Ultrasound in Med. & Biol., Vol. ■, No. ■, pp. 1–4, 2017

0301-5629/$ - see front matter

http://dx.doi.org/10.1016/j.ultrasmedbio.2017.01.002

● *Technical Note*

GUIDELINES FOR CLEANING TRANSVAGINAL ULTRASOUND TRANSDUCERS BETWEEN PATIENTS

JACQUES S. ABRAMOWICZ,* DAVID H. EVANS,† J. BRIAN FOWLKES,‡ KAREL MARŠAL,§ and GAIL TERHAAR¶ ON BEHALF OF THE WFUMB SAFETY COMMITTEE

*Department of Obstetrics and Gynecology, University of Chicago, Chicago, Illinois, USA; †Department of Cardiovascular Sciences (Emeritus), School of Medicine, University of Leicester, UK; ‡Basic Radiologic Sciences Division, Department of Radiology, University of Michigan Health System, Ann Arbor, Michigan, USA; §Department of Obstetrics and Gynecology (Emeritus), Lund University, University Hospital, Lund, Sweden; and ¶Therapy Ultrasound, Division of Radiotherapy & Imaging, Joint Department of Physics, Royal Marsden Hospital, Institute of Cancer Research, Sutton, Surrey, UK

(*Received* 1 *January* 2017; *in final form* 5 *January* 2017)

Abstract—The purpose of this article is to provide guidance regarding the cleaning and disinfection of transvaginal ultrasound probes. These recommendations are also applicable to transrectal probes. (E-mail: Jabramowicz@bsd.uchicago.edu) **© 2017 World Federation for Ultrasound in Medicine & Biology.**

Key Words: **Infection control, Ultrasound, Transducer cleaning.**

INTRODUCTION

Transvaginal ultrasound (TVUS) transducers (also designated as *endovaginal probes* in some countries) are routinely used in clinical obstetrics and gynecology. Strict decontamination is essential between patients because these transducers may come into contact with mucous membranes. The main pathogens of concern are human immunodeficiency virus (HIV), cytomegalovirus (CMV), human papillomavirus (HPV), enteric gram-negative pathogens (*e.g., Escherichia coli*, *Klebsiella* spp.), for both transvaginal and transrectal ultrasound examinations. In addition, specific concerns include gonorrhea and syphilis for TVUS and *Clostridium difficile* for transrectal ultrasound (Leroy 2013).

CLASSIFICATION OF MEDICAL DEVICES ACCORDING TO INFECTION RISK

Medical devices may be classified according to the infection risk they present. Systems used for this purpose include the original 1957 classification: non-critical, semi-critical and critical (Spaulding 1957), also referred to as low risk, medium risk and high risk (McDonnell and Burke 2011). Accordingly, cleaning of these instruments between uses depends on the aforementioned classification status and ranges from simple wiping to sterilization.

Non-critical devices pose the lowest risk to patients, because the only contact is with intact skin (such as abdominal probes). Low- or intermediate-level disinfection is recommended. Most bacteria (but not bacterial spores) and fungi, as well as certain types of viruses, including human immunodeficiency virus (HIV), will be eradicated. If added decontamination is desired (for a wider range of viruses and mycobacteria), additional use of disinfectants, such as alcohol, aldehyde, phenolic and quaternary ammonium compound-based disinfectants, is recommended (McDonnell and Burke 2011). This represents mid-level disinfection (inactivation of bacteria, most viruses, most fungi, *Mycobacterium tuberculosis* and some bacterial spores).

Semi-critical devices are those that pose a higher risk because of contact with non-intact skin or mucous membranes (as is the case with TVUS probes). High-level disinfection with destruction/removal of all microorganisms except bacterial spores is recommended using various chemical components (see details below).

"*Critical devices*" pose the highest risk. They are used in sterile body areas, such as the intravascular space. Sterilization of these devices is imperative.

Transvaginal ultrasound transducers are categorized as semi-critical or medium risk (Leroy 2013). The real risk of infection associated with TVUS transducers

Address correspondence to: Jacques S. Abramowicz, Department of Obstetrics and Gynecology, University of Chicago, 5841 South Maryland Avenue Chicago, IL 60637, USA. E-mail: Jabramowicz@bsd.uchicago.edu

used without a protective covering or decontamination is unknown. No case of related specific infection (cross-contamination between patients) has been reported in the literature, but ultrasound transducers can become contaminated with bacterial pathogens and, hence, are a potential vector for transfer of microorganisms (Fowler and McCracken 1999; Ohara et al. 1998). It is the recommendation of experts that specific measures be taken to avoid such an occurrence (Westerway et al. 2014). Given the fact that transducers should routinely be encased in a disposable probe cover, the risk may be considered less critical. However, leakage rates of 0.9%–2% for condoms and 8%–81% for commercial probe covers have been reported (Chalouhi et al. 2009; Rooks et al. 1996). These are relatively old studies and numbers may be different today, but the only more recent publication indicated a 9% risk of condom perforation in patients undergoing transrectal biopsy under ultrasound guidance (Masood et al. 2007), and recent data comparing the two types of covers are not available. The presence of human papillomavirus has been reported after low-level disinfection (Casalegno et al. 2012). Therefore, high-level disinfection of the transducer between uses is required. A new condom or probe cover should be applied after each use of the instrument, for a new patient (American Institute of Ultrasound in Medicine [AIUM] 2009). Review of clinical practices reveals various protocols, many of which are considered inadequate (Gray et al. 2012). Often, failures in eradication of microorganisms result from poor education and non-optimal adherence to reprocessing guidelines or protocols (Ofstead et al. 2010). An additional consideration is the fact that the transducer handle and cable can also become contaminated and may also require disinfection (Alfa 2015) (see below).

RECOMMENDATIONS

After a patient has been examined, and before the TVUS transducer is used in the next patient, the following procedures should be performed: (i) removal of the transducer cover, (ii) transducer cleaning, (iii) transducer disinfection, and (iv) application of new transducer cover.

After removal of the transducer cover, the transducer is cleaned. Running water is usually sufficient to remove any residual gel or debris from the transducer. Additionally, a damp soft cloth with a small amount of mild non-abrasive liquid soap (such as household dishwashing liquid) may be used, followed by running water. A paper towel or soft cloth should be used to dry the transducer. The additional use of a high-level disinfectant will ensure further reduction in microbial load, and because of potential leakage of the protective sheath (see above), high-level disinfection is recommended. The disinfection method may need to be adapted to local conditions, with the assistance from infection control authorities. High level disinfectants recommended by various ultrasound manufacturers include:

- Glutaraldehyde 2.4%–3.2% products, such as Cidex (Advanced Sterilization Products, ASP, a division of Cilag International, a Johnson & Johnson company, New Brunswick, NJ, USA), Metricide (Metrex Research, Orange, CA, USA)] and Procide (Medline Industries, Mundelein, IL, USA). Mode of action is powerful binding of the aldehyde to the outer cell wall of the organism. These products are sporicidal, bactericidal, fungicidal, tuberculocidal and virucidal and has been found to achieve high-level disinfection in 20 min at 20°C and to be long-lasting and reusable for up to 14 days when monitored with CIDEX Solution Test Strips. These products have mostly been replaced by the next type of product.
- Non-glutaraldehyde agents such as Cidex OPA (*o*-phthalaldehyde). The mechanism of action of *o*-phthalaldehyde is similar to that of glutaraldehyde. It achieves high-level disinfection in 5 min at 20°C and has long-lasting efficacy (reusable for up to 14 days when monitored with CIDEX OPA Test Strips). The Advantages over the glutaraldehyde agents are its mild odor and its lack of a requirement for activation or mixing, thus reducing handling. Furthermore, it has low vapor pressure for minimal inhalation exposure risk.
- Chlorine dioxide, used extensively in the United Kingdom and Australia (Tristel Trio and Duo, Tristel Solutions Unit 1B, Snailwell, UK), acts as an oxidizing agent. It reacts with several cellular constituents, including the cell membrane of microorganisms and has sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal efficacy. Chlorine dioxide has been proven effective against microorganisms of concern in ultrasound, such as hepatitis B and C, HIV, human herpesvirus, simian virus 40 (surrogate of human papillomavirus), *Candida albicans, Aspergillus* spp., *Staphylococcus aureus, Pseudomonas aeruginosa, Bacillus* spp., *Clostridium difficile*, *Mycobacterium tuberculosis*, *Mycobacterium avium*, *Neisseria gonorrhoeae*, *Gardnerella vaginalis*, *Streptococcus agalactiae* and *Acanthamoeba castellanii* (one of the causative organisms of *Acanthamoeba* keratitis). The use is relatively simple with (i) a pre-decontamination wipe for gross contamination with a tissue impregnated with an enzymatic detergent; then (ii) use of another wipe which is effective in 30 s against all organisms mentioned above; and (iii) a rinse wipe that is a sterile packed, non-woven tissue impregnated with de-ionized water. It has been reported to be very effective in high-level disinfection of flexible endoscopes (Coates 2001) and

nasendoscopes (Hitchcock et al. 2016) and would, presumably, be equally effective in TVUS probes. It should be noted that both these studies were supported by a grant from Tristel Solutions (Snailwell, UK), but according to authors, Tristel Solutions had no role in the study design, data analysis, interpretation of results or manuscript preparation. A slightly simpler method, by the same manufacturer, consists of using a tissue impregnated with citric acid onto which is applied an activator solution (sodium chlorite), under a foam form. When mixed, chlorine dioxide chemistry is generated.

- Hydrogen peroxide 7.5% solution works by producing destructive hydroxyl free radicals. These attack membrane lipids, DNA and other essential cell components. Hydrogen peroxide is active against a wide range of microorganisms, including bacteria, yeasts, fungi, viruses and spores.
- Common household bleach (5.25% sodium hypochlorite) diluted to yield 500 ppm chlorine (10 mL in 1 L of tap water), although effective, IS NOT recommended by manufacturers because of potential damage to metal and plastic parts of the transducer.

The labels on these various chemicals and manufacturer's recommendations for cleaning TVUS probes should be consulted. A list of U.S. Food and Drug Administration (FDA)-approved disinfectants for reusable medical devices is available (FDA 2015). A similar document was issued by the International Organization for Standardization (2004).

Caution is necessary when handling some of these chemical disinfectants (*e.g.*, Cidex) because they are potentially toxic and many require precautions such as adequate ventilation, personal protective wear (gloves, face/eye protection, *etc.*) and thorough rinsing before re-use of the transducer (see label for specific instructions). As a further caution, Most systems for chemical disinfection are such that the transducer handle is not in the solution and may remain contaminated, a risk for the end-user, as well as the patient (Buescher et al. 2016).

Recent studies have reported the persistence of HPV viruses with many of the traditionally accepted methods of disinfection described above (Ma et al. 2012; Meyers et al. 2014; Ryndock et al. 2016). In addition, there may be lapses in training and lack of adherence to protocols (if they exist) regarding recommended methods of transducer disinfection. The Centers for Disease Control and Prevention (2015) issued an alert regarding this specific issue in September 2015. Therefore, alternative methods may have to be implemented.

One such method for sterilizing the probe is shortwave ultraviolet radiation (UVC, 200–280 nm) technology (Kac et al. 2010). After the transducer is cleaned with a towel/wipe impregnated with a disinfectant spray, UVC light is applied for 10 min. This results in rapid and complete eradication of bacteria and viruses. The entire transducer is enclosed in the commercially available appliances; hence, the handle is also disinfected. This technology, however, may not be available in many regions of the world, and human exposure to UVC light levels above recommended limits may cause erythema and keratoconjunctivitis.

A newly commercialized chemical method for high-level disinfection (Trophon EPR, Nanosonics, Alexandria, NSW, Australia) is based on an automated and closed system. It has been shown to be effective against all: *Clostridium difficile*; methicillin-resistant *Staphylococcus aureus* (MRSA, responsible for several difficult-to-treat infections); vancomycin-resistant *Enterococcus* (VRE); *Mycobacterium terrae* (surrogate pathogen for *Mycobacterium tuberculosis*); *Staphylococcus aureus* (one of the five most common causes of health care-acquired infections); *Pseudomonas aeruginosa* (a most common component of biofilms, highly resistant to antibiotics), *Salmonella choleraisuis*; *Mycobacterium avium* (opportunistic pathogen affecting immune compromised patients and extremely difficult to control); *Geobacillus stearothermophilus* (heat-resistant microorganism); *Clostridium sporogenes* (anaerobic bacterium, highly resistant to heat, drying, toxic chemicals and detergents); *Bacillus subtilis* (protective endospore allows it to survive under extreme anaerobic or aerobic conditions); *Aspergillus niger*; *Trichophyton* mentagrophytes (one of the leading causes of hair, skin and nail infections in humans and difficult to control using chemicals); *Candida albicans* (causal agents of opportunistic oral and genital infections in humans); poliovirus (enterovirus recognized as the most resilient of viruses to disinfect., including HPV) (Johnson et al. 2013; Vickery et al. 2014). The process is tolerable, very efficient, rapid (approximately 7 min), environmentally friendly and quality-ensured and disinfects the transducer handle (Ngu et al. 2015). Of note, several of the referenced studies (Johnson et al. 2013; Meyers et al. 2014; Ngu et al. 2015; Ryndock et al. 2016; Vickery et al. 2014) were supported by grants from a commercial company (Nanosonics).

It is important to remember that regular household detergent wipes are used by many practitioners, but are not considered high-level disinfectants and can damage transducers.

The transducer should be covered with a barrier. This can be a commercially available condom or a dedicated commercial probe cover. Condoms should be non-lubricated and non-medicated. Condoms have been found to be less vulnerable to leakage than commercial probe covers (see above) and are superior to standard examination gloves and equivalent to surgical gloves. One needs to be

cautious of latex allergy. Some recommend a double cover when there is concern that disinfection is less than optimal.

Additional precautions

The ultrasound machine keyboard should undergo low-level disinfection after each examination. The transducer holder (if used) and the gel container should undergo low-level disinfection at the beginning and end of each day.

CONCLUSIONS

Removal of transducer cover (step 1), cleaning of the transducer (step 2) and application of a new transducer cover (step 4) are steps that are absolutely required. Disinfection (step 3) is also mandatory, and the method to be used should be discussed with local infection control authorities.

REFERENCES

American Institute of Ultrasound in Medicine (AIUM). Practice guideline for ultrasonography in reproductive medicine. J Ultrasound Med 2009;28:128–137.

Alfa MJ. Intra-cavitary ultrasound probes: Cleaning and high-level disinfection are necessary for both the probe head and handle to reduce the risk of infection transmission. Infect Control Hosp Epidemiol 2015;36:585–586.

Buescher DL, Mollers M, Falkenberg MK, Amler S, Kipp F, Burdach J, Klockenbusch W, Schmitz R. Disinfection of transvaginal ultrasound probes in a clinical setting – comparative performance of automated and manual reprocessing methods. Ultrasound Obstet Gynecol 2016;47:646–651.

Casalegno JS, Le Bail Carval K, Eibach D, Valdeyron ML, Lamblin G, Jacquemoud H, Mellier G, Lina B, Gaucherand P, Mathevet P, Mekki Y. High risk HPV contamination of endocavity vaginal ultrasound probes: An underestimated route of nosocomial infection? PLoS One 2012;7:e48137.

Centers for Disease Control and Prevention (CDC). CDC Health Update. HAN00383 CDC/FDA Health Update about the immediate need for healthcare facilities to review procedures for cleaning, disinfecting, and sterilizing reusable medical devices. Atlanta: Author; 2015.

Chalouhi GE, Salomon LJ, Marelle P, Bernard JP, Ville Y. [Hygiene in endovaginal gynecologic and obstetrical ultrasound in 2008]. J Gynecol Obstet Biol Reprod (Paris) 2009;38:43–50.

Coates D. An evaluation of the use of chlorine dioxide (Tristel One-Shot) in an automated washer/disinfector (Medivator) fitted with a chlorine dioxide generator for decontamination of flexible endoscopes. J Hosp Infect 2001;48:55–65.

Food and Drug Administration (FDA). Reprocessing medical devices in health care settings: Validation methods and labeling; guidance for industry and Food and Drug Administration staff; availability. Docket No. FDA-2011-D-0293. Document No. 2015-06029. Fed Regist 2015;80:13864–13865.

Fowler C, McCracken D. US probes: Risk of cross infection and ways to reduce it—Comparison of cleaning methods. Radiology 1999;213:299–300.

Gray RA, Williams PL, Dubbins PA, Jenks PJ. Decontamination of transvaginal ultrasound probes: review of national practice and need for national guidelines. Clin Radiol 2012;67:1069–1077.

Hitchcock B, Moynan S, Frampton C, Reuther R, Gilling P, Rowe F. A randomised, single-blind comparison of high-level disinfectants for flexible nasendoscopes. J Laryngol Otol 2016;130:983–989.

International Organization for Standardization (ISO). Sterilization of medical devices: Information to be provided by the manufacturer for the processing of resterilizable medical devices. Geneva: Author; 2004. ISO 17664.

Johnson S, Proctor M, Bluth E, Smetherman D, Baumgarten K, Troxclair L, Bienvenu M. Evaluation of a hydrogen peroxide-based system for high-level disinfection of vaginal ultrasound probes. J Ultrasound Med 2013;32:1799–1804.

Kac G, Podglajen I, Si-Mohamed A, Rodi A, Grataloup C, Meyer G. Evaluation of ultraviolet C for disinfection of endocavitary ultrasound transducers persistently contaminated despite probe covers. Infect Control Hosp Epidemiol 2010;31:165–170.

Leroy S. Infectious risk of endovaginal and transrectal ultrasonography: Systematic review and meta-analysis. J Hosp Infect 2013;83:99–106.

Ma ST, Yeung AC, Chan PK, Graham CA. Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department. Emerg Med J 2012;30:472–475.

Masood J, Voulgaris S, Awogu O, Younis C, Ball AJ, Carr TW. Condom perforation during transrectal ultrasound guided (TRUS) prostate biopsies: A potential infection risk. Int Urol Nephrol 2007;39:1121–1124.

McDonnell G, Burke P. Disinfection: Is it time to reconsider Spaulding? J Hosp Infect 2011;78:163–170.

Meyers J, Ryndock E, Conway MJ, Meyers C, Robison R. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. J Antimicrob Chemother 2014;69:1546–1550.

Ngu A, McNally G, Patel D, Gorgis V, Leroy S, Burdach J. Reducing transmission risk through high-level disinfection of transvaginal ultrasound transducer handles. Infect Control Hosp Epidemiol 2015;36:581–584.

Ofstead C, Wetzler H, Snyder A, Horton R. Endoscope reprocessing methods: A prospective study on the impact of human factors and automation. Gastroenterol Nursing 2010;33:304–311.

Ohara T, Itoh Y, Itoh K. Ultrasound instruments as possible vectors of staphylococcal infection. J Hosp Infect 1998;40:73–77.

Rooks VJ, Yancey MK, Elg SA, Brueske L. Comparison of probe sheaths for endovaginal sonography. Obstet Gynecol 1996;87:27–29.

Ryndock E, Robison R, Meyers RC. Susceptibility of HPV16 and 18 to high level disinfectants indicated for semi-critical ultrasound probes. J Med Virol 2016;88:1076–1080.

Spaulding E. Chemical disinfection and antisepsis in the hospital. Hosp Res 1957;9:5–31.

Vickery K, Gorgis VZ, Burdach J, Patel D. Evaluation of an automated high-level disinfection technology for ultrasound transducers. J Infect Public Health 2014;7:153–160.

Westerway S, Basseal J, Brockway A, Hyett J, Carter D. Potential risks associated with an ultrasound examination: a microbial perspective [abstract]. Ultrasound Obstet Gynecol 2014;44(S1):332.