Quality assurance testing of transoesophageal echocardiography probes

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Abstract

Introduction: In response to an ultrasound imaging issue with transoesophageal echocardiography probes, a testing protocol was developed to check features pertinent to the operation of these probes. The imaging problem was detected in multiple probes of the same make and model.

Methods: Over a two-year period, a series of 26 probes of this model were tested at acceptance, then three to six months later before being replaced due to a defect. A range of visual, mechanical and electrical tests were performed. Image tests comprised low-contrast penetration measurements and a comparison of phantom images at regular intervals to highlight artefacts in both B-mode and colour Doppler imaging.

Results: Of the 26 defective probes replaced, 7 suffered mechanical/electrical problems, 5 of which prevented imaging results being obtained. Low-contrast penetration reduction of greater than 5% occurred in 14 probes. B-mode artefacts were observed on 12 probes and Doppler noise artefacts on 6 probes. No faults were found on five probes. The manufacturer addressed the imaging problem identified and of the seven subsequent probes supplied, only one suffered an imaging fault.

Conclusions: The implementation of a quality assurance protocol for transoesophageal echocardiography probes resulted in cost savings on replacements/repairs. When provided with the evidence gathered, the manufacturer supplied 23 probes under warranty or as loan equipment. The regular testing of the probes substantially reduced the impact of downtime and poor diagnosis from this equipment on the clinical service.

Keywords

Echocardiography, transoesophageal, equipment, quality assurance

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Introduction

Transoesophageal echocardiography (TOE or TEE) probes are used for diagnosis of cardiac disease and perioperative cardiac monitoring.¹ The design of a TOE probe is similar to a flexible endoscope, but contains a phased array ultrasound transducer at the tip rather than traditional optics and biopsy channels. The first TOE probes developed in the 1970s used single element transducers to perform M-mode and Doppler assessment of the heart.^{2,3} With the introduction of miniaturised phased array transducers,⁴ modern TOE probes are capable of utilising the full range of ultrasound imaging modes and technologies. The probe's

position in the oesophagus allows structures such as the lung and ribs to be avoided when imaging the heart. Moreover, due to its proximity to the heart, higher ultrasonic frequencies are utilised than in trans-thoracic imaging, giving greater resolution and improved signal to noise.⁵ Associated clinical risks with these probes are low when handled by trained staff and properly maintained.⁶

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There is little documented evidence of equipment failure in TOE probes; this is despite faults with endoscopes being common,⁷ the most frequent failures resulting from physical damage and imaging faults. Similar results have been reported for general radiology ultrasound probes.⁸ The proper management of TOE probes is, therefore, of considerable importance to the clinical departments concerned. A number of authors have described ultrasound quality assurance (QA) programs with tests that can be applied or adapted to TOE probes.^{8–12} Using commercially available test objects, a number of the ultrasound beam qualities can be quantified, such as resolution, penetration and grey-scale contrast. Changes to one or more of these parameters have been seen in general radiology probes known to be faulty,⁹ but more evidence is required to establish methods that maximise fault detection. In-air reverberation tests allow sensitivity and uniformity to be measured without the need for test objects. Changes in reverberation depth that correlate with output power have been shown for linear and curvilinear array probes but not phased array probes.¹⁰ Direct detection of faulty ultrasound elements has been used by some groups with the Unisyn (Unisyn, Golden, CO, USA, formerly Sonora) First Call system.^{8,10} For new or uncommon probes, First Call's usefulness is dependent on Unisyn providing compatible adapters.

The Royal Infirmary of Edinburgh is a tertiary referral centre performing approximately 70 cardiothoracic surgery procedures a month.¹³ A fleet of nine TOE probes are used across site in a number of theatre and intensive care areas, with an approximate capital value of £135,000. In 2013, staff raised concerns that degradation had occurred in image quality on TOE probes within theatres. Operators reported the B-mode images were unusually dark, lacked sharpness and contained bright echo artefacts (suspected grating lobe artefacts). Isolated instances could have been associated with specific operational artefacts such as poor contact with the oesophageal wall, air bubbles within the probe sheath, or artefacts associated with fatty tissue or calcifications. However, the frequency of occurrences, and an initial comparison of TOE images with those obtained in another centre for the same patient, pointed to a potential equipment issue. Over a two-year period, 26 probes were supplied as the manufacturer worked to resolve the image degradation issue. The aim of this study was to devise a QA testing protocol for use on a routine basis, to detect and quantify faults, thus reducing the adverse clinical and financial impact on services.

Methods

The testing protocol implemented for TOE probes comprised a series of visual, mechanical, electrical and

imaging quality tests. Before each probe was tested, it was passed through the hospital's central decontamination unit. Decontamination procedures were checked to ensure compliance with manufacturer's guidance. After decontamination, suitable personal protective equipment (PPE) was worn during a thorough visual inspection for signs of physical damage. On a small number of occasions, dried blood was found on the handle or connector, which is not decontaminated by the automated endoscope reprocessor and must be manually cleaned. To minimise disruption to the clinical lists, the probes were decontaminated-tested-decontaminated and returned to theatres within one day.

Visual inspection

A 20× handheld magnifier glass (Part code 732-858, RS Components Ltd, United Kingdom) was used to inspect the TOE probe outer sheath for indications of breaches in the protective layer (e.g. small marks or superficial indents). Any and all findings of the visual inspection were recorded (Figure 1). If a break in the outer protective layer of the insertion tube was identified, the probe was removed from service.

Mechanical test

The mechanical test monitored the movement and angulation of the probe tip. This was performed by rotating the control wheels on the probe handle and recording the maximum angles of deflection. If the angulation was 10° less than the manufacturer's specification, in any direction, it was deemed to be defective and removed from service.

Electrical test

Electrical safety testing followed the manufacturer's recommendations and IPEM reports 97 and 102.^{14,15} The insertion tube was submersed in an aqueous saline solution (1 g L⁻¹) to form a conducting path with a 5 cm² steel test plate; the test plate provided a suitable conductive surface area and protected the probe of the electrical safety tester from corrosion. A Rigel 288 safety tester (Seaward Electronic Ltd, Peterlee, UK) was used to test applied part leakage as per IEC 60601-1: 2005¹⁶ (normal condition <0.01 mA, single fault condition <0.05 mA) and insulation resistance tested as per IPEM report 97 (>50 MΩ) used as a substitute for dielectric strength testing.

Image quality test

To gauge probe performance, a series of images were obtained using a tissue mimicking test object, the

Figure 1. Left, example of visible damage on the TOE insertion tube. Right, visual inspection documentation for the same probe showing the extent of the damage along the insertion tube.

Edinburgh Pipe Phantom.^{17,18} The resolution integral calculated from measurements made with this test object can be used to characterise grey scale imaging performance. Welsh et al.¹⁹ established that simulated failed elements in phased array probes led to a reduction in the resolution integral. A smaller reduction was also seen in low-contrast penetration (LCP); however, the sensitivity of the measurement was still able to detect changes to the probe's performance. By comparison to the resolution integral, the relative speed and ease of conducting LCP measurements on TOE probes made it particularly suitable for the regular testing conducted during this investigation. An initial cross check with two scanners was performed to rule out a scanner/preset issue as the source of the reported faults. Once the probe was confirmed to be at fault, all following assessments were conducted with the same scanner and clinical preset. To collect images of the test object, the probe was positioned as shown in Figure 2. This allowed the operator to obtain two orthogonal views, including LCP measurement of the test object, without applying additional strain to the mechanics within the insertion tube. With the scanner settings optimised, LCP measurement was performed in real time so as to distinguish speckle from noise on the phantom. Ambient light levels during image tests were less than 50 lux with no more than 20 lux directly incident on the monitor.

Images of the test object were obtained from each probe three to six months after purchase and compared to those acquired at acceptance. A reference dataset was collected with new probes that had yet to be used clinically, and this was used for comparison where baseline data were unavailable for a specific probe. Assessment of grating lobe artefact was carried out by visualising the angular broadening of the high amplitude echo generated from the reflection at the interface between the tissue mimicking material and tank wall.

Figure 2. Diagram of the setup used to obtain images from the Edinburgh Pipe Phantom. View (a) used for qualitative test of grating lobe artefact as shown in Figure 4. View (b) used to make LCP measurement as shown here by imaging a region between the fluid filled pipes. For electrical safety, a second water tank with 0.9% saline solution is used.

Doppler function tests were introduced to the testing protocol to ascertain what effect, if any, the reported imaging faults had on Doppler performance. The functionality of colour, pulsed wave (PW) and continuous wave (CW) Doppler was checked. In lieu of a suitable Doppler test object, operators imaged their own radial artery or carotid artery if the radial proved difficult to locate. Acoustic exposure was minimised as per BMUS guidelines for non-clinical scanning;²⁰ Doppler images took 1 minute on average to obtain. Safety indices

Figure 3. Chart of low-contrast penetration (LCP) measurements; recorded acceptance or baseline value shown, second measurement after three to six months clinical use. Mean initial LCP was $12.8 \text{ cm} \pm 4\%$ (2 s.d.).

*indicates grating lobe artefact present. † indicates Doppler artefact. Probes 2, 4, 6, 10 and 11 were not tested for Doppler artefacts.

peaked on colour Doppler ($\text{TIS} = 1.0$, $\text{MI} = 0.8$), lower values were seen on PW ($\text{TIS} = 0.3$, $\text{MI} = 0.16$) and CW ($\text{TIS} = 0.5$, $\text{MI} = 0.04$). Images were compared to previous tests for the appearance of artefacts or increases in noise levels.

Any probe found to operate outside expected values was withdrawn from service and reported to the manufacturer. For the imaging test, this was a greater than 5% drop in LCP between acceptance and subsequent testing or an artefact seen in either B-Mode or Doppler test images. This value is based on guidance in IPPEM report 102¹⁵ that an acceptable reduction in LCP should be no more than 5%. Repeatability measurements for LCP on the model of TOE probe investigated were $\pm 3\%$ (2 s.d.).

Results

During this investigation, 26 probes were tested. These consisted of the original compliment of probes and replacements supplied in three batches over a period of two years. Figure 3 displays the imaging results collected from 21 probes. Five of the 26 were excluded, as mechanical/electronic faults resulted in the probes being removed from service and without image tests being carried out. The darkening of the ultrasound image reported by clinical users was confirmed in 14 of the 21 probes as noticeably weaker speckle echoes with a reduction in LCP greater than 5%. Increasing the gain to make the speckle brightness comparable to that of a new or working probe produced a noisy image throughout the field of view. A detectable broadening of the reflection echo from the bottom of the tank shown in Figure 4 was found on 12 of the 21 probes.

Of the 21 probes, 16 were checked for Doppler artefacts; 6 of these exhibited artefacts as shown in Figure 5 after three to six months. Probes labelled 2, 4, 6, 10 and 11 in Figure 3 were removed from service before the introduction of Doppler tests to the protocol. The mean LCP of new probes at acceptance was $12.8 \text{ cm} \pm 4\%$ (2 s.d.). After being used clinically for 3 to 6 months, the mean drop in LCP for all 21 probes was -9% , with a range of -30% to 0% .

A total of seven mechanical/electronic faults were detected, five of which compromised safety resulting in the probes being removed from service and without image tests being collected. Image data were collected for two probes which suffered intermittent temperature sensor faults (probes 13 and 15 in Figure 3). These sensor faults along with connection/motor calibration errors (two of five probes) became apparent via error messages displayed when connecting the probes to the scanner ahead of performing the electrical safety tests. Both the motor and temperature sensor are located within the tip of the probe near the transducer, and these faults may also have been linked to the cause of image degradation. Mechanical/electronic faults (three of five probes) were the result of accidental damage. Damage to the insertion tube was seen on two probes during visual inspection. The third probe, reported to have fallen into a cleaning solution, failed electrical safety testing probably due to fluid ingress into the connector/handle electronics.

Of the 26 probes supplied, only three replacements had to be purchased due to accidental damage. The rest were replaced under warranty or provided as free of charge loan items. Seven new probes were subsequently supplied by the manufacturer, which passed acceptance

Figure 4. Left, Pipe Phantom cross section imaged with TOE probe at acceptance. Right, same section six months later showing reduced speckle brightness and a grating lobe artefact. 12 other probes showed similar grating lobe artefacts, identified by an asterisk (*) in Figure 3.

Figure 5. Left, normal Doppler signal from the radial artery shown side-by-side with image of the Doppler artefact. This Doppler artefact was seen in six probes, indicated by a cross (†) in Figure 3.

testing. After three months, five of the new probes showed a substantial fall (mean 66%, range 38% to 75%) in electrical applied part insulation resistance. The imaging results showed no B-mode or Doppler imaging artefacts, but one probe had a reduction in LCP of 6%. Clinical users reported no imaging issues with the seven new probes.

Discussion

Reduction in LCP has the potential to identify real faults in phased array probes, as put forward by Welsh et al.¹⁹ when testing simulated failed elements.

The QA testing protocol described here found a mean LCP change of -9% , with image degradation seen in 16 of 26 probes over a period of six months after acceptance. When the manufacturer implemented a fix to the design/construction, the mean LCP change measured was -0.5% with image degradation seen in one of seven new probes over the same period after acceptance. These results confirm that LCP measurement can be successfully used to identify phased array image degradation with probes in clinical use. Adopting the QA testing protocol also resulted in better communication with the equipment manufacturer. Collaboration between Medical Physics and clinical users led to an

improvement in equipment management, with better equipment labelling, and sharing between theatres and intensive care areas.

On supplying the results of our investigation to the manufacturer, and as a result of their own investigation, the manufacturer made a change to the transducer head, seven probes of this model were supplied. While one probe showed a LCP drop of 6%, the lack of change in LCP across the other six replacements suggested an improvement in reliability. We have continued working closely with the manufacturer since the imaging investigation and the continuing mechanical/electrical issues. Manufacturer guidance recommended visual, mechanical and electrical tests suitable for the probes. However, the manufacturer provided no guidance on testing the image quality of the TOE. It was also found that the manufacturer did not test TOE probes as part of the ultrasound scanners' routine service. The manufacturer continues to be supportive and has worked to improve the reliability of the probes.

LCP measurements proved a suitable means of tracking the image degradation. Of the 14 probes that failed LCP measurement after three to six months, seven recorded a reduction greater than 10%, double the action level at which it would be removed from service. Directly observing damaged elements in the image of a phased array transducer is difficult as all elements contribute to each scan line. However, a significant proportion of non-functional elements in a phased array creates a reduction in LCP.²⁰ Another sign of probe deterioration was the grating lobe artefact apparent in the broadening of the echo at the interface between the tissue mimicking material and tank wall (Figure 4). Of the 12 instances where this was found to have increased, 10 coincided with a greater than 5% reduction in LCP (Figure 3). Beam forming plays an important role in grating lobe suppression.^{21,22} If the position of non-functional elements led to a reduction in aperture size, it may explain why the grating artefact is seen in some but not all of defective probes.

Doppler artefacts were seen in 6 of 15 probes during the testing process. The artefacts appeared as distinct noise or interference along the scan lines in the colour flow mode (Figure 5). In CW or PW Doppler, this artefact would only be present when the sample gate was positioned over a scan line registering the artefact. The occurrence of the Doppler artefact always appeared in conjunction with grating lobe artefact, although there were five instances where grating lobe artefact was seen without the presence of Doppler artefact. Further knowledge of the underlying fault would be required to explain a definitive link between the two. While the Doppler tests implemented here are somewhat subjective, a string phantom has been purchased for use in

future routine testing.²³ With a string phantom, maximum and average velocity measurements may be used as a further indication of damaged elements in the probe.²⁴

Previous investigations on endoscopes and ultrasound equipment^{7,8} have found that mechanical/electrical faults are the most prevalent, with imaging faults also being frequent. The faults recorded in this study were predominantly imaging in nature, which can be expected as the QA program was put in place to address reported imaging problems. The Edinburgh Pipe Phantom was used to collect the image data, although similar results could be obtained using a variety of commercially available greyscale test objects that allow LCP measurement. The use of LCP measurement and qualitative image tests successfully characterised a problem known to be impacting clinical images and also provided sufficient evidence to obtain a positive response from the manufacturer. Having in place a well-documented process was as important as the choice of tests in achieving this successful outcome.

Conclusion

Conducting straightforward imaging tests allowed a significant manufacturing defect to be characterised and monitored in a specific model of TOE probe. As a result, costs to the Health Board were reduced, with 23 probes being provided under warranty or as loan equipment with a capital replacement value of £345,000. Only three probes which suffered accidental damage required replacements to be purchased. Importantly, the effect of faulty equipment on downtime and poor diagnosis for clinical services was minimised.

To ensure similar problems are detected promptly in future, a proactive testing procedure is now in place that incorporates the visual, electrical and image quality tests described in this paper.

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CM.

Contributorship

CM and KMcN conducted the tests. CM researched and wrote the first draft of the manuscript. All authors reviewed and edited drafts of manuscript then approved the final version.

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