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EXPERT REVIEWS

Sterile working in ultrasonography: the use of dedicated ultrasound covers and sterile ultrasound gel

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Ultrasound is currently an important tool for diagnostic and interventional procedures. Ultrasound imaging provides significant advantages as compared to other imaging methods. The widespread use of ultrasound also carries the risk of drawbacks such as cross-infections. A large body of literature reports this possibly life-threatening side effect and specific patient populations are particularly at risk (e.g., neonates). Various methods of ultrasound probe disinfection are described; however, none of the mechanical or chemical probe disinfection procedures is optimal and, in particular, disinfection with high concentration of alcohol might be associated with ultrasound probe damage. The preparation of ultrasound probes with dedicated probe covers is a useful alternative for sterile working conditions. One ultrasound probe cover discussed in this paper is directly glued on to the ultrasound probe without the use of ultrasound coupling gel. By the use of sterile ultrasound coupling gel at the outer surface, additional effects on aseptic working conditions can be obtained.

KEYWORDS: cross-infection • diagnostic ultrasound • interventional ultrasound • sterility • ultrasound cover • ultrasound transmission gel

Ultrasound has become the most important bedside imaging tool for diagnostic and interventional procedures performed by physicians of all medical specialities. Many steps were required to be taken to reach the present level of quality. The history of ultrasound technology goes back to 1794, when Lazzaro Spallanzani, an Italian priest, philosopher and scientist, explored the navigation method of bats via echolocation. He found that bats emit and receive echo-waves and the time sequence of the received echo-waves enables an orientation in a dark environment (contrary to owls, which are not able to orientate in a dark environment). In 1826, Jean Daniel Colladon, a Swiss physicist, measured the exact speed of ultrasound waves in the water of Lake Geneva as 1435 m/s. In 1880, Pierre and Jacques Curie discovered the Piezo-electric effect and just 1 year later, Gabriel Lippmann, a French physicist and later Nobel Prize award winner, discovered the reversed Piezo-electric effect, which provided the physical principle for ultrasound.

The first practical application of ultrasound was recorded during the First World War, when Paul Langevin, a French physicist, developed a 150 kHz ultrasound transmitter between 1915 and 1918 to detect submarines. Karl Theodor Dussik, a Viennese neurologist, recorded the first medical application of ultrasound in 1942. He called his technique 'hyperphonography', which was thought to visualize brain pathologies. In fact, he misinterpreted artifacts, so this theoretically brilliant concept was clinically useless. Ian Donald, a British gynecologist, was the first to use ultrasound for clinical applications in 1955 to detect ovarian cysts, and Alfred Kratochwil, a Viennese obstetrician, used the application in 1966 to investigate the placenta. Nevertheless, ultrasound at that time was of minor clinical interest and, therefore, no purposeful efforts were taken to make ultrasound popular.

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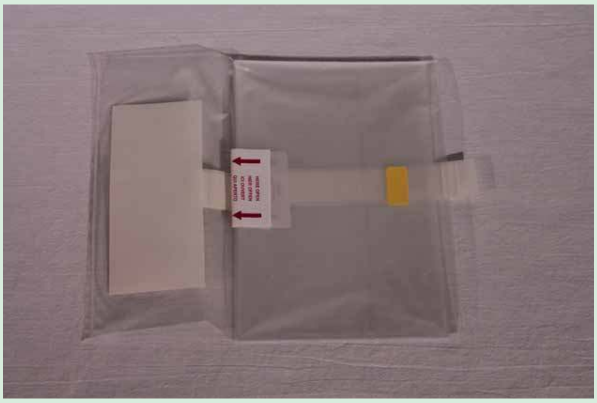

Figure 1. The telescope-folded sterile ultrasound probe cover.

The minimization of technical components was an important promotor to increase the popularity of ultrasound. Large machines were only useful in radiological departments, but the use of ultrasound as a real bedside technique required smaller and mobile equipment. This equipment is available since approximately 15 years and, consequently, more or less all medical specialities use ultrasound as a diagnostic or interventional tool. The spectrum of indications nowadays is extremely broad and the advantages of ultrasound in comparison with other imaging techniques are:

- No radiation exposure
- Fast availability
- Fast diagnostic findings
- Fast therapeutic reaction times
- High diagnostic sensitivity
- High diagnostic specificity (in comparison to conventional radiology)

Beside these advantages, ultrasound is also associated with potential hazards. The quality of ultrasound diagnosis is extremely user-dependent, and therefore, misinterpretation of results can lead to wrong therapeutic consequences. The frequent use of ultrasound equipment is associated with another, so far underestimated, problem: cross-infection between patients. This review article summarizes the current knowledge regarding ultrasound equipment as a source of infection and a useful strategy to keep the ultrasound probes clean. The concept of sterile use for diagnostic and interventional applications is another important step of evolution in ultrasound technology.

Ultrasound for diagnostic & interventional purposes: an underestimated source of infection

WHO identified healthcare-associated infections as the most frequent adverse events in health care in the year 2011 [1]. The prevalence of healthcare-associated infections varies between 3.5 and 12% (7.1% in Europe, 4.5% in USA) in developed countries and between 5.7 and 19.1% in low- to middle-income countries. The annual financial impact has been calculated as €7 billion in Europe and US$ 6.5 billion in USA. It is important to highlight that particular patient populations (e.g., newborns, immunocompromised patients) are at higher risk for healthcare-associated infections. The CDC recognized that critical items such as surgical instruments, cardiac and urinary catheters, and ultrasound probes (used in sterile body cavities) confer a high risk for infection if they are contaminated with microorganisms [2].

Cross-infection between patients have been described since the 19th century, when the Hungarian obstetrician, Ignaz Semmelweis, identified insufficient hand hygiene as the main cause for the extremely high incidence of maternal childbed fever and subsequent maternal mortality [3]. Medical equipment has been identified as a source of infection since more than five decades. Gerken *et al.* described stethoscopes as a potential hazard for infection [4]. Breathnach *et al.* [5] and Kei and Richards [6] confirmed these observations and findings. Ultrasound is nowadays described as the 'new stethoscope' in medicine [7–10], and therefore, this method may be associated with equal sterility problems. Publications in the field of ultrasound and cross-infection are heterogeneous. Spencer and Spencer described a large number of ultrasound probes contaminated with *Staphylococcus aureus* after scanning of postoperative wounds [11]. Frazee *et al.*, who found *S. aureus* (including methicillin-resistant *Staphylococcus aureus* [MRSA]) contaminations in uncovered ultrasound probes, confirmed these findings [12]. Contrary to these previous findings, Sanz *et al.* did not find MRSA contamination on ultrasound probes in an emergency department setting [13]. Bloc *et al.*, who investigated the role of ultrasound probes as a vector of cross-infection during regional anesthetic blockade techniques, performed one of the few prospective studies in this field [14]. Their results suggest a low risk of cross-infection during ultrasound guidance in loco-regional anesthesia. Nevertheless, the evidence regarding ultrasound probes as a possible vector for cross-infection is low and further prospective, randomized trials are required to increase our knowledge in this

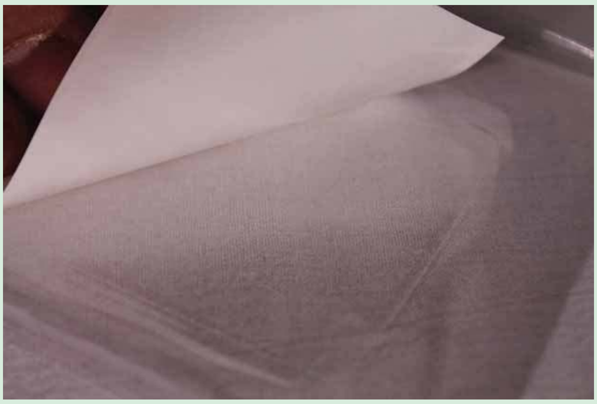

Figure 2. The inner surface of the ultrasound probe cover is equipped with an adhesive component, which can be directly glued to the active area of the ultrasound probe.

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field. Further studies with various scientific methods (e.g., multicenter trials, *in vitro* investigations, etc.) are required to investigate the role of ultrasound probe–based cross-infections.

The role of ultrasound coupling gel in cross-infection is well described, but unfortunately underestimated. Gaillot *et al.* found *Klebsiella pneumoniae* resistant to ceftazidime in six adults and two neonates in the Department of Obstetrics and Gynecology and identified the ultrasound coupling gel as source of infection [15]. An outbreak of methicillin-susceptible *S. aureus* in a neonatal clinic due to contaminated ultrasound coupling gel was described by Weist *et al.* [16]. Another case of cross-infection (*Burkholderia cepacia*) due to ultrasound coupling gel in a pediatric population has been described by Jacobson *et al.* [17]. It seems obvious that the routine use of sterile ultrasound coupling gel is associated with less ultrasound-related cross-infections.

Strategies to keep the ultrasound equipment clean & sterile

Various methods have been described to keep the ultrasound probes clean and/or sterile. In principle, ultrasound probes can be cleaned by dry wiping either alone or followed by wiping with alcohol-based disinfectants. Bello *et al.* [18] and Fowler and McCracken [19] recommend single paper wipe for out-of-hospital patients and double paper wipe for hospitalized patients. Bloc *et al.* recommend double paper wipe for ultrasound-guided peripheral regional anesthetic techniques [14]. Muradali *et al.* suggest the use of a liquid cleaning solution at the end of each working day to increase the margin of safety regarding cross-infections [20]. Karadenz *et al.* suggest a more specified approach by using dry paper cleaning for abdominal ultrasound and cleaning with alcohol for inguinal and axillary ultrasound investigations [21]. Frazee *et al.* describe that skin and environmental flora is frequently present on ultrasound probes, and that MRSA can be reliably removed by the use of a quaternary ammonia germicidal wipe [12]. A different two-step method to disinfect ultrasound probes has been described by Bloc *et al.* where the probes are wiped with a dry and disinfectant-impregnated paper, followed by disinfection with UV-C for 90 s [22].

Wiping ultrasound probes with alcohol (minimum 70%) seems to be an effective method for disinfection. Alcohol is efficient against bacteria, fungi and viruses, but shows lack of sporicidal action. Nevertheless, there is a possibility of ultrasound probe damage by repetitive contact of the sensitive active surface of ultrasound probes with alcohol. Koibuchi *et al.* described a decrease of the brightness of imaging in linear probes after a certain period of alcohol disinfection, whereas the brightness of imaging was not affected in convex ultrasound probes [23,24]. The authors speculate that linear ultrasound probes are more sensitive to alcohol disinfection due to the thinner elements and narrower intervals between the element arrays, as compared with convex ultrasound probes. They also consider that even convex-array ultrasound probes may be damaged after a long period of alcohol disinfection.

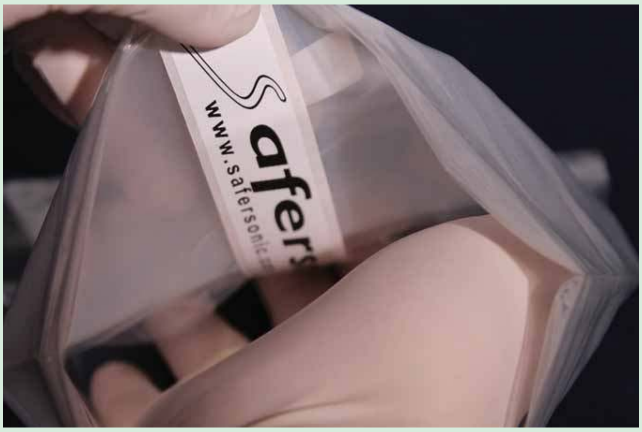

Figure 3. The handling of the ultrasound probe cover is self-explanatory.

Similar to the principal question regarding the role of ultrasound in cross-infections, no scientific evidence is available regarding the optimal cleaning method of ultrasound probes. Sterile ultrasound probe covers seem to be a useful and safe alternative to sterile working conditions during invasive, interventional and non-invasive (diagnostic) ultrasound procedures. Conventional ultrasound probe covers are associated with a possibly decreased ultrasound image quality and problematic handling because ultrasound coupling gel is required between the ultrasound probe and the inner layer of the ultrasound probe cover and between the outer layer of the ultrasound probe cover and the skin. Various sterile ultrasound covers are available (e.g., sterile probe cover, Cone Instruments, 6850 Southbelt Dr., Caledonia, MI 49316, USA; ultrasound probe covers, Access Medical USA, 10440 Belga Dr., San Antonio, TX 78240, USA; ultrasound

Figure 4. Direct attachment of the active area of the ultrasound probe to the adhesive inner surface of the ultrasound probe cover.

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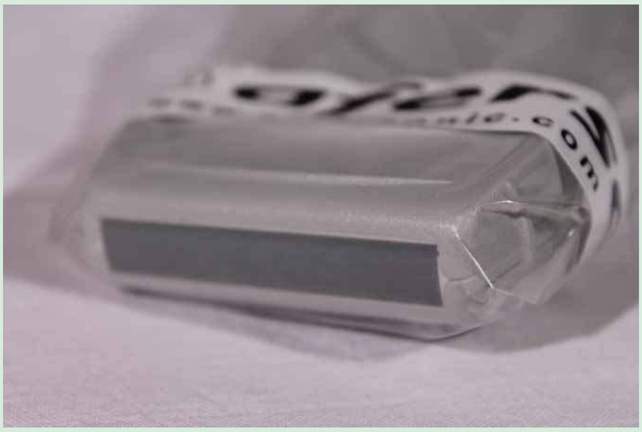

Figure 5. The ultrasound probe prepared in a sterile manner.

probe covers, Civko Medical Solutions, 2301 Jones Blvd., Coralville, IA 52241, USA). All these sterile probe covers require ultrasound coupling gel between the ultrasound probe and the inner surface of the ultrasound probe cover and have the potential disadvantage that wiping of the ultrasound probe is required after the procedure and there is subsequent probe damage due to the cleaning procedure. In addition, the ultrasound image quality might be impaired due to two ultrasound coupling gel layers – one between the ultrasound probe and the inner surface of the ultrasound probe cover and the other one between the ultrasound probe cover and the skin.

The Safersonic™ ultrasound cover & the ultrasound coupling gel

The Safersonic ultrasound cover is CE (0408) and US FDA approved and equipped with an adhesive component which can be directly glued to the ultrasound probe, and therefore, ultrasound coupling gel is only required between the outer layer of the ultrasound cover and the skin. The latex-free polyethylene sleeve is available in three different sizes: 18 × 28 cm (single), 18 × 120 cm (conti) and 18 × 250 cm (long). The adherent surface for direct contact with the ultrasound probe has a size of 6 × 12 cm and fits for all common ultrasound probes. The telescopic folding of the sleeve enables an unproblematic handling.

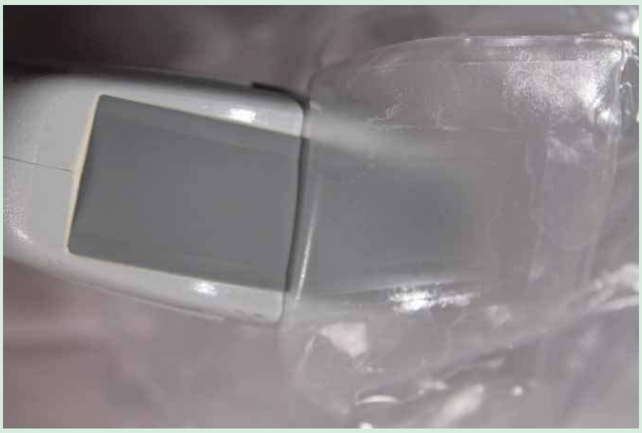

Figure 6. Removal of the ultrasound probe cover.

The ultrasound probe is specified as a class 2a product via ethylenoxid sterilization for 'short-term' (≤30 days continuously or repeatedly) invasive and intraoperative applications. The biocompatibility test series were performed by Bioserv Analytics and Medical Devices GmbH (Dr. – Lorenz-Weg 1, 18059 Rostock, Germany) according to a standardized protocol:

- Intracutane reactivity ('polar extraction' – DIN EN ISO 10993-10): conformed
- Intracutane reactivity ('apolar extraction' – DIN EN ISO 10993-10): conformed
- Allergization ('apolar extraction' – DIN EN ISO 10993-10): conformed
- Allergization ('polar extraction' – DIN EN ISO 10993-10): conformed
- Cytotoxicity (DIN EN ISO 10993-5): conformed

The final evaluation of this medical product did not show toxicological or biological cell damage or cell growth interference (test plan No. 41869-03-022), no allergization (test plan No. 41869-11-123) and no intracutane reactivity (test plan No. 41869-11-122).

Handling of the ultrasound cover is described in Figures 1–4. Figure 5 illustrates the crease-free covering of an ultrasound probe and Figure 6 shows the removal of the ultrasound probe cover from the ultrasound probe without adhesive residues. The adhesive inner contact surface does not damage the ultrasound probe (personal experience of the authors over a period of >5 years) and the decrease in ultrasound image brightness caused by the cover is negligible. The range of costs for the ultrasound probe covers is between €3 and 6 with small variations between different counties.

As previously mentioned, ultrasound coupling gel is a significant factor regarding cross-infection. Therefore, it is recommendable to use sterile ultrasound coupling gel. The Safergel™ is a sterile gel, which consists of water and glycerine without preservatives and has a pH value of 5.8–5.9. The content is 15 g and is equipped with a so-called twist-and-use™ screw cap (Figure 7). The inner side of the tube is aluminum coated to enable an ethylene oxide sterilization process for a gastight primary packaging. Thus, this ultrasound coupling gel can be used as a component for kits.

Expert commentary

Ultrasound imaging for diagnostic and interventional procedures plays an important part in the daily clinical practice. Almost all clinical specialties use ultrasound. The minimization of ultrasound technology was the most important factor for this enormous increase in popularity. As every medical bedside technology, ultrasound is associated with the risk of cross-infection between patients. From a logical point of view, the use of sterile ultrasound probe covers and sterile ultrasound coupling gel avoids cross-infection and protects ultrasound probes. The Safersonic ultrasound probe cover conforms to all the requirements of ultrasound probe covers.

Further research is required to evaluate the possible increased margin of safety regarding sterile working in ultrasound and to investigate the economical balance between avoidance of secondary costs of cross-infection caused by ultrasound and the costs of dedicated ultrasound probe covers. We believe that costs between €3 and 6 per ultrasound probe cover are acceptable to guarantee a safe avoidance of ultrasound-related cross-infection. Every ultrasound-related infection is associated with significant costs and the therapy of hospital-acquired infection is more and more difficult. Thus, sterile working in ultrasonography is a significant contribution to the safety of patients.

Five-year view

The awareness that the current ultrasound practice is a significant factor of cross-infection between patients is still low. The scientific evidence in this context has to be improved. In particular, prospective and multicenter trials are required to increase the understanding of the exact mechanism of ultrasound-related cross-infection. Anyway, the current clinical practice of surface cleaning of ultrasound probes is unreliable and may damage the ultrasound probes. Consequently, the most important next step in this field is to increase the awareness of clinicians regarding sterile working in ultrasonography. Otherwise, this important tool for fast diagnosis and direct imaging during invasive procedures will be associated with disbeliefs. The awareness of clinicians can only be increased with high-level scientific efforts and permanent training. In addition, the economical departments of hospital provider need to be convinced regarding the current best practice for sterile working in ultrasound. The economic implications of cross-infection (not only caused by ultrasound) are huge and the savings through indirect returns of the simple solution of sterile ultrasound probe covers and sterile single-use ultrasound coupling gel are significant.

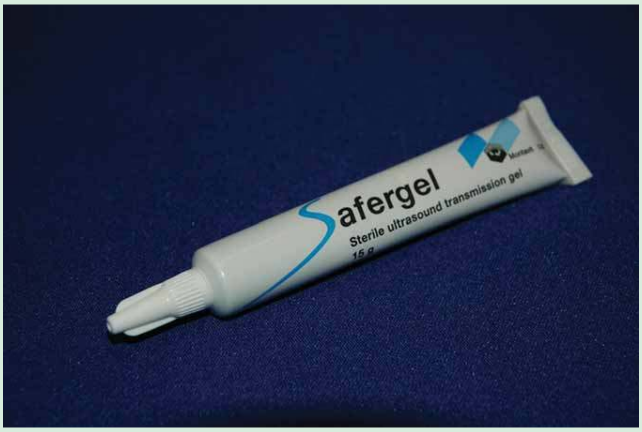

Figure 7. The Safergel™ sterile ultrasound coupling gel with the twist-and-use™ screw cap.

In summary, the important steps to realize sterile working in ultrasonography during the next 5 years are:

- High-level scientific efforts
- Training of all staff who are involved in ultrasound, regarding the best knowledge of sterile working in all fields of ultrasound
- An intensive discussion regarding the economic benefits of sterile ultrasound probe covers and sterile single-use ultrasound coupling gel.

Financial & competing interests disclosure

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Key issues

- Hospital-acquired infection is a serious problem worldwide and WHO and the CDC have recognized this issue. The prevalence of healthcare-associated infections is between 3.5 and 19.1% and the annual financial impact is estimated to be more than €10 billion.
- It is well documented that medical devices can cause cross-infections between patients. Some patient categories are particularly endangered in this context (e.g., neonates, postoperative patients).
- Ultrasound is nowadays the most important bedside diagnostic tool and is used more and more for interventional procedures to increase the safety and efficiency.
- The role of ultrasound equipment as a vector for cross-infection is obvious. Therefore, all efforts should be taken to minimize the risk of cross-infections caused by ultrasound equipments.
- So far, many clinicians have ignored the role of ultrasound equipment as a vector of cross-infection. The awareness of medical staff that all kind of microbes can be transferred via ultrasound probes from one patient to another is still very low.
- Strategies to keep ultrasound probes clean in order to avoid cross-infections are an important further step for the safe and effective application of ultrasound in the daily clinical practice and are equally important as compared to previous technical developments.
- Single-use sterile ultrasound probe covers are cost-effective and prevent cross-infection. The Safersonic™ ultrasound probe cover is Conformité Européenne and US FDA approved and conforms to all requirements for ultrasound probe covers (sterile, latex free, minimal impact on ultrasound image quality, no damage detected of ultrasound probes so far). The adhesive component of the cover enables a direct connection with the ultrasound probe to minimize the probe cover related decrease in image brightness.
- Sterile single-use ultrasound coupling gel is recommended instead of the widely used ultrasound coupling gel in a large, refillable container.
- The concept of providing sterile ultrasound probe covers in combination with sterile single-use ultrasound coupling gel in a set is promising in reducing the cross-infections caused by ultrasound.

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