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The development of a new technique for the decontamination of trans-oesophageal echocardiography probes

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Abstract

Decontamination of trans-oesophageal echocardiography (TOE) probes to a validated standard is a troublesome area, since their electrical components prohibit full immersion. We report the development of a novel device designed to keep the electrical components of the TOE probe dry while allowing the rest of the probe to be subjected to a validated decontamination process.

The thorough decontamination of trans-oesophageal echocardiography (TOE) probes is difficult. In this paper we discuss the development of a technique of decontamination for these probes that occurred in our institution over the last year. The procedural changes that have been implemented bring the decontamination of TOE probes in line with nationally recognised and validated processes to a standard consistent with those for endoscopes and similar devices (Department of Health, 2007).

TOE probes are classed as 'intermediate risk (semi-critical)' devices with regards to cross-infection risk (Spaulding, 1972) and are used widely by cardiologists, anaesthetists and intensivists. Preoperatively the main indication for use is the evaluation of cardiovascular disease, especially valvular dysfunction. Intraoperative indications include the assessment of valvular repair procedures and the identification of causes of haemodynamic instability (American Society of Anesthesiologists and the Society of Cardiovascular Anesthesiologists Task Force on Transesophageal Echocardiography, 1996). The intraoperative use of TOE has transformed decision-making in cardiac surgery and there has been a marked increase in the number of TOE examinations performed in recent years (Wright, 2007). There are increasing indications for the use of TOE as a diagnostic tool in other areas, including the general intensive care unit (Orme et al, 2009).

TOE probes essentially have developed from a form of modified gastroscope. They comprise (see Figure 1) a small ultrasound transducer mounted onto the end of a probe that is inserted into the patient's oesophagus. The handle houses mechanical controls for probe movement and an electronic switch to adjust the ultrasound transducer plane angle, with a cable and plug to allow connection to an ultrasound machine. In the same way as other flexible endoscopes, the TOE probe is heat sensitive. However, TOE probes differ from other endoscopes in that the electrical component housed within the probe handle and connection plug cannot be immersed. This makes an effective decontamination process that can be fully validated more difficult for TOE probes than for standard endoscope instruments.

Current manufacturers instructions for the GE 6T-RS TOE probe advise that the probe is manually cleaned only and advocates for example the practice of 'rinsing for 1 minute with a large volume of fresh water, typically 2 gallons, before soaking in an enzymatic solution' or the 'use of a soft cloth lightly dampened in a mild soap or an enzymatic cleaner to remove any particulate matter or body fluids and to remove remaining particulate and cleaning residue by rinsing thoroughly with water up to the immersion point'. Following this initial cleaning it is suggested to soak the probe in a disinfection solution prior to final rinsing. Clearly it is difficult to establish the efficacy and validation of manual cleaning by individuals who carry out these instructions using their own interpretations and to varying degrees of aptitude.

Historically, TOE probes within the Trust were decontaminated with a process that consisted of manual cleaning using an enzymatic detergent followed by the use of a 'modified' endoscopy reprocessor. It should be emphasised that the reprocessor manufacturer carried out the said modification solely for the purpose of TOE probe reprocessing. The modification consisted of a carrier fitted above the bowl of

the machine so that the electrical component could be held there, whilst the remainder of the probe was immersed in the solution. The machine was 10 years old and had no mechanical washing action but was merely an automated means to disinfect the probe by a number of stages of immersion and rinsing using detergent and disinfectant. The machine was tested to HTM2030, although by the very nature of this type of machine, not all tests as specified in table 2e could be carried out (Department of Health Estates and Facilities, 1997).

Over recent years it has been the aim of the decontamination experts within our Trust to centralise all endoscope decontamination reprocessing. This has been largely successful with the building of a new endoscopy suite including decontamination facilities, and the centralisation of all of the scope work around the Trust. However, TOE probes remained an exception to this. The issue became particularly acute with a planned increase in the use of TOE that was coupled to the expansion in cardiac surgical services in this centre.

A multidisciplinary team consisting of a consultant cardiac anaesthetist, the Trust decontamination lead and the endoscopy charge nurse set out to find an alternative decontamination method to that which was currently employed. The team were supported by

advice from the Trust's approved person who strongly advocated the development of centralised cleaning and validation of TOE probe cleaning.

The team discussed a number of options for TOE decontamination including the use of sheaths, the use of near-patient cleaning wipes and the installation of an endoscope reprocessor within the theatre complex. After considerable debate and following advice from the 'approved person', these options were dismissed as against the spirit of the national guidelines on decontamination and against the local Trust policy of centralisation of decontamination services (Department of Health Estates and Facilities, 1997).

During this time the team were approached by a company that were developing a unit designed to keep the electrical components of the TOE probe dry while allowing the rest of the probe to be subjected to a validated decontamination process. The team entered into dialogue with the company (NeoCare) to develop a practical and workable solution. A number of changes were made to the original prototype including changing the material used for the body of the device, adjustments in the seal around the probe and the incorporation of a leak tester device (see Table 1).

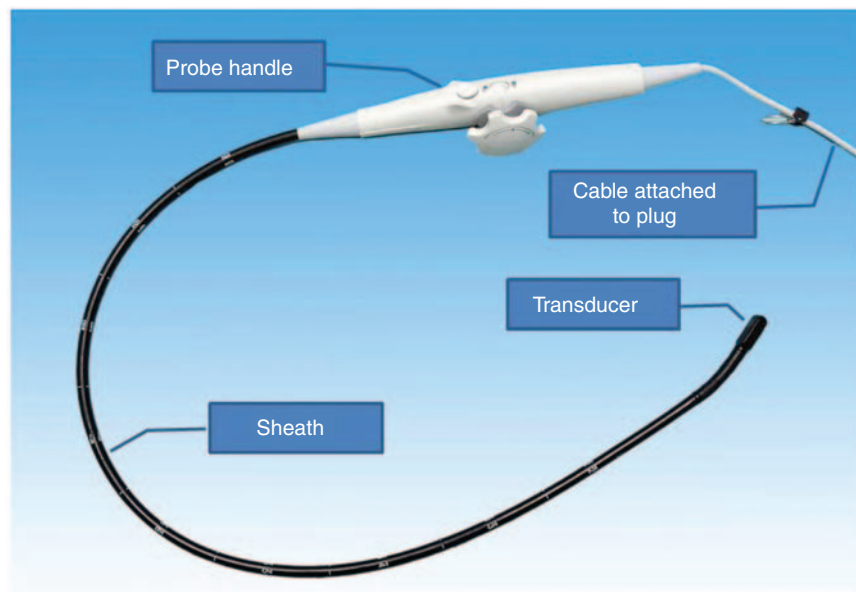


Figure 1. A typical trans-oesophageal echocardiography probe

Table 1. List of modifications made to the original design

Design Modification	Rationale for Modification
An elevated stand	To assist with loading of trans-oesophageal echocardiography (TOE) probe
Body casing material change (steel to polypropylene)	To reduce device weight
Lid material change (to Tecamid)	To improve pressure resistance
Inclusion of a leak tester connection and miniature valve	To allow automated endoscope reprocessor (AER) leak tester function
Adjustment in the orientation of probe sealing elements	To facilitate correct loading of the probe
Adjustment in size of the body casing	To accommodate all makes of TOE probes and to allow two devices to be located in the AER at any one time
Sealing element material changed	To improve performance of the seals and enhance longevity
Electric pressurisation device	To make pressurisation quicker and easier



Figure 2. The Scopevault™ with trans-oesophageal echocardiography probe loaded

Approximately 20 test decontamination cycles using an obsolete TOE probe were performed during the development phase of the device. This initial testing period also allowed decontamination staff to become familiar with handling the TOE probes and avoiding potential damage. Following this a more formal testing protocol was performed over 100 cycles to specifically identify any pressure leaks and any signs of fluid ingress that could harm the fluid-sensitive portions of the TOE probes (see Appendix 1). No episodes of de-pressurisation or signs of fluid ingress occurred over the 100 cycles.

The device consists of a housing for the probe handle and plug; the probe shaft is then separated from this portion via a flexible waterproof seal (see Figure 2). The whole casing is then pressurised and inserted into a standard decontamination machine (the Lancer automated endoscope reprocessor [AER] machine). The whole process for decontamination is summarised in Appendix 2.

The system of using this device (called the 'Scopevault™') for TOE decontamination has been used for all probes used in the cardiac theatres in our centre since October 2008. To date we have had no incidents of TOE probe damage after over 1000 cycles. There has been one case of a leak around the Scopevault™ seal. This is a serviceable item that requires changing periodically. The seal is pressure tested during the loading phase each time the Scopevault™ is prepared for use. The leak was picked up during this loading phase and before decontamination commenced. This was rectified by replacement of the seal.

In summary, we have demonstrated that TOE probes can be decontaminated to a cleaning standard and with validity equivalent to what is considered to be the current national standard for all endoscopy devices. We believe that with the development of this device we can offer the most effective and validated decontamination process for TOE probes currently available.

Conflict of interest statement

None of the authors have any financial interest in any decontamination company or any form of decontamination equipment.

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Appendix 1: Testing protocol for the Scopevault™

Testing the validity of the Scopevault™ in the holding of TOE probes during decontamination in an AER was undertaken in the main flexible endoscope decontamination facility within the Trust. This was undertaken by the endoscope technicians working in the unit.

Working with the Scopevault™ manufacturer, we ran a small number of cycles through our AERs to determine whether it was a viable option. To reduce risk to equipment we used an obsolete TOE probe. We initially ran 20 cycles looking at the logistics of handling and assembling the Scopevault™ as well as working out how to fit it into the AER without damaging either the probe or the AER. Once staff were comfortable handling the TOE probe and the Scopevault™, we then set the following criteria.

Evaluation criteria

1. Decontamination staff were given training on handling and assembling the TOE probe and the Scopevault™.
2. The evaluation was to be conducted over a series of 100 cycles using the obsolete TOE probe.
3. Each cycle was run as if it were a live cycle. This included fitting the probe into the vault, reprocessing the probe and removing from the Scopevault™ at the end of the cycle.
4. At the end of each cycle, checks would be made for fluid ingress.
5. At the end of each cycle, checks would be made for loss of pressure in the Scopevault™.
6. All data collected, including pre-cycle pressure, post-cycle pressure, fluid ingress, operator and cycle number were logged and filed.
7. Lancer Fibro cleaner FC4.
8. AER Serial number: 6M091465.
9. Endoscope name: TOE.
10. Endoscope library number: 13.
11. Programme Number: 4. No channel monitoring. No leak testing.
12. TOE Scope: ACUSON TE-V5MS.
13. TOE Scope Serial number: 30595260.
14. Pressure test: 200 mbar.

All of the collected data was added to a collection sheet. This sheet recorded:

- name of operator;
- pre- and post-cycle pressure test results;
- fluid ingress;
- cycle number of the AER.

Appendix 2: Decontamination process

The decontamination process for the TOE probe is as follows.

1. Place the Scopevault™ and its tray on the work surface next to the decontamination sink.

2. Operator will examine the umbilicus of the probe and gently clean with hard surface wipes, and dry with soft lint-free paper towels.
 3. Check the Scopevault™ is dry inside and free from contamination.
 4. Place the umbilicus of the TOE probe into the Scopevault™.
 5. Fit the lid to the Scopevault™ by sliding the soft seal into the lid and fitting the sliding plate in position.
 6. Attach the pressure pump to the Scopevault™ and pressurise to manufacturer's predetermined pressure.
 7. Inspect the intubation end of the probe for obvious damage.
 8. Place intubation tube in the sink of clean water at no greater temperature than recommended by probe manufacturer. Observe the probe for signs of leaking demonstrated by the release of bubbles. Leave in the water for at least 30 seconds.
 9. Once satisfied that there are no leaks in the probe, gently clean using an enzymatic sponge and gently wipe the probe to remove any body fluids and debris.
 10. Rinse off any enzymatic detergent using clean tap water.
 11. Place the insertion tube on the Scopevault™ tray as per manufacturer's instructions.
 12. Place Scopevault™ and tray into the AER.
 13. Check that probe and Scopevault™ are situated in the AER in a safe manner and close the door.
 14. Set programme on AER as per manufacturer's instructions.
 15. Once cycle has run, open AER in clean room.
 16. Place transit tray on appropriate trolley next to AER.
 17. Place sterile tray liner in tray.
 18. Open sterile waxed sheet and place in tray with half hanging over the edge of the tray.
 19. Wearing clean gloves pick up clean paper towel and gently wipe dry the probe and around the lid of the Scopevault™.
 20. Place a clean yellow tip protector on the end of the TOE probe.
 21. Release the pressure from the Scopevault™.
 22. Lift the probe from the Scopevault™ and place the patient intubation tube on the sterile paper in the tray. Cover over the probe with the free end of the paper and place the umbilicus on top of the paper.
 23. Place liner lid onto tray and cover with hard lid. The probe is ready for dispatch.
- Throughout the decontamination process there are checks made with tracking, traceability and validation as these form part of the process.