Chapter

3

Infection Control and Radiation Safety in the Bronchoscopy Suite

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INTRODUCTION

Since the advent of flexible bronchoscopy over 30 years ago, application of an expanding array of bronchoscopic procedures has risen dramatically worldwide. In 1996, nearly 500,000 bronchoscopies were performed in the United States alone (1). The rate of direct, procedure-related complications has been well-documented, ranging from 1% to 3% (2). In contrast, reports of adverse events indirectly attributable to bronchoscopy have been scattered and largely anecdotal. Under-reporting of such mishaps has contributed to a sense of complacency regarding safety in the bronchoscopy suite. With the burgeoning sensation of time pressure and administrative demands for economic thrift, temptation to "cut corners" is likely to intensify. In this context, reexamination of safety in the bronchoscopy suite are needed to minimize risks for both patients and medical staff.

Infection or concerns for infection have been the most frequently described adverse events related to bronchoscopy. Recent episodes have been well publicized in the mainstream news media (3,4). An accumulating body of literature is most remarkable for demonstrating the wide range of potential avenues available for contamination by hardy bacteria, fungi, or mycobacteria. In contrast, infectious complications due to aerosolization of viruses and risks of radiation exposure accrued during fluoroscopy have been the subject of few reports and minimal investigation. This chapter reviews the available evidence regarding infectious and noninfectious hazards of bronchoscopy. We will also provide guidelines for the prevention and surveillance of infections associated with bronchoscopes, as well as practical radiation safety procedures.

INFECTION

Infectious complications attributable to bronchoscopy include:

- distal spread of organisms within a patient during bronchoscopy
- transmission of organisms to subsequent patients via contaminated instruments, accessories, or solutions
- transmission of infectious agents to medical personnel or nearby patients

Distal spread of infection may include contamination of the lower respiratory tract with organisms from the upper respiratory tract, extension of infection within the lung, and hematogenous dissemination to distant organs (5). Because it is an uncommon event, distal spread of pathogens is within the spectrum of complications subsumed by bronchoscopy itself and will not be discussed further in this chapter.

The use of contaminated bronchoscopes can lead to clinical infections and *pseudo-infections*. Pseudo-infections are isolates obtained from a contaminated bronchoscope that suggest an organism in the absence of clinical disease. In many reports, the instrument had been disinfected in an ostensibly appropriate manner. *Pseudo-epidemics* are clusters of positive cultures of bronchoscopic samples from the same organism and infection control breach. When actual clinical infection occurs, the term "true infection" is applied. Attributable disease due to the contaminating organism can usually be traced retrospectively back to an index case. Pseudo-infections may lead to unnecessary worry, unwarranted treatment of isolates, delay in diagnosing the disease that originally precipitated bronchoscopy, and need for further investigations to exclude infection (5,6).

Historic Examples

We reviewed all available English-language reports of infection transmission by bronchoscopy. To be comprehensive, we have included some abstracts. In many of the reports, the evidence for causality ascribed to specific infection control breaches is tenuous. Some of the reports describe temporal trends in isolate frequencies without documentation of a source

for contamination. In aggregate, however, the body of literature is developed well enough to support the principle that any step in instrument cleaning, disinfection, or postdisinfection handling may be responsible for cross-contamination. An emerging theme is that most recent epidemics have occurred when preexisting infection control guidelines were not adhered to carefully.

Reports of pathogen transmission via contaminated bronchoscopes are relatively uncommon when one considers the large number of procedures performed. To date, the English-language literature includes 59 reports, totaling 953+ patients (Table 3-1 and Table 3-2). The majority of reports describe pseudo-infections, also termed "cross-contamination." Theoretically, the contaminating organism is confined to the bronchoscope in most instances and never comes into contact with the patient's respiratory tract (64).

Pseudo-infection

Most reported episodes of pseudo-infection have involved environmental or commensal organisms (Table 3-1). A review of temporal trends in pseudo-infections suggests that the proportion of nontuberculous mycobacteria, environmental fungi, and *Pseudomonas* species has increased in the past 15 years. We speculate that this trend may be due to more efficacious disinfectants and better procedural technique, which have nearly eliminated episodes ascribed to less-hardy organisms. Most pseudoepidemics are identified when astute clinicians or microbiology laboratories observe dramatic or unexpected increases in isolation of relatively uncommon organisms. Although reporting of suspected pseudo-infections to state health departments and the Food and Drug Administration (FDA) is highly encouraged, they are likely underreported (19,65).

It is also important to be aware that thoroughly disinfected bronchoscopes may still harbor DNA residues from organisms such as *Mycobacterium tuberculosis*. One group found that washing saline through the channel of post-disinfection bronchoscopes provided sufficient amplifiable DNA in two of 55 (3.6%) samples to cause false positive polymerase chain reaction (PCR) results (66). Twenty percent of the samples also contained amplifiable human DNA. In a second study, Carricajo et al were able to demonstrate both amplifiable DNA and rRNA from the channel of a bronchoscope previously used on a patient with pulmonary TB (67). False positive assays represent a type of pseudo-infection that may be seen with increasing frequency as PCR use expands.

True Infection

Fortunately, true infections caused by bronchoscopy have been rare; there are 13 well-documented reports involving 21 patients in the English-language literature (Table 3-2). The earliest description involved occurrence of *Serratia* pneumonia in three patients, two of whom expired due to possibly related pneumonia (10). All three patients had undergone bronchoscopy within 4 days of an index patient; all had already experienced prolonged ICU stays, tracheostomies, broad-spectrum antibiotics, and steroid treatment. Cultures from multiple areas of the bronchoscope grew *Serratia marcescens*; substituting Betadine disinfection in place of 2-minute aspiration with 70% ethanol resolved the contamination. *Pseudomonas aeruginosa* pneumonia has been described in 34 patients (3,4,15,16,19,20). Earlier cases were due to inadequate cleaning procedures or failure to dismantle suction ports for cleaning and sterilization (15,16). More recently, an outbreak of three cases in New York, along with 14 pseudo-infections were described; failure to follow the manufacturer's recommendations for connecting an automated endoscope reprocessor (AER) was held accountable (19,20).

Five other reports also describe bacterial infections due to bronchoscopy, but a paucity of clinical details makes them difficult to interpret (14,18,60,62, 63). In these cases, the authors do not clearly describe whether the positive cultures represent true infection or only pseudo-infection. Two articles describe outbreaks of *P. aeruginosa* infections due to contamination of the AER filter, pump housing, and tubing (18,62). Ostensibly, the AERs recontaminated the instruments with every disinfection cycle. In both instances, the AER was not equipped to flush appropriate disinfectant through the working channel of the bronchoscope. More recent AER models have rectified this design flaw. A third outbreak leading to endotracheal colonization was traced to contamination of the disinfectant solution dispensed by an automated system (63). The concentration of the solution was mistakenly preset to 0.04% instead of the suggested 3.0%. A 1997 paper traced an outbreak of multiresistant *S. marcescens* in a surgical ICU to an improperly decontaminated bronchoscope used for urgent cases (14). In this report, it is not clear whether the cases resulted from transmission from the bronchoscope or merely recontaminated the instrument in the setting of endemic ICU colonization. *Burkholderia pseudomallei* infection has been ascribed to rigid bronchoscopy in one instance, although the evidence for causality was tenuous (60).

With increasing numbers of immunocompromised patients and the worldwide epidemic of mycobacterial disease, concern over transmission of mycobacteria has surged. Nelson et al report a case of skin-test conversion 6 weeks after bronchoscopy with an instrument that had been used earlier the same day in a heavily infected patient (31). Transmission was attributed to sterilization with povidone-iodine and ethanol, relatively weak antimycobacterial agents. A nondisposable, contaminated suction valve was thought to be responsible for the first reported case of active TB (32). Subsequently, multiple attempts by the authors to eradicate experimental *M. fortuitum* contamination of the suction valves were unsuccessful, despite aggressive use of potent antimycobacterial agents. The authors concluded that nondisposable suction valves should be autoclaved after each use. Four more recent reports describe six further episodes, with one death and one case limited to skin-test conversion only (35-37,61). All but one case occurred when guidelines promulgated by the Association for

Table 3-1. Reports of Pseudo-infections

Reference	Organism	Year	Number of Affected Patients	Cause
Webb and Vall-Spinosa (10)	*S. marcescens*	1975	2†	inadequate cleaning of biopsy ports
Weinstein et al (7)	*Proteus sp.*	1977	8	inadequate cleaning and weak disinfectant
Surratt et al (11)	*P. aeruginosa*	1977	76*	no disinfection stage
	K. pneumonia		19*	
	S. marcescens		20*	
Kellerhals (12)	*S. marcescens*	1978	7	weak disinfectant? (iodophore)
Hussain (15)	*Pseudomonas sp.*	1978	5†	failure to dismantle suction-valve assembly before disinfection
Steere et al (54)	*M. gordonae*	1979	52	colonized anesthetic solution
Leers (30)	MTB	1980	1	inadequate disinfectant (iodophore)
Schleupner and Hamilton (29)	multiple fungal species‡	1980	8	contaminated anesthetic solution
Dawson et al (38)	MAI	1982	2	specimen collection tubing
Sammartino et al (16)	*P. aeruginosa*	1982	10†	inadequate regimen
Nelson et al (31)	MTB	1983	1	inadequate disinfectant (iodophore)
Pappas et al (41)	*M. chelonae*	1983	70†	puncture in lumen
Goldstein and Abrutyn (8)	*Bacillus spp.*	1985	9	suction valves not sterilized
Siegman-Igra et al (13)	*S. marcescens*	1985	4	reused "sterile water"
Richardson et al (9)	*Bacillus spp.*	1986	14	suction ports and tap water
Stine et al (55)	*M. gordonae*	1987	8	tap water
Duckworth (59)	various NTM	1988	7	tap water
Prigogine et al (33)	MTB	1988	8	aspiration adapter
Wheeler et al (32)	MTB	1989	2†	reused suction valves
	MAI		2	
Hoffmann et al (25)	*Rhodotorula rubra*	1989	30	inner cannula cleaning brushes
Nye et al (42)	*M. chelonae*	1990	7	tap water
CDC (43)	*M. chelonae*	1991	14	colonized AERs (biofilm)
Elston and Hay (44)	*M. chelonae*	1991	7	colonized AER
Fraser et al (46)	*M. chelonae*	1992	14	colonized AER
Flournoy et al (22)	*M. mesophilicum*	1992	7	tap water
Whitlock et al (26)	*R. rubra*	1992	15	inadequate drying of valves
Nicolle et al (28)	*Blastomyces dermatitidis*	1992	2	inadequate cleaning
Gubler et al (45)	*M. chelonae*	1992	7	AER rinsing tank colonized
	M. gordonae		1	
Vandenbrouke-Grauls et al (14)	*S. marcescens*	1993	1†	multiple procedural breaches
Brown et al (6)	*M. xenopi*	1993	14	AER tubing contaminated
	M. chelonae			
	M. fortuitum			
Bryce et al (34)	MTB	1993	NS	malfunctioning AER
Kolmos et al (17)	*P. aeruginosa*	1994	8	ports not mechanically cleaned
Pentony et al (39)	MAI	1994	NS	tap water filters contaminated
Petersen et al (57)	*M. abscessus*	1994	18	unclear
Bennett et al (40)	*M. xenopi*	1994	13	tap water
Campagnaro et al (47)	*M. chelonae*	1994	12	tap water, AER
Maloney et al (56)	*M. abscessus*	1994	15	tap water, AER
Hagan et al (27)	*R. rubra*	1995	11	suction channel
Wang et al (48)	*M. chelonae*	1995	18	inadequate cleaning of suction channels
Takigawa et al (50)	*M. chelonae*	1995	15	contamination of tap water, glutaraldehyde, and detergent
Kiely et al (49)	*M. chelonae*	1995	7	tap water
Cox et al (51)	various NTM	1997	22*	colonized atomizers, reused multiple times
Agerton et al (35)	MTB	1997	1†	multiple procedural breaches
Blanc et al (18)	*P. aeruginosa*	1997	35*#	contaminated AER
Mitchell et al (21)	*L. pneumophilia*	1997	5	tap water
Wallace et al (52)	*M. chelonae*	1998	46§	multiple causes
Belleguic et al (53)	*M. chelonae*	1998	39	contaminated AER
CDC (19)	*P. aeruginosa*	1999	14†	wrong connector between AER and bronchoscope port
	MAI		7	
	MTB		4	

Table 3-1. *Continued*

Reference	Organism	Year	Number of Affected Patients	Cause
Strelczyk (58)	NTM	1999	10	wrong connector between AER and bronchoscope port
Wilson et al (24)	*Aureobasidium* sp.	2000	9	reuse of single-use stopcocks
Kressel and Kidd (23)	*M. chelonae*	2001	20	colonized AER (biofilm)
	M. mesophilicum		18	
Ramsey et al (37)	MTB	2002	6†	failure to leak test
Srinivasan et al (3)	*P. aeruginosa*	2003	85*#†	? defective valve cap prevented reprocessing
Kirschhe et al (4)	*P. aeruginosa*	2003	20†	? defective valve cap prevented reprocessing
	S. marcescens			

Key: AER = automated endoscope reprocessor, MAI = *Mycobacterium avium-intracellulare*, MTB = *Mycobacterium tuberculosis*, NS = not stated, CDC = Centers for Disease Control, NTM = nontuberculous mycobacteria

* Precise number of pseudo-infections not specified—number of affected cases estimated from the excess positive bronchoscopy cultures compared to control periods.
† Additional patients developed true infections in these instances (see Table 3-2).
# Number of true versus pseudo-infections unclear.
‡ Eight isolates each with *Penicillum sp*. and *Trichosporon cutaneum*; *Phialophora sp*. and *Cladosporium* isolated from one patient each.
§ Number includes only those cases mentioned in this report and not described in other reports.

Table 3-2. Bronchoscopy-related Infections

Reference	Year	Organism	Mechanism	Outcome
Webb et al (10)	1975	*S. marcescens*	Inadequate cleaning and disinfectant (alcohol)	Three true infections (one probable death); two pseudo-infections
Hussain (15)	1978	*Pseudomonas sp.*	Suction attachment not detached prior to attempted disinfection	One true infection; five pseudo-infections
Markovitz (60)	1979	*Burkholderia* pseudomallei†	Unknown (rigid bronchoscope)	Causality tenuous
Sammartino et al (16)	1982	*P. aeruginosa*	Inadequate disinfectant (povidone-iodine) Insufficient disinfection time (5 min) Re-introduction of cleaning brush after disinfection	One true infection; 10 pseudo-infections
Nelson et al (31)	1983	*M. tuberculosis*	Inadequate disinfectant (povidone-iodine)	One patient each with true and pseudoinfection
Pappas et al (41)	1983	*M. chelonae*	Damaged suction channel prevented adequate disinfection	Two true infections 70 pseudo-infections
Wheeler et al (32)	1989	*M. tuberculosis*	Use of nondisposable suction valves	One patient acquired active TB/two pseudo-infections each with MTB and MAI
Vandenbroucke-Grauls et al (14)	1993	*S. marcescens*	Regimen inadequate at multiple steps	Six cases (five possible true infections)—causality tenuous
Michele et al (61)	1997	*M. tuberculosis*	Multiple deviations from APIC guidelines	One patient developed active TB
Agerton et al (35)	1997	Multiple drug-resistant *M. tuberculosis*	Multiple deviations from APIC guidelines	One patient each with active TB (expired due to TB) and skin test conversion; one pseudoinfection
Blanc et al (18)	1997	*P. aeruginosa*	Contaminated AER	Number of true and pseudo-infections not specified
CDC (19)*	1999	Imipenem-resistant *P. aeruginosa*	Wrong connectors used for lumen disinfection by AER	Three true infections; 14 pseudo-infections
Schelenz et al (62)	2000	*P. aeruginosa*	Contaminated AER/ not routinely serviced or cleaned	Two or more of eight total patients with true infection
Kramer et al (63)	2001	*P. aeruginosa*	Inadequate disinfectant concentration from automatic dispenser	Six ICU patients colonized
Southwick et al (36)	2001	*M. tuberculosis*	Reuse of lidocaine atomizers?	One patient each with lung and ocular TB
Ramsey et al (37)	2002	*M. tuberculosis*	Punctured sheath/leak test not done	Two patients developed active infection/six pseudo-infections
Srinivasan et al (3)	2003	*P. aeruginosa*	? Defective valve cap	Up to 32 infections (pneumonia, bloodstream infections, sinusitis); 3 possible deaths
Kirschke et al (4)	2003	*P. aeruginosa*	? Defective valve cap	One pneumonia; up to 19 pseudoinfections

* Outbreak also reported by Sorin et al (20).
† Formerly known as *Pseudomonas pseudomallei*.

Professionals in Infection Control and Epidemiology (APIC) were not followed. The exception, which occurred in 1997, was due to reuse of a lidocaine atomizer nozzle without disinfecting between patients (36).

Most of the TB cases involved index patients with florid pulmonary TB and patients with significant immunocompromise, due primarily to steroid use or underlying malignancy. All of the cases could have been prevented with the use of disposable suction valves and potent antimycobacterial agents such as glutaraldehyde (discussed below), and assiduous implementation of sterilization guidelines. Circumspection regarding flexible bronchoscopy in patients suspected for active TB will help minimize the chances for propagation of true infection via the bronchoscope (68). Although nontuberculous mycobacteria are less virulent, their ubiquity and hardiness make it likely that more true infections may be seen in the future. The at-risk population is expanding markedly due to more frequent use of immunosuppressive agents and growing numbers of organ transplants. To date, *M. chelonae* infection has been described once, with an episode of two true infections and 70 pseudo-infections (41). A damaged suction channel with residual biofilm accumulation at the site of a puncture was found to be responsible.

Principles of Bronchoscope Reprocessing

Basic Principles

The general steps in instrument reprocessing are as follows:

1. Cleaning to mechanically remove organic debris
2. High-level disinfection
3. Rinsing with sterile water or high-quality tap water followed by alcohol
4. Appropriate storage conditions
5. Quality control of reprocessing equipment and procedures

Medical instrument reprocessing is commonly governed by the Spaulding classification of medical devices, as devised by Earle H. Spaulding (69). Three classes of devices are recognized: critical, semicritical, and noncritical. Critical instruments are those that enter normally sterile body spaces. Surgical instruments and endovascular devices fall into this group. Critical instruments must be sterilized between uses, meaning that all microbes must be rendered inactive, including spores. Critical instruments used in bronchoscopy include biopsy forceps and transbronchial needles because they penetrate normally sterile body spaces. Sterilization can be accomplished with physical (steam) or chemical (ethylene oxide) methods.

Semicritical instruments are those that contact intact mucous membranes; high-level disinfection is sufficient for these devices. High-level disinfection implies destruction of all organisms except bacterial endospores. Some disinfectants (e.g., periacetic acid) accomplish sterilization with sufficient exposure time and are termed "chemical sterilants." Bronchoscopes are classified as semicritical instruments. However, this classification is problematic. For example, should bronchoscopes still be considered semicritical when used in patients with endobronchial ulcerations, pulmonary hemorrhage syndromes, or for biopsying friable lesions?

Flexible bronchoscopes are not easily sterilized. Ethylene oxide gas is effective but requires 24 hours and luminal penetration may be incomplete if cleaning is inadequate (70). Steam sterilization is quick but damages the fiberoptic parts. From a practical standpoint, sterilization is unnecessary—it is costly, time-consuming, and not likely to confer significant added protection from infection (71). Thus, high-level disinfection is used worldwide for decontamination. Factors impeding effective disinfection are inherent in the design of all bronchoscopes: long, narrow working channels (2.6 mm), multiple internal angulations, mated surfaces, springs, and valves. Failure to adequately remove organic debris or provide effective disinfectant contact within all crevices of the instrument may facilitate contamination. Recent episodes highlight the fact that even careful instrument design may not completely obviate the risk inherent in these characteristics (4). In the spring 2002 reports, the cause for contamination may have been crevices where the valve apparatus is seated on the body of some bronchoscope models.

Steps in Bronchoscope Reprocessing

Cleaning Failure to mechanically clean the flexible bronchoscope has been responsible for several episodes of contamination (10,17,32,35). Begin cleaning immediately after bronchoscopy to prevent drying or hardening of organic debris. Detach all suction ports or biopsy attachments prior to cleaning and inspect instruments for damage. Sterilize or use disposable devices, such as biopsy forceps or suction valves, that cannot be cleaned adequately (24,32,52). Cleaning of bronchoscopes begins with full immersion for leak testing. The presence of a leak indicates a breach in the integrity of the luminal surface; puncture sites and breaches will lead to concretions of debris (blood, mucus) that cannot be disinfected (Figure 3-1). This mechanism has caused several episodes of contamination (37,41).

Manually clean/wipe all external surfaces of the bronchoscope with an enzymatic detergent. Pay particular attention to the

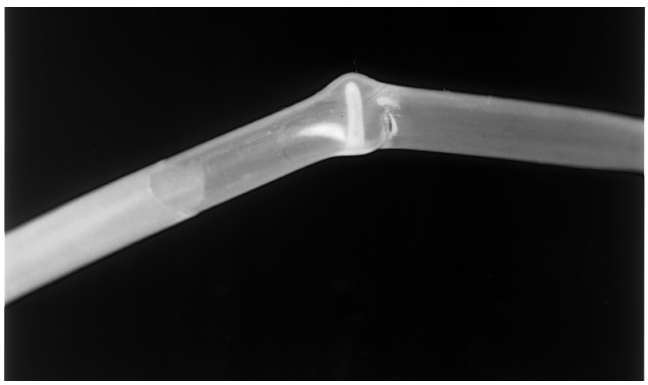

FIGURE 3-1. *Working channel of the flexible bronchoscope. This channel has been damaged by a needle, and the accumulation of debris in the defect will prevent effective cleaning. A positive leak test led to its discovery.*

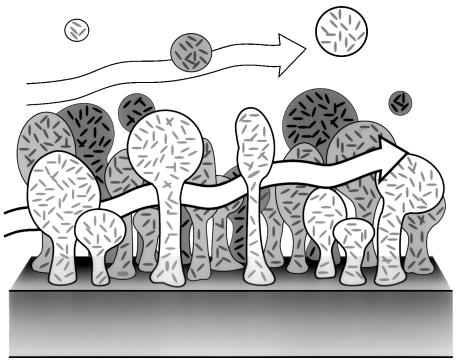

FIGURE 3-2. *Biofilms arise when micro-organisms adhere to solid surfaces, forming structures composed of colonies and extracellular material. Liquid flow through the biofilm provides nutrients and removes waste.*

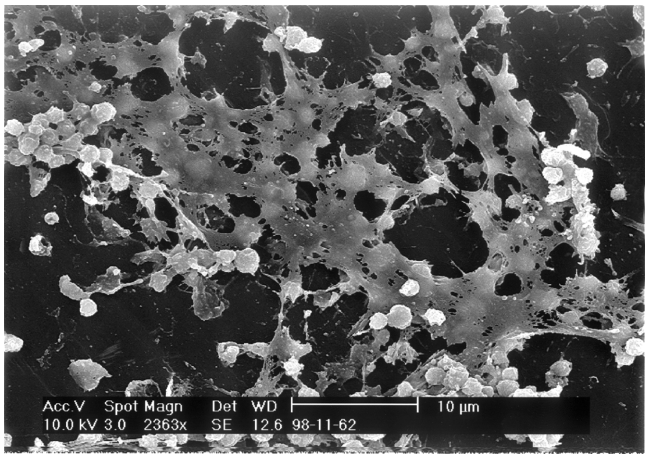

FIGURE 3-3. *Electron micrograph of a biofilm. Courtesy of Drs. Rodney Dolan and Janice Carr, Centers for Disease Control, Atlanta, GA.*

distal end of the instrument. Do not reuse detergent preparations. Flush detergent solution or water through all ports to loosen organic debris. Then, pass a cleaning brush multiple times through all ports. After brushing, flush channels again to remove loosened material. Cleaning brushes should either be single-use or receive mechanical cleaning followed by sterilization or high-level disinfection after each use. Reuse of nonsterilized brushes was the likely cause for a pseudo-epidemic of *Rhodotorula rubra* in 30 patients (25).

Microorganisms are capable of forming biofilms, thin layers of organic material and colonies at the interface of the luminal and solid surfaces (Figure 3-2 and Figure 3-3). Biofilms frequently harbor non-tuberculous mycobacterias (NTM) in water supply pipes or holding tanks; they may also develop within bronchoscopes or AERs (72,73). Except for spores, these organisms are the most difficult to eradicate (74). They are environmentally ubiquitous and thrive in tap water and damp environments, such as moisture pooled in bronchoscopes that have not been stored in a hanging position (52,72). Municipal

FIGURE 3-4. *Steris system automated endoscope reprocessor (Steris Corp, Mentor, OH) with bronchoscope in place in preparation for automated chemical sterilization.*

water systems and hospital water supplies harbor a variety of NTM, which can be cultured from biofilms at the interface of the liquid and solid (pipes) phases (52,72). Some species (*M. xenopi, M. avium*) tolerate hot water temperatures and are capable of slow growth even in distilled or chlorinated water (52,72).

Effective disinfection necessitates mechanical removal of any biofilms and of encrusted organic material. Damaged internal surfaces, puncture sites, reusable suction valves, and crevices between joined parts may all harbor biofilms or organic material (73). The presence of organic debris may preclude contact of the disinfectant with micro-organisms or even inactivate some agents (73). Even gas sterilization may not be effective in this circumstance (70). This is not a trivial problem, since immediately after routine bronchoscopy, instruments are contaminated with an average of 6.4×10^4 CFU/ml of bacteria (75). Thus, the most important step in decontamination is adequate mechanical cleaning (76).

Disinfection Disinfection can be done manually or with an AER (Figure 3-4). AERs have replaced manual disinfection in many centers, due to ease of processing and toxicities of glutaraldehyde among personnel, including epistaxis, contact dermatitis, asthma, eye irritation, nausea, headaches, and rhinitis (73,77). If glutaraldehyde is used for manual disinfection, precautions should include adequate ventilation (7 to15 air exchanges per hour), personal protective equipment (gloves, goggles), exhaust hoods or fume hoods, and tight-fitting lids on immersion baths (77). Other agents approved for this purpose include periacetic acid (a chemical sterilant), ortho-phthalaldehyde, and hydrogen peroxide formulations (Table 3-3). However, hydrogen peroxide may cause oxidant damage to bronchoscopes and is therefore not widely used (77). Antiseptics, such as alcohols and iodides, are not sufficient for this purpose. Use of antiseptics alone has been responsible for past infections (7,30,31).

All currently approved agents are effective high-level disinfectants in experimental conditions, by definition achieving a greater than 4 log reduction in microbial burden (71). Overreliance on

Table 3-3. FDA-Approved Agents for High-Level Disinfection

Agent	Conditions (min/temperature in C°)	Maximum Reuse (days)
Glutaraldehyde Preparations		
2.4%	45/20° or 25°	14 or 28
2.5%	5/35° or 90/25° or 45/22°	28 or 30
2.6%	45/25°	14
3.0%	25/25°	28
3.2%	40/20°	28
3.4%	45/20° or 20/25° or 90/25°	28
1.12% glutaraldehyde/ 1.93% phenol-phenate	20/25°	14
7.5% hydrogen peroxide	30/20°	21
7.35% hydrogen peroxide/ 0.23% periacetic acid	15/20°	14
1.0% hydrogen peroxide/ 0.08% periacetic acid	25/20°	14
0.55% *ortho*-phthaldehyde	12/20°	14
0.2% periacetic acid	12/50°	single use

Note that the maximum reuse period refers to specific commercial product formulations. Go to www.fda.gov/cdrh/ode/germlab.html for details.

the disinfection step is risky and many bronchoscopists place excessive faith in the efficacy of the disinfection step. Parenthetically, meticulous cleaning alone achieves a 3.5–4.0 log reduction in organism load (78). The choice of specific disinfectant varies by institution and depends on cost, volume of procedures, use of AERs, number of bronchoscopes in use, and cleaning facilities available. With regard to specific agents, a number of studies have demonstrated that 20 minutes in 2% alkaline glutaraldehyde at 20° C provides adequate disinfection if cleaning with detergent precedes disinfection (71,73,78,79). For the practical purpose of achieving high-level disinfection, the choice of agent is probably unimportant. Careful cleaning and assiduous adherence to an appropriate protocol are far more important determinants of successful disinfection (71).

Depending on the formulation, disinfectant solutions may be reused for 14 to 28 days (Table 3-3) (80). It is important to note that dilution of solutions occurs over time. For example, Mbithi et al. found a 14-day decline from 2.2% to 1.1% in alkaline glutaraldehyde concentration used for manual and AER disinfection (81). For this reason, solution concentration as well as pH should be tested periodically with commercially available test kits. Glutaraldehyde solutions should not be used if concentration is less than 2%. We recommend testing solutions at the beginning of every day of use. Even if the concentration is adequate, disinfectants should not be used longer than the approved time frame. Over time, aldehyde groups will polymerize, abrogating their microbiocidal activity (77).

AER-specific Issues AERs help maintain standards of disinfection and consistency between operators, and eliminate human errors. Biologic and chemical markers are available to assess disinfectant strength, pH, and efficacy of decontamination. Provided adequate cleaning and high-level disinfection are achieved for all devices, bronchoscopes can be separately reprocessed in the same AERs that are used for gastroenterologic endoscopes.

AERs are associated with a number of potential routes for contamination. Although the inside of the devices are periodically disinfected, water supply tanks, tubing, and pumps are not in contact with disinfectant. These areas may serve as reservoirs for ongoing contamination (6,43,45,56,62). Organisms may colonize the inside of AERs despite periodic disinfection, presumably protected by development of biofilms (44,46,53,62). Once colonized, it may be impossible to disinfect such devices (43,46). In some instances, after multiple attempts to sterilize AERs have failed, manual cleaning has been necessary to stop outbreaks. Other cases have occurred when routine maintenance or disinfection were not performed (62).

It is important to ensure compatibility between bronchoscopes and AERs. User manuals should be easily accessible to provide information on which specific instrument models have been tested for AER use (5). For example, failure to provide adequate internal channel penetration of disinfectant will thwart successful disinfection. The use of wrong connectors has been responsible for several cases, including true infections (19,20,58). All lumened devices in AERs should have connectors to ensure adequate flow though narrow lumens or around sharp bends (82).

Reprocessing of Instruments after Use in Patients with Mycobacterial Disease Some authors have recommended intensification of reprocessing procedures after bronchoscopy of patients suspected to have mycobacterial disease (83). We agree with others that this approach is unnecessary if all current infection control guidelines are followed (Table 3-4) (71,84). This stance is validated by the available evidence. For example, in a simulated model, Jackson et al contaminated bronchoscopes with 10^8 CFU/ml of *M. gordonae* (79). As noted earlier, *M. gordonae* is among the most difficult microorganisms to eradicate (74,85). Two percent glutaraldehyde disinfection for 20 minutes at 20° C and 10 minutes at 25° C was completely effective. Efficacy has been similarly demonstrated for *M. tuberculosis*, as well as for automated bronchoscope disinfection with periacetic acid (78,86).

Viruses To date, there have been no reported instances of bronchoscopic virus transmission. In the gastroenterologic endoscopy literature, there is one report each of Hepatitis B (HBV) and C (HBC) transmission via inadequately disinfected endoscopes (87,88). Most viruses, including HBV, HBC, and HIV are readily neutralized with disinfectants as well as with antiseptic agents such as iodides or ethyl alcohol (74,77). Experimentally, the risk for virus transmission is low. For example, Hanson et al demonstrated that seven of seven bronchoscopes had significant levels of HIV RNA immediately after use on AIDS patients (89). They were unable to demonstrate infective particles, however, and cleaning alone decontaminated

Table 3-4. Summary of Recommendations for Bronchoscope Reprocessing

(1) Inspect the external surface of the bronchoscope for damage and leak test after each procedure.
(2) Adequate mechanical cleaning immediately after each use and prior to disinfection, including wiping of external surfaces with detergent and thorough brushing of all internal channels.
(3) Discard detergent solutions after each use. Cleaning brushes should be either disposable or thoroughly cleaned with high-level disinfection or sterilization after each use.
(4) Disinfect with an agent of sufficient microbiocidal intensity at an adequate temperature for sufficient duration.
(5) Ensure compatibility between the bronchoscope and AERs, including the provision of appropriate connectors to provide luminal flow of disinfectant.
(6) Disinfection entails complete immersion of the instrument. Nonimmersible bronchoscopes should be replaced if economically feasible.
(7) Routinely test disinfectant concentration for facilities using nonprepackaged kits if the disinfectant is used repeatedly for more than several days.
(8) Rinse with high quality (filtered) tap water followed by 70% ethyl alcohol or sterile water after disinfection.
(9) Allow bronchoscopes to dry thoroughly in a designated area prior to storage. Dry with forced air, if feasible.
(10) Store bronchoscopes in a hanging position.
(11) Use single-use stopcocks because reusable ones may be very difficult to clean.
(12) Mechanical cleaning (e.g., by ultrasonics) followed by autoclaving or sterilization of heat-stable parts and accessories, such as biopsy forceps.
(13) Do not reuse atomizers between patients unless resterilized.
(14) Schedule regular maintenance and disinfection of automated washers and associated supplies.
(15) Maintain a log of bronchoscope use as well as AER maintenance and disinfection.
(16) Ensure accessibility of cleaning and disinfection protocol manuals from bronchoscope and AER manufacturers. It is important to contact the manufacturer to ensure compatibility between bronchoscopes and AERs, with appropriately matched connectors.
(17) Provide regular staff-training sessions, with specific provision of device-specific instructions when a new bronchoscope or AER is introduced.
(18) Microbiology laboratories should regularly monitor isolates to discern patterns suggesting outbreaks or pseudo-outbreaks.
(19) Notify the institutional infection control officer, the bronchoscope manufacturer, the CDC, the FDA, and the state health department when infections or pseudo-infections are suspected.

Adapted from references 5,52,73.

all of the instruments when PCR was repeated prior to disinfection. In another experiment, the authors artificially contaminated endoscopes with HIV; cleaning followed by 2 minutes immersion in glutaraldehyde eliminated all virus antigen (90). Hepatitis B virus is similarly sensitive to routine methods (91).

The main theoretical risk of virus transmission resides in potential failure to adequately remove biologic debris via mechanical cleaning, thus allowing viruses to escape contact with disinfectants. Failure to clean endoscopes adequately has been shown to preclude effective disinfection of HBV and HCV (76). Ostensibly, this was the mechanism for the case of colonoscopic HCV transmission (87). If routine guidelines are followed appropriately, it is not necessary to implement augmented disinfection techniques after bronchoscopy in patients with HBV, HCV, or HIV. Further, since serologic status is often not known, it is more prudent simply to use adequate precautions for all patients.

Prions Inactivation of prions (including Creutzfeldt-Jakob disease [CJD] and variant CJD disease) requires unique decontamination protocols. Prions resist normal inactivation methods, and steam sterilization for at least 30 min at 132° C in a gravity-displacement sterilizer is the preferred method. Infectivity is tissue dependent, with central nervous tissues (e.g., brain, spinal cord, and eye) having the highest risk. Because pulmonary tissues are not suspected to be at risk for transmission of these agents, there is no recommendation for sterilization of bronchoscopes used in patients with proved or suspected CJD disease.

Bacillus Anthracis As of July 2002, a total of 23 cases of anthrax had been reported to the CDC following the intentional distribution of *Bacillus anthracis* spores through the U.S. postal system in the fall of 2001. Eleven cases were inhalational anthrax with five deaths, of whom at least one underwent bronchoscopic procedure (92), raising the issue of disinfection. *B. anthracis* is a large, spore-forming, encapsulated, aerobic, nonmotile, toxin-producing gram-positive rod. Although the spores of anthrax are resistant to high-level disinfectant, they are produced only in soils and in dead tissues, not in blood or living tissues. Therefore, since spores are not present in infected humans, high-level disinfection of bronchoscopes is adequate for patients with known or suspected inhalational anthrax.

Postdisinfection Handling

Residual moisture in the bronchoscope may serve as a nidus for microbial colonization, even after careful disinfection. One potential source for organisms is tap water used for rinsing the scopes after disinfection (39,73). Thorough rinsing, including the internal channels, is necessary because retained disinfectants may cause mucositis in subsequent patients (77). Tap water rinsing has accounted for several outbreaks (39,40,49,59). To avert recontamination, we recommend rinsing with sterile water or with high-quality tap water followed by 70% alcohol. Alcohol has excellent antimicrobial properties and will also facilitate drying. After rinsing, inner channels should be dried by insufflating air through the working port.

Store instruments in an upright (hanging) position to prevent accumulation of moisture. Valves and suction devices should not be reassembled until the time of the next procedure—in one instance, residual accumulations of moisture in reassembled valves caused an episode of 15 *Rhodotorula rubra* pseudoinfections (26). Storage of instruments in cases or coiled positions may have contributed to several other outbreaks (14). Adoption of storage in a hanging position decreased overnight contamination from 35% to 0% in a study of gastrointestinal endoscopes (93).

Adequately disinfect or sterilize other accessories. For example, multiple-use anesthetic atomizers must be cleaned and

sterilized between patients. Spraggs et al found that 75% of atomizer lumens and 42% of their fluid reservoirs were contaminated after a single use (94). Active TB has reportedly developed by this mechanism (36). Clean and sterilize reusable instruments, such as biopsy forceps, since they penetrate intact mucosa during normal use. Cleaning may be difficult due to multiple crevices and tightly wound coils. Ultrasonication is most efficacious for this purpose (75).

Quality Control and Isolate Surveillance

To combat the risk of infections and pseudo-infections, especially in an era of increasing numbers of immunocompromised patients, it is necessary to maintain a high degree of vigilance for infectious complications. Institutions should have formal mechanisms in place for routine review of isolate trends and surveillance of isolate results for unexpected pathogens. Suspected clustering suggesting outbreaks (true or pseudo) should trigger previously-articulated, thorough investigations that include review of case characteristics, assessment for patient outcomes, and cultures from relevant devices in the bronchoscopy suite. Such cultures include all internal surfaces of the bronchoscope, AERs, and tap water used for rinsing, as well as other situation-appropriate objects or solutions. Cultures of the bronchoscope ports should use a brush rather than saline flushes since flushes are less sensitive (73). In these instances, the infection-control practices of the staff should be reviewed. Ideally, personnel should be observed while reprocessing the instruments.

Although they are not currently recommended by the FDA or APIC, routine surveillance cultures may allow earlier discovery of breaches in infection control. However, there are no clear criteria specifying what to do with positive culture results, the number of organisms that are relevant, or with what frequency to perform such cultures. Cost is another factor mitigating against blind surveillance cultures. For these reasons, we do not recommend this strategy. Further study in this area would be useful. The potential for unrecognized epidemics is highest in settings with fewer procedures, multiple bronchoscopists, no staff or physical area dedicated solely to bronchoscopy, and absence of routine training in disinfection techniques. These settings require especially careful coordination of data and formalization of isolate surveillance strategy.

Reasons for Failure

Prior to the most recent cases, nosocomial infections had not been reported in any case where all modern guidelines were followed carefully. However, numerous surveys have suggested poor adherence to published preventive guidelines (73,95,96). For example, an observational study of 26 facilities conducted by the FDA revealed that the vast majority of endoscopes (bronchoscopes and gastroendoscopes) were improperly disinfected (95). Multiple procedural breaches were documented, including failure to use a disinfectant, not testing the concentration of disinfectant routinely, not cleaning all channels, failure to flush all channels with disinfectant, failure to time manual disinfection periods, and failure to fully immerse the endoscope in disinfectant solution. In 78% of facilities, biopsy forceps were not sterilized after each use. As a result, washings from 17 of 71 (23.9%) of gastrointestinal endoscopes were culture-positive for $>10^5$ bacterial CFU/ml. A more recent audit of practice in the United Kingdom was equally disturbing—the vast majority of centers did not follow national guidelines (96). In this survey, for example, 43% of departments did not rinse bronchoscopes with sterile or filtered water after chemical disinfection, despite numerous literature reports of microbial tap water contamination. Hospitals with dedicated endoscopy units and staff training sessions complied more closely with standards.

Transmission to Personnel and Bystanders

Diagnostic Bronchoscopy

A major advantage of flexible bronchoscopy is that it can be performed without general anesthesia, in an ambulatory suite. However, there is often marked coughing with use of conscious sedation and topical anesthesia alone, leading to the possibility of airborne pathogen spread. Three organisms may be present that mandate the use of airborne precautions: chickenpox and disseminated zoster, rubeola (measles), and pulmonary or laryngeal tuberculosis. Morice reported a case of apparent adenovirus transmission (97). Six days after bronchoscopy of a viremic patient, the physician developed a culture-positive severe viral illness. An outbreak of TB (six patients) in a renal transplant unit was possibly exacerbated by flexible bronchoscopy and endotracheal intubation of a patient with active pulmonary TB while in the transplant ward (98). Pulmonary fellows-in-training have higher rates of PPD skin-test conversions than infectious disease fellows, despite approximately equal exposure to TB (99). This discrepancy may originate in bronchoscopy-associated exposure among pulmonary fellows. Also, analysis of TB skin-test conversions after an episode of widespread nosocomial exposure revealed that conversion rates were highest among staff members in close physical proximity during bronchoscopy (100). To date, there have been no reports of well-documented active TB or other infections developing among health care providers after bronchoscopy.

Infection precautions should be in place for every procedure. These include full barrier clothing (gowns, gloves, masks and goggles or eyeshields), needlestick precautions, and adequate ventilation (at least 14 air exchanges per hour) (Figure 3-5). A 1997 survey of bronchoscopy departments revealed that 93% of bronchoscopists did not routinely wear protective (full barrier) clothing (96). This finding is alarming, since there are well-documented instances of HIV transmission through mucocutaneous contact with blood and body fluids (101). Needles should not be used to remove biopsy specimens from forceps: HBV has been transmitted by an accidental prick during this maneuver (89).

Bronchoscopy suites should have negative air pressure and either discharge air directly to the outside or monitored high-efficiency particulate air (HEPA) filtration of air before it is

FIGURE 3-5. *The bronchoscopist wears full protective covering, including gown, gloves, mask, and eye protection.*

FIGURE 3-6. *High-efficiency particle exchanger, such as the HEPA-Care (Abatement Technologies Inc, Atlanta, GA), which cycles room-volume air at least 14 times/hour.*

recirculated (Figure 3-6). For patients with suspected or confirmed tuberculosis infection, the need for bronchoscopy should be carefully weighed against the risks to staff and bystanders. Where available, we recommend use of a power air-purifying respirator (PAPR) hood, which provides superior protection (5,102). The N95 particulate respirator is a minimally acceptable alternative (102).

Therapeutic Bronchoscopy

Therapeutic bronchoscopic techniques, such as laser photoresection or endobronchial electrosurgery (EBES), may liberate viable infectious pathogens. Human papilloma virus (HPV) infection, potentially acquired during treatment of recurrent respiratory papillomatosis (RRP), has garnered the most concern to date. Intact viral DNA can be isolated from the vapor plume in lesions treated with the CO_2 laser or with EBES (103,104). HIV DNA may also be found in laser smoke (105). One survey found a positive correlation between surgical use of the CO_2 laser for treatment of papilloma and development of laryngeal papillomatosis (106). Comparing CO_2 surgeons and a population-based control, incidence of nasopharyngeal warts was 13% versus 0.6%, although the two groups had similar overall (any anatomic site) incidences of HPV. Another study failed to show an association (107). There is at least one case report describing development of laryngeal papillomatosis following Nd:YAG laser treatment of anogenital condylomata (108). To date, however, there have been no reports of intact viral particles or documented transmission due solely to endobronchial therapy. Recommendations to minimize the risk of acquiring laryngeotracheal papillomatosis include use of tight-fitting masks with small pore sizes and dedicated smoke evacuators (108,109).

RADIATION SAFETY IN BRONCHOSCOPY

Overview

Radiation exposure is inherent in modern flexible bronchoscopy. The safety emphasis for radiation is on minimizing rather than completely eliminating exposure. Techniques to minimize exposure for patients and medical personnel overlap—most of the precautions for exposure minimization effect lower doses for patients and staff. This section focuses only on practical safety adjustments for bronchoscopists.

There is scant literature concerning radiation protection for medical personnel using fluoroscopy. Most recommendations are based on theoretical physical principles or case reports. There are no studies addressing radiation doses, procedural characteristics, or health risks to personnel specific to the bronchoscopy setting. In general, fluoroscopy duration for bronchoscopy procedures is less than that for interventional radiology, cardiology, or gastroenterology (110). Thus, the true health risk for bronchoscopy personnel is unknown. All recommendations in this chapter are based on extrapolation from other specialties or generic principles. Further study is needed in this area.

Procedures for which fluoroscopy is used in bronchoscopy include:

Transbronchial lung biopsy
Checking for pneumothorax postprocedure
Localizing peripheral lesions for cytology brushing
Transbronchial needle aspiration of peripheral lesions
Brachytherapy

Airway stent placement
Balloon bronchoplasty
Localizing radio-opaque foreign bodies

In addition, with the growing popularity of real-time CT-guided procedures, especially transbronchial needle aspiration, an expanding number of bronchoscopic procedures may entail radiation exposure. It is important to bear in mind that all these procedures involve risk to nurses, respiratory therapists, trainees and other support staff, in addition to physicians.

Because occupational radiation exposure rarely results in immediate adverse health effects, safety precautions may be easily ignored. Many fluoroscopy users do not receive adequate initial radiation safety training or periodic recertification. Pressure to minimize costs and maintain frenetic work paces may subvert well-intentioned safety rules even after adequate training. Perhaps because they are less attuned to radiation hygiene, nonradiology personnel who are frequent fluoroscopy users may be exposed to higher cumulative doses than radiologists (111). Bronchoscopists should assume responsibility for the adequacy of radiation protection for all involved personnel during procedures.

Basic Principles and Terms in Radiation Protection

Essential components of any fluoroscopy system include an x-ray tube and an image intensifier attached to a video camera (Figure 3-7). Most modern fluoroscopy systems are the under-couch type—the x-ray tube is under the patient. The radiation beam is produced when electrons are accelerated from an anode to a cathode in an evacuated glass tube. An opening in the tube shielding—the radiation port—allows egress of the primary x-ray beam. Each x-ray may be absorbed or scattered by patient tissues, or may pass through the patient to the image intensifier. Tissue-specific variation in degree of absorption

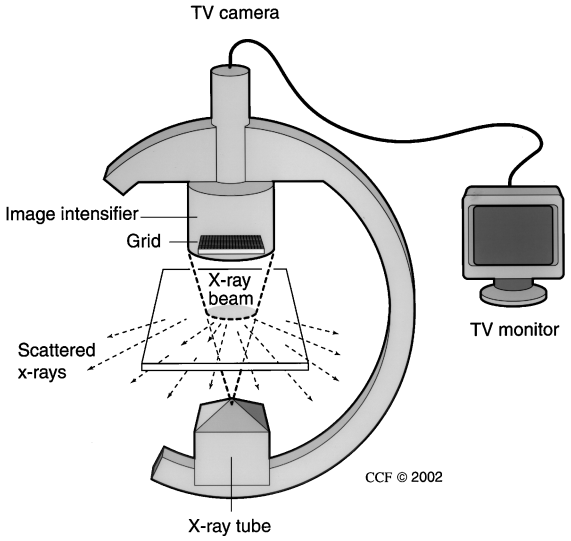

FIGURE 3-7. *Essential components of C-arm type fluoroscopy units.*

accounts for image formation. A portion of the beam is reflected by the patient's tissues, and may exit from all sides of the patient, generating scattered radiation. For the patient, the primary beam conveys the main health risk, whereas scattered radiation is the main risk to staff. In some situations, such as affixing skin markers, the main beam may also pose risks to the operator's hands.

The radiation exposure rate depends on several factors, many of which can be adjusted on modern fluoroscopy units. Adjustable factors include tube potential (voltage), current (milliamperes), number of x-ray pulses per second, use of collimation, source to skin distance, patient-to-image receptor distance, filtration, and total fluoroscopy time. Collimation refers to adjustment of the primary beam size to minimize exposure of areas of the patient that are not of interest. Increasing the distance from the x-ray tube to the surface of the patient—the source to skin distance—decreases the patient's exposure. Filtration can be pre-set to remove low-energy rays that are mainly absorbed by tissues rather than contributing to image acquisition. In general, increasing the tube potential will increase x-ray production and decrease absorption, thereby increasing image brightness but decreasing the contrast. Larger patients require upward adjustments in voltage. Increasing the current will provide better contrast, but also increases exposure rates to the patient and staff dramatically. Many modern fluoroscopy units function in automatic modes, with dose-rate control and automatic brightness control algorithms titrating the current and tube potential in a pre-set fashion. Some settings in the algorithm may be adjusted depending on the needs of the usual operators.

Common radiation protection terms are outlined in Table 3-5. Theoretically, the most useful unit for assessing and comparing overall risk is the effective dose. The concept of effective dose accounts for differing tissue sensitivity and exposure rates to ionizing radiation. For example, the lens is far more radio sensitive than the hand; even though the operators' hands typically receive higher effective radiation doses, the lens is more prone to damage. The risk to the whole individual is derived from tissue-specific weighting factors summed over all the exposed tissues. The effective dose (or equivalent dose) may also be described in roentgen-equivalent-man (rem) units. One rem is equal to 1/100 Sv.

Table 3-5. Radiation Safety Terminology

Term	Unit	Definition
Absorbed dose	Gray (Gy)	Energy absorbed per tissue mass 1 Gy = 1 joule/kg
Equivalent dose	Seiverts (Sv)	Absorbed dose weighted for harmfulness of radiation type For x-rays, 1 Sv = 1 Gy
Effective dose	Seiverts (Sv)	Dose weighted for tissue susceptibility and exposure
Dose area product	cGy/cm^2	Concentration of energy per cross-sectional area

Table 3-6. Health Effects of Radiation

Deterministic Effect	Stochastic Effect
Erythema	Cancer
Desquamation	Germ cell DNA damage
Skin necrosis	
Bone marrow suppression	
Organ atrophy	
Sterility and low fertility	
Cataract	

Table 3-7. Dose Limits for Occupational Exposure

Effective dose:	20 mSv/year, on average 50 mSv in any one year
Annual equivalent dose to:	
Lens of the eye	150 mSv
Skin	500 mSv
Hands and feet	500 mSv

A limitation of effective dose calculations in bronchoscopy is that there is significant variability in scatter angle, the energy of the scattered radiation, the size of the individual, the types of shielding used, and the positioning of fluoroscopy equipment. Dose area product (DAP) is useful for monitoring radiation output at any location in space.

Health Risks

Health risks due to radiation exposure are conventionally divided into deterministic and stochastic categories (Table 3-6). Deterministic consequences of radiation demonstrate a dose-effect relationship, as exemplified by the stages of radiation-induced skin damage. In contradistinction, only the probability of stochastic effects is affected by radiation dose. Severity of the event is unrelated. An example of a stochastic radiation effect is the induction of cancer. Another way to view the difference between these two categories is that stochastic effects require radiation changes to only a single cell, whereas many cells must be damaged to cause deterministic effects. Most risks to the patient are deterministic.

Although direct exposure to the x-ray beam is the main source of radiation exposure for patients, scattered radiation accounts for almost all staff exposure. For occupational safety, therefore, cumulative exposure is more relevant than one-time exposure dose. Low-dose, cumulative exposure is more likely to result in stochastic, rather than deterministic effects. The International Commission on Radiation Protection (IRCP) recommends that 5-year-averaged effective dose should not exceed 2 rem/year, with an absolute yearly limit of 5 rem (112). Organ-specific dose limits are listed in Table 3-7.

The actual risks to personnel from fluoroscopy are unknown. The effect size is small, the latent period prolonged, and radiation-induced cancer is impossible to distinguish from cancer due to other causes. Cancer mortality among early-twentieth-century radiographers and fluoroscopists was higher than that of other physicians, but has fallen to equivalent levels with the advent of safer radiation practices (113). A number of studies have found that occupational radiation exposure is well within acceptable limits for a variety of medical specialties, including interventional radiologists, invasive cardiologists, orthopedic surgeons, urologists, anesthesiologists, and gastroenterologists (114–119). However, since no dose of radiation has proved to be harmless, the foundation of radiation protection is dose minimization. This principle is codified by the acronym ALARA (As Low as Reasonably Achievable) (120).

Table 3-8. Techniques to Limit Radiation Dose

Maintain the highest acceptable peak kilovoltage (beam hardening) and lower current (mA)
Maximize distance between the fluoroscopy unit and staff
Last image hold
Grid removal
Dose settings—prefer medium
Variable pulsed fluoroscopy
Low frame speed
Collimation
Maximize source-to-image (to skin) distance and minimize image-to-receptor distance

Radiation Protection

The most important factor in radiation safety is proper training and recertification. Such training includes an understanding of the biologic effects of radiation exposure, the implications of varying modes of fluoroscopy, methods to limit exposure (Table 3-8), and tools to individualize fluoroscopy settings for disparate cases (121).

Exposure Minimization

Fluoroscopy Time Control over total fluoroscopy time has a direct effect on radiation exposure. Inexperienced operators typically use longer exposure times, and attention should be directed by trainee supervisors toward reduction of use. Most systems have a last-image-hold feature, which allows the operator to study the prior images without using continuous fluoroscopy. A newer feature is pulsed fluoroscopy, in which x-rays are produced only intermittently (e.g., 15/second) rather than continuously and the duration of the pulse is significantly less than the pulse time. While the images obtained may be choppy, they are usually of sufficient quality for procedural purposes.

Maximization of Distance Other than protective shielding, the most important safety maneuver for personnel is to maximize distance from the radiation source. Exposure decreases by the square of the distance. Thus, the rate is decreased by four times if one moves from a distance of 1 meter to 2 meters. Tight collimation also decreases the radiation dose, both by minimizing exposed surface area and by decreasing the amount

of scatter radiation. Because scatter radiation accounts for all the risk to personnel, collimation may significantly decrease occupational risk.

Equipment Positioning Overcouch fluoroscopy equipment (x-ray tube above the patient) results in higher staff exposure rates (122), and should be abandoned in favor of undercouch devices.

Some procedures, such as obtaining oblique views to confirm instrument positioning, require repositioning of the x-ray tube. It is important to be aware of source-to-skin distance (SID) in these instances, since oblique and lateral projections may result in significant patient skin injuries (123). Similarly, with undercouch positioning of the C-arm, shorter bronchoscopists should resist the urge to lower the patient's table closer to the x-ray tube; instead, a riser should be used to facilitate operator comfort. To further ensure minimum safe SID, use of a spacer affixed to the x-ray tube is required in the United States. Although the spacer may be removed briefly for special positioning, it should generally be left in place.

By maximizing the SID, the operator automatically minimizes the distance between the image (patient) and the image receptor for units with a fixed source to receptor configuration. Some units allow independent positioning of the x-ray tube and image receptor. For these systems, the image receptor should be moved as close to the patient as possible (124). By doing so, the quantity of x-rays affording equal image intensity will decrease since the source is nearer the receptor. The skin-entrance dose will therefore be lower.

Magnification Most fluoroscopy units have the option of electronically magnifying the image, usually by decreasing the size of the x-ray field. For most equipment, magnification results in increased radiation dose (124). We therefore recommend use of the lowest magnification necessary in each situation.

Grid Removal The grid is a flat screen positioned directly in front of the image receptor that filters out scattered x-rays that would degrade image clarity. Use of a grid requires much higher radiation doses. In selected instances, the grid can be removed with little image degradation but with substantial decreases in radiation dose. Three instances where this would be appropriate are: procedures for which image clarity is less important, for thin patients who will induce little scatter, and for procedures that require a large area between the patient and image receptor.

Protective Shielding

Lead Aprons Leaded aprons are effective for personal protection from radiation. The degree of protection afforded by the aprons is expressed in millimeters of lead equivalent. Most lead aprons have a lead-equivalent thickness of 0.5 mm. In prolonged procedures, operator fatigue or back pain may occur because the aprons are heavy. As a result, composite materials are being tested that decrease the weight of these aprons (125). Another option is decreasing the thickness of the aprons to 0.25 mm lead-equivalent, although x-ray attenuation is compromised slightly at this thickness (125). Special aprons that provide extra protection to the abdomen and pelvis are available for pregnant personnel. All aprons must be tested yearly under fluoroscopy for leaks.

Thyroid Shields Although they are frequently ignored by bronchoscopy personnel, we recommend routine use of thyroid shields. Such shields are comfortable, do not impinge on freedom of movement, and are inexpensive. Since thyroid cancer may be a stochastic effect of ionizing radiation, there is no minimum dose that can be presumed to be safe. Although exposures to bronchoscopists are likely to be low, the principle of ALARA suggests use of shields even with "low" effective thyroid doses. Standard collars decrease dose by a factor of 23, corresponding to background radiation levels for wearers (126).

Eye Protection High radiation doses may lead to cataract formation (127). This injury is far less likely to occur with undercouch fluoroscopy systems. Eye exposure may be reduced by a factor of 6–8 by 0.6 mm leaded glasses (128). However, these glasses are heavy and may be uncomfortable in prolonged cases. In bronchoscopy, ocular exposure is unlikely to be high; we therefore believe that decisions regarding whether or not to use leaded glasses are best determined by the individual.

Monitoring

Fluoroscopy time does not accurately measure the actual radiation dose, since multiple other factors contribute to the dose. All personnel in the bronchoscopy suite must therefore wear personal radiation monitoring devices. Film badges and thermoluminescent dosimeters (TLDs) are the two most commonly used devices. Film badges contain film that is checked monthly to ascertain radiation dose; filters in the badge provide information on radiation energy and direction (129). TLDs contain lithium crystals, which store radiation energy. When heated, the energy is liberated as light, with intensity of the light proportional to the stored energy and therefore the absorbed radiation dose. Film badges are inexpensive but may be sensitive to heat. TLDs are expensive but reusable.

Electronic dosimeters are also available. These can be equipped with an audible alarm that is triggered whenever exposure exceeds a predetermined limit. They are most useful for operators who frequently perform long, complex procedures, for pregnant workers, or for trainees who may overuse fluoroscopy. Electronic dosimeters are not able to monitor cumulative exposure reliably, so they must be used in conjunction with standard devices. Bronchoscopists who frequently must place their hands in the radiation field should also use ring-type dosimeters to monitor hand exposure.

The issue of where to wear dosimeters has elicited some controversy in the radiation safety literature. Over-the-collar placement significantly overestimates the whole-body effective dose, whereas under the apron underestimates dose (114).

Some authors have recommended formulas or correction factors to increase the accuracy of the raw dosimeter measurements (120,130). Multiple monitors may be required to accurately gauge exposure. In actual practice, effective dose is commonly calculated by dividing the reading from a single badge worn at the collar level outside the lead apron by a factor of 5.6 (131).

Exposure and Compliance

Dosimeter measurements must be carefully recorded each month. Each institution should have a standardized procedure in place to investigate putative overexposure episodes. Investigations of overexposure includes assessment of caseload, equipment performance, duration of fluoroscopy use, compliance with personal protective devices, and individual radiation safety practices (129).

Quality control of radiation protection begins with design of the bronchoscopy suite. Where possible, we recommend involvement of a radiation physicist in the planning, design, and construction of bronchoscopy facilities. Ideally, such an individual would also assist with initial set-up, periodic recalibration, and quality control checks of fluoroscopy equipment. Education of bronchoscopy personnel, radiation exposure monitoring, and investigation of overexposure also fall under the purview of a dedicated radiation safety officer.

CT Fluoroscopy

CT fluoroscopy has been studied for interventional radiology procedures. Carlson et al demonstrated that doses to personnel were well within acceptable range for 203 consecutive procedures (1.0 mGy or less) (132). In the vast majority of cases, intermittent fluoroscopy was used exclusively, resulting in personnel doses less than 0.01 mGy. In this series, the longest total fluoroscopy time was 36 seconds. Other studies have confirmed safety for patients and staff (133,134). Even with the least-optimal fluoroscopy settings, patient skin dose for an 80-second procedure was no higher than that for cardiac catheterization. By analogy, CT-guided bronchoscopic procedures should be safe for patients and personnel, as long as intermittent image acquisition modes are employed, direct hand exposure is avoided, and total fluoroscopy times are minimized. In addition, tube current should be set at the minimum level necessary for adequate image clarity. The safest strategy for CT use is as a "quick check" to ensure correct instrument positioning relative to the region of interest.

CONCLUSION

The provision of noncontaminated bronchoscopy equipment requires strict adherence to cleaning and disinfection protocols. Fortunately, almost all contamination is preventable if guidelines are assiduously followed. It is important to recognize that microbial transmission may occur via any part of the instruments or anything in contact with the instruments, including solutions, rinsing water, automated washers, atomizers etc. (see Table 3-1). In short, any fluid reservoir that is not routinely and effectively disinfected or sterilized may become a source of pathogens. Environmental organisms are notoriously difficult to eradicate. Four major potential avenues for cross-contamination via bronchoscopy are: failure to follow recommended guidelines for disinfection, organisms harbored in a site that is not accessible to the disinfectant, presence of resistant organisms, and recontamination of the bronchoscope or accessories after adequate disinfection. Reliance on AERs may instill a false sense of security by downplaying other aspects of successful disinfection. Processes must be developed that stress infection-resistant engineering and facilitate easy reprocessing. A sheathed bronchoscope that may obviate many of the pitfalls in reprocessing is currently undergoing clinical evaluation (135).

Radiation protection in bronchoscopy derives from the fundamental ALARA principle. Bronchoscopists should make efforts to be aware of appropriate safety precautions and to be attuned to the presence of adjustable fluoroscopy factors that can decrease patient and personnel dose rates. Training programs should implement radiation safety programs. In addition, we advocate development of formal evidence-based expert guidelines specific to bronchoscopy. Further study of the radiation risks to patients and staff in pulmonary and critical care settings should be initiated.

Safety of bronchoscopists, staff, and nearby patients can likewise be maximized by adherence to well-known protocols. Universal infection precautions are underutilized. Continuing education of bronchoscopists and support staff should stress their use. Most of the historic examples of infection control breaches and radiation-induced injuries have stemmed from failure to follow preexisting guidelines carefully. Bronchoscopists must take responsibility to ensure that relevant safety protocols are in effect at their own institutions and continue to educate themselves on practical ways to minimize safety risks.

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