

ORIGINAL ARTICLE

Disinfection of a Probe Used in Ultrasound-Guided Prostate Biopsy

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BACKGROUND. Transrectal ultrasound (TRUS)-guided prostate biopsies are among the most common outpatient diagnostic procedures in urology clinics and carry the risk of introducing pathogens that may lead to infection.

OBJECTIVE. To investigate the effectiveness of procedures for disinfecting a probe used in ultrasound-guided prostate biopsy.

METHOD. The effectiveness of disinfection was determined by inoculating 10^7 colony forming units (cfu) of *Pseudomonas aeruginosa* at the following 3 sites on the probe: the interior lumen of the biopsy needle guide, the outside surface of the biopsy needle guide, and the interior lumen of the ultrasound probe where the needle guide passes through the transducer. Each site was investigated separately. After inoculation, the probe was immersed in 2% glutaraldehyde for 20 minutes and then assessed for the level of microbial contamination.

RESULTS. The results demonstrated that disinfection (ie, a reduction in bacterial load of greater than 7 log₁₀ cfu) could be achieved if the needle guide was removed from the probe. However, if the needle guide was left in the probe channel during immersion in 2% glutaraldehyde, disinfection was not achieved (ie, the reduction was approximately 1 log₁₀ cfu).

CONCLUSIONS. Recommendations for probe disinfection are provided and include disassembling the device and immersing the probe and the needle guide separately in a high-level disinfectant.

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Each year in the United States, approximately 46.5 million surgical procedures are performed. An even larger number of invasive medical procedures are conducted annually,¹ including approximately 5 million gastrointestinal endoscopies. Each of these procedures involves contact between a medical device or surgical instrument and sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogens that may lead to infection. Failure to properly disinfect or sterilize equipment carries a risk of infection due to residual microbial contamination (eg, by *Pseudomonas aeruginosa*).²⁻⁴

Achieving disinfection or sterilization through the use of appropriate practices is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Since it is unnecessary to sterilize all patient-care items, healthcare policies must identify, primarily on the basis of the items' intended use, whether cleaning followed by disinfection or sterilization is indicated.

Transrectal ultrasound (TRUS)-guided prostate biopsies are among the most common outpatient diagnostic procedures performed in urology clinics, with an estimated 624,000 procedures performed annually in the United States.² In July 2005, the Centers for Disease Control and Prevention investigated 4 cases of *P. aeruginosa* infection after TRUS-guided prostate biopsies in which contamination of the TRUS equip-

ment was the likely source.² All 4 patients were hospitalized, and 3 patients were admitted with a diagnosis of septicemia. One of 16 environmental samples from the narrow lumen of the needle guide grew *P. aeruginosa* on culture, and this isolate had a pulsed-field gel electrophoresis pattern that was indistinguishable from that of the isolates recovered from the 3 patients. Since *P. aeruginosa* is exquisitely susceptible to ortho-phthalaldehyde and glutaraldehyde,⁵ a likely origin for these infections was tap water contamination of the probe and needle guide during inadequate rinsing and drying (ie, by means of an alcohol rinse following the tap water rinse and forced-air drying).

In 2003, we investigated the effectiveness of our procedures for disinfecting prostate biopsy probes, because of concerns about proper reprocessing of the devices. This report summarizes that investigation.

METHODS

We performed experiments to determine the effectiveness of disinfection after *P. aeruginosa* inoculation of the following 3 sites on a probe (Type 8551; B-K Medical) used in TRUS-guided prostate biopsy: the interior lumen of the biopsy needle guide, the outside surface of the biopsy needle guide; and the interior lumen of the ultrasound probe where the needle

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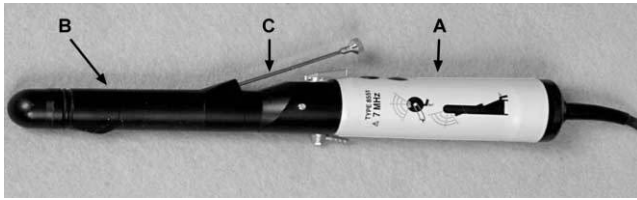


FIGURE. Transducer used for prostate imaging and targeted biopsies, showing the handle (A), the probe (B), and the biopsy needle guide partially removed from the probe channel (C).

guide passes through the transducer (then the needle guide was replaced into the channel). Each of the 3 sites was investigated separately. Each site was inoculated on 5 or 6 occasions with 100 μL of a solution containing approximately 10^7 colony forming units (cfu) of *P. aeruginosa* grown in trypticase soy broth. The inoculum was allowed to dry for 30 minutes in a biological safety cabinet. A validation study determined that approximately 70% of the inoculated *P. aeruginosa* cfu were recoverable after 30 minutes of drying. After drying, the probe (with the needle guide) was submerged in glutaraldehyde (concentration, greater than 2% [Cidex {reusable for 14 days}; Advanced Sterilization Products]) for 20 minutes at 20°C. Cold Sterilog Strips (3M Health Care) were used to monitor the minimum effective concentration (1.5%) of the glutaraldehyde solution on a daily basis.

Following the 20-minute exposure to glutaraldehyde, the probe was placed in sterile water for 1 minute, after which specimens from the inoculated site were cultured in D/E neutralizing broth (Becton Dickinson). If the outside surface of the needle guide was assessed, the needle guide was placed in a tube containing 10 mL of D/E neutralizing broth and vortexed (Fisher Scientific) on setting 8 (high) for 1 minute. Specimens from the internal lumen of the needle guide and the internal lumen of the probe were obtained by slowly pushing 20 mL and 10 mL, respectively, of D/E neutralizing broth through the lumen in 5-mL increments. Ten-fold serial dilutions with D/E neutralizing broth were performed to assess the extent of microbial reduction, and 100 μL of each dilution were plated onto sheep blood agar, in duplicate, using

the spread plate method. All dilutions were evaluated. Plates were cultured at 37°C for 48 hours.

After it was determined that the assembled probe could not be effectively disinfected, we assessed the effectiveness of disinfecting the needle guide and transducer probe separately. The internal lumen of the ultrasound probe without the needle guide attached to the probe, as well as the inside and outside surfaces of the needle guide separate from the probe, were assessed as described above.

RESULTS

The probe used in these experiments is shown in the Figure. Overall, 5 sets of experiments were conducted, with 5 or 6 replications per set (Table 1). The initial 3 sets of experiments (A, B, and C) were conducted with the needle guide in place in the probe. In set A, complete inactivation of the *Pseudomonas* organisms inoculated in the internal lumen of the needle guide was achieved, for a reduction in bacterial burden of greater than 7 \log_{10} cfu. However, in no case was inactivation achieved when either the outside surface of the needle guide was inoculated (set B; reduction, approximately 1 \log_{10} cfu) or the internal lumen of the probe was inoculated (set C; reduction, approximately 1 \log_{10} cfu). After the failure to achieve disinfection when the probe was assembled, we then assessed the efficacy of disinfection when the needle guide was removed from the probe and disinfected separately. This method of disinfection resulted in complete inactivation of *Pseudomonas* organisms in the internal lumen of the ultrasound probe (set D; reduction in bacterial burden, greater than 7 \log_{10} cfu) and on the inside and outside surfaces of the needle guide (set E; reduction, greater than 7 \log_{10} cfu).

DISCUSSION

Urologists use ultrasound transducer assemblies to view internal structures of the urinary tract and to obtain biopsy samples. To allow biopsy, these devices may have a needle guide attached to direct the insertion of a biopsy needle. All prostatic biopsy procedures likely result in contamination of the probe with blood or feces. Therefore, during these pro-

TABLE 1. Effectiveness of Glutaraldehyde Disinfection of Various Components of a Probe Used in Ultrasound-Guided Prostate Biopsy

Inoculation site and status	Experiment set	Size of <i>P. aeruginosa</i> inoculum, cfu	No. of positive results/no. of experiments	<i>P. aeruginosa</i> yield on culture, mean cfu
Internal lumen of needle guide in probe	A	1.56×10^7	0/5	No growth
Outside surface of needle guide in probe	B	1.21×10^7	6/6	1.2×10^6
Internal lumen of probe				
Needle guide not removed from probe	C	1.69×10^7	6/6	2.82×10^6
Needle guide removed from probe	D	1.81×10^7	0/5	No growth
Inside and outside of needle guide removed from the probe	E	1.81×10^7	0/5	No growth

NOTE. CFU, colony forming units; *P. aeruginosa*, *Pseudomonas aeruginosa*.

TABLE 2. Recommendations for Reprocessing Probes Used in Transrectal Ultrasound-Guided Prostate Biopsy

Cleaning
Clean immediately after use
Disassemble the transducer (ie, remove needle guide from the probe)
Brush clean (if possible) or flush each lumen and thoroughly clean all surfaces of reusable components with enzymatic or nonenzymatic detergent
Rinse with tap water
Dry with disposable cloth and/or towel or air dry
Perform visual inspection to ensure the device is clean
High-level disinfection or sterilization
Steam sterilize all heat stable reusable components
Alternatively, perform high-level disinfection of the probe and the needle guide separately following disassembly
Perform high-level disinfection for all heat-sensitive components to ensure that the disinfectant reaches all areas inside the lumens and that the minimum effective concentration of the high-level disinfectant is used
Rinse with sterile water, filtered water, or tap water (the US Food and Drug Administration specifies use of sterile water for rinsing)
If filtered water or tap water is used, follow with an alcohol rinse (not immersion of the probe in alcohol) to enhance drying and ensure that no residual water is left for microbial growth
Dry
Store appropriately to ensure the device is not recontaminated

NOTE. Users should be familiar with the manufacturer's recommendations for use and disinfection of the specific device used by the facility.

cedures, the transducer assembly is generally covered with a barrier sheath.⁶

Disinfection or sterilization of ultrasound transducer components is based on the function or use of each component. Because the biopsy needle penetrates sterile tissue, it should also be sterile. Ideally, the needle guide should be sterilized between uses. However, if this is not possible (eg, in clinics where no sterilization materials are available because biopsy needles are purchased as single-use sterile devices), then high-level disinfection after disassembly and cleaning is acceptable, because the needle guide has contact with mucous membranes but not sterile tissue.

A US Food and Drug Administration (FDA) patient safety alert⁶ and a recent article from the Centers for Disease Control and Prevention² recommended that the needle guide be sterilized because the biopsy needle contacts the needle guide before it penetrates sterile tissue. These recommendations are inconsistent with the current recommendation for the disinfection of endoscopes.⁴ It is currently recommended that gastrointestinal endoscopes undergo high-level disinfection at minimum but that medical devices that pass through the endoscope and enter sterile tissue (eg, biopsy forceps) be sterilized. There is no recommendation that the lumen or channel through which devices pass should also be sterilized. One possible explanation for the inconsistency is that there is no practical way to sterilize gastrointestinal endoscopes, whereas the reusable needle guide for prostate probes can be sterilized (M. J. Arduino, personal communication). Although a barrier sheath is used on the transducer assembly

during biopsy, the sheath is compromised by the penetration of the needle.⁶ Although prostate probes and other endocavitary probes are often covered with a disposable sheath or condom,⁶ such covers do not adequately protect the probe from microbial contamination (failure rate, 0.9%-81% of covers). Thus, the use of a cover does not alter the requirement for high-level disinfection at minimum.⁴ The FDA recommends the use of a sterile barrier sheath for reprocessing reusable ultrasound transducer assemblies.⁶ It is appropriate to use a sterile barrier sheath when an ultrasound probe is entering a sterile body cavity, but for probes entering the rectum, the need for a sterile barrier sheath is unclear.

All medical devices used in semicritical and critical procedures must be thoroughly cleaned with enzymatic or nonenzymatic detergents before they undergo high-level disinfection or sterilization, respectively. Brushes should be used, when possible, to effectively clean the transducer assemblies, especially the lumens. Our investigation shows that the needle guide and prostate probe can be effectively disinfected with glutaraldehyde but that the needle guide must be disassembled from the transducer assembly before disinfection.

The FDA issued the alert mentioned above⁶ as a follow-up to a Veterans Health Administration patient safety alert, which reported that a soiled lumen from a needle guide of an ultrasound transducer assembly was found during patient safety rounds. The FDA provided several recommendations for reprocessing ultrasound transducers. Do not reuse items labeled for single use (eg, single-use biopsy needles). We evaluated the FDA steps and suggest some modifications

(Table 2). Additional recommendations may be available in the operator's manuals or user guides. It is important that these recommendations be consistent with disinfection and sterilization guidelines and principles or that these recommendations have been validated by appropriate scientific studies. Do not use any disinfectant that can cause irreparable damage to the materials used to construct the probe. For example, if an alcohol rinse is not compatible with the probe, rinse with sterile water (not filtered water or tap water) instead. These recommendations can be adapted to include ultrasound transducer probes with an external needle guide attachment.

Because equipment used during semicritical procedures has been associated with reprocessing errors that result in retrospective notification of the patients exposed, it is essential that control measures be instituted to prevent patient exposures.⁷ Before new equipment (especially devices used in semicritical procedures, because the margin of safety for these devices is less than that for devices requiring sterilization⁸) is used for patient care on more than 1 patient, reprocessing procedures for that equipment should be developed. Staff should receive training on the safe use and reprocessing of the equipment and, ideally, undergo competency testing. Infection control rounds or audits should be conducted annually in all clinical areas that reprocess semicritical devices, to ensure adherence to reprocessing standards and policies. Results of infection control rounds should be provided to the unit managers, and deficiencies in reprocessing should be corrected and corrective measures documented to infection control within 2 weeks.

In conclusion, our results demonstrated that disinfection of the probe could be achieved only when the needle guide was removed from the TRUS probe. Otherwise, microorganisms that contaminate the surfaces of the probe lumen or outside surfaces of the needle guide will not be exposed to the high-level disinfectant (eg, glutaraldehyde) and may sur-

vive the disinfection process, resulting in a risk of patient infection.

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