterilization followed by microbiological testing before use.

Surveillance specimens are obtained from endoscopes for culture with a retrograde technique as described previously [5]. The biopsy/suction and the water/air channels of the instrument are flushed twice with 20-ml sterile demineralized water, first, from the distal to the proximal end and the second time from the suction port to the biopsy port when the endoscope is turned upside-down. All samples from endoscopes are sent for culturing. In case of positive results, all isolated strains are stored.

**Discussion**

We have described an outbreak of multidrug-resistant P. aeruginosa sepsis following ERCP in three patients. Our investigation and molecular typing of the Pseudomonas strains confirmed that this microorganism was most likely transmitted by one endoscope. P. aeruginosa could not be removed from endoscope channels by repetitive HLD procedures. The presence of structures suggesting the presence of biofilm on the undamaged channels in this ERCP scope were acknowledged by the manufacturer.

P. aeruginosa, a Gram-negative opportunistic pathogen, is the one most commonly responsible for transmission of infection during endoscopy. It is known by its preference for a moist environment and by its ability to form biofilms on the inner surface of endoscope channels [3, 6]. While early reports of Pseudomonas infection resulting from endoscopy were most commonly related to inadequate disinfection and drying procedures [10], recent large outbreaks of P. aeruginosa infection following endoscopy procedures have been associated with design failures or with defects in endoscope channels and accessories [11–13]. The ERCP scope implicated in the present Pseudomonas contaminations had no defects in the internal channels or accessories.

Modern endoscopes contain multiple channels and ports which allow for the collection of organic material and for the forming of biofilms. Biofilms are extremely difficult to remove and show increased resistance to disinfectants and antibiotics [6]. According to Alfa et al., even ETO sterilization may fail when organic material is present and microorganisms are entrapped in narrow lumens [14]. The use of biofilm removal agents, antimicrobial coating inside washer-disinfectors and sterile-sheathed endoscopes with disposable parts could reduce biofilm build-up inside endoscopes and the risk of infectious complications [2, 15–17].

Microbiological surveillance of endoscope reprocessing has been recommended by several organizations [3, 18, 19] but not by the Dutch national guideline [7]. Our center developed a microbiological surveillance protocol for evaluation of the efficacy of endoscope reprocessing [5]. Endoscope culturing with a retrograde technique is effective in monitoring of disinfection and the testing is easy to perform.

The literature related to the costs associated with endoscope reprocessing and the economic consequences of endoscope contamination is very limited. A recently published study analysed the cost of 4-weekly surveillance microbiological testing of endoscopes and disinfectors over a 5-year period [20]. The overall cost for testing and for time for nursing staff to collect the samples was estimated at € 51 000. The costs of an outbreak with a number of clinical complications are usually a multiple of this amount.

Our microbiological surveillance protocol can trace contaminations of endoscopes and was helpful in detecting the source of the recent P. aeruginosa outbreak. Although the current surveillance did not prevent three serious infections, many more contaminations and infections might have occurred without implementation of this surveillance system, using retrograde endoscope sampling. It is our opinion that bacteriologic safety in endoscope reprocessing has to be improved and surveillance protocols should be more stringent.

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**Competing interests:** None
References


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