ORIGINAL ARTICLE

Evaluation of Current Disinfection Practice of Transvaginal Ultrasound Probes in a Philippine Tertiary Referral Hospital: A Comparative Study on the Performance of Manual Reprocessing Methods

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ABSTRACT

Objectives. There are no standard infection control regulations in transvaginal ultrasound probe disinfection followed in the most prominent local public tertiary referral hospital. Likewise, no studies have evaluated the efficacy of the current method that uses an inexpensive multipurpose antiseptic spray solution. This study aims to evaluate the efficacy of the current practice of manual disinfection of TVS probes and compare it with the performance of an acceptable manual reprocessing method.

Methods. A prospective, randomized, controlled study was carried out using a crossover, quasi-experimental design, collecting 119 total samples from the ultrasound transducers before (35 samples) and after disinfection with two manual reprocessing methods, either a locally manufactured multipurpose antiseptic spray (A-Septic® Multipurpose Antiseptic Spray) that is currently used for disinfection or Mikrozid Sensitive®, a ready to use impregnated wipes (42 samples each arm). Disinfection efficacy was evaluated based on microbial culture results.

Results. Before disinfection, bacterial growth was observed in 77.1% (27/35) of the probes. After disinfection, 80.95% (34/42) remained contaminated with the antiseptic spray and 21.43% (9/42) with the wipes. The cultures revealed many environmental and pathogenic bacterial isolates, including *Burkholderia*, *Staphylococcus*, *Acinetobacter*, *Diphtheroids*, and *Pseudomonas*.

Conclusions. The currently used method for disinfecting transvaginal transducers in the division is not adequate for decontamination and decreasing the risk of cross contamination among patients. The results call for aggressive disinfection measures and highlight the need to update local standards and formulate and institutionalize these recommendations.

Keywords: transvaginal ultrasound, manual reprocessing, TVS transducers/probe disinfection, quaternary ammonium compounds, isopropyl alcohol

INTRODUCTION

Ultrasound is increasingly utilized as an essential diagnostic imaging modality, especially in obstetrics and gynecology. Each ultrasound procedure involves contact between an ultrasound transducer and a patient's skin, mucous membranes, or sterile tissues. Although not standardized for all, there are guidelines for reprocessing the ultrasound probes recommended by international societies.[1-5] Failure to adhere to minimum infection control standards, including the proper cleaning and reprocessing of the equipment and transducers, increases the risk of pathogen

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transmission and subsequent infection. Lack of compliance with scientifically-based guidelines for infection control has led to numerous outbreaks arising from ultrasound examinations, including cases of infection resulting from ultrasound-guided procedures and ultrasound transducers that have not undergone appropriate disinfection or have been damaged.[6-20]

A general guideline for disinfection and sterilization of instruments in healthcare facilities from the Asia Pacific Society of Infection Control is used locally.[21] However, it does not mention specific guidelines on the disinfection of ultrasound probes. In our institution, considered the country's largest public tertiary referral university hospital, the ultrasound probes used for transvaginal (TVS) or transrectal (TRS) ultrasound examinations are covered with a one-time use non-sterile probe cover per patient. After each procedure, the TVS probes are wiped clean with dry, soft, absorbent paper towels and then disinfected with A-septic® multipurpose antiseptic spray. However, it remains a question whether this provides a sufficient level of decontamination. There has been no study regarding the effectiveness of this manual reprocessing method being used in the institution. Hence, it is necessary to compare its efficacy to a previously studied manual disinfection method (Mikrozid Sensitive® ready-to-use impregnated wipes).[22]

METHODS

Study design

The study employed a prospective, randomized, controlled clinical study using a crossover, quasi-experimental design to compare the efficacy between two manual reprocessing methods of TVS probe disinfection in three pre-selected ultrasound machines of the Division of Ultrasound, Department of Obstetrics and Gynecology of the Philippine General Hospital (PGH) during the 3-week study period (May 2019). The UP-PGH Ethics Review Board approved the study protocol.

Sample size

There were 35 microbial samples collected from TVS probe bodies before disinfection of the probes. Subsequently, 84 post-disinfection samples were collected after disinfection, equally allocated with either manual reprocessing methods (42 samples each arm).

The computation of sample size was based on the result of a previous study which suggested that manual disinfection has a contamination rate of around 20%.[22] At least 39 after-disinfection samples per cleaning method are needed to reject the null hypothesis that the failure rates for both methods are equivalent, with the power of 80% while using an alpha set at a one-tailed, 95% level. An additional 15% was included to account for the possibility of incomplete information or lack of appropriate data, hence the total of 45 samples per arm. The same previous study demonstrated that microbes were found in 98.8% before disinfection which served as the basis for the 35 before-disinfection samples. This served to determine which antiseptic technique would have a lesser proportion of contamination before disinfection, considering that almost all samples would probably have contamination.

Conduct of the study

No patients were recruited for the study, and no demographic information nor clinical data were recorded. However, randomization to the two disinfection methods used patients as reference points, including emergency referrals, out-patient, and admitted patients referred for TVS or TRS during the study period. TVS probes of the ultrasound machines in cubicles B, C, and D of the division were used during the study period. Patients were assigned randomly to one of the three cubicles on a first-come, first-serve basis, depending on which machine was available. Each room was pre-allocated to a disinfection technique on a scheduled basis (Table 1). The collection of samples was assigned by drawing lots since the patients scheduled for ultrasound were assigned queue numbers.

In the first group, the transducers were disinfected manually on the body with Mikrozid Sensitive® (Shülke & Mayr GmbH, Norderstedt, Germany) ready-to-use impregnated wipes (with quaternary ammonium compounds), according to the manufacturer's instructions for use. This was chosen among commercially available wipes since it has been previously studied and published. When this study was conducted, it was not yet available locally, hence the need to obtain from abroad. In the second group, the

Table 1. Schedule of sample collection

Day	Week	UTZ 1 (Cubicle B)	No. of samples after disinfection	Week	UTZ 2 (Cubicle C)	No. of samples after disinfection	Week	UTZ 3 (Cubicle D)	No. of samples after disinfection
Monday	Week 1	Mikrozid	5	Week 3	A-septic*	6	Week 2	Mikrozid*	6
Tuesday	Week 2	A-septic*	6	Week 1	Mikrozid	5	Week 3	A-septic	6
Wednesday	Week 3	Mikrozid	5	Week 2	A-septic	6	Week 1	Mikrozid	5
Thursday	Week 1	A-septic	6	Week 3	Mikrozid*	5	Week 2	A-septic*	6
Friday	Week 2	Mikrozid*	6	Week 1	A-septic	6	Week 3	Mikrozid	5

**Schedule of collection of the 35 samples before disinfection*

transducers were disinfected with A-septic® multipurpose antiseptic spray (composition: Isopropyl alcohol, deionized water, preservative, and wetting agent), which is the current ultrasound probe disinfecting agent used by the division.

The fellows in training performed ultrasound examinations. The TVS probes were covered by one-time use/disposable probe covers per patient, and the sonologists were wearing sterile, powder-free gloves. After each examination, the TVS probes were cleaned with a dry paper towel to remove the cover and gel residues and disinfected using either agent. The principal investigator performed disinfection and collection of samples after being trained in sterile sample collection techniques by hygiene experts from the Hospital Infection Control Unit (HICU).

Collection of samples

Baseline samples from the coupling gels used in the three ultrasound machines were initially collected using moistened cotton swabs, then immersed in Tryptic Soy Broth (TSB) provided by the PGH Microbiology laboratory. Before-disinfection samples were collected right after a TVS, or TRS procedure was performed and before disinfection. Before- and after-disinfection samples were collected using moistened sterile cotton swabs and sterile gloves. The moistened cotton swabs were rolled carefully over the TVS probe body up to the tip twice and immersed in TSB. All samples were individually labeled and coded and sent immediately to the Medical Research Laboratory (MRL) of PGH, Section of Microbiology, to process and assess the growth and identification of microorganisms using VITEK® 2 COMPACT automated Identification/Antibiotic Susceptibility Testing (ID/AST) instrument. The medical technologists who processed the samples were blinded to the disinfection method used.

A crossover, quasi-experimental design was used to determine the comparability of both disinfecting agents. A washout period of one day was maintained between treatments to limit the carryover effects on the three ultrasound machines used for the study. Randomization was done using a Latin square design method to ensure uniformity of treatments within sequences and between periods, thus reducing position and carryover biases in the study.

Statistical Analysis

All the data were encoded and analyzed using the software STATA13. Descriptive statistics, specifically the frequency and percentage, were used for the categorical data variables. A series of chi-square tests of association were performed to determine a difference in the frequency and percentage of positive contamination across these two disinfection methods. Interval estimates were also computed to determine the overall rates of contamination. Two samples test of proportions were performed to compare the contamination rate among transducers during the baseline (before use) and after using these agents. The significance level for all analysis sets was set at a p-value of less than 0.05 using two-tailed comparisons.

RESULTS

No sample was excluded from the statistical analysis during the study period. The microbial culture results of the baseline sampling from the coupling gel revealed the *Burkholderia cepacia* group and *Burkholderia gladioli*. To determine the presence of baseline bacterial growth without the use of any disinfecting agent, there were 35 samples collected, of which 27 (77.1%; 95% CI: 60.7-88.2%) showed bacterial growth. Among these before-disinfection samples, 17 (94.4%) of the 18 samples in the A-septic® group and 10 (58.5%) of the 17 samples in the Mikrozid® group were contaminated. A summary of the isolates is listed in Table 2.

Of the 84 after-disinfection samples, half of the probe bodies were cleaned using A-septic® and the other half using Mikrozid®. In the A-septic group, 34 (80.95%) showed microbial growth after disinfection, while in the Mikrozid® group, only 9 (21.43%) remained contaminated after disinfection (Figure 1). A chi-square test of association was performed with results suggesting that there was still a higher proportion of contaminated samples among A-septic® cleaned probes even after disinfection than those cleaned by

Table 2. Microorganisms identified on baseline sampling of the coupling gels and the ultrasound transducers before and after disinfection

Bacterial isolates	n (%)
Coupling gels (n = 3 tubes, 1 per cubicle)	
Burkholderia cepacia group	2 (66.7)
Burkholderia gladioli	1 (33.3)
Total	**3 (100)**
Transducers before disinfection (n = 35)	
Burkholderia cepacia group	23 (85.2)
Burkholderia gladioli	2 (7.4)
Staphylococcus epidermidis	2 (7.4)
Total	**27 (77.1)**
Transducers after disinfection (n = 84)	
Acinetobacter haemolyticus/iwoffii	2 (4.3)
Bacillus species	2 (4.3)
Burkholderia cepacia	8 (17.0)
Burkholderia cepacia group	16 (34.0)
Burkholderia gladioli	8 (17.0)
Diphtheroids species	1 (2.1)
Pantoea species	1 (2.1)
Pseudomonas aeruginosa	1 (2.1)
Staphylococcus epidermidis	2 (4.3)
Staphylococcus haemolyticus	1 (2.1)
Staphylococcus hominis species	5 (10.6)
Total	**43 (51.2)**

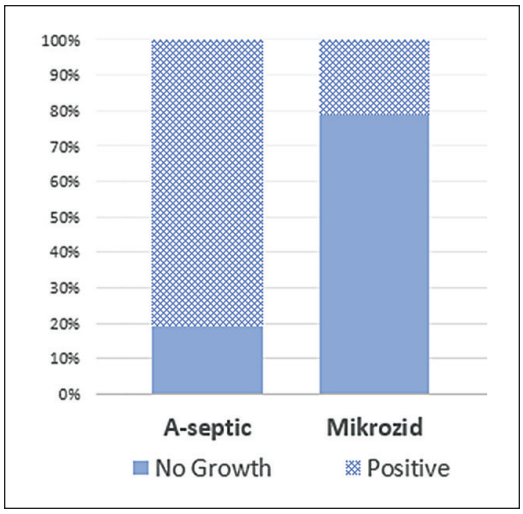

Figure 1. Proportion of transvaginal ultrasound probes contaminated after disinfection.

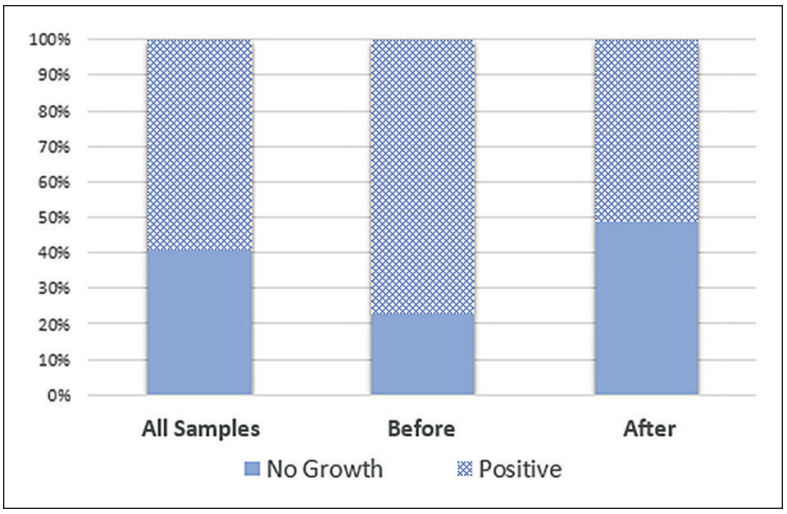

Figure 2. Proportion of TVS probes contaminated before and after disinfection of either agent.

Mikrozid® (χ2,1: 29.78, p<0.01). Moreover, a pair of z-test of proportions was performed to determine differences in the proportion of contaminated samples across disinfecting agents against the before-disinfection samples taken. It can be noted that there was no difference in the rate of contaminated TVS probes before disinfection and those that were cleaned using the agent A-septic® (z: -0.41, p: 0.68). At the same time, there was a significant reduction in the rate of contamination among those samples cleaned by Mikrozid® compared with the baseline rate (z: 4.88, p<0.01) (Figure 2).

Out of the 43 samples that remained contaminated after disinfection, four (9.30%) were noted to have multiple bacterial isolates identified, with an interval estimate between 3.12 to 22.16 percent – all of which were disinfected using the agent A-septic®. The bacterial isolates found among TVS transducers disinfected by Mikrozid® were *Burkholderia* and *Staphylococcus* species. At the same time, all other organisms can be seen among those disinfected by A-septic (*Acinetobacter haemolyticus/iwoffii, Bacillus* species, *Burkholderia* spp, *Diphtheroids, Pantoea, Pseudomonas, Staphylococcus* species).

There was no association with the day of the week or timing of the procedure (morning or afternoon) in terms of contamination. However, it can be noted that there were significantly more culture-positive swabs sampled in ultrasound machine 2 (cubicle C) compared with the others (Table 3) based on the chi-square test performed (χ2,2: 6.29, p: 0.04).

DISCUSSION

Contamination of ultrasound probes with bacteria and the potential for transmission to patients is a legitimate concern. This study showed that 77.1% of TVS probe bodies were contaminated before disinfection. This highlights the importance of TVS probe disinfection before every patient use. While some might argue that there is still adequate protection since TVS ultrasound procedures use disposable probe covers, evidence from the literature describes the possibility of probe cover leakage in 0.9-9.0% of cases.[23-26] Transvaginal probes can become contaminated with human papillomavirus, Epstein-Barr virus, and bacteria.[27-29] Unfortunately, this study did not investigate contamination with viral agents due to the high detection cost.

Table 3. Microorganisms identified per ultrasound transducer after disinfection

Bacterial isolates	n (%)
UTZ 1 (Cubicle B) Transducer (n = 28)	
Burkholderia cepacia group	2 (7.1)
Burkholderia gladioli	6 (21.4)
Staphylococcus epidermidis	2 (7.1)
Staphylococcus haemolyticus	1 (3.6)
Staphylococcus hominis species	3 (10.7)
UTZ 2 (Cubicle C) Transducer (n = 28)	
Acinetobacter haemolyticus/iwoffii	2 (7.1)
Bacillus species	1 (3.6)
Burkholderia cepacia	4 (14.3)
Burkholderia cepacia group	11 (39.3)
Burkholderia gladioli	1 (3.6)
Pantoea species	1 (3.6)
Staphylococcus hominis species	2 (7.1)
UTZ 3 (Cubicle D) Transducer (n = 28)	
Bacillus species	1 (3.6)
Burkholderia cepacia group	1 (3.6)
Burkholderia gladioli	1 (3.6)
Diphtheroids species	1 (3.6)
Pseudomonas aeruginosa	1 (3.6)

Another possible source of infection is the use of ultrasound gels.[6-14] Although both sterile and non-sterile gels are available, the use of non-sterile gel is common for practical reasons. In our institution, non-sterile gel in multi-dose containers is used. The results of the baseline sampling from the coupling gel revealed growth of the *Burkholderia cepacia* group and *Burkholderia gladioli*, the same organism identified in previous studies.[11,12,14] The use of non-sterile ultrasound gel has been implicated in outbreaks of nosocomial infections, and hence, a sterile gel is recommended whenever there is a concern for potential infection.[30]

With the steady growth of ultrasound, combined with an increasing awareness of infection control practices, medical device manufacturers have recently developed automated reprocessors for ultrasound transducers. The development of automated ultrasound disinfection systems was not possible until recently. Some transducer parts cannot contact liquid, and a probe cannot be fully submerged in liquid. Automated disinfection systems help standardize disinfection processes, improve staff workflow and meet compliance standards, all of which will improve patient and healthcare staff safety. In other countries, automated techniques are generally recommended owing to their reproducibility and their capacity for standardization of procedures.[22] In Germany, where the Mikrozid® wipes used in this study were obtained, the German Federal Institute for Drugs and Medical Devices (BfArM) released a statement concerning the hygiene requirements for the reprocessing of medical devices.[1] There are no other guidelines from German gynecological societies on the disinfection of transducers. However, it is currently a common practice to use impregnated wipes for manual disinfection of TVS probes.

There are currently no available set guidelines for TVS probe disinfection from gynecological societies in the Philippine setting. Given the high cost of purchasing an automated reprocessor, manual reprocessing remains a popular option, particularly for facilities with a low volume of procedures or budget constraints.

In the ultrasound division of the Department of Obstetrics and Gynecology of PGH, an automated reprocessor for the TVS probes is not available. Hence manual reprocessing is currently being done. In general, the preparation and cleaning of the ultrasound transducers, as detailed in published guidelines,[5] consists of 2 critical steps, cleaning, and disinfection before and after removal of the disposable probe covers. Cleaning the transducers requires running water and a small amount of mild non-abrasive liquid soap to remove any residual gel or debris. However, this step is not routinely performed in the division, and its place is the use of dry tissue to wipe out the gel. For disinfection, specific agents or methods are required based on the classification system of the medical devices, which in turn is according to the infection risk they present. Unlike the transabdominal curvilinear transducers, which are considered low-risk and require low- or intermediate-level disinfection, the TVS and TRS transducers are considered semi-critical or medium-risk devices with relatively higher risk for infection because of contact with non-intact skin or mucous membranes.[1,2,5] Hence, high-level disinfection is recommended to destroy all microorganisms, including pathogenic viruses, which can be achieved using solutions containing sodium hypochlorite or other disinfectants. The US Food and Drug Administration (FDA) has approved ortho-phthalaldehyde (OPA), hydrogen peroxide, glutaraldehyde, and peracetic acid with hydrogen peroxide as high-level disinfectants.[3,4] The main components of A-septic® and Mikrozid® are isopropyl alcohol and quaternary ammonium compounds, respectively. Quaternary ammonium compounds are cationic surfactants, i.e., their positively charged surface-active agents bind readily to the negatively charged cell walls and membranes of microbes. They are potent disinfectant chemicals commonly found in household wipes and cleaners. Both isopropyl alcohol and quaternary ammonium compounds represent mid-level disinfection appropriate for transabdominal probes but are inadequate for TVS transducers.[5] There has been no study regarding the effectiveness of the manual reprocessing method being used for TVS probes in this institution, more so a mid-level type of disinfection, hence this study. An evaluation of the efficacy of the A-septic® disinfectant was also compared to a previously studied manual disinfection method commonly used in other countries for TVS probes and the Mikrozid® impregnated wipes.

This study demonstrated a significantly higher proportion of contaminated samples among A-septic® cleaned probes than those cleaned by Mikrozid®. Interestingly, A-septic® spray after-disinfection samples showed multiple bacterial isolates. The bacterial isolates found among TVS transducers disinfected by Mikrozid® were only *Burkholderia* and *Staphylococcus* species, whereas all other isolated organisms can be seen among those disinfected by A-septic®. While most *Staphylococcus* species are harmless and usually reside on humans' skin and mucous membranes, the other bacterial isolates in this study are frequent and significant nosocomial pathogens. *Burkholderia* sp. were found in the coupling gel and persisted even after use of either disinfection agent. This finding is important, considering that its presence in coupling gels has been implicated in infection outbreaks.[11,12,14] *Burkholderia gladioli* in humans is a relatively uncommon opportunistic pathogen but essential for hospital-associated infections.[31-32] All these findings highlight that disinfection with A-septic® is not practical in significantly decreasing contaminants in transducers and preventing possible cross-contamination among the patients. Furthermore, the use of another manual reprocessing method, albeit not the recommended level of disinfection for TVS transducers, provides a better alternative. The results, however, justify the need for an adequate and appropriate disinfection method for use in the division.

While this study demonstrated the presence of organisms in the main body of the transducers, evaluation of the

probe handle was not included. Current guidelines do not specify its inclusion for routine manual disinfection, more so in automated reprocessing methods that require probe immersion to a liquid disinfectant. Due to its material or composition, the inclusion of the handle in liquid immersion is often contraindicated as per some manufacturer's specifications. Contamination has been reported in 80.5% of handles even with the body immersed in glutaraldehyde and 83% when handles are not disinfected.[33,34] Just like the ultrasound transducer body, the handle is also a reservoir for microbial contaminants and a possible source of cross-infection. Other proponents have suggested decontamination of other surfaces and components in the sonographer's clinic, including probe holders, keyboards, cords, and the entire ultrasound equipment. Studies have documented contamination of these parts with both pathogenic and non-pathogenic isolates, including skin and environmental organisms.[33,35]

These findings on the entire ultrasound environment point to the potential roles of the ultrasound personnel and patients. The sonologists are in direct contact with the handles and the equipment. At the same time, patients who may be infected may either come into direct contact with the equipment or indirectly may occur via the healthcare worker or the probe sheath. Fortunately, there have been no documented reports on the local and institutional outbreak from ultrasound use. Likewise, no local study has been conducted to document cross-infection among patients undergoing ultrasound in the division. However, some authors have advocated for hand disinfection and keyboard disinfection based on the current evidence before and after each procedure. These steps may seem inconsequential and are therefore not routinely performed by sonologists, more so in large centers like PGH. Other measures suggested are using a gel with antibacterial properties, disinfection of probe holder and gel bottle at the start and end of each day, and appropriate cleaning of the entire machine.[34,35] Hence, to ensure the safety of both the sonographer and the patient, there is a need to revise the current infection prevention and control guidelines. This should extend to the entire ultrasound environment, hand in hand with proper education of the sonologists.

Limitations of the study

The culture study done for this study covered only aerobic bacterial growth. Contamination of TVS probes with anaerobes and viral agents was not investigated, primarily due to the high cost for detection.

CONCLUSION AND RECOMMENDATIONS

In conclusion, the current practice of transvaginal ultrasound probe disinfection in the division is inadequate in decontamination and decreasing the risk of possible cross-contamination among patients.

A review and revision of the institution's standards of disinfection of the ultrasound transducers and sterile ultrasound gel used for transvaginal or transrectal ultrasound are recommended. The need to formulate and institutionalize these recommendations is vital to ensure the safety of all our patients and health workers against cross-contamination. Further studies should also examine viral contamination of the TVS probes since manual wipes are only partially virucidal.

Statement of Authorship

Both authors participated in the data collection and analysis and approved the final version submitted.

Author Disclosure

Both authors declared no conflicts of interests.

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