Infectious diseases linked to cross-contamination of flexible endoscopes

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Bibliography
DOI http://dx.doi.org/10.1055/s-0034-1392099
Published online: 19.6.2015
Endosc Int Open 2015; 03: E259–E265

E-ISSN 2196-9736

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Flexible endoscopes are widely used to examine, diagnose, and treat medical disorders. While the risk of endoscopy-related transmission of infection is estimated to be very low, more health care-associated infections are related to contaminated endoscopes than to any other medical device. Flexible endoscopes can get highly contaminated with microorganisms, secretions and blood during use. The narrow lumens and multiple internal channels make the cleaning of flexible endoscopes a complex and difficult task.

Despite the availability of international, national and local endoscope reprocessing guidelines, contamination and transmission of microorganisms continue to occur. These transmissions are mostly related to the use of defective equipment, endoscope reprocessing failures, and noncompliance with recommended guidelines. This article presents an overview of publications about case reports and outbreaks related to contamination of flexible endoscopes.

Introduction

Flexible endoscopes are widely used to examine, diagnose, and treat medical disorders. Although the risk of endoscopy-related transmission of infection is estimated to be very low, more health care-associated infections are related to contaminated endoscopes than to any other medical device. Flexible endoscopes can get highly contaminated with microorganisms, secretions, and blood during use. The narrow lumens and multiple internal channels make the cleaning of flexible endoscopes a complex and difficult task. Bacteria are able to form biofilms on the inner channel surfaces, which can contribute to failure in the reprocessing of endoscopes [1]. Therefore, standardizing guidelines for cleaning and disinfection is important. Several federal agencies, such as the Centers for Disease Control and Prevention (CDC), and professional organizations such as the American Society for Gastrointestinal Endoscopy (ASGE) and the European Society of Gastrointestinal Endoscopy (ESGE), have developed endoscope reprocessing guidelines. Most of the European recommendations are based on publications from the International Organization of Standardization, ISO 15883.

In general, endoscope reprocessing includes precleaning (at bedside), leak testing, manual cleaning, high-level disinfection, rinsing, drying, and storage. An automated endoscope reprocessor (AER) could be used to perform leak testing, high-level disinfection, and to rinse the flexible endoscope. The US Food and Drug Administration has approved only one AER that eliminates the manual cleaning step. Still, manual cleaning before disinfection is necessary because flexible endoscopes can contain a high bio burden. Because post-marketing clinical data on the efficacy of the cleaning phase of the AER are limited, manual cleaning is still recommended [4,5].

Lack of cleaning or failure during the cleaning process could lead to the survival of pathogens after disinfection, increasing the risk of cross-contamination between patients. In addition, bacteria that remain after insufficient reprocessing may form a biofilm inside the instruments.

A problem or outbreak due to a flexible endoscope can be detected in two ways. The first is a deviation in data on infections gathered through active surveillance in the hospital. If the same endoscope was used on two patients who have become infected, the device will can be cultured to confirmation colonization. The second way to detect an outbreak is through surveillance of endoscopes and AERs to ascertain bacterial growth, which should lead to screening of patients. When an endoscope, AER, or screened patients show growth of the same bacteria, typing should be performed to determine whether the cluster

Table 1 Publications related to damaged or defective flexible endoscopes

Reference	Origin	Micro-organism(s) (resistance)	Problem	No. of patients exposed (positive cultures)	No. of infections (type(s))	Action taken
[9]	Bronchoscope	*Pseudomonas aeruginosa*	Several defects in the different tubes and bending section	20 (11)	2 (sepsis, pneumonia)	Preventive maintenance
[10]	Bronchoscope	*Pseudomonas aeruginosa*	Damaged internal channel due to defective biopsy forceps	36 (16)	4 (pneumonia, bronchitis)	Replacement of channels; use of disposable biopsy forceps
[11]	Bronchoscope	*Pseudomonas aeruginosa*	Loose biopsy-port cap	414	32 (respiratory tract and bloodstream infections)	Bronchoscopes removed from service
[12]	Bronchoscope	*Pseudomonas aeruginosa* and *Serratia marcescens*	Loose biopsy-port cap	Not mentioned (20)	1 (pneumonia)	Manufacturer initiated recall of defective bronchoscopes.
[14]	Bronchoscope	*Mycobacterium tuberculosis*	A hole in the external sheath of the manoeuvrable tip	19 (10)	4 (tuberculosis)	Strict adherence to the reprocessing protocol
[13]	Bronchoscope	*Pseudomonas putida, Pseudomonas aeruginosa, Stenotrophomonas spp.*	Loose biopsy port	77 (25)	0	Recordkeeping for tightness of the biopsy port; standard operating procedure for cleaning and disinfection of bronchoscopes; competency training; tracking system for bronchoscopes enhanced
[15]	Bronchoscope	*Klebsiella pneumoniae, Proteus vulgaris, Morganella morganii, Proteus mirabilis*	Loose biopsy port; Disinfectant did not reach all areas.	418 (117)	0	Removal and replacement of plastic cap
[16]	Bronchoscope	*Klebsiella pneumoniae (CRE)*	Defects in internal channel surfaces	Not mentioned (6)	5 (pneumonia, sepsis)	Repair of internal channel surfaces

Abbreviation: CRE; Carbapenem-resistant enterobacteriaceae

(outbreak) is due to a contaminated endoscope or AER.
Incidence of carbapenem-resistant enterobacteriaceae (CRE) and other multidrug-resistant micro-organisms (MDRO) are increasing worldwide, and with them, the threat to public health because of limited treatment options. Given the linkage between contaminated flexible endoscopes and outbreaks of CRE and other MDROs, it is not surprising that they have been associated with higher patient morbidity and mortality [6].
Despite the availability of international, national, and local endoscope reprocessing guidelines, contamination and transmission of microorganisms continue [7]. Most such transmissions are related to use of defective equipment, endoscope reprocessing failures, and non-compliance with recommended guidelines [3, 8]. This article presents an overview of publications on case reports and outbreaks related to contamination of flexible endoscopes.

Method

The following search terms or combinations of terms were used to search in PubMed: *endoscope, endoscope reprocessing, outbreak* and *infection.* English-language studies published from 2000 on were included. In this review, the collected studies are divided into four categories: damaged or defective flexible endoscopes, failures during manual endoscope reprocessing, reprocessing failures where the disinfection step was carried out by an AER, and failure or malfunctioning of the AER.

Results

Thirty-two publications were included in this review. Of them, eight incidents involved damaged or defective flexible endoscopes, eight were related to failures during manual endoscope reprocessing, 11 reports related to reprocessing failures associated with disinfection carried out using an AER, and five reports documented failure or malfunctioning of the AER.

Damaged or defective flexible endoscopes

Eight publications were identified in which damaged bronchoscopes were involved in cross-contamination (**Table 1**). Damage ranged from deteriorated equipment (e.g., a damaged internal channel) to a loose biopsy-port cap. Five incidents were due to contamination of the endoscope with *Pseudomonas aeruginosa*, including three publications that reported contamination of damaged bronchoscopes with both *Pseudomonas aeruginosa* and three other species *(Serratia marcescens, Pseudomonas putida, Stenotrophomonas* spp.*)* [9 – 13]. Contamination of an endoscope with *Mycobacterium tuberculosis* also was described [15], as was contamination of two endoscopes with *Klebsiella pneumoniae, Proteus vulgaris, Proteus mirabillis,* and *Morganella morganii* in

Table 2 Publications related to failures during manual endoscope reprocessing

Reference	Origin	Micro-organism(s) (resistance)	Problem	No. of patients exposed (positive cultures)	No. of infections (type(s))	Action taken
[22]	Endoscope	*Klesbsiella spp. (NDM-1)*	No guidelines for cleaning video camera head; no disposable plastic camera sheaths	Not mentioned (12)	3 (urosepsis)	Standardized practice in the use of camera sheath and infection control processes
[17]	Cytoscope	*Pseudomonas aeruginosa*	Incorrect disinfection method	Not mentioned (7)	7 (bloodstream, urinary tract)	Revision of cleaning and disinfection processes
[18]	Ureteroscope	*Pseudomonas aeruginosa*	Inadequate cleaning and disinfection	81 (12)	12 (bloodstream, urinary tract)	Strict adherence to reprocessing procedures; sustained education
[19]	Bronchoscope	*Pseudomonas aeruginosa*	Inadequate cleaning and disinfection during the weekend	Not mentioned (17)	17 (respiratory tract, bloodstream, urinary tract, pressure ulcer, surgical site)	Strict adherence to reprocessing procedures and maintenance
[20]	Bronchoscope	*Pseudomonas aeruginosa* and *Serratia marcescens*	Inappropriate measures used for cleaning and disinfection	Not mentioned (41)	0	Revision of infection control measures
[21]	Duodenoscope	*Pseudomonas aeruginosa*	Inadequate high-level disinfection	12 (5)	4 (cholangitis)	Awareness for opportunistic infections
[23]	Gastroscope	*Trichosporon*	Strain resistant to disinfectant Biopsy forceps not sterilized	1 (1)	1 (esophagitis)	Not mentioned
[24]	Ureteroscope	*Enterobacter cloacae* (Ertapenem)	Disinfection failure of a contaminated ureteroscope	Not mentioned (15)	15 (flank pain, fever, frequency, rurbid urine)	Implementation of a revised disinfection protocol

Abbreviations: AER; automatic endoscope reprocessor; NDM-1; New Delhi-metallo-bèta-lactamase

another publication , and contamination of a bronchoscope with a CRE *K. pneumoniae* in another report [17].

Failures during manual endoscope reprocessing

Table 2 lists eight publications in which failures during endoscope reprocessing were reported. Problems ranged from inadequate use of equipment to non-compliance with endoscope reprocessing guidelines. Five out of eight publications described contamination with *P. aeruginosa,* including one publication that reported contamination with both *P. aeruginosa* and *Serratia marcescens* [18–22]. One study described contamination with *K. pneumoniae (*New Delhi Metallo-beta-lactamase (NDM)-positive*)* [23]. In two other studies, contamination with, *Trichosporon spp.* and *Enterobacter cloacae* (resistant to Ertapenem) was described [26,27].

Reprocessing failures related to disinfection with an AER

Table 3 lists 11 publications in which failures during endoscope reprocessing were described that involved disinfection carried out with an AER. In four of the studies, contamination of endoscopes was with *P. aeruginosa* [28–31]. In three other studies, involving a duodenoscope, contaminated was with *K. pneumoniae* (ESBL- and CRE-positive) [24,25,32]. The other two publications involving a duodenoscope described contamination with *Escherichia coli* (NDM- and CRE-positive) and *Methylobacterium mesophillicum* [14,33]. Two studies listed in **Table 3** also described contamination with *Mycobacterium tuberculosis, Mycobacterium chelonae*, and *Methylbacterium mesophillicum* [34,35]. Only three of the 11 studies involved failure of an AER.

Failures due to a defective or malfunctioning AER

Five publications that related problems with an AER are listed in **Table 4**. In three of the studies, endoscope contamination with *Burkholderia cepacia, Pseudomonas aeruginosa*, and *Mycobacterium chelonae*, respectively, due to a problem with the AER were described [36–38]. Two other publications reported malfunctioning AERs that did not lead to transmission of microorganisms [39,40].

As shown in table 1, 2, 3 & 4 contaminated endoscopes cause infections and may have contributed to the death of some patients. The most common infections are bloodstream (bacteraemia or sepsis), pneumonia and urinary tract infections.

Discussion

There is an assumption that the risk of cross-contamination is almost non-existent when flexible endoscopes are reprocessed in accordance with accepted guidelines [7]. Nevertheless, studies have found that, despite adherence to cleaning and disinfection guidelines, endoscopes can remain contaminated, leading to infections [41,42]. Defects, either during production or during use, such as a loose biopsy-port cap, can cause outbreaks or infections [11–13]. Lack of maintenance also can lead to contamination of flexible endoscopes. Therefore, manufacturers recommend periodic maintenance to ensure that no defect occurs during the life cycle of a flexible endoscope. The CDC guidelines concur with this recommendation [2].

Table 3 Publications related to reprocessing failures where the disinfection step was carried out by an AER

Reference	Origin	Micro-organism(s) (resistance)	Problem	No. of patients exposed (positive cultures)	No. of infections (type(s))	Action taken
[25]	Endoscope	*Pseudomonas aeruginosa* (ESBL)	Deviations from the agreed processes (pre-cleaning and drying process)	182 (4)	3	Strict adherence to reprocessing procedures; quarterly microbiological testing
[29]	Duodenoscope	*Klebsiella pneumoniae* (CRE)	No optimal drying process	17 (7)	2 (bloodstream)	Revision of disinfection processes; monthly microbiological controls
[30]	Duodenoscope	*Klebsiella pneumonia* (ESBL)	Insufficient manual cleaning and drying before storage	Not mentioned (16)	12 (bloodstream, biliary tract)	Strict adherence to reprocessing procedures; regular auditing
[26]	Ureteroscope	*Pseudomonas aeruginosa*	Contaminated water due to failure in ultraviolet disinfection system	Not mentioned (10)	10 (urinary tract)	New water disinfection system
[27]	Bronchoscope	*Pseudomonas aeruginosa*	No procedure for cleaning and disinfecting bronchoscope; no instruction for use of AER	Not mentioned (11)	Not mentioned	New reprocessing procedure; sustained education
[34]	Bronchoscope	*Mycobacterium chelonae* and *Methylobacterium mesophilicum*	Bronchoscope not adapted to connection for final alcohol flush; improper execution of 8-hour disinfection cycle	Not mentioned (20)	0	Replacement of automated washer and disinfection unit; quarterly maintenance and surveillance cultures
[35]	Bronchoscope	*Mycobacterium tuberculosis*	Inadequate high-level disinfection; use of AER was not approved for this bronchoscope.	11 (2)	0	Education and training for health care providers, staff and laboratory workers
[32]	Duodenoscope	*Escherichia coli (NDM-1)*	Recommended reprocessing process inadequate.	156 (35)	6	Gas sterilization
[33]	Duodenoscope	*Methylobacterium mesophillicum*	Contaminated water used to rinse inner channel.	Not mentioned (1)	1 (bloodstream)	Replacement of inner channel sheath
[31]	Duodenoscope	*Klebsiella pneumoniae (CRE)*	Inadequate cleaning technique	53 (10)	7 (bloodstream, pneumonia, urinary tract)	New reprocessing procedure
[28]	Bronchoscope	*Pseudomonas aeruginosa*	Detergent tank of AER Contaminated; inappropriate disinfection procedure	Not mentioned (7)	7 (pneumonia, bronchitis)	Cleaning and remodelling of the AER; disinfection of bronchoscopes

Abbreviations: AER; automatic endoscope reprocessor; ESBL; Extended-Spectrum Beta-Lactamase; CRE; Carbapenem-resistant enterobacteriaceae; NDM-1; New Delhi-metallo-bèta-lactamase

Table 4 Publications related to failure due to a defective or malfunctioning AER

Reference	Origin	Micro-organism(s) (resistance)	Problem	No. of patients exposed (positive cultures)	No. of infections (type(s))	Action taken
[36]	AER	*Burkholderia cepacia*	No 0.2 µm bacteria-retentive filter	Not mentioned (3)	0	Installation of bacteria filter; microbiology surveillance
[37]	AER	*Mycobacterium chelonae*	Filtration system failure	57 (9)	0	Renewal of AER
[39]	AER	None	Pump for injecting disinfectant did not work; non-functioning alarm system	236 (0)	0	Stop use of AER
[40]	AER	None	No detergent	72 (0)	0	Improve monitoring of procedure; traceability of cleaning process
[38]	AER	*Pseudomonas aeruginosa* (Imipenem)	Faulty connection of bronchoscope to processor	Not mentioned (18)	3 (pulmonary infection)	Monthly surveillance cultures

Abbreviation: AER; automatic endoscope reprocessor

Guidelines for reprocessing of flexible endoscopes are ineffective if not implemented and applied correctly [11, 20]. Several studies have shown that non-compliance with reprocessing guidelines may lead to endoscope-related health care-associated infections [7, 8, 43]. Studies suggest that lack of education is one of the reasons that guidelines are not strictly followed. Staff assigned to reprocess flexible endoscopes should receive device-specific reprocessing training to ensure that they follow procedures for proper cleaning and high-level disinfection or sterilization. In addition, competency testing of staff responsible for reprocessing of flexible endoscopes should be implemented and only staffed deemed competent should be allowed to perform this task [3, 44 – 46].

Periodic auditing of procedures followed for reprocessing should be carried out. The Clean-Trace adenosine triphospathe (ATP) water test, which is performed on manually cleaned endoscopes, can be considered as an auditing tool [47, 48]. It is a rapid and practical way to check the cleanliness of endoscopes immediately after they have been manually cleaned. The test measures ATP levels, which are present in microorganisms and human cells; levels up to 200 relative light units (RLUs) are considered acceptable. As described in Alfa et al [47], the elevator guide-wire channel is more often found contaminated in duodenoscopes than in colonoscopes. The problems with duodenoscopes documented in the literature identified in this review were often related to this channel (**Table 2** and **Table 3**). Therefore, incorporating an ATP test into the auditing procedure would help detect and prevent cross-contamination of duodenoscopes. In addition, health care workers involved in reprocessing should be made aware of the patient safety issues that can arise from any oversights and inaccuracies in their work.

AERs improve standardization of the reprocessing steps, reduce personnel exposure to high-level disinfectants, infectious material and lower the possibility of human errors [2]. They reduce the amount of hands-on work and provide documentation of each cleaning cycle [43]. Despite their obvious advantages, the use of AERs is not specifically mentioned in various guidelines and recommendations [4, 8, 49]. In addition, failures of AERs are reported and linked to infection outbreaks or colonization [2]. Furthermore, the function of the water filtration system in AERs might not be reliable in providing bacteria-free water [50]. In view of their advantages, as well as the fact that they can be a potential source of contamination, AERs should be intergraded in endoscope reprocessing guidelines. There is no evidence available that manual disinfection of endoscopes increases the risk of microorganisms transmission compared to using an AER. However, manual reprocessing cannot be standardized and validated, and are prone to human error.

As with the use of AER, not all guidelines recommend routine microbiological testing of flexible endoscopes and AERs for quality assurance [2, 51]. Testing remains controversial in the absence of a standardized procedure for microbiological testing, frequency of testing, and interpretation of results. Also problematic is the lack of a threshold beyond which colonization of an endoscope by different bacteria becomes problematic. In the absence of guidelines, health care facilities have created their own procedures for microbiological testing, thus potentiating the risk of inadequate testing. An outbreak already has been documented that is believed to be a result of contamination of flexible endoscopes due to inadequate testing procedures, which was overlooked [25]. Standardized routine microbiological testing should be implemented based on existing guidelines, as has been done with German, Dutch, and Australian guidelines [52 – 54].

Fig. 1 Head ERCP scope with forceps elevator.

In addition, given the recent CRE outbreaks, attention needs to be given to strict adherence to instructions for brushing the area around, near, and behind the forceps elevator, which is located at the distal end of the duodenoscope. That part is difficult to clean because of its design, which consists of a small tube that includes a small mobile metal piece called the elevator (**Fig. 1**). The "extra" manual step of brushing is needed to prevent possible transmissions of CRE and of other multidrug-resistant organisms during flexible endoscopy. When confronted with an outbreak of CRE due to contaminated flexible endoscopes, the use of ethylene oxide (EtO) sterilization for reprocessing is worth considering [6].

Because not all incidences are reported or published, the studies described here probably represent just a fraction of the total number of reprocessing failures. In a recent publication, Dirlam Langlay et al. [55] summarized reprocessing lapses that occurred but were not documented in the published literature over a 7-year period in North America. Based on media reports and related sources, the authors found 27 lapses, whereas only one case was described in a peer-reviewed article.

Despite the fact that colonoscopy is the gastrointestinal endoscopic examination most frequently performed worldwide, no outbreaks related to the procedure have been described in the peer-reviewed literature. A review by Morris et al. [56] describes no transmission with blood-borne viruses either. The risk of patient-to-patient transmission of blood-borne viruses seems to be low, even with inadequate decontamination procedures. Only one case of probable hepatitis B transmission and two cases of probable hepatitis C transmission were described. No cases of HIV transmission at endoscopy were found in literature. The lack of publications in peer-reviewed literature gives the false perception that reprocessing failure is a rare occurrence. Mandatory reporting of lapses to a national registry would give a better overview of incidents and facilitate more in-depth investigations, leading to better guidelines.

In conclusion, mandatory competency training and periodic auditing are necessary to ensure the quality of reprocessing of flexible endoscopes. Early detection of contamination would be easier if standardized periodic microbiological testing were included in the guidelines. Because AERs are often used for flexible endoscope reprocessing, they should be included in the guidelines. Periodic maintenance of flexible endoscopes and AERs should al-

ways be carried out as the manufacturer advises. Mandatory reporting of lapses would provide a broader perspective on the worldwide incidence of cross-contamination of flexible endoscopes.

Competing interests: None

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