Infections Associated with Use of Ultrasound Transmission Gel: Proposed Guidelines to Minimize Risk

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COMMENTARY

Infections Associated with Use of Ultrasound Transmission Gel: Proposed Guidelines to Minimize Risk

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Ultrasound transmission gel (USTG) is used in a variety of healthcare settings for both diagnostic and interventional procedures. Its potential role as a vehicle for spread of infections to patients is frequently overlooked. It has been shown on multiple occasions that USTG can become contaminated with bacteria, leading to significant outbreaks of infection among patients.[1-7] It is incumbent upon all medical professionals to be aware of the potential risks these products pose to patients. Manufacturers of USTG should label products clearly as to their intended use. Producers of medical devices where USTG is likely to be used should provide explicit instructions on the type of USTG recommended and methods of use. Finally, standardized professional society guidelines would enhance patient safety and improve outcomes. On the basis of our recently described outbreak of infections associated with intrinsically contaminated ultrasound gel[7] and a review of all other clusters, we would like to describe the differences between gels and propose guidelines for use of both nonsterile and sterile ultrasound gel.

USTG is available from multiple manufacturers and comes in a variety of formulations and dispenser sizes, often without clearly defined differences between products or suggested uses. A review of one manufacturer's website found 6 separate USTGs available for purchase, although it was not made clear what significant differences existed between products or if there were specific intended uses for them.[8] Although these gels are often considered bacteriostatic because of components such as parabens or methyl benzoate, one study demonstrated that an ultrasound gel had no intrinsic antimicrobial properties and could function as a medium for bacterial growth.[9] *Pseudomonas aeruginosa*, *Escherichia coli*, and *Staphylococcus aureus* were all demonstrated to survive in USTG in another in vitro study.[10] The term "bacteriostatic" should not be used unless the product meets defined requirements to prove this.

Contaminated USTG has been associated with outbreaks of infection due to a variety of procedures and microorganisms (Table 1).[1-6] In all circumstances, the outbreaks were aborted after a switch to single-dose sterile gel.

Our more recent report of cases of respiratory infections and colonizations with *P. aeruginosa* strongly suggested that gel contaminated at or around the time of manufacture was associated with infections.[7] In this series, 16 patients were found to have *P. aeruginosa* in their respiratory tract after undergoing cardiovascular surgery. Laboratory isolates for 10 patients were saved, and all 10 proved to be more than 99% similar by molecular typing via repetitive extragenic palindromic polymerase chain reaction (rep-PCR). This surgery included the use of an intraoperative transesophageal echocardiogram (TEE) that utilized USTG as a conducting agent. The TEE probes were culture negative, but cultures of in-use multidose bottles of gel as well as sealed, unopened bottles of gel grew *P. aeruginosa*, which were also more than 99% similar to the outbreak strain by rep-PCR.

Procedures utilizing USTG can range from noninvasive studies (such as transthoracic echocardiography, bladder scans, and vascular scans), to those with mucous membrane contact (such as TEE and transvaginal ultrasonography), to frankly invasive procedures (such as transrectal prostate biopsy [TRPB], thyroid biopsy, epiaortic ultrasonography [EAU], and stereotactic breast biopsies). As such, the Spaulding classification scheme[11] can be applied to guide clinicians in making decisions regarding proper disinfection and sterilization of devices on the basis of the risk of infection involved with use of the item. By this scheme, scanning devices used for noninvasive procedures could be considered "noncritical devices" because of their contact with intact skin. Likewise, diagnostic studies using TEE or TRPB would require "semicritical" disinfection because of contact with mucous membranes. EAU transducers are required to be sterile, as they are introduced directly into the surgical field.

On the basis of the Spaulding classification scheme, how does one define the appropriate use of USTG for procedures? Any procedure involving sterile skin preparation would likely also require sterile USTG. Sterility is not a necessary require-

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TABLE 1. Ultrasound Transmission Gel–Related Outbreaks in Hospitals

Study, year	Type of facility	Risk factors	Patient population	Organism	Contamination[a]	No. of cases
Chittick et al,[7] 2012	University-affiliated hospital	TEE	Cardiovascular surgery patients	*Pseudomonas aeruginosa*	Intrinsic	16
Olshtain-Pops et al,[1] 2011	University-affiliated hospital	TRPB	Urology patients	*Achromobacter xylosoxidans*	Unknown	4
Jacobson et al,[6] 2006	University-affiliated hospital	Urodynamic; TTE; Doppler BP	Pediatric patients	*Burkholderia cepacia*	Unknown/ intrinsic	Sustained endemicity
Hutchinson et al,[3] 2004	2 distinct university-affiliated hospitals	TRPB	Urology patients	*B. cepacia*	Intrinsic	6
Weist et al,[4] 2000	University-affiliated hospital	Hip joint sonography	Neonatal patients	*Staphylococcus aureus*	Unknown	10
Gaillot et al,[5] 1998	Acute care hospitals	5 TVUS, 1 AUS	OB/GYN, neonatal patients	*Klebsiella pneumoniae,* ESBL producing	Unknown	6 adults, 2 neonates
Keizur et al,[2] 1993	Acute care hospital	TRPB	Urology patients	*B. cepacia*	Unknown	9 possible

NOTE. AUS, abdominal ultrasound; BP, blood pressure; ESBL, extended-spectrum β lactamase; OB/GYN, obstetrics/gynecology; TEE, transesophageal echocardiogram; TRPB, transrectal prostate biopsy; TTE, transthoracic echocardiogram; TVUS, transvaginal ultrasound.
[a] Intrinsic, extrinsic, or unknown.

ment for devices in contact with mucous membranes. However, how to ensure that a type of USTG is safe for a semicritical type of procedure is uncertain. While USTG is generally presumed to be free of bacteria or even bacteriostatic, the above-mentioned studies suggest that this is clearly not always the case. As such, use of a sterile product may be the simplest and safest solution in this scenario and is definitely warranted if any type of puncture, biopsy, or other specimen may be obtained. Use of nonsterile ultrasound gel on intact skin is reasonable, although steps should be taken to ensure that the product being used is not contaminated.

Healthcare-associated infection surveillance and professional infection prevention consultation may be absent or minimal in ambulatory centers, such as freestanding radiology centers or urology clinics. Clusters of infections occurring at low rates may be completely undetected and unrecognized. As such, it is important to establish standardized guidelines for use of USTG and for device manufacturers to include specific labeling. While no such guidelines exist in the United States, Health Canada has published preliminary recommendations on the appropriate use of medical gels, suggesting the use of single-dose sterile gels for invasive procedures that pass through a tissue for all studies involving neonates, for all procedures involving sterile equipment or nonintact skin, and for procedures on intact mucous membranes.[12] We further recommend the following additional guidelines:

- Follow the Centers for Disease Control and Prevention's guidelines for disinfection and sterilization in healthcare facilities when reprocessing imaging scan heads and transducers of all types.[13]
- Single-dose sterile USTG should be used whenever a biopsy or puncture is being performed, regardless of body site. Likewise, single-dose sterile USTG should be used for procedures involving mucous membranes and when scanning nonintact skin or near fresh surgical wounds.
- Single-dose sterile USTG should be used when caring for neonates and critically ill pediatric patients.
- Nonsterile USTG may be used on intact skin (single dose or multidose).
- If multidose containers of nonsterile USTG are used on intact skin, the container must be sealed appropriately when not in use.
- Containers of USTG should never be washed and refilled for use but should be replaced when empty.
- Use of water baths as a warming method for USTG should be done with caution given previously described outbreaks in other circumstances.[14,15] Dry heat is the preferred method for warming.
- Manufacturers of medical devices designed for entry into sterile body sites utilizing ultrasound transducers should recommend that practitioners use sterile USTG.
- USTG manufacturers should provide instructions on appropriate and intended uses of specific products.
- Development of standardized professional society guidelines on the appropriate use of USTG would be helpful to guide healthcare facilities and practitioners.

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