A proposal to reduce the risk of transmission of human papilloma virus via transvaginal ultrasound

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The problem

Commonly used disinfectants glutaraldehyde and orthophthalaldehyde have negligible activity against human papilloma virus, and commercial ultrasound probe covers have high rates of leakage, so there is a potential for transmission of human papilloma virus by transvaginal ultrasound examination if these methods are used.

A solution

Disinfection of internal-use ultrasound probes with sonicated hydrogen peroxide (H_2O_2) and covering them with condoms during examinations will greatly reduce the potential for human papilloma virus transmission.

Three steps must be followed to prevent the transmission of infection via a contaminated transvaginal ultrasound probe: cleaning the probe after every use, high-level disinfection, and covering the probe with a single-use barrier during the examination. There may be critical flaws in at least 2 of these steps as they are currently practiced. First, 2 widely used disinfectants, glutaraldehyde and orthophthalaldehyde, have recently been found to be ineffective at neutralizing human papilloma virus type 16 and type 18. Second, commercial ultrasound probe covers have an unacceptable rate of leakage (8–81%) compared to condoms (0.9–2%). We recommend the use of a sonicated hydrogen peroxide disinfectant system rather than aldehyde-type disinfectants. We recommend that the probe be covered with a condom rather than a commercial probe cover during transvaginal ultrasound examination. Combined with probe cleaning, these 2 steps are estimated to result in an 800 million- to 250 billion-fold reduction in human papilloma virus viral load, which should translate to greatly enhanced patient safety.

Key words: disinfection, human papilloma virus, nosocomial infection, patient safety, sterilization, ultrasound safety, vaginal ultrasound

Introduction

The safety of transvaginal ultrasound depends critically on procedures to reduce the risk of transmission of microbes from patient to patient or from provider to patient. Guidelines from the American Institute of Ultrasound in Medicine[1] recommend 3 steps to reduce this risk: (1) the endovaginal probe must undergo a thorough cleaning after each use; (2) after cleaning, the probe must undergo high-level disinfection with an approved disinfectant; and (3) the probe must be covered by a single-use barrier during the examination.

Recent evidence suggests that there may be critical flaws in 2 of these steps as currently performed by many practices. Specifically, 2 widely used disinfectant solutions (glutaraldehyde and orthophthalaldehyde) appear to have virtually no virucidal activity against human papilloma virus types 16 and 18.[2,3] Furthermore, commercial ultrasound probe covers have reported leakage rates of 8–81%.[1] These 2 flaws combined may result in a high risk of human papilloma virus transmission if practices use glutaraldehyde or orthophthalaldehyde in combination with commercial probe covers.

Human papilloma virus is the most prevalent sexually transmitted infection in the United States, affecting more than 8 million reproductive-age women.[4,5] Human papilloma virus 16 and human papilloma virus 18 are responsible for about 70% of cervical cancers worldwide.[5,6] It has been known for years that this nonenveloped, capsid virus retains its infectivity for days or weeks on environmental surfaces, including medical equipment, and is highly resistant to low-level disinfection procedures.[7,8] But newer studies show that human papilloma virus is also resistant to glutaraldehyde and orthophthalaldehyde,[2,3] which are considered high-level disinfectants.

In this review, we aim to alert ultrasound providers about potential pitfalls in common disinfection and probe-covering practices and to suggest safer alternative practices. Although there have not been proven cases of iatrogenic human papilloma virus transmission via infected ultrasound probes,[9] isolated cases would be difficult or impossible to prove, even if iatrogenic transmission were suspected. Patient safety requires that we adopt the safest practices to prevent such infection before any cases occur. We must not wait for cases to be proven before we abandon suboptimal practices.

Step 1: cleaning

Cleaning is defined by a guideline from the Centers for Disease Control and Prevention[10] and quoted by the American Institute of Ultrasound in Medicine guidelines[1] as:

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> "… the removal of visible soil (eg, organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic material that remains on the surfaces of instruments interfere with the effectiveness of these processes."

The American Institute of Ultrasound in Medicine guidelines[1] recommend cleaning with quaternary ammonium sprays or wipes, running water, liquid soap, and/or a brush to clean crevices and angulations, although they do not specify a single preferred combination or order for these methods. The guidelines[1] estimate that cleaning results in a 99% reduction in microbial load on the surface of the transducer, but this may be optimistic.[7]

Step 2: high-level disinfection

The American Institute of Ultrasound in Medicine and the Centers for Disease Control and Prevention guidelines[1,10] describe several levels of disinfection and sterilization:

> "Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores.
>
> Low-level disinfection—destruction of most bacteria, some viruses, and some fungi. Low-level disinfection will not necessarily inactivate *Mycobacterium tuberculosis* or bacterial spores.
>
> Midlevel disinfection—inactivation of *Mycobacterium Tuberculosis*, bacteria, most viruses, most fungi, and some bacterial spores.
>
> High-level disinfection—destruction/removal of all microorganisms except bacterial spores.
>
> Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health care facilities by physical or chemical methods."

The American Institute of Ultrasound in in Medicine guidelines[1] also specify the level of cleaning and/or disinfection required for different types of devices:

> Critical instruments: devices intended to penetrate skin or mucous membranes (eg, surgical instruments) require sterilization.
>
> Semicritical instruments: devices that come into contact with mucous membranes (eg, vaginal ultrasound probes) require high-level disinfection.
>
> Noncritical devices that come into contact with intact skin but not mucous membranes (eg, external ultrasound probes) require only cleaning.

The US Food and Drug and Drug Administration lists a variety of sterilants and high-level disinfectants.[11] Commercial ultrasound probe-cleaning systems using glutaraldehyde, orthophthalaldehyde, and H_2O_2 are marketed in the United States under various brand names.

Two recent studies investigated the efficacy of various high-level disinfectants against human papilloma virus 16 and human papilloma virus 18. In the first study, human papilloma virus 16 was mixed with several disinfectants and incubated for 45 minutes.[2] Only peracetic acid-silver and hypochlorite significantly inactivated human papilloma virus 16 (5.2 and 4.8 $\log_{10}$ reduction in viral load, respectively). Glutaraldehyde and orthophthalaldehyde were ineffective at various concentrations (<0.02 $\log_{10}$ reductions), as were ethanol, isopropanolol, and phenol. The 45 minute incubation time was much longer than the 12 minute soaking time recommended in commercial probe-cleaning systems using glutaraldehyde and orthophthalaldehyde.

In the second study,[3] a solution containing human papilloma virus 16 or human papilloma virus 18 was spread onto a carrier made of the type of plastic used to make utrasound probes. After air drying, the carriers were treated with a hypochlorite or an orthophthalaldehyde disinfection system (Cidex orthophthalaldehyde; Advanced Sterilization Products, Irvine, CA) or an sonicated H_2O_2 system (Trophon EPR; Nanosonics, Lane Cove, Australia) according to the manufacturer's instructions. The hypochlorite and sonicated H_2O_2 systems both showed strong virucidal activity (4.6—5.0 and 5.2—7.4 $\log_{10}$ reductions in viral load, respectively), but the orthophthalaldehyde system did not (0.4 and 0.5 $\log_{10}$ reductions of human papilloma virus 16 and human papilloma virus 18, respectively).

The Food and Drug and Drug Administration's listing of glutaraldehyde and orthophthalaldehyde as high-level disinfectants is based on extensive testing demonstrating that these agents are effective against a variety of microbes. To demonstrate disinfectant efficacy against nonenveloped viruses, the Food and Drug and Drug Administration requires testing against poliovirus. However, one cannot extrapolate to assume that disinfectants are effective against all viruses. As stated by Meyers et al,[2] "Presently, hospitals' and other health care institutes' use of disinfectants to inactivate human papilloma virus is based on what is used for other viruses or simply on what someone thinks should be effective."

At present, the only system for high-level ultrasound probe disinfection with specific, proven efficacy against human papilloma virus is the sonicated H_2O_2 system, which treats the probe with a mist of H_2O_2 nanodroplets.

We are aware of another H_2O_2 system that involves soaking the probe rather than treating with a mist. We have 2 reservations about H_2O_2 soaking. First, at present, we do not have empiric evidence that soaking is actually effective against human papilloma virus. Second, unlike the sonicated H_2O_2 system, the soaking system disinfects only the transducer head, not the probe handle. Disinfection of the handle has been advocated as an important step in reducing risk of infection transmission[12,13] because the handle is not covered by many probe covers and may

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