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AD-41-25 REV 1

Comparison of Low-Level to High-Level Disinfection in Eliminating Microorganisms From Ultrasound Transducers Used on Skin

A Noninferiority Randomized Controlled Trial

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Research grant funding received from the Australasian Society for Ultrasound in Medicine.

Nathan Peters, Frances Williamson, Michelle J Bauer, Stacey Llewellyn, Peter J Snelling, Adam G Stewart: None to declare. Nicole Marsh: Griffith University and the University of Queensland have received on her behalf speaker fees from 3 M and investigator-initiated research grants from 3 M, Becton Dickinson, Eloquest and Cardinal Health, (unrelated to the current project). Patrick N. A. Harris has served on advisory boards for OpGen, Sandoz and MSD; has received research grants from Merck, Sandoz and Shionogi and has received speaker's fees from Pfizer, Novartis and Sandoz, paid to the University of Queensland. Claire M. Rickard: Employer (Uni of Queensland or Griffith University) has received research or consultancy funding on her behalf from 3 M, BBraun, BD, Cardinal Health, Eloquest, ITL Biomedical (unrelated to this project).

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Abbreviations

CFU, colony forming unit; HBA, horse blood agar; HLD, high level disinfection; LLD, low level disinfection; US, ultrasound

doi:10.1002/jum.16286

Introduction—There is a lack of international consensus as to whether high- or low-level disinfection (HLD or LLD) is required for ultrasound (US) transducers used during percutaneous procedures. This study compared the effectiveness of LLD to HLD on US transducers contaminated with microorganisms from skin.

Methods—Two identical linear US transducers repeatedly underwent either LLD or HLD during the study. Randomization determined which of these transducers was applied to left and right forearms of each participant. Swabs taken from transducers before and after reprocessing were plated then incubated for 4–5 days, after which colony forming units (CFU) were counted and identified. The primary hypothesis was the difference in the proportion of US transducers having no CFUs remaining after LLD and HLD would be less than or equal to the noninferiority margin of −5%.

Results—Of the 654 recruited participants 73% (n = 478) had microbial growth from both transducers applied to their left and right forearms before reprocessing. These were included in the paired noninferiority statistical analysis where, after disinfection, all CFUs were eliminated in 100% (95% CI: 99.4–100.0%) of HLD transducer samples (n = 478) and 99.0% (95% CI: 97.6–99.7%) of LLD transducer samples (n = 473). The paired difference in the proportion of transducers having all CFUs eliminated between LLD and HLD was −1.0% (95% CI: −2.4 to −0.2%, *P*-value <.001).

Conclusions—Disinfection with LLD is noninferior to HLD when microorganisms from skin have contaminated the transducer. Therefore, using LLD for US transducers involved in percutaneous procedures would present no higher infection risk compared with HLD.

Key Words—disinfection; infection control; ultrasonography

Ultrasound (US) guidance for percutaneous procedures is commonly and widely adopted throughout healthcare settings due to the demonstrated improvements in safety

and procedural success.[1–3] As a reusable medical device, the US transducer must undergo reprocessing between patients, which involves cleaning followed by disinfection.[4] Cleaning is an essential first step, as it removes gel and other visible contaminants, such as blood, from the transducer to allow disinfection to be most effective.[4] Disinfection then reduces the number of viable microorganisms present on the transducer before use on the next patient.[4]

During an US-guided percutaneous procedure the microorganisms that can contaminate the transducer are those present on the patient's skin. Commensal skin microorganisms are predominately gram-positive bacteria (ie, *Staphylococcus* spp., *Micrococcus* spp., or *Corynebacterium* spp.) and less frequently gram-negative bacteria and yeasts.[5] Importantly, it is also these microorganisms that may lead to infection during percutaneous procedures. Using peripheral venous cannulation as an example of a commonly performed percutaneous procedure, most published reports emphasize the overall preponderance of gram-positive bacteria, particularly skin colonizers, as the pathogens responsible for infection.[6–8] Such studies report *Staphylococcus aureus* (*S. aureus*) and coagulase-negative staphylococci (CoNS) as the most commonly identified organisms causing infection.[7,9–12] Less frequently gram-negative bacteria such as *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter* spp., as well as yeasts such as *Candida* spp., have also been known to cause infection associated with these devices.[13,14] As such it is these pathogenic organisms that are both present and require elimination by disinfectant agents when reprocessing ultrasound transducers for percutaneous procedures.

During a percutaneous procedure, the patient's blood may be present in the area surrounding the skin puncture site and potentially contaminate the US transducer. So, in addition to the contaminating microorganisms from skin, disinfection agents used on these transducers should also be effective against blood-borne viruses (ie, Human Immunodeficiency Virus and Hepatitis B & C viruses). Fortunately, these lipid-enveloped viruses are the most susceptible of all microorganisms to disinfectant agents.[15] This means that low-level and high-level disinfection are both effective in disrupting their encapsulating outer lipid membrane rendering them non-infectious.[16] So when considering which level of disinfection is required for US transducers used in percutaneous procedures, it is not determined by the potential presence of these lipid-enveloped viruses, but by other microorganisms which are known to be more resistant to disinfection, such as bacteria and fungi.[16]

There remains a lack of international consensus as to which type, or level, of disinfection is required for US transducers used in percutaneous procedures. Some guidelines recommend low-level disinfection (LLD) for the transducer while others have recommended only high-level disinfection (HLD).[17–19] In contrast to LLD, HLD is additionally effective against organisms which are more resistant to disinfection such as mycobacteria and spores produced by some species (eg, *Clostridium difficile*).[16–18] However, HLD requires more financial resources, including additional staff time, which has led to concern about this requirement restricting US availability and negatively impacting on patient care.[20,21] To resolve this uncertainty, a comparison of reprocessing methods using LLD and HLD on US transducers for commonly encountered pathogenic microorganisms during these procedures is required. Therefore, the objective of this study was to determine whether LLD was noninferior to HLD in the elimination of all microbial colony forming units (CFU) from US transducers contaminated during use on skin.

Materials and Methods

Trial Design

This randomized, noninferiority trial was conducted at a large metropolitan hospital in southeast Queensland, Australia. Before the study commencement ethical approval was granted by the local human research ethics committee (HREC/2021/QRBW/77718) and the trial was prospectively registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12622000296730). This manuscript follows the CONSORT guidelines for reporting parallel group randomized trials.[22]

Participants

Research team members enrolled patients and healthcare staff who were eligible to participate in the study during times convenient for them (eg, during

meal breaks, in waiting areas, inpatients not receiving active medical care). The eligibility criteria for participants are listed in Table 1. All participants provided written, informed consent before study enrollment. Participant demographics were collected and included age, gender, residential postcode, and whether they were a healthcare worker or patient.

Intervention

Two identical linear US transducers (Sonosite® HFL38x/13–6 MHz) disconnected from an US machine were used exclusively throughout the study timeframe with one labeled and identified as being only reprocessed with LLD (Clinell Universal Wipes®) and the other only with HLD (Tristel Trio Wipes®). Both disinfection products have been reviewed and listed on the Australian Register of Therapeutic Goods by the Australian Therapeutics Goods Administration as providing LLD and HLD, respectively.[23,24]

Following enrollment, participants were randomized into one of two groups to determine which transducer was applied to the participant's left or right arm: Group A—HLD transducer right arm and LLD transducer left arm; and Group B—LLD transducer right arm and HLD transducer left arm. Each transducer had half of a 20G sterile single-use US gel sachet (Aquasonic®, Vue®, Sunsonic®) applied to it before being continuously moved up and down the participants volar and dorsal forearm ∼10 times including the cubital fossa to the wrist (simulating the area typically assessed before peripheral venous catheter insertion). No skin antisepsis took place. This procedure, aiming to contaminate the US transducer with microorganisms from the participant's skin, was standardized and performed by trained research assistants. Sterile cotton-tipped swabs, premoistened with two drops of sterile 0.9% sodium chloride solution from a single use 10 mL sterile plastic ampoule using a no-touch technique were used to collect samples from transducers. Swabbing was performed in a standardized manner so that the entire cotton tip covered the area of the transducer that had been in contact with the participant's skin.

Reprocessing and sample collection were performed by the same research staff member wearing nonsterile gloves and occurred in the area the participant was recruited as this was representative of the real clinical practice environment. At the conclusion of a day's recruitment, and after the last participants transducer reprocessing was completed, both US transducers were covered with a clear sterile plastic bag to prevent environmental contamination occurring between collection days. To ensure that manufacturer's instructions were followed, all research staff members undertook training in transducer reprocessing using online manufacturer training videos and written instructions for both methods of disinfection (Tristel® and Clinell®). Their satisfactory demonstration of reprocessing methods was confirmed and recorded in a research training log by a member of the investigator team (NP). For reprocessing with LLD two Clinell® wipes were used, the first wipe for cleaning, the second wipe for disinfection of the transducer allowing a minimum of 60 seconds of drying time before samples were collected. For HLD, Tristel Trio Wipes® were used, the first wipe being the cleaning wipe, the second wipe being the disinfection wipe allowing a minimum of 30 seconds drying time, following which the sterile water rinse wipe was used as the third wipe. After disinfection was completed, the same area of the transducer was again swabbed using identical methodology. All swabs were labeled with a participant code, whether they were taken from the transducer applied to the participants left or right arm, and type of US the swab was collected from (contaminated or disinfected). All samples from each participant were stored in a single clear plastic pathology bag and transported on the day of collection to the microbiology laboratory. The microbiology laboratory was a dedicated research facility located within the University of Queensland Centre for Clinical Research, Australia.

Table 1. Eligibility Criteria

Eligibility criteria
• ≥18 years of age
• Willing and able to expose both arms from hands to above the elbow
• Have healthy intact skin between the wrist and elbow on both arms
• Not performed a surgical scrub on the day of the procedure
• Not applied any skin disinfectant above the wrist within the last hour
• Not known to be colonized with resistant bacteria, eg, methicillin-resistant *Staphylococcus aureus* (MRSA).

Microbiological Laboratory Methods

The presence of microorganisms on transducers was confirmed by microbial growth from the swabs taken before and after reprocessing. Each swab was directly streaked across the entire surface of a 5% horse blood agar (HBA) culture plate while being rotated to collect all possible microorganisms and were examined for colonies after 4–5 days of incubation in ambient air at 37°C. HBA plates allow for the culture and isolation of a wide variety of aerobic gram-positive (ie, streptococci, staphylococci) and gram-negative (ie, Enterobacterales, *Pseudomonas* spp.) bacteria as well as *Candida* spp., in addition to many other microorganisms (eg, rapid-growing mycobacteria or molds).[25] CFUs were counted, recorded, and then summarized according to Westerway on a scale of 0–3 where 0 = no growth, 1 = 1–3 colonies, 2 = 4–10 colonies, and 3 = >10 colonies and up to confluent growth.[26] Representative colonies were identified by Matrix-assisted laser desorption/ionization time-of-flight (MALDI-ToF; Vitek MS, bioMérieux) according to manufacturer's instructions.

Outcomes

The primary outcome was successful disinfection defined as the elimination of all viable microorganisms (CFUs = 0) from US transducers following reprocessing with LLD or HLD (binary; yes/no).

Sample Size

The nonsterile handling and storage conditions recommended following HLD and LLD create a risk of environmental contamination of transducers between uses.[4] Knowing this and with expert consensus from within the research group, a noninferiority margin of −5% was selected as the maximum acceptable difference in this study when comparing LLD to HLD for the successful disinfection of US transducers. For a one-sided noninferiority test of the difference between two correlated proportions with a noninferiority margin of −5%, an analysis population sample size of 470 participants was required to achieve 80.0% power at a 2.5% significance level. This allowed for the proportions of transducers successfully disinfected with low- and high-level to be 96 and 98%, respectively. To achieve the 470 participants required for the analysis population, initially a sample size of 522 participants was estimated to allow for 10% of participants being ineligible due to one or both of the transducers applied to their forearms demonstrating no microbial growth before reprocessing. This 10% estimate was refined based on early laboratory feedback examining microbial growth rates which indicated that a sample size of 650 would be required to achieve the analysis population sample size of 470 participants (the primary outcome was not reviewed at this time).

Randomization

The randomization sequence, along with unique participant identification numbers, were generated with randomly permuted blocks of size 2 and 4 in an equal allocation using Stata version 15 (StataCorp, College Station, TX). Study data were collected and managed using a REDCap (Research Electronic Data Capture) database hosted by Metro North Hospital and Health Services. The REDCap software platform incorporated a defined randomization sequence model to ensure allocation concealment.

Blinding

Researchers responsible for reprocessing, and sample collection were not blinded to participant group. However, the microbiologists measuring the primary outcome were blinded to participant group so were unaware of which swabs had been collected from the LLD or HLD transducers with data matching only occurring at the conclusion of recruitment.

Statistical Methods

The primary hypothesis was that the difference in the proportion of US transducers having no CFUs remaining after LLD and HLD would be less than or equal to −5% (LLD – HLD). To demonstrate disinfection was effective, and as statistical testing using matched pairs of samples was planned, only participants for whom pairs of swabs taken from both LLD and HLD transducers before reprocessing that demonstrated CFUs present on culture media were included in the statistical analysis. The proportion of samples with the elimination of all CFUs following disinfection (CFUs = 0) between LLD and HLD methods was reported with exact binomial 95% confidence intervals (CI) and compared using a noninferiority test of the differences between correlated proportions using Nam's

restricted maximum likelihood estimate (REML) approach, with a noninferiority margin of −5% and significance at the 2.5% level.[27,28] Tango's score confidence intervals of the difference in correlated proportions were calculated using the PropCIs package.[29]

Baseline characteristics of participants were summarized by frequency and percentage overall and by randomization group, and microbial growth described per participant arm. Microbial growth following disinfection was summarized as frequency and percentage at the participant level and disinfection level. Associations between participant characteristics and absent growth from swabs taken before reprocessing were assessed using a Pearson's Chi-squared tests with significance at the 5% level. Characteristics of microbial growth from swabs before reprocessing were described overall. R statistical package version 4.1.0 was used for all analyses.[30]

Results

The characteristics of the 654 participants recruited between May and December 2022 are described in Table 2. The amounts of microbial growth from all swabs taken from US transducers before reprocessing are demonstrated in Table 3. There was no statistically significant difference observed in the presence of microbial growth between participants who were healthcare staff or patients. However, there were statistically more ($P < .001$) males than females with microbial growth observed before disinfection (Table 4).

Paired samples from a participant were those that demonstrated microbial contamination before reprocessing from both the LLD and HLD transducers. Paired samples were obtained in 73% (n = 478) of participants and in this group there were five instances where CFUs were noted to be present following reprocessing with LLD. Unpaired samples from a participant occurred when microbial growth was observed from only one of the LLD or HLD transducers before reprocessing and was seen in 13% (n = 82) of participants. In this group there were 27 participants where the LLD transducer, and 55 where the HLD transducer, had microbial growth before reprocessing. Within these unpaired samples there were two instances where CFUs were noted to

Table 2. Participant Demographics by Randomization Group

Characteristic	Overall n = 654	Group A n = 327	Group B n = 327
Participant details, n = 652	n (%)	n (%)	n (%)
Patient	495 (76%)	244 (75%)	251 (77%)
Staff	157 (24%)	81 (25%)	76 (23%)
Patient Location, n = 495			
Inpatient	417 (84%)	208 (85%)	209 (83%)
Outpatient	78 (16%)	36 (15%)	42 (17%)
Age, n = 649			
<35	164 (25%)	83 (26%)	81 (25%)
36 to 50	156 (24%)	75 (23%)	81 (25%)
51 to 65	169 (26%)	83 (26%)	86 (26%)
66+	160 (25%)	83 (26%)	77 (24%)
Gender, n = 654			
Female	309 (47%)	147 (45%)	162 (50%)
Male	345 (53%)	180 (55%)	165 (50%)
Remoteness area of domicile, n = 643			
Inner Regional Australia	82 (13%)	44 (14%)	38 (12%)
Major Cities of Australia	537 (84%)	267 (83%)	270 (84%)
Outer Regional Australia	16 (2.5%)	6 (1.9%)	10 (3.1%)
Remote Australia	2 (0.3%)	2 (0.6%)	0 (0%)
Very Remote Australia	6 (0.9%)	2 (0.6%)	4 (1.2%)

Note: Group A = HLD transducer right arm and LLD transducer left arm; Group B = LLD transducer right arm and HLD transducer left arm. HLD, high-level disinfection; LLD, low-level disinfection.

be present following reprocessing with HLD. There were 14% (n = 94) of participants where there was no microbial growth observed from both the LLD and HLD transducers before reprocessing. When pooling the paired and unpaired samples there were 1038 transducers with microbial growth before reprocessing, 48.7% (n = 505) subsequently underwent LLD and 51.3% (n = 533) underwent HLD. Overall, disinfection led to the elimination of all CFUs in 99.0% (n = 500) of transducers following LLD and 99.6% (n = 531) of transducers following HLD. Further details of the transducers with microorganisms present following disinfection can be seen in Table 5.

The noninferiority statistical analysis required matched pairs of samples and therefore only included the 478 participants with microbial growth from both transducers before reprocessing. In this group of participants disinfection eliminated all CFUs in 99.0% (n = 473) (95% CI: 97.6–99.7%) of LLD transducer samples and 100% (n = 478) (one-sided 95% CI: 99.4–100.0%) for HLD transducer samples. With a predetermined noninferiority margin of −5%, for LLD to be noninferior the lower limit of the 95% confidence interval needed to be above this 95% noninferiority margin to confirm the noninferiority hypothesis. The paired difference in the proportion of eliminated bacterial growth following disinfection

Table 3. Amounts of Microbial Growth Observed From Transducers Before Reprocessing

	Right Arm				
Left Arm	**None**	**1–3 Colonies**	**4–10 Colonies**	**>10 Colonies**	**Total**
None	94 (14.4%)	27 (4.1%)	7 (1.1%)	5 (0.8%)	133 (20.3%)
1–3 colonies	31 (4.7%)	76 (11.6%)	25 (3.8%)	25 (3.8%)	157 (24.0%)
4–10 colonies	5 (0.8%)	27 (4.1%)	32 (4.9%)	36 (5.5%)	100 (15.3%)
>10 colonies	7 (1.1%)	31 (4.7%)	38 (5.8%)	188 (28.8%)	264 (40.4%)
Total	137 (21.0%)	161 (24.6%)	102 (15.6%)	254 (38.8%)	654 (100.0%)

Table 4. Microbial Growth From Both Transducers Used on Each Participant Before Reprocessing According to Participant Characteristics

Characteristic	**Both Transducers With Growth**	**Only One Transducer With Growth**	**No Growth From Both Transducers**	***P*-Value**
Gender, n = 654				<.001
Female	199 (64%)	49 (16%)	61 (20%)	
Male	279 (81%)	33 (9.6%)	33 (9.6%)	
Participant details, n = 652				.70
Patient	361 (73%)	60 (12%)	74 (15%)	
Staff	115 (73%)	22 (14%)	20 (13%)	

Table 5. Characteristics of Transducers Which Had Microbial Growth Present After Reprocessing

Participant	**Group**	**Sample Type**	**CFUs Before Reprocessing**	**Disinfection Method**	**CFUs After Reprocessing**	**Remaining Organism**
1	B	Paired	14	LLD	1	*M. luteus*
2	B	Paired	6	LLD	1	CoNS
3	B	Paired	8	LLD	1	CoNS
4	B	Paired	496	LLD	2	CoNS
5	B	Paired	150	LLD	2	CoNS
6	A	Unpaired	3	HLD	10	*S. aureus*
7	A	Unpaired	4	HLD	1	CoNS

Note: Group A = HLD transducer right arm and LLD transducer left arm; Group B = LLD transducer right arm and HLD transducer left arm. CoNS = Coagulase-negative staphylococci; *M. luteus*, *Micrococcus luteus*; *S. aureus*, *Staphylococcus aureus*.

Figure 1. Noninferiority plot of the paired difference in proportion of transducers having had all microorganisms eliminated between LLD and HLD.

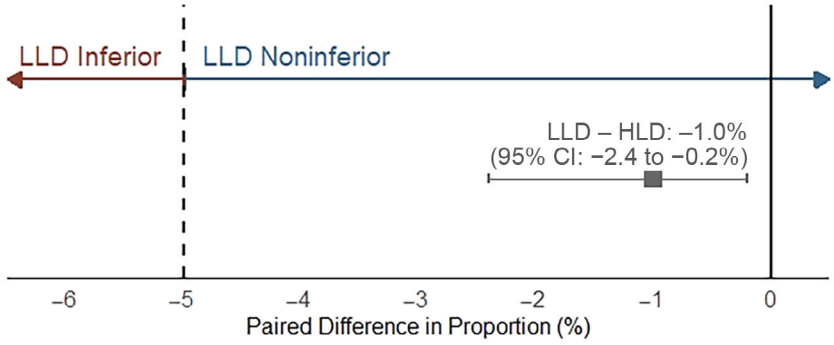

Table 6. Characteristics of Microorganisms Identified From Transducers Before Reprocessing

Characteristic	n (%)
Microorganism classification (*n = 1817*)	
Gram-positive	1577 (86.8%)
Gram-negative	36 (2.0%)
Yeast	47 (2.6%)
Mold	9 (0.5%)
Not able to be identified	148 (8.1%)
Microorganism type (*n = 1669*)	
Acinetobacter baumanii	1 (<0.1%)
Acinetobacter lwoffii	2 (0.1%)
Actinomyces spp.	2 (0.1%)
Aerococcus viridans	1 (<0.1%)
Agrobacterium radiobacter	1 (<0.1%)
Bacillus cereus group	3 (0.2%)
Bacillus spp.	62 (3.7%)
Brevibacterium casei	1 (<0.1%)
Coagulase-negative *Staphylococcus* (CoNS)	844 (51%)
Corynebacterium spp.	4 (0.2%)
Dermacoccus nishinomiyaensis	1 (<0.1%)
Enterococcus faecalis	2 (0.1%)
Enterococcus faecium	7 (0.4%)
Enterococcus spp.	14 (0.8%)
Klebsiella spp.	1 (<0.1%)
Micrococcus luteus	478 (29%)
Moraxella spp.	14 (0.8%)
Mold	9 (0.5%)
Pseudomonas spp.	1 (<0.1%)
Rhodococcus spp.	1 (<0.1%)
Roseomonas mucosa	5 (0.3%)
Rothia dentocariosa	1 (<0.1%)
Serratia spp.	11 (0.7%)
Staphylococcus aureus	141 (8.4%)
Streptococcus spp.	13 (0.8%)
Streptomyces griseus	1 (<0.1%)
Tsukamurella spp.	1 (<0.1%)
Yeast	47 (2.8%)

between LLD and HLD was −1.0% (95% CI: −2.4 to −0.2%) at the 2.5% significant level, therefore LLD was noninferior to HLD (Z-statistic = 5.52, P-value <.001; Figure 1).

Microorganisms

At baseline, microorganisms were observed on growth media 1817 times from the 654 recruited participants with 86.8% (n = 1577) being gram-positive bacteria, 2% (n = 36) gram-negative bacteria, 3.1% (n = 56) mold and yeast, and 8.1% (n = 148) not able to be identified. The most common reasons for not identifying an organism were mixed microbial growth or the smearing caused by the presence of US gel on culture plates preventing accurate counting and identification. The top three most cultured organisms were CoNS (51%; n = 844), *Micrococcus luteus* (29%; n = 478), and *S. aureus* (8.4%; n = 141). A list of all organisms identified and the frequency with which they occurred can be found in Table 6.

Discussion

This randomized controlled trial demonstrated that LLD is noninferior to HLD in the elimination of microorganisms from US transducers that pose a risk of infection during percutaneous procedures. Importantly these results now provide a robust evidence base for adopting LLD for reprocessing US transducers used as part of percutaneous procedures. These findings also challenge current guidelines,

which without a similarly strong evidence base, continue to recommend only HLD for reprocessing these transducers.[18,19,21]

These results have important worldwide implications given the frequency with which US is now used for percutaneous procedures.[31] At the time this study was conducted the cost of the wipes required for each cycle of Tristel® for HLD was 13.20 AUD and Clinell® for LLD was 0.10 AUD at the study institution. Adopting LLD for these transducers, and avoiding the costs associated with the acquisition and implementation of HLD systems, would likely result in large financial savings for healthcare organizations without any compromise in patient safety.[20] Although a detailed cost analysis was not incorporated into this study, future research exploring this would be recommended.

Owing to its simplicity and inexpensive nature, LLD is more likely to be easily implemented across a wider variety of healthcare settings such as remote healthcare clinics and prehospital environments. Patients, irrespective of their location, are entitled to expect equity in accessing safely reprocessed US transducers when undergoing percutaneous procedures. Guidelines requiring HLD to be implemented across every location where US transducers are used in percutaneous procedures potentially threatens this equity. Given the results of this study organizations that have developed guidelines stipulating that only HLD provides safely reusable US transducers for percutaneous procedures should now strongly reconsider their position.

Our pragmatic approach to reprocessing US transducers at the bedside is also important as it indicates that US practitioners can reprocess transducers effectively and efficiently at the patient's bedside, avoiding the need for transducers to be sent away from clinical areas for reprocessing. All research staff reprocessing US transducers in this study had undertaken brief training to ensure adherence to manufacturers' instructions for reprocessing. Replication of this training for staff, and adherence to manufactures instructions, would be important in ensuring these results are translatable into clinical practice. Reprocessing US transducers at the patient's bedside is also important in ensuring that in time critical or high demand clinical environments the availability of US can be maintained and patients can continue to receive the well-proven benefits.[20,21,32]

The methodology used in this study was robust, and the strong results are reinforced by the very narrow noninferiority margin of −5% demonstrated at a significance level of 2.5%. The pooled data demonstrates that <1% of transducers from both the LLD and HLD groups had microorganisms present following disinfection, with typically only one or two CFUs. While this study considered the elimination of all microorganisms from a transducer as the primary endpoint, the clinical significance of one or two CFUs in increasing the risk of infection during the conduct of a percutaneous procedure is uncertain. The risk of infection generated by this number of microorganisms being present should be considered within the clinical context of these transducers being stored in conditions which do not guarantee them being free from environmental contamination with microorganisms before their next use.[4] It is possible that the nonsterile handling and storage conditions seen in real clinical practice, and replicated in this study, were responsible for some, or all, of the seven cases of microorganisms observed on transducers following disinfection. This may explain the one instance where the number of CFUs following HLD was seen to increase from three before reprocessing to 10 afterwards. Also, the additional protective effects of incorporating standard infection prevention steps during the conduct of these procedures, such as skin preparation and transducer covers, may also further reduce the clinical significance of these very small numbers of microorganisms.[20,21,32]

The amount of microbial contamination observed on the transducers during this study was likely higher than would be seen after typical clinical use. This was because of study participants not having routine infection prevention steps replicated such as the use of single use transducer covers in addition to skin disinfection (eg, chlorhexidine and/or alcohol-based solutions). Despite this, 20.6% (n = 270) of US transducers applied to unprepared patient skin had no microbial growth on culture. Contributing factors to this may have been the presence and amount of US gel acting as a barrier between the transducer and the patients' skin, or the effects of gel on microorganisms themselves, but further research is needed to confirm this. Another interesting finding was the significant difference between males and females in the rates of transducer contamination. This is likely explained by

the variation in quantity and population of microorganisms that make up skin flora, with men carrying more microorganisms than women due to differences in skin characteristics.[33,34]

The results of this study are widely generalizable having recruited a matched distribution of participants across gender, age, and clinical locations. Reprocessing occurred in conditions representative of common clinical US practice and the study examined for clinically important microorganisms. This study used one type of LLD and HLD as comparator groups (Clinell® vs Tristel Trio Wipes®, respectively) with each having a proprietary formulation. Clinell® uses polyhexamethyl-biguanide, an agent in the same class as chlorhexidine, and Tristel® uses a chlorine dioxide based system for its disinfectant activity.[15] While the results of this study are likely to be translatable across other products having met the same registration requirements and in vitro testing, further comparative research would be required to confirm this.

Limitations

Although this study used participants from within a hospital setting and clinically meaningful simulated techniques, it did not compare patient infection rates arising from ultrasound-guided percutaneous procedures using transducers which had undergone LLD or HLD. As infections arising from percutaneous procedures are relatively rare and result from the interaction between patient, device, insertion, and proceduralist factors a study with this as a primary endpoint was not feasible.[7,35] However, what the results of this study demonstrates is that the contribution an US transducer has to the overall risk of infection for a percutaneous procedure would be no higher if it was disinfected with LLD compared with HLD.

The HBA growth media used in this study was able to support the aerobic growth of bacteria and fungi which are recognized as clinically relevant microorganisms for infectious complications in percutaneous procedures.[25] HBA is not a suitable growth media for other microorganisms such as *Neisseria gonorrhoea*, slow-growing *Mycobacterium* spp., *Legionella* spp., *Bordetella* spp., and strict anaerobes (eg, *Bacteroides* spp.) which require a different growth media and/or environmental conditions to be cultured.[25] However, these organisms are not reported in the publications detailing the known infectious pathogens complicating percutaneous vascular access procedures.[7–13]

Conclusion

This study demonstrates that reprocessing with LLD is noninferior to HLD when microorganisms from skin have contaminated an US transducer. These findings are important for patient care as they demonstrate that the contribution an US transducer has to the risk of infection during a percutaneous procedure would be no higher having undergone LLD compared with HLD. The results of this study should be used by healthcare organizations worldwide to support updating guidelines which adopt LLD for the reprocessing of US transducers used for percutaneous procedures. Future studies would be useful in quantifying the patient and healthcare system benefits of widespread adoption of LLD instead of HLD for reprocessing these US transducers.

Acknowledgment

Open access publishing facilitated by The University of Queensland, as part of the Wiley - The University of Queensland agreement via the Council of Australian University Librarians.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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