

Establishing a Protocol for the Cleaning and Sterilisation/Disinfection of Ultrasound Transducers

Susan Backhouse S.R.N. Dip H.E.
Senior Nurse/Clinical Nurse Specialist Radiology

Acknowledgement: Professor Audrey Paterson. Director of Interprofessional education faculty of Health Christchurch College Canterbury.

Introduction and Background

In the ultrasound department decontamination of ultrasound transducers is an important issue because of the risks of cross infection from dirty probes. This is particularly relevant in interventional ultrasound procedures and certain endocavity examinations.

Cleaning and sterilisation of ultrasound probes is important when the procedure involves contact with mucus membranes, sterile body cavities, intact skin, blood, body fluids and infectious material. Good practice would be to always use a probe cover. However in reality, and anecdotally, it is evident that probe covers are not always used.

Ayliffe G⁽¹⁾ summarises infection control guidelines and appropriate methods of decontamination in hospitals, but these guidelines need modification to make them applicable to the ultrasound department.

Establishing best practice

To establish best practice for ultrasound probe cleaning it was important firstly to ascertain the practices of others. Adjacent centres were contacted to elicit their practice. Initial analysis of these suggested that procedures differed markedly between departments for a range of reasons, including the differing recommendations from the manufactures of the ultrasound probes.

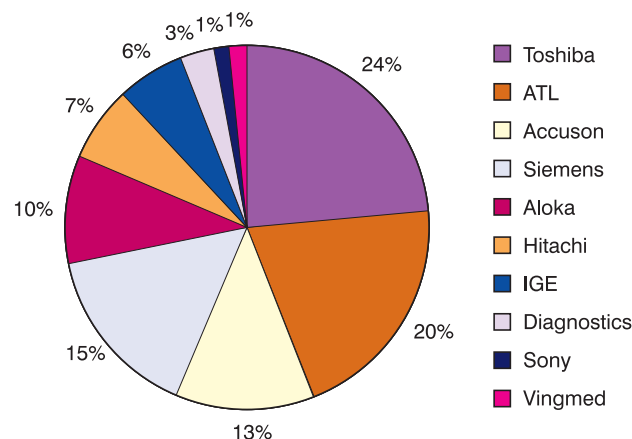
There are problems associated with the use of alcohol wipes as these may degrade the probe heads^(2,3,4), also T Spray II is a quaternary ammonium product, not a sterilant and appears to have deficiencies in viricidal activity. A risk assessment on T Spray II was undertaken using the initial data sheet supplied by Pharmaceutical Innovations Inc⁽⁵⁾. This suggested that staff should wear impervious gloves, full face shield or goggles when handling the product and if vapours are present, use an approved respirator mask as its by-products are nitrous oxides and ammonical vapours. Subsequent information received from the manufacturers states that there has been a modification to the spray bottle that effectively eliminates personal exposure thus removing the need for personal protective equipment⁽⁶⁾.

A literature search was undertaken to assist in identifying best practice. Whilst this demonstrated a need to clean and sterilise ultrasound probes, no definitive protocol describing best practice was found. As a result, we decided to carry out a wider survey in an attempt to establish common practices in ultrasound departments.

An audit questionnaire was constructed which consisted of 8 multiple-choice questions and 6 open questions. A sample size of 100 hospitals was selected using a national listing of radiology nurses in order to identify the hospitals selected.

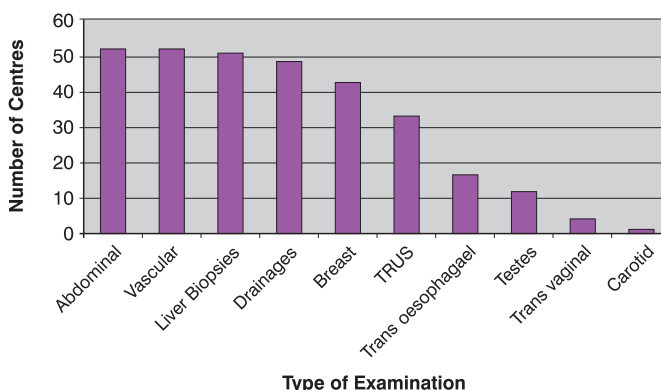
Results of the survey

One hundred questionnaires were sent out and fifty-four were returned. Of these, 41 departments used ultrasound equipment and probes from more than one manufacturer. Graph 1 demonstrates the relative percentages of equipment used in the study hospitals.



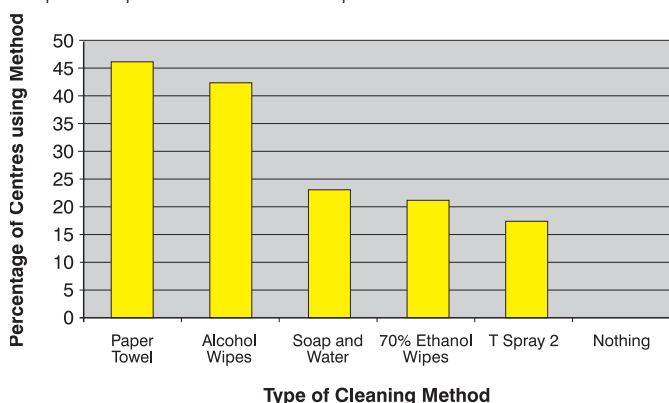
Graph 1: Showing the Distribution of Make of Ultrasound Machines used in this Study.

Centres were asked about the procedures they performed, concentrating on those with the greatest risks of cross infection. As can be seen in Graph 2, all hospitals undertook a variety of examinations where probe decontamination is essential.

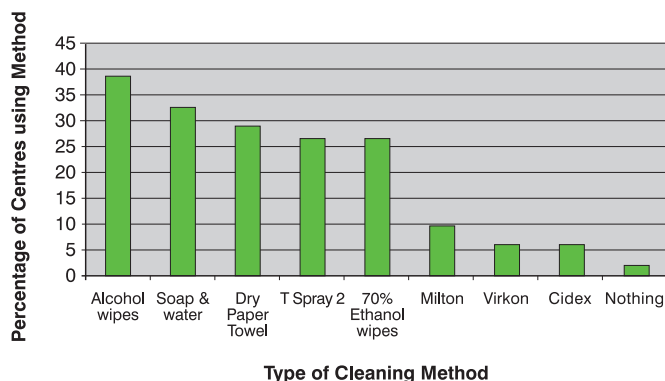


Graph 2: Showing the Range of Examinations Undertaken by Centres Participating in this Study.

Centres were asked about their procedures for cleaning probes following non-invasive examinations (graph 3). All used something and in total 23 different cleaning methods were identified, with the most common being paper towels, alcohol wipes and soap and water (24, 22 and 12 responses respectively). Some centres used more than one method. Similarly, centres were asked to identify cleaning methods following invasive procedures (graph 4), and to provide a copy of their cleaning protocol if one was available. 20 respondents also identified patients with known Methicillin-Resistant Staphylococcus Aureus (MRSA) as requiring probe cleaning as per the protocol for invasive procedures.



Graph 3: Showing Cleaning Processes Used for Non-Invasive Procedures. (Refer to results for list of other methods used.)



Graph 4: Showing Cleaning Processes Used for Invasive Procedures. (Refer to results for list of other methods used.)

Only two respondents returned their hospital's protocol for ultrasound probe cleaning. Because so few were returned, no analysis of these was carried out.

The question regarding whether scanning radiologists followed a set protocol for probe cleaning found that in 30 hospitals all or some did, but in 23 they did not, (one centre did not respond to this question). This question elicited a range of responses when asked why a set protocol was not followed. These included:

- "Radiologists are a law unto themselves and leave the cleaning up to someone else".
- "Each radiologist has different ideas as to the correct procedure".
- "Hard to teach old dog new tricks".
- "Unless told by us (radiology nurses) to use protocol radiologists would not comply with guidelines – simply because they forget".
- "One has not been written, personal preferences apply".
- "Personal preference".

A specific question addressed the use of probe covers and found that these were always used in 12 hospitals, never used in 2 hospitals and sometimes used in 40 hospitals. A total of 19 different types of probe covers were identified, ranging from proprietary covers, through cling film, freezer bags and condoms, to the sterile bag from the dressing pack.

Survey conclusion

The survey demonstrated a considerable range of practice in relation to ultrasound probe cleaning, some of which could be considered questionable. While the results were interesting, they contributed little toward the identification of best practice. In fact reference to the literature, to colleagues in adjacent centres and to the survey of 100 hospitals, failed to identify a consensus on practice in relation to cleaning and decontamination of ultrasound probes. However, the literature on ultrasound probe cleaning and minimising the risks of cross infection agrees that cleaning and sterilising is essential^(2,7,8).

Manufacturer's recommendations

The manufacturers of ultrasound probes recognise that proper cleaning and sterilisation of the probes following various types of procedures is essential, but advise protection against glutaraldehyde exposure, recognising the health hazards that have been observed with its use. This contrasts alarmingly with the fact that of the 47 products identified in their transducer care recommendations data sheet, 40 are glutaraldehyde solutions.

Five products contained hydrogen peroxide, peracetic acid, acetic acid or ortho-phthalaldehyde but advice against their use is given because, the long-term health and safety effects of the active components are unknown. One product in the summary contained formaldehyde, which is an irritant, and the final product Milton was not recommended for use on the particular transducers in question.

Although the manufacturers recognise the need for appropriate cleaning and sterilisation of their transducers, no readily available proprietary agent or established cleaning methods were recommended or approved. The use of transducer sheaths is recommended but there are some radiologists/sonographers who believe that the quality of the images obtained can be affected. Latex allergies can also be a problem, although there are now products on the market, which are latex free. However, as the survey demonstrated the use of probe covers is not consistent and tearing or leakage may occur. Probe covers cannot be considered as an alternative to a proper cleaning process.

Developing a Protocol for best practice

The lack of a suitable cleaning/sterilising agent that is safe to use from patients and practitioners' perspectives, and acceptable to manufacturers was apparent. A further search was made to find a sterilant/high level disinfectant process that satisfies the following criteria:

- Safe and accords with COSHH legislation.
- Simple, cheap, easy to use, particularly when working against time limitations as the probe may be out of action during a busy list.
- Effective against the biological organisms in question.
- Approved by the manufacturers of the transducers.

Liaison with all the stakeholders took place (risk management, infection control, manufacturers and staff). Further search identified a single product in a new form on the market – Chlorine Dioxide (ClO₂)™ Tristel at 250ppm[®]. The occupational exposure standards (OES) for Chlorine Dioxide measured over an eight hour period is 0.1 parts per million, 8 hours TWA, (HSE, EH72/14). This product appeared to meet all the requirements. It is a highly effective biocide, has rapid action and is non-selective in the microorganisms it will kill. Microbiological tests have been carried out on its sporicidal, mycobactericidal, bactericidal, fungicidal and virucidal, activity and have demonstrated its effectiveness. The cost is 75 pence per litre for 24 hours viability. The manufacturers have supplied a product indemnity and our local infection control group has confirmed its acceptability. A local risk assessment has also taken place in accordance within the Control of Substances Hazardous to Health Regulation 1999⁽¹⁰⁾; this concluded that there was a limited risk to users provided a working protocol was followed.

The Chlorine Dioxide product has been tested in the United States by Acuson/Siemens (2002)⁽¹¹⁾. Five different types of transducer were subjected to a standard 500 hours room temperature soak in the chlorine dioxide solution. At the conclusion of the soak, the probe materials were examined for any signs of incompatibility. The transducers were also evaluated for performance (Hipot and Leakage safety test). The lenses were checked for separation as a result of a loss of adhesion. No compatibility issues were found. The devices were also checked for any evidence of staining material attack and for any changes in the acoustic safety parameters.

Air monitoring, to determine the level of Chlorine Dioxide liberated into the air, in conjunction with training on the use and preparation of the product took place in the local department. And a decision was made to purchase the product.

Finally, having established a suitable cleaning/sterilising product, a protocol for its use was drawn up and depicted in the form of a flow/tree diagram. See figure 5.

Conclusion and Recommendation

Critical evaluation of clinical practice demonstrated the need to formulate an appropriate protocol for the cleaning of ultrasound probes where cross infection is a risk. This proved difficult as there was no existing consensus on best practice, and manufacturers care instructions for ultrasound probes precluded the use of almost all available cleaning and decontamination agents and methods. Persistence fuelled by a belief that proper cleaning of probes was essential, led to the identification, testing and acceptance by one large ultrasound manufacturer of a new chlorine dioxide based product and the development of a protocol for implementation in Maidstone hospital. Importantly, all key stakeholders developed the protocol collaboratively (radiologists, radiology nurses, the cross infection team, the risk management team and the ultrasound equipment manufacturers with equipment in the department). This should bode well for effective implementation.

It is recommended that other ultrasound departments review their probe cleaning and sterilising procedures to assess whether they are safe. In particular, do they provide safe working environment for the practitioner, do they comply with manufactures requirements and restrictions, and do they ensure that the risk of cross infection is minimized?

It may be that other ultrasound departments should consider adapting the Maidstone protocol for their needs.

References

1. Ayliffe G, Babb J, Taylor L. Cleaning, disinfection or sterilization? Hospital Acquired Infection 3rd Edition, Arnold London, pp124, table 9.1, 2001
2. Grouden MC, Keogh E, Moore DJ, Shanik DG. Results of an infection control survey in ultrasound departments and recommended guidelines. BMUS Bulletin 1999; 7: 15-18
3. Fowler & McCracken. Ultrasound probes: risk of cross infection and ways to reduce it. Comparison of cleaning methods. Radiology 1999; Oct; 300
4. Murphy Irwin K. Establishing infection control standards in Ultrasound departments. Medical Ultrasound 1979; 3: 145-147
5. Data sheet for T Spray II. 1995. Pharmaceutical Innovations Inc. Ref. Osha 174 Sept 1985.
6. Data sheet for T Spray II 2001. Pharmaceutical Innovations Inc. Revised data sheet as per website www.pharminnovations.com
7. O'Hara T, Itoh Y, Itoh K. Contaminated ultrasound probes: a possible source of nosocomial infections. Hosp Infect. 1998; 40: 73-77
8. AIUM. Ultrasound practice committee report for cleaning and preparing endocavitary ultrasound transducers between patients. AIUM official statement and report 1995. Abstracted from website aiumsafety.statements.html
9. TRISTEL. Chloride Dioxide (ClO₂) registered trademark of Tristel. Manufactured by Tristel Pharmaceutical Ltd, Fordham, Cambs.
10. Control of substances hazardous to health at work. Health and Safety Commission 1999.
11. Manufacturers information. 2001 and 2002. Siemens/Acuson ultrasound, Siemens House, Oldbury, Bracknell RG12 8FZ

Decontamination of Ultrasound Transducers

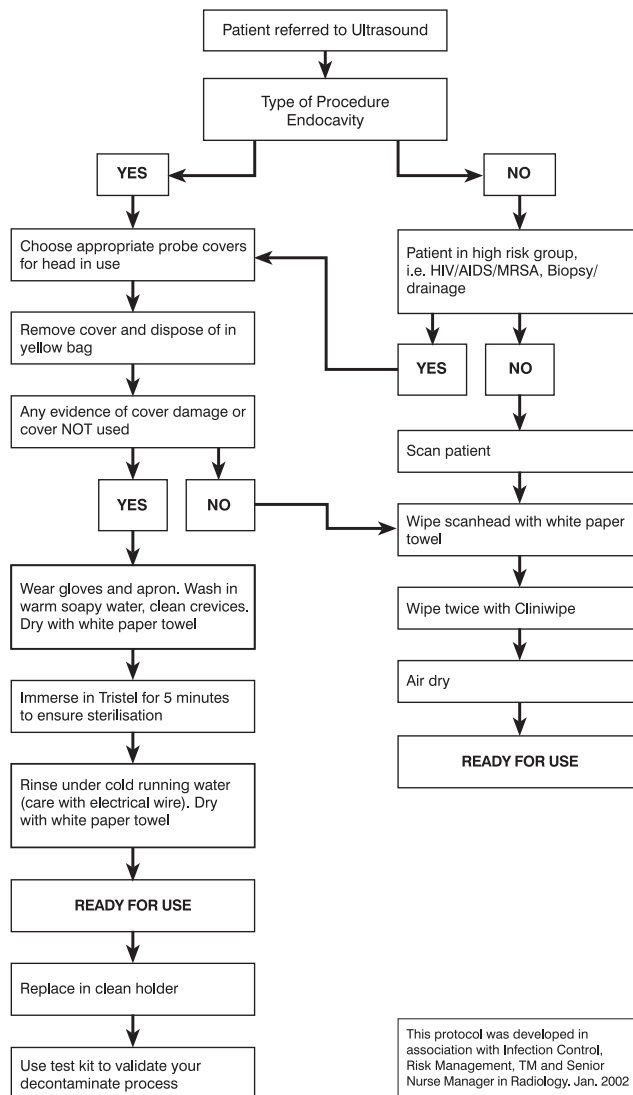


Figure 5.